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**Part III**

**MANUAL OF CIVIL AVIATION MEDICINE**  
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**International Civil Aviation Organization**

**PART III. MEDICAL ASSESSMENT**

*Approved by the Secretary General  
and published under his authority*

INTERNATIONAL CIVIL AVIATION ORGANIZATION

## Part III

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## Chapter 1. CARDIOVASCULAR SYSTEM

### INTRODUCTION

The ICAO Class 1 medical Standards and Recommended Practices (SARPs) relating to the cardiovascular system are contained in Annex 1, Chapter 6:

6.3.2.5 The applicant shall not possess any abnormality of the heart, congenital or acquired, which is likely to interfere with the safe exercise of the applicant's licence and rating privileges.

6.3.2.5.1 An applicant who has undergone coronary bypass grafting or angioplasty (with or without stenting) or other cardiac intervention or who has a history of myocardial infarction or who suffers from any other potentially incapacitating cardiac condition shall be assessed as unfit unless the applicant's cardiac condition has been investigated and evaluated in accordance with best medical practice and is assessed not likely to interfere with the safe exercise of the applicant's licence or rating privileges.

6.3.2.5.2 An applicant with an abnormal cardiac rhythm shall be assessed as unfit unless the cardiac arrhythmia has been investigated and evaluated in accordance with best medical practice and is assessed not likely to interfere with the safe exercise of the applicant's licence or rating privileges.

*Note.— Guidance on cardiovascular evaluation is contained in the Manual of Civil Aviation Medicine (Doc 8984).*

6.3.2.6 Electrocardiography shall form part of the heart examination for the first issue of a Medical Assessment.

6.3.2.6.1 Electrocardiography shall be included in re-examinations of applicants over the age of 50 no less frequently than annually.

6.3.2.6.2 **Recommendation.**— *Electrocardiography should be included in re-examinations of applicants between the ages of 30 and 50 no less frequently than every two years.*

*Note 1.— The purpose of routine electrocardiography is case finding. It does not provide sufficient evidence to justify disqualification without further thorough cardiovascular investigation.*

*Note 2.— Guidance on resting and exercise electrocardiography is contained in the Manual of Civil Aviation Medicine (Doc 8984).*

6.3.2.7 The systolic and diastolic blood pressures shall be within normal limits.

6.3.2.7.1 The use of drugs for control of high blood pressure shall be disqualifying except for those drugs, the use of which is compatible with the safe exercise of the applicant's licence and rating privileges.

*Note.— Guidance on the subject is contained in the Manual of Civil Aviation Medicine (Doc 8984).*

6.3.2.8 There shall be no significant functional nor structural abnormality of the circulatory system.

Corresponding requirements for private pilots (Class 2) and air traffic controllers (Class 3) are given in 6.4 and 6.5 respectively. They differ from the requirements for commercial pilots (Class 1) only with regard to the frequency of electrocardiographic examinations.

The full cardiological standard, which runs to less than 350 words, leaves much scope for interpretation in the context of reduced medical fitness. Medical certification outside the requirements in Chapter 6 is

reliant upon the so-called “flexibility standard”, paragraph 1.2.4.8 and is allowable subject to accredited medical conclusion (see also Part I Chapter 2), provided that this “is not likely to jeopardize flight safety”. The word “likely” is defined in Annex 1 to mean “a probability of occurrence that is unacceptable to the Medical Assessor.” This permits latitude to be taken by him or her. An explicit standard would give rise to loss of flexibility with risk of unfairness to individual aircrew. Discussion of acceptable incapacitation risk in pilots may be found in Part I Chapter 3 of this manual, and below.

*This chapter is not intended as a primer in clinical cardiology but as guidance for medical assessors, designated medical examiners (DMEs), cardiologists and others seeking to investigate and manage cardiological problems in accordance with ICAO SARPs.*

## **Levels of operation**

As detailed in Part I, Chapter 1 there are three levels of Medical Assessment: Class 1 - commercial pilots, Class 2 - private pilots (including glider and balloon pilots), and Class 3 - air traffic controllers (ATC). No international standard has been established for microlight pilots. In this chapter, reference will be made to a “full” or “unrestricted” Class 1 Medical Assessment, whilst “restricted” certification refers to a Class 1 Medical Assessment with an operational multi-crew limitation (OML) thereon. Note that not all Contracting States utilise the OML concept, and in such States an applicant may be assessed either as unfit or as fit for unrestricted certification whereas in those utilising an OML, the same individual would be allowed to fly with such a restriction applied to the licence, for example, following recovery from a myocardial infarction.

## **The development of cardiological experience**

Thirty years ago, a number of reports on cardiovascular problems were sponsored by the aviation regulatory agencies in some Contracting States. These included the Federal Aviation Administration (FAA) in the United States, the Civil Aviation Authority (CAA) in the United Kingdom, and the Civil Aviation Authorities of Canada and Australia. Their purpose was to address the need for appropriate scientific data to assist in making aeromedical decisions more consistent and fair. The United Kingdom and European Workshops in Aviation Cardiology, four in number over a 16 year period between 1982 and 1998, focused on the epidemiology, natural history and outcome of most of the commonly encountered cardiological problems. From them a methodology was evolved which was coherent with the man-machine interface in regulatory terms. The pilot was identified as one component in an aviation system, the failure of any part of which would lead to an erosion of safety with the ultimate potential risk of catastrophic outcome.

Accidents are most commonly the result of a series of adverse events, which may include cardiovascular incapacitation, none of which in isolation needs to lead to disaster because of safety redundancy in the system. Taking these aspects into account, the workshops formed the basis of the first and second drafts of the European Joint Aviation Authorities (JAA) Joint Aviation Requirements - Flight Crew Licensing (JAR - FCL) Part 3 (medical) in cardiology and contributed by providing a cardiological “road map” in regulatory terms. Since the 1990s, this material has been used as guidance by many regulators outside Europe. The guidance contained in this chapter is based on recommendations that have been found acceptable to the JAA.

## **Determination of the limits of cardiological certification**

There should be separation between the regulator and the specialist advisor (in cardiology). The cardiologist is required to identify the probability of a cardiovascular event in a given individual over a defined period. It is for the regulator to set a cut-off point for the cursor which denies, or restricts, certification. In general terms, the following questions need to be satisfied:

- What is the operational exposure? This may be expressed in terms of number of hours flown, number of departures, or number of passenger-kilometres travelled.
- What is the fatal/non-fatal accident rate expressed in the same units? Accidents are often expressed per one million hours flown or per one million departures, but they can also be expressed per unit of time, usually one year.
- What is the medical (cardiological) contribution to this accident experience, and is it acceptable? Such data may be difficult to come by with certainty in the single-crew situation, because such accidents are less well investigated than those involving large aircraft: the finding of a cardiac abnormality in the context of an otherwise unexplained accident does not necessarily imply cause and effect.
- What level of routine medical examination is appropriate, what is its sensitivity, and is it cost-beneficial, bearing in mind the parallels with regular airframe/engine review? What additional investigations can reasonably be requested?
- Should there be an explicit cardiovascular level of risk, which, if exceeded by an individual, results in denial of certification to fly? Without such a defined limit, there is the chance of inconsistency, of lack of objectivity and fairness. However, not all Contracting States utilise an objective limit in assessing risk, and of those which do, not all publicise what it is.

## **Aviation and cardiovascular risk**

Aviation is involved with risk of event. Airframes have a predicted number of hours of “life”, and engines have a “time before overhaul”. This proscription attempts to reduce the possibility of failure to a predetermined target level in the interest of safety. The same applies to the heart of a pilot. At a young age the probability of a cardiovascular event is very remote. In the four decades from age 30–34 to 70–74 years, male cardiovascular mortality in the Western nations increases by a factor of 100 (two orders of magnitude), but there are mitigating circumstances in the air with some studies showing that older, more experienced, pilots have fewer accidents. In accidents attributable to incapacitation of the pilot there are important differences between single-pilot and multi-pilot operations: in those aircraft in which there is only one crew member, the rate of complete incapacitation will approach the accident rate. Subtle incapacitation will also erode safety. In multi-crew operations, an incapacitating cardiovascular event, like an engine failure, should be containable in all but the most adverse circumstances. There is a strong case, therefore, to demand a higher standard of fitness for pilots engaged in single-crew operations. This is the basis of the OML restriction (see above).

During the 1960s, civil air-transportation accidents in which cardiovascular incapacitation was a contributory factor occurred on a worldwide basis at the rate of approximately one every 18 months, culminating in the loss of a British European Airways (BEA) Trident 1 at Staines near London Heathrow Airport in June 1972. There were, however, major aircrew training and operational differences at that time when compared with modern airline operations and less was understood about the multi-factorial nature of accident causality. In the near one billion multi-crew jet hours flown since 1974, when an ICAO requirement for experience in procedures for crew incapacitation — “incapacitation training” — was adopted (see Annex 1, 2.1.5.2.a)), hull loss accidents caused by pilot cardiovascular incapacitation has been all but eliminated. There have, however, been a small number of significant incidents with safety degradation, and cardiovascular deaths continue to occur whilst pilots are on duty, varying at a recorded rate of two to four per annum worldwide.

Early cardiovascular-cause accident experience led to reports by certain “expert” groups which were not commissioned by any Licensing Authority. These recommended, *inter alia*, that exercise electrocardiography, still in its early days, might be helpful in the detection of occult coronary artery disease. This was at a time when resting electrocardiography had only relatively recently been made mandatory by ICAO (1963). A better understanding of probability theory in populations with a low prevalence of disease led to the rejection of this suggestion at the ICAO cardiovascular study group in Montreal in 1980.

### **The “1% Rule”**

A seminal contribution to regulatory judgement was made by the suggestion that there was symmetry between the cardiovascular event rate in aircrew and the accident rate of aircraft. From this beginning emerged what has become known as the “1% Rule”. This is a mathematical model of accident probability based on the epidemiology of coronary artery disease. It may, however, be applied to other medical conditions as well (see Part 1, Chapters 2 and 3). In cardiology, it is easier to apply to those cardiac conditions for which event rates can be reasonably predicted, such as the coronary syndromes, rather than to the more capricious problems, such as atrial fibrillation. Inevitably such predictions apply to groups of individuals rather than the individual himself.

It calculates that provided the predicted cardiovascular mortality of an individual does not exceed approximately one per cent per annum (that of a Western male aged 70 years), the probability of an accident to a multi-crew aircraft from cardiovascular incapacitation of the pilot should be “very remote”, i.e. no more than  $1:10^9$  (one per one billion) flying hours.

In spite of the rule being predicated on the basis of cardiovascular mortality, confusion continues in distinguishing this from the non-fatal cardiovascular event rate. Every coronary death will be clustered with perhaps three to four non-fatal co-morbid events but in aviation the population will have been factored, as some of the co-morbid events will have brought about the earlier removal (because of a regulatory “unfit” assessment) of higher-risk pilots. In regulatory terms, the cardiovascular death rate thus approximates to the cardiovascular incapacitation rate.

The “1% Rule” is only one of several means of defining regulatory cut-off points. The rule has been reviewed comprehensively recently and some Contracting States have found a two per cent cut-off point to be justified.

### **Cardiovascular causes of incapacitation**

Incapacitation due to cardiovascular disease may be insidious or sudden in onset, and subtle or obvious in its manifestation. The coronary syndromes are not infrequent in aircrew in the Western world or the Indian sub-continent. Apart from causing (sudden) death, acute cardiovascular events such as stroke, aortic rupture and myocardial infarction may cause complete incapacitation, whilst the pain of acute myocardial ischaemia may be disabling. Non-lethal cardiac arrhythmias may be sufficiently subtle to cause distraction without the aircrew member being fully aware as to what is absorbing his or her attention. In the single-crew environment major events have a high probability of a catastrophic outcome. Fortunately, the very large database on natural history and the impact of intervention, notably in coronary artery disease, has permitted the development of algorithms of aeromedical management that assist safe, fair and evidence-based decisions.

## HISTORY AND MEDICAL EXAMINATION

There is some variation worldwide in the implementation of the ICAO Standards and Recommended Practices. In many Contracting States, routine review of pilots is carried out by medical practitioners with some training in the field of aviation medicine. Such physicians (normally identified as “designated” or “authorized” medical examiners (DMEs or AMEs)) are usually family doctors without special training or experience in cardiology. In some States the responsibility is devolved to the military. Almost universally, a standardized form (see Part I Chapter 2 for an example of such a form) is used to record factors such as age, past and family history, weight, blood pressure, smoking habit, use of medicines, and clinical observations, such as changes in the fundus oculi, and heart murmurs, if present. Increasingly, these forms are being computerized and transmitted online. Certain regulatory agencies, including the JAA, also require routine measurement of the serum cholesterol at specified times. A few require routine exercise ECG (see below) and this investigation is also a requirement of some airline employers.

### **Resting electrocardiography (ECG)**

A regular 12-lead resting ECG is required in the routine scrutiny of aircrew, depending on age and level of certification. It was not until 1957 that resting electrocardiography was made an ICAO Recommended Practice (becoming mandatory as a Standard in 1963). Minor anomalies are common, requiring comparison with earlier recordings (where available) in at least 10 to 15 per cent of cases. In a review, three per cent of UK civilian personnel demonstrated abnormality of the ST segment and/or T wave on routine scrutiny.

The resting ECG is an insensitive tool for the detection of pre-symptomatic coronary artery disease, although it does identify a small number of people who have suffered a silent myocardial infarction. In one ten-year period, 72 “silent” myocardial infarctions were detected in 48 633 aircrew screened at the US School of Aerospace Medicine. Twenty-five per cent of those suffering such events in the Framingham study<sup>1</sup> did not experience symptoms that they recognized as significant and 15 per cent of those dying suddenly do so without premonitory symptoms. As the risk of further cardiovascular events is increased substantially following myocardial infarction, the identification of minor anomalies should provoke further and fuller review. Sometimes ECG changes are variable, but it is a misconception that a stable “abnormal” recording is necessarily acceptable on the grounds of its stability – a recording demonstrating a pattern of myocardial infarction remains predictive of outcome even if it does not change. Nevertheless, a stable but abnormal recording in follow-up ECGs subsequent to satisfactory investigation may be relatively, although not absolutely, reassuring. A resting ECG is rather better at detecting disturbances of rhythm and conduction than ischaemic heart disease.

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<sup>1</sup> Framingham Heart Study: a cardiovascular study based in Framingham, Massachusetts (USA). The study began in 1948 with 5,209 adult subjects from Framingham, and is on its third generation of participants at present. Most of the now common knowledge concerning heart disease, such as the effects of diet, exercise, and common medications such as aspirin, are based on this longitudinal study. It is a project of the National Heart, Lung, and Blood Institute, in collaboration with (since 1971) Boston University.

## Recording the resting electrocardiogram

A resting ECG should be recorded with the subject at rest in a warm environment. The skin should be prepared with spirit or abrasive, or both. The position of the limb electrodes is not important, but those on the chest must be placed accurately. Leads V1 and V2 should be placed in the fourth inter-costal spaces on either side of the sternum. Lead V4 is placed at the position of the apex of the normal heart – the fifth inter-costal space in the mid-clavicular line. Lead V3 is placed midway between V2 and V4. Leads V5 and V6 are placed at the same level as V4 in the anterior and mid-axillary lines, respectively (see Figure 1).

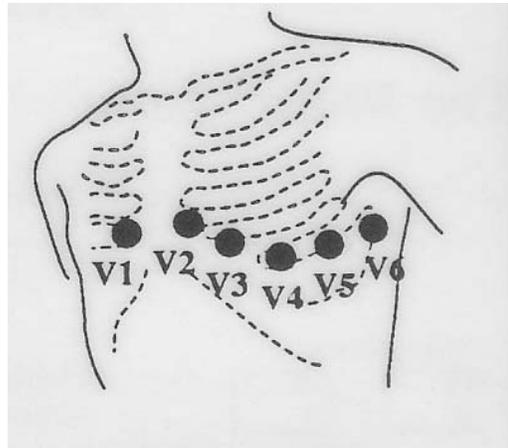


Figure 1.— Diagram of the electrode positions of the chest lead used for the standard 12-lead electrocardiogram. The limb leads are placed on the right and left arms, and the right and left legs respectively. The right leg is an indifferent electrode. During exercise the limb leads are positioned on the shoulders and the iliac crests on each side. This gives a slightly different read out and these positions should not be used for making standard recordings.

The preferred instrument should record at least three channels simultaneously and be optimally filtered and damped. On such a machine, the length of a recording is 12 s at the standard speed (25 mm/s) and is presented on a single sheet of A4 paper. Some recording techniques use thermo-sensitive paper which needs special care when archiving as the recording fades over time. A further 24 s of rhythm strip using an inferior, anterior and lateral lead such as SII, V1 and V6 should be recorded. If a q wave is present in SIII, a recording during inspiration should be included. If the q wave is less than 40 ms wide and disappears with inspiration, it is probably innocent. A normal ECG is illustrated in Appendix 1b, ECG no. 1.

In Europe, interpretation of the resting ECG is required to be by “specialists acceptable to the JAA Aeromedical Section” under JAR FCL 3.130 (d) (where the “Aeromedical Section” is part of the regulatory authority). In the USA scrutiny is by on-line computer with skilled technician/cardiologist back up. As computer formatting and reporting have become more reliable and widespread, the need for specialist interpretation of large numbers of mainly normal ECGs is questionable. Nevertheless, an experienced interpreter is likely to be more sensitive and more accurate than a computer working to a preset profile, perhaps for no reason other than he or she can better factor in experience and probability bias. None of the presently available commercial programmes are approved for the task in the context of aviation. In practice, although the computer programmes tend to err on the side of caution, i.e. they over-report (as may scrutinizers due to fatigue or lack of experience). In safety terms, the difference between

computer reporting and reporting by an experienced scrutineer is not likely to be measurable, although delegation of the responsibility for processing the reports raises issues of process accountability and audit.

For a further exposition on interpretation of the resting ECG see Appendix 1a, and for some ECG examples in aircrew, see Appendix 1b.

### Exercise electrocardiography

There is no requirement for routine exercise ECG in Annex 1. Some airlines require the investigation either routinely or before employment. When exercise recordings are carried out, often to clarify some minor ECG anomaly, a standardized protocol such as the Bruce treadmill protocol<sup>1</sup> or equivalent should be employed. The Bruce protocol is not the only one available (Table 1), but it is the most widely used. It suffers from a shortcoming that it does not present the same challenge to anthropomorphically different individuals in terms of height and weight.

STAGE	Bruce		Sheffield		Naughton		Ellestad	
	(mph)	(%)	(mph)	(%)	(mph)	(%)	(mph)	(%)
1	1.7	10.0	1.7	0.0	1.0	0.0	1.7	10.0
2	2.5	12.0	1.7	5.0	2.0	0.0	3.0	10.0
3	3.4	14.0	1.7	10.0	2.0	0.0	4.0	10.0
4	4.2	16.0	2.5	12.0	2.0	3.5	5.0	10.0
5	5.0	18.0	3.4	14.0	2.0	7.0	5.0	15.0
6	5.5	20.0	4.2	16.0	2.0	10.5	6.0	15.0
7	6.0	22.0	5.0	18.0	2.0	14.0		

**Table 1.— Standard treadmill protocols**

The exercise ECG should utilize the 12 standard leads, displaying at least three simultaneously, and be optimally filtered and damped. The limb leads should be placed on the shoulders and the lower trunk. Recordings should be made at rest in the erect and lying positions, and after hyperventilation for ten seconds. A 12-second recording should be made for each of the resting observations, for each minute of exercise, and for each of *10 minutes* of recovery. Not infrequently, diagnostic changes are seen only in the recovery phase.

The subject should be exercised to symptom limitation and be expected to complete **at least three stages** — nine minutes — of the protocol or achieve an oxygen uptake equivalent to 11 metabolic equivalents (METs)<sup>2</sup>. The age-predicted maximum heart rate is calculated by subtracting the age in years from 220 (beats/minute (bpm)). The test is most sensitive when taken to symptom limitation rather than any percentage of the age-predicted maximum. The reason for discontinuing the test should be recorded, together with the presence or absence of any symptoms.

In some countries, bicycle ergometry is still employed widely. This suffers from the relative disadvantage that the subjects do not have to bear their own weight, and there is no imperative to maintain speed. Furthermore, some people are not used to riding a bicycle. The bicycle protocol that approximates to the Bruce treadmill protocol is the 20 Watt protocol. The subject is seated and the workload increased from zero by 20 Watts every minute to the same symptom/heart-rate endpoints. Neither of the two test methods

<sup>1</sup> Bruce treadmill protocol: standardized treadmill test for diagnosing and evaluating heart and lung diseases, developed by Robert A. Bruce, American cardiologist (1916-2004).

<sup>2</sup> 1 MET is the resting oxygen requirement of a 70-kg 40-year-old male (3.5 ml/min/kg).

are completely sensitive — they do not detect non-flow-limiting lesions, nor are they completely specific — they may falsely suggest the presence of coronary artery disease. Thus:

- *Sensitivity* = true positives / (true positives + false negatives). It reflects the percentage of all subjects with coronary disease with an abnormal test.
- *Specificity* = true negatives / (false positives + true negatives). It reflects the percentage of negative tests in subjects without coronary disease.
- *Positive predictive accuracy* = true positives / (true positives + false positives). It reflects the percentage of abnormal responses in subjects with coronary disease.
- *Negative predictive accuracy* = true negatives / (true negatives + false negatives). It reflects the percentage of negative responses in subjects without coronary disease.

Interpretation of exercise ECG data has been reviewed widely. There remains an excessive interest with interpretation of the ST segment, the depression (or elevation) of which is measured at 60 ms after the J point - the junction of the S wave and the ST segment. Its pattern needs to be examined closely at rest and in the early stages of exercise, during the recording and especially during the early stages of recovery - the recovery ECG should be recorded for 10 minutes. It is at its most sensitive and specific when the resting ECG is normal and at its least when it is abnormal, e.g. in left bundle branch block. Often 2 mm of plane ST segment depression is referred to as “positive” (i.e. for coronary artery disease), but this is a confusing term as such disease may not be present with this observation. The skilled interpreter will be more influenced by the walking time, symptoms (if any) and pattern of change, rather than numerical values.

Ventricular function is a good predictor of outcome, and its surrogate, the exercise walking time reflects this. A walking time > 10 minutes using the standard Bruce treadmill is associated with an annual event rate of <1 per cent, even if the ECG response is not completely normal. This predictive capability also applies following myocardial infarction, coronary surgery, angioplasty and coronary stenting. The argument against routine exercise ECG scrutiny of aircrew is as follows and depends on the Bayesian theory of conditional probability:<sup>1</sup>

- In an average middle-aged pilot, the prevalence of significant coronary artery disease may be only one to two per cent.
- The exercise ECG is only 60 to 70 per cent sensitive, i.e. it detects only this percentage of those subjects with coronary artery disease — the true positives.
- If 1 000 pilots underwent such a study, then 10 to 20 (1 to 2 per cent) might have the disease, but only 6 to 14 (60 to 70 per cent of 1 to 2 per cent) would be detected.
- With 95 per cent specificity of the test (at best, and it may be much lower than this), 5 per cent (perhaps 50 pilots) would have diagnostic changes but no disease, i.e. would be false positives.
- The false-positive responders to exercise could thus outnumber the true-positive responders by a factor of up to seven or more.

This effect was demonstrated in one study of healthy police officers with a mean age similar to the pilot population (38 years) of whom 916 were followed up with serial exercise ECG for between 8 and 15 years (mean 12.7 years). Twenty-three had an initially abnormal exercise response and 38 converted to an abnormal response during the follow-up period. There were nine coronary events in the first group and 12 in the second. In the much larger normally responding group, there were 44 events. The positive predictive accuracy was 25.3 per cent, but there was only one sudden death in the initially abnormal group. There were seven sudden deaths in the much larger “normal” group.

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<sup>1</sup> Bayes' theorem: A simple mathematical formula used for calculating conditional probabilities. In a medical context, it can be paraphrased as ‘the rarer the condition for which we are testing, the greater the percentage of the positive tests will be false positives’. After British cleric Thomas Bayes (1702-1761)

Middle-aged males in the Seattle Heart Watch programme<sup>1</sup> who had more than one abnormal exercise ECG response in the presence of vascular risk factor(s) had an annual coronary event rate >5 per cent. By comparison, the risk of an event was only 0.22 per cent if there were no vascular risk factors and the exercise recording was normal. If there was one abnormal recording and no vascular risk factor present the risk of an event was 0.42 per cent per annum. Under such circumstances, the finding of a normal exercise ECG identifies a group in whom the risk of event is acceptably <1 per cent per annum.

The American College of Cardiology (ACC)/American Heart Association (AHA) guidelines state that in patients with suspected coronary artery disease with a low or high pre-test probability of its presence, exercise ECG is less appropriate than if the probability is intermediate. This is based on greatest value in terms of diagnostic outcome: low-risk subjects are likely to have a normal response and high-risk subjects the reverse. In a study of 5103 patients with symptoms suggestive of angina pectoris in whom the overall sensitivity of the investigation was 70 per cent and specificity 66 per cent, there was a progressive increase in positive predictive value – 21 per cent, 62 per cent and 92 per cent for low, intermediate and high pre-test probability, respectively – and a fall in the negative predictive value – 94 per cent, 72 per cent and 28 per cent, respectively. Although this group is not representative of the pilot population in terms of prevalence of disease, it emphasizes the usefulness of exercise ECG in returning aircrew to flying when the probability of coronary artery disease is low (i.e. lack of symptoms, unremarkable vascular risk burden (including age), non-specific ECG changes) due to the high negative predictive value.

Further investigation should be carried out when the probability of coronary disease is high (i.e. symptoms, significant vascular risk (including age), possibly significant ECG changes, known coronary artery disease), irrespective of the result of the exercise test. With the intermediate group, exercise evaluation alone may be insufficient as some authors have noted a statistically significant difference between the pre-/post-test predictive values ( $P < 0.0001$ ). A significant false-negative rate following investigation does not sit easily in the regulatory environment.

Although aviation used to be an almost exclusively male preserve, increasing numbers of females recruited over the past three decades have brought the need for investigation for coronary artery disease in a group in which its prevalence, overall, is low. One meta-analysis of exercise testing for coronary artery disease in women revealed an overall sensitivity of 61 per cent and a specificity of 70 per cent, comparable to males, but of limited value due to the high number of both false-positive and false-negative results. Additional guidance should be sought, depending on the clinical situation.

Some examples of normal and abnormal exercise ECG responses are illustrated in Appendix 2

### **Pharmacological stress echocardiography**

In a subject with a low probability of coronary artery disease, routine resting ECG anomalies are initially best assessed by exercise ECG. When an exercise recording is equivocal or abnormal, and the probability of coronary artery disease is intermediate or high, then further evaluation will be clinically indicated.

Of the techniques available, stress echocardiography is the least invasive but the one with which, in many centres, there is the least experience. Using exercise or a beta-agonist (such as dobutamine) to increase myocardial oxygen requirement, stress echocardiography demonstrates ventricular wall motion abnormality in the presence of myocardial ischaemia. In one study, the three year event free survival in a group of patients of mean age 68 with a normal stress echocardiogram was 97.4 per cent.

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<sup>1</sup> The Seattle Heart Watch program: a study, initiated by Drs. Robert A. Bruce et al. in 1971, involving community physicians in hospitals, offices, and the medical department of the Boeing Company. It tested the feasibility, utility and reproducibility of results of symptom-limited exercise testing in ambulatory cardiac patients and apparently healthy subjects. A database of more than 10,000 individuals was developed over a period of 10 years.

This was better than their age and gender matched peers. Another study found a one per cent six year annual mortality in a large group of patients of mean age 54 years with a normal exercise echocardiogram. But a third, which was the largest that has assessed long term survival and outcome following a normal stress echocardiogram, concluded that prognosis was “not necessarily benign”. The patient mean age was older (68 years).

This technique is being increasingly used and has the benefit that there is no radiation burden. However, it has to be carried out in an experienced centre and more long term outcome data are needed.

### **Myocardial Perfusion Imaging**

A more widely available investigation is myocardial perfusion imaging (MPI). The largest experience with MPI has been obtained with thallium-201, a radionuclide with a half-life of 72 hours which decays to mercury-201. The standard dose is 80 MBq<sup>1</sup>; approximately four per cent are cleared in the first pass through the coronary circulation. The radiation dose is quite high and is equivalent to 18 mSv<sup>2</sup>, exceeding the radiation dose received during coronary angiography by a factor of two or three although with the most modern equipment, doses are often lower. It behaves as potassium in the exercising myocardium being taken up by the myocardial cells via a sodium-potassium adenosine triphosphatase (ATP-ase)-dependent mechanism.

Exercise is now being supplanted by pharmacological agents, commonly adenosine, as the means of myocardial stress. It causes maximal vasodilatation, the heart rate response being limited. A pharmacological agent is preferred in the presence of left bundle branch block. Imaging takes place following maximum stress and three hours later to permit redistribution of the isotope. Other stressor agents include dipyridamole and dobutamine. Other radionuclides such as technetium-99m-2-methoxy-isobutyl-isonitrile (MIBI) provide better resolution for a smaller radiation burden.

The power of MPI in the prediction of outcome has been established and surpasses exercise ECG although it, too, has incomplete specificity and sensitivity in diagnostic terms. The exercise ECG can be expected to be of the order of 68 per cent sensitive and 77 per cent specific; thallium scanning is a few percentage points better on both counts. Both modalities depend crucially on the prevalence of coronary disease in the population being studied. In one study of 3573 patients with angiographic coronary artery disease and a normal MPI, the incidence of death or myocardial infarction was 0.9 per cent per annum over a mean of 28 months. A more recent review of the outcome of 7376 consecutive patients with a normal exercise or adenosine MPI, hard events (cardiac death, myocardial infarction) were more common with increasing age, male gender, diabetes and known coronary artery disease, but the highest event rate was 1.4 to 1.8 per cent per annum over the two-year study period. Many regulatory authorities would regard these figures as failing to provide adequate confidence for certification.

The incremental prognostic value of sequential investigation of patients suspected of suffering from coronary artery disease has also been evaluated. The addition of exercise ECG to the clinical examination and resting ECG adds significant predictive power, while the addition of MPI improves it further. The hierarchical prognostic gain from adding exercise ECG, exercise single photon-emission computed tomography (SPECT) thallium-201 imaging and coronary angiography has been reviewed and demonstrated that imaging quadrupled the prognostic power but coronary angiography provided no additional improvement over exercise ECG.

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<sup>1</sup> MBq: Megabecquerel = 1000 kBq. 1 Bq = 1 event of radiation emission per second, named after Antoine Henri Becquerel, French physicist (1852 – 1908).

<sup>2</sup> mSv: millisievert. 1 Sv = 1 J/kg is the dose equivalent for the biological effect of radiation. The unit is named after Rolf Maximilian Sievert, Swedish medical physicist (1896-1966).

Myocardial Perfusion Imaging is an expensive investigation with a significant radiation burden. This is of potential concern in younger subjects. It is neither completely sensitive nor completely specific but it is non-invasive. From the certificatory point of view, it may be indicated as the investigation of election when, for example, evidence of satisfactory revascularization is being sought following coronary surgery/angioplasty/stenting. The JAA now accepts the investigation for this purpose, provided there is also a coronary angiogram available in relation to the index event. As the primary investigation in the presence of an abnormal exercise ECG, it will give an indication of prognosis, but only indirect evidence on the coronary anatomy. This may be inadequate from the clinical point of view. The recommendation to perform the investigation depends on both the clinical and the certificatory situation.

### **Cardiovascular Magnetic Resonance / Magnetic Resonance Imaging**

Cardiovascular Magnetic Resonance (CMR) is safe, bears no radiation burden and is non-invasive. It is capable of defining anatomy, function, flow, tissue perfusion and the anatomy of the larger coronary vessels. It has an established role in the investigation of the cardiomyopathies and in the definition of congenital heart disease. It is also useful in the assessment of the ischaemically damaged ventricle, and the great vessels. It is for these indications that a Magnetic Resonance Image (MRI) scan may be helpful in establishing a fit assessment in certain aircrew.

### **Electron-beam Computerized Tomography and Multi-Detector Computed Tomography Coronary Angiography**

Electron-Beam Computerized Tomography (EBCT) is a comparatively new radiographic technique which detects calcium in the coronary arteries, the Agatston score<sup>1</sup> correlating with the presence of calcium in the wall of the coronary artery, and, by extrapolation, atheromatous disease. Its value in determining prognosis is under evaluation. At a recent American College of Cardiology consensus conference, a 70 per cent predictive accuracy for obstructive disease was identified for the technique but with lower specificity. It is not required for regulatory purposes but may prove useful once there are more data on its prognostic power. Like exercise ECG, it is likely to have a high negative predictive accuracy in subjects with a low probability of coronary artery disease. If an aircrew member undergoes the investigation for whatever reason, and the result suggests the possibility of coronary artery disease, further investigation is indicated using available techniques.

Electron-beam computerized tomography has a radiation burden about half that of coronary angiography but is being supplanted by Multi-Detector Computed Tomography Coronary Angiography (MDCTCA) in the non-invasive assessment of the coronary arteries. The radiation burden of the latter is the same as thallium MPI and at least twice that of coronary angiography. It has not yet replaced coronary angiography in the pre-intervention assessment of coronary artery disease,

### **Coronary angiography**

Coronary angiography has long been regarded as the gold standard in the assessment of prognosis in coronary artery disease. If other tests have not been reassuringly negative during an assessment, this investigation may be warranted and certification may not be possible without it. It carries a very small risk of death — less than one in 5000 in healthy individuals (such as an aircrew population) with a slightly higher risk of vascular damage to the vessel of entry or due to stripping of the intima of the coronary artery. The latter may provoke a myocardial infarction. In private flyers, the procedure is difficult to justify for certificatory purposes alone, except at the insistence of the individual.

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<sup>1</sup> Agatston score: a score for quantification of coronary calcification, based on the size and density of calcified plaques on CT. Named after Dr. Arthur Agatston, contemporary American cardiologist.

There is an assumption that a normal coronary angiogram showing no evidence of obstructive coronary artery disease, together with a normal contrast ventriculogram, bears a low risk of future event. From the certificatory point of view this is probably correct, but there remains a small group of people who have abnormal exercise ECG responses without clinical or other explanation. In these people, the tendency to regard them as fit, based only on their coronary anatomy, should be regarded with caution as they may subsequently demonstrate a myocardial abnormality. Follow-up therefore is advisable.

## **Specific problems in cardiology and cardiovascular medicine**

### **Vascular risk factors**

Vascular risk factors are those inherited or acquired (often metabolic) abnormalities, or lifestyle patterns, which are associated with an increased risk of coronary (and cerebro-vascular) events. They include hypertension, hyperlipidaemia, diabetes, smoking, obesity, and lack of exercise. The Metabolic Syndrome (sometimes known as Syndrome X or Reaven's Syndrome<sup>1</sup> — hypertension, hyperlipidaemia, insulin resistance and trunkal obesity) carries a significantly increased risk of such event. Vascular risk factors predict coronary artery disease and coronary artery disease predicts coronary events. Hypertension has been called the most powerful and predictive of all the vascular risk factors although in reality age is the most important. To assess one risk factor in isolation is not appropriate as they all interact powerfully and multiple risk factors present in minor extent are as lethal as a single one present in large extent. There is no provision in Annex 1 which directly relates to vascular risk factors but in the introduction to Chapter 6, Note 2 states that “predisposing factors for disease, such as obesity and smoking, may be important for determining whether further evaluation or investigation is necessary in an individual case”. 6.3.2.7 states that the blood pressure shall be “within normal limits” and 6.3.2.5.1 states that a fit assessment following a coronary event shall be in accordance with “best medical practice”.

### **Hypertension**

The blood pressure should be <140/90 mm Hg, treated or untreated and this may be achieved by lifestyle adjustment (reduction of alcohol intake, weight reduction) in those with modest elevation. If the 10-year cardiovascular mortality is < 5 per cent and there is no evidence of target organ damage, slightly higher levels are tolerable in the short term. If it is >5 per cent, medical treatment will be needed. In the presence of diabetes and micro-albuminuria, the lower target of 130/80 mm Hg is applicable. A pressure consistently >160/95 mmHg is disqualifying from all classes of medical certification. In aviation, most of the currently employed agents are permissible as follows:

1. The sartans (angiotensin receptor blocking agents - ARB's) — e.g. losartan, candesartan
2. The angiotensin converting enzyme (ACE) inhibitors — e.g. enalapril, lisinopril,
3. The slow channel calcium blocking agents (CCB's) — e.g. amlodipine, nifedipine
4. The beta-blocking agents — e.g. atenolol, bisoprolol
5. The diuretic agents — e.g. bendroflumethazide, indapamide

The alpha 1 blocking agents, i.e. doxazosin, prazosin and the centrally acting products clonidine, moxonidine and methyldopa, are not permitted. Anti-hypertensive therapy should be supervised by a physician. On commencement or following change in treatment or its dosage, the pilot should be assessed

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<sup>1</sup> Reaven's syndrome: named after Gerald M. Reaven, American endocrinologist (1928- )

temporarily unfit until there is evidence of stable control and freedom from side effects, such as orthostatic hypotension.

### **Serum cholesterol**

Although some Licensing Authorities require measurement of the cholesterol, it is not an ICAO requirement. However, a level >8 mmol/L (320 mg/dL) should be treated (best with a statin, eg simvastatin, atorvastatin) whether or not there are other risk factors present. In the presence of overt coronary artery disease, targets should be: total cholesterol <5 mmol/l (<190 mg/dL) and LDL cholesterol <3 mmol/L (<115 mg/dL) or, in the presence of diabetes <4.5 mmol/L (<175 mg/dL) and <2.5 mmol/L (100 mg/dL) respectively.

Non-insulin dependent diabetes mellitus is permitted under ICAO SARPs “subject to satisfactory control”. Intervention against vascular risk factors is influenced to some extent by the presence or absence of other risk factors and whether or not there is evidence of target organ damage (left ventricular hypertrophy, loss of vascular compliance, reduced renal function, micro-albuminuria in diabetes). From the point of view of good clinical practice, which should be inseparable from good regulatory practice, the European Society Committee for Practice Guidelines (like other groups) has developed risk tables, calculating 10-year cardiovascular mortality in males and females in high and low risk countries, which relate age, systolic blood pressure, total cholesterol and smoking. A subject in middle age with a 10-year mortality of >5 per cent is in need of specialist advice.

Prevention strategies, applicable to all, should start with attention to lifestyle — no smoking, maintenance of optimum body weight, and avoidance of excessive alcohol intake (many States have developed a maximum recommended daily or weekly intake of alcohol<sup>1</sup>), and frequent exercise. Pilots, on the basis of their regular medical review and need to maintain medical fitness, should be in an ideal position to instigate preventative strategies with the object of health maintenance. It remains a lamentable fact that often this opportunity is lost on account of inadequate advice on the part of the AME/physician or failure of its uptake by the pilot, usually based on the misconception that preventative and regulatory medicine are incompatible and must be kept separate from each other. The result is that careers are destroyed and future health impaired.

Atherosclerotic disease of the great vessels (i.e. the aorta) and the medium-sized vessels (i.e. the coronary and cerebral arteries) is insidious in onset, often having an origin in early adulthood. It has a trajectory of many years’ duration and may present abruptly with some cerebrovascular or myocardial event. In Europe, there is a north-south gradient, death from coronary heart disease being three times more common in the north than in the southern “olive belt”. There is also an East-West gradient: heart-attack rates in Western Europe are generally lower than those in Eastern Europe. The dietary, environmental and genetic factors involved have been demonstrated in the INTERHEART study<sup>2</sup> to be shared worldwide by both sexes in all regions.

Historically, some nations have experienced low heart-attack rates. In some of these nations, this finding has changed. South Asians, for example, both locally and following emigration, now demonstrate rates that are generally some 50 to 60 per cent higher than those observed in the West. Numerous factors,

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<sup>1</sup> Maximum daily or weekly alcohol intake, recommended by the public health authorities in several States, is usually expressed in ‘units of alcohol’, the definition of which varies from one State to another. In one Contracting State, a unit of alcohol is defined as 15 mL of pure alcohol (ethyl alcohol, ethanol), which is equivalent to one standard serving of beer, wine or spirits. If not accompanied by food, one unit of alcohol will entail a blood alcohol concentration of c. 0.2g/L in a man (70 kg) and of c. 0.3g/L in a woman (55 kg). The recommended weekly maximum intake for males is 21 units and for women 14 units.

<sup>2</sup> INTERHEART: A global case-control study of risk factors for acute myocardial infarction, led by Dr. Salim Yusuf of McMaster University, Canada, involving >29 000 people in 52 countries (published in 2004).

including inherited metabolic anomalies and insulin resistance, are involved. Japan and China, sharing with other countries in the Far East commendably low mean levels of plasma cholesterol and some of the lowest heart-attack rates in the world, are showing signs of increase in the prevalence of coronary artery disease. Japanese who emigrate to the United States tend, like other migrant populations, to assume the risk of their country of adoption. This global burden is thus reflected unevenly in the aviation environment.

## **CORONARY ARTERY DISEASE**

The presence of coronary artery disease, in general, predicts an adverse outcome. The presence of one or more vascular risk factors implies a greater probability of event in an individual without identifying whether or when it might occur. It remains what has been called the “prevention paradox” that the greatest number of events will be seen in those individuals with a near-normal vascular risk profile - on account of their far greater numbers. Predictions on the probability of an event, which should be over a defined period, often a year, should be based on data from an age and sex-matched control population.

Coronary artery disease remains a significant cause of premature death. Death from coronary artery disease is falling in the West, but elsewhere the trend is less favourable or may even be reversed. In northern Europe, nearly 40 per cent of the population die from cardiovascular disease. One in four men and one in six women die from coronary artery disease. Ten per cent of the population die from stroke. One-third of cardiovascular deaths in males and one-quarter in women are premature (<age 75 years).

Of those presenting with a new coronary syndrome, one-sixth will present as sudden cardiac death (SCD) without recognizable premonitory symptoms; two-fifths will present with angina pectoris and two-fifths with myocardial infarction. The remainder will suffer an unstable ischaemic syndrome. Of the untreated third that die within 28 days following acute myocardial infarction, about half will do so within 15 minutes of the onset of symptoms, 60 per cent being dead at one hour and 70 per cent within 24 hours. As the average pilot spends some eight to ten per cent of his/her year on duty, the possibility of some manifestation at work is to be expected. Although in safety terms, incapacitation (obvious or subtle) will be at greatest risk of occurrence at the time of the index event, the risk of fatal event is still increased substantially in the days and weeks that follow. With the exponential increase in cardiovascular events that occurs with increasing age, older pilots will be at greatest risk of an event, particularly if other risk factors such as hypertension, hyperlipidaemia, smoking, insulin resistance and/or a family history are present.

Most of the coronary syndromes are attributable to obstruction of the vessels with atheroma. This lipid-rich material, which accumulates at sites of vascular injury, may be present in early adulthood and it may progress very slowly. These atheromatous foci are known as plaques and contain “foamy macrophages” — cells of monocytic origin, smooth muscle cells and lipids in the form of cholesterol, fatty acids and lipoproteins. There is significant variation in the composition of the plaques, their state of development and their behaviour in individuals. Their behaviour may also be modified by medication. Thrombosis occurs in association with plaque rupture, tripping the clotting cycle via several different mechanisms. The subsequent sequence of events depends on the morphology of the plaque, its site in the coronary artery, the extent of the related thrombus and the presence or absence of a collateral circulation. Flow varies as the fourth power of the radius and symptoms may not be present until one or more major epicardial arteries are occluded by 50 to 70 per cent of the luminal diameter. Myocardial infarction due plaque rupture can occur on a minimally obstructing plaque, however.

If the thrombotic event is minimal and the plaque not large, there may be no symptoms. Or, with disruption in the plaque, symptoms such as angina pectoris may occur. If the vessel is occluded, infarction of the myocardium subtended by the vessel will occur unless an adequate collateral circulation is present.

As collateral formation is most common when near-obstruction has been long-standing, such an outcome is less likely to apply to aviators who must not only be asymptomatic but also pass routine medical surveillance. By way of these patho-physiological processes, the coronary syndromes of stable/ unstable angina pectoris and myocardial infarction occur.

### **Angina pectoris**

The pain or discomfort that is angina pectoris is one of the more familiar symptoms in medicine. Yet the diagnosis is sometimes made casually with little thought of the consequences for the patient. Its characteristics — crushing central pain or discomfort, commonly but not exclusively radiating to the left arm and brought on by exertion, should make its identification possible. But it may also be present on the right, in the back or in the throat. Unless presenting as an unstable syndrome or during myocardial infarction, angina is of brief duration (<2 to 3 minutes) and likely to be associated with exercise, especially first thing in the morning, in the cold or after a meal. It may also be provoked by emotion.

The severity of angina pectoris correlates poorly with the extent of coronary artery disease present. An inactive subject may have no symptoms in spite of significant three-vessel obstruction; a branch vessel obstruction may give rise to symptoms in an active individual. Crude mortality in angina pectoris is of the order of four per cent per annum. “Chest pain ? cause” is a familiar cardiological default diagnosis which underscores the difficulty sometimes experienced in the diagnosis of chest pain (see below). Angina pectoris may also occur in the presence of normal coronary arteries as Prinzmetal<sup>1</sup> or variant angina. There is a diurnal pattern, pain often occurring in the early morning. Other, non-coronary explanations for angina include hypertrophic or dilated cardiomyopathy, aortic stenosis, severe hypertension and anaemia. Such diagnoses should not have passed unnoticed in an otherwise healthy aviator.

*The presence of angina pectoris from whatever cause, even when symptoms are suppressed by medication, disbars from all classes of medical certification. .*

### **Chest pain ? cause**

“Chest pain ? cause” is a common cardiological diagnosis in outpatient clinics implying that, although there may be symptoms, full evaluation does not lead to a cardiovascular explanation. Such a diagnosis is rare in aircrew but the presence of obstructive coronary artery disease needs to be excluded, often with the help of an exercise ECG. Any recurrent symptoms should be pursued in view of their potential to cause subtle incapacitation. In the presence of normal coronary arteries, such symptoms carry a normal prognosis.

### **Minor coronary artery disease**

Coronary angiography has predictive power in terms of future cardiovascular events. It is noteworthy that of 347 patients who presented with chest pain in one study, but who had normal coronary arteries, only two (0.6 per cent) died from coronary artery disease over the following ten years. Those with obstruction of <30 per cent had a two per cent ten-year mortality; in those with obstruction of > 30 per cent but < 50 per cent, the ten-year mortality was 16 per cent. The Coronary Artery Surgery Study (CASS)<sup>2</sup> registry

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<sup>1</sup> Prinzmetal’s angina: an atypical form of angina, in which the attacks occur during rest and often in the early hours of the morning. Focal spasm of an epicardial coronary artery causes transient, abrupt reduction of arterial diameter resulting in myocardial ischaemia. After Myron Prinzmetal, American cardiologist ( 1908-1994)

<sup>2</sup> CASS - Coronary Artery Surgery Study: a multicenter patient registry and a randomized controlled clinical trial, designed to assess the effect of coronary artery bypass surgery on mortality and selected non-fatal end points. It was carried out under the auspices of the National Heart, Lung, and Blood Institute, Bethesda, Maryland (USA), and involved 24 959 patients, enrolled between 1974 and 1979.

data gave a 96 per cent seven-year survival for the 3136 patients with normal coronary arteries or arteries which were stenosed only minimally. The long-term study of the natural history of 1487 flyers with “normal” vessels and vessels with “luminal irregularity” from the US Air Force demonstrated no events in either group at five years. Between five and ten years, the event rate was 0.1 per cent per annum in the first group and 0.56 per cent per annum in the second group. The event rate for “minimal or non-occlusive coronary disease of <50 per cent” was 1.2 per cent per annum over the second five-year period.

*In the absence of disqualifying symptoms or other contraindication, aircrew with chest pain and normal coronary arteries or with only minor irregularities may be permitted unrestricted certification to fly, subject to ongoing review. Stenosis > 30 per cent in any major vessel should predicate a restriction to multi-crew operation, while stenosis > 50 per cent is disbaring. When the left main-stem or proximal left anterior descending vessels are involved, pilots with lesions >30 per cent should be denied certification.*

### **Moderate/severe coronary artery disease and sudden cardiac death (SCD)**

It is conventional to describe the coronary circulation as consisting of three arteries — the right main vessel and the two branches of the left main vessel, i.e. the anterior descending and circumflex branches. There is, however, significant individual variation in the size, relative importance and physiological balance of the vessels. The early Cleveland Clinic data demonstrated a five-year survival of 83 per cent in patients with at least “moderate” single-vessel disease, falling to 62 per cent and 48 per cent at 10 and 15 years, respectively. Such a high event rate is not tolerable in the context of aviation. But much has changed over the past 30 years: not only has there been a general decline in the prevalence of coronary artery disease in many (predominantly Western) countries but there is also overwhelming evidence that brisk intervention against vascular risk factors (hyperlipidaemia, hypertension, smoking, diabetes) significantly improves outcome in terms of reduction of a major adverse cardiac event (MACE) and stroke.

Two-thirds of sudden deaths are attributable to the cardiovascular system with a population incidence of approximately one per 1000 persons per year. The majority of such events in middle years and later are due to coronary artery disease. Increased left ventricular muscle mass is a powerful predictor, as are hypertension, hyperlipidaemia, smoking, diabetes mellitus and a family history (male death < age 55 years, female death < age 60 years). In the Framingham study, electrocardiographic left ventricular hypertrophy was associated with a five-year mortality of 33 per cent in males and 21 per cent in females. Left ventricular hypertrophy bears a relative risk, independent of the presence or absence of hypertension, similar to that of coronary artery disease.

Other causes of sudden cardiac death include hypertrophic cardiomyopathy, dilated cardiomyopathy (including arrhythmogenic right ventricular cardiomyopathy), ischaemic left ventricular dysfunction, ion channelopathies, catecholaminergic polymorphic ventricular tachycardia, aortic stenosis, possibly mitral leaflet prolapse, anomalous origin of the coronary arteries, myocardial bridging, Wolff-Parkinson-White syndrome<sup>1</sup>, atrioventricular (AV) conduction disturbances, myocarditis and certain medications. Many of these causes are rare and their disposal in the aviation context is beyond the scope of this chapter; others are covered below.

### **Medical certification in the presence of known coronary artery disease**

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<sup>1</sup> W-P-W syndrome: is classically the association of atrio-ventricular reciprocating tachycardia and an ECG showing a short P-R interval and a wide QRS complex which includes a delta wave. Experience has indicated greater breadth to the syndrome and related atrioventricular nodal reciprocating tachycardias, atrial flutter and atrial fibrillation are also seen. After Louis Wolff, American cardiologist (1898-1972), Sir John Parkinson, English physician (1885-1976) and Paul D. White, American cardiologist (1886-1973).

Myocardial infarction disqualifies, at least initially, from certification to fly. Predictors of an adverse outcome after myocardial infarction include previous history of the same, reduced ejection fraction, angina pectoris, smoking (current or ex-), history of hypertension, systolic hypertension, diabetes, increased heart rate and reduced effort tolerance.

The best-risk subject, by comparison, will be asymptomatic, non-diabetic and normotensive, with a normal ejection fraction and with coronary artery disease restricted to the vessel subtending the infarction (which should, preferably, be patent). Subjects with single-vessel disease subtending a completed infarction may be considered for restricted certification, although in one study of 262 patients with a mean age of 52.3 years, there was no difference in five- and ten-year survival regardless of whether the infarct-related artery was patent. At 96.9 per cent versus 93.8 per cent for five-year survival, and 90.7 per cent versus 92.7 per cent for ten-year survival, for patent and non-patent vessels, respectively, such outcomes in an asymptomatic individual are likely to be satisfactory for certificatory purposes but only if the ejection fraction is normal. The ten-year survivals were 94.8 per cent, 90.6 per cent and 74.8 per cent with ejection fractions > 60 per cent, 40 to 60 per cent, and < 40 per cent, respectively.

It is well established that left ventricular function powerfully predicts both cardiovascular events and outcome. Data from the Cleveland Clinic first demonstrated five-year survival with single-vessel disease at 89 per cent and 77 per cent in the absence and presence, respectively, of wall-motion abnormality. CASS registry data revealed six-year survival in two-vessel disease spanning 49 to 88 per cent, the best outcome being predicted by normal left ventricular function. CASS registry data further confirmed the excellent outcome in males without ventricular damage who had undergone coronary artery bypass grafting (CABG) whose survival was significantly better than that of their Framingham peers. Reduction in left ventricular function rendered the prognosis less favourable, mild to moderate impairment function being associated with a significantly poorer outcome at five years.

## **Revascularization of the myocardium**

### **Coronary artery bypass grafting (CABG)**

The long-term outcome following CABG is now well established, although proof of benefit over medical treatment depends largely on the outcome of three studies completed in the 1980s. Subsequent developments include more generalized use of arterial conduits, including the internal mammary arteries, and radial artery as a graft in addition to, or instead of, saphenous vein grafts. These have been demonstrated to have enhanced late patency. Off-pump grafting and minimally invasive off-pump bypass (minimally invasive direct coronary artery bypass, MIDCAB) have less morbidity, but long-term outcome has yet to be determined with confidence.

There are important differences between CABG and percutaneous transluminal coronary angioplasty (PTCA) in terms of early and late morbidity. One early meta-analysis contrasting outcome of the two techniques identified mortality and non-fatal myocardial infarction at 10.1 per cent versus 9.8 per cent at 2.7 years, but the additional intervention rate in the first year was 33.7 per cent in the PTCA group, ten times that in the CABG group. Surgery bore a prolonged period of rehabilitation, while PTCA was burdened by repeated late hospitalisation. This was in the pre-drug-eluting stent era, the technique having transformed the early outcome, the expected MACE event rate now being of the order of 3 - 4 per cent in the first year.

Late outcome, however, may not always be as satisfactory as was originally believed. Surgical graft attrition occurs steadily, and 10 per cent, 20 per cent and 40 per cent of saphenous grafts occluded by one, five and ten years, respectively, in the pre-statin era. Early recurrence of symptoms is likely to be due to graft attrition, and late recurrence to progression of disease in the native circulation. Aggressive lipid management improves the outcome whilst the robust performance of the internal mammary artery conduit is well known - a 93 per cent ten-year survival in patients in whom an internal mammary artery conduit

was implanted into the left anterior descending coronary artery. The ejection fraction was an important predictor of outcome.

Coronary artery bypass grafting has a low risk of MACE once rehabilitation has taken place. Actuarial survival following saphenous vein bypass grafting in one group of 428 patients with a mean age of 52.6 years at 5, 10 and 15 years was 94.2 per cent, 82.4 per cent and 63 per cent, respectively. This was in the pre-statin era. The cumulative probability of event-free survival for cardiac death, acute myocardial infarction, re-intervention and angina pectoris at 5, 10 and 15 years was as follows:

Cardiac death — 97.8 %, 90.1 % and 74.4 %;

Acute myocardial infarction — 98.5 %, 89.0 % and 77.4 %;

Re-intervention — 97.0 %, 83.0 % and 62.1 %;

Angina pectoris — 77.8 %, 52.1 % and 26.8 %.

Left ventricular function and the number of vessels involved are independently predictive of survival. For certificatory purposes these figures are reassuring only for the early years after intervention.

### **Percutaneous transluminal coronary angioplasty (PTCA) and intracoronary stenting**

PTCA has been established since the 1980s. The technique has the advantage that an early return to full activity is usual but with the disadvantage that the subsequent trajectory is often not unblemished. The original technique employed a balloon inserted via a guide-wire which was inflated across the obstructing lesion. More recently, the insertion of a stent — a small wire basket — has been shown to improve the prognosis, while more recently still, stent performance has been enhanced by the elution of drugs (anti-mitotic agents such as paclitaxel) from its surface, although long-term data are not yet available. See Appendix 3, panels A & B.

In the context of aviation, medical certification following PTCA requires both freedom from symptoms and complete revascularization. PTCA is good for the former but less easy to achieve for the latter. In the BARI trial<sup>1</sup>, complete revascularization in the presence of multi-vessel coronary artery disease was achieved in only 57 per cent of PTCA patients but in 91 per cent of those undergoing CABG. In contrast to the results of surgery, no survival advantage over medical treatment has been demonstrated for PTCA. Indeed, in one study, the group treated with high-dose (80 mg) atorvastatin had a 36 per cent lower event rate than the PTCA group. Similar results were seen in the RITA-2 study<sup>2</sup>. Death was significantly more common in the angioplasty group versus the medically treated group after three years whilst at seven years there was no difference in mortality between the two groups. Symptoms were fewer in the angioplasty group.

Diabetic patients fared significantly worse following PTCA when compared with CABG in terms of survival (65.5 per cent versus 80.6 per cent at five years) in the BARI study, while the Coronary Angioplasty versus Bypass Revascularization Investigation (CABRI) study<sup>3</sup> confirmed a more favourable

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<sup>1</sup> BARI trial: Bypass Angioplasty Revascularization Investigation trial, in which 1 829 patients with symptomatic multivessel coronary artery disease requiring revascularization were randomly assigned to undergo either CABG or PTCA between 1988 and 1991. In 1995 the US National Heart Lung and Blood Institute (NHLBI) issued an alert warning about the poorer outcome following angioplasty in diabetic patients

<sup>2</sup> RITA-2 study: the second Randomised Intervention Treatment of Angina. Coronary angioplasty versus medical therapy for angina; the trial ran for seven years.

<sup>3</sup> CABRI study: A randomized study of 1054 patients from 26 European centres, all with symptomatic, multivessel coronary disease who underwent either CABG or PTCA (1988-1992)

surgical outcome. Likewise, saphenous vein graft angioplasty has a poor outcome. In the Arterial Revascularization Therapy Study (ARTS)<sup>3</sup>, the MACE difference between surgery and angioplasty (on average 30 to 40 per cent) was reduced to 14 per cent with stenting at one year — still not impressive in the context of aviation. Some 70 per cent of lesions undergoing the percutaneous approach are now stented.

It is likely that the early hopes for drug-eluting stents will be sustained although there may be performance differences, and other, unforeseen, complications may arise. However, in a meta-analysis of 14 trials using paclitaxel and sirolimus-eluting stents, there was no significant improvement in rates of death or non-fatal myocardial infarction when compared with the bare metal stent. Current guidelines by the National Institute for Clinical Excellence (NICE) in the United Kingdom state that “stents should be used routinely where percutaneous coronary intervention (PCI) is the clinically appropriate procedure” but they do not endorse unlimited use of drug eluting stents.

In the context of aviation, a very low post re-vascularisation MACE rate is needed before certification can be considered. Graft angioplasty and angioplasty in diabetic patients should not be acceptable due to the high subsequent event rate. Furthermore, in multi-vessel disease, the technique is relatively less good than surgery in obtaining “full” revascularization. In some Contracting States, pilots are certificated following stenting of one or more coronary arteries, provided there is not evidence of reversible ischaemia (judged by exercise ECG and/or thallium scintigraphy) in spite of an annual MACE rate which may very significantly exceed 1 per cent per annum.

### **Intervention against vascular risk factors**

There is now massive published evidence that intervention against the major vascular risk factors — hypertension, hypercholesterolaemia, smoking and diabetes — is associated with a significant reduction in fatal and non-fatal cardiovascular events. This holds good in both primary (i.e. before declared disease) and secondary prevention (i.e. after a cardiovascular event), across all ages, especially if there are multiple risk factors present. With such convincing evidence, the requirement that a reduction of risk factors must be undertaken in the presence of known coronary artery disease represents best clinical practice.

- Targets in the treatment of hypertension should be <90 mm Hg diastolic, taken to D5<sup>1</sup> with an appropriate sized arm cuff (<85 mm Hg on a 24-hour ambulatory recording); 80 mm Hg in the context of diabetes
- Targets for the treatment of hyperlipidaemia (with a statin, if tolerated) should be at least a reduction of 30 per cent in the level of total cholesterol or <5 mmol/L total, and <3 mmol/L low density (LD) or better.
- Diabetes should be managed as indicated in Part III, Chapter 4
- Smoking must be avoided completely
- Programmed exercise should be undertaken
- Weight reduction is beneficial with increased consumption of fruit and vegetables and substitution of saturated fats by mono-unsaturated fats such as olive oil

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<sup>3</sup> ARTS study: The Arterial Revascularization Therapy Study: a large randomized, controlled trial that compared percutaneous coronary intervention (PCI) with stent placement to coronary artery bypass graft (CABG) surgery in patients with multivessel disease. ARTS was designed in Salzburg in April 1996 and was performed at 67 centres in Australia, Europe, New Zealand, and South America.

<sup>1</sup> D5: fifth phase Korotkoff sound, i.e. no sound, for the determination of diastolic blood pressure

*In summary, an applicant may regain a Class 1 Medical Assessment to fly as/with a suitably qualified co-pilot (OML) no sooner than six months following the index event (i.e. myocardial infarction / re-vascularisation procedure in the presence of known coronary artery disease), provided that:*

- *he/she is asymptomatic and requires no anti-anginal medication*
- *vascular risk factors have been addressed, including smoking cessation, lipid lowering (with a statin, unless contraindicated), and treatment of hypertension (with an angiotensin-converting enzyme inhibitor (ACE inhibitor), an angiotensin receptor blocker (ARB) and/or a calcium channel blocker (CCB), and the administration of aspirin and/or clopidogrel, if indicated. Subjects with an abnormality of glucose metabolism demand special scrutiny and management. Diuretic agents and the beta-blocking agents are better avoided*
- *left ventricular function is normal (> 50 per cent) as measured by echocardiography (Simpson's rule<sup>1</sup>), multiple-gated acquisition (MUGA) study, or contrast ventriculography*
- *exercise ECG to stage IV of the Bruce treadmill protocol can be achieved without evidence of myocardial ischaemia, significant rhythm disturbance or symptoms*
- *coronary angiography carried out at or around the time of the index event demonstrates <50 per cent stenosis in any major untreated vessel or in any venous/arterial graft remote from any infarction; < 30 per cent if the proximal the left anterior descending or left main-stem vessels are involved*
- *Holter monitoring, if indicated, shows no significant rhythm disturbance*
- *Stress thallium MPI, or equivalent, shows no evidence of a reversible defect. A small fixed defect is permissible, provided the ejection fraction is within the normal range. This investigation should be carried out no sooner than six months following the index event*
- *Class 1 Assessment is restricted with an OML, indefinitely. Unrestricted Class 2 Assessment may be permissible*
- *Annual follow-up by an accredited cardiologist with exercise ECG and review of vascular risk factor status is arranged. Further investigation may be required, if indicated.*

## **RATE AND RHYTHM DISTURBANCES**

The human heart beats some 100 000 times a day and in health remains remarkably regular. An increase in the heart rate — a tachycardia — is present when the rate is > 100 beats/min and a bradycardia when the rate is < 50 beats/min. A sinus bradycardia in a subject of aircrew age is rarely of importance and may reflect only physical fitness. A sinus tachycardia in an otherwise fit individual may suggest anxiety, and although most aircrew become used to routine scrutiny, some continue to demonstrate an alarm reaction, which may be associated with so-called “white-coat hypertension”. Rhythm and conduction disturbances continue to form the single largest problem group and together they form some of the more difficult problems encountered in aviation cardiology.

### **Atrial and ventricular premature beats**

The routine aircrew ECG should be recorded on a three-channel system (see above). With a three-lead presentation, the recording will last 12 seconds on a page of A4 size at the standard paper speed of 25mm/s; further rhythm “strips” are unlikely to be longer than another 12 seconds. If an isolated atrial or ventricular premature contraction is recorded, it may be a coincidence; if more than one is present, it is

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<sup>1</sup> Simpson's rule, also known as ‘the parabolic rule’ as it uses sums of areas under parabolas to determine approximate values of definite integrals, is a geometric algorithm for calculating ventricular mass and volume based on two-dimensional measurements. After Thomas Simpson, English mathematician (1710-1761).

more likely that such events are sufficiently frequent to justify review. With increasing age the probability of rhythm disturbance increases. As a rule, a single atrial or ventricular premature beat is not of prognostic importance and is likely to pass unnoticed. Anxiety, excessive tea, coffee or alcohol, or smoking, may be the explanation; if the subject becomes symptomatic, anxiety may contribute to their continuation. Frequent atrial ectopy may predict atrial fibrillation.

More complex rhythm disturbances including frequent ventricular premature complexes, with or without multiformity or multifocality, couplets and salvos may or may not be of prognostic importance in the otherwise normal heart. In the aviation environment cardiological assessment with echocardiography, Holter monitoring and exercise ECG is nevertheless required.

*As a general rule, ventricular premature complexes with a density of < 200 per hour are acceptable if the non-invasive investigations are satisfactory. As complexity increases, even in an asymptomatic and otherwise normal individual, a multi-crew endorsement may have to be applied in view of our inability to predict outcome with confidence.*

### **Sinoatrial disease (sick sinus syndrome; bradycardia syndrome)**

Sinoatrial disease (evidenced by sinus pauses, sinoatrial block and paroxysmal atrial tachyarrhythmia from a variety of causes) is not commonly seen in subjects of pilot age. The sinoatrial node and atrial myocardium are primarily affected, although the atrioventricular (AV node) and more distal conducting tissue may also be involved. There is a tendency towards excessive bradycardia, especially at night when sinus arrest may occur. Pauses of >2.5 s are likely to be abnormal if the subject is in sinus rhythm. Characteristic salvos of atrial and/or junctional complexes followed by prolonged sinus node recovery time are a feature. There is an increased risk of thromboembolic stroke. There may be overlap with “athlete’s heart”, which tends to be associated with excessive vagal inhibitory activity and which is a not uncommon finding in younger pilots.

*Patients with sinoatrial disease may remain relatively or completely free of symptoms for many years or may become symptomatic quite rapidly. For this reason, regular review with exercise ECG (seeking chronotropic incompetence — an attenuated exercise heart-rate response) and Holter monitoring<sup>1</sup> is justified. Echocardiography should confirm the continuing structural integrity of the heart. Restriction to multi-crew operation is preferable, unless the disturbance is no more than minor and the pilot is asymptomatic. Once symptoms occur, certification to fly should be denied.*

### **Atrial tachyarrhythmia**

The abrupt onset of rhythm disturbances may be both alarming and distracting and is a cause of incapacitation, subtle or obvious. If the rate is very rapid, then systemic hypotension may occur and lead to altered consciousness. If there is structural abnormality of the heart, such as myocardial hypertrophy with associated impairment of diastolic function, the disturbance may be tolerated poorly. With increased atrial or ventricular internal diameters, the risk of thromboembolic stroke increases. The disturbance, underlying structural abnormality (or non-structural cause) and outcome all need to be considered in the context of certification.

**Atrial fibrillation (AF)** is the most common rhythm disturbance causing intermittent or persisting symptoms. It is often associated with structural abnormality of the heart and has as its basis continuous wave fronts of depolarisation arising mainly in the left atrium. It has a prevalence in the population of 0.4 per cent in those < age 60 years, two to four percent in those aged 60 to 80 years, and > ten per cent in

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<sup>1</sup> Holter monitor: an ambulatory ECG device for monitoring and recording heart activity for 24 hours or more. After Norman J. Holter, American biophysicist (1914-1983).

those > age 80 years. It may be associated with cardiovascular disease, there may be an extra-cardiac cause (i.e. secondary to hyperthyroidism), or it may be “lone” - without obvious pathology. Common causes of atrial fibrillation are shown in Table 2 and an example in fig 4.

**Table 2.— Common causes of atrial fibrillation (AF)**

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AF with cardiovascular disease
AF with extra-cardiac disease
Lone AF
Hypertension
Infection
Coronary artery disease
Alcohol abuse
Valvar heart disease
Thyrotoxicosis
Myocardial disease
Electrolyte disturbance
Congenital heart disease
Pulmonary disease
Cardiac surgery (recent and remote)
Pericarditis

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The clinical management of atrial fibrillation involves identification of cause with reversion to sinus rhythm, if possible, either pharmacologically or by DC shock. The European Atrial Fibrillation Consensus Conference in 2003 suggested that management be directed towards the maintenance of sinus rhythm or regulation of the heart rate. Anticoagulation will be required > age 65 years, and/or in the presence of structural abnormality of the heart, hypertension and/or enlargement of the left atrium. Anticoagulation disqualifies from all classes of medical certification in many States, but not all.

The following presentations of atrial fibrillation are seen:

- *Single episode* with a defined cause, e.g. vomiting
- *Paroxysmal* atrial fibrillation, defined as more than one self-terminating episode, usually of <24 hours' duration.
- *Persistent* atrial fibrillation, in which the return to sinus rhythm occurs only following therapeutic intervention. The duration is > seven days.
- *Permanent* atrial fibrillation, in which a return to sinus rhythm cannot be accomplished or has not been attempted. The duration is >12 months.

The condition commonly comes to light in one of two ways in the aviation scene: the rhythm is uncovered by ECG at routine examination or the aviator presents with symptoms. In general, pharmacological cardioversion with an agent such as flecainide is most likely to be successful if undertaken in the first few hours after the onset of the episode. A DC shock may be needed. Overall, 50 to 80 per cent will return to sinus rhythm by such means in the first attack, depending on the presence or absence of other pathology, and the duration of the attack. All attempts at cardioversion require anticoagulation with warfarin and the maintenance of the international normalized ratio (INR) at 2.5 to 3.0 for one month. This is required beforehand and afterwards, unless undertaken within 24 hours of onset or if the left atrial appendage is demonstrably free of thrombus at trans-oesophageal echocardiography (TOE). Before attempting cardioversion, the thyroid-stimulating hormone (TSH) level should be

measured and thyrotoxicosis treated, if necessary. Likewise, the liver function tests (LFTs) and mean corpuscular volume (MCV) should be checked to review potential alcohol abuse. After one year, about 50 per cent are likely to have relapsed at least once; a minority (<25 per cent) will maintain sinus rhythm at three years.

*Aircrew certification in the context of atrial fibrillation requires:*

- freedom from symptoms
- sinus rhythm and normotension
- normal TSH, LFTs and MCV
- no history of transient ischaemic attack (TIA)
- absence of other risk factors for recurrence and/or for thromboembolic stroke, including age > 65 years, hypertension, diabetes, left ventricular hypertrophy, valvar heart disease, coronary heart disease (predicating need for warfarin)
- normal cavity and structural dimensions of the heart, normal valves and normal Doppler<sup>1</sup> flows on echocardiography. The left atrial internal diameter should be <4.5 cm
- exercise walking time to be normal (> 10 minutes). In atrial fibrillation, the maximum heart rate should be < 230 bpm and the longest pause <3.5 s
- three Holter recordings over two to three months to have shown no evidence of atrial fibrillation – arbitrarily defined as at least three to five consecutive normally conducted complexes
- restriction of the licence with a multi-crew limitation. After an event-free period of two years, the restriction may be considered for removal, subject to review.

These are rigorous standards, which will be achieved by only a minority. Subjects of pilot age not fulfilling the above and who demonstrate paroxysmal/permanent atrial fibrillation in spite of medication may require anticoagulation with warfarin, which itself is disqualifying in many Contracting States. Aspirin/clopidogrel may be recommended by the supervising cardiologist in the absence of treatment with warfarin. In the event of default, further fitness consideration will require satisfactory answers to the following:

- is the thromboembolic rate acceptable without warfarin?
- are there symptoms at any time, i.e. on switching rhythm, and if so are they minimal?
- is the heart rate controlled well at rest and on exercise?
- is an approved /non-approved drug being taken?

Products that are permitted include:

- digoxin (mainly of value in controlling resting heart rate in the established condition)
- beta-blocking agents, usually atenolol or bisoprolol, which may help preserve sinus rhythm and reduce the heart rate in atrial fibrillation. Sotalol also has some class III effect (as well as some pro-arrhythmic effect) and is permitted provided there is no demonstrated pro-arrhythmic effect
- verapamil, which may help to preserve sinus rhythm and control the heart rate
- diltiazem, both alone and combined with the foregoing (with care in the presence of beta-blockade) is helpful in rate management.

None of these products is particularly effective, and in the long term atrial fibrillation is likely to become established. Their side-effect profile, however, is generally not high.

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<sup>1</sup> Doppler: ultrasonography. After Christian Doppler, Austrian physicist (1803-1853).

Products not permitted include the following:

- Class Ia anti-arrhythmic agents, such as:
  - quinidine (excessive risk of torsades de pointes and sudden cardiac death (SCD))
  - disopyramide (excessive anti-cholinergic side effects)
  - procainamide (lupus-like syndrome and occasionally agranulocytosis).
- Class Ib drugs (e.g. mexiletine) which are ineffective in atrial rhythm disturbances,
- Class Ic agents (flecainide, propafenone) which are effective in bringing about the restoration of sinus rhythm and its maintenance but which have undesirable effects such as tremor and visual disturbances. Both may provoke atrial flutter in a minority (about five per cent).
- The most effective class III drug, amiodarone, which has a high-side effect profile and thus cannot be considered. The most common side effect, photo-sensitisation, is less important than the disturbance of sleep and sedation that it may cause. Patients receiving this drug develop corneal micro-deposits, which may give a halo effect around lights at night.
- Class III drugs — moricizine, dofetilide and ibutilide.
- Warfarin

Neither flecainide nor propafenone is permitted in aviators although some Contracting States have approved flecainide at a dose of 50 mg twice daily on an individual basis following special consideration. Amiodarone is usually barred, on account of its side effects and likely coexisting pathology, although in some Contracting States flight engineers have been certificated while using it.

### **Warfarin and anticoagulation in atrial fibrillation**

Warfarin is associated with a risk of bleeding in the order of one per cent per annum, for a 70 per cent reduction of stroke risk. It is not permitted in European aviators at present although it has been allowed in individual cases as “special issuances” by the FAA<sup>1</sup> in the United States. A number of primary stroke-prevention trials have identified the following risk factors for thrombo-embolic stroke in paroxysmal or persistent atrial fibrillation :

- males / females > 65 years of age
- diabetes mellitus
- previous transient ischaemic attack (TIA)
- reduced ventricular fractional shortening
- coronary heart disease
- hypertension (systolic blood pressure >160 mm Hg)
- left atrial internal diameter >4.5 cm (2.5 cm/m<sup>2</sup> of body surface)

In about a third of subjects < age 65 years, atrial fibrillation will be "lone" (being excluded from the above). They will be at a low (< one per cent per annum) risk of a cerebral thromboembolic event per annum and warfarin, conventionally, will not be indicated. Pilots satisfying this requirement and the criteria expressed in the previous section may be certificated with a restriction (Class 1 OML). Aspirin reduces the embolic risk by about 20 per cent and should be given if it is tolerable. Studies are under way to determine whether higher-risk subjects are protected with aspirin and clopidogrel, and by new direct thrombin inhibitors; the latter do not need the INR to be checked regularly.

### **Atrial flutter**

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<sup>1</sup> FAA: Federal Aviation Administration (before 1967 the Federal Aviation Agency), the Licensing Authority of the United States.

Atrial flutter presents special problems. It usually originates in the right atrium as a continuous reentry circuit, often around a ridge between the superior and inferior caval orifices called the crista terminalis. It reciprocates at a rate approximating 300 b p m. Rates of 150 b p m are commonly encountered with 2:1 AV conduction deficit whilst the risk remains for 1:1 conduction at 300 b p m to occur. Symptoms may be troublesome due to abrupt rate change. For these reasons it is incompatible with flying status.

*The introduction of radiofrequency ablation of the flutter circuit has revolutionized treatment. If the flutter circuit has undergone successful ablation with demonstrated bidirectional block, the arrhythmia has not recurred for three months, and the following protocol can be fulfilled, a Class 1 Medical Assessment with restriction to multi-crew operations may be issued subject to cardiological follow-up:*

- *exercise ECG (completion of at least three stages of the Bruce protocol) is normal*
- *echocardiography shows a structurally normal heart*
- *absence of atrial flutter on Holter monitoring (evidence of atrial fibrillation will need further review)*
- *electrophysiological study shows bidirectional isthmus block.*

*Unrestricted certification may be considered after 12 months.*

### **Atrioventricular nodal reciprocating tachycardia**

Atrioventricular nodal reentry is the most common single cause of regular narrow complex tachycardia, accounting for some 50 per cent of all tachycardias. It is caused by a micro reentry circuit with two pathways, one fast and one with decremental conduction. It often has a rate of about 200 bpm, sufficient to cause breathlessness, chest discomfort and sometimes polyuria due to the release of atrial natriuretic peptide. As the disturbances tend to recur throughout life and cannot reliably be suppressed completely, the condition is normally incompatible with certification to fly. An exception may be the subject who has undergone slow pathway modification and in whom the rhythm cannot be induced on electrophysiological study (cf. atrial flutter, above).

### **Atrioventricular reciprocating tachycardia**

Atrioventricular reentrant tachycardias are caused by an extranodal fast-conducting pathway which “pre-excites” the ventricle. This pathway is known as the Kent bundle<sup>1</sup>, although other variations (e.g. Mahaim<sup>2</sup> fibers with a nodofascicular pathway) are also seen. The eponymous term, Wolff-Parkinson-White<sup>3</sup> (WPW) pattern, implying the appearance only of the characteristic configuration of the ECG, is often applied. If there is a tachycardia (from a number of causes), the term “syndrome” is applied. In a study of WPW pattern in 238 military aviators of mean age 34.3 years, 17.6 per cent were symptomatic and 82.4 per cent were not. Fifteen per cent of pilots with the pattern alone developed the

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<sup>1</sup> Kent’s bundle: a muscular bundle in the heart, forming a direct connection between the atrial and ventricular walls. After Albert F.S. Kent, English physiologist (1863-1958).

<sup>2</sup> Mahaim’s fibers: specialised tissue in the heart, connecting components of the conduction system directly to the ventricular septum. After Ivan Mahaim, French cardiologist (1897-1965).

<sup>3</sup> W-P-W syndrome: is the association of paroxysmal tachycardia (or atrial fibrillation) and pre-excitation, in which the ECG shows a short P-R interval and a wide QRS complex. After Louis Wolff, American cardiologist (1898-?), Sir John Parkinson, English physician (1885-1976) and Paul D. White, American cardiologist (1886-1973).

syndrome over a mean of 22 years. The characteristic appearance of the QRS complex with a slurred inscription of the R wave (the “delta” wave) and a short PR interval (but normal PT interval) is seen in about 1.6 per 1000 routine resting ECGs. See ECG 20, Appendix 1b. It is more common in men than women.

The prevalence of atrioventricular reciprocating tachycardia varies between five and 90 per cent in hospital patients with the WPW pattern due to the phenomenon of “ascertainment bias” (individuals with WPW pattern and a tachycardia are likely to be over-represented in the hospital population when compared with the general population). If there is prograde (orthodromic) conduction through the slow nodal pathway with retrograde conduction via the fast accessory pathway, the QRS complex will be narrow. If there is prograde conduction via the accessory pathway with retrograde (antidromic) conduction via the slow nodal pathway, the QRS complex will be broad. The appearance of the delta wave may be intermittent, implying that it is refractory part of the time. This is usually associated with a longer effective refractory period (ERF) - 300 to 500 ms; and the term “safe” is applied, suggesting a low risk of rapid atrioventricular reciprocating tachycardia. This also implies the absence of ability to conduct at very fast rates in atrial fibrillation in which total anomalous conduction may occur via the accessory pathway.

Although many subjects with preexcitation never experience an episode of tachycardia and in an unknown number the pathway is concealed, the possibility of a re-entry tachycardia with abrupt onset at a rapid rate, or of atrial fibrillation with anomalous conduction, gives rise to certificatory difficulties. Atrial fibrillation with very rapid conduction may provoke ventricular fibrillation and sudden cardiac death, but the risk is very low. There is also an association with other anomalies such as hypertrophic cardiomyopathy and Ebstein’s anomaly<sup>1</sup>.

*On first presentation with the WPW ECG pattern an aviator should be made unfit. Provided there is no history of arrhythmia, and an echocardiogram, exercise ECG and 24-hour ambulatory ECG recording are within normal limits, Class 1 restricted (OML) certification may be considered. The exercise electrocardiogram in the presence of a delta wave may be associated with gross ST segment depression which may mimic myocardial ischaemia. In this situation, further investigation with a thallium MPI or equivalent may be indicated. In view of the generally more favourable outcome, it is helpful if, at least part of the time, the accessory pathway is refractory.*

*For unrestricted certification, an electrophysiological study (EPS) is required demonstrating no inducible re-entry tachycardia and an ante-grade ERF > 300ms. If the subject has a history of re-entrant tachyarrhythmia, certification is possible only following the demonstrated of ablation of the accessory pathway. This may be accomplished by an adenosine challenge or further EPS.*

## **ATRIOVENTRICULAR CONDUCTION DISTURBANCES**

First degree atrioventricular block is present if the PR interval exceeds 210 ms. It is present in at least one per cent of asymptomatic aircrew applicants. In the absence of broadening of the QRS width >100ms, the condition is very likely to be benign. The interval should shorten on exercise. Occasionally, very long PR intervals are seen of up to 400 ms; these, too, seem to be benign, provided the QRS width is normal, the interval shortens on exercise, and following atropine. It is sometimes associated with Mobitz type I atrioventricular block<sup>2</sup> (decremental atrioventricular conduction), which should be of short periodicity and occur only at night in young adults. The additional presence of a bundle branch disturbance,

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<sup>1</sup> Ebstein’s anomaly: atrialisation of the right ventricle with involvement of the tricuspid valve. After Wilhelm Ebstein, German physician, (1836-1912)

<sup>2</sup> Mobitz’ block type I and II: Second degree atrioventricular block in which progressive PR interval prolongation precede a nonconducted P wave.(type I), and in which the PR interval remains unchanged prior to the P wave that suddenly fails to conduct to the ventricles After Woldemar Mobitz, Russian-German cardiologist (1889-1951).

particularly if the mean frontal QRS axis is abnormal, raises the possibility of distal conducting tissue disease.

*In the absence of such a complication an aviator may be certificated without restriction.*

Second degree atrioventricular block is much less common than the first degree form in those of pilot age. It was seen in only 4 (~0.003 per cent) of the 122 043 aviator ECGs reviewed in a Contracting State in 1962. Short periodicity (i.e. 2 : 3 and 3 : 4) Mobitz type I atrio-ventricular block, in which the PR interval progressively prolongs until there is a non-conducted P wave, is sometimes seen during sleep in normal young, especially athletic, individuals. It appears to carry no special risk and represents delayed conduction at the level of the atrioventricular node which is of vagal origin. The coexistence of a bundle branch disturbance will raise the possibility of distal conducting tissue (His-Purkinje) disease.

*Mobitz type I atrioventricular block is very uncommon in normal subjects during the day and should provoke investigation with 24-hour ambulatory monitoring and an exercise recording. In such cases, long term follow-up is necessary, and a multi-crew (OML) restriction is required on the medical certificate. The additional presence of an abnormal electrical axis and/or bundle branch disturbance is likely to disbar.*

More commonly, although not exclusively, Mobitz type II and 2 : 1 atrioventricular blocks represent delay in the His-Purkinje network<sup>1</sup> and carry a risk of progression to complete atrioventricular block with risk of syncope.

*Such abnormalities should lead to a denial of medical certification.*

Complete (third degree) atrioventricular block disbars from all classes of medical certification. Provided that there is no other disqualifying pathology and an endocardial pacemaker has been inserted, limited Class 2 certification may be possible. Pacemaker dependence normally disqualifies from Class 1 operations. Congenital complete atrioventricular block is rare and although survival to middle years and beyond is the rule, there is an excess risk of sudden cardiac death.

*Mobitz type II, 2:1 atrioventricular block and complete atrioventricular block are inconsistent with any class of medical certification.*

## INTRAVENTRICULAR CONDUCTION DISTURBANCES

### Right bundle branch block

Incomplete right bundle branch block is a common anomaly that carries a normal prognosis in otherwise normal subjects. It is seen in one to three per cent of professional aircrew. No special precautions are needed. If there is significant right axis deviation, then the possibility of a secundum atrial septal defect should be considered. See Appendix 1b: 15. Complete right bundle branch block is present in 0.2 per cent of pilot applicants. It is characterized by a QRS width >120 ms, with significant S waves in SI, V5 and V6. There will be an rSR pattern in V1 and V2. See Appendix 1b: 16. Established complete right bundle branch block appears to carry no adverse risk in asymptomatic and otherwise normal males of aircrew age. It is seen in one per cent of professional aircrew. Even if it is newly acquired, the risk of a cardiovascular event is likely to be minimal unless the block is the result of anteroseptal infarction. On first presentation, applicants should undergo cardiological review including:

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<sup>1</sup> His-Purkinje network: a portion of the conducting system of the heart, beginning with the bundle of His and ending at the terminus of the Purkinje fiber network within the ventricles. After W. His, Jr., Swiss physician (1863-1934) and Johannes E. Purkinje, Czech physiologist (1787-1869)

- exercise ECG (to at least three stages of the Bruce protocol)- satisfactorily achieved
- Holter monitoring – no significant rhythm or conduction disturbance
- echocardiography – no significant structural or functional abnormality of the heart
- electrophysiological study, if indicated, and/or coronary angiography, if indicated

*The medical certificate should be restricted to multi-crew operation, if acquired >age 40 years: if acquired < age 40 years, no restriction is necessary.*

*Satisfactory cardiological review at 12 months will usually permit unrestricted certification in those > 40 years.*

### **Left bundle branch block**

Incomplete left bundle branch block is an ECG diagnosis which applies when the standard criteria for left bundle branch block are satisfied (absent q wave in SI, aVL, V5 and V6; absent r' in V1, with or without secondary T wave changes) but the QRS complex width is <120 ms. See Appendix 1b: 2. The distinction is arbitrary. If long-standing and the heart is structurally and functionally normal, there appears to be little or no increased risk, and such individuals need not be restricted.

*In the event of new presentation, the structural integrity of the heart needs to be established with echocardiography. The possibility of coronary artery disease needs to be considered and excluded with pharmacological stress thallium MPI or coronary angiography as an exercise ECG is likely to be abnormal due to secondary repolarisation change.*

Complete left bundle branch block has had a malign reputation, partly on account of its association with coronary artery disease in older subjects in whom the incidence may be as high as 25 to 50 per cent. It is one-tenth as common as right bundle branch block in the general population. Newly acquired left bundle branch block in one study observed a risk ratio for sudden cardiac death of 10:1 (i.e. 10 times greater than expected) > age 45 years, although below that age the risk ratio was 1.3:1. Notwithstanding, stable complete left bundle branch block appears to carry little excess risk of cardiovascular event in the otherwise normal heart and may be consistent with multi-crew operation. See Appendix 1b: 17 for an example and morphological description. Coronary angiography or pharmacological stress myocardial perfusion imaging (MPI) is needed to exclude the possibility of coronary artery disease.

*Applicants with the first presentation of left bundle branch block may be considered for a restricted Class 1 (OML) Medical Assessment provided that:*

- *left ventricular function is normal, eg the ejection fraction is > 50 per cent as measured by echocardiography (Simpson's rule), multiple-gated acquisition (MUGA) study, or contrast ventriculography*
- *exercise ECG to stage IV of the Bruce treadmill protocol can be achieved without evidence of myocardial ischaemia, significant rhythm disturbance or symptoms*
- *pharmacological stress thallium MPI, or equivalent, shows no evidence of a reversible defect. A small fixed defect is permissible, provided the ejection fraction is within the normal range*
- *coronary angiography, if carried out, demonstrates <50 per cent stenosis in any major untreated vessel or in any venous/arterial graft remote from any infarction; <30 per cent if the proximal the left anterior descending or left main-stem vessels are involved*
- *Holter monitoring, if indicated, shows no significant rhythm disturbance*
- *Annual follow up is carried out by a cardiologist acceptable to the Licensing Authority.*

### **The Hemiblocks**

Left anteroseptal and left inferoposterior fascicular (hemi)blocks in the absence of other abnormality appear to carry little or no excess risk of cardiovascular event in subjects of pilot age. The prevalence of the former increases from 0.5 per cent at age 30 years to five per cent at age 60 years and in a few will reflect coronary artery disease or progressive fibrosis of the conducting fascicles (Lenègre's disease<sup>1</sup>). See Appendix 1b: 14.

*At first presentation > age 40 years, and if present at the initial issue of a licence, cardiological review with exercise ECG and echocardiography is justified. If there is doubt, the possibility of coronary artery disease needs to be excluded with pharmacological stress thallium MPI or equivalent, particularly in the case of acquired left anterior and posterior hemiblock. The emergence of a change in axis on routine scrutiny justifies such review.*

## ION CHANNELOPATHIES

The ion channelopathies form a rare group of inherited disorders of the sodium and potassium channels that regulate cardiac depolarisation. Over 250 mutations involving six different genes have been identified. They are transmitted as autosomal dominants with incomplete penetrance and expression. They are associated with ventricular tachycardia — *torsades de pointes*<sup>2</sup> and sudden cardiac death — commonly in the first two or three decades of life.

Brugada syndrome<sup>3</sup> is transmitted as an autosomal dominant gene with incomplete penetrance. It appears to be linked to the SCN5A gene which encodes the sodium channel. Its prevalence has been reported as between five and 66 per cent per 100 000 but it is more common in the Far East and in Japan where the prevalence may be as high as 146 per 100 000. It is characterized by a male preponderance of eight or nine to one. The ECG anomaly is characteristic of the syndrome and tends to vacillate. In the type 1 form, there is coved upward ST segment elevation with a J wave amplitude >0.2 mV followed by an inverted T wave in V1 and V2 (the Brugada sign). Less striking abnormalities are seen in types 2 and 3. The tendency to mimic right bundle branch aberration and its variability may give rise to interpretative difficulties.

The QT interval may be normal or slightly prolonged. It is rare in the pilot population, having a prevalence of 0.08 per cent in 16 988 French Air Force personnel. This was increased by a further 0.05 per cent following challenge with ajmaline. Of 334 Brugada phenotypes in one study, the pattern was recognized in 71 subjects following resuscitation after a cardiac arrest, in 73 subjects following a syncope event, and was recorded in a further 190 asymptomatic individuals. See Appendix 1b: 15. In a recent report, in 2,479 Finnish aircrew applicants, morphological ECG changes similar to, but not diagnostic of the Brugada pattern (eg type 2 and 3) had a normal outcome. Pedro Brugada has also expressed concern that the sign is being over-reported.

Long QT syndrome (LQTS) may be congenital or acquired. It is characterized by an abnormality of myocardial depolarisation: either sodium or potassium channels may be involved. In the congenital form, it used to be known as the Romano-Ward syndrome<sup>4</sup> or, if associated with nerve deafness, as the Jervell

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<sup>1</sup> Lenègre's disease: acquired complete heart block due to primary degeneration of the conduction system. After Jean Lenègre, French cardiologist (1904-1972).

<sup>2</sup> Torsades de pointes: an atypical rapid ventricular tachycardia with periodic waxing and waning of amplitude of the QRS complexes on ECG and rotation of the complexes around the isoelectric line (Fr. "fringe of pointed tips").

<sup>3</sup> Brugada syndrome: genetic disease characterized by right bundle branch block, ST segment elevation in V1 to V3 and sudden death, also a cause of the Sudden Arrhythmic Death Syndrome (SADS). The syndrome or rather disease is the most common cause of sudden death in young men without known underlying cardiac disease. After the brothers Pedro, Josep and Ramón Brugada, Spanish cardiologists, who described the disease in 1992.

<sup>4</sup> After C. Romano, Italian physician, and O.C. Ward, Irish physician (20<sup>th</sup> century).

and Lange-Nielsen syndrome<sup>1</sup>. Eight different genotypes and six different phenotypes (LQT1 - 6) have been identified. In all, there is an increased risk of syncope, ventricular tachycardia (torsades de pointes) and sudden cardiac death. The T waves are bizarre and the QT interval often significantly prolonged (> 550 ms (normal < 440 ms in males, < 460 ms in females)). Nevertheless, 30 per cent of carriers of the gene have a normal QT interval.

Outcome is related to the length of the QTc (Bazett's formula<sup>2</sup>), the genotype, and the presence or absence of complex ventricular rhythm disturbances including the characteristic torsades de pointes tachycardia. Acquired prolongation of the QT interval can occur in electrolyte disturbance (hypocalcaemia, hypomagnesaemia), metabolic disturbance (myxoedema) and drug administration (including quinidine, amiodarone, sotalol, phenothiazines and tricyclics, erythromycin, quinine, chloroquine, ketanserin, cisapride, terfenadine, tacrolimus and probucol). Hypokalaemia increases the risk of event.

One of the problems with both syndromes is the overlap with the normal ECG. Fifty per cent of LQT carriers are asymptomatic although up to four per cent may die suddenly. The LQT3 phenotype is the most lethal and LQT1 the least. A QTc > 500 ms powerfully predicts an unfavourable outcome and such people should not be certificated. Initial issue of a Medical Assessment in the future may require genotyping for this condition. If the condition is confirmed, certification is likely to be denied. LQT1 and LQT2 phenotypes in females and LQT3 phenotype in males are particularly adverse findings

*In the absence of genotyping, likely candidates for certification with the LQTS or the Brugada syndrome will:*

- *be asymptomatic*
- *have no family history of sudden cardiac death (SCD)*
- *have minimal ECG features or features seen only intermittently or following pharmacological provocation*
- *have no evidence of complex ventricular rhythm disturbance on regular Holter monitoring.*
- *be restricted to multi-crew operations*

## ENDOCARDIAL PACEMAKING

Conditions requiring the implantation of an endocardial pacemaker are uncommon in candidates of aircrew age; coexisting pathology or congenital abnormality are likely to disbar from flying duty. Anti-tachycardia devices and implantable defibrillators are disbaring.

*The subject should:*

- *have no other disqualifying condition, including unsuppressed atrial or ventricular rhythm disturbance*
- *have bipolar lead systems*
- *have a normal echocardiogram, Holter recording and satisfactory exercise ECG*
- *not be pacemaker-dependent (however defined)*
- *be restricted to Class 1 OML/Class 2*
- *undergo regular cardiological/pacemaker review.*

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<sup>1</sup> After Anton Jervell and Frederik Lange-Nielsen, Norwegian cardiologists (20<sup>th</sup> century).

<sup>2</sup> Bazett's formula: formula for calculating the heart-rate-corrected QT interval *QTc*.  $QTc = QT : \sqrt{R-R}$ , measured in seconds. After Henry Cuthbert Bazett, English-American physiologist (1885-1950).

## HEART MURMURS AND VALVAR HEART DISEASE

Heart murmurs are very common, particularly in the young and the slim. Most are innocent flow murmurs, which, by definition, will be brief and early systolic. Although a harsher murmur is more likely to be of significance, it may still be unimportant and reflect turbulence in the left and/or right ventricular outflow tracts. In older people, this may reflect thickening (sclerosis) of the aortic valve. Pan-systolic, late systolic or continuous murmurs are always abnormal.

*When any murmur is found at the initial examination for the issuance of a Medical Assessment, a cardiological opinion should be sought. Usually a single consultation, with or without echocardiography, will be sufficient to identify the few people in whom further review is justified. The remainder can be reassured. A previously unidentified murmur discovered in later years should also be reviewed.*

### **Aortic valve disease**

#### **Bicuspid aortic valve**

Bicuspid aortic valve is one of the most common congenital cardiac malformations and affects at least one per cent of the population. A significant percentage of subjects with such an anomaly will progress in later years to aortic stenosis and/or regurgitation. For this reason at least biennial (every two years) review is required. It may be associated with aortic root disease which, when present, needs to be followed closely and eventually will disbar on account of risk of dissection and/or rupture. Finally it may also be associated with patent ductus arteriosus or coarctation of the aorta. Any increase in the aortic root diameter needs ongoing echocardiographic follow-up; if this exceeds 5.0 cm, certification is no longer possible. There is a small but finite risk of endocarditis, which underscores the need for antibiotic cover for dental and urinary tract manipulation, although the need for this has recently been challenged.

As an isolated finding, following cardiological review, bicuspid aortic valve may be consistent with unrestricted certification to fly. Many aircrew developing aortic stenosis are likely to have a bicuspid valve, although calcification of a tricuspid aortic valve is more common with age. Isolated rheumatic involvement is rare in Western countries. Aortic regurgitation, if mild or moderate, is well tolerated over many years, the exception being if it is associated with root disease. Mild non-rheumatic aortic regurgitation (arbitrarily <1/6) not associated with aortic root disease or other potentially disqualifying condition may be permissible for unrestricted certification to fly.

#### **Aortic Stenosis**

*Mild aortic stenosis (Doppler peak aortic velocity 2.5 m/s) may be acceptable for unrestricted certification, but 2.5 - 3.0 m/s will restrict to multi-crew operation subject to annual cardiological review. A velocity >3.0 m/s needs very close cardiological supervision in the regulatory context. Evidence of valvar calcification should restrict the licence to multi-crew operations. Attributable symptoms will disbar. Any increase in left ventricular wall thickness (> 1.1 cm) or history of cerebral embolic event will also be disqualifying.*

#### **Aortic regurgitation**

*There should be no significant increase in the left ventricular end systolic diameter of the heart (arbitrarily >6.0 cm) and no increase of the left ventricular end diastolic diameter (> 4.1 cm) measured on echocardiography. There should be no significant arrhythmia, and the effort performance should be normal. An aortic root diameter >5.0 cm will disqualify. Significant increase in the end-systolic (> 4.4 cm) and/or end-diastolic (> 6.5 cm) diameters of the left ventricle, with or without evidence of*

*impairment of systolic/diastolic function will also disqualify. Annual cardiological follow-up with echocardiography is required.*

## **Mitral valve disease**

**Rheumatic mitral stenosis/regurgitation**, unless minimal with the subject in sinus rhythm, disbars from all forms of certification to fly. This is due to the excess risk of incapacitation, secondary to the unpredictable onset of atrial fibrillation, and a significant risk of cerebral embolism. In mitral stenosis the onset of atrial fibrillation, if the rate is rapid, may be associated with hypotension or pulmonary oedema.

**Non-rheumatic non-ischaemic mitral regurgitation** in subjects of pilot age is usually due to prolapse of either or both leaflets of the valve. When caused by rupture of the chordae or ischaemic injury to the papillary musculature, it disbars from certification to fly. Mitral leaflet prolapse is a common condition affecting up to five per cent of males and eight per cent of females, but definitions vary. It has been associated with a tendency to atrial and/or ventricular rhythm disturbances and atypical chest pain. There is a very small risk of cerebral embolus, sudden death and endocarditis (all <0.02 per cent per annum) and also of chordal rupture. Thickening or significant redundancy of the valve leaflets is associated with a higher embolic risk and needs special consideration.

Precautions need to be taken against the risk of endocarditis in the context of dental or urinary tract manipulation although this has recently been challenged for a subject with no history of previous infection. Isolated mid-systolic click needs no special precaution other than occasional cardiological review. Minor degenerative mitral regurgitation in the presence of a pan or late systolic murmur, normal left ventricular dimensions on echocardiography and no other potentially disqualifying abnormality may be consistent with unrestricted certification but requires close cardiological review with early restriction if there is any change, especially in the end-systolic/diastolic diameters of the heart. Ischaemic mitral regurgitation is disqualifying.

*In non-rheumatic non-ischaemic mitral regurgitation, annual cardiological review will be required, to include echocardiography and 24-hour ambulatory monitoring. Exercise ECG may also be indicated. A left ventricular systolic diameter > 4.1 cm and /or an end-diastolic diameter > 6.0 cm should disbar from all classes of certification to fly. The presence of atrial fibrillation in this context is also disbaring.*

## **Valvar surgery**

In a review of the long-term outcome of prosthetic heart valve insertion over a 15-year period, survival was better ( $P < 0.02$ ) with a mechanical prosthesis than with a tissue prosthesis; bleeding rates were higher with mechanical valves in the aortic (but not mitral) position and replacement rates were higher with bio-prosthetic valves. Rates of haemorrhage were approximately 2.5 per cent per annum for mechanical valves and 0.9 to two per cent for porcine valves in the aortic position. In the mitral position, the haemorrhage rate was similar.

Survival at 15 years is of the order of 66 to 79 per cent following aortic valve replacement and 79 to 81 per cent following mitral valve replacement. Risk factors for a poorer outcome include greater age, left ventricular dysfunction, higher New York Heart Association (NYHA) functional class<sup>1</sup>, concomitant

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<sup>1</sup> **New York Heart Association (NYHA) Functional Classification:** a simple way of classifying the extent of heart failure. It places patients in one of four categories based on how much they are limited during physical activity:

I No symptoms and no limitation in ordinary physical activity.

coronary disease/surgery, hypertension, renal failure and lung disease. Bioprosthetic valves, including homograft prostheses in the aortic position in patients < age 40 years, have a structural deterioration rate of 60 per cent at ten years and 90 per cent at 15 years.

With modern mechanical valves, the thromboembolic risk in patients receiving anticoagulants is similar to that of the bioprosthetic valves without anticoagulants but the additional haemorrhagic risk in the former has to be considered. Bioprosthetic valves start to deteriorate at five years in the mitral position and at eight years in the aortic position, deterioration being more rapid in younger subjects. There appeared to be no important performance differences between the stented and stentless porcine valves in one review. The Carpentier-Edwards porcine xenograft has an embolic risk approximating to one per cent per annum which, in the absence of a history of cerebral embolism, is normally managed with aspirin alone.

Aortic valve replacement with the unmounted aortic homograft valve performs most favourably in terms of the risk of thromboembolism (assuming sinus rhythm) but its survival may be shorter than that of the porcine valve, particularly in younger individuals. In the certification of subjects of professional aircrew age, it is likely that a mechanical valve will be recommended on the grounds of its long-term performance and this will disbar from certification to fly. Mitral valve repair due to prolapse of either or both cusps has a survival of 88 per cent at eight years in one review with a 93 per cent freedom from thromboembolic events at six years. The majority maintained NYHA class I status as well as sinus rhythm.

*Certification may be considered in the best-risk subjects who have undergone aortic valve replacement with a bioprosthesis / mitral valve repair at least six months previously and who:*

- *are free of symptoms*
- *are in sinus rhythm and do not require treatment with warfarin*
- *have no significant left ventricular hypertrophy on echocardiography (> 1.3 cm, septum and free wall) or dilation (> 6.0 cm end diastole / 4.1 cm end systole), nor dilation of the aortic root (> 4.5 cm)*
- *have no abnormality of wall motion on echocardiography (except that due to left bundle branch block)*
- *have no significant (un-grafted) coronary artery disease*
- *have no significant rhythm disturbance on Holter monitoring*
- *are restricted to fly on multi-crew operations only*
- *undergo annual cardiological review.*

In the case of aortic valve replacement, only a cadaver homograft or possibly a Carpentier-Edwards or similar xenograft may be considered for certification. Following mitral valve repair, only subjects who are in sinus rhythm may be considered for certification. Amputation of the left atrial appendage may be an advantage. Mitral valve replacement is disbaring. Any history of thrombo-embolism will be disqualifying. Precautions are needed for the antibiotic cover of dental and urinary tract procedures.

## **PERICARDITIS, MYOCARDITIS AND ENDOCARDITIS**

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II	Mild symptoms and slight limitation during ordinary activity. Comfortable at rest.
III	Marked limitation in activity due to symptoms, even during less-than-ordinary activity. Comfortable only at rest.
IV	Severe limitations. Experiences symptoms even while at rest.

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Pericarditis involves inflammation of the fibrous sac in which the heart lies; it has a number of pathological causes. Acute benign aseptic pericarditis is the condition most likely to be encountered in aircrew. It is also the condition most likely to be associated with full recovery and eventual unrestricted certification to fly. Identifiable causes of pericarditis include the following:

- idiopathic (acute benign aseptic)
- viral: Coxsackie B, echovirus 8, Epstein-Barr virus, varicella, mumps
- bacterial: *Staphylococcus*, *Pneumococcus*, *Meningococcus*, *Gonococcus*
- mycobacterial: tuberculosis
- filamentous bacterial: actinomycoses, nocardia
- fungal: candidiasis, *Histoplasma*
- protozoal: *Toxoplasma*, *Entamoeba*
- immunological: Dressler<sup>1</sup>, rheumatoid arthritis, systemic lupus erythematosus, scleroderma, polyarteritis
- neoplastic
- traumatic
- metabolic
- post-irradiation.

### **Acute benign aseptic pericarditis**

Acute benign aseptic pericarditis is a self-limiting illness. It is often associated with a systemic disturbance resembling influenza, a friction rub, and characteristic midsternal discomfort which may be worsened by inspiration. It is commonly relieved by bending forward. It is sometimes misdiagnosed as a coronary syndrome. Spontaneous recovery is to be expected, with supportive treatment such as aspirin. The identification of a viral infective agent may or may not be possible. The characteristic ECG changes seen are widespread concave ST segment elevation, with later diffuse ST-T changes which may be persistent and raise the possibility of myocardial involvement — so-called myopericarditis. The QRS voltages may be reduced if significant pericardial fluid has accumulated. This justifies subsequent monitoring until there is confidence that myocardial function remains unimpaired.

*Three to six months should elapse before restricted certification is permitted which is contingent upon the subject being asymptomatic with a normal echocardiogram, 24-hour ambulatory ECG and exercise ECG. Follow-up for at least two years is required. Coronary angiography or stress thallium MPI may be needed to resolve doubt surrounding non-invasive investigations. Relapse following idiopathic pericarditis is not uncommon, particularly in the first year. The pain of such an episode may be incapacitating and recurrence is inconsistent with Medical Assessment. The certification of aircrew following pericarditis attributable to other pathologies will depend on the cause, completeness of resolution, clinical stability and expected long-term outcome.*

Constrictive pericarditis may follow a number of infections or may be idiopathic. Fatigue, breathlessness and fluid retention are late clinical features, which, when evident, disbar from all forms of certification to fly. Following pericardectomy, re-certification may be possible subject to essentially normal ventricular function and demonstrated electrical stability. Such individuals however, commonly have a restrictive myocardial defect and are likely to be unfit.

### **Myocarditis**

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<sup>1</sup> Dressler's syndrome: post-myocardial infarction syndrome. After William Dressler, Polish-American physician (1890-1969).

Acute viral myocarditis may merge seamlessly into dilated cardiomyopathy. Viral myocarditis is more frequent than is diagnosed and may be present in one in 20 patients with a viraemia. Up to one-third of patients with a recent diagnosis of dilated cardiomyopathy will have a past history of febrile illness consistent with a myocarditis. In 1995 the WHO<sup>1</sup> task force on the classification of the cardiomyopathies introduced the “inflammatory cardiomyopathy” — DCMi. Characteristically, there is a systemic upset which is associated with evidence of impaired ventricular function or heart failure and disturbance of rhythm and/or conduction. Sudden cardiac death is also a feature. There may be an associated myalgia. Most cases recover spontaneously, although the possibility of the development of late cardiomyopathy is present. An MRI scan is likely to be helpful but myocardial biopsy may not be useful.

Viruses are not the only agents responsible for myocarditis. A large number of pathogens, metabolic abnormalities, toxins and other causes have been described. The most common is ethanol (ethyl alcohol). Acute alcoholic intoxication reduces myocardial function and predisposes to atrial and ventricular rhythm disturbance, the most important of which is atrial fibrillation. Other toxins include carbon monoxide, halogenated hydrocarbons, insect or snake bites, and cocaine. One cause of occult myocardial damage, both acutely and long-term, is an anthracycline given in childhood for treatment of lymphoma and other neoplastic conditions. There may be an initial myocarditis followed years later by the insidious development of a cardiomyopathy. Unfortunately, the resting ECG is insensitive in the detection of the subtle abnormalities of function in this group of patients who appear to have a potentially vulnerable myocardium. Likewise, the echocardiogram may be unhelpful. An MRI will be more sensitive.

*Following an episode of myocarditis, full investigation should include echocardiography, exercise ECG and repeated 24-hour ambulatory monitoring to search for complex ventricular rhythm disturbances, conduction disturbance and/or atrial fibrillation. The echocardiogram should have returned to normal (i.e. have no evidence of impaired left or right ventricular function) and should be repeated in regular follow-up. It is likely that an MRI scan will have been performed and contributed to the diagnosis. This should include repeated Holter monitoring. Any evidence of increasing (left or right) ventricular internal diameters and/or reduction of systolic (and/or diastolic) function is incompatible with certification.*

## **Endocarditis**

Endocarditis has an overall mortality of six per cent, although the presence of a virulent organism and/or involvement of a prosthetic valve can elevate this up to ten-fold. Causes of death include sepsis, valve failure giving rise to heart failure, and mycotic aneurysm. The acute illness disbars from all forms of certification to fly. Treatment involves at least six weeks of antibiotic therapy, and recovery to full health may take weeks longer, with a risk of relapse for several months. Once a patient has suffered an episode of endocarditis, re-certification depends on good residual function of the heart as judged by standard non-invasive techniques. The risk of re-infection with recurrence of endocarditis is increased. Such patients require special antibiotic precautions with dental and urinary tract surgery.

Outcome is influenced favourably if renal and myocardial functions are normal after an attack and there has been no systemic embolism. Involvement of the mitral or aortic valve, if it does not lead to significant regurgitation, may leave a sterile vegetation that provides a nidus for cerebral embolism and re-infection. There are several reports that post-discharge survival is reduced; for the above reasons, restricted certification is the only possibility following recovery.

## **CARDIOMYOPATHY**

Cardiomyopathy is a primary heart-muscle disorder not associated with coronary heart disease, valvar heart disease, hypertension (which are all secondary diseases of heart-muscle) or congenital abnormality.

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<sup>1</sup> WHO – World Health Organization

If the ventricle is dilated with predominantly systolic dysfunction (it may also demonstrate secondary diastolic dysfunction), the term 'dilated cardiomyopathy' is appended. If it is inappropriately hypertrophied, sometimes grossly and asymmetrically, in the absence of provocative circumstance, the term 'hypertrophic cardiomyopathy' is used. In this case systolic function is normally preserved, but diastolic function is likely to be impaired. If the ventricle is stiffened due to infiltration by, for example, amyloidosis, sarcoidosis or a glycosphingolipid (Fabry's disease<sup>1</sup>), the term 'restrictive cardiomyopathy' is more appropriate, although hypertrophy may also be present as will both systolic and diastolic dysfunction.

### **Hypertrophic cardiomyopathy**

Hypertrophic cardiomyopathy (HCM) has a prevalence of about one in 500 adults. Most adults with the condition have inherited it as an autosomal dominant characteristic, and about 60 per cent have one of over 100 mutations involving 11 genes that encode the contractile proteins. It is marked by the diversity of its phenotypes and has a fairly specific histological appearance, which includes disarray of the myocytes with bizarre forms. An otherwise inexplicable wall diameter >1.5 cm, often with characteristic asymmetry of the interventricular septum, may lead to the diagnosis but there is much variation. About 25 per cent will have sub(aortic) valve obstruction caused by the hypertrophied septum. One to two per cent die each year, half of these suddenly and usually due to ventricular arrhythmia. Stroke is also a cause of death in such individuals.

Although often asymptomatic, the patient with established HCM may suffer breathlessness (50 per cent); a smaller percentage will also suffer syncope at some point. The condition is likely to present in aviators with an abnormal resting ECG. There are no truly typical features and changes range from diffuse ST-T abnormalities through QS waves in the inferior or high septal leads (the so-called pseudo-infarct pattern with a discordant QRST angle) to significant and widespread voltage increase with deep symmetrical T wave inversion. See Appendix 1b: 22. It may also present as a sustained ejection systolic murmur reflecting at least "physiological" obstruction in the left ventricular outflow tract together with a third or fourth heart sound. Mitral regurgitation may be present due to distorted architecture. The association of systolic anterior motion of the mitral valve (SAM) with (asymmetric) septal hypertrophy (ASH) and premature closure of the aortic valve on M mode echocardiography<sup>2</sup> is more or less pathognomonic of the condition.

The natural history of the condition complicates certification. Outcome may be genetically determined but progress can be very slow and the condition benign. Risk factors for sudden cardiac death include previous cardiac event, family history of sudden death, ventricular tachycardia on ambulatory monitoring, abnormal blood pressure response (a fall) on exercise ECG, inter-ventricular septum >3 cm and sub-aortic gradient >30 mmHg. Half of the sudden deaths occurring in young male athletes >35 years of age are due to the condition. Atrial fibrillation, especially if paroxysmal and uncontrolled, may prove incapacitating and also worsens the prognosis.

*Certification requires that:*

- *the subject can complete at least three stages of the Bruce treadmill protocol without symptoms, electrical instability or a fall in the blood pressure (which may be predictive of sudden cardiac death (SCD))*

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<sup>1</sup> Fabry's disease: diffuse angiokeratoma. An X-linked lysosomal storage disease of glycosphingolipid catabolism, leading to accumulation of ceramide trihexoside in the cardiovascular and renal systems., After Johannes Fabry, German dermatologist (1860-1930).

<sup>2</sup> M mode echocardiography: recording of the amplitude and rate of motion (M) of a moving structure in real time by repeatedly measuring the distance of the structure from the single transducer at a given moment. It yields a monodimensional image, sometimes called an "icepick" view of the heart.

- *there is no ventricular tachycardia (defined as three or more consecutive ventricular complexes) whether sustained or not*
- *there is no family history of related SCD*
- *the interventricular septum is < 2.5 cm*
- *the airman is restricted to OML operation*

*A history of atrial fibrillation, whether paroxysmal or sustained, is disqualifying*

*Ongoing certification requires the absence of the above risk factors and long term cardiological follow up with annual echocardiography to determine (left) ventricular configuration and performance, Holter monitoring to search for life threatening rhythm disturbance, and exercise ECG to record an appropriate blood pressure response (see above)*

### **The athlete's heart**

Endurance training (running, swimming, bicycling) is associated with end-diastolic dilation of the left ventricle with an increased ejection fraction, while power work (weight lifting) is associated with hypertrophy. In the former, both the left ventricle muscle mass and the end-diastolic diameter are related to lean body mass. Apart from the exercise history, the ECG is helpful. Both athletes and subjects with HCM will have increased voltages but the latter will often show left axis deviation and a wide QRST angle. Sometimes they will also show QS waves in the inferior or antero-septal leads while the athlete's heart is likely to demonstrate right axis deviation with no more than minor depolarisation change in the ST-T segment. See Appendix 1b: 8. The echocardiogram in the athlete will show a normal left atrial internal diameter (< 4.0 cm); in subjects with HCM, it will be > 4.5 cm. Likewise, in the athlete and HCM respectively, the inter-ventricular septum will be < 1.5 cm and > 1.5 cm, and the left ventricular end-diastolic diameter will be > 4.5 cm and < 4.5 cm respectively.

*Having established the diagnosis of the athlete's heart and in the absence of any other anomaly, unrestricted certification is to be expected*

### **Restrictive cardiomyopathy**

Restrictive cardiomyopathy is a rare disorder characterized by normal or near-normal dimensions of the heart, sometimes with normal systolic function, but with failure of diastolic function due to increased stiffness of the myocardium. The causes include infiltrative conditions such as amyloidosis and sarcoidosis, storage diseases such as haemosiderosis and haemochromatosis, and endomyocardial disease, including fibrosis, the eosinophilic syndromes, carcinoid syndrome and radiation damage.

The majority of patients with a restrictive myocardial defect will be unfit for any form of certification to fly. Amyloidosis of the heart has a very poor prognosis by way of rapid deterioration of function complicated by rhythm disturbance. Eosinophilic heart disease is equally problematic

*Haemochromatosis that is controlled well by venesection in a patient with normal glucose tolerance, normal echocardiogram, normal exercise ECG and normal ambulatory ECG may be considered for restricted certification, subject to regular review. Those with transfusion-dependent anaemias will be unfit.*

### **Dilated cardiomyopathy**

The causes of dilated cardiomyopathy are various, with 40 to 60 per cent being familial and transmitted, predominantly by an autosomal dominant gene. The prognosis has improved strikingly since the 1980s, and mortality is now about 20 per cent at five years. Thirty per cent will die suddenly, many from a life

threatening tachyarrhythmia, this outcome not being restricted to severe disease. In one study, nearly 50 per cent of 673 subjects with dilated cardiomyopathy were labelled idiopathic, while a further 12 per cent were considered to have myocarditis, and only three per cent were considered to be due to alcohol. An earlier study, however, suggested that alcohol was responsible in up to one-third of cases. The electrocardiographic changes are non-specific but incomplete left bundle branch aberration is common. Echocardiography will demonstrate global reduction in wall motion with dilation of the left, right or both ventricles. MRI scanning is a useful additional investigation. In the event of coronary artery disease being suspected, a pharmacological stress thallium 201 scan or coronary angiogram may be indicated.

One group that bears special consideration is that in which the subjects have received an anthracycline, often in childhood for malignant disease. There is some evidence of a dose relationship in the incidence of subsequent myocardial abnormality; in one study of long-term survivors (median 8.9 years) of malignant bone disease aged between ten and 45 years (mean 17.8 years), the incidence of cardiac abnormalities increased with length of follow-up. These subjects often have only minor abnormalities on echocardiography, and MRI scanning is more sensitive in detecting myocardial abnormality. Life-long cardiological follow-up with regular echocardiography and Holter monitoring is required.

The cause of death in dilated cardiomyopathy may be divided more or less equally into those perishing from pump failure and those suffering a sudden arrhythmic event. The presence of high-grade ventricular rhythm disturbances is both common and predictive of outcome.

*In view of the generally poor prognosis, the diagnosis of dilated cardiomyopathy is inconsistent with any form of certification to fly. Mild global reduction in left ventricular systolic function (with the ejection fraction > 50 per cent) that has been stable for a period of at least one year and with no evidence of electrical instability may be considered for restricted certification, subject to close follow-up with echocardiography and Holter monitoring.*

## **Sarcoidosis**

Sarcoidosis presents special problems in certification due to its ubiquity and its occasional involvement of the heart. It is commonly a self-limiting condition seen in young adults with the extent of systemic involvement being largely unknown. There is often no significant systemic illness and presentation may be fortuitous with bilateral hilar lymphadenopathy on routine chest X-ray. Or there may be erythema nodosum, malaise, arthralgia, iridocyclitis, respiratory symptoms or other constitutional upset. In those with systemic involvement, five percent will also have cardiac involvement. Its aetiology is not understood, but a genetically determined sensitivity to pine pollen or an infective agent may be involved.

Involvement of the heart is associated with a poor prognosis and a significant risk of sudden death; half of those diagnosed with the condition die from the disease. Cardiac involvement may exist without concomitant involvement of other systems. Sudden death may be due to life threatening ventricular rhythm disturbance or granulomatous involvement of the conducting system. Dilation of the ventricles due to patchy involvement of the myocardium may lead to the development of a dilated or restrictive cardiomyopathy.

There are no characteristic ECG features although Holter monitoring may be premonitory of rhythm and conduction disturbance. Echocardiography may show patchy or generalized hypokinesia, especially if the basal myocardium is affected, with ventricular dilation and reduction of the ejection fraction. Deposits thicker than 3 mm may be detected non-invasively. Multiple Gated Acquisition (MUGA) and thallium MPI are inconclusive but magnetic resonance imaging (MRI) scanning may demonstrate localized high-intensity lesions with gadolinium enhancement. Raised plasma angiotensin-converting enzyme (ACE) activity is not diagnostic but may give an indication of active disease. A scalene node biopsy will confirm

systemic sarcoidosis if present but myocardial biopsy is often unhelpful due to the patchy nature of the disease.

*The diagnosis of sarcoidosis (sometimes by way of the chance discovery of bilateral hilar lymphadenopathy) requires that the pilot should be made unfit. Satisfactory evaluation for restricted Class I certification should attempt to establish that the disease is inactive and include:*

- *no increase in hilar lymphadenopathy on serial chest radiography*
- *stable gas transfer factor*
- *no evidence of active disease elsewhere (including scalene node biopsy)*
- *normal resting and exercise ECG (to at least nine minutes of the Bruce protocol)*
- *no significant rhythm or conduction disturbance on Holter monitoring*
- *normal echocardiogram.*

*Trans-oesophageal echocardiography and/or MRI scanning will be required in the event of possible myocardial abnormality.*

*Restricted certification may be permitted subject to six-monthly cardiological follow-up for at least two years. Minimum re-investigation should include echocardiography and Holter monitoring. Full certification may be considered no sooner than two years after the initial observation, subject to regular follow-up. Any evidence of systemic involvement (except erythema nodosum) requires permanent restriction to multi-crew operation. Evidence of involvement of the heart disbars for all licences.*

### **Right ventricular cardiomyopathy**

Right ventricular cardiomyopathy (previously arrhythmogenic right ventricular dysplasia (ARVC)) is characterized by dilation of the right ventricle with regional or global replacement of the myocardium with fibro-fatty tissue. It may also involve the left ventricle.

It may account for up to 25 per cent of sudden cardiac death (SCD) in young adults and is transmitted as an autosomal dominant gene with incomplete penetrance in at least 30 per cent of those affected. The characteristic ECG pattern is one of QRS prolongation with T wave inversion in V1-V3. Epsilon waves may also be present<sup>1</sup>. Monomorphic ventricular rhythm disturbances with left bundle branch block and right-axis deviation, including sustained ventricular tachycardia, are commonly seen. An early sign may be minor T wave changes in the right ventricular leads. Exercise-induced ventricular tachycardia and SCD are common. A family history has an uncertain predictive value but early presentation (< age 20 years) is likely to be an adverse factor. Syncope is an adverse event but QT dispersion, Holter monitoring, exercise ECG and programmed electrical stimulation are not reliable predictors of ventricular tachycardia.

*Although right ventricular outflow tract tachycardia should prompt the search for dysplasia, isolated ventricular premature beats with a right ventricular outflow tract pattern may be benign in young adults. However, our ability to disentangle those with “innocent” (and, perforce, asymptomatic) ventricular tachycardia from those with a potentially fatal outcome is not yet secure. For these reasons, associated right ventricular dilation disbars from all forms of certification to fly.*

## **CONGENITAL HEART DISEASE**

Improvements in diagnostic and interventional techniques in the management of congenital heart disease have led to the emergence of the specialty of "grown-up congenital heart disease" (GUCH). A patient

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<sup>1</sup> Epsilon waves are seen on the ST segments of leads V1 and V2 as small ‘crinkles’. They are best seen in Fontaine leads (SI, SII, SIII in the parasternal position). They are not diagnostic of ARVC and may be seen in right ventricular hypertrophy and sarcoidosis. They probably represent late potentials in the right ventricle.

with such an anomaly on achieving adulthood naturally expects to lead as normal a life as possible which includes carrying on employment and pursuing hobbies and pastimes, some of which will have defined fitness requirements. These pursuits are not confined to aviation but include activities such as diving, vocational driving, and motor-racing.

In general terms the principles applied to other cardiovascular problems are equally applicable to GUCH, the defining requirement being that the risk of sudden or insidious incapacitation does not exceed that appropriate to the age of the individual. As we learn more about the long-term outcomes of these conditions, it is increasingly possible to make certificatory recommendations that are both safe and fair, although an individual may not remain fit for a conventional career span. At present only those who have a normal, or almost normal, event-free outlook with or without surgery can be considered. Many forms of congenital heart disease are not consistent with flying status. Cardiological review with appropriate, usually non-invasive, investigation and follow-up is mandatory in those accepted.

### **Atrial septal defect**

Atrial septal defect is one of the most common congenital anomalies of the heart accounting for one-quarter of all. Three-quarters are ostium secundum defects, one-fifth are ostium primum defects and one in 20 are sinus venosus defects.

The life expectancy with all but small (pulmonary/systemic flow ratio  $< 1.5 : 1$ ) uncorrected secundum defects is not normal with an increasing risk of atrial rhythm disturbances including flutter and fibrillation from the fourth decade, and the eventual onset of right-sided heart failure in the sixth and seventh decades. Early (age  $< 24$  years) closure of the defect carries a very low operative mortality and normal life expectancy, but later closure is associated with a poorer outcome — increasingly poor as the age of intervention rises — due to atrial fibrillation, thrombo-embolism and the onset of right heart failure. The use of clam-shell and angel-wing devices is accepted and may encourage the closure of smaller defects although long-term outcome data are not yet available.

*Small or early-corrected ostium secundum defects are consistent with unrestricted certification, subject to occasional review. Larger defects, or those complicated by atrial rhythm disturbance, may lead to unfitness or restricted certification only.*

Ostium primum defects present additional problems to those outlined above because the mitral valve and conducting system may be involved. Such involvement significantly worsens the outcome.

*Applicants with this condition can be considered only for restricted certification. Regular review is required. Mitral regurgitation should be minimal and there should be no significant disturbance of rhythm or conduction. Sinus venosus defects bear the problem that significant rhythm disturbances are frequent both before and after correction. These need to be excluded before certification can be considered. Life-long periodic ambulatory ECG monitoring is required.*

### **Ventricular septal defect**

Isolated ventricular septal defect accounts for about one-third of congenital heart defects. Small (pulmonary/systemic flow ratio  $< 1.5 : 1$ ) defects either close spontaneously or remain stable lifelong. There is no increased risk of sudden or insidious incapacitation, although there is a small risk of endocarditis, and appropriate measures should be taken for its prophylaxis. Such candidates may be fit for unrestricted certification. Closure in childhood likewise carries a good outcome — five percent mortality at 25 years, but larger defects that have undergone closure do not appear to have a normal life expectancy with an 82 per cent 30-year survival compared with 97 per cent in age-matched controls. Age at surgery

and the presence of pulmonary vascular change are predictors of survival. Applicants with such defects should undergo full cardiological review.

### **Pulmonary stenosis**

Pulmonary valvar stenosis accounts for one in ten subjects with congenital heart disease. Stenosis of the infundibulum of the right ventricle and of the supra-valvar region are much less common. The former may be present as a fibromuscular ring or as concentric hypertrophy in an otherwise normal heart with an intact interventricular septum. Valvar stenosis may also be present. Supra-valvar stenosis may be associated with multiple stenoses of the pulmonary trunk and its branches.

*Mild degrees of pulmonary valvar stenosis (peak gradient < 30 mmHg across the valve — tricuspid valve Doppler velocity < 2.5 m/s) are consistent with unrestricted certification. Following surgery, 25-year survival is 95 per cent — not quite normal — but discretion may be exercised in “best-risk” subjects, judged by non-invasive and invasive means. Supra-valvar stenosis should normally disbar from all forms of certification to fly.*

### **Aortic stenosis**

Aortic stenosis has been reviewed above. Congenital abnormalities of the aortic valve or the aortic outflow tract requiring surgery in childhood carry a relatively poor prognosis, the 25-year mortality being 17 per cent. Nevertheless, in one small study there were no late deaths in the 16-year period following resection of isolated discrete subaortic stenosis. This condition is normally incompatible with certification to fly.

### **Coarctation of the aorta**

Coarctation of the aorta may be diagnosed in childhood or the diagnosis may be delayed until later years. In terms of outcome the difference is significant. In about one-third of patients a bicuspid aortic valve will also be present. Early intervention is important. The 20-year survival of patients aged 14 years or younger at the time of operation was 91 per cent compared with an 84 per cent survival of those in whom surgery was delayed. The best outcome was in those operated on under the age of nine years. Age at operation predicted subsequent hypertension, which was also associated with an increased risk of sudden death, myocardial infarction, stroke and aortic dissection.

*Unrestricted certification can be considered in normotensive subjects who underwent correction of the anomaly below the age of 12 to 14 years. Continuous subsequent review is required to monitor the blood pressure. Echocardiographic follow-up should be determined by the presence or absence of a bicuspid aortic valve. Ascending aortic dilation is not compatible with certification. Treated hypertension following late closure may be compatible with restricted certification.*

### **Tetralogy of Fallot<sup>1</sup>**

The tetralogy of Fallot is classically the only cyanotic congenital heart condition that is consistent with survival into adult life if uncorrected. Such survivors do not have a normal life expectancy and late

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<sup>1</sup> Tetralogy of Fallot: ventricular septal defect, pulmonary stenosis (which protects the pulmonary circulation), overriding aorta, and right ventricular hypertrophy. After Étienne-Louis Arthur Fallot, French physician (1850-1911).

closure (>12 years) carries a less favourable outlook than early closure. In one study, the 32-year actuarial survival was 86 per cent overall compared with 96 per cent for an age- and sex-matched control population; for patients operated on before the age of 12-years, the figure was 92 per cent — still not normal. An increased frequency of complex rhythm disturbances has been noted as has a higher than expected incidence of late SCD. The former do not appear to predict the latter reliably. In one study, the 25-year mortality was five per cent, - higher than predicted.

*It is possible that in early years (< age 40 years), the best-risk subjects can be considered for unrestricted certification but our present inability to identify later risk indicates that the tetralogy of Fallot is incompatible with unrestricted certification in the long term. Initial unrestricted certification should be confined to applicants operated on before the age of 12 years who have no evidence of residual right ventricular hypertrophy, significant pulmonary regurgitation or complex ventricular rhythm disturbance, subject to regular monitoring by a cardiologist.*

### **Patent ductus arteriosus**

Patent ductus arteriosus is usually recognized early in life and closed surgically. In one review, the 25-year mortality was less than one per cent, with no late deaths.

*There is an association with bicuspid aortic valve, subaortic stenosis, pulmonary stenosis and aortic root disease. In the absence of such complications, an applicant may be considered for unrestricted certification. Complicating pathology requires further consideration and review.*

Many congenital heart conditions are now consistent with long-term survival. Only those with the most favourable outcomes will be acceptable for medical certification but as new data become available the certificatory position will require further updating.

### **DISEASE OF THE GREAT VESSELS**

Aortic aneurysm involves dilation of the aorta and in one-sixth of cases this will involve more than one segment. Most commonly involving the abdomen, one-quarter of subjects with a thoracic aneurysm will also have involvement of the ascending thoracic segment.

The condition is four times more common in men > age 55 years than in women, the prevalence in this age group being three per cent. Increasing age, atheromatous degeneration of the wall, hypertension and familial factors are all involved in the pathogenesis of abdominal aortic aneurysm. Aneurysms < 4.0 cm in diameter have a two-year risk of rupture of less than two per cent, but aneurysms > 5.0 cm the risk is 22 per cent. One, five- and ten-year survival rates following surgical repair in one large series were 93 per cent, 63 per cent and 40 per cent respectively in an older mean age group than the pilot population, attrition being due to concomitant vascular complications. In another study, five-, ten- and 15-year survival was 71 per cent, 38 per cent and 16 per cent respectively in the absence of coronary artery disease in a population with a mean age of 69.8 years. Coexistent coronary artery disease reduced survival further. Hypertension significantly impairs outcome both before and after treatment.

Thoracic aneurysms show less age-related increase in incidence, the descending, ascending and arch portions being involved in that order. Aneurysm of the ascending aorta most frequently shows cystic median degeneration with increasing prevalence of atheromatous disease distally. Occasional causes are giant-cell arteritis and syphilis. In younger patients, the inherited disorders of collagen will be more important. As with abdominal aneurysms, a luminal diameter > 5.0 cm is associated with a significantly increased risk of rupture. Surgery carries a five to ten per cent mortality and significant morbidity.

## Marfan's syndrome<sup>1</sup>

Marfan's syndrome is transmitted as a dominant gene with variable expression. It is one of several conditions marked by an inherited abnormality of the extra-cellular matrix, including the Ehlers-Danlos syndrome<sup>2</sup>. It is a mutant form in about one-sixth of cases. Its prevalence in the population may be as high as one per 10 000.

At times its variability makes it difficult to diagnose with confidence although the causative gene has now been identified. In a report from the Cleveland Clinic, males outnumbered females by a ratio of two to one. Three-fifths and two-fifths, respectively had a diastolic murmur and/or cardiomegaly on presentation; follow-up was a mean of 99 months. Thirty-one of the 81 patients died at a mean age of 35 (range 3 to 63) years, 87 per cent from cardiovascular cause. Even after surgery the survival is not good — 75 per cent at five years and 56 per cent at ten years. Survival following surgery for non-Marfan cystic median necrosis of the aorta is equally bleak, at 57 per cent at five years. Increased ascending aortic diameter predicts the onset of aortic regurgitation but less reliably of dissection.

*Pilots in whom the diagnosis of aortic aneurysm has been queried require evaluation with transthoracic echocardiography, MRI or magnetic resonance angiography (MRA) and, if indicated, aortography. A luminal diameter > 4.0 cm but < 5.0 cm should lead to restriction of the Class 1 Medical Assessment, whilst a diameter > 5.0 cm should lead to denial. Regular follow-up is mandatory, with careful control of the blood pressure.*

*In view of the relatively poor outcome in patients with aortic aneurysm after surgery, only the best risk subjects in whom coronary artery disease has been excluded may be considered for restricted certification. In applicants with a forme fruste<sup>3</sup> of Marfan's syndrome and in whom the echocardiographic dimensions of the heart and great vessels remain within the normal range, any valvar regurgitation, whether aortic or mitral, should be minimal before restricted certification may be considered subject to indefinite subsequent review.*

## PERIPHERAL VASCULAR DISEASE

Peripheral vascular disease powerfully predicts the presence of a generalized arteriopathy that is likely to involve the coronary and cerebral circulations. The discovery of absent (lower) limb pulses, with or without symptoms suggestive of intermittent claudication, should always provoke full cardiovascular review. In 84 consecutive patients with peripheral vascular disease but no cardiac symptoms followed for a mean of 66 months, more than two-thirds had significant coronary artery disease on angiography and their mean left ventricular ejection fraction was reduced at 44 per cent. There were 23 events in the follow-up period. Dipyridamole stress thallium MPI was a significant predictor of outcome. In general terms, the younger the age of onset, the worse the outcome. The presence of peripheral vascular disease following coronary artery surgery is associated with a significantly higher mortality. On account of the co-morbid risk of a coronary event associated with peripheral vascular disease all such applicants should at least undergo pharmacological stress thallium MPI. If abnormal, certification should be denied unless a subsequent coronary angiogram satisfies the standard requirements for minor coronary artery disease (see above).

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<sup>1</sup> Marfan's syndrome: a congenital disorder of connective tissue characterized by abnormal length of extremities, especially fingers and toes, subluxation of the lens, cardiovascular abnormalities (commonly dilation of the ascending aorta) and other deformities. After Antonin Bernard Jean Marfan, French paediatrician (1858-1942).

<sup>2</sup> Ehler-Danlos syndrome: a group of inherited disorders of the connective tissue. The major manifestations include hyperextensible skin and joints, easy bruisability, poor wound healing, and orthopaedic and ocular defects. After Edvard Ehlers, Danish dermatologist (1863-1937) and Henri A. Danlos, French dermatologist (1844-1912).

<sup>3</sup> *forme fruste*: a partial, arrested, or inapparent form of the disease (French 'unfinished form').

*Indefinite supervision is required, and class 1 Medical Assessment must be restricted to multicrew operations.*

## **VENOUS THROMBOSIS**

A number of factors predispose to deep venous thrombosis, with consequent risk of pulmonary embolism. In spite of the attention of the news media that deep venous thrombosis has attracted recently, it is rare or very rare in otherwise fit aircrew. The risk is enhanced in the thrombophilic syndromes (factor V Leiden; deficient protein S and C and anti-thrombin). Occult malignancy may also be associated. Following an episode, recurrence is common - 20 per cent at five years which will require long term treatment with warfarin. Aspirin is not a substitute.

*Once diagnosed, deep venous thrombosis is normally treated with warfarin for 3 - 6 months which precludes certification until one week after this medication is discontinued.*

### **Pulmonary embolism**

Pulmonary embolism is an important complication of deep venous thrombosis and is now often investigated by spiral computed tomography (CT) scanning. This procedure has taken over from ventilation/perfusion (V/Q) scanning.

Pulmonary angiography may be performed if the pulmonary artery pressure is also to be measured. It is essential to secure the diagnosis in view of the risk of recurrence although this is low in the absence of risk factors. Warfarin is the mainstay of treatment. This medication disbars from any form of certification in many States due to the risk of haemorrhage which is in addition to any risk from the underlying condition. New direct thrombin inhibitors are under trial. These do not require follow-up of the prothrombin time and may have a lower rate of haemorrhagic complication. They are not yet generally available.

Following pulmonary embolus, the pulmonary artery pressure must be shown to be normal before medical certification can be considered. Good Doppler signals may enable a non-invasive assessment of the tricuspid valve regurgitant velocity and thereby assessment of the pulmonary peak systolic pressure. Right heart catheterization may be required.

*A period of six months is usually recommended for treatment with warfarin following pulmonary embolism, and medical certification should not be considered during this time. Certification will require restriction to multi-crew operations. Pulmonary hypertension (systolic pressure > 30 mm Hg – tricuspid valve Doppler velocity > 2.5 m/s), whether primary or secondary, should disbar from all forms of certification to fly.*

## **SYNCOPE**

Syncope (Gr. 'cutting off') may be defined as transient loss of consciousness, usually associated with falling. The mechanism is global cerebral hypoperfusion due to a number of causes. As a rule, recovery is spontaneous and complete but although recovery to consciousness is usually rapid, full return of intellectual function may be delayed. Depending on cause, syncope may be abrupt and without warning, or there may be a prodrome (presyncope) of variable length with symptoms such as nausea, weakness, light-headedness and visual disturbance. Retrograde amnesia occurs in some, particularly older, individuals. Recovery, although somewhat subjective, may be rapid (seconds/minutes), as in the case of

an Adams-Stokes attack<sup>1</sup>, or prolonged sometimes, as in vasovagal syncope. If the attack is complicated by an anoxic epileptic seizure, recovery will inevitably be delayed further.

Differential diagnosis of syncope due to circulatory cause:

- *Neurocardiogenic* syncope is marked by a variety of autonomic circumstances including nausea/vomiting and gastrointestinal disturbance. It is associated with systemic hypotension and cerebral hypoperfusion. It may also be associated with either bradycardia or tachycardia.
- *Orthostatic* hypotension may be caused by blood loss or impairment of autonomic regulation from a number of causes. It occurs in severe left (or right) ventricular dysfunction. It is a common transient experience in normotensive subjects on gaining the erect position.
- *Structural heart disease*, exemplified by valvar aortic stenosis (or subaortic stenosis as in some forms of hypertrophic cardiomyopathy), if severe, is associated with syncope. More than one mechanism is involved.
- *Cardiac arrhythmias*, including supraventricular and ventricular tachycardias and sinoatrial or atrioventricular conduction disorders, may be complicated by syncope.
- *The “steal” syndromes* in which there is competitive demand for cerebral perfusion are rarely seen in the pilot population.

Consciousness may also be impaired or lost due to hypoglycaemia, hypoxia, hyperventilation, somatization disorders, and epilepsy.

### **Vasovagal (neurocardiogenic) syncope**

Vaso-vagal (neurocardiogenic) syncope or the common faint was described over 200 years ago and is the mechanism of what used to be known, in classical literature, as the “drawing-room swoon”. It is a common phenomenon — it has been suggested that between one-third and two-thirds of the population experience an attack at least once during their lifetime. The attacks are sporadic and often cluster, the population being heterogeneous. It often presents in teenage years and disappears, reappearing later in life, sometimes as clusters of episodes. It contributes to at least 40 per cent of the syncopal events seen in the outpatient setting. It is difficult to manage, partly because the triggering mechanisms, even after having been investigated extensively, are imperfectly understood.

The regulation of the circulation involves a number of interacting reflexes. Initially, on change in posture, baroreflex mechanisms are activated to counteract the effect of gravity on the venous blood pool. The renin-angiotensin-aldosterone axis is also involved, both interacting with the autonomic nervous system and influencing salt and water metabolism. Adequate blood pressure is needed to maintain the blood supply to the vital organs, including the brain, kidneys and gut. If it falls beyond a certain point, cerebral auto-regulation fails and the subject loses consciousness. With an abrupt fall in blood pressure, this occurs very rapidly — within five to ten seconds. Provided the pressure is restored rapidly (often brought about by the patient falling to the ground), recovery of consciousness ensues but, depending on the provocative circumstances, a minimum period of some 30 minutes is required for effective recovery. This can be prolonged considerably if there is recurrence of the syncopal episode, if the provocative circumstance is ongoing, e.g. in the case of nausea or vomiting, or if the period of hypotension was sufficiently prolonged for cerebral anoxia to provoke epileptic seizure. Twitching movements during the period of unconsciousness are common and should not be confused with epileptic seizure.

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<sup>1</sup> Adams-Stokes attack: an episode of syncope in Adams-Stokes syndrome, i.e. episodic cardiac arrest due to transient complete atrioventricular block, caused by failure of normal and escape pacemakers. After Robert Adams, Irish physician (1791-1875) and William Stokes, Irish physician (1804-1878).

Maintenance of the systemic blood pressure requires adequate circulating blood volume, sufficient peripheral arteriolar tone in the “resistance” vessels, regulation of the “capacitance” vessels (which contain 70 per cent of the circulating blood volume), and also regulation of the inotropic and chronotropic state of the heart. All patients experiencing an episode of vasovagal syncope suffer a fall in the blood pressure with ensuing impairment of consciousness; in some there is a profound bradycardia but in others there is a tachycardia. This paradox involves loss of regulation of venous tone (and return of circulating blood to the heart), inadequate arteriolar tone, and ventricular myocardial mechanisms.

The symptoms of vasovagal syncope include a prodromal syndrome of variable duration with light-headedness, weakness, a sensation of air hunger or hyperventilation, detachment from surroundings, palpitations, blurring of vision, and field disturbance, nausea, dizziness and eventually syncope. “Malignant” syncope is characterized by little or no warning and injury may result. Another definition of the malignant form relates to the period of asystole during tilt testing. Depending on the circumstances, recovery may be prolonged by repeated episodes of hypotension followed by partial recovery of consciousness. Recovery invariably takes place but the symptoms can persist for hours. Patients with the condition have a normal life expectancy unless the incident causes hazard.

Provocative factors in vasovagal syncope are several although some of the features may form part of the syndrome. Specifically, nausea, vomiting, a sensation of abdominal churning, diarrhoea, an awareness of warmth, heat or coldness, and sweatiness are common. Other input may come from fatigue, emotional disturbance or anxiety, circadian stress, dehydration, pain or visual stimuli, such as the sight of a needle. Sometimes cause and effect can be blurred. A glass of wine on an empty stomach in a susceptible individual may have the same effect. As up to one-third of aircrew may experience incapacitation at some time in their career, in 60 per cent of cases due to gastroenteritis, the likelihood of such an event in a susceptible individual is significant.

Sufficient investigation of suspected vasovagal syncope is needed to exclude other causes and establish the diagnosis. An exercise and 24-hour (Holter) ECG and echocardiography, should be undertaken and be within acceptable limits. An electroencephalogram (EEG) and brain CT/MRI scan are not indicated, unless there is doubt as to the cause. The head-up tilt test, in which the subject is raised from the supine position to an angle of 60-70 degrees for 45 minutes, is the procedure of choice if tilt table testing information is thought necessary to improve the certificatory decision. In the most severely affected individuals, the test is almost 100 per cent sensitive; in others, it is about 70 per cent sensitive with provocation with nitroglycerine. The false-positive rate is about 13 per cent, rising to 20 per cent with nitroglycerine. The reproducibility of the test is in the range of 70 to 80 per cent, but a negative test cannot be taken as an assumption that the diagnosis is incorrect or that the condition has improved.

The treatment of vasovagal syncope is unsatisfactory due partly to its sporadic appearance, often with long intervals between attacks. Drug therapy e.g. with beta-blocking agents, has to be taken continuously, and the results are disappointing. Few convincing trials have been carried out. Endocardial pacemaking is helpful in a few cases. Subjects with the syndrome have a normal life expectancy unless syncope causes some accident, such as falling under a vehicle, or occurs while driving a vehicle or flying as single pilot in a light aircraft. This has been recorded by at least one Contracting State. Intervention is for symptoms alone, as it has no effect on prognosis.

The certification of subjects with vasovagal syncope in the aviation environment is problematic, as it is a potential cause of sudden, incomplete or total incapacitation, yet no underlying physical pathology will be demonstrated. Whereas a single syncopal episode, when the diagnosis is secure, need not preclude certification, a history of repeated or clustered attacks will normally lead to loss of medical fitness. This is based on the unpredictability of the episodes, their tendency to cluster, their variable symptomatology and the risk of incapacitation for an uncertain length of time. However, some individuals suffer periods of apparent vulnerability to such episodes but followed by long periods of freedom from attacks. This may

allow certain individuals to eventually regain their Medical Assessment, normally with an enduring restriction to multi-crew operations.

The aviation environment is one that is marked by fatigue due to disrupted sleep, circadian stress, and at times high temperatures and humidity in places that are visited. There is also a significant risk of gastroenteritis which may provoke an episode in a vulnerable individual.

*Malignant and recurrent vaso-vagal syncope should disbar from all classes of medical certification. Following a single episode of unexplained syncope, a full cardiological examination is required; a neurological examination is necessary only if the diagnosis is subsequently unclear. Loss of consciousness due to structural abnormality of the heart, or significant arrhythmia, will disbar. When vasovagal syncope is the diagnosis, recurrence within 12 - 24 months is likely to result in a long term unfit decision. However, due to the tendency of episodes to cluster, recertification may be possible after a significant interval of freedom from attacks (arbitrarily two years) during which the pilot should remain on the ground.*

*Restricted certification after a single episode may be permitted after an interval, arbitrarily of three to six months with full certification no sooner than five years after the attack, provided there has been no recurrence. Aircrew in whom the diagnosis has been made need to be counselled about the condition and told when attacks are likely to occur and how to manage them should they do so.*

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## APPENDIX 1A.— BASIC ELECTROCARDIOGRAPHY

Resting electrocardiography forms part of the clinical examination for the medical assessment. Its frequency is dictated by age and class of medical assessment applied for. The requirements are specified in ICAO 6.3.2.6, 6.4.2.6 and 6.5.2.6 with sub-paragraphs for commercial pilots, private pilots and air traffic controllers respectively.

The technique for recording the 12-lead resting electrocardiogram is given on page 7. Standard amplification gives a deflection of 1mV/cm, and the standard paper speed is 25 mm/s. Faster paper speeds are sometimes employed for more detailed scrutiny of the PQRS-complex and different amplifications may be employed in the case of lower (or higher) voltages being encountered. As the great majority of electrocardiographs are now AC-coupled, recording the decay time constant is now rarely required.

Recordings made on apparatus in which A/D conversion<sup>1</sup> is sub-optimum, or if filtering and/or damping is inappropriate, may demonstrate artefacts. These often involve the important ST-segment and T-wave. The standard presentation of a resting electrocardiogram is upon A4 graph paper; the faint lines on both axes measure 1 mm. On the x-axis this represents 40 ms at the standard paper speed of 25 mm/s. The heavy lines are 5 mm apart and represent 200 ms on the x-axis at the standard paper speed. On the y-axis 10 mm is standardised as reflecting 1 mV (see above).

### Lead systems

The leads are divided into the limb leads — S1, S2, and S3 (also named leads I, II and III); the augmented vector leads — aVR, aVL, aVF; and the chest leads. The first six leads are known as the hexaxial leads and are used to define the PQRS and T-wave angles in the frontal plane — the “mean manifest frontal QRS-axis”.

### Basic definitions and limits

#### Heart rate (without definition of rhythm).

60 to 100 bpm<sup>2</sup> – normal limits.  
50 to 60 bpm – bradycardia  
<50 bpm – significant bradycardia  
>100 bpm – tachycardia

#### The PR interval: 120 to 210 ms.

**Longer PR intervals (up to 280 ms)** are not infrequently encountered and, provided the QRS-complexes are of normal width, likely to be unimportant. Shortening with exercise to the normal range is to be expected without decrement in AV conduction. Shorter PR-intervals (<120 ms) need to be examined for the presence or absence of early depolarisation – pre-excitation. In the absence of this, they are likely to reflect a normal variant unless particularly short (< 100 ms) or unless there is a history of atrioventricular nodo reentrant tachycardia (the Lown-Ganong-Levine syndrome) or atrioventricular reciprocating(reentrant) tachycardia (the Wolff-Parkinson-White syndrome).

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<sup>1</sup> A/D conversion: conversion from analog to digital signals for transmission and further computer storage/processing.

<sup>2</sup> bpm: beats per minute

### **The QRS duration: 70 to 90 ms.**

**The QRS width** may be non-specifically prolonged (>100 ms) but is not absolutely prolonged until 120 ms, often by the presence of right or left bundle branch aberration and sometimes by ventricular hypertrophy or dilatation.

### **The QTc: 340 to 440 ms - up to 460 ms in the female**

**The QT-interval and the QTc.** The QTc is used to adjust QT-interval for heart rate. It is calculated by using Bazett's formula (see page 31) As the T-wave may fuse with the U-wave, precise description of the QT-interval may be difficult or impossible and such measurements need to be treated with caution.

**The ST-segment** is fused with the T-wave and commences at the J-point where it takes off from the return deflection of the S-wave. Depression of the ST-segment, particularly on exercise, may be attributable to myocardial ischaemia. However, the exercise walking time and the pattern of evolution of ST-segment displacement in exercise and recovery is more important than a numerical measurement of ST-segment displacement.

**The T-waves** are in the same direction as the dominant deflection of the QRS in the hexaxial leads (i.e. normally within 30° of the mean frontal QRS-axis). They should be asymmetric with a slow upstroke and relatively sharper down stroke. They are normally upright in the hexaxial leads and the left chest leads. They may be inverted in V1 as a normal variant, and sometimes in V2. Loss of amplitude is a non-specific observation. Inversion is potentially important but may be a normal variant in young individuals in whom "normalisation" with exercise is the rule.

### **U-waves**

U-waves follow the T-wave, are generally of lower amplitude, and should always be in the same direction of the T-wave. U-wave inversion is commonly abnormal and may represent systolic overload in the left ventricle, or myocardial ischaemia.

### **Epsilon waves**

Epsilon waves are seen on the ST segments of leads V1 and V2 as small "crinkles". They are best seen in Fontaine leads (SI, SII, SIII in the parasternal position). They are not diagnostic of ARVC and may be seen in right ventricular hypertrophy and sarcoidosis. They probably represent late potentials in the right ventricle.

### **Delta Waves**

Delta waves are seen in at the onset of the QRS complex in the WPW pattern. There is preexcitation of the ventricle which has the effect of shortening the PR interval whilst the QT interval remains normal. They may be positive or negative, their polarity depending on the lead and also the delta vector which reflects the position of the accessory pathway.

### **Osborn Waves**

Osborn Waves are seen at the junction of the S wave and the ST segment. They are seen as early repolarisation phenomena in healthy young adults (commonly males) but also are seen, inter alia, in hypothermia and subarachnoid haemorrhage.

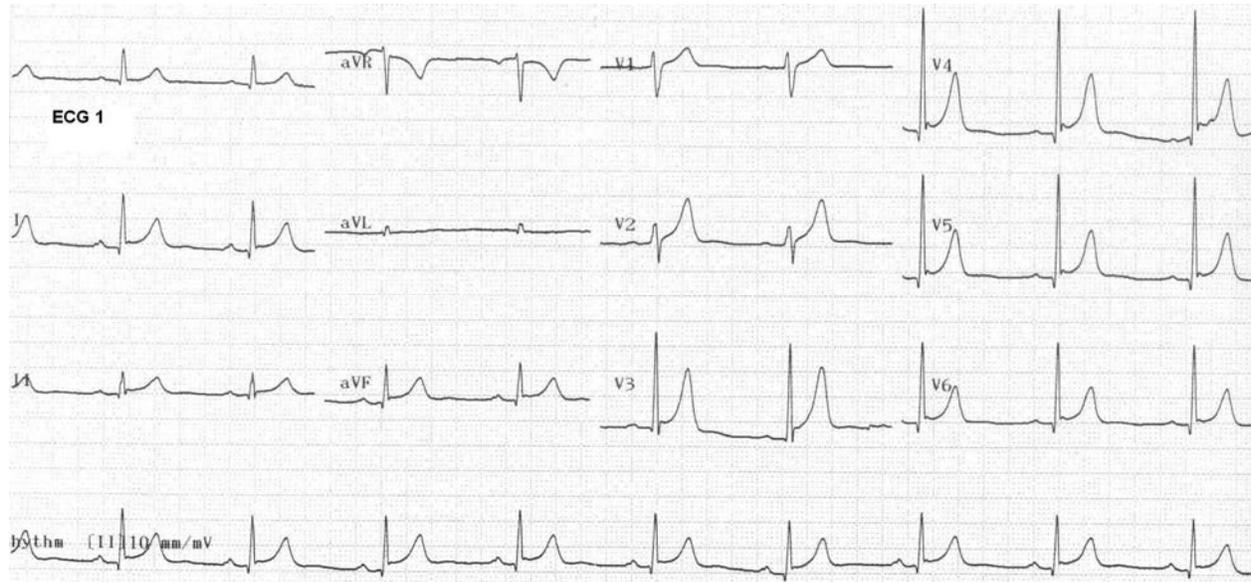
### **The mean frontal QRS axis**

The QRS-axis of the heart is normally  $0^{\circ}$  to  $+90^{\circ}$ . Right axis deviation is present when the axis is  $>90^{\circ}$ . Leftward axis deviation is present between  $0^{\circ}$  and  $-30^{\circ}$ , and left axis deviation is present when the axis is  $> -30^{\circ}$ .

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## APPENDIX 1B.— ILLUSTRATIVE RESTING ELECTROCARDIOGRAMS

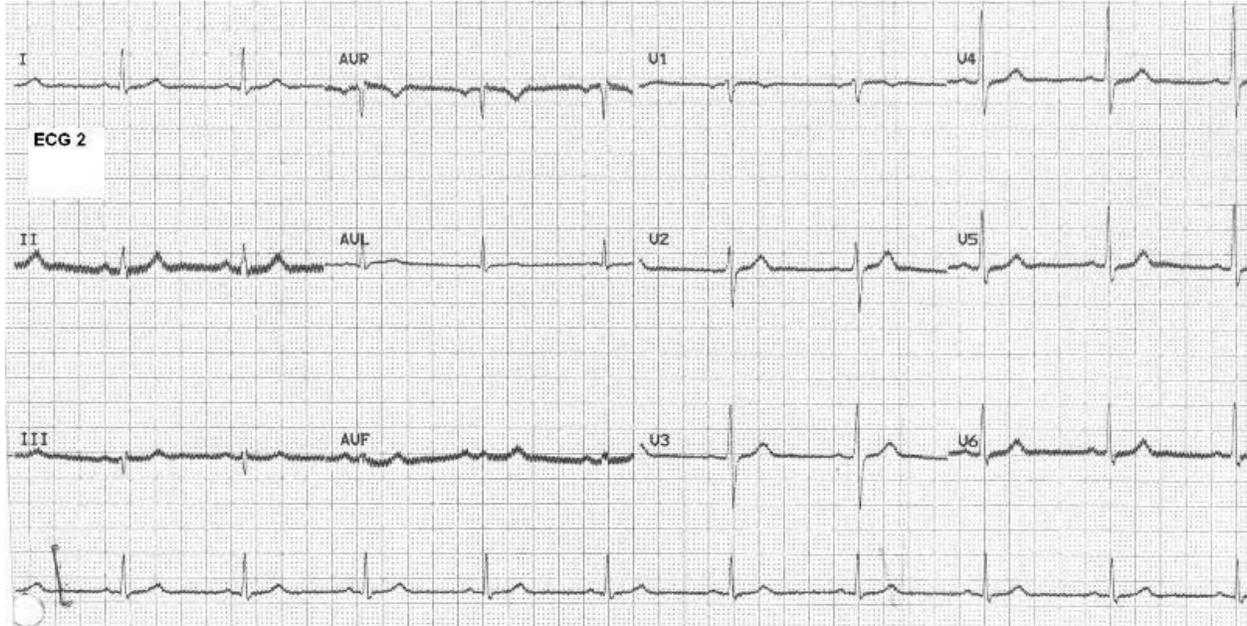
The following cases include a representative, but by no means complete, record of some commonly encountered electrocardiographic patterns. They are illustrative only.



1. 28-year-old pilot, applying for class I medical assessment. The mean frontal QRS-axis is  $+60^\circ$ . There is a sinus bradycardia. The pilot is very slim and large voltages in the chest leads are normal in a slim individual - the horizontal plane voltages obey the inverse square law. Osborn-waves<sup>1</sup> at the point of take-off of the ST-segment are present in V4, V5, and V6. This is so-called “early re-polarisation” and is a normal variant in this case.

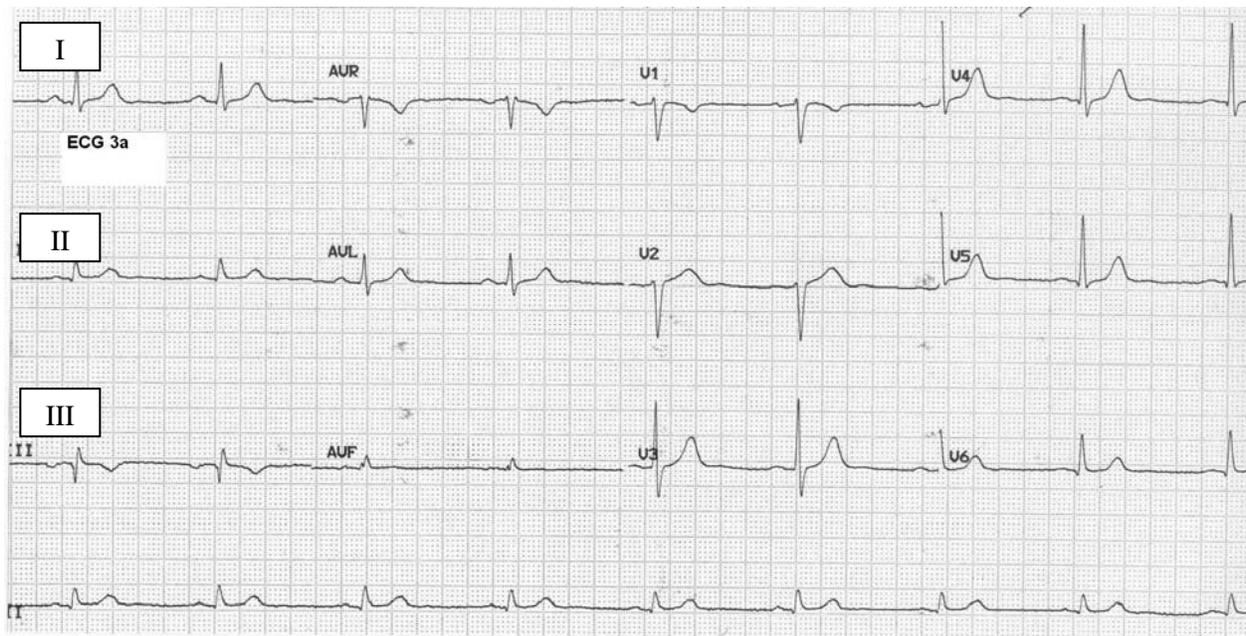
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<sup>1</sup> Osborn-waves: positive deflections occurring at the junction between the QRS complex and the ST-segment; also known as J-waves. After J.J. Osborn, American physiologist (20<sup>th</sup> century).

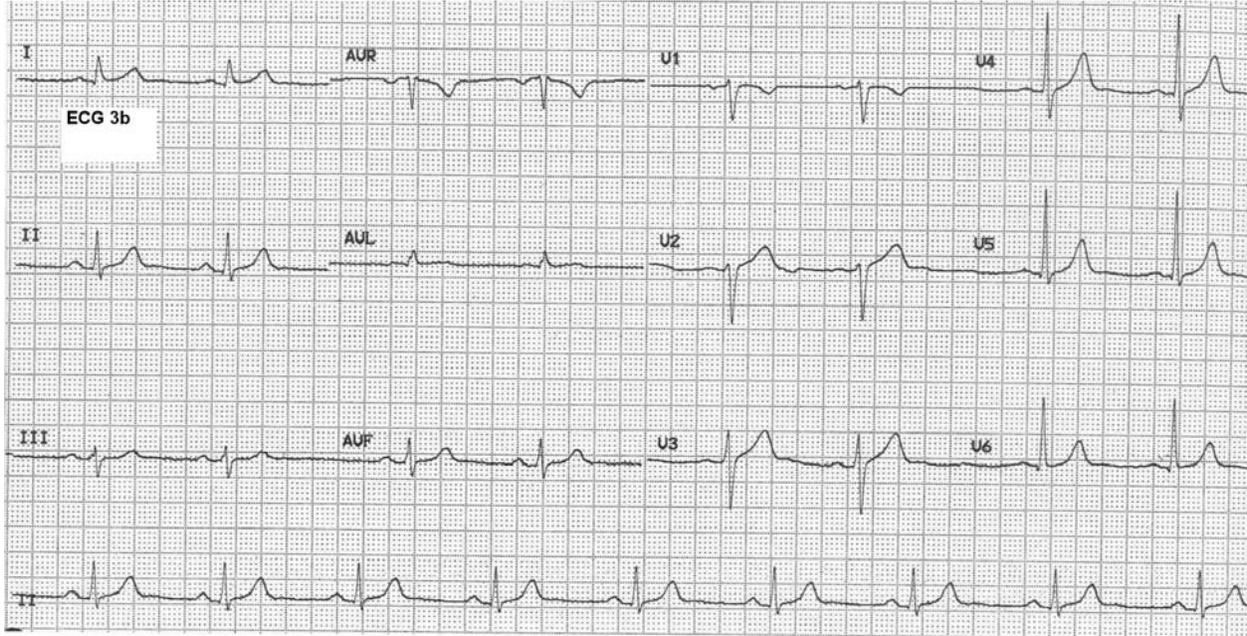


2. 48-year-old air traffic controller with a heart rate of 72 bpm; the recording is normal. The significant AC interference in the hexaxial leads underscores the difficulty in making accurate measurements from poor quality recordings. Good technique is therefore vital.

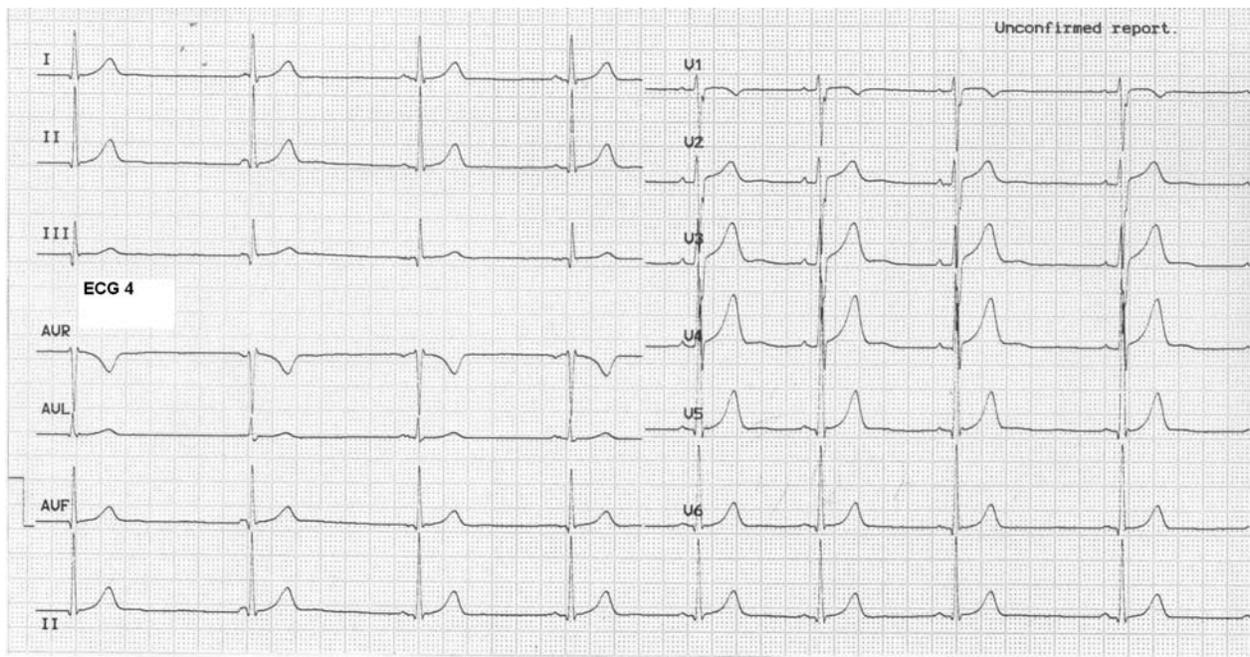
There are no septal q waves in SI, aVL and V6: incomplete bundle branch block may be present. As an isolated observation in an otherwise normal subject, this is likely to be innocent. It is also seen in dilated, inter alia, in cardiomyopathy. Exercise ECG, even in the otherwise normal subject may demonstrate repolarisation abnormality which will justify further investigation with echocardiography /thallium MPI in cases of doubt.



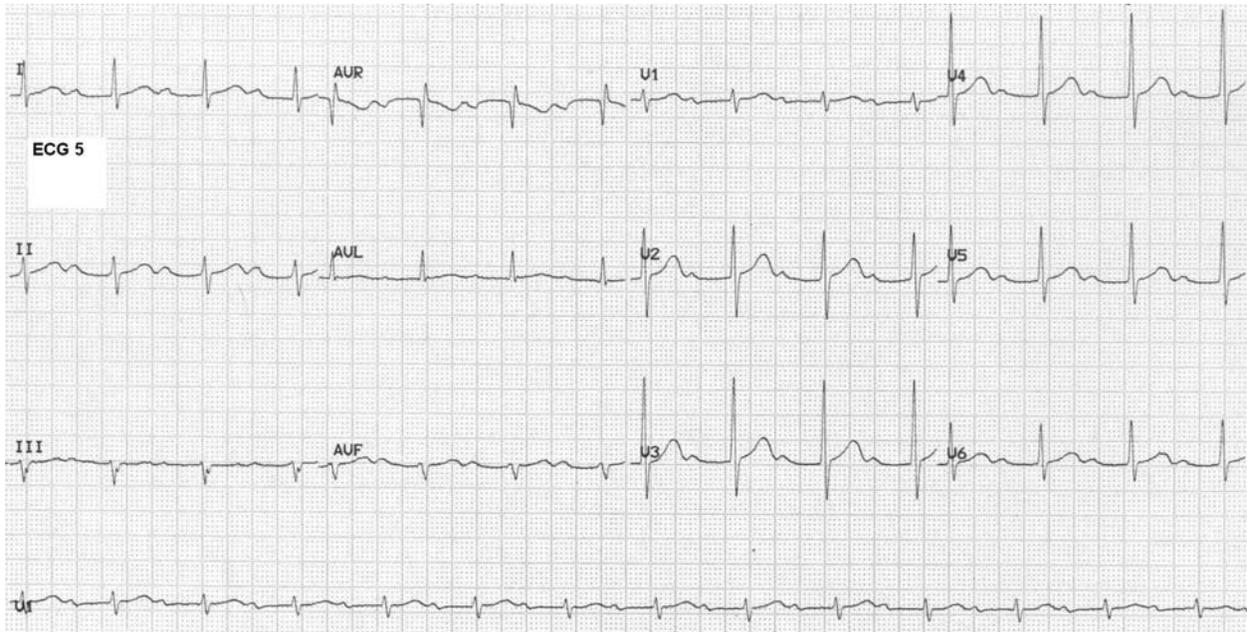
- 3a. 44-year-old private pilot with a heart rate of 52 bpm. Superficially, the recording resembles an inferior myocardial infarction with a Q-wave in SIII and T-wave inversion (although the T-wave is asymmetrically inverted). This is a left arm/left leg lead transposition.



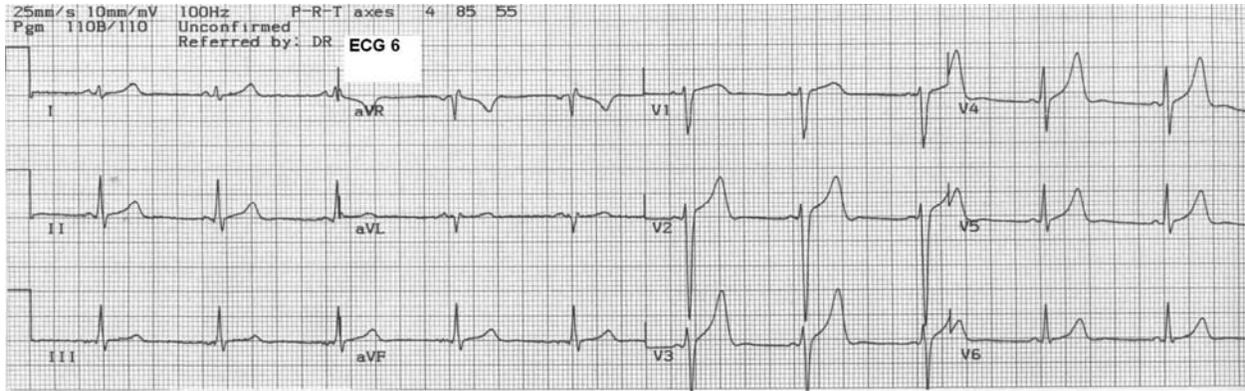
- 3b. Here the leads are in the correct position and the recording is normal. Good technique is therefore vital.



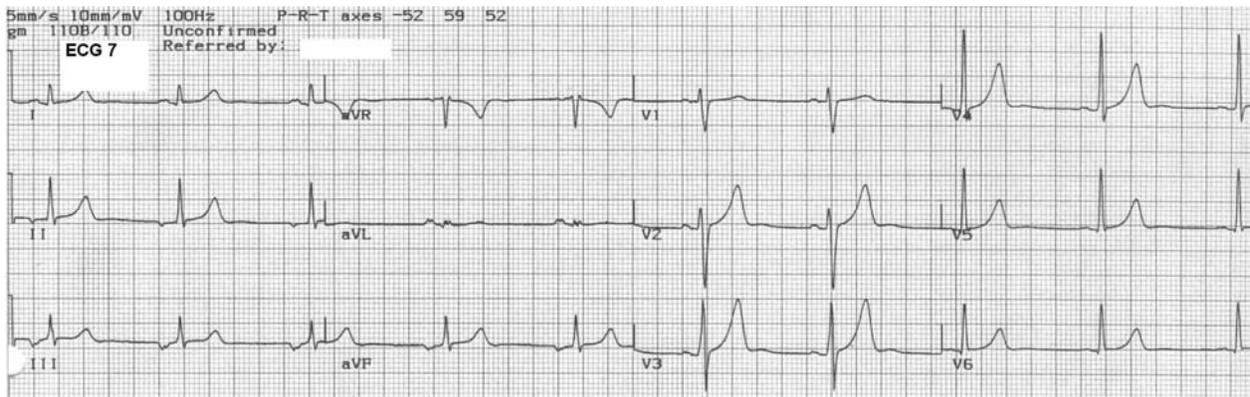
4. 24-year-old CPL-holder with marked sinus arrhythmia and atrioventricular dissociation of the first three complexes. There is junctional escape. This is not uncommon in fit young men particularly at night. The pilot was asymptomatic and if an exercise recording had been performed, it would have been normal. He was assessed as fully fit.



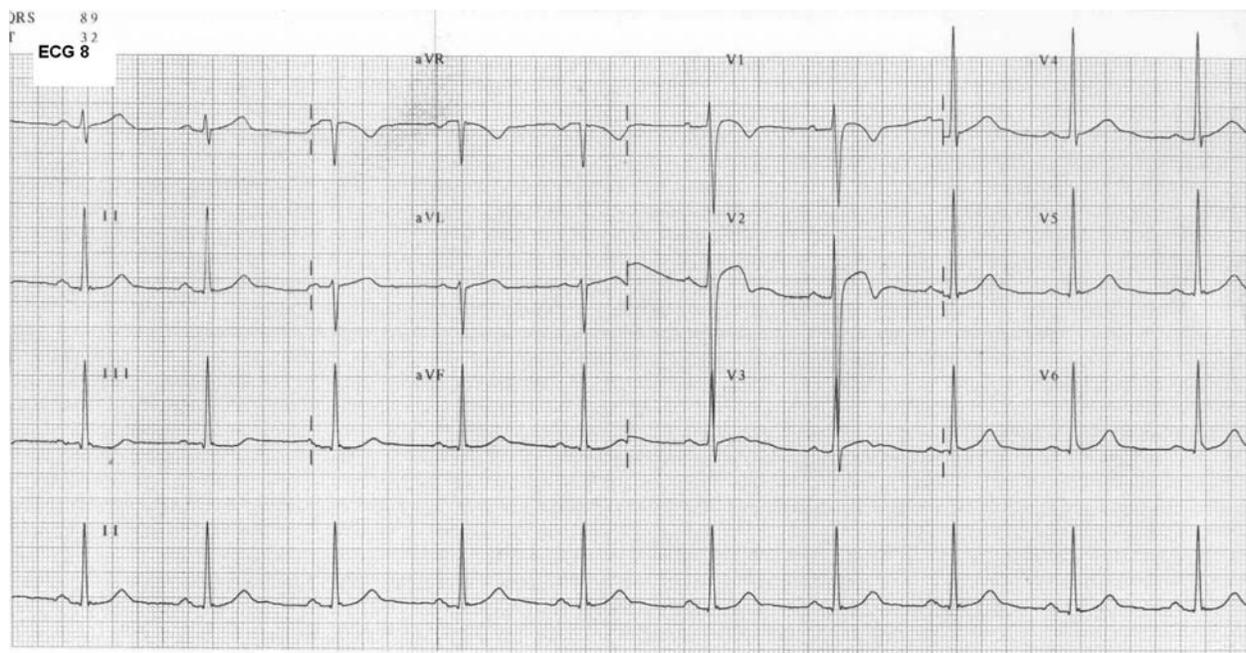
- 34-year-old airline pilot who demonstrates a normal resting electrocardiogram apart from a very long PR-interval – 360 ms. The narrow width of the QRS segment suggests that the block is at the level of the AV node. The situation is most often benign in young subjects, and fitness can be granted without restriction provided the QRS segment is of normal width (<90 ms) and the PR-interval shortens with exercise to <180 ms. There should be no evidence of decremental conduction.



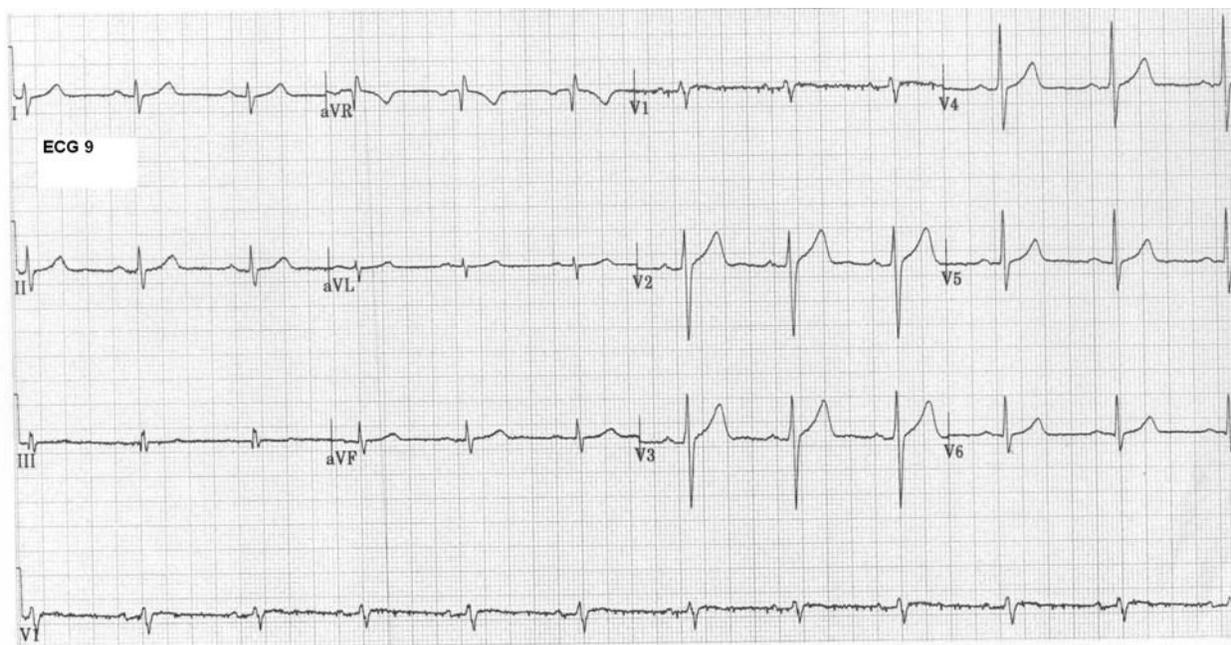
6. 34-year-old ATPL-holder who demonstrates a heart rate of 62 bpm. The heart is vertically disposed as evidenced by small voltages in S1 and prominent voltages in the inferior leads SII, SIII and aVF. The T-waves are tall but asymmetric. The PR-interval is at the lower limit of normal – 116 ms. Provided the applicant is asymptomatic and there is no history suggestive of nodal reciprocating tachycardia; this is a normal variant.



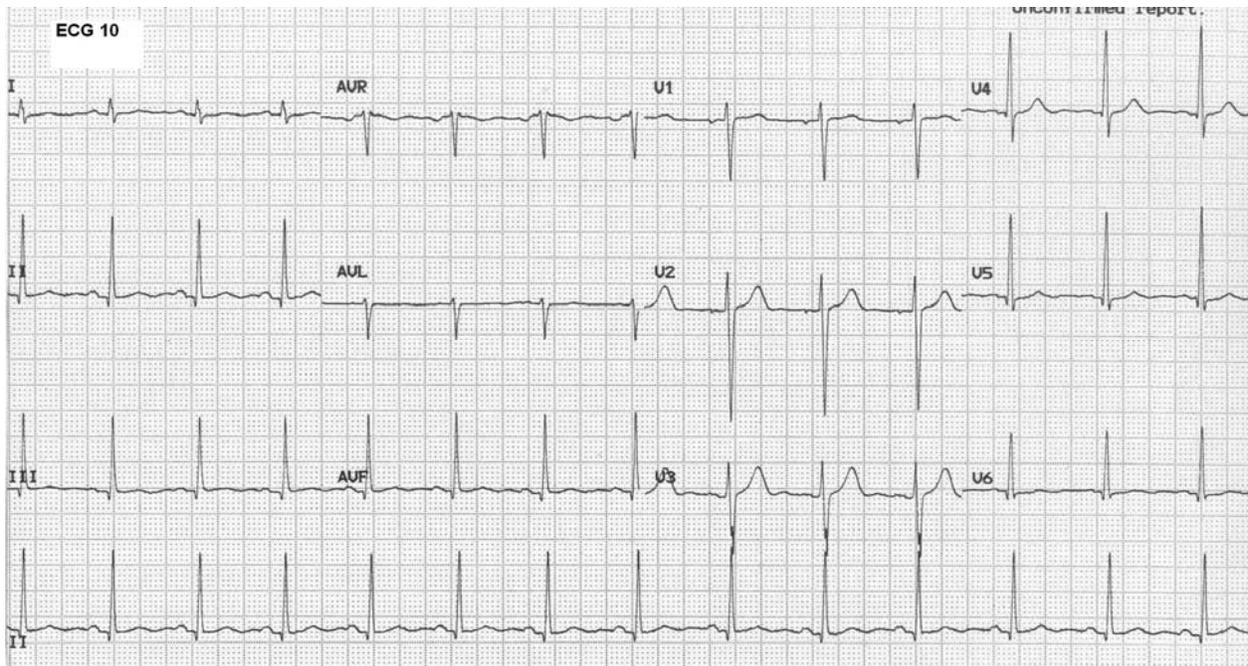
7. 40-year-old, asymptomatic PPL-holder with low right atrial rhythm. This is sometimes called coronary sinus rhythm. The PR-interval is normal but the P-waves are inverted in SII, SIII and aVF. It is a commonly a normal variant and should not interfere with certification in the absence of other abnormality.



8. 31-year-old airline pilot who was in the habit of running 50 miles a week. There is rightward axis deviation. The voltages are prominent and the T-waves inverted/notched V1 – V3. Thallium scanning was negative. This variant is sometimes seen in the “athlete’s heart”. T wave inversion is not abnormal in V1 and if present should diminish progressively, sometimes as notching, in V2 and V3. T wave inversion in V3 should be regarded as abnormal and is seen in right ventricular abnormality, and in anterior ischaemia.



9. 38-year-old asymptomatic CPL-holder who demonstrates the S1, 2, 3 syndrome in which all the deflections in the hexaxial leads look very similar. S-waves are also seen in V5 and V6. This is a normal variant. In an older age group, if a new change, the possibility of anteroseptal injury needed to be considered and excluded.

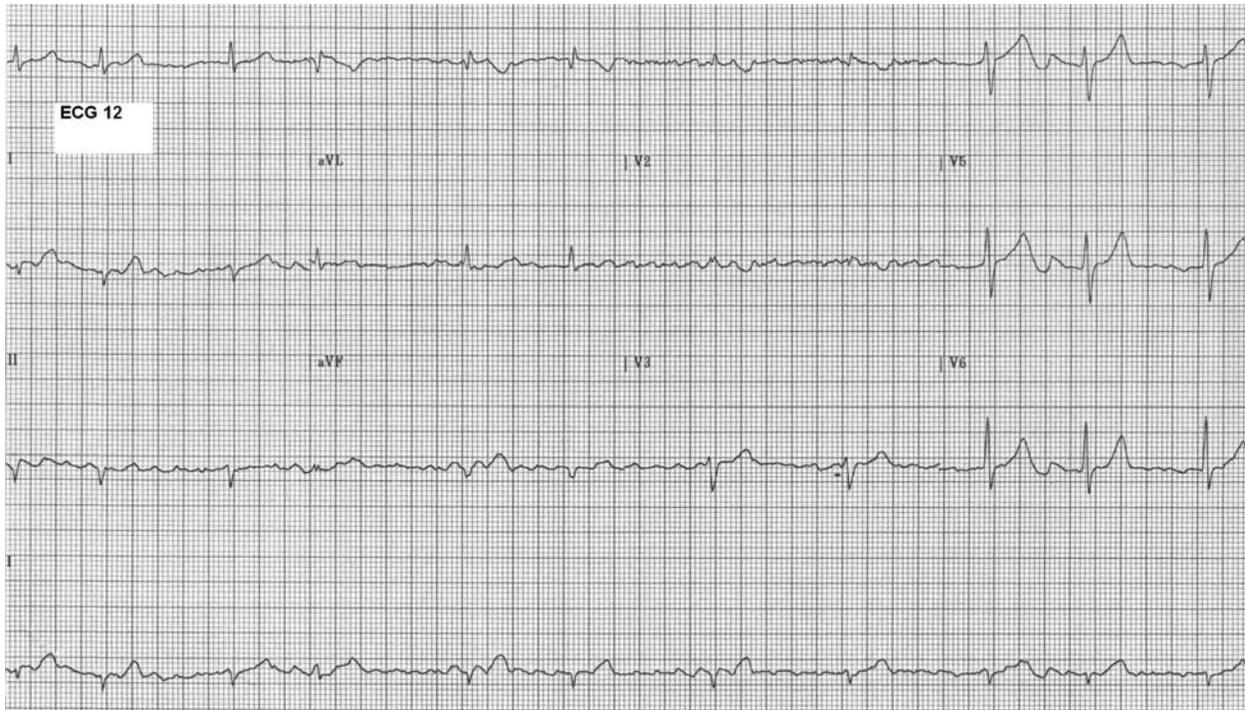


10. 21-year-old Class I applicant who demonstrates sinus rhythm at a heart rate of 84 bpm. There is loss of amplitude of the T-waves in the inferior and left chest leads. This is a normal variant in a young person, and a normal response to exercise is to be expected. There is a point of comment with regard to the U waves which are inverted in V5 and V6. No cause was evident but this finding is often a surrogate for pathological T wave inversion in an older subject.



11. 47-year-old asymptomatic ATPL-holder who demonstrates frequent junctional premature complexes, conducted with minor aberration (incomplete right bundle branch block) due to prematurity. At slow heart rates the right bundle has a slightly longer ERF<sup>1</sup> than the left bundle and with prematurity, delay in the former may be expected. Atrial prematurity can be premonitory of atrial fibrillation and a history of excess alcohol intake is not uncommon. It was absent in this case, and together with normal echocardiogram and normal exercise electrocardiogram, a fit assessment with annual follow-up was given. The downsloping ST segment in SIII is anormal variant in this case as the QRST angle is not wide ( $+40^{\circ}$ )

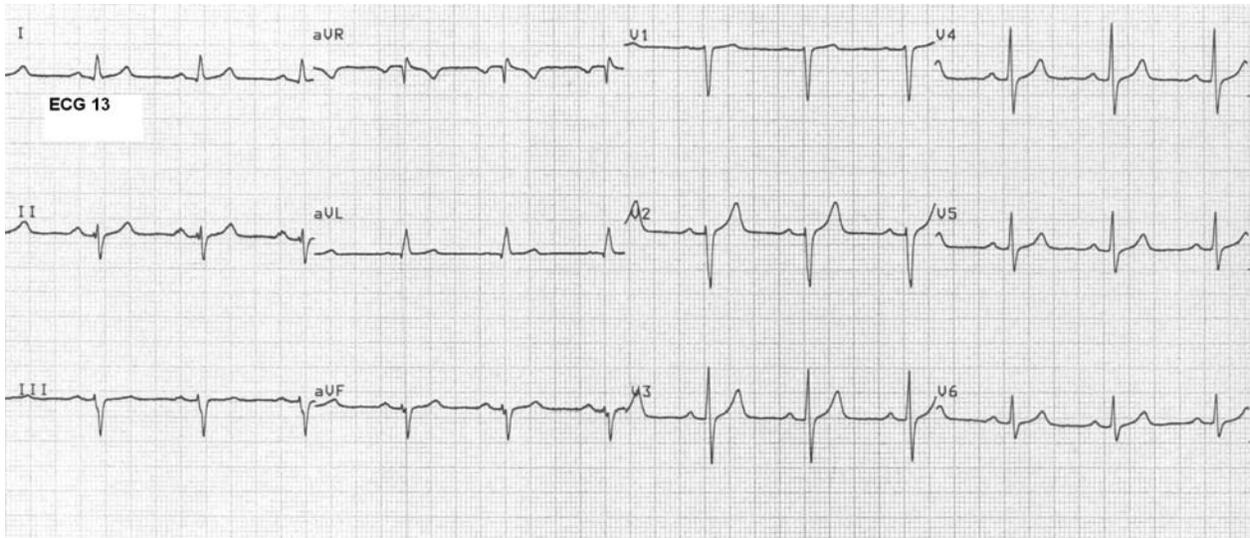
<sup>1</sup> ERF – Effective refractory period



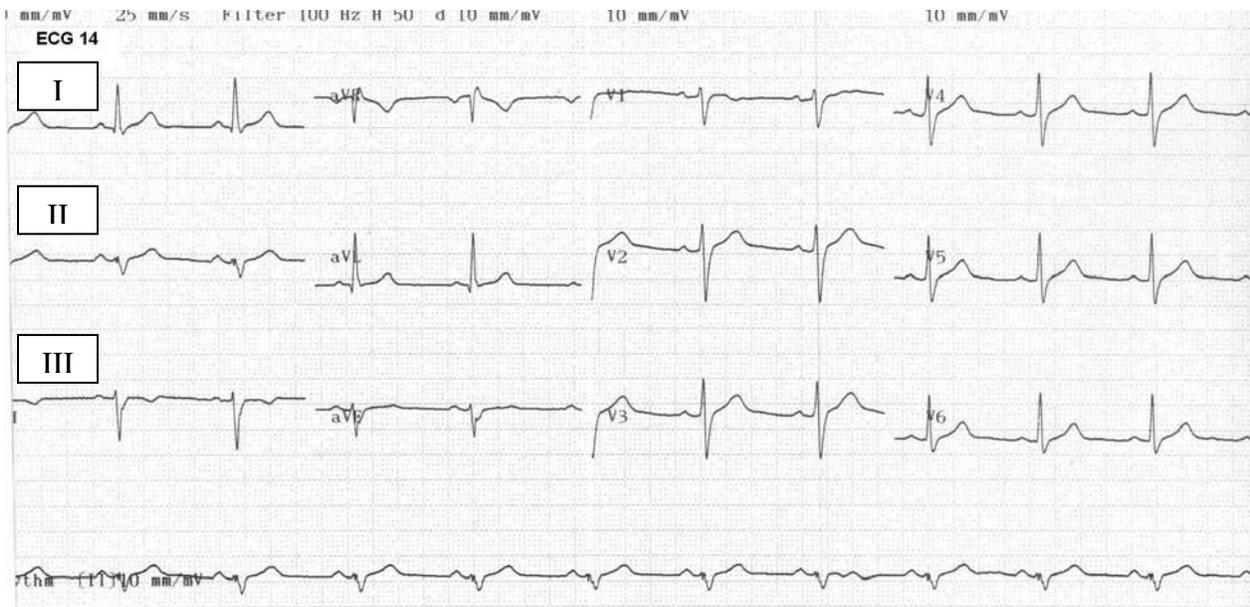
12. 56-year-old ATPL-holder who is in atrial fibrillation. The voltages are low. The dominant negativity of the inferior leads reflects a probable co-existent left anterior fascicular block (hemiblock), although an inferior myocardial infarction needs to be excluded. Although always asymptomatic, this pilot initially developed paroxysmal atrial fibrillation which became persistent and then permanent<sup>1</sup>. His echocardiogram and exercise recording were always normal. Provided the pilot is asymptomatic and there is no indication for warfarin (i.e. there is no associated cardiac abnormality, hypertension, diabetes, history of TIA<sup>2</sup> or age >65 years), a fitness assessment with restriction to multicrew duties may be considered.

<sup>1</sup> *Paroxysmal*: recurrent, intermittent atrial fibrillation that previously terminated without specific therapy. Paroxysmal atrial fibrillation is self-limited. *Persistent*: recurrent, sustained atrial fibrillation that was previously terminated by therapeutic intervention. Persistent atrial fibrillation may be the first presentation, a culmination of recurrent episodes of paroxysmal atrial fibrillation or long-standing atrial fibrillation (greater than one year). Persistent atrial fibrillation is not self-limited, but may be converted to sinus rhythm by medical or electrical intervention. *Permanent*: Continuous atrial fibrillation which cannot be converted to normal sinus rhythm by pharmacologic or electrical conversion techniques.

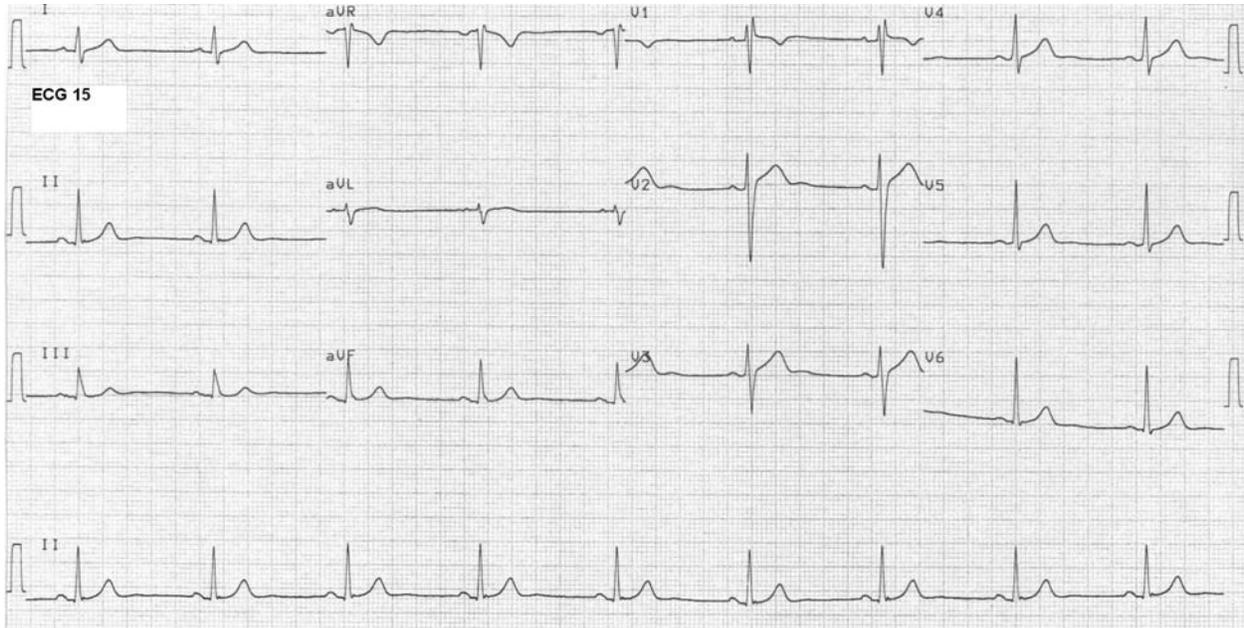
<sup>2</sup> TIA – transient ischaemic attack



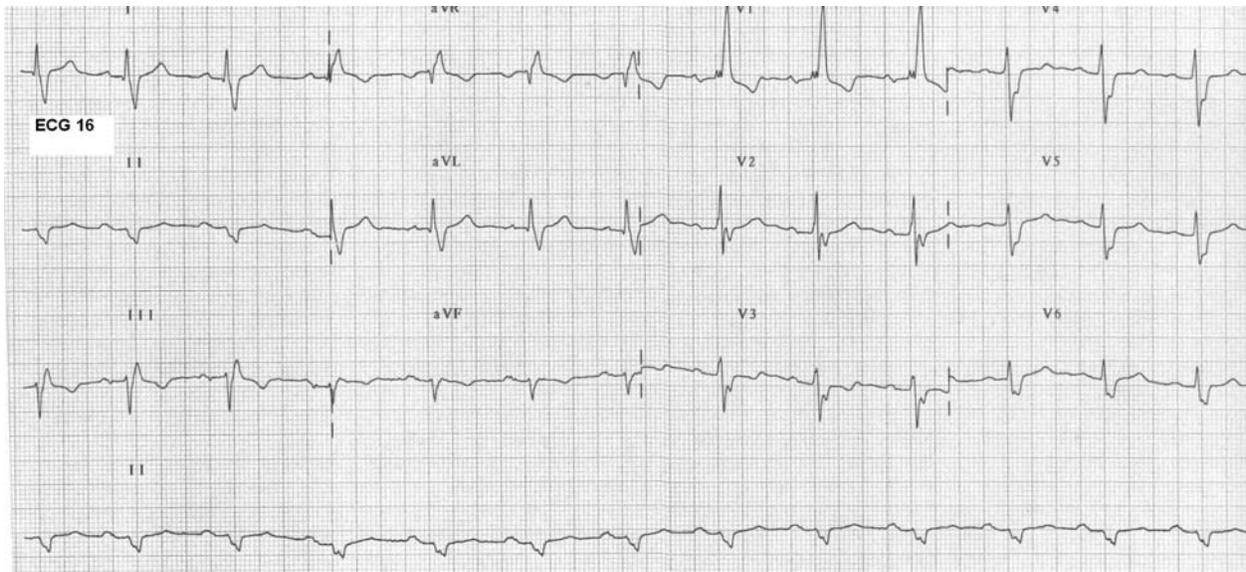
13. 64-year-old PPL-holder who demonstrates sinus rhythm with a heart rate of 74 bpm. The S-waves are dominant in SII, SIII and aVF, giving a mean frontal QRS-axis of  $-50^{\circ}$ . Clockwise rotation of the heart is present about its longitudinal axis with S-waves in V5 and V6. This pattern had developed over 20 years and reflects the gradual acquisition of left antero-superior fascicular block (hemiblock). It is generally a benign condition consistent with fitness to fly. If the change is abrupt, the possibility of anterior myocardial infarction needs to be considered. Follow-up is required for any evidence of progression consistent with progressive fibrosis of the conducting tissue. In this case exercise electrocardiography was normal, and a fit assessment was issued.



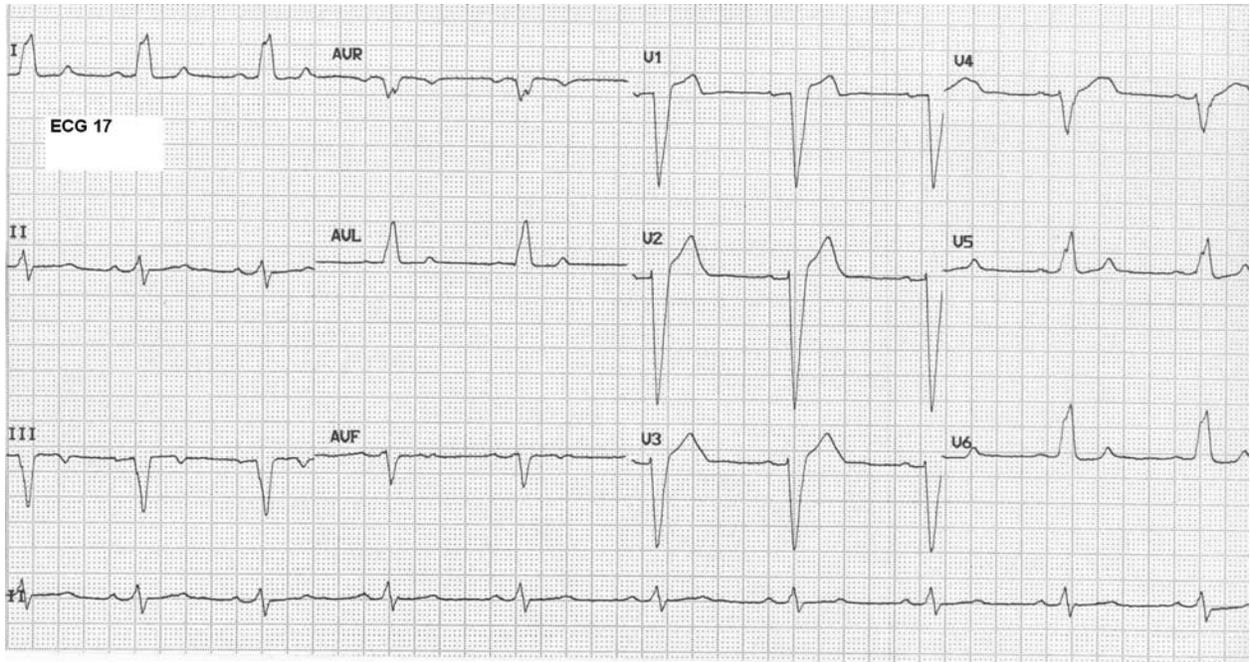
14. 49-year-old normotensive ATPL-holder who demonstrates sinus rhythm with a heart rate of 60 bpm. There is a non-specific increase in the QRS duration to 110 ms, although part of this is a contribution from right bundle branch delay, reflected as an S-wave in S1 and V6. There is an S-wave in S1, S2 and S3, but the S1,2,3 pattern is not present. The heart is clockwise rotated about its longitudinal axis. The pilot was exercised on account of apparent deepening of the S-wave in SII (consistent with left anterior hemi-block) but the recording was normal. He was made fit without restriction but with annual follow up to watch for the possibility of progressive evidence of conduction disturbance.



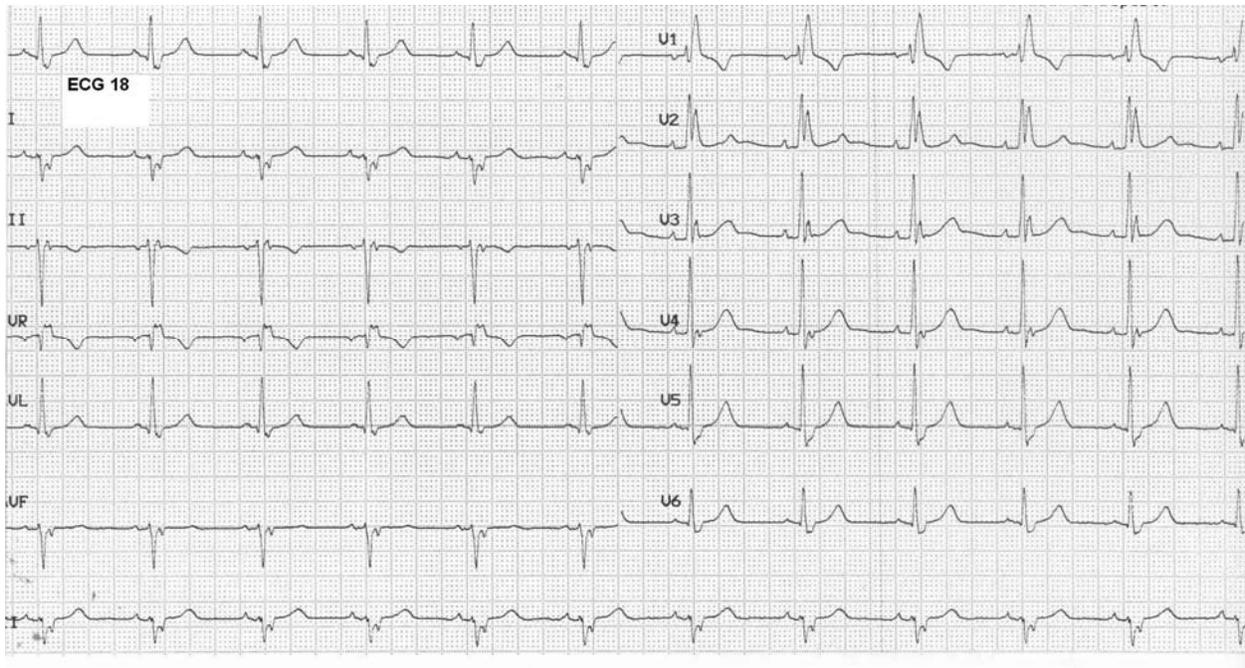
15. 28-year-old first officer who demonstrates a sinus bradycardia at a rate of 55 bpm. The recording is normal apart from the rSr' in V1. This reflects incomplete right bundle branch aberration. It is a common normal variant. If significant right axis deviation is present, the possibility of a secundum atrial septal defect should be considered and an echocardiogram carried out.



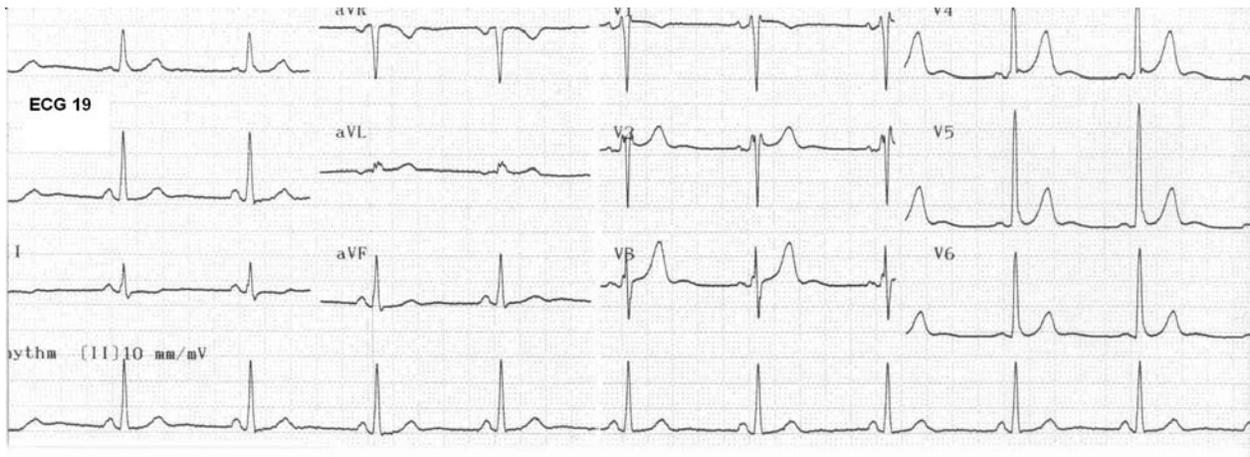
16. 57-year-old training captain who demonstrates complete right bundle branch aberration which had been present for 24 years. This is evidenced by the deep S-wave in SI and aVL together with V5 and V6. Furthermore there is an rsR complex in V1. The axis is indeterminate but the increasing depth of the S-waves in SII, SIII and aVF led to exercise electrocardiography which was negative at 11 minutes of the Bruce protocol. Likewise the echocardiogram and Holter monitoring were normal. The PR-interval was at the upper limit of normal at 202 ms. The blood pressure was borderline – 146/84 mm Hg. The medical assessment was restricted to multi-crew operations.



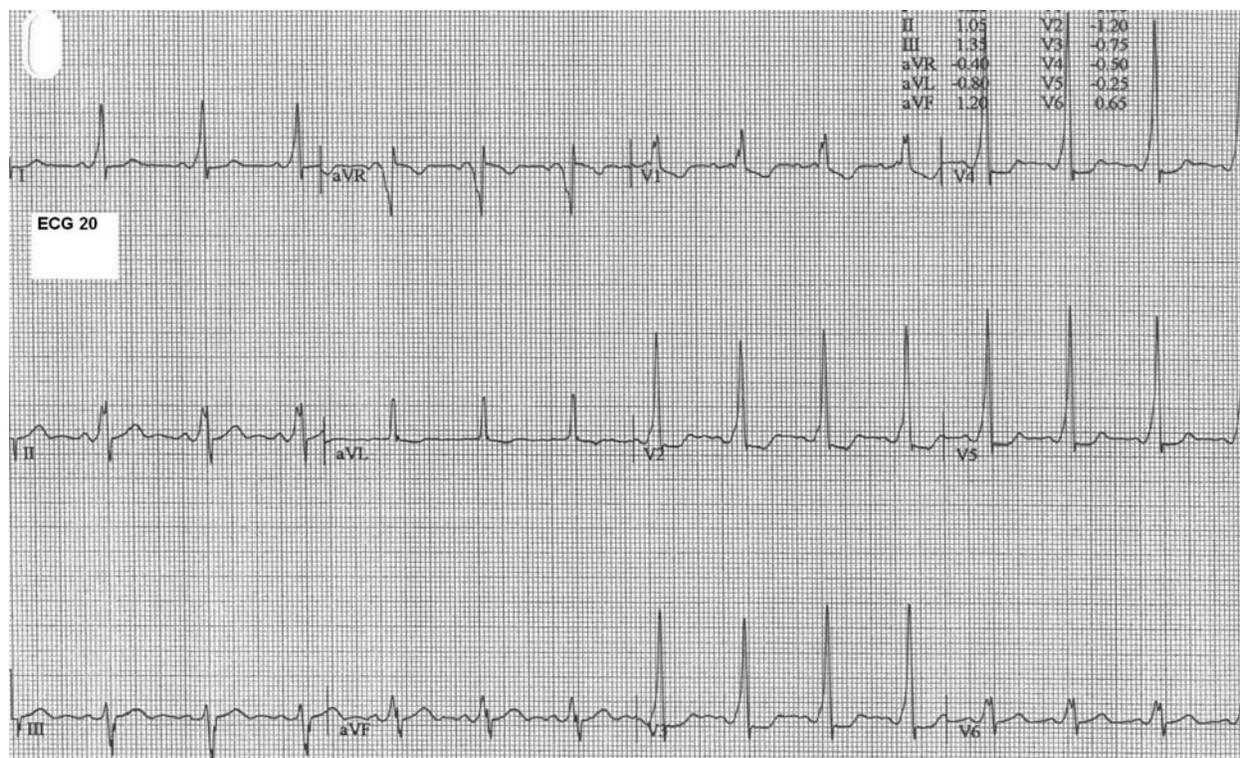
17. 48-year-old airline captain with complete left bundle branch aberration with a heart rate of 57 bpm. The condition had been stable for eleven years. The axis is left  $-30^{\circ}$ . This pattern is not completely characteristic as the T-waves would normally be expected to be asymmetrically inverted in SI, aVL and V5 and V6. The notch on the inscription of the R-wave is characteristic as is the absence of a septal Q-wave in SI, aVL, V5 and V6. The QRS duration is 140 ms. Poor R-wave progression in the chest leads is also a feature. He was investigated with exercise electrocardiography, thallium scanning, echocardiography, and Holter monitoring. All were reassuringly negative. After three years of follow-up, he was given an unrestricted medical assessment.



18. 43-year-old normotensive private pilot who is in sinus rhythm at a heart rate of 69 bpm. He has significant left axis deviation ( $-56^\circ$ ) giving rS deflections in SII, SIII and aVF. This reflects left anterior hemi-block. The broad S-wave in S1, V5 and V6 together with rsS deflection in V1 indicates that complete right bundle branch aberration is also present. The latter was longstanding but the former was acquired. Exercise electrocardiography was normal at 12 minutes whilst echocardiography and Holter monitoring revealed no abnormality. As an acquired pattern in an asymptomatic individual, it is likely to be caused by very slowly progressive fine fibrosis of the conducting tissue (Lenègre's disease). Coronary artery disease may be present and this possibility should be investigated. Regular cardiological review with exercise electrocardiography and Holter monitoring is required. A medical assessment with limitation to multi-crew operations is recommended.



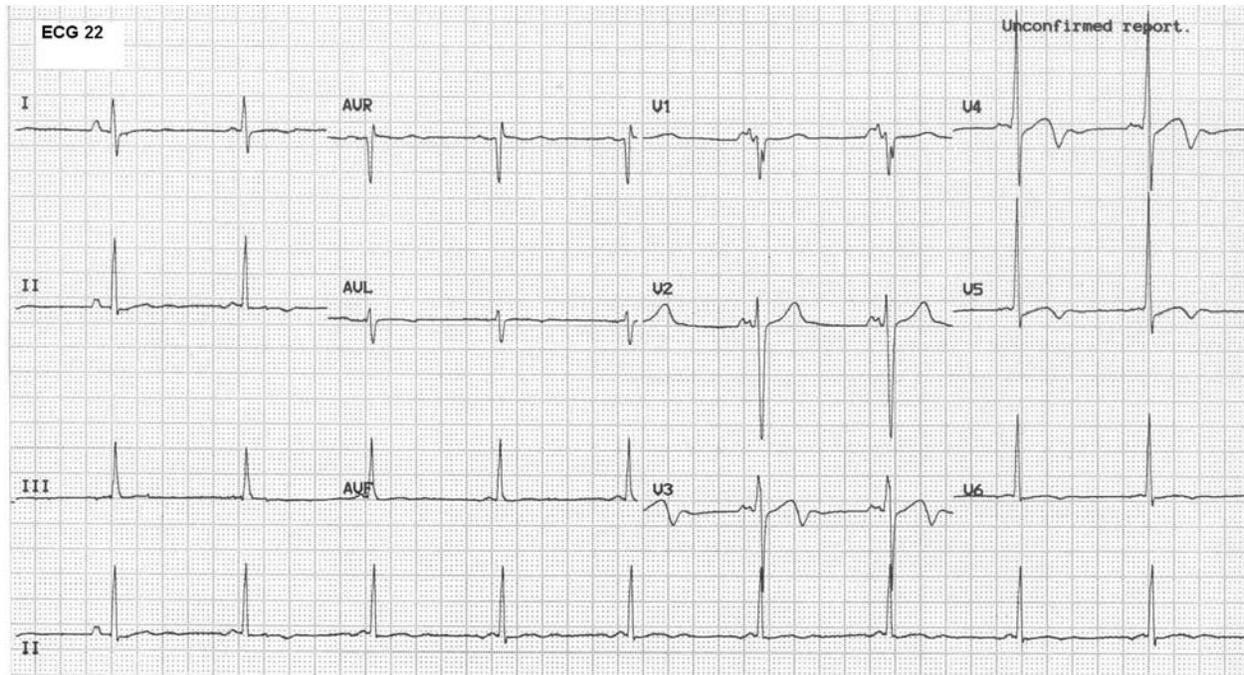
19. 49-year-old air traffic controller who demonstrates an rSr complex in V1 and V2 suggestive of incomplete right bundle branch delay although there is no matching S-wave in the left chest leads. In this situation, leads V1 and V2 may have been placed in the 2<sup>nd</sup> rather than the 4<sup>th</sup> intercostal spaces. High take-off of the ST-segment is seen in V4, the small notch on the S-wave reflecting an Osborn-wave. This is a normal variant. The PR interval is short – 114 ms and there is possibly a delta wave in V4 consistent with a minor degree of pre-excitation. Minor degrees of pre-excitation are sometimes mistaken for incomplete left bundle branch aberration, which this may be. He had always been asymptomatic and exercise electrocardiography was normal. He received an unrestricted medical assessment.



20. 48-year-old asymptomatic air traffic controller who had always demonstrated the Wolff-Parkinson-White (WPW) pattern. There are delta-waves on the upward inscription of the R waves in S1 aVL and V4 – V6. The delta vector is  $-30^\circ$  and the R-wave positive in V1. This implies a left anterior para-septal insertion of the accessory pathway. Initial issue of a medical assessment is not possible in the presence of a history of atrioventricular reentrant tachycardia. In the event of the demonstration of successful accessory pathway ablation, certification without restriction is possible. If the WPW pattern alone is present, certification is possible following an electrophysiological study demonstrating an antegrade effective refractory period of the pathway  $>300$  ms, an HV interval  $<70$ ms, a  $\Delta$ - $\Delta$  interval during atrial fibrillation  $>300$ ms, no evidence of multiple pathways, and no inducible AV re-entry tachycardia. Long-term asymptomatic individuals with this pattern may be granted unrestricted medical assessment.



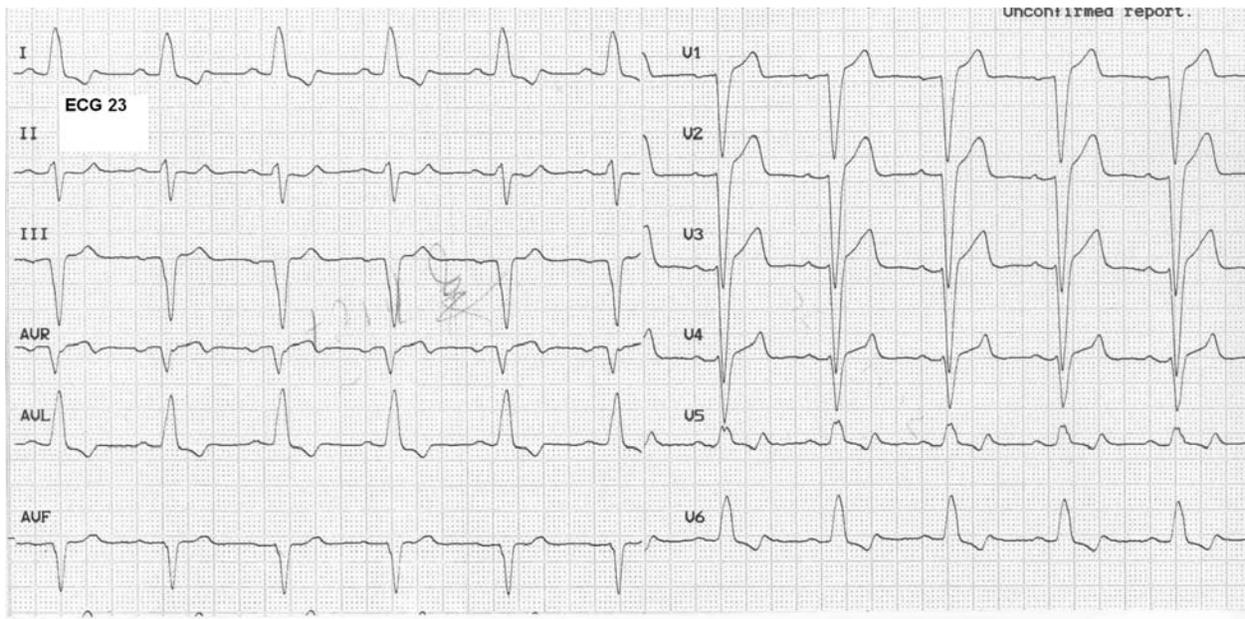
21. 49-year-old normotensive airline pilot who had demonstrated this pattern of diffuse ST-T-wave flattening/inversion for twenty-five years whilst flying on active service. Although he was normotensive, the inter-ventricular septum was increased at 2.1 cm. It is thus likely that he is expressing a gene for hypertrophic cardiomyopathy. The exercise electrocardiogram “normalised” at a high workload, and there was no evidence of electrical instability on Holter monitoring. Most cases of hypertrophic myopathy require a limitation to multi-crew operations but an inter-ventricular septum diameter  $>2.5$  cm, ventricular tachycardia on Holter monitoring, a family history of sudden cardiac death (SCD) and/or a fall in the blood pressure on exercise are all indicators of excess risk of incapacitation and must be considered incompatible with medical certification.



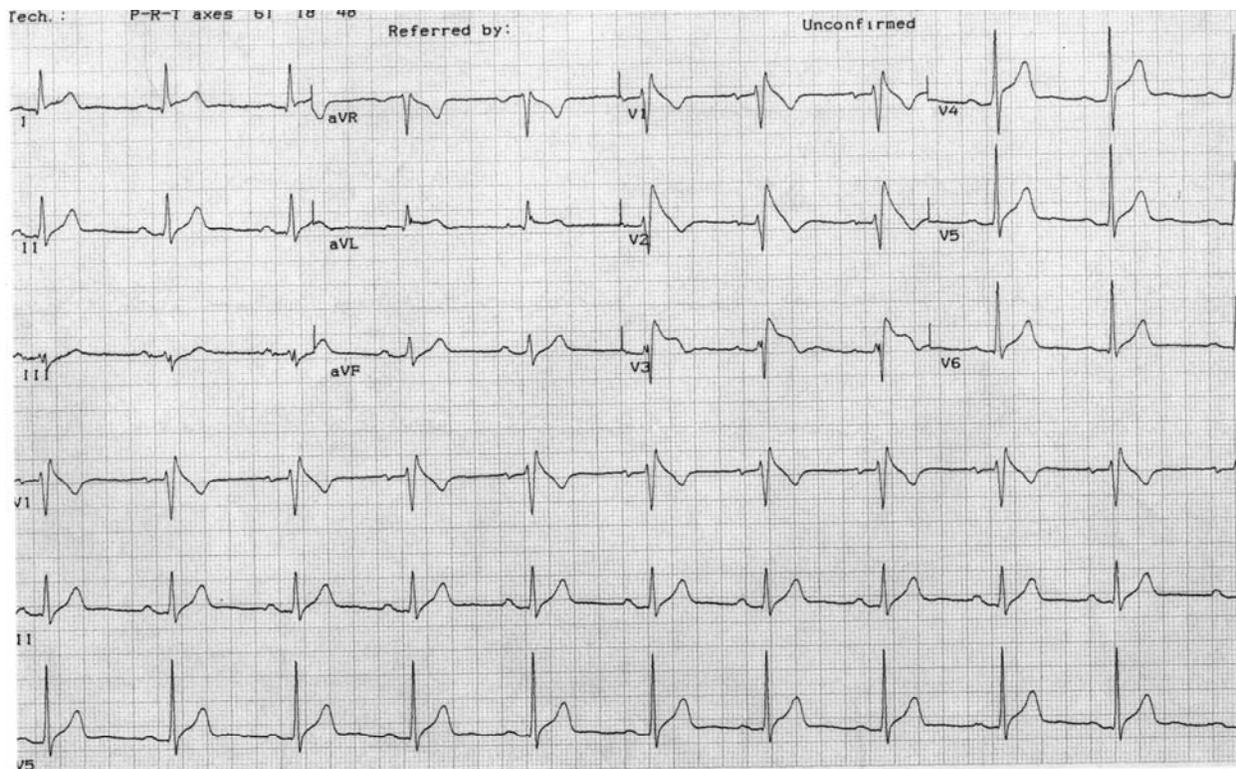
22. 50-year-old ATPL-holder with HCM<sup>1</sup>. A bradycardia, probably of left atrial origin, is present with a heart rate of 57 bpm. In the hexaxial leads the T-waves are flat but otherwise unremarkable. The “dome and dart” P-waves in V1 suggest a left atrial focus whilst the T-waves are biphasic in V3 and V4 with late notching in V5. The pilot’s exercise performance is excellent and no electrical instability is detected on repeated Holter monitoring. His medical assessment was restricted to multi-crew operations.

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<sup>1</sup> HCM (hypertrophic cardiomyopathy) is a condition with protean ECG manifestations and the condition should be borne in mind when confronted with a bizarre recording.



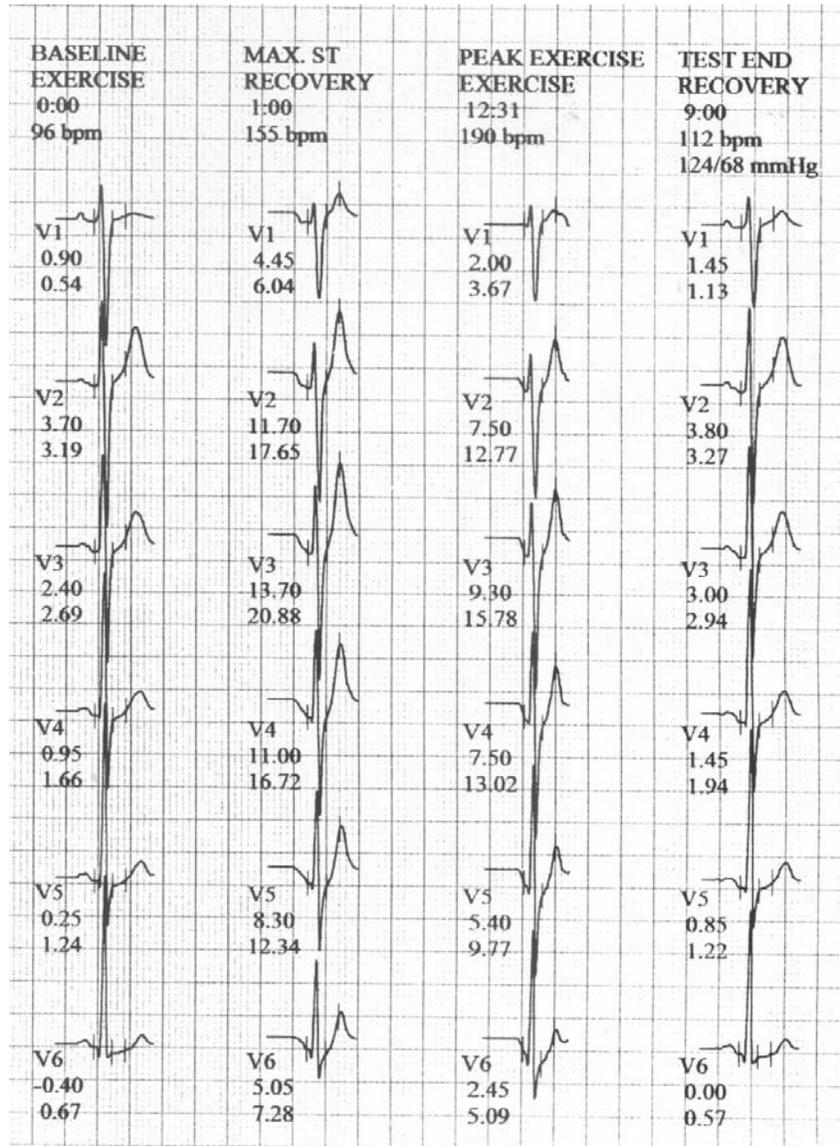
23. 0-year-old PPL-holder who demonstrates a heart rate of 73 bpm. Although the pacing spikes are not evident, a bipolar dual chamber pacemaker is present. The pacemaker had been inserted on account of first degree atrioventricular block with a PR-interval of 400 ms, left axis deviation ( $-60^{\circ}$ ) and QRS duration of 158 ms. Mobitz type I AV block was seen at night. Thallium MPI was negative. As the pilot was not technically pacemaker dependent, a Class 2 medical assessment was permitted.



24. 38-year-old applicant for a class I medical assessment who demonstrates the characteristic features of the Brugada pattern although he had always been asymptomatic. Specifically there is an incomplete right bundle branch aberration with drift of the ST-segment away from the r' rather than a firm downward inscription. This is an example of an ion channelopathy, the sodium encoding gene SCN5a being involved. An initial applicant should be refused medical certification but new presentation in an existing licence-holder should be reviewed in the light of family history and past history of any event consistent with syncope. Holter monitoring should search for possible ventricular tachycardia (*torsade de pointes*). If these findings were present, medical assessment should be denied. Minor variants overlapping with normal ones are common and specialist input is needed.

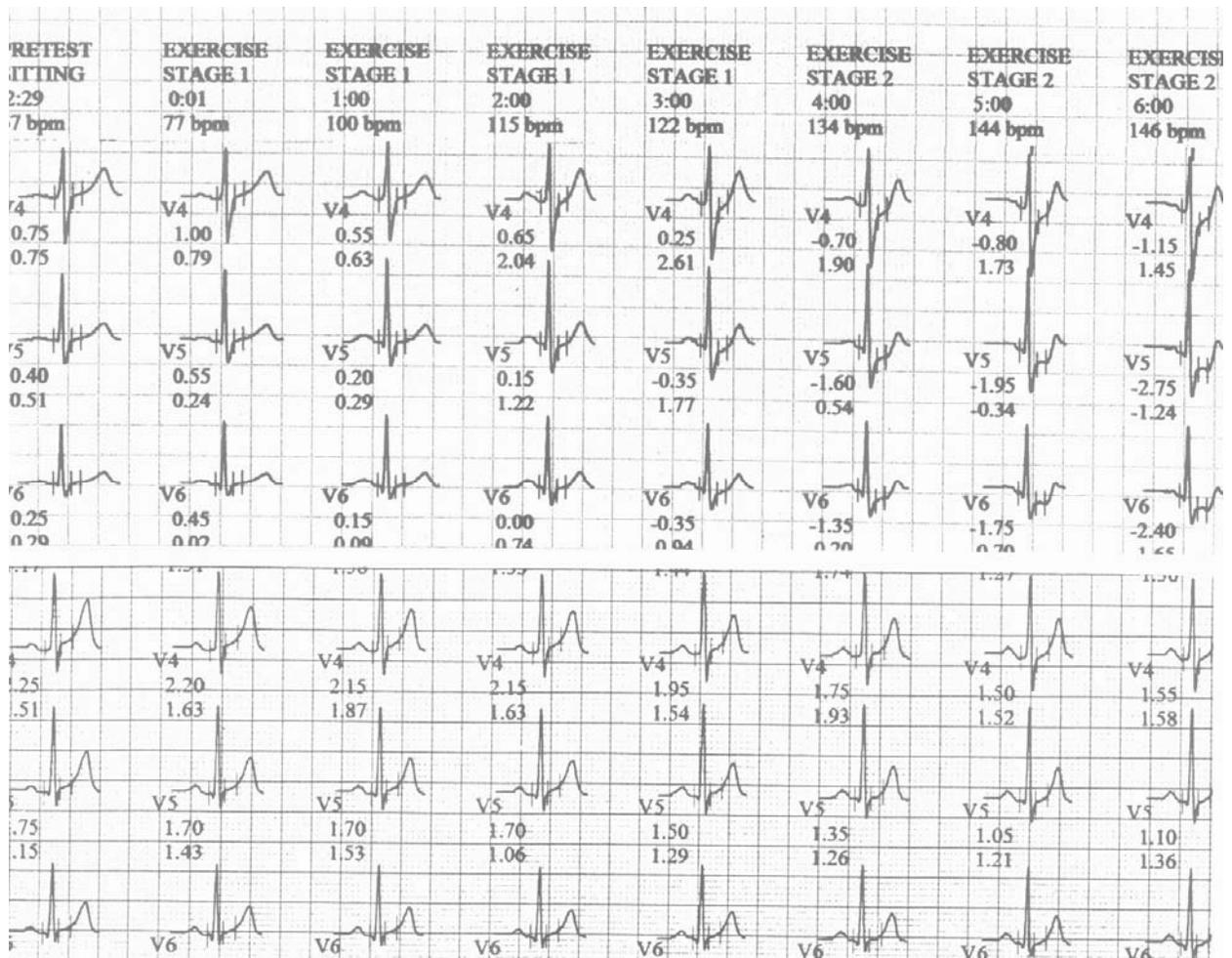
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**APPENDIX 2.— ILLUSTRATIVE EXERCISE ELECTROCARDIOGRAMS**



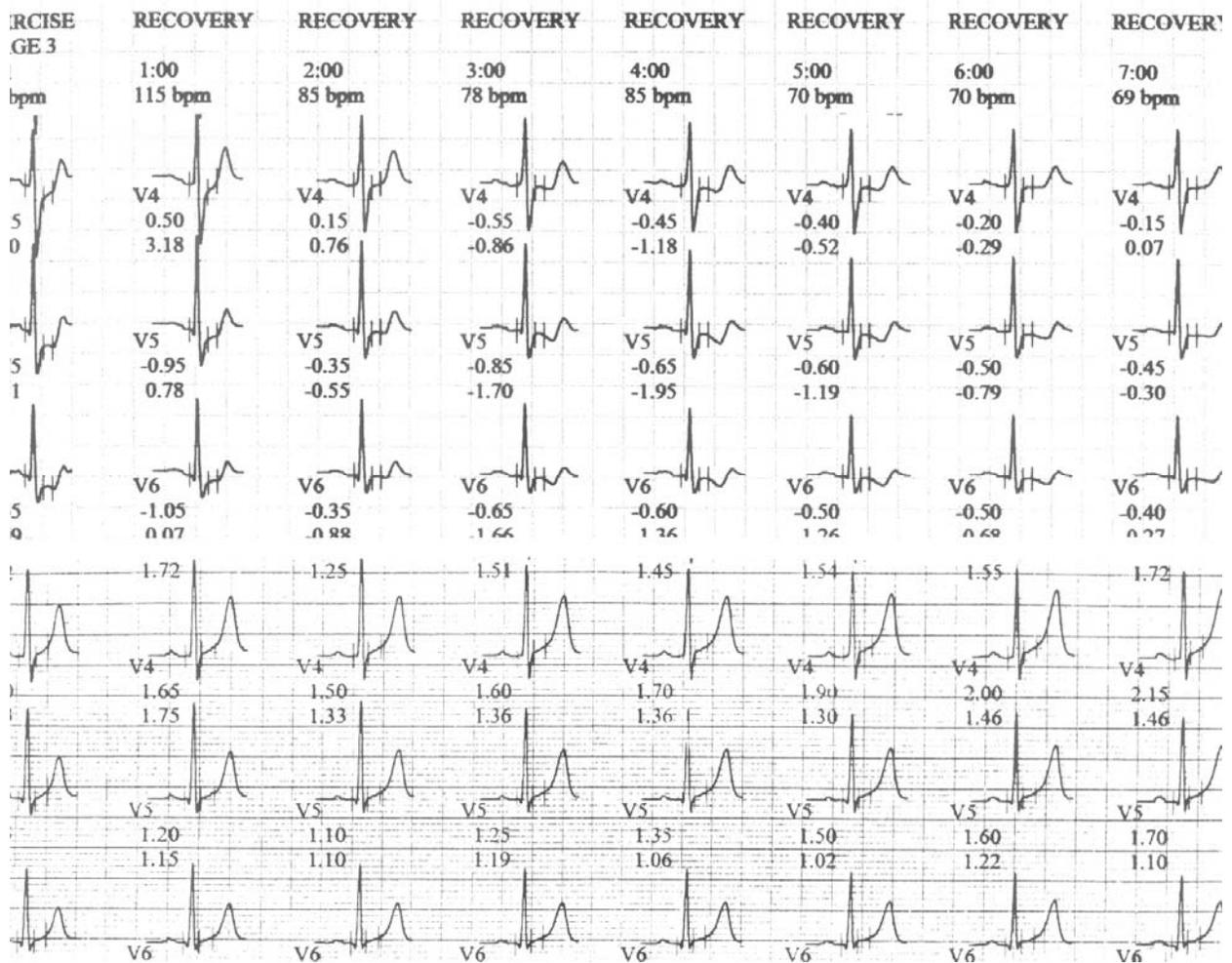
25. 30-year-old ATPL-holder who underwent exercise electrocardiography for variable T-wave flattening in the left chest leads of his resting electrocardiogram. He achieved 100% of his age predicted maximum heart rate of 190 bpm on the Bruce treadmill protocol after 12 minutes exercise and was limited by exhaustion.

The panel demonstrates the chest leads V1 – V6 at baseline, maximum ST-segment shift in recovery and at peak exercise and, finally, at the end of recovery. The recording is completely normal. Note the Ta phenomenon in which the PR-segment falls progressively with effort but is matched by displacement of the J-point – the junction between the S-wave and the ST-segment. This is a normal variant. Such a good walking time predicts a low (<1% / annum) risk of significant cardiovascular event/year.



26. 53-year-old obese and hypertensive ATPL-holder who developed “indigestion-like” symptoms whilst on a stop-over. He reported sick following his return to base. Cardiological review was carried out with exercise electrocardiography. The upper three leads, V4,5,6, represent his electrocardiographic response to exercise, which was limited by central chest pain to 6.05 minutes of the Bruce treadmill protocol. Progressive J-point depression is seen, the ST-segments becoming flat at the end of effort.

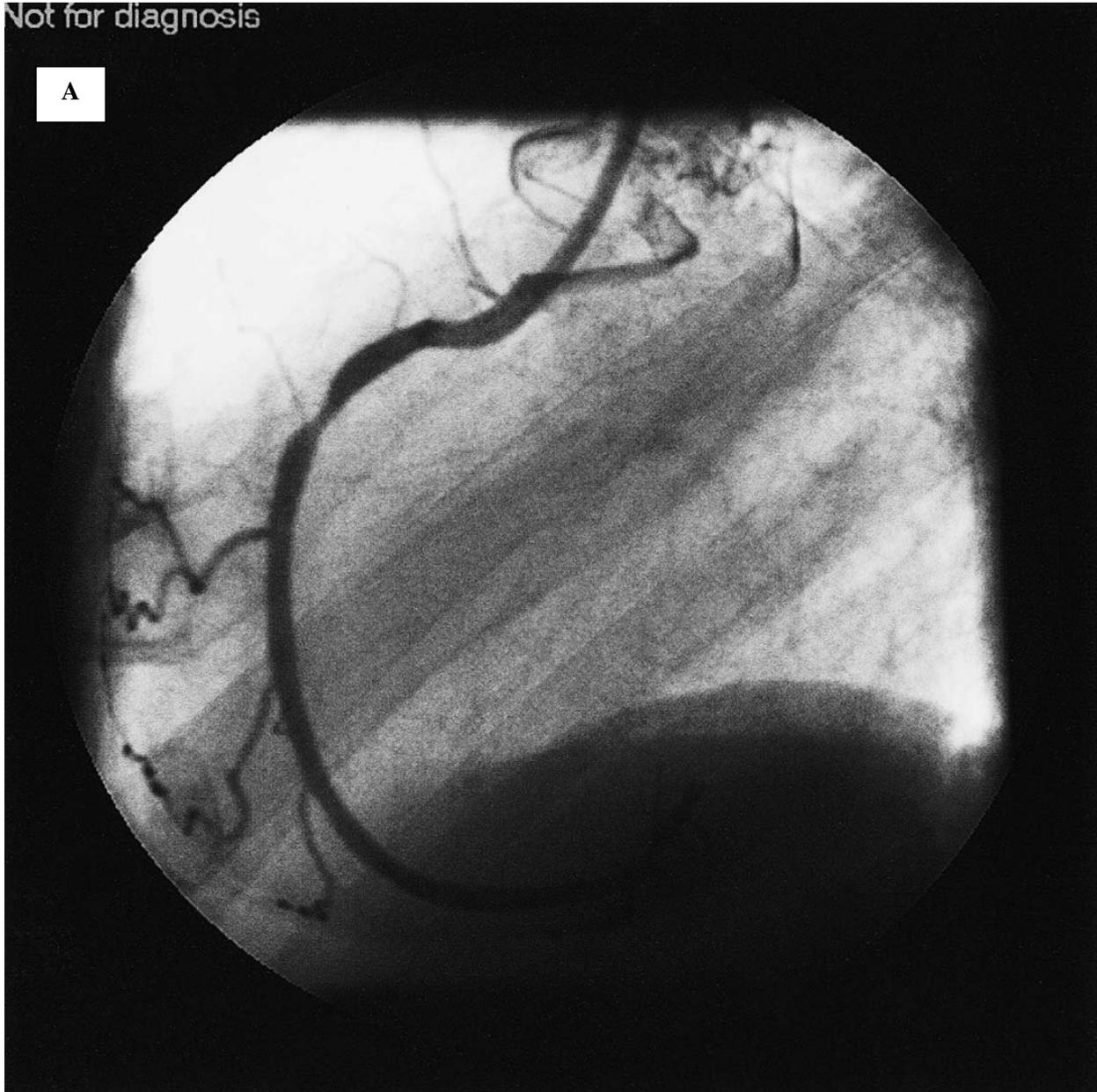
The lower panel reflects his normal response to exercise following the insertion of three coronary artery bypass grafts. Six months following the index intervention, he was assessed fit following clinical and exercise electrocardiographic review: attention had been paid to his vascular risk factors. His exercise electrocardiogram was normal at 11 minutes of the Bruce protocol. He was limited to fly as/with co-pilot only and will not be able to fly in future as pilot in sole command.



27. The same pilot as in 26, above, demonstrating the same leads during recovery from exercise. It is noteworthy that the ST-changes in the upper panel are more impressive during recovery than during exercise, underscoring the need for recording the full ten minutes of the recovery period.

The lower panel shows the normal response following coronary surgery.

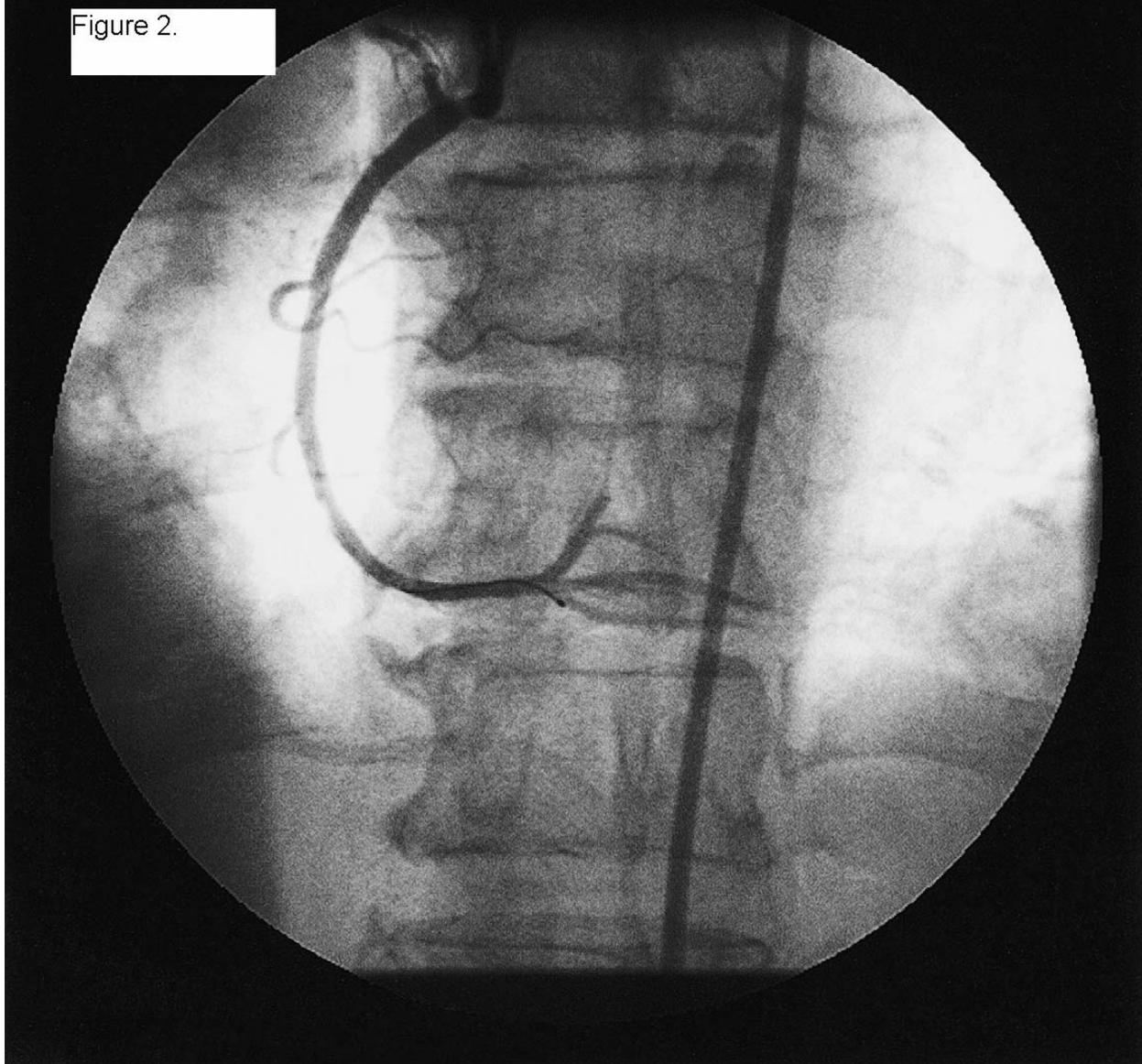
APPENDIX 3.— ILLUSTRATIVE ANGIOGRAM AND ANGIOPLASTY



**Panel A.** Left anterior oblique image of the right main coronary artery in a 54-year-old professional pilot who demonstrated an 80 per cent proximal stenosis. He had presented with angina pectoris. His exercise electrocardiogram was abnormal at seven minutes of the Bruce protocol and he was limited by chest pain.

Not for diagnosis

Figure 2.



**Panel B.** The same individual during angioplasty. The index lesion has been successfully dilated. The guide wire is in the posterior descending branch. The left ventricular branch is blocked. Six months later and free of symptoms, he was made fit for multi-crew duties, having successfully undergone exercise electrocardiography, echocardiography (to determine the left ventricular ejection fraction) and pharmacological stress thallium myocardial perfusion imaging (MPI). Stress echocardiography would have been an alternative.

— END —

## PART III

### Chapter 2. RESPIRATORY SYSTEM

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## Chapter 2. RESPIRATORY SYSTEM

### INTRODUCTION

In the introductory chapters of this manual the basic principles for the assessment of an applicant's medical fitness for aviation duties are outlined.

The general provisions of Annex 1, 6.2.2, state that an applicant shall be required to be free from any abnormality, disability, etc. "such as would entail a degree of functional incapacity which is likely to interfere with the safe operation of an aircraft or with the safe performance of duties."

Medical fitness requirements referring specifically to the respiratory system are detailed in Annex 1, 6.3.2.9 to 6.3.2.12.1 for a Class 1 Medical Assessment (and in the corresponding paragraphs of Chapter 6 for Class 2 and Class 3 Medical Assessments).

6.3.2.9 There shall be no acute disability of the lungs nor any active disease of the structures of the lungs, mediastinum or pleurae likely to result in incapacitating symptoms during normal or emergency operations.

6.3.2.9.1 **Recommendation.** — *Chest radiography should form part of the initial examination.*

*Note.* — *Periodic chest radiography is usually not necessary but may be a necessity in situations where asymptomatic pulmonary disease can be expected.*

It is, however, understood that a degree of interpretation and flexibility must always be exercised at the discretion of the medical examiner and the medical assessor, taking into consideration not only medical but also operational and environmental factors of relevance for the over-all aviation medical fitness of an applicant.

*Note.* — *The environmental conditions of aviation causing physiological disturbances such as hypoxia and decompression are detailed in Part II, Chapter 1.*

### GUIDELINES FOR ASSESSMENT

For aviation duties, it is important to bear in mind that the functional integrity of the respiratory system and its capability to provide adequate oxygenation during flight is more important than strict anatomical integrity. Due consideration must be given to the flight operation involved (e.g. pressurized or unpressurized aircraft) and the capability to perform during a prolonged and difficult flight. In evaluating the functions of the respiratory system, special attention must be given to its interdependence with the cardiovascular system. Satisfactory tissue oxygenation during aviation duties can only be achieved with an adequate capacity and response of the cardiovascular system.

In the evaluation of borderline cases, simple breathing tests will serve a screening purpose to select those applicants who require further investigation, which might call for more sophisticated techniques. The examination of the respiratory system should be directed specifically to the early detection of the two most prevalent pathophysiological manifestations of pulmonary disease, namely:

- a) presence and/or degree of restrictive impairment; and
- b) presence and/or degree of obstructive impairment.

When assessing the respiratory system, the medical examiner should in particular note the following groups of diseases.

### **Pulmonary tuberculosis**

Tuberculosis remains one of the world's leading infectious causes of death among adults. About one-third of the world's population, or two billion people, carry *mycobacterium tuberculosis*. Most do not develop clinical disease, but about two million people die of tuberculosis each year.

World-wide, 136 new cases/100 000, totaling 8.8 million new cases, were reported to the World Health Organization in 2005. In the Western world, tuberculosis has become a relatively uncommon disease, although its association with HIV has given rise to escalating tuberculosis case rates in many countries. In sub-Saharan Africa up to 70 per cent and in North America close to 90 per cent of patients with sputum smear-positive pulmonary tuberculosis are HIV-positive. The case rates for pulmonary tuberculosis in parts of North America, although low at 4.8/100 000, have not gone down since 1996, and between 2003 and 2004 the case rates increased by nine per cent. In addition, the emergence of multidrug-resistant tuberculosis<sup>1</sup> and extremely drug-resistant tuberculosis<sup>2</sup> as a threat to public health and tuberculosis control has raised concerns of a future epidemic of virtually untreatable tuberculosis.

Annex I specifies that:

6.3.2.12 Applicants with active pulmonary tuberculosis shall be assessed as unfit.

6.3.2.12.1 Applicants with quiescent or healed lesions which are known to be tuberculous, or are presumably tuberculous in origin, may be assessed as fit.

*When assessing an applicant suffering from, or undergoing treatment for, pulmonary tuberculosis, the medical examiner should keep in mind that any doubt about the activity of a lesion (where symptoms of activity of the disease are clinically lacking) must lead to an assessment as unfit for a period of not less than three months from the date of the medical examination. At the end of the three-month period, a further radiographic record should be made and compared carefully with the original. If there is no sign of extension of the disease and there are neither general symptoms nor symptoms referable to the chest, the applicant may be assessed as fit for three months. Thereafter, provided there continues to be no sign of extension of the disease as shown by radiographic examinations carried out at the end of each three-month period, the validity of the license should be restricted to consecutive periods of three months. When the applicant has been under observation under this scheme for a total period of at least two years and comparison of all the radiographic records shows no changes or only retrogression of the lesion, the*

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<sup>1</sup> Multidrug-resistant tuberculosis: tuberculosis with resistance to at least isoniazid and rifampin (first-line drugs)

<sup>2</sup> Extensively drug-resistant tuberculosis: cases in persons with tuberculosis whose isolates were resistant to isoniazid and rifampin and at least three of the six main classes of second line drugs (aminoglycosides, polypeptides, fluoroquinolones, thioamides, cycloserine, and para-aminosalicylic acid).

*lesion should be regarded as “quiescent” or “healed”.*

In case of an applicant undergoing treatment, the general principles of drug treatment with regard to flight safety, undesirable side effects, allergies and idiosyncrasies should be taken into account. Common adverse effects of first-line drugs against tuberculosis are as follows:

Isoniazid: hepatitis, peripheral neuropathy  
Rifampin: gastrointestinal upset, hepatitis, skin eruptions  
Ethambutol: retrobulbar neuritis, blurred vision, scotomata  
Pyrazinamide: hepatitis, hyperuricaemia  
Streptomycin: ototoxicity with vertigo and hearing loss.

When active tuberculosis has been diagnosed in a patient, isoniazid is frequently used as chemoprophylaxis for the other members of the household.

*As isoniazid only rarely gives rise to side effects and these, if they occur, do not cause acute, incapacitating symptoms, prophylactic treatment does not entail unfitness.*

### **Chronic obstructive pulmonary disease**

6.3.2.10 Applicants with chronic obstructive pulmonary disease shall be assessed as unfit unless the applicant’s condition has been investigated and evaluated in accordance with best medical practice and is assessed not likely to interfere with the safe exercise of the applicant’s licence or rating privileges.

Chronic obstructive pulmonary disease (COPD) is a heterogeneous condition, combining features of emphysema and chronic bronchitis. Emphysema is characterized by destruction of the parenchyma of the lung, resulting both in wasted ventilation and in a loss of elastic support to the internal airways, which leads to dynamic collapse on exhalation. Chronic bronchitis is characterized by inflammation of the airways, with mucosal thickening, copious sputum production, and ventilation-perfusion mismatching, which in some cases may be difficult to reliably separate from chronic asthma. Although most individuals with COPD will have some features of each disorder, the majority will have predominant emphysema or predominant chronic bronchitis, with the former being the more common pattern.

Emphysema-predominant COPD is characterized by the following features:

- a) dyspnoea on exertion, often severe
- b) obstruction to expiratory flow, not significantly improving after bronchodilator challenge
- c) decrease (often marked) in diffusion capacity
- d) increased total lung capacity (TLC), and increased residual volume (RV) to TLC fraction
- e) usually modest decrease in arterial oxygen saturation, with normal carbon dioxide tension
- f) bullous changes on radiography

Bronchitis-predominant COPD is characterized by the following features:

- a) variable dyspnoea, depending on presence of bronchitic exacerbation
- b) obstruction to expiratory flow, with significant but incomplete improvement after bronchodilator challenge
- c) modest decrease in diffusing capacity
- d) increased RV to TLC fraction

- e) arterial hypoxaemia, often marked, with carbon dioxide retention and pulmonary hypertension in later stages
- f) relatively normal radiography (in the absence of heart failure)

In the aviation environment, emphysematous patients are at particular risk from barometric changes, whereas bronchitic patients are more likely to be affected by ambient hypoxia, although as noted earlier, most COPD patients have some features of both disorders. The degree of functional impairment due to any or all of the above factors determines whether an applicant may be assessed as fit for aviation duties. In addition, most patients with moderate or advanced COPD are treated with drugs, often the same as those used for asthma (vide infra), and these may have adverse effects that preclude safe flying.

*Because of decreased tolerance to the hypoxic environment, bullous changes, pulmonary hypertension, and adverse effects from drug treatment, most COPD patients are unfit for all classes of certification. Applicants with early COPD who are physically fit and have no or only mild symptoms, a normal chest X-ray, and do not smoke, may be considered for restricted certification or even, in certain cases, for unrestricted certification.*

### **Pneumothorax**

The primary form of spontaneous pneumothorax is most common in young, healthy males between 20 and 30 years of age and occurs not infrequently in the pilot population. The assessment of applicants with a recent history of spontaneous pneumothorax should take into account not only clinical recovery after treatment (conservative and/or surgical), but primarily the risk of recurrence. There are significant first, second and third recurrence rates with conservative treatment of 10%-60%, 17%-80% and 80%-100% of cases, respectively. After chemical pleurodesis, the recurrence rate is 25-30%; after mechanical pleurodesis or pleurectomy, the rate is 1-5%.

*In the case of an initial applicant, a history of spontaneous pneumothorax need not be disqualifying provided that the applicant has had only one attack with complete clinical recovery, and that the medical investigation has revealed no evidence of predisposing disease such as bullous emphysema.*

*A history of two or more attacks should be considered as constituting a more serious risk. In such cases an applicant should be assessed as unfit until at least three months after surgery (i.e. wedge resection or pleurectomy).*

It should be noted that many thoracic centres have abandoned the use of chemical pleurodesis since this procedure has been shown to result in a relatively high recurrence rate. A final decision should be made by the medical assessor and based on a thorough investigation and evaluation in accordance with best medical practice.

### **Bronchial Asthma**

Bronchial asthma is caused by airway inflammation and characterized by recurring acute attacks of wheezing, coughing, and shortness of breath. Between attacks the patient is frequently asymptomatic and often has normal pulmonary function.

6.3.2.11 Applicants with asthma causing significant symptoms or likely to cause incapacitating symptoms during normal or emergency operations shall be assessed as unfit.

6.3.2.11.1 The use of drugs for control of asthma shall be disqualifying except for those drugs, the use of which is compatible with the safe exercise of the applicant's licence and rating privileges.

Asthmatic attacks, which can be caused by allergens, infection, exercise, emotional distress, and various irritants, is more or less incapacitating. Treatment with anti-inflammatory agents includes cromolyn, nedocromil and corticosteroids. Beta-agonists, theophyllines and ipratropium are frequently used but have severe side-effects, such as dizziness, cardiac arrhythmia, and anticholinergic effects. Cromolyn and inhaled corticosteroids have hardly any side-effects and may be relied upon to control the disease, but recurring attacks may still happen and they may be unpredictable and incapacitating.

*Consequently, applicants with asthma should in general be assessed as unfit. However, if the clinical course is mild and drug treatment is not required, or treatment with acceptable drugs has been demonstrated to reliably prevent attacks, restricted certification may be considered.*

### **Post-operative effects of thoracic surgery**

*These conditions should always be assessed individually based on comprehensive pulmonary function studies.*

The pathology requiring the surgical intervention, the residual functional capacity, cardiovascular function and possible displacement of the mediastinum, which might be aggravated by pressure differences during flight, require careful consideration. The over-all prognosis is a factor which must be borne in mind.

*In general, such cases should not be assessed as fit until four to six months have elapsed following major surgical procedures. The aeromedical decision should be made by the medical assessor and based on a thorough investigation and evaluation in accordance with best medical practice.*

### **Pulmonary sarcoidosis**

Most cases come to light because of an abnormal chest radiograph, while almost as many present with banal respiratory symptoms. Most cases are accompanied by enlarged hilar and mediastinal lymph-nodes. Some patients have granulomas in the lungs, causing radiographically evident changes. Usually the enlargement of lymph nodes subsides within three years, sometimes faster. In patients with pulmonary granulomas, the development of fibrosis may lead to increasing dyspnoea and abnormal lung function tests. Sometimes a severe defect in gas transfer may be found. In half to two-thirds of patients, pulmonary sarcoidosis resolves, leaving radiographically clear lungs.

Many patients with sarcoidosis develop uveitis. In some patients, the heart may be affected, causing cardiomyopathy, arrhythmia, and sudden death (see Chapter 1). Central nervous system involvement may manifest as seizures or neurological deficit. Extensive pulmonary sarcoidosis may lead to cor pulmonale. Sarcoidosis may also affect the skin, the liver, the spleen, the kidneys, etc.

There is no known cure for sarcoidosis. In general, the prognosis is good, especially if the disease is limited to the lungs. However, the potential for involvement of the eyes, the heart, and the central nervous system mandates a thorough examination and evaluation.

*Active pulmonary disease entails unfitness for all classes of assessment. Applicants may be assessed as fit for aviation duties once they are asymptomatic, off all medication (particularly steroids), and all test*

*results are normal. The aeromedical decision should be made by the medical assessor and based on a thorough investigation and evaluation in accordance with best medical practice. Close follow-up is essential.*

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## PART III

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## INTRODUCTION

In the introductory chapters of this manual the basic principles for the assessment of an applicant's medical fitness for aviation duties are outlined.

The general provisions of Annex 1, 6.2.2 state that an applicant shall be required to be free from any abnormality, disability, etc., "such as would entail a degree of functional incapacity which is likely to interfere with the safe operation of an aircraft or with the safe performance of duties."

The minimum standards for the digestive system of an applicant with regard to Class 1 Medical Assessment are detailed in Annex 1, 6.3.2.13 to 6.3.2.14.1 (and in the corresponding paragraphs of Chapter 6 for Class 2 and Class 3 Medical Assessments).

6.3.2.13 Applicants with significant impairment of function of the gastrointestinal tract or its adnexa shall be assessed as unfit.

6.3.2.13.1 Applicants shall be completely free from those hernias that might give rise to incapacitating symptoms.

6.3.2.14 Applicants with sequelae of disease of, or surgical intervention on, any part of the digestive tract or its adnexa, likely to cause incapacitation in flight, in particular any obstruction due to stricture or compression, shall be assessed as unfit.

6.3.2.14.1 **Recommendation.**— *An applicant who has undergone a major surgical operation on the biliary passages or the digestive tract or its adnexa with a total or partial excision or a diversion of any of these organs should be assessed as unfit until such time as the medical assessor, having access to the details of the operation concerned, considers that the effects of the operation are not likely to cause incapacitation in flight.*

It is, however, understood that a degree of interpretation and flexibility must always be exercised at the discretion of the medical examiner and the medical assessor, taking into consideration not only medical but also operational and environmental factors of relevance for the over-all evaluation of the medical fitness of an applicant. In general, instances of acute or chronic intra-abdominal disease vary greatly in severity and significance and will, in most cases, be cause for disqualification until after satisfactory treatment and/or complete recovery.

Any condition causing acute abdominal pain of either intra- or extra-abdominal origin occurring in connexion with aviation duties should be considered as "decrease in medical fitness" according to Annex 1, 1.2.6.1. Such conditions are being reported frequently and are a common cause of in-flight crew incapacitation. If or when surgical therapy is necessary, the provisions of 6.3.2.14 and the Recommendation attached to it must be considered.

When assessing an applicant's medical fitness with regard to the digestive system, the medical examiner should in particular note the following conditions.

## GASTRITIS

An important aetiological factor, often encountered in applicants with a history of gastritis, is the use or abuse of alcohol as well as habitual use or misuse of "over-the-counter" pain-relieving drugs such as aspirin. The use of antacids, which might indicate an underlying cause for subjective symptoms from the digestive tract, should also be explored.

## PEPTIC ULCER

A common problem, which gives rise to special certification considerations, is peptic ulcer. Careful examination and good clinical judgement are imperative in a realistic appraisal of any individual situation. Certain generalizations would seem indicated, however, to serve as an over-all guide.

### **Uncomplicated peptic ulcer**

Gastric ulcers are much less common than duodenal ulcers. Diagnosis is based on clinical symptoms and gastro-duodenoscopy. More than 90 per cent of duodenal ulcers are caused by infection with helicobacter pylori (*H.pylori*). It is possible to test non-invasively for *H. pylori* infection with a blood antibody test, stool antigen test, or with the carbon urea breath test (in which the patient drinks <sup>14</sup>C- or <sup>13</sup>C-labelled urea, which the bacterium metabolizes producing labelled carbon dioxide that can be detected in the breath). However, the most reliable method for detecting *H.pylori* infection is a biopsy taken during endoscopy with a rapid urease test, histological examination, and microbial culture. *H. pylori* should be eradicated to allow the ulcer to heal. The standard first-line therapy is a one week “triple-therapy”: amoxicillin, clarithromycin and a proton pump inhibitor such as omeprazole. Metronidazole may be used in place of amoxicillin in those allergic to penicillin. This treatment of peptic ulcers will often cure the disease. However, the proton pump inhibitor should be continued for at least another four weeks or until the ulcer has healed; this may take up to eight weeks, sometimes even longer. If medication is repeatedly required, a decision on medical fitness should be based on a thorough investigation with emphasis on ruling out malignancy.

*Pilots with uncomplicated peptic ulcer should be considered as unfit for all aviation duties during any period of clinical activity sufficient to warrant treatment beyond simple dietary control. The general criteria for medical fitness are that an applicant with a history of uncomplicated peptic ulcer be symptom-free on a suitable diet and that there is endoscopic evidence of the ulcer healing. Irregular work schedules and eating habits of flight crews on duty need to be considered as a complicating factor.*

### **Complications**

The most common complications of gastric or duodenal ulcer are: a) recurrence; b) bleeding; and c) perforation.

#### ***Recurrence***

*Applicants suffering from ulcers complicated by chronicity, obstruction or haemorrhage should generally be considered unfit for aviation duties, with the following exceptions:*

*An applicant with a history of one episode of recurrence might be assessed as fit if symptom-free on a normal (suitable) diet and provided there is evidence of clinical recovery. More than one episode of recurrence calls for comprehensive medical investigation and evaluation. Should such an applicant undergo surgery and the post-operative follow-up indicates complete recovery and virtual elimination of the excess risk associated with complications, the condition may be regarded as an uncomplicated (peptic) ulcer in remission which should require action as outlined above before return to flying duties.*

#### ***Bleeding***

*An applicant with a history of one single episode of bleeding as a complication may be assessed as fit if without symptoms for a reasonable observation period (at least eight weeks), if no medication is required, and if there is endoscopic evidence of healing. Assessment of fitness after recurrent bleeding episodes should be made by the medical assessor and based on a thorough investigation. The medical assessment should normally be limited to a period of validity of six months during the three years following a bleeding episode. The need for follow-up should, however, be considered on an individual basis which might require re-examination and evaluation at more frequent intervals than suggested above (every two to three months). At each re-examination a statement from the attending surgeon on the current status of the condition should be forwarded to the Licensing Authority for evaluation by the medical assessor.*

### ***Perforation***

Perforation should be considered on an individual basis. The primary treatment, if technically possible, is always a simple local procedure such as purse-string closure. This must be followed by eradication of H.pylori. Only rarely is gastrectomy needed.

*Cases treated surgically may be assessed as fit if the applicant shows endoscopic evidence of healing and is free of subjective symptoms while performing flight duties.*

## **GASTRO-OESOPHAGEAL REFLUX DISEASE**

Gastro-oesophageal reflux disease (GERD) is a common disease in which the acid content of the stomach is regurgitated up into the oesophagus. The primary symptoms of uncomplicated GERD are heartburn, regurgitation, and nausea. The condition is chronic; once it begins, it is usually lifelong. The diagnosis is made by oesophago-gastro-duodenoscopy, oesophageal pH probe, and manometry. Treatment includes antacids, foam barriers, histamine H<sub>2</sub> receptor antagonists, prokinetic agents, cytoprotective agents, and proton pump inhibitors. Some patients may require surgery (fundoplication). Long-term maintenance therapy may be necessary in many patients. In addition, the condition demands life style modifications, especially dietary ones, which often are impractical for pilots.

*Medical certification may be considered in cases where the frequency and intensity of episodes are low, where complications such as oesophagitis, oesophageal ulcer, strictures, bleeding, and Barrett's oesophagus<sup>1</sup> are absent, and where the medication prescribed has no significant side-effects.*

## **BILIARY DISORDERS**

*Applicants with asymptomatic (large, solitary) gallstones need not require any special action and may be assessed as fit.*

*Small multiple asymptomatic stones with functional gall-bladder may, however, cause colic and potential incapacitation and are disqualifying until adequately treated.*

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<sup>1</sup> Barrett's oesophagus: peptic ulcer of the lower oesophagus, often with stricture and sometimes pre-malignant, followed by oesophageal adenocarcinoma. After Norman R. Barrett, English surgeon (1903-1979)

## **PANCREATITIS**

*This condition, unless very mild, is disqualifying for aviation duties.*

*Alcohol abuse as a causative factor should always be explored. Applicants with a history of pancreatitis should be assessed individually and the aeromedical decision should be made in consultation with the medical assessor and based on a thorough investigation and evaluation in accordance with best medical practice. Close follow-up is essential.*

## **IRRITABLE COLON**

This is not an uncommon condition among aviation personnel. It may be aggravated by change of environmental and working conditions e.g. operating routes, and might lead to incapacitating conditions of varying severity.

*The condition should generally be disqualifying if medication is necessary for control of symptoms. Often the condition can be controlled by a diet rich in fibre, fruits and vegetables. If the symptoms are mild and regular use of psychotropic or cholinergic medication is unnecessary, it may not be disqualifying.*

## **ULCERATIVE COLITIS AND CROHN'S DISEASE**

The primary symptoms of ulcerative colitis are abdominal pain, bloody diarrhoea and weight loss. The course of the disease is characterised by frequent exacerbations and many, often severe, complications including anaemia, and a high frequency of colonic carcinoma. Medical treatment is often unsatisfactory and many patients will require surgery (colectomy). Crohn's disease is usually more severe with a poor quality of life for most patients regardless of treatment.

*For both conditions, an assessment as unfit is the rule, although rare cases with mild and infrequent symptoms and without need for long-term treatment may be considered fit under close monitoring.*

## **HERNIA**

The medical examiner, when evaluating an applicant with hernia, should keep in mind that some hernias might not originate symptoms of an acute pattern, whereas other hernias may cause incarceration or strangulation, which would compromise flight safety.

*To assess an applicant as fit, the medical examiner should be satisfied that the applicant is completely free from the latter kind of hernias.*

In assessing inguinal hernias, distinction should be made between the presence of a hernial orifice only and the demonstration of a hernial sac. The existence of a hernial orifice *per se* should not be considered disqualifying for aviation duties. An applicant with such a condition should, however, be referred for surgical evaluation.

## **OTHER DISEASES**

Pilonidal disease and haemorrhoids are common diseases. They are usually of a benign character; they rarely, if ever, give rise to certification problems.

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## Part III

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## INTRODUCTION

In the introductory chapters of this Manual the basic principles for the assessment of an applicant's medical fitness for aviation duties are outlined.

The general medical provisions of Annex 1, 6.2.2, state that an applicant shall be required to be free from any abnormality, disability, etc., such as would entail a degree of functional incapacity which is likely to interfere with the safe operation of an aircraft or with the safe performance of duties.

The provisions of Annex 1, 6.3.2.15, state, for all classes of licences and ratings, that applicants with metabolic, nutritional or endocrine disorders that are likely to interfere with the safe exercise of their licence and rating privileges shall be assessed as unfit.

## THE ENDOCRINE SYSTEM

The endocrine system is controlled by the hypothalamus, which is subject to regulatory influences from other parts of the brain, especially the limbic system. A number of releasing hormones from the hypothalamus cause stimulating hormones to be released from the anterior pituitary gland (adenohypophysis) to act on specific end organs. The resulting hormone production from the end organs acts as a complex system of feedback to inhibit further production.

In such a finely tuned homeostatic environment any disturbance of secretion of the trophic hormone or of the end organ itself may result in clinical disease.

In aircrew, the most important question the aeromedical examiner must ask is whether the disease or its treatment will affect performance.

## DISEASES OF THE THYROID

The production of triiodothyronine (T3) and thyroxine (T4) in the thyroid gland is stimulated by thyrotrophin (Thyroid Stimulating Hormone, TSH) which is released from the pituitary in response to thyrotrophin releasing hormone from the hypothalamus. There is negative feedback by the thyroid hormones on thyrotrophin to ensure homeostasis. It is self-evident that any upset in this mechanism may result in under- or over-activity of the thyroid gland.

### Hyperthyroidism - Thyrotoxicosis

Thyrotoxicosis is common with a prevalence of 1-2 per cent in women in countries which do not have iodine deficiency; men have a 5-10 fold lower incidence. The commonest cause is auto-immune thyroid disease (Grave's disease<sup>1</sup> or Basedow's disease<sup>2</sup>). More rarely thyrotoxicosis is caused by multinodular goitre or a single autonomously functioning solitary nodule (toxic adenoma).

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<sup>1</sup> Grave's disease: diffuse toxic goitre, named after Robert James Graves, Irish physician (1796-1853)

<sup>2</sup> Basedow's disease: the same, named after Karl Adolf von Basedow, German physician (1799-1854)

Grave's disease results from the stimulation of thyrotrophin receptors on thyroid follicular cells by circulating TSH-receptor antibodies of the IgG class. Genetic factors may play a role with the association of various HLA-DR antigens (*Human Leucocyte Antigens*), especially HLA-DR3, although no specific gene has been shown to confer a strong susceptibility to the condition.

### *Clinical features*

Classically patients develop heat intolerance, sweating, and weight loss in spite of increased appetite. They may be anxious and irritable and are often depressed. In women menstrual upset is common. Palpitations are frequent symptoms, and the elderly may develop atrial fibrillation. Goitre (struma) may be present and there may be a thrill or bruit over the gland. The clinical features are those of increased sensitivity to circulating catecholamines. There may be elevation of levator palpebrae superioris, giving a startled appearance, and personality changes may be marked.

Mild ocular involvement with proptosis is an integral part of the clinical syndrome of Grave's disease. However, severe ophthalmopathy occurs in 25-50 per cent of cases with marked proptosis, ophthalmoplegia, chemosis and increasing retro-orbital pressure, which can lead to papilloedema or optic atrophy with loss of vision (malignant exophthalmos). These severe eye signs usually accompany the general picture of hyperthyroidism, but may occur after the patient has been treated and is euthyroid.

### *Investigation of thyrotoxicosis*

Laboratory analysis of TSH, T3 and T4 by radioimmuno-assay has simplified the biochemical diagnosis. TSH is low or undetectable, and T3 and T4 are elevated. T3 may be raised before T4 and this makes early diagnosis possible.

If there is a nodular goitre, imaging techniques may be useful with scans using <sup>99m</sup>Tc labelled pertechnetate.

### *Management of thyrotoxicosis*

There are three forms of treatment for hyperthyroidism: medical, radioactive iodine, and surgical.

- a) **Medical management.** The major anti-thyroid drugs are thiourea compounds. Carbimazole is used widely in the United Kingdom and propylthiouracil and methimazole in the United States. Treatment is usually continued for 12-18 months; the relapse rate is high.

Beta-blockers (e.g. propranolol) are useful for the relief of symptoms in the first 1-2 months until the definitive treatment renders the patient euthyroid.

- b) **Surgical management.** This kind of surgery is only carried out in specialist centres; the indications vary, and patient preference may influence decisions. Potential problems include recurrent laryngeal nerve trauma, damage to the parathyroid glands, and late hypothyroidism.
- c) **Radioactive iodine.** In many centres this is now the treatment of choice for toxic multinodular goitres; it is increasingly being used for Grave's disease and the single hot nodule. There are numerous regimes in use and all accept that the patient will become hypothyroid and thus will require lifelong thyroxine.

### *Operational implications*

Frank thyrotoxicosis is obviously incompatible with aviation duties until stable euthyroidism has been established and a satisfactory report from an endocrinologist is received.

### *Aeromedical considerations*

*Applicants with hyperthyroidism may be considered for medical assessment in any class when they have been euthyroid for at least two months. The continued use of anti-thyroid drugs is usually well tolerated; side effects are rare and should not preclude safety-sensitive duties. A condition of the medical certificate should be life-long follow-up by an endocrinologist to ensure no recurrence of the hyperthyroidism and no insidious onset of late hypothyroidism.*

## **Hypothyroidism**

Isolated hypothyroidism beginning in adult life is almost always due to autoimmune thyroid disease or previously treated hyperthyroidism. It is a common condition, affecting one per cent of the general population and there are data to show that four per cent of those over 60 years of age are on long-term treatment with thyroxine. Hypothyroidism may be caused more rarely by failure of hypothalamic production of TRH or pituitary production of TSH.

Hypothyroidism is more common in females with a 5-10 fold lower prevalence in males.

### *Clinical features*

The onset is gradual and often the diagnosis is not recognised for some time. The signs and symptoms include:

- a) lethargy, increased weight, cold intolerance, slow cerebration, constipation;
- b) puffy face, dry skin, hoarse voice, slow ankle reflexes;
- c) macrocytic anaemia, hypercholesterolaemia;
- d) complications (relatively rare) include pericardial effusion, hypertension, psychosis, and
- e) coma.

There may be other associated autoimmune disease, e.g. coeliac disease and pernicious anaemia. The aim is to diagnose the condition early, before frank myxoedema with complications develop.

TSH is raised and free T4 is low. Serum T3 can remain normal for a considerable period of time. If the cause has been Hashimoto's thyroiditis<sup>3</sup>, one may demonstrate TSH receptor antibodies and antibodies to thyroid components. The ECG may show non-specific ST and T changes and low voltage complexes in extreme cases.

### *Management*

Before treatment is commenced, it is important to ensure that the patient is not hypopituitary or hypoadrenal. This can be done by checking ACTH levels.

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<sup>3</sup> Hashimoto's thyroiditis: autoimmune, chronic lymphocytic thyroiditis - diffuse infiltration of the thyroid gland with lymphocytes, leading to diffuse goiter with progressive destruction of the parenchyme and hypothyroidism. After Hashimoto, Japanese surgeon (1881-1934).

Once the diagnosis has been established, treatment is with thyroxine. It is normal practice to start slowly in doses of 50 µg per day (or 25 µg/day in the elderly or those with cardiac involvement) and increase every 2-3 weeks until the correct maintenance dose, as indicated by a normal TSH, is reached. A normal maintenance dose lies between 100 and 150 µg per day.

Thyroxine should be taken as a single daily dose as its plasma half-life is approximately seven days. Patients again should be followed for life to ensure compliance.

#### *Operational implications*

*Florid hypothyroidism is clearly incompatible with aviation duties and the denial of the medical assessment will probably be between 3-4 months.*

#### *Aeromedical considerations*

*Applicants may be considered for medical assessment in any class provided they remain euthyroid. It should be a condition that there is a regular supervision by an endocrinologist.*

Many endocrinologists use computer recall to ensure follow-up and compliance with medication. The duration of compliance is a significant problem and many patients when euthyroid cease medication because they feel so well. Insidious development of hypothyroidism may not be obvious to the patient or his/her associates; any decrement in performance has obvious implications in the aviation situation.

## **DISEASES OF THE PITUITARY**

A wide variety of diseases can affect the pituitary gland and, in common with other endocrine organs, result in over or under activity.

### **DISEASES OF THE ANTERIOR PITUITARY**

#### **Anterior pituitary hypofunction**

Hypopituitarism may be partial or complete and may be caused by either pituitary or hypothalamic disease, resulting in hormonal deficiency. Clinical manifestations may vary depending on the extent and severity of the pituitary hormone deficiency. Thus an individual may present *in extremis* with acute adrenal insufficiency or profound hypothyroidism or with rather non-specific symptoms of fatigue or malaise which could be erroneously labelled as jet lag or crew fatigue.

The commonest cause of hypopituitarism is a pituitary tumour, but there are other infiltrative and vascular causes.

#### *Clinical features*

The emerging tumour may produce local pressure effects, the principal symptoms being headache and visual field disturbances. The classic visual field defect is an upper quadrantic bitemporal hemianopia if the tumour is below the optic chiasm. Rarely, pressure on the third ventricle may produce a Korsakoff-

like syndrome and the aircrew member may be thought to have an alcohol abuse problem. Funduscopy may reveal early optic atrophy.

Other clinical features depend on the age of onset, but only disease in adulthood is relevant to aviation medicine practice. Patients will have rather non-specific symptoms, they may appear pale, but are not anaemic; the skin has a waxen doll appearance. They have cold intolerance but do not have the classic myxoedematous appearance. Supine blood pressure may be normal, but orthostatic hypotension may be present. Women have ammenorrhoea and men may lose their sex drive. Acute hypopituitary crisis may mimic an acute abdomen or an atypical presentation of decompression sickness. Patients may become hypoglycaemic but, because of the lack of a sympathetic response, without the classical symptoms; consequently they may proceed to coma. They develop hyponatraemia, which can also cause coma and, therefore, adequate biochemical testing is required for evaluation.

### *Diagnosis*

Detailed description of the dynamic tests used is not appropriate to this text, but the basic principle is assay of the relevant trophic hormones and cortisol levels, which will be low.

### *Treatment*

The individual is treated to replace the deficiencies documented usually with hydrocortisone 20 mg in the morning and 10 mg in the afternoon (or cortisone acetate 25 mg + 12.5 mg) to simulate the normal circadian rhythm. Thyroxine may or may not be required depending on the biochemical investigations. Hypopituitarism is treatable and the patient should be able to perform normal activities as long as an appropriate hormonal therapy is used consistently and properly. Once the appropriate regime has been determined with appropriate laboratory back-up, the doses rarely need to be changed except for an increase in the glucocorticoid dose (which is generally doubled) during inter-current illness. Even after the proper regime has been stabilised, life long follow up by a specialist in endocrinology is required.

### *Operational indications*

*Florid hypopituitarism is clearly incompatible with aviation duties.*

### *Aeromedical considerations*

*If the applicant has panhypopituitarism with multiple replacement therapy, medical certification will normally not be possible. The possibility of not having replacement drugs taken consistently and properly and the risk of intermittent illness away from specialised help have obvious implications.*

## **Anterior pituitary hyperfunction**

Most syndromes of hyperfunction are due to pituitary tumours. The particular syndrome presenting will depend on which cell in the pituitary is involved. The tumours are mostly benign epithelial neoplasms that result from mutation and subsequent expansion of single adenohypophyseal parenchymal cells. They account for 10-15 per cent of intracranial neoplasms and 75 per cent of them secrete inappropriate amounts of pituitary hormones. The presence of residual cells in the parasellar structures following treatment may account for local recurrences, but metastatic spread and direct invasion of surrounding structures is rare.

The majority of patients with pituitary adenomas present with signs and symptoms of hormone hypersecretion, visual field defects and headaches, either alone or in combination.

The diagnosis is usually clear from the history and examination, but should be confirmed by pituitary imaging (CT-scanning and MRI) and specific hormone assays.

## **SPECIFIC CLINICAL SYNDROMES**

### **Over-production of growth hormone (GH)**

#### *Aetiology and Pathogenesis*

Over-secretion of GH by an eosinophilic tumour of the pituitary gland will produce acromegaly in the adult.

#### *Clinical features*

The diagnosis is made from the classic clinical features:

- a) coarse facial features
- b) jaw growth and malocclusion
- c) hypertrichosis
- d) tiredness, weakness and somnolence
- e) carpal tunnel syndrome
- f) possible hypertension with or without cardiomegaly
- g) impaired glucose tolerance

#### *Investigation*

The diagnosis is confirmed by increased basal growth hormone levels on two or more occasions ( $>5$  mU/L or 2.5 ng/mL), particularly with a raised concentration of insulin-like growth factor I. Borderline cases may require a glucose tolerance test, which in the normal individual would suppress growth hormone to levels below 2 mU/L.

#### *Radiological investigation*

In 90 per cent of cases, a lateral skull X-ray shows enlargement of the pituitary fossa with or without erosion of the clinoid processes.

#### *Treatment*

Transphenoidal surgery reduces circulating growth hormone in 60 per cent of patients, but normal pulsatile growth hormone may not be restored. Radiotherapy alone produces an annual fall in growth hormone of approximately 20 per cent, improves headaches in over 75 per cent of patients, and reduces the risk of further visual loss due to tumour expansion. In many centres radiotherapy produces similar results to surgery but it may take up to four years for growth hormone levels to fall to  $<2$  mU/L in a glucose tolerance test. In 50 per cent of patients, growth hormone levels remain elevated ten years post surgery, and in the long term hypopituitarism may develop.

Bromocriptine may reduce growth hormone in about 75 per cent of mild cases but rarely produces levels below 10 mU/L. However, it may produce nausea, vomiting and postural hypotension. Somatostatin analogues (e.g. octreotide) have replaced dopamine agonists as the first line medical treatment for somatotroph adenomas. They are given by injection twice or thrice daily. They reduce circulating growth hormone in more than 80 per cent of patients but gall stones have been documented on long term treatment.

#### *Operational implications*

*An applicant with a symptomatic excess growth hormone due to tumour is unfit for all aviation duties.*

#### *Aeromedical considerations*

After treatment the individual must be carefully reviewed to assess the efficacy of the treatment.

*Those with gross physical changes which do not regress are unlikely to be fit for medical certification. Specialist endocrinological and ophthalmic review would be required before any assessment by the aeromedical authority.*

### **Overproduction of prolactin**

Prolactinomas are the most common functional pituitary adenoma and account for approximately 25 per cent of asymptomatic pituitary adenomas diagnosed at post mortem examinations.

#### *Symptoms and signs*

The classic symptoms of hyperprolactinaemia in the female are:

- a) amenorrhoea, oligomenorrhoea or infertility
- b) galactorrhoea
- c) decreased libido
- d) vaginal dryness/dyspareunia
- e) delayed menarche

Although less common, hyperprolactinaemia presents in the male with:

- a) decreased libido
- b) impotence
- c) galactorrhoea
- d) reduced body and facial hair
- e) small soft testis
- f) apathy
- g) weight gain

The diagnosis is confirmed by raised prolactin levels. A prolactin level of >5000 mU/L suggests a prolactinoma while a level of < 2500 mU/L is more likely to be the result of compression of the pituitary stalk by an inactive adenoma.

Radiological views of the pituitary fossa should be undertaken to look for any disruption to the sella.

## *Treatment*

The dopamine agonist bromocriptine reduces galactorrhoea, restores menstruation and returns serum prolactin to normal in the majority of patients, and results in visual field improvement in approximately 75 per cent of cases. Although it is a highly effective drug, the side-effects - nausea, vomiting, fatigue, mood changes - can be dose limiting. The side-effect profile can be minimized by starting with a low dose at bedtime. If symptoms persist, the newer dopamine agonists, such as cabergoline, can be used. Although there is no evidence of teratogenicity, most physicians stop bromocriptine when pregnancy is diagnosed and monitor the visual fields carefully. Long term treatment with bromocriptine or an alternative agonist is the most common regime for microprolactinomas. In some centres with good neurosurgical facilities transphenoidal surgery is the treatment of choice, although the majority of endocrine units generally advocate surgery only in those patients who cannot tolerate dopamine agonists or whose tumour does not respond. The advantage of micro-neurosurgery, however, is that it is curative. Surgery in macroadenomas is rarely curative and carries the risk of hypopituitarism and, thus, dopamine agonists are the treatment of choice in the macroadenoma group.

## *Operational implications*

*An applicant with an active pituitary tumour with or without an enlarged sella turcica is unfit for all aviation duties.*

## *Aeromedical considerations*

*An applicant on continuing medication or following successful surgery may be considered for medical certification after three months if closely supervised by an aviation medicine specialist and an endocrinologist and, if visual problems have been present, by an ophthalmologist.*

Continued treatment with bromocriptine will probably have to be lifelong on the basis of current evidence.

## **Over-production of adrenocorticotrophic hormone (ACTH)**

An over-production of ACTH — usually caused by a microadenoma in the pituitary gland — can cause Cushing's syndrome<sup>4</sup> by hyperstimulation of the adrenal cortex which produces an excess primarily of cortisol.

## *Symptoms and Signs*

Typical features of excess cortisol production are:

- a) weight gain and trunkal obesity
- b) moon face
- c) plethora
- d) menstrual irregularity
- e) hirsutism
- f) thinning of the skin with easy bruising
- g) depression and psychosis

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<sup>4</sup> Cushing's syndrome: Hyperadrenocorticism caused by a neoplasm of the adrenal cortex or adenohipophysis, or by excessive intake of glucocorticoids. Named after Harvey Williams Cushing, American surgeon (1869-1939).

- h) purple striae
- i) proximal myopathy
- j) oedema
- k) diabetes mellitus

### *Diagnosis*

Screening for Cushing's syndrome is most easily performed by measuring urinary free cortisol. Assays vary between laboratories, but in Cushing's syndrome, the level is usually >275 nmol/24 hours. If this is abnormal the dexamethasone suppression test is of value. If dexamethasone produces some suppression of cortisol production, this is suggestive of pituitary disease, while complete failure of suppression suggests primary adrenal disease or ectopic ACTH production by tumour, e.g. small-cell bronchogenic carcinoma. If there is any doubt, further tests using the response to exogenous corticotrophin releasing hormone may be helpful.

### *Treatment*

Transphenoidal hypophysectomy is the first line treatment for Cushing's disease<sup>5</sup> when caused by microadenoma and is curative in over 80 per cent of patients. The pituitary is irradiated in the remaining 20 per cent to prevent Nelson's syndrome.<sup>6</sup>

Bilateral adrenalectomy remains a useful treatment for patients who are not cured by hypophysectomy, but again pituitary irradiation must be given to limit the development of Nelson's syndrome. Radiotherapy alone has been shown to be curative in approximately 40 per cent of patients over the age of 18, and in approximately 80 per cent of those under 18. Pharmacotherapy has a limited role in Cushing's disease. The most commonly used drug is metyrapone which blocks 11-hydroxylase in the adrenal glands. Side-effects include nausea, oedema, somnolence, and hypertension. It is useful to render patients euadrenal before surgery. Other drugs such as ketoconazole, cyproheptadine, and aminoglutethimide have only limited use.

### *Operational implications*

*Individuals with active Cushing's disease are unfit and would remain so until hormone secretion returns to normal.*

### *Aeromedical considerations*

*After adequate treatment, it may take six months or more for symptoms and signs to subside and thus medical certification should be denied for one year. The certification issue may be dependent on a satisfactory report from and continuous supervision by an endocrinologist. It is possible that recertification in any category may be feasible but continual surveillance with regular reports from the endocrinologist must be mandatory.*

## **The posterior pituitary (neurohypophysis)**

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<sup>5</sup> Cushing's disease is a term applied to Cushing's syndrome when of pituitary origin.

<sup>6</sup> Nelson's syndrome: hyperpigmentation, ACTH excess and pituitary expansion. Named after Donald H. Nelson, American internist (1925- ).

The posterior lobe of the pituitary gland consists principally of terminal extensions of neurones which arise in the pre-optic nucleus of the hypothalamus. The posterior pituitary secretes two principal peptides vasopressin (anti-diuretic hormone - ADH) and oxytocin, together with their carrier proteins (neurophysins).

## **DIABETES INSIPIDUS**

### *Aetiology and pathogenesis*

Diabetes insipidus (DI) may be idiopathic or caused by:

- a) trauma (head injury and neurosurgery)
- b) primary or secondary neoplasms of the hypothalamus
- c) vascular cause such as haemorrhage and thrombosis, Sheehan's syndrome<sup>7</sup> and sickle cell haemoglobinopathy
- d) granulomatous disease such as sarcoid and histiocytosis
- e) infections e.g. meningitis and encephalitis

Rarely DI may be genetically inherited. A primary form of neurogenic DI is the DIDMOAD syndrome (diabetes insipidus, diabetes mellitus, optic atrophy and nerve deafness), which is inherited as an autosomal recessive condition. The vast majority of cases may be idiopathic; an autoimmune mechanism has been postulated.

### *Signs and symptoms*

The most marked features are polydipsia and polyuria reaching 10 to 20 litres per 24 hours. The urine is of low specific gravity (< 1.003) and osmolality (50-100 mosmol/kg).

The major differential diagnosis is psychogenic polydipsia, which is more common than true DI. The plasma osmolality in true diabetes insipidus is usually greater than 290 mosmol/kg on a background of the urinary findings above. To confirm the diagnosis, a water deprivation test (under close supervision) is carried out. If the urine is not concentrated after eight hours, an injection of 2 µg of the ADH analogue DDAVP (desmopressin) is given and in the patient with true diabetes insipidus this produces a rapid concentration of the urine.

### *Treatment*

The long acting vasopressin analogue, desamino-D-arginine vasopressin (DDAVP) acts almost solely on the type I receptors in the renal tubule and is the mainstay of treatment.

It is usually given by intra-nasal spray (10-20 µg twice daily). Recently an oral formulation has become available and is used in a dose of 100-200 µg three times a day. The sulphonylurea chlorpropamide enhances the renal response to ADH, but is only used in partial forms of DI and carries a risk of hypoglycaemia.

### *Operational implications*

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<sup>7</sup> Sheehan's syndrome: necrosis of the anterior pituitary gland as a result of severe post-partum haemorrhage and shock. Named after Harold Leeming Sheehan, English pathologist (1900-1988)

A person who is required to void urine frequently and to drink large amounts of fluid would obviously be at a disadvantage in a control situation. However, if the diabetes insipidus is controlled adequately, there should be no hazard.

#### *Aeromedical considerations*

*Recertification in any category should be considered if the individual is adequately treated under the supervision of an endocrinologist. Chlorpropamide is unacceptable for aviation duties due to the risk of hypoglycaemia.*

## **THE ADRENAL GLANDS**

The adrenal glands are situated in the upper poles of the kidney. Anatomically and functionally they can be divided into outer cortex and inner medulla. The outer cortex produces aldosterone, cortisol and some androgens. The medulla is responsible for any adrenaline secretion in response to distress. The enzymatic conversion of nor-adrenaline to adrenaline is cortisol dependent.

### **DISEASES OF THE ADRENAL CORTEX**

#### **Addison's disease<sup>8</sup> (primary hypoadrenalism)**

In this condition the adrenal cortex fails to produce or produces inadequate amounts of normal hormones. Initially this was described by Addison as the result of caseating tuberculosis but it can also be caused by autoimmune induced destruction of the adrenal cortex.

#### *Signs and symptoms*

These include:

- a) lassitude, somnolence, depression
- b) hypotension, hyperkalaemia, salt and water loss, hypoglycaemia, hypercalcaemia
- c) associated vitiligo, myxoedema or pernicious anaemia
- d) ECG changes secondary to raised potassium (tall peaked T-wave)

If the onset is slow, the diagnosis may be missed and other labels attached such as depression or anorexia nervosa.

#### *Investigations*

A high index of suspicion is a useful aid to early diagnosis. If the patient presents hypotensive and severely ill, i.e. in Addisonian crisis, blood should be taken for electrolytes and cortisol assay and treatment initiated forthwith. If the patient is not critically ill, the investigation of choice is the short acting synacthen (tetracosactrin) test: in a normal person, i.m. injection of 250 µg synacthen will produce a rise in plasma cortisol 45 minutes later of approximately 550 nmol/L or more; values less than that are consistent with primary or secondary hypoadrenalism. Proof of primary adrenal insufficiency is measurement of ACTH levels which are extremely high; a long acting synacthen test over a 4-5 day

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<sup>8</sup> Addison's disease: chronic adrenocortical insufficiency. After Thomas Addison, English physician (1793-1860).

period may also confirm the diagnosis. Cortisol response only occurs in secondary adrenal failure. The aetiology can be identified by tests for autoantibodies, x-ray of the abdomen or CT-scanning showing adrenal calcification.

### *Management*

Long term management is by hydrocortisone (cortisol) 20 mg in the morning and 10 mg in the evening. The dose may be adjusted by measuring cortisol throughout the day if problems develop. Similar clinical effects can be expected from the following doses of steroids: cortisone acetate 25 mg, prednisolone 5 mg and dexamethasone 0.5 mg.

Mineralocorticoid may not be required in some patients as the zona glomerulosa of the cortex sometimes is spared. If replacement is required, fludrocortisone 0.05-0.2 mg in a single dose is used. Ideally the optimum dose is that which maintains renin levels within normal limits. This assay is expensive and not universally available. It is usual practice to monitor blood pressure and electrolyte levels.

Patients with adrenal insufficiency should carry a card or a *Medicalert* bracelet or necklace with details of the diagnosis and treatment. They must be advised to double or triple the dose of hydrocortisone during injury or febrile illness. Some physicians suggest they should be given ampoules of glucocorticoid for self-injection or glucocorticoid suppositories to be used in the case of vomiting.

### *Operational implications*

An individual receiving adequate substitution therapy should have no problems in a command situation. However, both the individual and his colleague should be aware of the possibility of stress-induced relapse.

### *Aeromedical considerations*

*The applicant may be certificated in any category with a specific proviso that therapy must be supervised by an endocrinologist with semi-annual review.*

## **Conn's syndrome<sup>9</sup>**

This syndrome is an extremely rare condition consisting of adenoma, carcinoma or hyperplasia of the zona glomerulosa of the adrenal cortex, resulting in excessive production of aldosterone and leading to sodium retention and renin suppression. The symptoms and clinical signs include muscle weakness, polyuria, hypertension, hypokalaemia, alkalosis, retinopathy, intermittent paralysis, cardiac arrhythmias, paraesthesiae, tetany-like symptoms, and psychiatric disturbances. It is slightly more frequent in women and usually occurs in patients 30 to 50 years of age. It is found in one per cent of those who present with mild hypertension and hypokalaemia. It can present with hypokalaemic paralysis, especially in the Chinese. If the hypertension has been treated with thiazide, this will obviously worsen the hypokalaemia. In over 80 per cent of cases, this syndrome is associated with an aldosterone producing adenoma or carcinoma.

### *Investigation*

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<sup>9</sup> Conn's syndrome: primary hyperaldosteronism. Named after Jerome W. Conn, American internist (1907-1981)

Repeated plasma potassium taken with care to avoid haemolysis. If confirmed, it is then appropriate to measure plasma aldosterone and renin activity. In Conn's syndrome, aldosterone levels would be elevated and the renin suppressed. An abdominal CT-scan or MRI may be helpful in visualising an adenoma.

#### *Treatment*

If an adenoma is demonstrated, the definitive treatment is surgical removal. If bilateral hyperplasia is the problem, the best treatment is with the aldosterone antagonist spironolactone. If glucocorticoid remedial hypertension is suspected, 2-3 weeks of dexamethasone may be given.

#### *Operational implications*

*Individuals with active Conn's syndrome with hypokalaemia and hypertension are unfit for all aviation duties.*

#### *Aeromedical considerations*

*If an adenoma is diagnosed and removed, the applicant is cured and medical certification should not be a problem with regular endocrinology follow-up. If the patient is on long term spironolactone, individual assessment is appropriate with full endocrinology reports to aid the decision on medical certification.*

## **ADRENAL MEDULLA**

### **Phaeochromocytoma**

#### *Aetiology and Pathogenesis*

The phaeochromocytoma is a tumour secreting catecholamines. It is a rare tumour, the figure often quoted is 0.1 per cent of cases of hypertension. Recent data suggests the prevalence may be higher. The tumours are usually found in the adrenal medulla, ten per cent being bilateral. However, ten per cent arise in extra-adrenal chromaffin tissue, usually in the sympathetic chain in the abdomen, but can be found anywhere in the sympatho-adrenal system from the neck to the urinary bladder. In multiple endocrine neoplasia syndrome, it is associated with medullary carcinoma of the thyroid and hyperparathyroidism. These syndromes are inherited as autosomal dominance; they are rare to aviation medicine practice.

#### *Symptoms and Signs*

- a) paroxysmal hypertension
- b) postural drop (volume depletion) attacks with pallor
- c) flushing
- d) palpitations, sweating, headache,
- e) angor animi
- f) abdominal pain, constipation
- g) weight loss, glucose intolerance

#### *Investigation*

Diagnosis is made by measurement of plasma adrenaline/noradrenaline or their metabolites vanillyl-mandelic acid (VMA), metanephrins and nor-metanephrins. The excretion may be paroxysmal and thus repeated sampling is mandatory.

Tumour imaging can be by ultrasound or CT-scanning, but scanning by MRI is superior as the T2-weighted image is usually intense. Radioisotope scanning with <sup>131</sup>I - MIBG (meta-iodobenzyl guanidine) is helpful in the demonstration of an ectopic site. This isotope is preferentially taken up by adrenergic cells.

#### *Treatment*

Surgery is the treatment of choice and is curative in some 75 per cent of cases. Before surgery, the patient must be fully  $\alpha$ - and  $\beta$ -blocked. Once the diagnosis is made, pharmacological treatment should be started. The drug of choice is the  $\alpha$ -adrenergic blocking agent phenoxybenzamine (10-20 mg twice daily) or doxazosin (1-2 mg twice daily), followed a few days later by a  $\beta$ -blocker, e.g. propranolol (10 mg twice daily). Approximately two weeks should be allowed to replace volume before surgery. When surgical removal is not feasible or has been incomplete, continued pharmacological treatment can be quite successful.

#### *Operational implications*

*Following successful surgery with complete removal of the tumour and no significant end organ damage, medical certification should be possible after a six-month period of observation.*

It is important to consider the possibility of recurrent tumour or malignant activity should hypertension again become a problem.

#### *Aeromedical considerations*

*The applicant can probably be certificated in any class if physically and biochemically normal. In common with all previous conditions, close surveillance by the aeromedical officer and an endocrinologist is mandatory.*

## **DIABETES MELLITUS**

Annex 1 specifies in Chapter 6 that:

6.3.2.16 Applicants with insulin-treated diabetes mellitus shall be assessed as unfit.

6.3.2.16.1 Applicants with non-insulin-treated diabetes mellitus shall be assessed as unfit unless the condition is shown to be satisfactorily controlled by diet alone or by diet combined with oral anti-diabetic medication, the use of which is compatible with the safe exercise of the applicant's licence and rating privileges.

#### *Introduction*

The guidance material contained in this section does not have any regulatory status beyond that of the medical provisions cited above. Its main purpose is to aid in the implementation of the medical provisions of Annex 1. It contains methods for comprehensive evaluation and assessment of applicants in whom there is a suspicion or overt manifestation of diabetes. The aim is to eventually achieve international uniformity of procedures which will allow comparison of data to assist in the assessment of aeromedical borderline cases. The prevalence of diabetes has increased over the past 100 years and the condition is

now common, affecting approximately three per cent of the population and increasing with age. There are a number of sound reasons why diabetes is one of the most common chronic disorders in the industrialized world. The life expectancy of the general population including diabetics with improved quality of control is increasing. In addition, the current high standard of living has led to a higher intake of calories accompanied by a lower level of physical activity, resulting in an increased prevalence of obesity. Contributing to the decrease in physical activity may be the dependency by many on private or commercial transport. Health screening programmes for the general population have also contributed to a perceived increase in the prevalence of diabetes by diagnosing a number of diabetics at an early stage. In obstetrics, it is now common practice to screen pregnant women for diabetes; those found to be diabetic are carefully monitored and controlled, and the resulting fall in perinatal mortality contributes to an increased number of offspring who will continue to transmit the disease. Routine periodic medical examinations of licence holders contribute to the early detection of diabetes in otherwise healthy individuals without subjective symptoms of disease. This also contributes to the increased prevalence in the aviation medicine practice.

To obtain accurate figures of prevalence, however, it is important that diagnosis of diabetes is equally accurate. With a glucose tolerance test using a 75 g glucose load and by applying the interpretation described by the WHO guidelines – see below – an accurate initial diagnosis can be made.

This section also contains guidance material on the acceptability of oral anti-diabetic therapy.

### *Definition*

Diabetes may be defined as a metabolic disease with some genetic predisposition which is characterised by an impaired ability to break down, store and utilise carbohydrates effectively. This may be due to failure of production of insulin from the beta-cells in the islets of Langerhans<sup>10</sup> in the pancreas or the presence of insulin resistance impeding the action of the endogenously produced hormone.

### *Aetiology and pathogenesis*

The precise aetiology of diabetes remains unknown, but there are many theories including antigenetic, autoimmune and viral causes, all with a common result: the destruction of the pancreatic beta-cells resulting in impaired production of insulin in response to glucose ingestion. Many factors may be simultaneously involved in an individual developing diabetes including obesity, pregnancy, infection and other mechanisms which might determine the onset of the disease in genetically predisposed individuals.

### *Symptoms*

Lack of insulin results in a disruption of the normal metabolic processes of all dietary elements including protein, carbohydrate and fat. The resultant metabolic upset causes water and electrolyte disturbance. The classic symptoms of insulin deficiency are characterised by polyuria, polydipsia, weight loss, itching, and a predisposition to chronic infection of the external genitalia. In severe cases that go on untreated, this may result in profound dehydration, raised blood sugar and ketoacidosis. This severe metabolic upset is a relatively rare presentation and is characteristic in the young insulin-dependent individual. In middle aged aircrew mild diabetes is often asymptomatic and detected at routine medical examination by the presence of glycosuria. In the older group diabetes may present with a vascular disorder or visual problems.

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<sup>10</sup> Islets of Langerhans: cellular masses in the interstitial tissue of the pancreas, composed of five different cell types that make up the endocrine portion of the gland, producing insulin, glucagons, somatostatin, pancreatic polypeptide and gastrin. Named after Paul Langerhans, German pathologist (1847-1888)

### *Diagnosis*

The diagnosis of diabetes mellitus requires a demonstration of abnormal carbohydrate metabolism with the exclusion of other causes for this disturbance. The other causes which may disturb carbohydrate metabolism include hepatic disease, starvation and malnutrition, potassium depletion, and other endocrine diseases previously described such as acromegaly, Cushing's syndrome and thyrotoxicosis.

The diagnosis, as in any clinical condition, depends on an adequate clinical history and evaluation of the symptoms and physical findings supported by laboratory examination using internationally agreed standards.

### *Glycosuria*

Glycosuria alone is not a reliable index and does not correlate well with circulating levels of blood sugar in many individuals. Some 45 per cent of the population have a low renal threshold for glucose and may present with glycosuria with normal circulating blood glucose.

### *Biochemical criteria for diagnosis*

In severe cases a random or a fasting blood glucose test may be diagnostic, but random blood sugar tests often produce uncertain results and in view of the career implication for aircrew members, a glucose tolerance test should be carried out. The criteria for diagnosis following a 75 g glucose load has been standardised by the WHO and were modified in 1999. The diagnostic levels are shown in Table 1.

**Table 1**

<b>Diagnostic criteria</b>	
<b>Condition</b>	<b>Blood glucose level</b>
Diabetes	fasting blood glucose: 7.0 mmol/L (126 mg/dL) and above or 2 hours after glucose load: 11.1 mmol/L (200 mg/dL) and above
Impaired glucose tolerance	fasting blood glucose: less than 7.0 mmol/L (126 mg/dL) and 2 hours after glucose load: 7.8 mmol/L (140 mg/dL) and above and less than 11.1 mmol/L (200 mg/dL)
Impaired fasting glucose	fasting blood glucose: 6.1 mmol/L (110 mg/dL) and above and less than 7.0 mmol/L (126 mg/dL) and 2 hours after glucose load: less than 7.8 mmol/L (140 mg/dL)
Modified from Definition, diagnosis and classification of diabetes mellitus and its complications. Report of a WHO consultation (WHO, Geneva, 1999) and the International Diabetes Federation	

IGT/IFG consensus statement (Unwin N, et al. International Diabetes Federation IGT/IFG Consensus Statement. Report of an Expert Consensus Workshop 1-4 August 2001, Stoke Poges, UK. Diabetic Medicine 2002; 19: 708-723)

Using these criteria, there are four diagnostic categories:

1. Normal
2. Impaired glucose tolerance
3. Diabetes
4. Impaired fasting glucose

The American Diabetes Association (ADA) has published new diagnostic criteria for diabetes, suggesting the diagnosis should be made with a fasting plasma glucose of  $>7$  mmol/L and impaired fasting glucose should be diagnosed when the fasting plasma glucose lies between 6.1 and 6.9 mmol/L. ADA also recommended abolishing the use of the oral glucose tolerance test. The WHO has retained the glucose tolerance test but have incorporated the lower fasting glucose level suggested by the ADA.

#### *Associated manifestations*

Micro- and macro-angiopathy are common consequences of diabetes. Micro-angiopathy classically affects blood vessels of the retina and the kidney. Macro-angiopathy affects the coronary circulation, and the incidence of coronary disease in the diabetic individual is approximately three times that of the non-diabetic population. This has obvious implications for aircrew. Neurological complications are probably the result of long standing metabolic upset but the pathogenesis is somewhat complex.

In type 1 diabetes the recent diabetic control and complications trial (DCCT) has shown clearly that good diabetic control can reduce the incidence of complications. More recently the UK prospective study on diabetes (UKPDS) has confirmed the benefit in those with type 2. It is thus essential in aircrew to reinforce the importance of good control of diabetes being the key element in management.

#### *Classification*

The classification of diabetes can essentially be divided into two categories; type 1 (insulin dependent diabetes) which presents in the young individual, and type 2 (non insulin dependent diabetes) which presents in the middle years.

#### *Treatment*

The goal of treatment in diabetes is to correct the metabolic disturbance and to improve the patient's quality of life by diminishing the long term complications. In type 1 diabetes the mainstay of treatment is insulin. In type 2 diabetes, treatment consists of dietary adjustment with the addition of oral hypoglycaemic agents as required. Insulin may be needed if adequate control is not achieved by these measures.

*When the diagnosis of diabetes is made, the licence holder will have to be removed from aviation duties and other safety-critical functions for a suitable period of time. The situation should then be reassessed after appropriate control has been achieved and a decision made based on relevant reports from the treating diabetologist/physician.*

#### *Operational implications of diabetes*

The risk in diabetic aircrew may be divided into those intrinsic to diabetes mellitus itself and those which are iatrogenic due to the therapeutic intervention in the disease process. The main risks, intrinsic to the disease process, are cardiovascular disease, visual problems, nephropathy and, to a lesser extent in the aircrew population, neuropathy. The only significant iatrogenic complication with profound implications in aviation is hypoglycaemia.

After assessment of the risks, a reasonable policy for medical certification must be established. The simple approach would be to disqualify all diabetic pilots. However, a more scientific approach can be developed from a cautious literature review, which can then be applied to the diabetic population and audited over time. The following section summarises the literature and discusses the development of a certification policy based on that literature.

### **Cardiovascular disease**

Premature vascular disease is one of the most common and serious complications of diabetes. The Whitehall Study (Fuller, 1980) showed that coronary heart disease mortality was approximately doubled for those with impaired glucose tolerance in a standard glucose tolerance test. Data from a number of studies suggest that the risk of cardiovascular disease is two to four times higher in patients with diabetes compared to those without, and that the annual rate of fatal and non-fatal cardiovascular disease among patients with type 1 diabetes (non-insulin dependent diabetes) is 2.5 per cent (Entmacher et al, 1964). The risk of cardiovascular disease is high, even at the time of diagnosis of type 2, and is independent of the duration of diagnosed diabetes, because diabetes is present for approximately seven to 12 years before formal diagnosis. Perhaps even before that time, patients would be classified as having impaired glucose tolerance, which from the Whitehall Study is associated with an increased risk of cardiovascular disease.

### **Nephropathy**

Kidney disease is a significant problem in the diabetic population. Nephropathy affects approximately 35 per cent of patients with type 1 diabetes and about 5 to 10 per cent of patients with type 2. Despite this lower prevalence in the latter group, the impact of renal disease caused by type 2 diabetes is substantially greater since type 2 diabetes is far more common than type 1, and cardio-vascular complications are the major cause of death in these patients. The importance of identifying those at risk of developing nephropathy, whether they are potential or active aircrew, lies in the finding that in type 1 patients with proteinuria the relative mortality from cardiovascular disease is almost 40 times that of the general population and in those without proteinuria only four times that (Borch-Johnson, 1987). Thus, the presence of nephropathy is a surrogate for cardiovascular disease.

There is evidence that the presence of micro-albuminuria (defined as urinary albumin excretion greater than 30 mg and less than 300 mg per 24 hours) may predict, with some accuracy, the development of diabetic nephropathy. Preliminary evidence is also available that therapeutic intervention with ACE inhibitors may halt this progression (Viberti et al, 1994). Thus, the measurement of micro-albuminuria is a useful adjuvant to risk assessment in the diabetic pilot.

### **Visual problems**

Approximately 80 per cent of flight information is accrued visually and thus any pathological process which interferes with visual function may result in human error and may contribute to an accident. Diabetes mellitus is known to affect all parts of the eye, e.g. cataract, retinal vein occlusion, ischaemic

optic neuritis and cranial nerve palsies resulting in diplopia. Diabetic retinopathy, however, is a highly specific vascular complication of diabetes mellitus and is estimated to be the most frequent cause of new blindness among adults between 20 and 74 years of age. Twenty years after the onset of the disease, almost all insulin dependent patients, and more than 60 per cent of those who are non-insulin dependent, have some degree of retinopathy (Klein et al, 1984). More than four fifths of cases of blindness among type 1 patients, and one third of cases among type 2 patients, are caused by diabetic retinopathy. Many forget that type 2 diabetes is not a benign disease, which has caused it to be called a *wolf in sheep's clothing*. The major determinants for the development of retinopathy are the quality of diabetic control and the duration of the diabetes.

## HYPOGLYCAEMIA

R D Lawrence<sup>11</sup> was a unique physician. He became a prominent specialist in a disorder from which he himself suffered most of his career. He was a meticulous physician and researcher and, in 1923, documented his first hypoglycaemic attack. He observed he felt *just a little shaky* some hours after injecting insulin and the next day was *slightly faint, dizzy, weak and tremulous*. He later wrote *I felt weak, sweaty, with an intense hunger which led me to the biscuit box and slow restoration. Obviously my first hypoglycaemic attack* (Lawrence, 1961). This description by Lawrence illustrates the dual symptomatology of this un-physiological state: a combination of neuroglycopenia and autonomic neural stimulation. Either of these symptom complexes may degrade pilot performance. A study carried out (Holmes, 1986) in type 1 patients subjected to modest hypoglycaemia of 3.1 mmol/L showed a decrement in performance which increased with the complexity of the task performed. In this and other studies researchers have shown that reaction times do not return to normal until some 20-30 minutes after euglycaemia has been restored. The implications in the aviation environment are self-evident.

As hypoglycaemia is a significant concern in the aviation environment, accurate risk assessment is vitally important. This requires good data on the incidence of hypoglycaemia in both insulin and non-insulin dependent patients. Such data, however, have proven difficult to obtain.

### Type 1 Diabetes

It is very difficult to assess the frequency of hypoglycaemia in insulin treated diabetic populations, because of the wide variation in severity and outcome. Another problem is the common occurrence of asymptomatic biochemical hypoglycaemia that is only evident if blood glucose is measured frequently, and the failure to recognise or record many mild episodes, including those during sleep. The development of diminished symptomatic awareness of hypoglycaemia also reduces the identification of episodes by the affected patient, and sometimes symptoms are attributed to hypoglycaemia when the blood sugar is not in fact low. The true prevalence of unawareness has been estimated at between three and 22 per cent (Heller et al, 1995).

Severe hypoglycaemia, defined by the need for external assistance to resuscitate the patient, is a more robust and consistent measure for estimating frequency and is reliable even in retrospective reporting. Where a similar definition for severe hypoglycaemia has been applied, the lowest annual prevalence is nine per cent, but the average is approximately 20-30 per cent. The higher figures come from studies in which the patients' relatives or other observers were asked about the symptoms, rather than the patients themselves. Despite the difficulties in assessment, the frequency of mild hypoglycaemia in one good

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<sup>11</sup> Robert Daniel Lawrence, English physician (1912-1964)

study was 1.6 episodes per patient per week, approximately 83.6 episodes per patient per year (Praming et al, 1991). This is an alarmingly high figure.

Strict glycaemic control, usually resulting from intensive insulin therapy, is recognised to be a risk factor for severe hypoglycaemia. In the Diabetes Control and Complications Trial (1993), strict glycaemic control was associated with a threefold increase in severe hypoglycaemia. The risk of severe hypoglycaemia increased continuously with lower monthly glycosylated haemoglobin values. Unfortunately, analysis of the glycosylated haemoglobin data did not support the prediction of a specific target value at which the benefits of intensive therapy were maximised and the risks minimised. Other risk factors for severe hypoglycaemia in the study were a longer duration of diabetes and a history of previous hypoglycaemia. Another worrying feature from the DCCT research group was that no warning symptoms were experienced in 36 per cent of severe hypoglycaemic episodes, which occurred while patients were awake. While loss of hypoglycaemic awareness is associated with strict diabetic control, it is also a complication acquired with increasing duration of diabetes, which may underline the emergence of age and duration of diabetes as risk factors for severe hypoglycaemia.

### **Type 2 Diabetes**

Type 2 diabetics can be managed on diet, diet and sulphonylureas, diet and biguanides or diet and a combination of sulphonylurea and biguanide. The alpha-glycosidase inhibitors, which have recently been introduced, may potentiate the hypoglycaemic effect of a sulphonylurea. Increasingly the glitazones, which enhance the sensitivity of the insulin receptor, are being used as monotherapy or in combination with the agents above. Thus, in assessing the risk of hypoglycaemia, it is vitally important that the precise therapeutic regime of the diabetic is detailed.

Severe hypoglycaemia associated with sulphonylureas is well documented, but the frequency of mild hypoglycaemia not requiring urgent hospital admission is more difficult to assess, because symptoms are often brief and many patients treated with oral agents have poor knowledge of the symptoms of hypoglycaemia. Despite these difficulties, trials have recorded an incidence of symptomatic hypoglycaemia ranging from 1.9 to seven per cent per annum. A study by Jennings et al. found a prevalence of symptomatic hypoglycaemia of the order of 20 per cent when using direct questioning of the patients and the relatives. When assessing risk, it is important to know which agent the patient is on, since the risk of sulphonylurea induced hypoglycaemia appears to be greater for some agents than others. Taking the incidence of hypoglycaemia among patients treated with chlorpropamide as 100, the standardised incidence ratios are 111 for glibenclamide, 46 for glipizide and 21 for tolbutamide (Berger et al, 1986). There is no mathematical formula, neither simple nor complex, which predicts with certainty hypoglycaemia in sulphonylurea treated patients. The risk factors for sulphonylurea induced hypoglycaemia are primarily:

- a) age over 60
- b) impaired renal function
- c) poor nutrition and, often forgotten,
- d) multi-drug therapy.

Since the withdrawal of phenformin in the early 1970s, due to the incidence of metabolic acidosis, the only biguanide in use in the United Kingdom is metformin. Its mechanism of action does not involve the stimulation of insulin secretion and it does not cause hypoglycaemia. A rare, but serious side-effect of metformin is metabolic acidosis. The incidence has been recorded as 0.04 cases per 1 000 patient years, with a mortality of 0.024 per thousand patient years (Berger, 1985). The mortality risk from metformin

induced lactic acidosis has been estimated to be not significantly different from that of sulphonylurea induced hypoglycaemia (Berger, 1986). The risk of metabolic acidosis may be almost eliminated by not exceeding 2.5 g per day and excluding patients with any renal or hepatic insufficiency.

In summary, therefore, the sulphonylureas carry a risk of hypoglycaemia which lies outside the usually accepted one per cent per annum (see 1% Rule, Part I, Chapter 3). Metformin does not cause hypoglycaemia and it carries a risk of metabolic acidosis which is acceptable in appropriately selected pilots.

### *Aeromedical considerations*

#### **Diet control**

Hypoglycaemia is not the issue in the risk assessment in this group of pilots. The main area of concern is the vascular tree, for the reasons previously discussed. If the diet controlled diabetic is to be returned to flying, and his fitness status maintained, a screening for coronary disease is important. The gold standard for diagnosing coronary artery disease is coronary angiography; this method, however, is not without risk and cannot be repeated on a regular basis. The resting ECG alone lacks the sensitivity and specificity required in this group of high risk patients and it is thus logical to use a non-invasive technique which will predict coronary artery disease with somewhat greater sensitivity than the resting ECG tracing. The exercise ECG is a useful diagnostic tool on selected patients. It is not of value as a routine method for general screening, as the prevalence of coronary artery disease in the pilot population over all is low.

*If the exercise ECG is normal, a diet-only controlled diabetic pilot with good quality control and no overt complications may return to flying subject to an annual assessment with an exercise ECG and a satisfactory report from the treating diabetologist/ physician.*

The newer agents, e.g. the  $\alpha$ -glucosidase inhibitors such as Glucobay, are acceptable as an adjuvant to diet.

#### **Biguanide control**

*A similar certification policy applies in this group. However, those pilots treated with metformin tend to be overweight and do carry a small albeit acceptable risk of lactic acidosis; their overall risk is slightly greater than the diet only patient. Their assessment requires exemplary diabetic control and annual review, to include an exercise ECG and, if this is satisfactory, they may be returned to flying with limitation to multi-crew operations.*

#### **Diet and sulphonylurea control**

The incidence of hypoglycaemia on sulphonylureas in the diabetic does not meet the one per cent per annum level previously described, and thus these pilots are not normally acceptable for recertification in commercial operations.

#### **Diet and glitazone control**

These drugs, more properly known as thiazolidenediones, enhance the sensitivity of the insulin receptor, and when used as monotherapy do not cause hypoglycaemia. They are, therefore, acceptable for certification. In combination with metformin and/or sulphonylureas hypoglycaemia is common and this regime is not normally acceptable for certification.

## CRITERIA FOR SATISFACTORY CONTROL FOR AVIATION DUTIES

*It is essential that aircrew have satisfactory control before being returned to the operational environment. They should be free from diabetic symptoms and maintain good nutrition.*

Their metabolic control should be good and should not focus solely on blood glucose. In order to decrease cardiovascular risk, a holistic approach should be taken. The targets for the relevant parameters are shown in Table 2.

**Table 2**

<b>Good control</b>	
Glucose:	
Fasting	< 6.7 mmol/L
Post-prandial peak	< 9.0 mmol/L
HbA1c	< 7.0%
Blood pressure	130/80 mmHg
Total cholesterol	< 4.8 mmol/L
LDL-C	< 2.5 mmol/L
Triglycerides	< 2.3 mmol/L
HDL-C	> 1.0 mmol/L

*The key to returning diabetic aircrew to aviation duties safely is to use evidence-based medicine to avoid incapacitation in the aviation environment.*

The aviation physician must liaise closely with the endocrinologist treating the aircrew, in order that the benefits of both disciplines can be consolidated to produce a fair and objective assessment. All policies for certification should be audited regularly in the light of developments in the world literature and modified accordingly.

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## Part III

### Chapter 5. HAEMATOLOGY

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## INTRODUCTION

In the introductory chapters of this manual, the basic principles for the assessment of an applicant's medical fitness are outlined.

The general provisions of Annex 1, 6.2.2, state that an applicant shall be required to be free from any abnormality, disability, etc., such as “would entail a degree of functional incapacity which is likely to interfere with the safe operation of an aircraft or with the safe performance of duties.”

The fitness requirements referring specifically to haematology are detailed for Class I Medical Assessment in Annex 1, 6.3.2.17 (and in the corresponding paragraphs of Chapter 6 for Class 2 and Class 3 Medical Assessments).

6.3.2.17 Applicants with diseases of the blood and/or the lymphatic system shall be assessed as unfit unless adequately investigated and their condition found unlikely to interfere with the safe exercise of their licence and rating privileges.

*Note.— Sickle cell trait or other haemoglobinopathic traits are usually compatible with a fit assessment.*

Applicants with haematological conditions should be considered on an individual basis depending on the problem, its cause and natural history. The overriding concern is that the blood must carry sufficient oxygen to satisfy metabolic requirements at rest, during exertion and anxiety, both at ground level and at altitude.

## ANAEMIA

Anaemia is a condition in which the haemoglobin concentration in the blood is below a defined level, generally 13 g/L for men and 12 g/L for women, resulting in a reduced oxygen-carrying capacity of red blood cells. About half of all cases of anaemia can be attributed to iron deficiency; other common causes include infections, such as malaria and schistosomiasis, and genetic factors, which result in thalassaemias and sickle-cell disease. In its severe form, anaemia is associated with fatigue, weakness, dizziness and drowsiness.

In those who fly, the reduced oxygen tension associated with altitude exacerbates the effects of anaemia. Applicants whose haemoglobin is less than normal should be further investigated. The final assessment would be dependent on the results of the investigation and the response to the treatment, if any. It is difficult to specify a threshold value of haemoglobin below which certification can no longer be granted. There is considerable variability of intolerance according to whether anaemia is chronic or acute as the body can adapt to anaemia by increasing its production of haemoglobin F and 2,3-DPG<sup>1</sup> which enhances oxygen affinity.

*Even so, those with a haemoglobin concentration below 10.5 to 11 g/L should be considered as not meeting the standards. If the anaemia is caused by thalassaemia minor or any other haemoglobinopathic trait, and the applicant has full functional capability and no history of crises, a fit assessment is usually possible.*

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<sup>1</sup> 2,3-DPG: 2,3-diphosphoglycerate

## GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PD) DEFICIENCY

G6PD deficiency is an X-linked recessive hereditary disease featuring non-immune haemolytic anaemia in response to a number of causes. The classic reaction to consumption of broad beans (*Vicia faba*) has led to the commonly used term “favism”, derived from the Italian name of the broad bean (*fava*).

Almost all patients are male, although some female carriers can be clinically affected. The most common clinical symptoms are chronic anaemia due to a continuous haemolytic process and haemolytic crises in response to certain medicines and certain foods, most notably broad beans. Also infections and diabetic ketoacidosis may give rise to a crisis, and very severe crises can cause acute renal failure. Many medicines have been linked to G6PD, in particular primaquine, sulphonamides, glibenclamide and nitro-furantoin.

*In some parts of the world, a screening test for G6PD is part of the initial medical examination for certification. However, G6PD deficiency is not necessarily a bar to certification provided the haemoglobin level is stable and the pilot is well aware of what foods and medicine should be avoided.*

## ERYTHROCYTOSIS

Applicants with higher than normal haemoglobin should be further investigated.

Traditionally, the term ‘polycythaemia’ has been used about several disorders with an increase in circulating red blood cells but ‘erythrocytosis’ is a better and more correct term. Applicants with a persistently raised venous haematocrit (>0.52 males, >0.48 females for > 2 months) should be investigated by measurement of their red cell mass (RCM). Normally RCM is expressed as mean predicted value based on surface area. The diagnosis of absolute erythrocytosis is made when an individual’s measured RCM is more than 25 per cent above their mean predicted value. The term ‘relative erythrocytosis’, where RCM is within the normal range and plasma volume is reduced, should be reserved for states of dehydration. ‘Apparent erythrocytosis’ is the term used for those individuals who have a raised venous haematocrit but with a red cell mass within the reference range.

It is important to distinguish between primary erythrocytosis which is a myeloproliferative disease and secondary erythrocytosis due to other conditions.

People living at high altitude (e.g. Mexico City) must be expected to have secondary erythrocytosis with an elevated haemoglobin and haematocrit. In cases of secondary erythrocytosis due to lung disease or cyanotic heart conditions, the underlying pathology would have a greater bearing on the final assessment than the erythrocytosis per se.

*Primary erythrocytosis, in particular polycythaemia rubra vera, should normally be considered disqualifying owing to its propensity to thromboembolic complications, cerebro-vascular accidents and its rapid, unpredictable progression. Depending on the results of a specialist’s report and response to treatment, primarily venesection, aspirin and cyto-reductive medication, selected cases may be considered for restricted certification.*

## ACUTE LEUKAEMIA

*Acute leukaemia of any type should be considered disqualifying. Depending on the specialist’s report, cases in remission may be considered for restricted certification.*

However, treatment of leukaemia often involves use of very toxic medicines as well as high doses of radiation or even bone marrow transplantation. Some antineoplastic medicines are known to be cardiotoxic, especially anthracyclines like doxorubicin and daunorubicin. Particular attention therefore needs to be paid to applicants with a previous history of successful leukaemia treatment to exclude the long-term consequences of such treatment, which can include subtle cardiac abnormalities, pulmonary fibrosis, cataracts, and endocrine dysfunction (including hypothyroidism).

## CHRONIC LEUKAEMIA

Chronic myeloid leukaemia (CML), like other myeloproliferative diseases, is usually an aggressive condition with very high white cell counts and systemic illness, associated with an enlarged spleen with the risk of splenic infarction and spontaneous or traumatic rupture. The typical course of CML is progression over three to five years with development of an acute blast crisis in the final stage.

*An applicant with a confirmed diagnosis of CML should normally not be considered for certification. In the early stages of the disease, restricted certification may sometimes be possible, provided there is no haemolytic anaemia and no requirement for chemotherapy or corticosteroids. Frequent review by an haematologist is necessary.*

Chronic lymphocytic leukaemia (CLL) is a relatively benign condition which often requires no treatment.

*Applicants with CLL may be assessed as fit provided they remain well and do not need any medication although periodic review by an haematologist would be indicated.*

## LYMPHOMAS

Applicants with lymphoma should be considered on an individual basis.

*Lymphomas in remission, especially Hodgkin's Disease<sup>2</sup>, may be considered for restricted certification after a disease-free period of at least two years after completion of treatment. Certification should be dependent on regular annual specialist's reports.*

## BLEEDING AND THROMBOTIC DISORDERS

*Applicants with a thrombocytopenia under  $75\,000/\text{mm}^3$  ( $75 \times 10^9/\text{L}$ ) are unfit for certification. The condition may be temporary, e.g. in persons with iron deficiency anaemia or alcoholic bone marrow suppression, and in such cases a fit assessment is possible once the thrombocyte count is normalized. Applicants with idiopathic thrombocytopenic purpura, treated by splenectomy and with stable platelet counts for six months, may be considered for certification after cessation of therapy. Platelet counts should be repeated every six months.*

*Applicants with an inherited coagulation disorder or any history of factor replacement should normally be considered unfit for certification. However, bleeding disorders are classified as severe, moderate and mild according to the level of the deficient factor. Severe and moderate cases of factor VIII deficiency (classical haemophilia) entails unfitness for professional flying. Mild cases of haemophilia may be considered if there*

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<sup>2</sup> Hodgkin's disease: a form of malignant lymphoma, characterised by painless, progressive enlargement of the lymphnodes, spleen and general lymphoid tissue. After Thomas Hodgkin, English physician (1798-1866).

*is no history of significant bleeding episodes. Also mild cases of von Willebrand's disease<sup>3</sup> may be compatible with certification.*

*A history of deep vein thrombosis requires a full haematological investigation for underlying pathology before certification. A history of pulmonary embolism entails unfitness until at least six months after the completion of the anticoagulant therapy. Applicants with recurrent pulmonary embolism are unfit.*

*The use of oral anticoagulant medicines such as coumarin and warfarin is always incompatible with certification. The use of low molecular weight heparine in low dose may be considered acceptable by the Medical Assessor. The use of anti-platelet agents such as acetylsalicylic acid (Aspirin®) in low dose is not disqualifying whereas use of more potent anti-platelet agents such as clopidogrel is a bar to flying.*

## **HAEMOGLOBINOPATHIES**

The haemoglobinopathies and allied disorders, which all result from inherited abnormalities that affect the function of human red blood cells, have potentially important effects with regard to medical fitness of licence applicants.

Amongst the haemoglobinopathies, one such condition found predominantly and in varying proportions in Africa, in the Mediterranean littoral and also in southern India is sickle-cell disease. Collectively known under this name are the homozygous state, sickle-cell anaemia, and heterozygous combinations of the sickle-cell gene with genes for other abnormal haemoglobin and for thalassaemia. The heterozygous combination of normal haemoglobin with sickle-cell haemoglobin is known as sickle-cell trait (AS) which must not be confused with sickle-cell disease.

The single most important qualitative haemoglobinopathy is sickle-cell anaemia. The most prevalent quantitative haemoglobinopathy is  $\beta$ -thalassaemia, which has a world-wide distribution.

### **Sickling conditions**

Sickling conditions are those in which red cells containing Hb S undergo the sickling deformation on deoxygenation. Hb S transports oxygen normally, and is harmless except for the effects produced by sickling of the erythrocytes. The clinical manifestations are the result of intravascular sickling, and if this phenomenon is prevented there is no evidence of disease. The occurrence of intravascular sickling depends on the degree of deoxygenation of the haemoglobin, which is largely determined by the oxygen tension and pH in the various local areas of the vascular system; the tendency to sickling is also affected by the concentration of Hb S in the red cells, and by the presence of other haemoglobins that may interact with Hb S. The sickling of red cells in the circulating blood has two major pathological effects:

- a) The deformed and elongated erythrocytes are rigid and their cell membrane is damaged; as a result, the sickled red cells are removed rapidly from the circulation by the reticuloendothelial system, producing haemolytic anaemia.
- b) The misshapen cells lack normal plasticity; they block small blood vessels, impairing blood flow and the delivery of oxygen, so that ischaemia and infarctions may occur in the tissue served by the occluded vessels. Vascular occlusions tend to occur in those areas in which conditions of blood flow and low oxygen tension enhance the tendency of erythrocytes to sickle, notably in the spleen and

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<sup>3</sup> von Willebrand's disease: a congenital bleeding disorder, caused by deficiency of von Willebrand's factor (factor VIII-related antigen) and characterized by increased bleeding after trauma and surgery. Called also angiohaemophilia and pseudohaemophilia. After Erik von Willebrand, Finnish physician (1870-1949).

bone marrow, although any vascular area may be involved. Local pain, functional impairment, and other clinical manifestations are attributable to the vascular blockade.

### ***Sickle-cell disease***

Splenic infarctions have repeatedly been reported occurring in flight due to sickling of red blood cells.

*Sickle-cell disease, which includes sickle-cell anaemia (SS), sickle-cell haemoglobin C disease (SC), sickle-cell thalassaemia (STh), sickle-cell haemoglobin D disease (SD) and other pathological genotypes involving haemoglobin S with other genetic variants, is disqualifying for flying.*

### ***Sickle-cell trait***

A clear distinction must be made between sickle-cell **disease** (SS, SC, SD and STh) and sickle-cell **trait** (AS). The diagnosis of sickle-cell trait should be based on the following findings (including results from sickling tests): the patient should not be anaemic, and should have normal red cell morphology, normal levels of haemoglobin F, and a haemoglobin electrophoretic pattern of haemoglobins A and S in which A predominates (i.e. the concentration of Hb S is less than 45 per cent of total haemoglobin).

*There is no reason to impose any limitations whatsoever on applicants with sickle-cell trait.*

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**PART III**  
**Chapter 6. URINARY SYSTEM**

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## Chapter 6. URINARY SYSTEM

### INTRODUCTION

The introductory chapters of this manual outline the basic principles of the assessment of an applicant's medical fitness. The requirements referring specifically to the urinary system are detailed in Annex 1, paragraphs 6.3.2.18 to 6.3.2.19.1 for Class 1 Medical Assessments (and corresponding paragraphs 6.4.2.18 to 6.4.2.19.1 for Class 2 and 6.5.2.18 to 6.5.2.19.1 for Class 3):

6.3.2.18 Applicants with renal or genito-urinary disease shall be assessed as unfit, unless adequately investigated and their condition found unlikely to interfere with the safe exercise of their licence and rating privileges.

6.3.2.18.1 Urine examination shall form part of the medical examination and abnormalities shall be adequately investigated.

6.3.2.19 Applicants with sequelae of disease of or surgical procedures on the kidneys or the genito-urinary tract, in particular obstructions due to stricture or compression, shall be assessed as unfit unless the applicant's condition has been investigated and evaluated in accordance with best medical practice and is assessed not likely to interfere with the safe exercise of the applicant's licence or rating privileges.

6.3.2.19.1 Applicants who have undergone nephrectomy shall be assessed as unfit unless the condition is well compensated.

Based on these requirements, an applicant should not be assessed as fit when signs or symptoms of urological or genitourinary disease are present that might interfere with flight safety. Any transient condition of the urinary system should be considered a decrease in medical fitness until recovery. These statements are consistent with the general provisions of Annex 1, paragraph 6.2.2, which state that an applicant for any class of Medical Assessment shall be required to be free from any abnormality, disability, sequelae from operation, etc. "such as would entail a degree of functional incapacity which is likely to interfere with the safe operation of an aircraft or with the safe performance of duties."

The urine should not contain any pathological element. Proteinuria should always be an indication for additional medical investigation, but need not be disqualifying for aviation duties. Further discussion of proteinuria, and specifically albuminuria, is found in the nephrology section of this chapter.

Sequelae of disease or surgical procedures on the kidneys and urinary tract, liable to cause sudden incapacitation are disqualifying for aviation duties. The examiner should seek urological consultation for any history of major surgery involving a partial or total excision or diversion of a urinary system organ in order to assess the condition's propensity for sudden incapacitation. Obviously, a degree of interpretation and evaluation must be exercised by the medical examiner and the medical assessor, often in collaboration with a consultant. Not only medical but also environmental and operational factors should be taken into consideration for the overall assessment of an applicant's medical fitness.

In this chapter, the aeromedical concerns commonly associated with genitourinary disease will be reviewed. In particular, the following conditions will be considered with respect to the disease process, diagnosis and treatment, and aeromedical implications and disposition:

- Renal calculus disease
- Haematuria of urological aetiology
- Incontinence
- Urological infection

Renal cystic disease  
Scrotal problems  
Benign prostatic hyperplasia and hypertrophy  
Urinary malignancy

## **Urology**

Urology is the discipline that specializes in the surgical and medical care of the urinary system in females and genitourinary system in males. The genitourinary system is multifaceted in that vascular, hormonal, barometric, and traumatic perturbations have significant influences on the overall function of its organs. From renal calculus disease to malignant transformation, the genitourinary system may have multiple diagnoses than can affect the pilot.

## **RENAL CALCULUS DISEASE**

### **Overview**

Urinary calculi can arise from anywhere along the urinary tract, with clinical manifestations varying with size, configuration, nature, and location of calculi. Small stones (<5 mm) with smooth contours can be expected to pass spontaneously, albeit with potentially incapacitating symptoms such as severe pain, nausea, profuse sweating (diaphoresis), or shock, all of which are clearly incompatible with safe flying. Larger stones typically require surgical intervention.

### **Clinical features**

Renal calculus disease can be identified in many age groups. The incidence of upper urinary tract stones in aircrew appears, however, to be highest during the fourth and fifth decades. Symptoms may be absent or may range from the negligible to the most excruciating pain. The attack can develop slowly and steadily or become suddenly incapacitating. Renal colic commonly arises gradually with flank, abdominal, back or groin pain. Although an episode that proceeds slowly may be recognized by those who have previously experienced renal colic, a rapid onset may lead to incapacitation during flight.

Renal pain is caused by acute distension of the renal capsule, resulting in focal symptoms at the ipsilateral costo-vertebral angle. This pain may radiate anteriorly towards the abdomen, umbilicus or ipsilateral testis or labium. It may be described as paroxysmal or colicky, owing to ureteral peristalsis against an obstruction, or steady, more commonly caused by an inflammatory process. Renal colic may present with gastrointestinal symptoms such as nausea and emesis secondary to reflex stimulation of the coeliac ganglion or proximity of adjacent organs. Renal pain typically has no association with peritoneal signs or diaphragmatic irritation.

Obstruction of the ureter may result in acute hyper-peristalsis, spasm of ureteral smooth muscles, and marked distension. This triad will result in acute ureteral symptoms, which can commonly be determined by the locus of the referred pain. Mid-ureteral pain may mimic appendicitis on the right (McBurney's point<sup>1</sup>) or diverticulitis on the left. Lower ureteral obstruction may induce ipsilateral scrotal or labial symptoms as in renal pain above. However, it may also cause vesical symptoms, which include

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<sup>1</sup> McBurney's point: a point about 5 cm superomedial to the anterior superior spine of the ilium, on a line joining that process and the umbilicus, where pressure elicits tenderness in acute appendicitis. After Charles McBurney, American surgeon (1845-1913).

irritability, frequency, urgency, and urethral pain. Patients with calculus obstruction usually have difficulty finding comfortable positions. These patients commonly sit, stand, or pace up and down the room without pain relief.

In general, fever is an uncommon sign in ureteral obstruction but blood pressure and pulse are often elevated. Emergency urinary diversion may be necessary in the setting of an obstructive calculus with fever. Immediate intervention and rapid relief of obstruction are mandatory to prevent urosepsis and urological demise. Relief can be accomplished with ureteral stenting or placement of a percutaneous nephrostomy tube.

## **Diagnosis**

Early assurance of normal blood pressure, pulse and body temperature is paramount when renal calculus disease is diagnosed. An evaluation of the renal function based on creatinine studies and urinalysis is also necessary. The urinalysis may commonly reveal moderate to severe micro-haematuria. Marked pyuria or bacteriuria and the presence of nitrite or leukocyte esterase should raise suspicion of an infected and possibly obstructed stone.

After initial evaluation and stabilization, the expeditious anatomical diagnosis and complete resolution of all renal or ureteral stones is mandatory in a licence holder. Diagnostic procedures such as stone analysis, urine pH, 24-hour urine collection, and serum studies are necessary to understand the source of the stone disease. Urine culture should be performed even in the absence of other signs of acute infection in order to rule out an occult infectious process. Radiographic studies are also important for further functional and anatomical evaluation of a possible obstructing calculus.

Of all the available radiographic studies, plain film radiographs of the kidneys, ureters and bladder are the initial choice. Calcium-containing calculi may have various degrees of opacity, with calcium apatite having the highest radiodensity. Radiolucent stones, which are difficult to see in plain films, may be identified by non-contrast enhanced computed tomography (CT). Pure indinavir stones are not visible on CT radiographs but are of little aeromedical concern as only patients treated for human immunodeficiency virus (HIV) infection are taking protease inhibitors such as indinavir.

The intravenous urogram (IVU) is the urological “gold standard” radiographic study for patients with renal colic. This study can provide both functional and anatomical information to guide the treatment of a licence holder with a urinary calculus. Delayed contrast uptake into the renal parenchyma may reveal an acute obstructive picture commonly known as the “obstructive” nephrogram. Further radiographic signs of acute obstruction may include dilation of the collecting system, ipsilateral renal enlargement, and even fornical rupture with urinary extravasation. Chronic obstruction may present with a dilated, tortuous ureter, renal parenchymal thinning, crescentic calyces, and a “soap bubble” nephrogram.

Although IVU provides a wealth of information in this disease process, computed tomography has in recent years become the standard means for emergent evaluation of patients with renal colic. Its current ubiquity, low risk of morbidity from contrast reactions, and speed make it an excellent choice for early diagnosis. Helical or spiral CT scanning does not require contrast agents, is cost-effective, and will reveal the vast majority of renal and ureteral stones. Furthermore, CT imaging can also assist with detection of non-urological abnormalities that can mimic renal colic, such as acute appendicitis, ovarian disease or other intra-abdominal diseases.

Additionally, other radiographic studies may be useful in diagnosis of renal lithiasis, either alone or as an adjunct to the above studies. Ultrasonography is a commonly used tool in patients that should not receive contrast or be exposed to radiation (e.g., because of pregnancy). Diuretic renography has less utility, but

other studies such as Doppler ultrasonography<sup>2</sup> with renal resistive indices, magnetic resonance imaging (MRI), and retrograde pyelography are excellent diagnostic tools and may be performed following appropriate consultation.

### **Causes of renal lithiasis**

The majority of renal stones are composed of calcium oxalate. Inciting aetiologies may include hypercalcaemia from hyperparathyroidism or other medical causes, idiopathic hypocalcuria, low urinary citrate, hyperoxaluria, and hyperuricosuria. Additional types of stones result from infectious sources (struvite stones), elevated uric acid (urate stones), renal tubular acidosis (calcium phosphate), cystinuria (cysteine stones), and even from medication for treatment of HIV (indinavir stones).

### **Management**

Parenteral narcotic analgesic medication is the initial standard treatment for renal colic. This treatment inherently disqualifies the patient from aviation duties but allows for the rapid resolution of pain and avoids the use of oral medications, which are often difficult to administer in nauseated patients. Some reports state that non-steroidal anti-inflammatory drugs (NSAIDs) may be as effective as narcotic analgesics. However, their use may diminish renal blood flow and intra-renal haemodynamics, which may be detrimental to renal function. Therefore, caution is necessary with the use of NSAIDs in patients with renal colic.

In the case of significant obstruction, the pressure transmitted onto the ureteral wall and renal capsule may need to be relieved through the use of indwelling ureteral stents or percutaneous procedures. Furthermore, relieving obstruction is necessary when there is evidence of progressive renal deterioration, pyelonephritis, or unrelenting pain. Temporizing manoeuvres may have to be undertaken until more definitive procedures can be carried out, such as extracorporeal shock wave lithotripsy, percutaneous nephrolithotomy, or ureteroscopic stone extraction.

### **Aeromedical considerations**

*The pain of renal colic can be severe and is likely to be incapacitating in flight. All treatment including conservative management aimed at encouraging the natural passage of the stone, surgery, and extracorporeal shock wave lithotripsy will necessitate grounding until recovery.*

Of these procedures, extracorporeal shock wave lithotripsy and percutaneous nephrolithotomy have lower morbidity and permit a quicker return to flying status than open procedures. The most common morbidity associated with both procedures is bleeding, which is usually self-limiting. Infection may occur with percutaneous nephrotomy. Interestingly, and ironically, some studies have shown reduction in ureteral peristalsis following fluid administration, which may inhibit further passage of stone in spite of increased diuresis. Luckily, the majority of calculi smaller than 4 to 5 mm spontaneously pass. Recovery of all stone fragments is necessary for further analysis.

*Cases of recurrent renal colic should be regarded with considerably more suspicion and may entail long term unfitness for aviation duties. Prior to issuance of a license or permitting a license holder to return to*

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<sup>2</sup> Doppler ultrasonography: application of the Doppler Effect in ultrasound to detect movement of scatterers (usually red blood cells) by the analysis of the change in frequency of the returning echoes. It makes possible real-time viewing of tissues, blood flow and organs that cannot be observed by any other method. After Johann Christian Doppler, Austrian physicist (1803-1853).

*aviation duties, a comprehensive urological examination should be performed. The assessment should be based on the presumptive risk of in-flight incapacitation. In some cases, a license may be issued with certain operational limitations such as a commercial pilot being allowed to operate “as or with co-pilot only.” Follow-up with renal function tests and radiology procedures should be performed at regular intervals as required by the licensing authority.*

The risk of recurrence in these patients is an important aeromedical consideration. For first-time stone formers, the risk ranges from 20-50% over the first ten years with an overall lifetime recurrence rate of 70%. Luckily, however, most smaller stones and even stones up to 8-10 mm diameter will pass spontaneously in less than two weeks, despite the often incapacitating pain they produce.

*Retained asymptomatic stones pose some risk for future renal colic. However, if the stones are located such that they are unlikely to pass into the calyx, the risk for incapacitation during flight is low. If the urinary studies do not reveal any underlying risk factors for recurrent stone formation, then medical certification for aviation duties may be considered. However, environments that predispose to dehydration may encourage renal stone formation without other underlying factors.*

## **HAEMATURIA OF UROLOGICAL ORIGIN**

Blood in the urine is a relatively common sign in the primary care or emergency department settings. Asymptomatic microscopic haematuria has a reported prevalence of 1.2 to 5.2% in young adult males and as high as 13% in community population-based studies. Haematuria may be the heralding sign for a medical condition, which may not necessarily be an aeromedical disqualifier, but may necessitate an aeromedical evaluation and disposition.

### **Disease process**

The differential diagnosis of asymptomatic urological haematuria without proteinuria or casts includes neoplasm, calculi, infection, and trauma (including exercise). Bleeding into the urinary tract from a source between the urethra and the renal pelvis should result in no protein, cells or casts. Haematuria at the beginning or end of the stream may indicate a urethral or prostatic source. Haematuria of any degree should never be ignored and, in adults, should be regarded as a symptom of urological malignancy until proven otherwise. Overall, it is uncommon for a patient with gross haematuria to have an unidentifiable source as opposed to the frequently negative urological examination in patients with microscopic haematuria.

### **Diagnosis**

The evaluation of upper and lower urinary tracts is mandatory for all patients with haematuria. Radiographic contrast studies such as the IVU or retrograde pyelogram will assist with urothelial evaluations. Renal parenchyma can be studied with ultra-sonography, computed tomography, or magnetic resonance imaging. The urethra and bladder will need cystourethroscopy.

### **Management**

Focused care for the identified source of bleeding is necessary. Stone eradication for patients with nephroureterolithiasis is necessary; definitive care for malignant or prostatic sources will have to be directed by urologists.

## **Aeromedical considerations**

*As mentioned previously, haematuria by itself in this setting is unlikely to be aeromedically significant.*

However, this sign must be fully evaluated. Calculi can cause extreme pain, lead to urinary tract infection, and obstruction. Urinary neoplasms are often slow growing but they must be diagnosed and treated early to optimize survival and function. Glomerular disease must be evaluated and renal function assessed to determine proper treatment and to address world-wide aviation duty (e.g. renal reserve, ability to tolerate dehydration, etc.). Although most sources recommend evaluation for those greater than 3-5 RBC/hpf<sup>3</sup>, any red cells found in the licence holder's urine should be the cause of a complete work-up.

## **INCONTINENCE**

Urinary incontinence is the failure of voluntary control of the vesical and urethral sphincters with constant or frequent involuntary urination. A careful history of the incontinent patient will often determine the aetiology. Urinary incontinence can be subdivided into four categories: continuous, stress, urge, and overflow incontinence.

### **Disease process**

Continuous incontinence is defined as involuntary urination regardless of time or position. Ectopic ureter and urinary fistulous disease are the predominant aetiologies, both of which warrant surgical remediation.

The sudden leakage of urine with activities that increase intra-abdominal pressures (i.e. coughing, sneezing, exercise, etc.) refers to stress urinary incontinence. Although stress incontinence is commonly associated with weakened pelvic support of the bladder neck and urethra in females, it may also be seen in males, most often after prostatic surgical procedures.

Urination preceded by urgency to void is known as urge incontinence. Urge incontinence may be a heralding symptom of malignant or infectious disease since these may cause urothelial irritation. Neurogenic bladder, resultant from multiple aetiologies, can also induce urge incontinence.

Overflow incontinence results from elevated residual urine and subsequent inability to completely empty the bladder. As the bladder overfills, urine tends to dribble in small amounts. The diagnosis is often challenging and the condition may be seen in patients with a chronic unrecognized problem.

### **Diagnosis**

The medical history will not always make clear what type of incontinence a patient has. However, multiparous females and patients with previous pelvic surgeries or radiation or neurological symptomatology may be able to guide the examiner towards the source and type of their incontinence.

Tools such as a pad test and voiding diary may elucidate the voiding habits and other conditions of a patient. Recording the situations, number of pads and estimated volumes (by weighing pads) may help

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<sup>3</sup> RBC/hpf: red blood cells per high power field

bring about an understanding of the patient's condition. In addition, objective recordings of intake and output of fluids along with timing may further elucidate the problem.

The physical examination should focus on anatomical and neurological signs. Complete pelvic and neurological examination will assist the clinical diagnosis of incontinence. Further examinations such as the Q-tip test<sup>4</sup>, uroflowmetry, post-void residual assessment, cystoscopy, formal video urodynamics, and an assessment of periurethral and vault supporting structures should be performed.

### **Management**

The aetiology of urinary incontinence is highly varied, as are the treatments. Continuous and stress incontinence typically warrant surgical treatment for definitive care, whereas urge incontinence tends to be best managed by medication. Treatment modalities including behavioural techniques such as biofeedback and pelvic floor exercises may alleviate the need for surgery. This approach may be a preferred initial treatment in a pilot. Of course, each category of incontinence requires a thorough urological evaluation to ensure adequate necessary care.

### **Aeromedical considerations**

*Incapacitation secondary to incontinence will warrant suspension from flight until definitive diagnosis and treatment are performed. Most incontinence is not of a degree in itself to warrant aeromedical disqualification and may be conservatively managed in many patients. If the condition requires surgical correction, the operative surgeon must document complete resolution and recovery prior to return to aviation duties.*

Pharmacological treatment may require further aeromedical review depending upon the drugs used. Anticholinergic medications are used for their direct relaxing effects on the smooth detrusor muscle of the bladder (m. detrusor vesicae). These medications are usually well tolerated by most but they may worsen an existing myopia. They may also cause dry mouth, fatigue, constipation and even, on rare occasions, supraventricular tachycardia. Finally, anticholinergic medications will exacerbate closed-angle glaucoma and is an absolute contraindication in such patients. Since these side-effects are of concern in the aviation environment, a ground trial is necessary. For similar reasons, any medications or herbal preparations used to treat this malady should be administered in carefully controlled settings and in consultation with the medical assessor of the licensing authority.

## **UROLOGICAL INFECTION**

Infection is the most common disease process of all that affects the urinary tract. Infections of the urinary system are globally categorized into two broad classifications: complicated and uncomplicated. Thorough urological investigation is mandatory in all but the simplest urinary infections in order to detect any anatomical or physiological pathology. Depending on the anatomical location, chronicity of infection, host factors, and source, an infection can result in incapacitation during flight. This concern is particularly

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<sup>4</sup> Q-tip test: a test for determining the mobility of the urethra by inserting a cotton-swab (Q-tip) into the female urethra and measuring the angle between it and the horizontal plane. Above 30 degrees is indicative of stress incontinence.

applicable in the face of urinary obstruction, which should always be treated as an emergency which requires immediate intervention.

*Acute infections of the urinary system should, as a rule, be disqualifying for aviation duties. Often a license holder will have clinically recovered from an acute infection but will require further suppressive drug treatment for an extended period of time. In such cases the medical examiner will have to decide if the medications used for treatment are compatible with safe flying.*

### **Disease process**

The inflammatory response and changes of the urothelium secondary to bacterial invasion, usually via ascension from the urethra, lead to urinary tract infection. The urine may also become contaminated with bacteria through haematogenous means. Bacteriuria may be either symptomatic or asymptomatic but often leads to pyuria. Pyuria is defined as the presence of pus (white blood cells) in the urine and is indicative of the inflammatory changes consistent with infection. Bacteriuria without pyuria typically indicates simple bacterial colonization; however, the converse warrants evaluation for tuberculosis, stones, or malignancy.

### **Clinical features**

Generally, urinary infections are defined clinically, but are further described by their site of origin. For example, the term acute pyelonephritis relates to the inflammatory changes resulting from bacterial infection within the renal parenchyma. Clinical characteristics of this diagnosis include fevers, rigors, flank pain, bacteriuria, and pyuria in the setting of infection proven by culture. Severe, complicated infections may produce sepsis, warranting emergent diagnosis and intensive monitoring. Complicated urinary infections may occur in immuno-compromised patients including those with diabetes, or in any patient with obstructed urinary system or aberrant urinary anatomy. At times, intra-renal and peri-renal abscesses may be an endpoint in the evolution of pyelonephritis, potentially warranting operative drainage.

Cystitis specifically refers to the inflammatory changes in the bladder secondary to bacterial urine infection. Irritative voiding symptoms such as dysuria, frequency, hesitancy, and urgency (with or without a component of incontinence) are characteristic of acute cystitis. Prostatic infection may produce similar symptoms as well as obstructive symptoms including nycturia, incomplete voiding, and a weak stream.

Pyelitis and urethritis are the terms used for infections of the upper collecting system and urethra respectively. Urethritis warrants further investigation for sexually transmitted diseases or for anatomical abnormalities. Sexually transmitted diseases tend to occur more commonly in younger, more sexually active individuals. Gonococcus sp. and Chlamydia sp. infections are common aetiologic organisms in patients presenting with urethritis or epididymitis. Coliform bacterial urethritis may be seen with complicated urinary fistulous disease or associated with anal intercourse. Rates are higher in men than in women, partially due to the fact that signs and symptoms in men are often more obvious. In these cases, the examining physician should also screen for other sexually transmitted diseases such as HIV, syphilis, and hepatitis B and C as well as visually inspect for signs of herpes and condylomata.

### **Diagnosis**

Complete history, physical examination, and laboratory work-up are keys to early diagnosis in patients suspected of having urinary infection. All patients should have a mid-stream clean-catch collection or

catheter collected urinalysis with microscopic studies and urine culture prior to initiation of antimicrobial treatment. Urinary symptoms, pyuria, bacteriuria, and evidence of active inflammatory changes in the urine such as the presence of nitrite and leukocyte esterase may warrant empiric treatment prior to culture and sensitivity reporting. Urinary infection is less likely in the absence of pyuria and may require urine culture data for verification. Conversely, pyuria without bacteriuria may indicate an atypical infectious aetiology such as genitourinary tuberculosis, staghorn calculi<sup>5</sup>, or other urinary stone disease. Finally, serum leukocytosis and positive blood cultures may indicate a complicated urinary infection in an acutely ill patient.

Radiographic studies may be useful in identifying anatomical anomalies in complicated urinary infections. Some helpful studies include intravenous urography, ultrasonography, computed tomography, and cystography. In patient groups without contraindications, IVU and contrast enhanced CT are important tools to evaluate nephroureterolithiasis, obstruction, anatomical aberrations, and renal enlargement as seen with pyelonephritis. Ultrasonography may aid in the differentiation of epididymitis from testicular torsion. Fullness of the testicular tail with ipsilateral increased epididymo-testicular blood flow indicates the diagnosis of epididymitis.

### **Management**

Coliform bacteria possess special virulence factors which allow them to adhere to the urothelium. Once adherent, the bacteria may ascend or descend the upper or lower urinary tract. Upper tract infections may range from uncomplicated to complicated, with the former requiring close outpatient follow-up with oral antimicrobials and the latter requiring hospitalization, catheterization or operative care. Although lower urinary tract infections are often less problematic, all cases of symptomatic urinary infection require antimicrobial treatment regardless of the locus.

Oral fluoroquinolones are excellent medications for the outpatient care of many urological infections. These medications allow for excellent urinary coverage of most uropathogens and provide “tissue penetration” for parenchymal infectious diseases such as pyelonephritis and prostatitis. Trimethoprim-sulfamethoxazole is an alternative medication; in many cases, it is less effective and it has a high incidence of microbial resistance. Ampicillin or cephalosporins are often required in gram-positive infections. Complicated infections with enterobacter species, pseudomonas or gram-negative bacilli may require combination therapy with aminoglycosides and ampicillin or broad-spectrum cephalosporins.

Although duration of therapy is a subject of debate, most uncomplicated cases of cystitis in females should be eradicated within five days if the bacteria are sensitive to the antimicrobial. Uncomplicated pyelonephritis usually requires fourteen days of therapy for complete resolution. In this scenario, urine cultures should be repeated after five to seven days of therapy to ensure adequate response. Lower urinary infections in men should raise suspicion of concomitant prostatic infection. In the case of prostatic infection, treatment should continue for 21 days or longer, ensuring negative urine cultures at the conclusion of therapy.

Finally, guidance on the recommended treatment for sexually transmitted diseases changes periodically and is regularly updated by the World Health Organization. Typically, gonococcal and chlamydial infections are found simultaneously in up to 50% of patients presenting with urethritis subsequent to suspicious sexual encounters. For this reason, these patients should be covered for both diseases and screened for the others previously mentioned.

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<sup>5</sup> Staghorn calculi: branched stones in the renal collecting system, usually involving two or more calyces.

## **Aeromedical considerations**

*As already mentioned, all urological infections should be considered disqualifying for aviation duties during acute disease. Medical assessment should not be entertained until a number of criteria are met:*

- *Assurance of no idiosyncratic reaction to appropriate culture-driven antimicrobial therapy.*
- *Complete haemodynamic stability after acute treatment has been initiated*
- *Culture-specific antimicrobial coverage for a minimum of 14 days except in cases of simple cystitis in a female patient.*
- *Repeat cultures revealing complete eradication of any organism*
- *In complicated infections, full urological consultation for any anatomical or other aberrations.*
- *Assurance that recurrent urinary infection has been completely eradicated or suppressed.*
- *A patient with a urological condition that has a high likelihood of causing recurrent urinary infections with rapid onset of symptoms should be disqualified from aviation duties until that condition is resolved.*

## **CONGENITAL AND RENAL CYSTIC DISEASES**

### **Disease process**

The urinary tract harbours more survivable congenital abnormalities than any other organ in the body. In childhood, diminished renal function commonly serves as the presenting factor to diagnosis of an anomaly. In adulthood, urological evaluations for haematuria, infection, and nephroureterolithiasis commonly uncover congenital cystic and renal anomalies. These anomalies may also be found incidentally on radiographic evaluations for other problems. They range from simple cysts and collecting system duplications to major anatomical problems that may cause end stage renal dysfunction and other systemic illness.

Simple cysts present typically as a discrete finding that may occur within the renal parenchyma or arise from its surface. They are commonly oval to round in shape, with a smooth outline bordered by a single layer of flattened epithelium and contain a clear or straw-coloured fluid. Simple renal cysts are commonly found in individuals during the third decade of life or later. They may be singular, multiple, unilateral or bilateral.

Medullary sponge kidney is an adult disease, commonly found incidentally during imaging of the abdomen. Its incidence is about 1 in 5 000 with nearly a two to one male predominance. Its cause is unknown and it does not follow any classical inheritance pattern. Although the disease is characterized by dilation of the papillary ducts of the renal medulla, renal function is usually normal. Cysts lined with cuboidal or transitional epithelium may be found in these ducts.

Cystic renal dysplasia, or polycystic kidney disease, may be of no aeromedical significance if it is unilateral and the other kidney is functional. Bilateral disease will nearly always be identified early in childhood, as commonly seen in autosomal recessive (“juvenile” or “infant”) polycystic kidney disease. Adult polycystic kidney disease (APKD), on the other hand, often leads to severe renal dysfunction. It is

an autosomally dominant acquired condition that commonly presents in later life. Its incidence ranges from 1 in 350 to 1 in 1000 individuals. APKD accounts for 5 to 15 percent of patients with renal failure requiring transplantation or dialysis. It presents in individuals from the second through the ninth decade of life.

It is important that patients with polycystic disease undergo radiographic imaging to rule out abdominal aortic or cerebral aneurisms, including those of the circle of Willis<sup>6</sup>. Other associated anomalies include hepatic, pancreatic, splenic, and pulmonary cysts as well as colonic diverticula, and mitral valve prolapse.

Aside from renal cysts, other common congenital defects include unilateral anomalies, malposition of the kidneys, and duplication of the collecting system. Renal hypoplasia is defined as an absent or adult kidney that weighs less than 50 g. The other kidney may compensate so well by physiologic hypertrophy that the condition is undetectable except by radiographic imaging.

Horseshoe kidney is a pelvic kidney with an inferior isthmus conjoining the two poles of the two renal units. This isthmus prevents normal renal ascent during development at the point of the inferior mesenteric artery. Complications of this congenital anomaly may include infection, stone disease and, later, arterial hypertension. Once the condition is identified, some references recommend routine screening for these complications.

Malposition of a kidney, such as a pelvic location, occurs in about one in 900 people. Complications may include kinking of ureters, obstruction of urinary flow, hypertension, and pain. If there are no complications and the patient is asymptomatic with normal function of the kidney, the condition has little aeromedical significance.

Duplication of the collecting system occurs in about three per cent of the population. In most cases it has no aeromedical significance, but occasionally it may be associated with obstruction and stasis of urine. In these instances, it may cause stone disease and recurrent infection.

### **Clinical features**

Adult polycystic kidney disease (APKD) most commonly presents in the fourth to sixth decades with haematuria, flank pain, gastrointestinal symptoms, renal colic, and/or hypertension. Anaemia or elevated serum creatinine may also be found during initial presentation. Up to 40 percent of APKD patients also have berry aneurisms, with nearly nine per cent of these patients dying from rupture and subsequent subarachnoid haemorrhage. Intracerebral arterial haemorrhage may be a presenting sign for this disease, secondary to the hypertension seen in this population.

Autosomal recessive polycystic kidney disease, conversely, results in death of nearly 50 per cent of all newborns with this condition within the first few hours or days of life. Of the infants that survive, approximately 50 per cent are alive at age 10, and some of those are completely asymptomatic throughout their lives. Obviously, the natural history of this disease makes it a rare diagnosis for the aeromedical examiner.

Medullary sponge kidney commonly presents as renal colic, followed by a urinary tract infection, then gross or microscopic haematuria. One third to one-half of all patients with medullary sponge kidney eventually develops urinary stone disease, and it is often an IVU that leads to the diagnosis. The other congenital anomalies mentioned are usually radiographically identified after clinical presentation of nephroureteral stone disease, haematuria, infection, hypertension, abdominal mass, or other symptoms.

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<sup>6</sup> Circle of Willis: cerebral arterial circle. After Thomas Willis, English physician (1621-1675)

## **Diagnosis**

Sonography is one of the mainstays of diagnosing and differentiating renal cystic disease from other anomalies. Using ultrasound, a common simple cyst reveals the absence of internal echoes, a sharply defined wall, good sound transmission through the cyst with acoustic enhancement behind the cyst, and a spherical or ovoid shape. Lack of the characteristics warrants further investigation, such as contrast enhanced CT or MRI, to rule out malignancy or other entities. APKD is classically bilateral and is characterized by a confluence of multiple large renal cysts on ultrasound images. Cysts may be found by the same technique in other organ systems such as the liver or pancreas. MRI of the brain should follow in all newly diagnosed cases of APKD to rule out aneurisms.

Contrast enhanced CT or IVU is useful in elucidating tubular ectasia or medullary calcifications found in medullary sponge kidney. Other anomalies previously mentioned may require ultrasound, CT, and MRI to diagnose parenchymal disease in addition to contrast studies such as IVU, retrograde pyelography or cystography to evaluate the ureters and bladder.

## **Management**

Asymptomatic simple cystic disease requires no further study or treatment. Symptomatic distension of the renal capsule, obstruction of the collecting system or infection may warrant percutaneous treatment, sclerosis or even laparoscopic or open operative excision.

The complications of medullary sponge kidney, including calculus formation and infection, require management. Hypercalciuria associated with the disease induces stone formation, and thus thiazides or inorganic phosphates are effective for lowering hypercalciuria and limiting stone formation. Phosphate administration may increase the risk of infectious stone development in the presence of urease-producing bacteria. Therefore, if phosphates are used, frequent urinary cultures should be performed to ensure absence of an asymptomatic infection. Long-term antibiotic prophylaxis may be required to prevent these infections.

## **Aeromedical considerations**

*Many of the cystic and congenital abnormalities are disqualifying for aviation duties. Simple cystic disease is compatible with flight as long as the cysts do not result in mechanical compromise to the kidney, collecting system or renal vasculature. It is important to differentiate cystic abnormalities from renal tumours.*

*Medullary sponge kidney is of aeromedical significance because of the disease complications. Pyelonephritis and nephrolithiasis are common, with potential sequelae including septicaemia and renal failure in symptomatic patients. For these reasons, it is disqualifying for aviation duties. Effective use of the drugs listed above decreases complications and increases the chance of resuming aviation duties.*

*Autosomal recessive polycystic kidney disease expresses itself early; if an applicant is asymptomatic, the disease is of little aeromedical importance. Adult polycystic kidney disease may threaten the safety of flight and so should only be considered with limitation to multicrew operations. Any aeromedical disposition of an applicant or aviator with polycystic kidney disease should be done in consultation with a specialist and the medical assessor of the licensing authority.*

*Although some States require two functioning kidneys for medical certification, an individual may have no risk of complications in an aviation environment with a single kidney. Normal renal function studies, absence of symptoms, and no evidence of infectious, obstructive or congenital disease are signs of a good prognosis. In such cases, unilateral agenesis and hypoplasia are of no clinical significance and are not at increased risk to interfere with aviation duties.*

*In summary, symptoms of the above diseases that could impair flying performance include flank pain, urinary urgency, frequency, dysuria, fever and malaise. Subtle decline of mental clarity and general health may also occur and will require regular follow-up examinations of those who continue to fly.*

## **SCROTAL PROBLEMS**

### **Disease processes/ clinical features**

The scrotum is a loose sac containing the testes, the epididymides, and the spermatic cord. Dermatological conditions, endocrinopathies, infection, vascular problems, malignancy, and other diseases may arise in the scrotum and its contents. Testicular examination should reveal a firm, rubbery, ovoid structure. Diminished testicular size suggests hypogonadism. Elevation of the testis in the hemiscrotum may indicate torsion or malignancy, especially if palpable masses are present. In the setting of these findings, the latter diagnosis should be suspected until proven wrong.

Hernias may present as a scrotal finding. Gentle pressure with the physician's index finger, causing invagination of the scrotum anterior to the testicle and spermatic cord up to the internal ring, may reveal this and other pathology. Valsalva manoeuvres<sup>7</sup> may assist with this diagnosis, and it may also be useful in finding a varicocele. This finding is noted by the presence of a dilated, tortuous spermatic vein within the hemiscrotum. Another diagnostic tool is transillumination: a cystic scrotal mass will transilluminate whereas a solid one will not pass light.

### **Diagnosis**

The most common physical finding in the testes is a mass. Painless, firm masses that clearly arise from the testis are malignant until proven otherwise. Solid extratesticular masses tend to be benign but radiographic evaluation and exploration are needed in virtually all cases of solid scrotal masses.

Testicular torsion is defined as the twisting of the testis on its spermatic cord with resultant loss of blood flow and testicular infarction. Commonly misdiagnosed as epididymitis, testis torsion warrants emergent urological evaluation and possible scrotal exploration. As it is a clinical diagnosis, testicular torsion should be seriously considered in any male patient aged 12-35 presenting with a sudden onset of pain, swelling, and elevated testis within the hemiscrotum. A testicular radionuclide scanning, considered the "gold standard" to reveal the absence of blood flow, or scrotal ultrasonography may assist with the diagnosis. Torsion will reveal absence of flow on either study but ultrasonography may also reveal hyperaemia of the epididymis and surrounding tissues. Interestingly, appendix testis or appendix epididymidis torsion may present in the same manner.

Ultrasound is the generally preferred method of imaging for most scrotal conditions. Infectious disease, varicoceles, hydroceles, and spermatoceles can be confirmed with ultrasound based on clinical suspicion.

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<sup>7</sup> Valsalva manoeuvre: forced expiratory effort against the closed glottis ("strain") in order to increase intrathoracic pressure. After Antonio M. Valsalva, Italian anatomist (1666-1723)

CT or ultrasound in the setting of infection may reveal air within the scrotum or gangrenous tissue. In this case, Fournier's gangrene<sup>8</sup> may be present and would require emergent débridement to prevent life-threatening infection.

### **Aeromedical considerations**

*The acute scrotal process precludes aviation duties. Testicular torsion and epididymitis can become rapidly incapacitating. Consequently, torsion, infection, and malignancy (see section VIII below) are incompatible with flying duty until they are resolved. Urological consultation in all of these cases is mandatory to prevent surgery, if possible, and to ensure testicular salvage.*

*Hydrocele, spermatocele, and hernia disease may be managed conservatively when asymptomatic. However, all pilots are required to be completely free of those hernias that might give rise to incapacitating symptoms during flight, so surgical consultation and remediation of inguinal hernia disease must be the rule. Especially during flight, because of the decrease in ambient pressure, this condition may suddenly result in bowel incarceration and strangulation, even when previously asymptomatic and reducible, causing an aeromedical emergency.*

## **BENIGN PROSTATIC HYPERPLASIA**

### **Disease process**

Benign prostatic hyperplasia affects nearly 50 percent of men ages 51-60 and 90 per cent of those over 80 years old. It is characterized by hyperplasia of both prostatic glandular epithelial and stromal cells, commonly in the central zone of the prostate. Dihydrotestosterone (DHT), converted from plasma testosterone by the enzyme 5-alpha-reductase, acts as a propagator of this condition. Medicinal therapy targets this enzyme, thereby decreasing intracellular DHT. Depending on race, most glands are stable until the fifth decade, when enlargement may occur. Only about 10 percent of men require an operative cure for their condition.

### **Clinical features**

Obstructive symptoms are predominant but they do not necessarily relate to the size of the prostate on examination. Prostatic urethral compression is the mechanism of obstruction, and it may occur even in glands of grossly normal size. Initial symptoms include decreased urinary stream force, hesitancy in initiation of voiding, post-void dribbling, and a sensation of incomplete emptying. As the degree of obstruction increases, nocturia, overflow incontinence, urinary retention, and obstructive uropathy may result. End-stage obstructive cases may result in renal compromise.

### **Diagnosis**

A thorough history and examination is required in any male with lower urinary tract symptoms (LUTS). Historical identification of haematuria, infection, diabetes, and neurological disease is important. The

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<sup>8</sup> Fournier's gangrene: an acute gangrenous type of necrotizing fasciitis of the scrotum, penis, or perinaeum involving gram-positive organisms, enteric bacilli, or anaerobes. After Jean Alfred Fournier, French dermatologist (1832-1914).

international prostate symptom score (IPSS)<sup>9</sup> is an important adjunct to the history. Previous urinary instrumentation, urethral stricture disease, or recent addition of medications may confound the differential diagnosis. Anticholinergics may impair bladder contractility, and alpha agonists such as pseudoephedrine may increase outflow resistance.

During the physical examination, a digital rectal examination and a focused neurological examination are mandatory. Abdominal and external genital examinations are necessary to exclude distension of the bladder, palpable urethral masses, and meatal stenosis.

Important diagnostic studies include urinalysis and a culture to rule out infection as well as urological procedures. When available, urinary flow rate, post-void residual (PVR), and pressure-flow urodynamic studies are appropriate tests to consider in men with moderate to severe symptoms. Urethrocystoscopy may be considered in men with moderate to severe symptoms who have either chosen or require surgical or other invasive therapy. This procedure is helpful in assisting the surgeon determine the best operative approach.

Radiographic studies of the upper tract are not helpful in men with lower urinary tract symptoms unless they also have haematuria, renal insufficiency, a history of ureterolithiasis, urinary tract infection or urinary surgery.

## **Management**

Therapy is usually guided by patient symptomatology. Early conservative management is successful in many patients; this may include lifestyle modifications such as decreasing fluid and salt intake and avoiding caffeine and alcohol. If the patient has refractory urinary retention, the AHCPR<sup>10</sup> and International Consensus Guidelines recommend operative resolution of symptoms. Refractory retention is defined as failing at least one attempt of urinary catheter removal. Other conditions that may mandate surgery include recurrent urinary tract infection, recurrent gross haematuria, bladder stones, renal insufficiency, or large bladder diverticula.

Transurethral resection of the prostate (TURP) is the most common definitive therapy for benign prostatic hypertrophy. However, some patients are relieved by alpha-adrenergic antagonists (terazosin, prazosin, doxazosin, and tamsulosin). Five-alpha-reductase inhibitors such as finasteride are effective in relieving men with larger palpable glands (>35 g) through its glandular “shrinking” effects, but it may take up to six months for these to achieve full effect.

Alpha-antagonist medications are known to cause postural hypotension, syncope, dizziness and fatigue. Although selective alpha-antagonists such as tamsulosin have some incidence of postural hypotension and mild dizziness, the incidence of these is far lower than in the alpha-agonists, especially in low doses. Lastly, finasteride has only minimal side effects which include headache, impotence, and decreased libido.

## **Aeromedical considerations**

*Temporary aeromedical disqualification may be necessary in the patient with symptomatic obstruction secondary to benign prostatic hyperplasia (BPH). Judgment must be used in determining the aeromedical*

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<sup>9</sup> IPSS: a scoring questionnaire, used to calculate the severity of voiding symptoms (see [http://www.usrf.org/questionnaires/AUA\\_SymptomScore.html](http://www.usrf.org/questionnaires/AUA_SymptomScore.html))

<sup>10</sup> AHCPR: Agency for Health Care Policy and Research, an agency of the United States Public Health Service.

*significance of minimal or mild symptoms. As a general rule, if the licence holder is concerned enough to mention the symptoms, then they are probably operationally significant.*

*Due to their side effects, alpha-antagonists are the least flight compatible medications of those mentioned. Selective alpha-antagonists may be useful in the aviation environment after an uneventful ground trial period. Even after ground trial, these medications should be considered unacceptable for high g-force environments (aerobatics). Finasteride's minimal side effects require a ground trial, but it should be acceptable for most aviation duties.*

*TURP usually results in complete resolution of urinary symptoms, although up to 20 per cent may require a second resection. The morbidity and mortality of this procedure is low but significant complications may include retrograde ejaculation, impotence, and urinary incontinence. If the procedure resolves the obstructive symptoms without morbidity, the individual will normally be qualified for aviation duties.*

## **UROLOGICAL MALIGNANCY**

### **Overview**

Urothelial malignancies, adenocarcinoma of the prostate, and renal cell carcinoma are the most commonly seen urological malignancies. Testicular cancer is a rarer entity and is the main urological malignancy that affects young populations.

Bladder cancer is the fourth most common cause of cancer in males and ninth in females. It has a 2.5 to 1 male to female ratio. With a median age of 65 at time of diagnosis, bladder cancer will be diagnosed in over 53 000 individuals in North America annually. Transitional cell carcinoma is the most common diagnosis, occurring most often in Caucasian males. Risk factors include increased age, industrial organic solvent exposure, and smoking. Haematuria is the first sign in nearly 90 per cent of cases. Survival is stage dependent, with lower stage cancers (Tis, Ta, T1 under TNM staging<sup>11</sup>) having a 90 per cent 5-year survival. T2, T3, and T4+ disease have 5-year survival rates of 70, 35-50 and 15 per cent respectively.

Prostate cancer is the most common malignancy in men in North America and the fourth most common male malignancy worldwide. Racial factors seem to play a role as it occurs more frequently in black men, less in Asian men, with Caucasian men in between. Its incidence increases with age; it is rare in men younger than 50 years of age. Although both minimal and advanced carcinomas tend to be asymptomatic at diagnosis, obstructive and irritative voiding symptoms are common in those patients who have symptoms. Metastatic disease may manifest itself as constitutional symptoms, or lumbar spine, rib or hip pain. Diagnosis is made by transrectal ultrasound-guided (TRUS) biopsy of the prostate.

Renal Cell Carcinoma (RCCa) is an uncommon malignancy, but it is disqualifying until definitive treatment has been completed. RCCa represents approximately two per cent of all new cancer malignancies and has a male predominance. Peak incidence occurs from the sixth to eighth decades with both familial and sporadic factors seen. The majority of renal tumours are incidentally discovered on radiographic evaluations for other conditions.

Testicular tumours account for one per cent of all tumours and 0.1 per cent of all cancer deaths in men. Testicular cancer occurs in early adulthood between 20 and 40 years and again in late adulthood over 60

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<sup>11</sup> TNM staging: staging of tumours according to three basic components – primary tumour (T), regional nodes (N), and metastasis (M). Adscripts are used to denote size and degree of involvement. 0 indicates undetectable, and 1, 2, 3 and 4 a progressive increase in size or involvement. In addition, Ta is non-invasive papillary carcinoma, and Tis is carcinoma in situ ("flat tumour").

years of age. Overall, the highest incidence is noted in young adult males, making these neoplasms the most common solid tumours of men aged 20 to 34 in the United States and Great Britain. Non-seminomatous tumours account for up to 60 per cent of testicular germ cell tumours. These tumours include embryonal cell carcinoma, teratocarcinoma, and teratoma. Up to ten per cent of men with testis tumours have a history of testicular maldescent and, accordingly, all patients with cryptorchidism have a four-fold risk of testis cancer.

*For these reasons, any pilot with a painless, hard scrotal mass has testicular cancer until proven otherwise and should be disqualified from flight until definitive diagnosis is made and eradication is complete.*

### **Clinical features**

Painless haematuria is the most common presenting symptom of bladder cancer, occurring in up to 90 per cent of cases. This haematuria is quite intermittent so that a negative result on one or two specimens does not rule out the presence of bladder cancer. No specific physical examination technique is useful in elucidating urothelial cancer but a history of exposure to risk factors may be helpful.

Prostatic cancer typically has benign symptoms, such as mild obstruction or irritation, until it becomes metastatic. Therefore, any man more than 50 years old with an abnormal digital rectal examination or an elevation in prostate-specific antigen (PSA) in the absence of recent infection should undergo investigation to rule out malignancy. Men of African descent with a family history of prostate cancer warrant screening at the age of 40 and Caucasian males with a similar history should be screened at 50.

The classic triad of renal cell carcinoma including haematuria, abdominal or flank pain, and an abdominal or flank mass occurs in less than 20 per cent of all patients that present with renal cell carcinoma. Renal cell carcinoma has classically been called the “internist’s tumour” secondary to the many paraneoplastic syndromes, presenting with erythrocytosis or anaemia, hypercalcaemia, non-metastatic hepatic dysfunction, dysfibrinogenaemia, hypertension, and hypercalcaemia.

The usual presentation of a testicular tumour is a nodule or painless swelling of one gonad. In about ten per cent of all patients, the presenting manifestations may be due to metastases. A pulmonary metastasis may present with cough or dyspnoea, whereas a supraclavicular lymph node metastasis may present as a neck mass. Other symptoms may include gastrointestinal symptoms from a retroduodenal metastasis, back pain or other bone pain, central and peripheral nervous system dysfunction, and venous stasis.

### **Diagnosis**

Malignant urothelial cells can be observed on cytological examination of the urinary sediment or bladder washings. However, cystoscopy is required in any patient with haematuria of malignant potential. Renal parenchymal and upper urinary tract contrast imaging (IVU or retrograde pyelography) is also mandatory to rule out a potential renal cancer or urothelial upper tract malignancy. Contrast enhanced CT and ultrasound are valuable in diagnosing renal parenchymal pathology, with the CT potentially aiding in tumour differentiation. MRI may be required to rule out malignancy in a patient with poor renal function.

Carcinoma of the prostate is commonly diagnosed via ultrasound guided, trans-rectal biopsy in any man with an abnormal digital rectal examination or elevated PSA. Transperineal biopsy of the prostate may be necessary in men with rectal anomalies.

The primary differential diagnosis of a testicular mass includes testicular cancer, testicular torsion, epididymitis, or epididymo-orchitis. Less common problems include hydrocele, hernia, haematoma, spermatocele, or syphilitic gumma. Ultrasonography of the scrotum is basically an extension of the physical examination. Any hypoechoic area within the tunica albuginea is markedly suspicious for testicular cancer. Initial studies to rule out metastasis include postero-anterior and lateral chest x-rays as well as abdominal CT scanning.

Tumour marker proteins are relatively specific and have an easily measurable assay for a patient suspected with testicular cancer. Alpha-foeto protein (AFP) may be produced by pure embryonal carcinoma, teratocarcinoma, yolk sac tumour, or combined tumours, but not by pure choriocarcinoma or seminoma. Syncytiotrophoblastic cells have been found responsible for the production of hCG<sup>12</sup>, which is found in all choriocarcinomas, around half of embryonal carcinomas, and up to ten per cent of pure seminoma. Lactate dehydrogenase (LDH) levels are found to correlate directly with tumour burden in germ cell tumours.

### **Management**

Urothelial carcinoma mandates urological evaluation, treatment, and very close follow-up. Lower grade cancers may often be managed transurethrally and, at times, with intravesical chemotherapeutic agents that warrant close surveillance. Upper tract tumours such as ureteral tumours typically require complete excision with the ipsilateral kidney as these are very difficult to survey and treat with a direct urothelial chemotherapeutic agent. Most cases do not respond to radiation or systemic chemotherapy. All patients with urothelial malignancies require regular surveillance, which may preclude regular flying duties.

Renal cell carcinoma is also a surgical disease when organ confinement is apparent. Laparoscopic, open, and even percutaneous ablative technologies may provide the best treatment for this disease. *Metastatic disease may respond to adjuvant immunomodulation (IL-2, interferon), improving survival in select patients upon excision of their primary tumour. This latter population obviously does not meet the requirements of fitness for flight.*

Management options for patients with clinically organ-confined adenocarcinoma of the prostate (stages T1-T2) include observation, radiation therapy, and radical prostatectomy. However, 75 percent of patients, when merely observed, will experience local progression and 20 per cent will develop metastatic disease. Radical prostatectomy may provide the greatest cure rate but it often results in impotence and incontinence. Primary radiation therapy consists of 60 to 70 Gy of radiation to the prostate and is associated with acute and chronic proctitis and urethritis, impotence, and occasional rectal stricture, fistula and bleeding. *Advanced prostate cancer is treated with surgical or medical castration and hormone therapy; it disqualifies an individual from aviation duties.* PSA is a useful prognostic marker; after treatment, progressive elevation of PSA is an indication of recurrent disease.

Non-sematomatous germ cell tumours have a reported cure rate in excess of 95 per cent in low stage disease treated with bleomycin-etoposide-cisplatinum (BEP) chemotherapy after orchiectomy. Higher stage disease may have similar cure rates if treated with retroperitoneal lymph node dissection in combination with the above therapy. Salvage chemotherapy in the event of tumour recurrence is very effective, but the patient must be closely followed with chest x-rays, abdominopelvic CT imaging, and tumour marker levels.

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<sup>12</sup> hCG: human chorionic gonadotropin

Potential late complications of BEP chemotherapy include decreased renal function, Raynaud's phenomenon<sup>13</sup>, neurotoxicity, major vascular occlusion, chronic pulmonary toxicity, and secondary malignancies. Pulmonary toxicity is a major concern in the aviation world because chronic exposure to 100 per cent oxygen, which can occur occupationally, may worsen this condition.

### **Aeromedical considerations**

*Fortunately, recurrent low-grade superficial urothelial carcinoma is unlikely to result in sudden incapacitation. However, recurrence may also present as metastatic disease, which can result in significant and potentially sudden impairment. Brain metastases of urological malignancy can result in significant unrecognized cognitive impairment. Ongoing treatment also poses risks to flight safety. For these reasons, the recommendation for a pilot to return to flying duties should occur only after the individual has been disease-free for two years.*

*Aeromedically, impairment from renal cell carcinoma may result more from complications of surgery than from any other cause. Lower-staged tumours have a favourable survival rate and, therefore, radical nephrectomy is usually recommended for these patients. The remaining kidney needs increased vigilance to ensure its function but if it is functioning well, the pilot may return to flying duties after two years provided he is disease free and off all medications.*

*A pilot with carcinoma of the prostate should not participate in flying duties until definitive therapy has been completed and no evidence of recurrence or metastasis has occurred for a period of at least two years. Testicular cancer has the same restrictions for aviation duties. Long-term morbidity potential of chemotherapy, especially with bleomycin, and the logistics associated with the surveillance of lower-stage patients make returning to flying sooner unreasonable.*

### **CONCLUSION AND SPECIAL CONSIDERATIONS**

As noted in the introductory statements of this chapter, it is understood that a degree of interpretation and assessment must be exercised by the medical examiner, often in consultation with specialists and the medical assessor of the Licensing Authority. Many such cases may have to be referred to the medical assessor for final aeromedical disposition. Many urological conditions have been discussed that are incompatible with flight, including infections, stone disease, malignancy, and some urological medications. One such medication not previously discussed is sildenafil (Viagra®), a selective 5-phosphodiesterase inhibitor that enhances the vasodilatory effects of nitric oxide on corporeal arterial sinusoidal smooth muscle. This medication is commonly used in the medical treatment of erectile dysfunction and is not to be used for 24 hours prior to anticipated flight. Furthermore, one must abstain from its use when concomitant nitrates are being used, as deaths have been reported with this combination.

*Testosterone replacement should not preclude a pilot from flying and is typically well tolerated with minimal side effects when taken for hypogonadal states. Of course, the individual must undergo a full work-up to rule out the pituitary gland as the cause. Appropriate evaluation for pituitary conditions includes ensuring normal follicular stimulating, luteinizing, and prolactin levels. An MRI of the pituitary gland and sella turcica is required for patients with any abnormalities of these hormones.*

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<sup>13</sup> Raynaud's phenomenon: intermittent bilateral ischaemia of fingers, toes, and sometimes ears and nose, with severe pallor and pain. After Maurice Raynaud, French physician (1834-1881)

*Adrenal pathology is discussed elsewhere in this Manual but the surgical care of many adrenal lesions is often performed by a urologist. Suffice it to say that lesions, such as adrenal adenoma, pheochromocytoma, neuroblastoma, and carcinoma will likely preclude medical certification. Complete eradication of these tumours with subsequent normal physiologic states or, in the case of malignancy, a two-year disease-free period is required prior to resumption of aviation duties.*

In this chapter, the most common urological conditions the aviation medical examiner may encounter have been reviewed. For urological diseases not included here, appropriate consultation with medical specialists and the medical assessor of the licensing authorities is key in providing appropriate aeromedical dispositions and ensuring flight safety.

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## Part III

### Chapter 7. GYNAECOLOGY AND OBSTETRICS

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## INTRODUCTION

In assessing gynaecological problems and pregnancy in relation to medical certification, the medical examiner should be familiar with the ways in which such conditions can affect the female applicant in the carrying out of her duties.

The guidance material contained in this chapter does not have any regulatory status; its main purpose is to aid in the implementation of Annex 1 provisions.

## GYNAECOLOGICAL DISORDERS

### MENSTRUAL DISTURBANCES

The provisions of Annex 1 state, for all classes of Medical Assessments, that:

6.3.2.21 (6.4.2.21, 6.5.2.21) Applicants with gynaecological disorders that are likely to interfere with the safe exercise of their licence and rating privileges shall be assessed as unfit.

Dysmenorrhoea is a common condition with symptoms ranging from mild discomfort to severe abdominal pain, headache and backache, nausea and vomiting, diarrhoea, dizziness and fatigue. Usually, the condition is limited to 24-48 hours around the onset of the menstrual flow, and fitness for aviation duties is rarely reduced to a significant degree. Treatment with oral contraceptives and NSAIDs (non-steroidal anti-inflammatory drugs) is very efficient and is generally well tolerated. The use of oral contraceptives is acceptable in the aviation environment, but when medication with an NSAID is first used, an initial off-duty trial should take place so that the medical examiner can ascertain that there are no significant side effects such as gastro-intestinal symptoms, visual disturbances and drowsiness. In severe cases, especially when an underlying disease such as endometriosis or pelvic inflammatory disease is suspected (secondary dysmenorrhoea), appropriate diagnostic evaluation is important and specialist opinion should be sought.

Premenstrual syndrome (PMS) may occur during the week before the onset of menstruation. The symptoms are partly mental such as mood swings, anxiety and depression, partly physical such as bloating, headache and poor coordination.

*Because of the broad spectrum of symptoms and their varying severity and the many different kinds of medication usually prescribed, each case has to be assessed on its own merits. In most cases pharmaceutical therapy will prove unsatisfactory, and fitness for aviation duties is often reduced for a number of days every month.*

### ENDOMETRIOSIS

Although a benign disease, endometriosis can cause quite severe discomfort such as lower abdominal or suprapubic pain, usually just before or during the first days of the menstruation period. There are several medical and surgical treatment options.

*If symptoms are well controlled by oral contraceptives or mild analgesics, this condition is usually compatible with aviation duties. Those who undergo surgical treatment with a successful outcome will normally be cured and able to fly safely after a suitable period of recovery. The middle group, consisting*

*of patients with moderate symptoms but on medication and with decreased fitness several days per month, is more difficult to evaluate and assess. Usually the final decision should be deferred to the medical assessor of the Licensing Authority. The medical examiner, in consultation with a gynaecologist, should weigh all relevant factors carefully before making a recommendation.*

## **GYNAECOLOGICAL SURGERY**

The provisions of Annex 1 state, for all classes of Medical Assessments, that:

6.3.2.19 (6.4.2.19, 6.5.2.19) Applicants with sequelae of disease of or surgical procedures on the kidneys or the genito-urinary tract, in particular obstructions due to stricture or compression, shall be assessed as unfit unless the applicant's condition has been investigated and evaluated in accordance with the best medical practice and is assessed not likely to interfere with the safe exercise of the applicant's licence or rating privileges.

*Major gynaecological surgery will normally entail unfitness for a period of two to three months and some procedures such as hysterectomy may require more extensive periods of recovery.*

## **PREGNANCY**

The provisions of Annex 1 state the following for Class 1 and 2 Medical Assessments:

6.3.2.22 (6.4.2.22) Applicants who are pregnant shall be assessed as unfit unless obstetrical evaluation and continued medical supervision indicate a low-risk uncomplicated pregnancy.

6.3.2.22.1 (6.4.2.22.1) **Recommendation.**—*For applicants with a low-risk uncomplicated pregnancy, evaluated and supervised in accordance with 6.3.2.22, the fit assessment should be limited to the period from the end of the 12th week until the end of the 26th week of gestation.*

6.3.2.23 (6.4.2.23) Following confinement or termination of pregnancy, the applicant shall not be permitted to exercise the privileges of her licence until she has undergone re-evaluation in accordance with best medical practice and it has been determined that she is able to safely exercise the privileges of her licence and ratings.

In an uncomplicated pregnancy, most organ systems adapt to the increased demands placed upon a healthy young female in such a way that the expectant mother can carry on with routine activities in her usual environment until close to the time of labour and delivery.

### **Pilots and pregnancy**

A pilot applicant who is pregnant faces an unusual and hostile air environment, in which organ adaptation can be affected. Once she believes that she is pregnant, she should report to her own doctor and an aviation medical examiner. It is advisable, not only for her own protection but also to ensure flight safety, that her obstetrician is aware of the type of flying she intends to carry out, particularly as the common complications of pregnancy can be detected and treated by careful prenatal evaluation, observation, and care.

The medical examiner should consider the important physiological changes associated with pregnancy, which might interfere with the safe operation of an aircraft at any altitude throughout a prolonged or difficult flight:

- nausea and vomiting of early pregnancy occur in 30 per cent of all pregnancies, and can cause dehydration and malnutrition;
- approximately 15 per cent of embryos will abort in the first trimester;
- cardiac output rises in early pregnancy, accompanied by an increase in stroke volume, heart rate, and plasma volume;
- haemoglobin (and haematocrit) begins to fall between the third and fifth month and is lowest by the eighth month;
- adequate diet with supplementary iron and folic acid is necessary, but self-medication and prescribed medicine should be avoided;
- the incidence of venous varicosities is three times higher in females than males and deep venous thrombosis and pulmonary embolism are among the most common serious vascular diseases occurring during pregnancy;
- as the uterus enlarges, it compresses and obstructs the flow through the vena cava;
- progressive growth of the foetus, placenta, uterus and breasts, and the vasculature of these organs, leads to an increased oxygen demand;
- increased blood volume and oxygen demands produce a progressive increase in workload on both the heart and lungs;
- hormonal changes affect pulmonary function by lowering the threshold of the respiratory centre to carbon dioxide, thereby influencing the respiratory rate;
- in order to overcome pressure on the diaphragm, the increased effort of breathing leads to greater consciousness of breathing and possibly greater cost in oxygen consumption; and
- the effect of hypoxia at increased altitude further increases the ventilatory effort required to provide for increasing demands for oxygen in all tissues.

*Once pregnancy is confirmed the pregnant pilot should report to the medical examiner. If declared fit, i.e. if her pregnancy is considered a normal, uncomplicated and low-risk pregnancy and medical information from her obstetrician, family physician and/or midwife supports this, she may continue to exercise the privileges of her licence from the end of the 12th week until the end of the 26th week of the gestational period. Close medical supervision must be established for the part of the pregnancy where the pilot continues flying, and all abnormalities should be reported to the medical examiner. Provided the puerperium is uncomplicated and full recovery takes place, she should be able to resume aviation duties four to six weeks after confinement.*

## Air traffic controllers and pregnancy

The provisions of Annex 1 state the following for Class 3 Medical Assessments:

6.5.2.22 Applicants who are pregnant shall be assessed as unfit unless obstetrical evaluation and continued medical supervision indicate a low-risk uncomplicated pregnancy.

6.5.2.22.1 **Recommendation.**— *During the gestational period, precautions should be taken for the timely relief of an air traffic controller in the event of early onset labour or other complications.*

6.5.2.22.2 **Recommendation.**— *For applicants with a low-risk uncomplicated pregnancy, evaluated and supervised in accordance with 6.5.2.22, the fit assessment should be limited to the period until the end of the 34th week of gestation.*

6.5.2.23 Following confinement or termination of pregnancy, the applicant shall not be permitted to exercise the privileges of her licence until she has undergone re-evaluation in accordance with best medical practice and it has been determined that she is able to safely exercise the privileges of her licence and ratings.

*Once pregnancy is confirmed the pregnant air traffic controller should report to the medical examiner. If declared fit, she may continue to exercise the privileges of her licence. Some Contracting States take the further precaution of endorsing her medical certificate as: "Subject to another similarly qualified controller being in close proximity while the licence holder exercises the privileges of her licence" or similar. Close medical supervision must be established for the part of the pregnancy where the air traffic controller continues to carry out her duties, and all abnormalities should be reported to the medical examiner. She should cease working by the end of the 34th week of the gestational period. Provided the puerperium is uncomplicated and full recovery takes place, she should be able to resume aviation duties four to six weeks after confinement.*

### Termination of pregnancy

Miscarriage (spontaneous abortion) is very common; about 15 per cent of all pregnancies are terminated spontaneously. Observation for a few days to ensure that bleeding has stopped may be all that is needed, but vacuum suction or dilatation and curettage to ensure completion of the abortion is frequently performed.

*Induced abortion, usually by vacuum suction or by dilatation and curettage, will in the majority of cases entail unfitness for less than a week as these procedures are generally very safe, the rate of serious complications is < 1% and the mortality rate is < 1 in 100 000 cases.*

Complication rates increase as gestational age increases. Although uncommon, post abortion bleeding and pelvic inflammation, peritonitis and septicaemia may occur.

The “abortion pill” (mifepristone, a progesterone-receptor blocker) is used within the first seven weeks of pregnancy. A second drug (prostaglandin) is given two days later to start uterine contractions and complete the abortion.

*This method is very safe and unfitness is limited to a few days.*

For most women, abortion has no adverse mental sequelae but for those who have a desired pregnancy terminated for medical reasons (maternal or foetal) or who have considerable ambivalence, the mental sequelae may be pronounced. The medical examiner should therefore pay particular attention to the psychological effects of induced abortion before allowing return to aviation duties.

**Part III**

**Chapter 8. MUSCULOSKELETAL SYSTEM**

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## INTRODUCTION

In the introductory chapters of this manual, the basic principles for the assessment of an applicant's medical fitness for aviation duties are outlined.

The general provisions of Annex 1, 6.2.2, state that an applicant shall be required to be free from any abnormality, disability, etc., "such as would entail a degree of functional incapacity which is likely to interfere with the safe operation of an aircraft or with the safe performance of duties."

The minimum levels of fitness to be accepted when assessing the musculoskeletal system of an applicant are detailed in Annex 1, 6.3.2.24 for Class 1 Medical Assessment (and in the corresponding paragraphs of Chapter 6 for Class 2 and Class 3 Medical Assessments.)

6.3.2.24 The applicant shall not possess any abnormality of the bones, joints, muscles, tendons or related structures which is likely to interfere with the safe exercise of the applicant's licence and rating privileges.

*Note.— Any sequelae after lesions affecting the bones, joints, muscles or tendons, and certain anatomical defects will normally require functional assessment to determine fitness.*

It is, however, understood that a degree of interpretation and assessment must always be exercised at the discretion of the medical examiner, taking into consideration not only medical but also operational and environmental factors of relevance for the over-all aeromedical evaluation of an applicant's fitness.

When assessing the musculoskeletal system, the medical examiner should specifically note the following points.

## BACK PROBLEMS

Back problems are commonly occurring and present a special case. Instability and muscular weakness are strong indications for shoulder harness support. Any stiffness of hips will also increase back strain with prolonged sitting and pedal usage. Neck motion and stability must be present.

### Cervical spine

A neck motion of 45° will in most cases provide enough lateral vision for flight safety; it is unlikely that a pilot with less motion ability will move shoulders and torso in flight sufficiently to compensate for lack of neck motion.

### Lumbar spine

Lower back pain is a common complaint among flight crew members. It may be accompanied by pain radiating to the legs in the distribution of the sciatic nerve. The causes may include:

- a) local mechanical defect, e.g. injury ("acute low back") or structural deficiency ("chronic low back"), or intervertebral disc abnormality;
- b) specific diseases of the vertebrae;

- c) physiologic or abnormal function elsewhere in the body.

Of special importance for flight safety is the sudden, and many times unpredictable, occurrence of acute attacks of pain which may result in serious in-flight incapacitation.

*Medical fitness for aviation duties should be based on the degree of functional recovery and risk of recurrence that might cause sudden incapacity.*

The treatment of different types of (low) back pain does not lie within the scope of this manual. A special problem facing the medical examiner, nevertheless, is how to evaluate the possible adverse effects of any long-term (analgesic/muscle relaxant) drug treatment, to which reference is also given in Part III, Chapter 13 of this manual.

### **ARTHRITIS**

When assessing the medical fitness of an applicant with a history of arthritis, the medical examiner should give consideration to:

- a) severity of the disease;
- b) rate of progression;
- c) musculo-skeletal function with special regard to any significant restrictions of motion;
- d) any complications that might cause sudden incapacity in flight.

As indicated above, the effects of long-term treatment should also be taken into consideration with regard to possible interference to flight safety or cause of sudden incapacity.

### **EXTREMITY DEFICIENCIES**

Any significant sequelae from disease, injury or congenital abnormality of the bones, joints, muscles or tendons should be assessed with regard to remaining functional capacity necessary for safe performance of aviation duties, including emergency procedures.

*Amputation of any part of an upper limb should be disqualifying for a professional pilot's licence unless a sufficient thumb-grip function is present on each hand enabling the applicant to manipulate the aircraft controls safely. Consideration might be given to whether or not a prosthesis may be acceptable under special circumstances. For Class 2 and Class 3 Medical Assessments an applicant may be considered fit if fitted with a satisfactory prosthesis.*

*In the case of lower extremity amputation, an applicant may be considered fit for a Class 1 Medical Assessment if fitted with a satisfactory prosthesis and adequate skill is demonstrated using it. Restriction to a specific aircraft type is likely to be required.*

Unwanted effects from the use of medication to control muscle spasm or other medical conditions e.g. sequelae from a head injury caused by an accident that resulted in the limb deficiency, must be considered. Sometimes the medication rather than the limb deficiency will be the limiting factor for certification.

### **GUIDELINES FOR ASSESSMENT**

Problems relating to orthopaedic deformities, amputations, limitations in the range of movement of joints, weakness of muscle groups, etc., must all be assessed on an individual basis. As with any other medical condition of importance for flight safety, the medical examiner must bear in mind both the possibilities of interference with the applicant's ability to perform necessary tasks under normal conditions, and the particular risk of sudden incapacitation or deterioration in flight, including prolonged and difficult flights. In the absence of objective neurological signs, this problem becomes a question of the degree of disability, and is rendered difficult but no less important by the predominantly subjective character of the available information.

The evaluation of these cases will often necessitate a special medical flight test as outlined in Part I, Chapter 2. This will give an opportunity for an applicant to demonstrate ability to carry out competently all the necessary tasks that may be required in each type of aircraft which the applicant is otherwise entitled to operate.

During a medical flight test the applicant should be assessed with regard to ability to reach readily and operate effectively all controls that would normally require the use of the deficient extremity (or extremities). The applicant should also be assessed with regard to his ability to move his head and torso to compensate for any lack of neck motion.

The distance over which any given control moves needs to be compared to full range of travel available to the limb in question, as well as full force required for each aircraft flown. In many aircraft elevator and rudder pedal control requires considerable force. Engine, accessory and propeller controls, as well as flaps and landing gear are usually activated by short control movements, fore and aft, up and down, or in rotary directions, with relatively little force. Radio controls and small switches, however, while requiring negligible force, do usually require reasonable pinch or opposition. Some prostheses do provide these functions. When assessing lower-limb function, the medical examiner should give special attention to the applicant's safe and efficient performance when ground braking action is applied.

A handicapped applicant should be required to demonstrate the ability to safely compensate for the handicap. The applicant should thus be required to be able to perform satisfactorily not only under normal flying conditions but also during any presumptive emergency procedures that might occur during flight, and during emergency evacuation. Lacking inherent stability, helicopters usually require more control inputs than aeroplanes.

The assessment of a prosthesis should also take into consideration the airworthiness aspects of any technical attributes required. When the prosthesis is required for safe aircraft operation, it should be considered as an extension of the controls of the aircraft and as such be of an equivalent airworthiness standard.

*The applicant's fitness for aviation duties should, as a rule, be based on a full medical investigation, including functional assessment in consultation with an operational expert. The licence may require endorsement with some special limitation or limitations, such as operation of a particular type of aircraft only or of an aircraft fitted with a special control or cockpit equipment. Although applicants with musculoskeletal difficulties may provide an aeromedical challenge, given adequate time and effort on behalf of the regulatory authority and the individual in order to devise a safe operating system, and with an appropriate limitation as necessary, many applicants with significant orthopaedic conditions can be safely assessed as fit to fly.*

## Chapter 9. MENTAL FITNESS

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## INTRODUCTION

To pilot an aircraft requires the utilization of a complex set of physical and cognitive skills. Interference with any aspect of these skills and their coordination may have serious personal and public safety consequences. The assessment of mental fitness shall therefore be made with due regard to the privileges of the licence and the ratings applied for or held, and to the conditions in which the applicants will have to carry out their duties. The period of validity of the Medical Assessment (between six months and five years) must also be taken into consideration.

The Standards and Recommended Practices of Annex 1, Chapter 6, while not sufficiently detailed to cover all individual conditions, require specific levels of mental fitness. Many decisions relating to individual cases will be left to the discretion of the medical examiner or will have to be decided by the medical assessor of the Licensing Authority. The contents of this chapter will provide guidance for making these decisions.

Annex 1 requirements on mental fitness, applicable to all categories of licences and ratings, are as follows:

6.3.2.2 The applicant shall have no established medical history or clinical diagnosis of:

- a) an organic mental disorder;
- b) a mental or behavioural disorder due to use of psychoactive substances; this includes dependence syndrome induced by alcohol or other psychoactive substances;
- c) schizophrenia or a schizotypal or delusional disorder;
- d) a mood (affective) disorder;
- e) a neurotic, stress-related or somatoform disorder;
- f) a behavioural syndrome associated with physiological disturbances or physical factors;
- g) a disorder of adult personality or behaviour, particularly if manifested by repeated overt acts;
- h) mental retardation;
- i) a disorder of psychological development;
- j) a behavioural or emotional disorder, with onset in childhood or adolescence; or
- k) a mental disorder not otherwise specified;

such as might render the applicant unable to safely exercise the privileges of the licence applied for or held.

*Note: Mental and behavioural disorders are defined in accordance with the clinical descriptions and diagnostic guidelines of the World Health Organisation as given in the International Statistical Classification of Diseases and Related Health Problems, 10th Edition — Classification of Mental and Behavioural Disorders, WHO 1992. This document contains detailed descriptions of the diagnostic requirements, which may be useful for their application to medical assessment.*

Any mental condition which the applicant experiences or has experienced in the past must be assessed to ascertain the associated functional deficit. The examiner must also consider the risk of recurrence of any disabling psychiatric condition. Furthermore, many psychiatric conditions exist co-morbidly with other psychiatric conditions and particularly with abuse or misuse of psychoactive substances. The examiner

must also be aware that, although the psychiatric condition may have responded well to treatment, the demands of the aviation environment are such that virtually any decrement in cognitive ability may have significant consequences.

In order to control an aircraft, aircrew members need:

- a) to know their position in space, which requires adequate sensory input (sight, hearing, balance, proprioception, etc.);
- b) to evaluate flight conditions and to choose a safe course to ensure the aircraft arrives safely at its destination, which requires the capacity to acquire information, process the information, and make relevant decisions;
- c) the physical capacity and the mental desire to carry out the chosen course of action.

Psychiatric conditions can cause an aircrew member to become incapacitated, which may be obvious or subtle, and the task of the medical examiner is to detect this or the likelihood thereof on the basis of the regulatory examination.

### **PREDISPOSITION TO PSYCHIATRIC ILLNESS**

The predisposition to psychiatric illness is a combination of nature, nurture, and life events.

The study of human genetics and the natural history of many psychiatric illnesses have made it evident that many conditions have a significant genetic component. It is now generally accepted that even human temperament has a significant genetic component. Although the genetic studies of psychiatric conditions including temperament are still in their infancy, it is to be expected that within a few decades, it will be possible to predict the emergence of mental illnesses in predisposed individuals.

This genetic predisposition, which may be stronger or weaker, is modified by life experiences related to childhood rearing or life events, which may result in the overt expression of a psychiatric illness. Persons with only a weak genetic predisposition may be able to withstand more nurture and/or life event stressors without expressing manifest psychiatric symptoms. In particular the study of psychiatric casualties of war and victims of disasters has demonstrated that no one is immune to the development of psychiatric symptoms when exposed to severe stressors.

In many cases, a psychiatric illness of adulthood has a harbinger of this illness in childhood and may be preceded by dissocial behaviour, poor academic achievement, difficulty in finding regular employment, use of addictive substances, anxieties, mood disorders, and attachment failures. A history of any of these should lead the medical examiner to attempt to gather further information from family, schools or health care providers.

## **PSYCHOLOGICAL TESTING**

Psychological testing of aircrew members is rarely of value as a screening tool. Personality tests alone have not been proven to be reliable tools to predict mental disorders or to assess with any degree of certainty an applicant's suitability for an aviation career. In general, the ability to pass the pilot ground school course is proof of adequate intelligence. Personality inventory testing may be of value in the hands of a psychiatric consultant when used as an adjunct to a psychiatric evaluation. Specific testing may be conducted for research and/or treatment purposes.

In neuropsychiatric conditions, sophisticated neuropsychological tests can be of benefit to determine the degree of cognitive, volitional and behavioural effect caused by the illness/injury. These tests can be used to monitor the progress of a neuropsychiatric disease process and may be conducted at intervals for this purpose.

## **PSYCHIATRIC DISORDERS IN AVIATION PERSONNEL**

In this chapter, the classification of psychiatric disorders follows that of the ICD-10 Classification of Mental and Behavioural Disorders of the World Health Organization (1992). There will be a cross-reference to the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) of the American Psychiatric Association where there are significant differences.

### **MOOD DISORDERS**

Depressive mood disorders (DSM-IV: Major Depressive Disorder) are common disorders which present with depressed mood, reduced energy, impaired concentration and memory, loss of interest in surroundings, slowed cerebration, difficulty in making decisions, alteration of appetite and sleep, guilt feelings, and low self esteem. Suicide is common; the incidence varies with cultural background, but may approach 20 per cent per depressive episode. The illness is usually of insidious onset and persists for many months when not treated adequately. Depression may be accompanied by a number of somatic symptoms. There may be diurnal variation in the symptoms, and many persons with depression may have some good days in between. It is not unusual for sufferers to try to modify their symptoms (especially the dysphoria and insomnia) by the use of alcohol and/or drugs.

Depression leads to subtle (and sometimes obvious) incapacitation, mainly due to the decreased ability to concentrate as well as to distractibility and indecision, which are frequent features of the illness. It is these symptoms, along with the risk of suicide, which make a depressed individual unsuitable to work in the aviation environment. Because the symptoms wax and wane during a depressive episode, there may be days when the individual is relatively well and may appear to be fit to fly. However, the impaired concentration and the lack of cognitive agility are always more or less present and may interfere with the ability to integrate the multiple sensory inputs required to make decisions in an emergency.

Depression is by nature a recurrent disorder and, although single episodes do occur, the history of a depressive episode should alert the medical examiner to ask specific questions to ensure that the applicant does not currently have the illness. Those persons who have had one serious depressive episode have approximately a 50 per cent risk of experiencing a second episode.

Response to treatment of depressive episodes may be very good and the sufferer may wish to return to his aviation position while still under treatment. It should be noted that even with good responses, there is usually some impairment of cognition and decision making ability which may impair performance in an

emergency, primarily by increasing the response time. The pronouncement of “being well” may refer only to relative improvement in comparison with the untreated state.

Because depressive mood disorders are recurring disorders, it is imperative that the “recovered” patient be monitored closely for signs of recurrence for a period of time following recovery. There is evidence that recurrence is most likely to happen during the first two years. An educative approach may help the individual recognize the earliest signs and thus facilitate early intervention. Ordinarily pilots should not be allowed to return to flying unless they have been off medication for at least some months after having returned to their euthymic state of health. In recent years, the use of SSRI (selective serotonin re-uptake inhibitors) has become widespread and there is indication that such treatment, aimed at preventing a new depressive episode, may be compatible with flying duties in carefully selected and monitored cases.

A history of mania, whether occurring in isolation or as part of a bipolar disorder, should lead to long-term disqualification. Mania is an unpredictably recurring disorder, which presents with grandiosity, increased energy, euphoria, reduced sleep, distractibility, and poor judgement. It may progress to overt delusions with marked irritability, anger, and danger to self and to others. Substance abuse is a fairly common consequence. Although this condition may respond moderately well to mood stabilizing agents, the risk of recurrence is significant and the degree of disruption of performance too great to allow a return to flying or air traffic control duties. When the episode of mania has remitted, the patient often feels as well as before and the reason why he should not assume an aviation career requires a great deal of explanation. However, the significant risk of recurrence even with mood stabilizing medication, along with the degree of disruption of mental function when there is a recurrence, precludes an aviation career.

Hypomania is a clinical condition that does not meet the full criteria of mania. It involves the same symptoms, but at a lesser degree of intensity. It usually includes expansive mood (may progress to euphoria), heightened sense of self (may progress to grandiosity), decreased need for sleep, increased energy, and distractibility. Judgement may be altered by the expansive mood and feeling of self-importance. Persons with hypomanic episodes have unstable moods and are prone to developing frank manic episodes and/or depressions. Consequently, they should be considered unfit for licensing.

## **SCHIZOPHRENIA AND DELUSIONAL DISORDERS**

The schizophrenic illnesses are disorders of thinking and perception. These disorders tend to occur in early adulthood (primarily in the 20's), often after a prodromal stage of several years. The perceptual disturbances most commonly take the form of auditory hallucinations, but may also involve visual or somatic hallucinations. The presence of delusions, often persecutory, along with the hallucinations may be quite pervasive in the life of the sufferer, who may become perplexed and experience marked disturbance of affect, drive, interest, memory and concentration. Suicide and homicide are significant risks.

Because of their recurring nature and because of the pervasiveness of the disruptions, these conditions are disqualifying for medical certification. The introduction of the newer anti-psychotic medicines, which often lead to better medication compliance, have resulted in better outcome for the schizophrenias. Nevertheless, the schizophrenic disorders remain incompatible with aviation safety.

Delusional Disorders may present without perceptual disturbances. Usually the delusions are relatively restricted and may follow only one theme, such as delusions of infidelity. The risk associated with a delusional disorder is that the person will act out behaviour to deal with the delusional belief without consideration of the effect of such action or behaviour on others.

A Brief Psychotic Disorder may involve all the symptoms of schizophrenia, but it lasts less than one month and is followed by a full return to the premorbid level of functioning. This disorder is usually secondary to

severe external stressors (“brief reactive psychosis”). If there is stability for at least one year without the need for anti-psychotic medication, this disorder need not preclude medical certification.

## **NEUROTIC, STRESS RELATED, AND SOMATOFORM DISORDERS**

### **(DSM-IV Anxiety Disorders, Somatoform Disorders, Dissociative Disorders, Adjustment Disorders)**

An aviation examiner must assess the degree to which any of the symptoms in this group of disorders will impair a pilot’s alertness and his ability to evaluate sensory input, to concentrate on the task at hand, to make decisions, and to execute those decisions with adequate cognitive and motor skill. Preoccupation with symptoms, a sense of anxiety, and the impaired cognition associated with many of these disorders would usually, at least temporarily, be disqualifying. Response to treatment, side effects of medications, and the risk of recurrence of symptoms are determining factors in the evaluation.

Any mental disorder with anxiety is disqualifying until the person has been asymptomatic without the use of psychotropic medicines for a period of at least six months. Since many of these disorders are of a chronic nature, it is important that in a new applicant, the natural history of his disorder should be part of the evaluation. Unless the disorder is likely to be resolved without long-term use of medication, an aviation career should be discouraged.

Persons who have experienced psychiatric symptoms in response to external stressors (Adjustment Disorders) should be assessed temporarily unfit but may be reassessed after a period of stability without use of psychotropic medication. Persons who undergo lengthy periods of stress frequently use alcohol and/or other psychoactive substances as a modifying agent. The medical examiner should always inquire about such use.

## **DISORDERS OF PERSONALITY AND BEHAVIOUR**

### **(DSM-IV Personality Disorders, Impulse Control Disorders, Paraphilias)**

Personality disorders are deeply ingrained maladaptive patterns of behaviour, which are present during the entire adult life of a person. These behavioural patterns may cause the person surprisingly little discomfort but are usually a source of distress to others. Because of the maladaptive quality of these personalities, they rarely fit well into society. They either marginalize themselves or are in various forms of conflict with their environment.

Many people have styles of behaviour which are far from optimal, but these must be differentiated from personality disorders, which are clearly maladaptive and may lead to conflict. People whose behavioural patterns are less than optimal also usually recognize the problem and have the ability to make changes that improve their situation.

It would be rare for a person with a personality disorder to have the emotional, intellectual and social flexibility to be a good, safe and functional pilot or air traffic control officer. Except in rare circumstances, persons with personality disorders should not be allowed to work in the aviation environment.

Persons with impulse control disorders are particularly unsuitable for careers in aviation. The inability to control an impulse when the adverse consequences are obvious is a major concern in someone accepting the responsibilities of a safety-sensitive function within aviation. Moreover, persons with these disorders are

also usually at odds with their environment, which is an added stressor and may lead to further inability to focus on the task at hand and detract from the attention required in aviation.

Applicants with disorders of behaviour (for example regarding habit, gender identity, sexuality) should be assessed on the basis of their ability to put aside the disorder (or any conflicts related to the disorder) in order to attend to the aviation task at hand. These persons may have significant conflicts with their environment, leading to further difficulties, which may become an impediment for them to hold an aviation licence.

## **ORGANIC MENTAL DISORDERS**

A wide range of agents can cause organic disturbances of the brain. The resultant symptoms depend on the causal agent, the part(s) of the brain affected, the previous health of the brain, and the current environment of the person. The causal agent may be external (alcohol, drugs, medication, injury, etc.) or internal (tumours, endocrine disorders, degeneration, etc.). An organic mental disorder may present with a wide array of psychiatric symptoms. The examiner may not always detect such a disorder unless he is aware of the possibility that the disorder may be present. The most common result of an organic insult to the brain is delirium or dementia, but anxiety, depression and behavioural changes may also have organic causes. An organic insult to the brain may result in reduced functioning, and once the insult is removed, there may still be concern about the continued optimal functioning of the brain.

The presenting symptoms of delirium are disturbed consciousness and a change in cognitive ability, developing over a short period of time. Return to the previous level of functioning may be swift once the causal agent is removed. A history of a delirium need not be a bar to licensing. If the delirium was caused by the use of alcohol or another psychoactive substance, a more intensive investigation should be undertaken. The operational aspects of cognitive incapacitation are further considered in Part I, Chapter 3.

Dementias are the result of progressive and irreversible brain damage, leading to impairment of memory and other cognitive disturbances. The most common dementia is Alzheimer's Disease, which usually has a slow, insidious onset after age 65 to 70. It is not unusual that older persons with disturbed cognition are given a diagnosis of Alzheimer's Disease without the benefit of a full psychiatric examination. It is imperative to rule out the presence of a depressive illness or indeed any reversible medical conditions, which may present with symptoms of dementia before deciding on a diagnosis. With older aircrew, the medical examiner should be aware of the possible presence of early dementia and at least carry out some rudimentary tests of cognition (e.g., The Mini-Mental Status Examination, Appendix 1). If this examination gives any evidence of deterioration, there would be reason to embark on more extensive medical and psychological investigations (e.g., neuropsychological testing, basic biochemistry, EEG, CAT scan, etc.).

## **SLEEP DISORDERS**

Insomnia affects up to one-third of the adult population, and large numbers of people complain of intermittent sleep difficulties. Individuals with insomnia become tense, anxious, preoccupied with sleep, and frequently complain of poor concentration and poor ability to focus on tasks. Persistent insomnia requires a complete history and thorough physical examination as the presence of organic causes must be ruled out (e.g. chronic pain, narcolepsy, sleep apnoea, episodic movement disorders).

Disturbed sleep is commonly associated with alcohol or substance abuse and with a host of psychiatric conditions including mood disorders, psychosis, and anxiety disorders. At times the sleep disturbance may be one of the presenting complaints and when further history is obtained, the other symptoms of the psychiatric disorder will be revealed. The sleep disorder may consist of initial insomnia (commonly

associated with anxiety), interrupted sleep (commonly associated with substance abuse, in particular alcohol), and early awakening (commonly associated with depression).

Insomniacs will frequently self-medicate with prescription or non-prescription medicines or with readily available substances such as alcohol.

Significant insomnia, if persistent, will lead to decreased function in many aspects of the insomniac's life. The consequences of the insomnia may be magnified by the presence of a psychiatric or medical illness.

Insomnia may exist without the presence of an underlying psychiatric disorder or substance abuse. Such cases are diagnosed as non-organic insomnia (ICD-10) or primary insomnia (DSM-IV). Polysomnographic studies will usually show increased stage 1 sleep and decreased stages 3 and 4 sleep.

Primary insomnia is a difficult condition to treat. Insomniacs frequently use hypnotics, prescribed or not, with little or no beneficial effect on the insomnia, but which may result in decreased alertness the following day. However, the use of hypnotics is normally disqualifying for those who need alertness to perform safely in an aviation environment.

Because of the decreased ability to function, persons with persistent insomnia pose a particular risk in the aviation environment. The risk is compounded by their frequent use of sedative medication and substances (especially alcohol) to relieve their distress. Because of the chronicity and complexity of the problem in many persons, this clinical problem is best managed by a psychiatrist or a psychologist with expertise in the treatment of insomnia.

Occasional sleeplessness or transient insomnia (usually difficulty initiating sleep) is a common disorder and is most often associated with situational concerns. This sleep disorder should not last for more than days and only if it persists beyond that will a more in-depth inquiry be required. Many sleep hygiene techniques may be helpful in alleviating brief periods of insomnia. These techniques include reduced intake of caffeine and alcohol, avoidance of heavy meals or vigorous exercise prior to sleep, a relaxing and comfortable sleep environment, and perhaps a non-stimulating warm drink prior to sleep.

Occasional sleeplessness may be managed with small doses of short acting sedatives with the proviso that no aviation related activity may be undertaken until the effects of the medication have passed. With short acting medications such as temazepam (Restoril®), zolpidem (Ambien®), or zopiclone (Imovane®), there should be a period of 8 to 12 hours after intake of a single dose of the medicine before undertaking aviation related tasks. Such medicines should only be taken under the direct supervision of a physician having specialist knowledge of aviation.

Changes in circadian rhythm may also lead to periods of insomnia. This rhythm disruption may be related to travel over several time zones or night duty and rotating-shift schedules at the place of work. Although insomnia associated with circadian rhythm changes is usually of short duration, the dysfunction may be more extreme and longer lasting in some people. In some controlled situations, there may be some value in the use of very short acting sedatives to aid in the adjustment of the circadian rhythm. There is some evidence that the use of melatonin may be helpful by accelerating the resynchronisation of the circadian rhythm, but because this substance is not an approved pharmaceutical medicine and its safety, purity and effectiveness have not been established by any government agency, its use in aviation is not recommended.

## FLYING AND PSYCHOACTIVE MEDICINES

With each passing year, physicians and patients are inundated with an ever wider range of psychoactive medicines which all promise better clinical response and fewer side effects. In many cases the marketing of these medicines implies that side effects are either not present or so minimal as to be insignificant. Although advances in psychopharmacology have been of great benefit in the treatment of psychiatric disorders, they rarely (if ever) return the patient to a pre-illness level of functioning. Most patients, on intensive examination, will report that although they feel much improved over their untreated state, they are aware that they have not had a total resolution of symptoms. Most will also report that although they have few side effects, they do experience some unwanted effects of the medication.

Because most psychiatric illnesses affect the ability to process information, to make a decision after the information processing, and then to undertake a course of action, any decrement in functioning could have a serious impact in an environment where events usually occur at a swift pace and where human beings are far from their natural habitat. It is for these reasons that psychoactive medicines may be used in the aviation environment only with the greatest degree of judiciousness and caution.

Aviation examiners must also be aware that their patients will not always volunteer information about taking medicine. As some of these medicines have few side effects, it may at times be difficult to detect their use. Medical examiners should therefore educate licence holders about the risks of psychoactive medicines.

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## Appendix 1

### MINI MENTAL STATUS EXAMINATION

The Mini Mental Status Examination (MMSE) is a widely used brief, standardized method for assessing cognitive mental status. It allows a gross assessment of orientation, attention, immediate and short-term recall, language, and the ability to follow simple spoken or written commands. It can be administered in the office whenever there is reason to suspect cognitive impairment. It takes about 20 minutes to administer. The maximum score is 30, and 95 per cent of persons should score 23 to 30. Anyone who scores less than 25 should undergo more sophisticated tests of cognition.

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**Part III**  
**Chapter 10. NEUROLOGICAL DISORDERS**

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## INTRODUCTION

Given the assumption that an intact and normally functioning nervous system is essential to flight safety, one might conclude that only the neurologically perfect person should hold an aviation licence. Since the nervous system is subject to abnormal conditions as are other body systems, not all licence holders are neurologically perfect. This chapter addresses neurological conditions that might compromise the safety of flight. Some can be accommodated with or without conditions, while others may preclude medical certification.

The neurological requirements in Annex 1 are as follows (identical for Class 1, 2 and 3 Medical Assessments):

6.3.2.3 The applicant shall have no established medical history or clinical diagnosis of any of the following:

- a) a progressive or non-progressive disease of the nervous system, the effects of which are likely to interfere with the safe exercise of the applicant's licence and rating privileges;
- b) epilepsy; or
- c) any disturbance of consciousness without satisfactory medical explanation of cause.

6.3.2.4 The applicant shall not have suffered any head injury, the effects of which are likely to interfere with the safe exercise of the applicant's licence and rating privileges.

## General Principles

When considering neurological disorders in licence holders, the medical assessor should be mindful of the following questions:

1. Does the licence holder have neurological disease at all?
2. If there is a static condition, does it functionally compromise flight safety?
3. Does the condition have a progressive temporal profile that can be monitored?
4. Does the condition have the potential for insidious incapacitation?
5. Does the condition have the potential for sudden incapacitation?
6. Has the licence holder recovered from the condition without functionally significant residual neurological compromise?

History is paramount in assessing neurological conditions, since the neurological examination and indeed laboratory studies are often normal. To emphasize this principle one need only consider syncope, migraine, the epileptic with a normal EEG, and the transient ischaemic attack with no cervical bruit or other finding. History is often the sole means of diagnosis, be it from the licence holder, the witness, the emergency responder, the medical professional, the medical records, or family and peers. Errors in aeromedical disposition are commonly rooted in historical inaccuracies.

Another important consideration in the evaluation of neurological fitness is the role of laboratory studies. The test result must be interpreted in the context of the entire clinical picture. Up to 40 per cent of epileptic individuals have normal electroencephalograms, and a significant proportion of normal individuals have false positive tilt table studies. The medical assessor must remain keenly aware of false positive and false negative laboratory studies.

When considering aeromedical disposition, the medical assessor should adopt an objective approach to risk assessment. What risk of recurrence is acceptable in an applicant? Incapacitation risk cannot be

reduced to zero since every individual has a risk of a first seizure, or a stroke, for example. After an increased risk has become apparent because of a neurological event or an investigation result, a decision has to be made concerning acceptable risk for aviation duty. Acceptable risk is likely to vary depending on the duty the applicant is licensed to perform. A professional pilot flying single pilot public transport operations requires a higher level of fitness than a private pilot. In this chapter, the approach has been taken that a risk of future incapacitation of one per cent per annum is a reasonable maximum risk to accept for a professional pilot engaged in multi-crew operations, although it is recognized that some States using objective risk criteria may consider this as too restrictive. However, for States seeking guidance on such issues, this figure is a reasonable starting point, for which there is considerable experience in some Contracting States. The topic of risk assessment and flexibility in medical certification is considered in more detail in Part I, Chapter 2.

A comprehensive review of neurological disorders is not within the scope of this chapter. Neurological conditions commonly encountered by the medical assessor will be addressed.

In the following text the terms “Operational Implications” and “Aeromedical Considerations” are used. The former refers to the initial decision concerning fitness to exercise the privileges of a licence, and the latter refers to a subsequent decision that may be made after further consideration, when time has passed and/or following appropriate examination and investigation.

## **Episodic Disorders**

By virtue of their ability to cause incapacitation, the episodic disorders are of clear aeromedical significance. Migraine headache, cluster headache, transient global amnesia, epilepsy, and the isolated seizure all are represented in the licence holder population, some being commonly encountered. Though vertigo is often of peripheral (labyrinthine) origin, central vertigo related to brain stem vascular or demyelinating disease may occur. The medical assessor must determine whether unrestricted certification, conditional certification, or disqualification is warranted. In general, a risk of sudden incapacitation exceeding one per cent per year is considered unacceptable for aviation duties of all classes, as well as safety-sensitive air traffic control duties.

### **Migraine**

Since migraine is common (17 per cent of women, 10 per cent of men), it is a frequent aeromedical certification issue. There are three varieties of migraine:

1. Common migraine: The headache occurs without aura, and is often but not invariably unilateral. Clinical features may include a throbbing quality, light and/or sound sensitivity, nausea, vomiting, and prostration. The headache may last hours or at times days, and often leaves the victim feeling drained.
2. Classic migraine: In classic migraine an aura precedes the headache by a number of minutes. Visual auras of myriad description are common and may include flashing or sparkling lights, coloured geometric patterns or whorls, zigzag patterns, or visual field compromise. Other focal neurological symptoms such as numbness in the face and hand or expressive speech difficulty may occur. The headache then follows.
3. Migraine Equivalent: In this condition, also known as migraine variant or acephalalgic migraine, there is a classic aura but no after-coming headache.

Rarely, other forms of migraine occur including “complicated migraine” (hemiplegic migraine or other form of stroke), ophthalmoplegic migraine with III nerve palsy, and basilar migraine with ataxia and confusion.

When determining medical fitness in migraine, the medical assessor should consider:

1. Prodrome: Some migraineurs experience an ill-defined uneasy, anxious, or unsettled feeling for a day or more before headache onset, allowing avoidance measures.
2. Precipitating factors: Certain foods (especially cheese and chocolate), sleep deprivation, exposure to sun, emotional stress, alcohol (especially red wine), and many other factors may be a specific trigger of migraine in an individual. Identification of these may allow countermeasures.
3. Aura: The nature of the aura is important in aeromedical disposition. A tiny scintillating or shimmering crescent in a small fraction of the visual field may be inconsequential, whereas transient loss of half of the visual field would be unquestionably compromising.
4. Rapidity of onset: In some persons rapid onset leads to relative incapacitation within minutes, whereas in others gradual onset over many hours affords ample time for avoidance while flying.
5. Frequency: Intervals between migraines may be years in some, and days or weeks in others.
6. Severity: Severe migraine may be essentially incapacitating due to pain, vomiting, and prostration. However, there is a range of severity from this level to a mild throb or almost imperceptible ache.
7. Therapy: Certain medications such as beta-adrenergic or calcium channel blocking agents may be aeromedically acceptable for migraine prophylaxis, while central nervous system effects of others (such as valproic acid, antidepressants, and narcotic analgesics) preclude their use in aviators.

*Operational implications:*

*A diagnosis of migraine is not compatible with any class of medical certification until a satisfactory determination of potential compromise to aviation safety has been made and effective countermeasures have been implemented.*

*Aeromedical considerations:*

*Applicants with migraine may be considered for medical certification if the disorder can be controlled. In some, simple avoidance of precipitating factors may be sufficient. The aura must be assessed. Loss of vision in one half of the visual field would not be acceptable, whereas in-flight occurrence of a minor scintillation in the far periphery of the visual field might not cause significant functional impairment. Slow onset over many hours might allow countermeasures, while rapid onset in minutes would be unacceptable. A frequency of one or two migraines annually may not be disqualifying, whereas several per month would bar certification. Severe migraine can be incapacitating, whereas mild migraine may be inconsequential. Satisfactory documentation of successful treatment with acceptable medications may allow medical certification. Beta-adrenergic and calcium channel blocking agents are among acceptable medications, whereas antidepressants, anticonvulsants, narcotic analgesics and several others are unacceptable.*

*Migraine may constitute an unacceptable risk in certain operations, such as single pilot operations having the prospect of immediate deployment. Multicrew operations can provide a measure of risk mitigation. The same might apply in air traffic control operations, where relief from a position is possible. Additionally, non-safety-sensitive air traffic control duties might be an option during an observation period.*

*An observation period of 6-12 months will often be appropriate to demonstrate effectiveness of avoidance countermeasures and/or treatment.*

## **Cluster Headache**

Cluster headache (Horton's headache<sup>1</sup>, histamine headache) is an uncommonly encountered distinct entity characterized by abrupt onset of severe intra-orbital, retro-orbital, or peri-orbital pain lasting 30-45 minutes, then rapidly subsiding. Associated clinical features may include unilateral nasal stuffiness, rhinorrhea, eye redness, lacrimation and, at times, Horner's syndrome<sup>2</sup>. A period with one or more headaches per day, sometimes occurring with clocklike precision, lasting several weeks might typify a "cluster". These headaches are severe and incapacitating, requiring intensive treatment during the episode. Intervals between clusters may be measured in years, during which medical certification warrants consideration.

*Operational implications:*

*Cluster headache is disqualifying for all classes of medical certification, since the headaches are incapacitating and medical treatment commonly precludes safety-sensitive duties.*

*Aeromedical considerations:*

*Headache clusters may be separated by months or years, and it is appropriate to consider medical certification when the cluster has cleared and treatment has ceased. Frequency of prior clusters is an important ingredient in this evaluation.*

## **Chronic Daily Headache**

Though not an episodic disorder, chronic daily headache is mentioned here for convenience. Formerly known by other names such as tension headache, these headaches are not incapacitating but nagging and frequent. Therapeutic agents (barbiturate-containing analgesics, antidepressants, minor tranquilizers, etc.) constitute the major aeromedical concern.

*Operational implications:*

*Chronic daily headache of significant severity and requiring treatment is disqualifying for all classes of medical certification.*

*Aeromedical considerations:*

*In addition to distraction and discomfort from the headache itself, chronic daily headache is often treated with narcotic analgesics, antidepressants, anticonvulsants, and perhaps sedative hypnotics and minor tranquilizers. The condition itself and the treatment thus preclude certification while these conditions prevail. Psychological factors also commonly need attention.*

*Medical certification may be possible when freedom from prohibitive medication and resolution of psychological factors have been achieved. A three to six month observation period to document resolution of symptoms is appropriate to the issue of chronic daily headache.*

## **Transient Global Amnesia (TGA)**

This condition is characterized by abrupt onset of severe anterograde and a variable degree of retrograde amnesia resolving in 24 hours (mean duration 4-6 hours). The individual performs normally, but asks

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<sup>1</sup> Horton's headache: after Bayard Taylor Horton, American physician (1895-1980)

<sup>2</sup> Horner's syndrome: ptosis of the upper eyelid, constriction of the pupil, and anhidrosis and flushing of the affected side of the face. After Johann Friedrich Horner, Swiss ophthalmologist (1831-1886).

repetitive questions and does not record new memories. Complex functions such as building a cabinet, putting together a bicycle, or flying an aircraft can be flawlessly performed during the event. When the episode resolves, retrograde amnesia shrinks in time, leaving a permanent retrograde gap of an hour or more. TGA usually occurs between ages 50-90, but it has been reported at any age, including adolescence.

Reported precipitants of TGA include cold water immersion, physical exertion, sexual intercourse, benzodiazepine use, medical procedures such as transfemoral angiography, and intense emotion.

Though typically an isolated event, a recurrence rate of three per cent per year over five years has been reported. The cause is unknown, but any association between TGA and cerebrovascular disease has been refuted by scientific evidence. Medical certification may be considered following an observation period.

#### *Operational implications:*

*A diagnosis of Transient Global Amnesia is disqualifying for all classes of medical certification because of risk of sudden impairment.*

#### *Aeromedical implications:*

In many individuals with Transient Global Amnesia there is a readily identifiable proximate precipitant, such as emotional stress, cold water immersion, or other factors.

*Absent the precipitating circumstances, medical certification is appropriate following a symptom free observation period of one year or more. Restriction to multicrew operations and non-safety-sensitive air traffic control duties can provide an additional measure of risk mitigation.*

## **Syncope**

Syncope is defined as loss of consciousness and postural tone due to global cerebral hypoperfusion, followed by spontaneous recovery. In near-syncope or pre-syncope, consciousness is compromised but preserved. The condition is common, occurring in three per cent of the population. The terms vasovagal, neurocardiogenic, neurally mediated, and neuroregulatory syncope are synonymous. In vasodepressor syncope there is collapse of peripheral resistance (relaxation of the peripheral arterial sphincter). This is the predominant mechanism in most cases of syncope, as opposed to cardio-inhibitory syncope characterized by bradycardia. Sudden syncope is almost always of cardiac origin (cardio-inhibitory). Syncope is a disturbance of homeostasis, the balance between cardiac output, blood volume, and peripheral resistance.

It is important to distinguish syncope clinically from other conditions, most importantly seizure. History is paramount, and the medical assessor should consider the following:

1. **Postural Setting:** Syncope characteristically occurs in the upright position, is unusual while sitting, and is rare in recumbency.
2. **Prodrome:** In vasodepressor syncope a significant prodrome of 2-5 minutes is common, during which distinct symptoms may occur. Visual symptoms (darkened vision or constricted visual fields, bleached white or yellow vision) point to retinal, not cerebral, ischaemia, indicating an extracerebral event. Nausea, queasiness, yawning, lightheadedness, pallor, and sweating are other usual features.
3. **The Syncopal Event:** Syncope is brief, lasting 10-15 seconds with little or no confusion. The individual is pallid, with shallow or imperceptible respirations. Collapse is a hypotonic event in which the individual softly folds into a heap (syncopal slump).

4. Convulsive Accompaniments and Urinary Incontinence: Brief convulsive twitching or tonic posturing occurs in ten per cent of individuals with syncope, and urinary incontinence occurs in a similar proportion. Care must be taken to avoid interpreting these features as indications of epileptic seizure.
5. Syncopal Setting: Specific circumstances are often associated with syncope. These include worry, fear, micturition, physical exertion (weightlifter's syncope), medical procedure such as venipuncture, pain, sight of blood, and others.

When determining the aeromedical significance of syncope, the medical assessor must search for the mechanism of its occurrence. Fortunately, benign situational syncope is the most common event. Other causes include orthostatic events related to medication, blood loss, dehydration, and other mechanisms. Disturbances of cardiac output and disturbances of cardiac rhythm must also be considered. Seizures may mimic syncope, and differentiating syncope from seizure has clear aeromedical implications. The nature and direction of evaluation for syncope is guided by the clinical setting. Once potentially serious mechanisms of syncope have been ruled out, medical certification can be considered.

*Operational implications:*

*Syncope should be considered disqualifying for all classes of medical certification until the cause for syncope is identified and the risk for recurrence has been determined.*

*Aeromedical considerations:*

*Fortunately syncope is mostly benign and often situational. Medical certification is appropriate when the benign nature of the event has been identified and potentially serious mechanisms of syncope have been considered and excluded. If treatment or other countermeasures are employed, an observation period ranging from three months to one year might be appropriate. A three month period might be appropriate when one or two fully explained benign events have occurred over time, whereas multiple recurrent episodes requiring treatment may warrant a six to twelve month period of observation before medical certification is considered. Restriction to multicrew operations and non-safety-sensitive air traffic control duties, at least for a period, may further mitigate the risk.*

## **Seizure Disorder**

A seizure is an abnormal paroxysmal excessive discharge of cerebral cortical neurons. Epilepsy, seizure disorder, and convulsive disorder are synonymous terms. Epilepsy is defined as a tendency towards recurrent, unprovoked seizures. An individual must experience recurrent (i.e. at least two) seizures to qualify for a diagnosis of epilepsy.

Not all seizures represent epilepsy. For example acute symptomatic seizures can occur with insulin induced hypoglycaemia, hypoxia from cardiac arrest, hyponatraemia, acute infection (e.g. pneumococcal meningitis with high dose penicillin) and other symptomatic precipitants. These conditions do not portend chronic seizure potential. On the other hand, symptomatic seizures related to a subdural haematoma six months earlier imply a glial scar and likely recurrent seizures.

For aeromedical purposes, a basic seizure classification suffices:

1. Generalized from Onset: At seizure onset, as the name implies, simultaneous epileptiform discharges appear in all areas of the cortex. Idiopathic grand mal epilepsy is a prime example of this condition. Brief lapses of awareness may occur with petit mal seizures (absence seizures), commonly occurring in childhood.

2. Partial Simple Seizures: Formerly known as focal seizures, partial simple seizures arise in a discrete area of cerebral cortex, with seizure content depending on location. By definition consciousness is preserved. Localized convulsive twitching of one hand might arise from a neoplasm in the contra-lateral cerebral cortex.
3. Partial Complex Seizures: Formerly known as temporal lobe or psychomotor seizures, these seizures are also focal (partial) in onset, but consciousness is impaired. An aura may occur such as a déjà-vu experience, forced thought, or memory. Consciousness is impaired, and a dreamy state may occur with non-responsiveness to the environment. Stereotyped movements (temporal lobe automatism) may occur. The episode lasts a minute or two, with an element of post-ictal confusion being common.
4. Partial Seizure with Secondary Generalization: Any partial seizure may spread to other cerebral structures and evolve to a generalized tonic-clonic seizure. For example, a seizure may begin in the hand and gradually spread to the limb and hemi-body (Jacksonian march<sup>3</sup>), then progress to a generalized (grand mal or generalized tonic-clonic) seizure.

It is important to recognize a partial (focal) seizure, since this type of seizure implies a focal lesion. The nature of the focal lesion (scar, haematoma, cavernous malformation, infarct, neoplasm, other) must be determined. However, 60 per cent of all seizures are of unknown cause.

A generalized tonic-clonic (grand mal) seizure begins with a tonic phase lasting 15-20 seconds. Eyes remain open and are deviated upward. Forced exhalation against partially closed vocal cords may lead to a long, eerie, decrescendo “epileptic cry.” There is cyanosis, apnoea, and tonic extension of the limbs. The tonic phase soon gives way to a clonic phase characterised by alternating clonic contractions and relaxations. Relaxed intervals increase progressively until the seizure ends, usually within one to two minutes. Tongue biting and incontinence commonly occur. Post-ictal confusion is characteristic, as is amnesia for the event. Headache, nausea, vomiting, muscle soreness, and fatigue frequently follow a seizure.

When evaluating seizures one must consider many factors, including family history, medication, alcohol, illicit drugs, and remote neurological insult, as well as EEG and imaging findings. History is of paramount importance in separating seizure from syncope with convulsive accompaniment.

History, neurological examination, electroencephalogram, and most often an imaging study (CT<sup>4</sup> or MRI<sup>5</sup> of the brain) are the components of a seizure evaluation. A drug screen may be appropriate along with routine laboratory studies. The EEG can be normal in up to 40 per cent of individuals with seizures, and a small number of persons have epileptiform EEGs but no seizures (respectively “fits without spikes” and “spikes without fits”).

Seizures tend to recur, and thorough evaluation is warranted before considering medical certification. Specific syndromes such as benign Rolandic<sup>6</sup> epilepsy with centro-temporal spikes are characterized by permanent remission from seizures. In others, seizures may recur after long intervals. Thorough neurological evaluation is warranted when considering medical certification in individuals with a history of seizures. A small number of individuals have been certified following epilepsy surgery.

*Operational implications:*

*The existence of or history of a seizure disorder is disqualifying for all classes of medical certification.*

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<sup>3</sup> Jacksonian march: the spread of abnormal electrical activity from one area of the cerebral cortex to adjacent areas. After John Hughlings Jackson, English neurologist (1835-1911)

<sup>4</sup> CT: computerised tomography

<sup>5</sup> MRI: magnetic resonance imaging

<sup>6</sup> Rolandic: named after Luigi Rolando, Italian anatomist (1773-1831)

*Aeromedical considerations:*

*It is prudent to adopt the position that seizures tend to recur, warranting permanent disqualification. Medical certification is appropriate only in very specific circumstances in which the subject has been fully evaluated and permanent remission has been assured. A history of febrile seizures does not portend long term seizure potential. Specific self-limited conditions such as Benign Rolandic Epilepsy with Centro-temporal Spikes will allow medical certification after an observation period of five years or more. Acute symptomatic seizures (e.g. related to hyponatraemia) do not portend chronic seizure potential and allow medical certification. Thorough neurological evaluation is warranted in all individuals with a history of seizure disorder. Additionally, recurrence risk must be assessed; if greater than one per cent per year, medical certification is not appropriate.*

### **The Single Seizure**

When an individual suffers his or her first ever seizure, a thorough search for cause is appropriate. Risk factors for recurrence include seizures in immediate family, a history of febrile seizures, prior acute symptomatic seizure, remote neurological insult, abnormal neurological examination, abnormal cerebral imaging study, and abnormal EEG. Absent these risk factors, recurrence risk is approximately 30 percent over four years. If there is no recurrence without medication in four years, the risk may then become acceptable for medical certification.

*Operational implications:*

*The occurrence of a single seizure is disqualifying for all classes of medical certification.*

*Aeromedical implications:*

*Medical certification is appropriate following a single seizure when all studies are normal and there are no risk factors for recurrence. Consideration should not be given until a four year seizure-free and medication-free observation period has been achieved. With normal studies and no risk factors, recurrence risk after four years approximates that of the normal population. Medical certification is appropriate at this juncture.*

### **The Screening EEG**

The use of the EEG for screening purposes, in applicants with no relevant history, has been controversial for many years. The United States Federal Aviation Administration and the European Joint Aviation Authorities do not require EEG investigation, except on indication. However, some States utilize the EEG as a risk assessment tool for potential epilepsy. As epileptiform discharges may occur in individuals who never have a seizure, such an EEG may lead to unnecessary disqualification. ICAO medical provisions do not require routine EEG screening and most of the major Contracting States have determined that a screening EEG is not essential to flight safety.

## **CEREBROVASCULAR DISEASE**

### **Ischaemic Stroke**

Eighty-five percent of strokes are ischaemic thrombotic events, the remainder haemorrhagic. Ischaemic strokes include large artery atherothrombotic stroke (e.g. extracranial carotid artery or intracranial middle

cerebral artery) and small vessel lacunar stroke commonly seen in hypertensive individuals. Embolic stroke (artery to artery or cardio-embolic source) must also be considered. In persons experiencing a transient ischaemic attack (TIA), risk of subsequent stroke is approximately 30 per cent within five years.

Risk factors for stroke include hypertension, hyperlipidaemia, diabetes, tobacco use, cardiac disease, atrial fibrillation, and asymptomatic carotid stenosis. In the young, additional factors must be considered such as hypercoagulable states, patent foramen ovale, and arteriopathies.

The medical assessor is usually not involved in the acute evaluation or treatment of stroke, but becomes involved when medical certification is sought. Clearly the existence of any persistent neurological deficit must be addressed in terms of functional compromise.

Assuming absence of significant neurological deficit, risk for recurrent stroke becomes the prime consideration in aeromedical disposition (and risk of cardiac disease in large artery stroke such as carotid disease). Beyond the first year, recurrence risk is about four per cent per year, with some variability depending on stroke subtype.

In considering medical certification following stroke, the medical assessor must consider stroke mechanism, corrective measures if undertaken (e.g. carotid endarterectomy), degree of attention to risk factors (e.g. treatment of hypertension and hyperlipidaemia), and neurological stability during a suitable observation period.

*Operational implications:*

*Ischaemic stroke is disqualifying for all classes of medical certification.*

*Aeromedical considerations:*

*Stroke is a heterogeneous entity with many causes, and careful individual evaluation is appropriate. Medical certification is appropriate when cause and risk factors have been identified and addressed and a recurrence risk has been assessed. Recurrent stroke may cause sudden incapacitation, and a recurrence risk exceeding one per cent per year is not acceptable. A recurrence free observation period is appropriate prior to medical certification following ischaemic stroke, and this will vary dependent upon mechanism and risk factors. Stroke in the young with known mechanism (e.g. patent foramen ovale with paradoxical embolism and successful closure) may allow medical certification after one year. If an individual with arterial dissection has no recurrence in one year, risk recurrence thereafter is less than one per cent per year. Lacunar stroke associated with hypertension-related small blood vessel disease may allow medical certification after one year, whereas stroke due to atherothrombotic disease with risk factors might allow medical certification after two years. In some instances, medical certification may never be appropriate.*

## **Haemorrhagic Stroke**

The vast majority of intracerebral, parenchymal haemorrhages occur in hypertensive individuals. Death or severe disability ordinarily precludes medical certification. Vascular malformations including cavernous angiomas may also lead to intracerebral bleeding, sometimes with complete recovery. In some instances, surgical cure is accomplished, allowing medical certification. Though surgical cure of a vascular malformation might preclude re-bleeding, the risk of residual seizures may still bar certification.

*Operational limitations:*

*Haemorrhagic stroke is disqualifying for all classes of medical certification.*

*Aeromedical considerations:*

Most haemorrhagic strokes occur in individuals with hypertension, and many result in death or severe disability. There are exceptions in which tissue destruction is minimal and recovery is complete or near complete. Haemorrhages related to anticoagulants may not result in significant deficit.

*If the cause of the haemorrhage can be identified and addressed satisfactorily, medical certification may be possible once the recurrence risk has been evaluated. The recurrence risk will depend upon the underlying mechanism. A one to two year observation period is appropriate following haemorrhagic stroke. A full neurological evaluation indicating satisfactory recovery and freedom from relevant risk factors may allow medical certification at that time.*

### **Subarachnoid Haemorrhage**

Most commonly subarachnoid haemorrhage results from sudden rupture of an intracranial saccular aneurysm. Aneurysms ordinarily arise from major arteries at the base of the brain (Circle of Willis<sup>7</sup>) and are thought to develop from congenital changes in the muscular wall of the artery and degenerative changes in the internal elastic lamina. Death occurs in 23 per cent, and half of the survivors have significant disability.

If an individual recovers from aneurismal, subarachnoid haemorrhage and the aneurysm is surgically isolated from the circulation, medical certification may be considered. Sequelae may include focal neurological deficit, seizures, and cognitive impairment. Absent these conditions and with a period of symptom free observation, medical certification may be possible. Surgical cure should be verified by postoperative angiography.

In some individuals subarachnoid haemorrhage occurs without demonstrable cause. If there is no recurrence within one year, statistics reveal an acceptably low risk of recurrence thereafter. In another specific condition, called peri-mesencephalic or pre-pontine subarachnoid haemorrhage, recurrence risk is low.

*Operational implications:*

*Subarachnoid haemorrhage is disqualifying for all classes of medical certification due to risk of sudden incapacitation.*

*Aeromedical considerations:*

*Successful isolation of the haemorrhagic source from the circulation and freedom from significant deficit should allow medical certification after one year, during which risk of complications including seizures declines. Partial obliteration of an aneurysm with residual lumen may present an unacceptable risk. For subarachnoid haemorrhage of unknown cause, a one year observation period is also warranted. The presence of a vascular malformation (cavernous angioma, arteriovenous malformation) requires individual evaluation. Residual malformation, hemosiderin deposition and other factors will affect risk for recurrent haemorrhage or seizure, and medical certification may not be possible.*

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<sup>7</sup> Circle of Willis: circulus arteriosus cerebri. After Thomas Willis, English anatomist (1621-1675).

## TRAUMATIC BRAIN INJURY

Traumatic Brain Injury (TBI) is a major cause of neurological disability in the licence holder population. Most head injuries, including some with a linear skull fracture, do not involve brain injury. Minimal criteria for TBI include loss or alteration of consciousness, focal neurological deficit, or cerebral imaging evidence of injury. Liberal use of modern imaging techniques may indicate parenchymal injury (localized haemorrhage) in individuals with no clinical signs or symptoms of injury.

The medical assessor becomes involved when the licence holder with TBI has presumably recovered and presents for medical certification. It is important to determine the nature and severity of injury as part of the evaluation.

Medical history and medical records should allow determination of the nature of the injury. Varieties of injury include simple concussion, traumatic subarachnoid haemorrhage, intracranial haematoma (epidural, subdural, intraparenchymal), cerebral contusion, diffuse axonal injury (DAI), and penetrating injury with laceration of cerebral tissue and supporting connective tissue.

Severity of injury can be assessed by records employing standardized measures of severity including the Glasgow Coma Scale<sup>8</sup> and the duration of Post Traumatic Amnesia (PTA - the amount of time between the injury and the return of continuous memory). PTA of 0-1 hour constitutes mild TBI, 1-24 hours moderate TBI, 1-7 days severe TBI, and beyond seven days very severe TBI.

Sequelae of TBI include post-concussion syndrome, focal neurological deficit, cognitive residual changes, and posttraumatic epilepsy (PTE).

### **Post-concussion Syndrome**

Post-concussion syndrome is characterized by a set of nonspecific symptoms including headache, insomnia, irritability, a non-specific dizziness, poor concentration, memory loss and other complaints. Neurological examination and imaging studies are normal. The condition is self-limited, generally resolving in weeks or months. Symptomatic medications are often employed, precluding medical certification until the condition subsides.

### **Focal Neurological Deficit**

The major part of recovery from focal deficits such as hemiparesis, aphasia and other deficits takes place within six months of injury, though further recovery occurs at a slower pace over two to three years. Medical records and current neurological functioning will provide information regarding persistent deficit.

### **Cognitive Residual Sequelae**

The frontal lobes of the brain have to do with personality and behaviour, and the temporal lobes with intellect and memory. Frontal deceleration is the most common mechanism of TBI, rendering these structures more susceptible to injury than more cushioned posterior structures. When there has been moderate to severe TBI, with Glasgow Coma Scale score of 9 or below or posttraumatic amnesia exceeding 24 hours, the medical assessor should have a high index of suspicion for cognitive residual

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<sup>8</sup> Glasgow Coma Scale: a standardized system for assessing response to stimuli in a neurologically impaired patient; reactions are given a numerical value in three categories (eye opening, verbal responsiveness, and motor responsiveness), and the three scores are then added together. The lowest values represent the poorest clinical scores. After Glasgow, in Scotland, where the scale was developed.

effects. When indicated, detailed neuropsychological testing by a qualified examiner may document the presence or absence of any cognitive residual sequelae.

### **Posttraumatic Epilepsy (PTE)**

The risk of seizures following TBI is a major concern. With penetrating injuries involving violation of the cranial vault, the risk is high and may approach 40 per cent. In more commonly occurring closed head injuries, risk is a much lower five per cent. Risk increases with severity of injury. Cerebral contusion, parenchymal haematoma, posttraumatic amnesia beyond one day, depressed skull fracture and subdural haematoma confer increased risk. The presence of blood within the parenchyma is of major concern, since PTE is believed to be an “iron driven” phenomenon.

A period of observation following TBI is often prescribed prior to medical certification, since risk of PTE declines with the passage of time. Approximately 50 per cent of individuals, destined to develop PTE, will experience their first seizure within six months, about 75 per cent within the first year, and about 90 per cent within two years. With penetrating injuries 97 per cent of the risk will have been achieved in three years, though some elevated risk still persists ten years after the injury.

*Operational implications:*

*Traumatic brain injury is disqualifying for all classes of medical certification.*

*Aeromedical considerations:*

*Post-concussion syndrome is characteristically self-limited, and medical certification may be considered within 3-6 months of symptom free observation. Depending upon severity, focal neurological deficit may warrant a six months to two years period of observation for maximal neurological recovery. In individuals with neuropsychological residual changes, usually indicating significant traumatic brain injury, a one to five year observation period is warranted depending upon severity of cognitive impairment. Careful cognitive evaluation for permanent impairment should then precede medical certification.*

*Posttraumatic epilepsy is a major concern following traumatic brain injury. The presence of blood (hence iron) in the brain parenchyma is thought to play an aetiological role in the development of posttraumatic epilepsy. Simple uncomplicated epidural haematoma without parenchymal blood might allow medical certification following a one to two year observation period. Subdural haematoma is often associated with underlying cortical contusion, increasing risk of posttraumatic epilepsy. Significant risk is present in the first two years post injury, though it declines with time. Medical certification may be appropriate after two years. With intraparenchymal haematoma, a two year period of observation is warranted due to the presence of parenchymal blood. Seizure risk also exists with diffuse axonal injury, and a period of one to two years of observation is appropriate.*

*In some individuals with severe injury, perhaps including intracranial haematoma, focal neurological deficit, and cognitive impairment, medical certification may yet be possible after eventual recovery. In such cases, however, an observation period up to five years may be appropriate.*

### **NEOPLASMS**

Intracranial neoplasms are not rare and will be encountered in the licence holder population. Neurological symptoms may include headaches and vomiting related to increased intracranial pressure, seizures, focal neurological deficit related to mass effect or infiltration, cognitive changes, and visual field defects related to pituitary neoplasms.

## **Benign Neoplasms**

Benign intracranial neoplasms may involve the dura mater, cranial nerves, or brain parenchyma. Extraparenchymal tumours include meningioma, neurofibroma, acoustic neuroma (Schwannoma<sup>9</sup>) and pituitary adenoma. Benign parenchymal growths include ependymoma, choroid plexus papilloma, and colloid cyst (considered a cyst rather than a neoplasm). Though craniopharyngiomas are benign, they may invade adjacent neural tissue and are subject to recurrence.

If complete excision can be accomplished, the licence holder may be cured and thus eligible for medical certification. At times there may be residual neoplastic tissue, since complete excision carries the risk of creating a neurological deficit. In such instances, medical certification may be possible, conditional upon satisfactory follow-up with serial imaging studies and current status reports.

### *Operational limitations:*

*The presence of a benign intracranial neoplasm is disqualifying for all classes of medical certification.*

### *Aeromedical considerations:*

*Successful removal of a benign intracranial neoplasm with uneventful recovery will allow medical certification following one year of observation, primarily related to seizure risk. Posterior fossa neoplasms, which characteristically do not lead to seizures, are an exception. Ordinarily limitations have to be imposed, with certification being conditional on periodic evaluation for tumour recurrence.*

## **Malignant Neoplasms**

Malignant glial neoplasms, including astrocytomas and oligodendrogliomas, characteristically have invasive qualities without distinct boundaries. The interdigitation of neoplastic with normal neuronal tissue precludes complete resection, and thus a “debulking” surgical procedure is commonly employed. Eventual recurrence is the rule, though with low grade glial neoplasms this may occur indolently over many years. Seizures are a risk, and subtle neurological impairment depending upon location is an additional concern. These features ordinarily preclude medical certification, though some cases of cure appear in the literature.

### *Operational implications:*

*Malignant intracranial neoplasms are disqualifying for all classes of medical certification due to risk of sudden or insidious incapacitation.*

### *Aeromedical considerations:*

*Malignant parenchymal neoplasms may be debulked by surgical measures, but neoplastic cells characteristically remain and recurrence is the rule. A permanent bar from certification is therefore warranted. There may be very rare exceptions following a long recurrence free and symptom free interval (e.g. ten years).*

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<sup>9</sup> Schwannoma: a neoplasm originating from the Schwann cells (of the myelin sheath) of neurons. After Theodor Schwann, German anatomist and physiologist (1810-1882)

## HEREDITARY, DEGENERATIVE, AND DEMYELINATING DISORDERS

Certain neurological conditions follow a benign course for many years, causing no significant concern for aviation safety. Others follow a slowly progressive temporal profile, lending themselves to monitoring measures that can identify the point of compromise to flight safety.

### **Familial and essential tremor**

Essential tremor is the most commonly occurring movement disorder with a prevalence of five to six per cent. Familial tremor is identical, apart from having a positive family history. Mean age of onset is in middle life. Over 90 per cent of affected individuals experience hand tremor, 33 per cent head tremor, 16 per cent voice tremor, and 12 per cent leg tremor. In familial tremor an autosomal dominant pattern is observed. Tremor progresses very slowly over many years. Handwriting, fine movements such as using a screwdriver or threading a needle, and drinking soup from a spoon, may be affected. The tremor is present with intention and maintaining posture.

Essential/familial tremor is most often an annoyance rather than a significant functional disability. Treatment with aeromedically acceptable beta-adrenergic blocking medicines is often highly effective. Other agents such as primidone have potential sedating and other central effects, precluding their use in licence holders.

*Operational limitations:*

*Familial and essential tremor is ordinarily not disqualifying unless significant functional impairment is present.*

*Aeromedical considerations:*

*In many individuals tremor is mild without need for treatment. Identification of the disorder, exclusion of other potentially serious conditions, and determination of functional impairment may allow immediate medical certification. In more severe cases with an element of functional impairment, treatment (e.g. propranolol) may warrant a three month observation for effectiveness prior to medical certification.*

### **Parkinson's Disease**

Parkinson's disease<sup>10</sup> is characterized by three major symptoms: tremor, rigidity, and bradykinesia (slowness of movement). The disease may progress slowly over many years in some, though disturbingly rapidly in others. Tremor at rest is a classic feature, giving rise to the term "shaking palsy" in earlier literature. Medical certification may be considered early in the course of the disease. Therapeutic agents including carbidopa/levodopa may be acceptable, while the dopamine agonists are unacceptable due to their sedative potential.

*Operational limitations:*

*A diagnosis of Parkinson's disease in itself is not disqualifying for any class of medical certification.*

*Aeromedical considerations:*

*A diagnosis of Parkinson's disease should lead to a thorough neurological evaluation, exclusion of related conditions, and evaluation of need for treatment. Medical certification may be appropriate*

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<sup>10</sup> Parkinson's disease: paralysis agitans. After James Parkinson, English physician (1755-1824)

*immediately in mild conditions. Medication must also be considered. Levodopa agents may be allowed, but dopamine agonists are prohibitive due to their potentially sedating effects. If certification is granted following medical evaluation, it should be conditioned upon periodic re-examination and re-evaluation. If disease progression presents a risk to aviation safety, the Medical Assessment should be revoked.*

## **Multiple Sclerosis**

Multiple sclerosis (MS, sclerosis disseminata) is an autoimmune disorder where the immune system attacks the central nervous system, causing patches or plaques of demyelination in the brain or spinal cord, with eventual axonal loss and glial scarring (sclerosis). The commonly known form is characterized by remissions and exacerbations (relapsing and remitting MS), but there are primary progressive and secondary progressive forms. Age of onset is often between age 20 and 40, and there is slight female preponderance. Symptoms are myriad and may include localized sensory disturbances, gait abnormalities, focal motor deficit such as hemiparesis or paraparesis, optic neuritis, speech disturbances, and sphincter disturbances.

Acute exacerbations are commonly treated with corticosteroids, whereas immuno-modulatory therapy is commonly employed to reduce the frequency and severity of exacerbations. Therapeutic agents include the interferons and glatirimer acetate. Chemotherapeutic agents are employed in severe cases.

Medical certification may be considered in licence holders with MS, ordinarily conditioned on stability, degree of deficit, and nature of deficit. Symptoms such as vertigo and diplopia would clearly compromise flight safety, while minor paresthesiae in an extremity might be inconsequential.

### *Operational limitations:*

*A diagnosis of multiple sclerosis is disqualifying for all classes of medical certification.*

### *Aeromedical considerations:*

*Some individuals with multiple sclerosis experience rapid progression of disease, and others have lesions in areas causing severe functional impairment (e.g. brain stem lesion with diplopia and vertigo). Others experience a benign course with little or no deficit. Treatment with immuno-modulatory agents (glatirimer acetate, beta-1a and beta-1b interferon) does not preclude certification. When recovery from an exacerbation has occurred and stability under observation has been documented, medical certification is appropriate. With minor occurrences, a three month period of observation may be sufficient, whereas six to twelve months may be more appropriate when more significant disease is present.*

## **Operational Considerations**

Operational considerations are important in medical certification of individuals with neurological disorders. Single pilot operations, with the prospect of immediate deployment may be disqualifying for certain conditions such as migraine and multiple sclerosis, whereas airline pilot operations may be compatible with certification. Multicrew operations will often confer an additional measure of risk mitigation, allowing favourable aeromedical dispositions. The same is true for air traffic control duties, where single controller positions can be avoided. Additionally, circumstances may allow assignment to non-safety sensitive air traffic control duties during a period of observation that might lead to favourable medical disposition. Thus operational considerations may allow some latitude in the medical certification process.

## CONCLUSION

In the aeromedical disposition of licence holders with neurological disorders, the medical assessor must use the time honoured tools of the history, the examination, review of records, and the laboratory findings. Combining these elements with his or her experience and the evaluation of a neurologist, the medical assessor can arrive at the appropriate aeromedical disposition.

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# Chapter 11

## OPHTHALMOLOGY

### 11.1 INTRODUCTION

11.1.1 This chapter outlines the principles of ophthalmologic examination and assessment of visual functions in relation to aviation duties. The medical examiner should be familiar with the visual requirements for safe flight and other aviation functions such as air traffic control. The ordinary clinical eye examination will be reviewed, and the requirement for special examinations in certain cases will be described. The material in this chapter does not have any regulatory status. Its main purpose is to serve as a guide in the implementation of the medical provisions of Annex 1. Methods are outlined for the comprehensive evaluation of the visual function of applicants at initial and periodic re-examinations. The aim is to achieve a measure of international uniformity of procedures and results in the assessment of both normal applicants and those in whom there is suspicion or overt manifestation of disturbed visual function or eye disease.

11.1.2 Proper visual performance is essential for flight crew and air traffic controllers if they are to carry out their duties safely and efficiently. In the flight environment the following factors should be kept in mind because they may reduce visual performance significantly:

- a) high speed
- b) altitude
- c) inadequate cockpit illumination
- d) glare
- e) acceleration
- f) vibration
- g) poor ergonomics
- h) adverse cabin environment.

11.1.3 The high speeds of modern aircraft while cruising and during take-off or landing make good static and dynamic vision and rapid reaction time particularly important. Visual perception is usually the first step in the reflex chain which initiates the motor activity to avoid collision.

11.1.4 Altitude affects the quality and quantity of electromagnetic radiation to which the flight crew are exposed. During flight above clouds, sunlight is reflected upwards. This inverse light distribution leaves the instrument panel in shadow while the outside is very bright. The human visual system is designed to function best with illumination coming from above; in some aircraft with "bubble" canopies, flight over brightly lit clouds may be very uncomfortable. With increasing altitude the sky becomes darker, and the contrast between objects seen against the sky increases.

11.1.5 In most commercial aircraft, cabin pressure is controlled but the slight degree of hypoxia experienced even in pressurized aircraft may impair dark adaptation, reduce visual fields and visual acuity and cause an increase in intraocular pressure.

11.1.6 In prolonged flight, the low humidity of the cabin air may cause dryness and irritation of the mucous membranes — especially of the eyes and the nasopharynx.

11.1.7 Space myopia, empty field myopia or night myopia may occur at high altitude or at any altitude when it is dark, owing to lack of visual targets outside the cockpit. Under low-contrast conditions a functional myopia of up to several dioptres may occur with blurred vision and loss of contrast sensitivity. Studies have shown that this kind of myopia is relatively common.

11.1.8 Inadequate cockpit illumination may produce visual problems. Low light levels cause reduced visual acuity and aggravate the symptoms of presbyopia making reading of small print difficult. Coloured maps may be difficult to see. These problems may be accentuated when red lighting is used because of the chromatic aberration of the human eye. As much of the in-flight information in commercial aviation is gained from instruments, the minor gain in dark adaptation level using red light or low levels of white light is generally considered to be outweighed by the loss in overall visual performance. Furthermore, runway illumination on international airports throughout the world has now reached levels well above the absolute threshold of light perception. On the other hand, there are numerous situations in general aviation where some degree of dark adaptation is necessary.

11.1.9 High acceleration forces are important in military aviation, agricultural flying and in aerobatics but less so in ordinary commercial flying. High G-forces may produce greyout, blackout or redout depending on the direction of the acceleration force.

11.1.10 Vibration of cockpit instruments and printed material, especially in the 22–64 Hz range, may impair vision significantly. This is particularly troublesome in helicopters. Low frequency vibrations of 2–10 Hz encountered in turbulence or on rough runways can also degrade vision.

11.1.11 Application of ergonomic principles and consideration of human factors have done a good deal to improve cockpit design and facilitate information flow to flight crew. Better instrument displays and thoughtful location of controls are found in many new aircraft but there is still room for improvement. Good visual function and adequate colour perception are necessary for proper use of the wide variety of maps, dials and gauges found in modern cockpits. The Electronic Flight Instrument System (EFIS) in particular employs many different colours. Although these systems are designed to provide critical information in monochrome in the event of colour failure, it has been shown that the addition of colours facilitates the perceptual process and improves the understanding of geometrical figures. Colours are likely to be increasingly important in the virtual cockpit environment of the future. With ever-increasing sophistication of aircraft, the tendency for information overload remains, and colour discrimination in all parts of the spectrum is desirable. The older colour perception testing methods which were mainly concerned with congenital red-green defects in men will not suffice because they fail to detect yellow-blue defects which are frequently seen in gender-neutral acquired colour vision deficiencies.

## 11.2 EXAMINATION TECHNIQUE

11.2.1 A careful history of all eye problems is of special importance in the assessment of an applicant. Where there is a history of ocular injury, surgery, use of eye medications, photophobia, constant use of tinted spectacles, irritation or itching of the eyes, current or previous use of spectacles or contact lenses, eye discomfort and headaches caused by close work or difficulty seeing in the dark, the applicant should be

referred to an ophthalmologist. Family history of pigmentary retinopathy, other tapeto-retinal diseases, optic nerve disease, corneal dystrophy or glaucoma should be noted. Early-onset cataracts, strabismus and retinal detachment in family members may be important. The applicant should be questioned about symptoms including blurred vision at distance or near, undue light sensitivity, eye pain, irritation or itching, discharge from the eyes, excessive tearing, double vision, visual fatigue, and any difficulties with spectacles or contact lenses.

11.2.2 Assessment of the visual function will be considered with later. Clinical examination of the eyes includes external examination of the eyes and adnexa, evaluation of the pupils, ocular movements, ocular alignment, funduscopy, visual field assessment and colour vision testing. Attention should be given to any significant facial asymmetry and to abnormal position of the eyelids or eyelashes, particularly caused by inversion or eversion of the lid margins. Exophthalmos or enophthalmos should be noted. The integrity of the lacrimal drainage system should be ascertained, especially if there is a history of nasal or other facial fractures. Corneal scars may result from trauma, corneal dystrophy or keratitis including herpes simplex, trachoma and many other inflammatory diseases. Pericorneal congestion, pain, blurred vision, light sensitivity, tearing and a small or irregular pupil suggest acute anterior uveitis and should prompt urgent referral to an ophthalmologist.

11.2.3 Pupils should be evaluated with regard to size, shape, symmetry and reaction to direct and consensual light stimulus and to a “near” stimulus. The swinging flashlight test<sup>1</sup> should be carried out to look for an afferent pupillary defect.

11.2.4 Ocular excursions should be tested to look for any impairment in extraocular muscle function implicating cranial nerves III, IV or VI. Evaluation of ocular alignment, visual fields and colour vision will be discussed later.

11.2.5 Funduscopy should be done in a systematic manner looking at the optic disc, the major vessel arcades and the macula. Some examiners may be comfortable performing tonometry, usually with an indentation instrument such as the Schiøtz<sup>2</sup> tonometer, but if there is any question about the intraocular pressure, the applicant should be referred to an ophthalmologist.

### 11.3 ASSESSMENT OF VISUAL ACUITY

#### Distant visual acuity

11.3.1 Although measurement of visual acuity is a routine procedure in general medicine and the most fundamental way of assessing visual function, there is still no internationally accepted standard test procedure. The generally accepted tests are based on the minimum visual angle. These tests measure the ability to distinguish two objects as separate. The earliest observations on visual acuity were made about 2 000 years ago by Persian astronomers who found that normal persons were able to distinguish more than 700 stars in the sky on a clear night. The classical measurements were made by the English physicist Robert Hooke (1635–1703) who noted that people with “normal” vision could just distinguish as separate the twin stars Alcor and Mizar in the constellation Ursa Major. He measured the distance between the two stars as approximately one minute of arc at the eye. This unit — 1 minute of arc — is the unity of visual acuity; it corresponds to a retinal distance of 4 microns (micrometres,  $\mu\text{m}$ ). A visual acuity of unity indicates a power of resolving detail

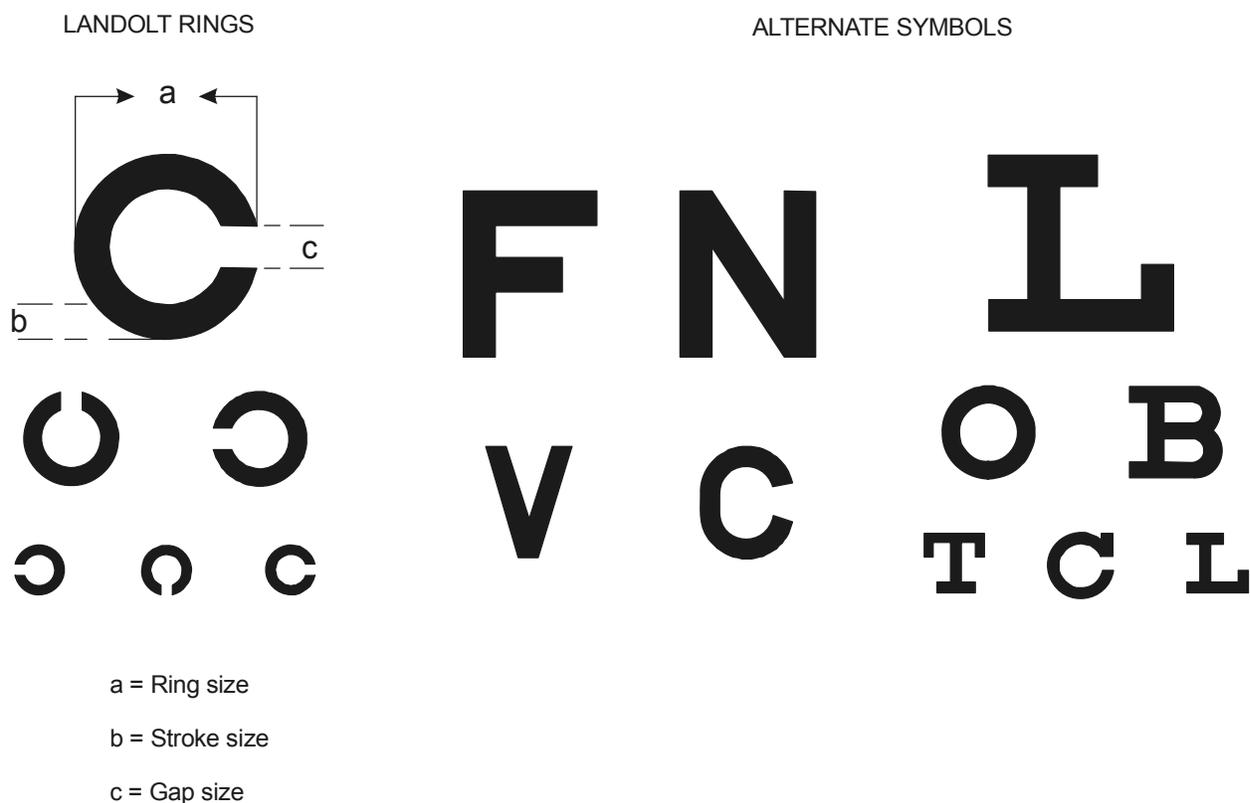
<sup>1</sup> Swinging flashlight test: Swinging the flashlight back and forth between the two eyes identifies if one pupil has less light perception than the other. Shine the flashlight at one eye noting the size of both pupils. Then swing the flashlight to the other eye. If both pupils now dilate then that eye has perceived less light stimulus than the opposite eye, indicating a defect in the sensory or afferent pathway.

<sup>2</sup> After Hjalmar Schiøtz, Norwegian physician (1850-1927).

subtending one minute of arc at the eye. It is usually expressed as 6/6; an acuity of a half as 6/12 and so on. This definition of visual acuity is the basis of the optotypes most widely used today. The first test chart of this type was published by the Dutch ophthalmologist Herman Snellen in 1862.

11.3.2 Test distances usually of 5 or 6 m (16 or 20 ft) are used, as this distance constitutes infinity for the normal eye and practically no accommodation is required to see clearly. The optotype is constructed so that the gaps between the letter components subtend an angle of one minute of arc at the prescribed distance. "Normal" visual acuity is defined as 6/6 (or 20/20 or 1.0). The numerator refers to the test distance and the denominator to the distance at which a "normal" eye could just see that particular size letter. Conventionally, a variety of different letters of the alphabet are used in test charts or projectors. This presents problems because some letters are more difficult to read than others (e.g. B is more difficult to identify than L), and the recognition of letters is a perceptual process which may vary from one individual to another. The use of symbols such as Landolt rings or a series of the letter "E" oriented in different directions has the advantage of presenting symbols of uniform difficulty and of not requiring knowledge of the names of the letters. See Figure 11-1.

11.3.3 Under optimum conditions many normal persons have visual acuity better than 6/6; measurements between 6/3 and 6/5 are usual. Nevertheless, 6/6 is widely accepted as a satisfactory level for performing most visual tasks. In addition to the resolving power of the eye there are other factors which affect visual acuity. These include physical contrast between the test symbols and their background, light adaptation status of the retina, exposure time of the test type, pupil size, clarity of the ocular media, and the state of the sensorium.



**Figure 11-1. Visual symbols in common use**

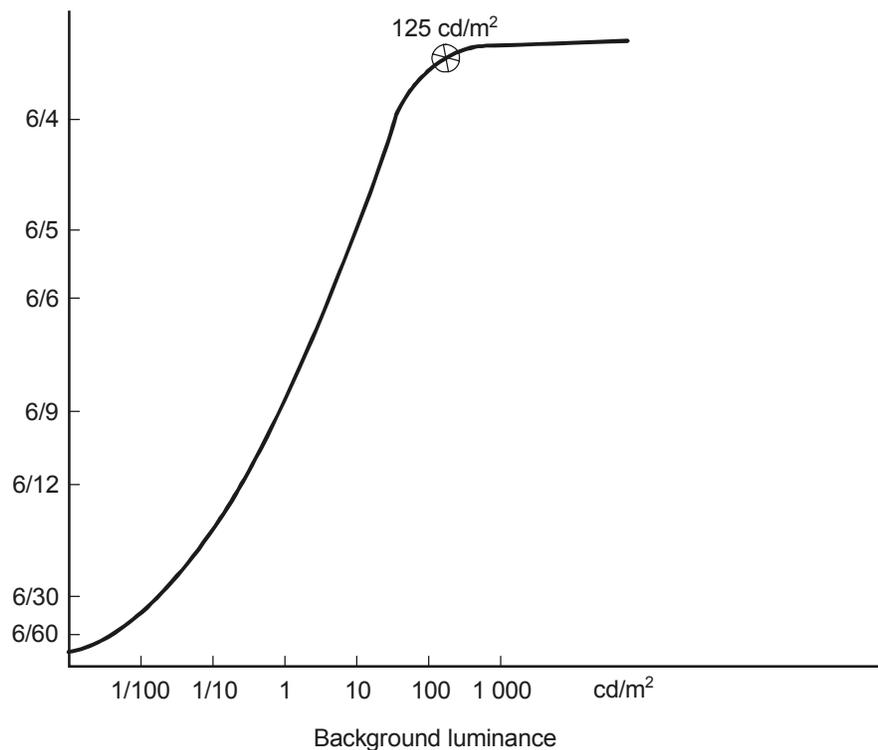
11.3.4 At very low levels of illumination the visual acuity will be poor. As illumination increases visual

acuity improves up to a certain level beyond which there is no further gain. Figure 11-2 illustrates the relationship between visual acuity and background luminance. Background luminance refers to the white background of the test chart against which the test symbols are viewed, it does not refer to the luminance of the walls of the examining room. Visual acuity improves significantly when the background luminance increases because this enhances the contrast between the black symbols and the white background. Above a background luminance level of 80  $\text{cd/m}^2$ , the visual improvement is minimal; this level is the recommended minimum for visual acuity test charts.

### Photometric units

11.3.5 To understand the visibility of objects some knowledge of photometric units is helpful. The term radiometry applies to measurements of the entire spectrum of radiant energy. Photometry applies to measurements of the visible portion of the electromagnetic spectrum (380 to 750 nm).

11.3.6 Before describing the more common photometric units, it should be mentioned that the term *brightness* refers to the subjective impression of a range of sensations varying from very dim to brilliant. It is a perception originating in the rods and cones of the retina. It is a complex sensation which is non-linear and dependent on the state of dark or light adaptation of the retina. Brightness cannot be measured in physical units and is not the same as luminance.



**Figure 11-2. Visual acuity and background luminance**

11.3.7 The following are the more important physical units dealing with light:

**Luminous flux**

11.3.7.1 This is the visible power or light energy per unit of time. The unit is the *lumen (lm)* which is defined as the flux emitted within a unit solid angle by an idealized uniform point source of 1 *candela* of luminous intensity. In physics, power is measured in *watts* and there is a correlation between *lumens* and *watts*. The human eye is most sensitive to light of 555 nm, and 1 *watt* of power at this wavelength (and at this specific wavelength only) is equivalent to a luminous flux of 675 *lumens*.

11.3.7.2 Thus 1 *lumen* is equivalent to approximately 0.0015 *watt*.

**Luminous intensity**

11.3.7.3 This is the luminous flux per unit solid angle from a point. Unit solid angle is called a *steradian* and is that solid angle which cuts an area of 1 m<sup>2</sup> from the surface of a sphere with a radius of 1 m. The light may be emitted or reflected. The unit of luminous intensity is the *candela (cd)*. One *candela* is 1 *lumen per steradian*. The *candela* was originally derived from the luminance of a black-body radiator at the temperature of solidifying platinum. *Candle*, *candela* and *candlepower* are all the same.

**Luminance**

11.3.7.4 This is the luminous intensity per unit area projected in a given direction, and the unit is the *candela per square metre (cd/m<sup>2</sup>)*. This unit is also called the *nit*.

11.3.7.5 Other luminance units are:

$$\begin{aligned} \text{stilb (sb)} &= 1 \text{ candela/cm}^2 \\ \text{lambert (L)} &= 1/\pi \text{ candela/cm}^2 \end{aligned}$$

11.3.7.6 It should be noted that the formula used to calculate luminance from illuminance contains the factor  $1/\pi$ .

**Illuminance**

11.3.7.7 This is the luminous flux on unit area of a surface. The unit is the *lux (or metre-candle)*. One *lm* uniformly distributed over 1 m<sup>2</sup> of surface produces illuminance of 1 *lux*. For a given luminous flux, the illuminance decreases as the illuminated area increases.

11.3.8 Most of the units described above are SI units. For countries using the foot-pound system (FPS) the conversion factors are as follows:

$$\text{Luminance can be measured in foot-lamberts (fL).} \quad 1 \text{ fL} = 3.426 \text{ cd/m}^2$$

$$\text{Illuminance can be measured in foot-candles (fc).} \quad 1 \text{ fc} = 10.75 \text{ lux}$$

11.3.9 There are numerous other units used in photometry but describing them all is beyond the scope of this outline.

11.3.10 To give the above units some practical meaning, the following luminance levels may be helpful

(Table 11-1):

**Table 11-1. Luminance levels for different types of lighting**

<i>Environment</i>	<i>Luminance (cd/m<sup>2</sup>)</i>
Sun	$10^9$
Clear sky at noon	$10^4$
Cloudy sky at sunset	10
Clear sky one quarter hour after sunset	1
Night sky, full moon	$10^{-2}$
Night sky, cloudy, no moon	$10^{-4}$
Pure scotopic (rod) vision	$<5 \times 10^{-3}$
Pure photopic (cone) vision	$>10$
Mesopic vision	$5 \times 10^{-3}$ to 10

11.3.11 The luminous intensity of lamps is measured in units called *mean spherical candlepower (MSCP)*. The *lumen* output of a lamp is found by multiplying *MSCP* by  $4\pi$ .

11.3.12 If a perfectly reflecting and diffusing surface is illuminated with 1 *lux* the luminance will be  $1/\pi$  *cd/m<sup>2</sup>*. White paper reflects about 75 per cent of the incident light so that when it is illuminated with 1 *lux* its luminance will be  $0.75 \times 1/\pi = 0.24$  *cd/m<sup>2</sup>* or 2 400 *stilb*.

11.3.13 There is no simple relationship between the specified wattage of a given lamp and the illumination it provides. Factors such as reflectors, angle of incidence of the light rays on the illuminated surface and the distance from the light source are decisive.

11.3.14 The approximate illuminance given by an ordinary 40-watt desk lamp with a white conical reflector aimed at 45 degrees to the surface is given in Table 11-2. This table also shows the corresponding luminance of a white surface (paper or visual acuity chart) viewed at right angles.

**Table 11-2. Approximate illuminance from a 40-watt bulb**

<i>Bulb-chart distance</i>	<i>Bulb illuminance</i>	<i>Chart luminance</i>
50 cm	350 lx	110 <i>cd/m<sup>2</sup></i>
75 cm	155 lx	45 <i>cd/m<sup>2</sup></i>
100 cm	85 lx	25 <i>cd/m<sup>2</sup></i>

With a 60-watt bulb, the light levels are as in Table 11-3:

**Table 11-3. Approximate illuminance from a 60-watt bulb**

<i>Bulb-chart distance</i>	<i>Bulb illuminance</i>	<i>Chart luminance</i>
50 cm	600 lx	180 $cd/m^2$
75 cm	270 lx	80 $cd/m^2$
100 cm	150 lx	45 $cd/m^2$

11.3.15 Figure 11-2 shows the relationship between illumination of the test chart and visual acuity. The minimum background luminance recommended for the test charts is 80  $cd/m^2$ .

11.3.16 In an ordinary office, the luminance of lightly coloured walls are approximately:

Moderately lit room	15 – 30 $cd/m^2$
Ordinarily lit room	30 – 60 $cd/m^2$
Brightly lit room	60 – 100 $cd/m^2$

11.3.17 The luminance of the white parts of a transparent visual acuity chart mounted in an examination box and illuminated from behind is 200 – 500  $cd/m^2$ . The additional luminance given by the ambient room lighting is insignificant.

11.3.18 Visual acuity testing should be done in a well-lit room. The ordinary room lights in the examining room should be left on. Extremes of room illumination, either very dark or very bright, may affect visual acuity measurements and should be avoided.

### **Exposure time**

11.3.19 Exposure time is not important during ordinary clinical measurement of visual acuity because the times used are well above the threshold values of about 0.5 second.

11.3.20 However, exposure time does become important in the dynamic visual environment of many flight operations. Angular motion exceeding 10 degrees/second produces significant blurring of vision. During the final seconds before touchdown the pilot relies on ground references when manoeuvring the aircraft, even with automated landing systems. With a landing speed of 145 kt (approximately 270 km/h) a surface area of 500  $m^2$  is all that can be inspected without exceeding the critical angular velocity (angular velocity at which visual acuity begins to deteriorate).

### **Physical contrast**

11.3.21 The physical contrast between an object and its background is a limiting factor in the resolving power of the eye. The contrast threshold is the just noticeable difference between an object and its background. Reflection from clean white paper is about 75 per cent while that from a black symbol is about 5 per cent. The contrast is  $(75-5)/75$  or 93 per cent providing excellent visibility. Old faded charts or improperly maintained vision chart projectors may present contrast of only around 30 per cent which is a critical value in maintaining optimum visual acuity. The importance of proper test equipment is obvious.

11.3.22 There are many situations in aviation where contrast is different from that normally used during clinical testing. Low light levels causing reduced vision are the most frequent but very high light levels can

produce glare sufficient to reduce visual acuity.

### **Pupil diameter**

11.3.23 Low light conditions cause dilatation of the pupil with resulting spherical aberration and blurring of the retinal image. This blurring may stimulate accommodation with induced myopia further reducing distance visual acuity. High light levels, up to a certain value, induce miosis. This reduction of the optical aperture leads to increased depth of focus and, by masking of the refractive errors of the eye, to improved acuity.

### **Test objects and symbols**

11.3.24 A wide variety of visual test objects are in use throughout the world. An attempt to have the Landolt rings adopted internationally as the test symbol was unsuccessful, and most of the designated medical examiners in ICAO's Contracting States continue to use the Snellen letters or variations based on the same visual angle. Since the object of the examination is to assess the applicant's general visual efficiency and refer those who do not meet the required standards for further evaluation, the use of Snellen type symbols is acceptable. The letters of the alphabet vary widely in their legibility, e.g. "L", "I" and "T" are much easier to identify than "G", "R" and "B". For this reason, uniform symbols such as the Landolt rings or the letter E oriented in different directions are better test objects from a scientific point of view.

11.3.25 Vision test charts of different designs show a wide variation in the number, appearance and choice of symbols in each row and the progression in size of the symbols. These variations introduce discrepancies in visual acuity measurements. To determine whether or not the visual requirements of Annex 1 are met, an internationally uniform standard such as the Landolt rings or the E-test is desirable. The chart should have, as a minimum, symbols representing the following levels of visual acuity: 6/60 (20/200, 0.1), 6/12 (20/40, 0.5), 6/9 (20/30, 0.7) and 6/6 (20/20, 1.0). A minimum of ten symbols should be available for the 6/12, 6/9 and 6/6 levels. Figure 11-1 shows examples of Landolt rings together with other symbols commonly used.

11.3.26 A chart of Landolt rings should contain ten symbols in each row with random gaps at 3, 6, 9 and 12 o'clock. Two different charts should be available to prevent possible memorization.

11.3.27 Vision chart projectors have several advantages including availability of a selection of different slides, the ability to display only one row of symbols at a time and much better durability than the less expensive printed charts.

11.3.28 Printed vision charts should be matt white and the symbols should be matt black. The gap in the Landolt rings must subtend an angle of 1 minute of arc at the prescribed distances. The Snellen letters are formed within a square subtending 5 minutes of arc at the prescribed distances or (on some charts) within a rectangle 4 minutes in width and 5 minutes in height and are made so that the constituent parts of the letter subtend 1 minute of arc.

11.3.29 Testing programmes to measure visual acuity, colour perception and other aspects of visual function are available for personal computers. Some of these programmes are used for testing aviation personnel but standardization remains a challenge.

11.3.30 Examiners should not allow the applicant to squint during testing as using the eyelids as a stenopaic slit may mask refractive errors. No error should be allowed per line of ten symbols. In cases where test letters other than Landolt rings are used, the Licensing Authority should ascertain that the methods used for measuring visual acuity will provide comparable results.

11.3.31 Any degree of myopia results in reduced visual acuity. A significant degree of myopia, i.e.  $-0.75$  D or more, will be detected during the screening examination, provided the applicant is not allowed to squint. In contrast, low or moderate degrees of hyperopia (hypermetropia), especially in young individuals, are compensated for by accommodation, and such applicants will have normal distance visual acuity and may not be detected during an ordinary screening examination. The full amount of hyperopia can only be measured by refraction under cycloplegia, but this possibility is not generally available to the designated medical examiner.

### **The +2.5 D lens test**

11.3.32 A useful screening test for hyperopia is to have applicants who read 6/6 or better without correction read the distance acuity chart while looking through a +2.5 D spherical lens. This can be done by holding a single lens in front of each eye or, more conveniently, by using a pair of full-size reading spectacles with +2.5 D lenses. Each eye is tested separately. If the eye is emmetropic, vision through the +2.5 D lens will be blurred, and the visual acuity will be reduced by about two lines on the Snellen chart. If the distance acuity is not reduced by the +2.5 D lens and the applicant sees just as well through these lenses as without them, some hyperopia is present.

11.3.33 Applicants who fail the +2.5 D lens test should normally be referred to a qualified vision care specialist for evaluation.

### **Annex 1 requirements for distant visual acuity**

11.3.34 Annex 1 requirements for distant visual acuity are as follows:

Class 1:

6.3.3.2 Distant visual acuity with or without correction shall be 6/9 or better in each eye separately, and binocular visual acuity shall be 6/6 or better. No limits apply to uncorrected visual acuity. Where this standard of visual acuity can be obtained only with correcting lenses, the applicant may be assessed as fit provided that:

- a) such correcting lenses are worn during the exercise of the privileges of the licence or rating applied for or held; and
- b) in addition, a pair of suitable correcting spectacles is kept readily available during the exercise of the privileges of the applicant's licence.

*Note 1.— 6.3.3.2 b) is the subject of Standards in Annex 6, Part I.*

*Note 2.— An applicant accepted as meeting these provisions is deemed to continue to do so unless there is reason to suspect otherwise, in which case an ophthalmic report is required at the discretion of the Licensing Authority. Both uncorrected and corrected visual acuity are normally measured and recorded at each re-examination. Conditions which indicate a need to obtain an ophthalmic report include: a substantial decrease in the uncorrected visual acuity, any decrease in best corrected visual acuity, and the occurrence of eye disease, eye injury or eye surgery.*

Class 2:

6.4.3.2 Distant visual acuity with or without correction shall be 6/12 or better in each eye separately, and binocular visual acuity shall be 6/9 or better. No limits apply to uncorrected visual acuity. Where this standard of visual acuity can be obtained only with correcting lenses, the applicant may be assessed as fit provided that:

- a) such correcting lenses are worn during the exercise of the privileges of the licence or rating applied for or held; and
- b) in addition, a pair of suitable correcting spectacles is kept readily available during the exercise of the privileges of the applicant's licence.

*Note.— An applicant accepted as meeting these provisions is deemed to continue to do so unless there is reason to*

suspect otherwise, in which case an ophthalmic report is required at the discretion of the Licensing Authority. Both uncorrected and corrected visual acuity are normally measured and recorded at each re-examination. Conditions which indicate a need to obtain an ophthalmic report include: a substantial decrease in the uncorrected visual acuity, any decrease in best corrected visual acuity, and the occurrence of eye disease, eye injury or eye surgery.

Class 3:

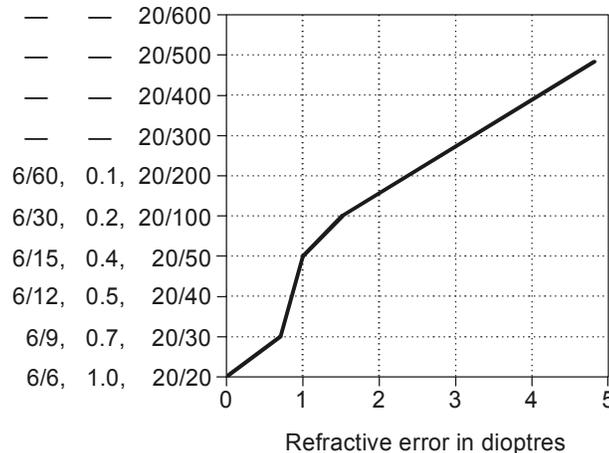
6.5.3.2 Distant visual acuity with or without correction shall be 6/9 or better in each eye separately, and binocular visual acuity shall be 6/6 or better. No limits apply to uncorrected visual acuity. Where this standard of visual acuity can be obtained only with correcting lenses, the applicant may be assessed as fit provided that:

- a) such correcting lenses are worn during the exercise of the privileges of the licence or rating applied for or held; and
- b) in addition, a pair of suitable correcting spectacles is kept readily available during the exercise of the privileges of the applicant's licence.

*Note.— An applicant accepted as meeting these provisions is deemed to continue to do so unless there is reason to suspect otherwise, in which case an ophthalmic report is required at the discretion of the Licensing Authority. Both uncorrected and corrected visual acuity are normally measured and recorded at each re-examination. Conditions which indicate a need to obtain an ophthalmic report include: a substantial decrease in the uncorrected visual acuity, any decrease in best corrected visual acuity, and the occurrence of eye disease, eye injury or eye surgery.*

### Relationship between refractive error and uncorrected visual acuity

11.3.35 There is considerable variation in the results of studies designed to determine the relationship between refractive error and uncorrected visual acuity. Figure 11-3 gives approximate values for this relationship. Examiners should note that myopes can often improve their uncorrected vision markedly by squinting and that hyperopes can overcome their refractive error to a greater or lesser degree depending on how much they are able to accommodate.



**Figure 11-3. Approximate relationship between visual acuity and refractive error**

## Refraction

11.3.36 Clinical refraction means the diagnostic procedure used to determine the refractive error in the eye. There are many ways to perform clinical refraction. Frequently, an objective component such as a retinoscope or an automated refractor of some kind is involved and sometimes cycloplegic drugs are used in the process. This is followed by subjective refinement of the results with the aim of providing a therapeutic prescription for spectacles which will give the person good and comfortable vision. Not all persons with a refractive error require correction with spectacles, contact lenses or by other means. In aviation, correction of a refractive error is only needed when uncorrected visual acuity is substandard or when there is visual fatigue or an ocular muscle imbalance related to that error. The determination of an appropriate optical correction for a person with a refractive error should be made by a qualified vision care specialist.

### **Refractive errors**

11.3.37 The refractive status of the eye depends on the curvature of the refracting surfaces (cornea and lens), the axial length of the eye, and the refractive indices of the ocular media. The most important of these is the axial length. Eyes which are longer than normal are usually myopic, and eyes which are shorter than normal are usually hyperopic.

11.3.38 An eye which has no refractive error is said to be emmetropic. In such an eye, parallel rays of light from a distant object are focused on the retina without the need for any accommodation so that objects in the distance are seen clearly.

11.3.39 Light entering the eye from near objects will be diverging, and an emmetropic eye will need to accommodate to see near objects clearly.

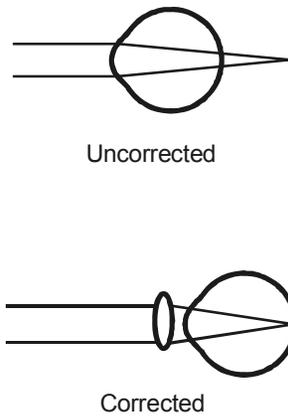
11.3.40 Most eyes have some error of refraction and are said to be ametropic. The errors of refraction are:

- a) hyperopia (hypermetropia) — farsightedness
- b) myopia — nearsightedness
- c) astigmatism
- d) combinations of the above.

### **Hyperopia**

11.3.41 The hyperopic eye is deficient in refractive power so that when it is not accommodating, parallel light rays from a distant object are not refracted sufficiently to be focussed on the retina. Distant objects will be blurred unless the person is able to use his accommodation to add the necessary refractive power. In young eyes there is ample accommodative power to compensate for significant amounts of hyperopia but as presbyopia develops this accommodative reserve diminishes. Thus a 20-year-old with 5 dioptres of hyperopia may need no spectacle correction to see well in the distance but at age 60 the same person will require almost full correction of the refractive error to see distant objects clearly.

11.3.42 The relationship between hyperopia and convergent strabismus will be discussed later. Figure 11-4 illustrates hyperopia and how it is corrected using a plus power lens.



**Figure 11-4. Correction of hyperopia — plus sphere**

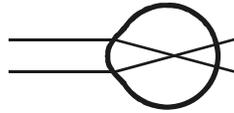
### **Myopia**

11.3.43 In myopia the eye has too much refracting power so that parallel light rays are focussed in front of the retina resulting in blurred distance vision. Light coming from near objects is diverging, and if the distance between the object and the eye matches the amount of myopia, the near object will be in focus. For example, an eye with 3 dioptres of myopia will see objects at a distance of 1/3 m clearly without accommodating. Bear in mind that an eye with uncorrected visual acuity of 6/6 may be slightly myopic and with appropriate correction may have an acuity of 6/3 or twice as good. Figure 11-5 illustrates myopia and shows how correction is achieved with minus power lenses.

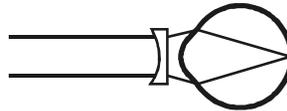
### **Astigmatism**

11.3.44 Astigmatism is defined as the inability of an optical system to form a point image of a point object. It results from different curvatures of the refracting surfaces of an optical system, including the eye. In an optical system with no astigmatism the curvature of each refracting surface is the same in all planes which is to say that the curvature in the horizontal plane (the 180-degree axis) is the same as the curvature in the vertical plane (90-degree axis). Such a surface is said to be spherical. If the curvature of the refracting surface is not the same in all planes the surface is said to be toric (from L. *torus* = swelling, bulge, knot), and there will be astigmatism. One way to visualize this is to think of the surface of an orange as spherical while the surface of a lemon would be toric.

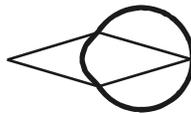
11.3.45 In clinical optics the different planes of the refracting surfaces are called meridians. In a toric surface there will be one meridian with a maximum curvature and one with a minimum curvature. These are called the principal meridians. If the principal meridians are at right angles (e.g. at 90 and 180 degrees or at 45 and 135 degrees) the astigmatism is said to be regular. Regular astigmatism in the eye can be corrected with cylinders. If the principal meridians are not at right angles, the astigmatism is said to be irregular. Irregular astigmatism cannot be fully corrected with spectacle cylinders but it can often be corrected with contact lenses.



a) Myopic eye looking at a distant object



b) Myopic eye corrected for distant vision

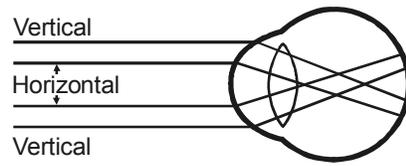


c) Myopic eye looking at a near object

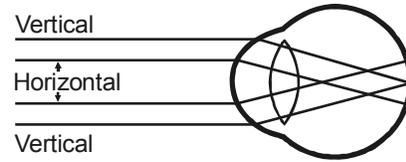
**Figure 11-5. Correction of myopia — minus sphere**

11.3.46 Many eyes have some regular astigmatism. The amount and orientation of the astigmatism is indicated by the cylindrical component of the spectacle correction. Figure 11-6 shows an astigmatic refracting system and illustrates how the astigmatism results in two focal lines rather than a point focus which would be the case if there were no astigmatism. In the astigmatic eye, the position of these two focal lines with regard to the retina is used to classify the astigmatism as follows:

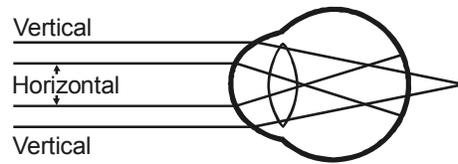
- a) If both focal lines are in front of the retina there is compound myopic astigmatism
- b) If one focal line is in front of the retina and the other is on the retina there is simple myopic astigmatism
- c) If one focal line is in front of the retina and the other is behind the retina there is mixed astigmatism
- d) If one focal line is on the retina and the other is behind the retina there is simple hyperopic astigmatism
- e) If both focal lines are behind the retina there is compound hyperopic astigmatism.



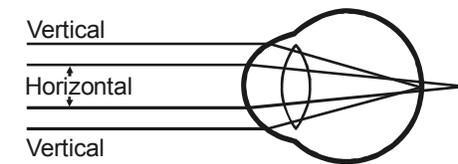
a) Compound myopic astigmatism



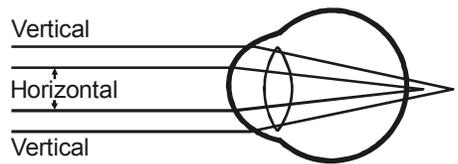
b) Simple myopic astigmatism



c) Mixed astigmatism



d) Simple hyperopic astigmatism



e) Compound hyperopic astigmatism

**Figure 11-6. Types of astigmatism**

### **Irregular astigmatism**

11.3.47 When the principal meridians are not at right angles, the astigmatism is called irregular. Irregular astigmatism occurs when there has been corneal scarring from any cause and in the developmental abnormality keratoconus. It is not possible to correct irregular astigmatism fully using spectacle cylinders. Contact lenses provide the best chance of optimum correction because the inner surface of the contact lens replaces the irregular surface of the eye as one of the refracting surfaces in the optical system.

11.3.48 All optical systems, including the eye, have aberrations. These include:

- a) Chromatic aberration due to the different amount of refraction of the different wavelength components of white light. Long wavelengths are refracted less than short wavelengths.
- b) A variety of optical aberrations including spherical aberration, coma (the unsharp halo which can result from objects being off-centre), astigmatism of oblique incidence, field curvature and distortion.

11.3.49 In low power lenses these aberrations are minimal but in the higher power lenses, say above plus or minus 5 dioptres, they become increasingly important so that distortion and alteration of visual field are of concern in the aviation environment. Improvements in lens design and manufacture such as high index, thin lenses have reduced the distortion in the higher power lenses but contact lenses provide better visual fields and less distortion than strong spectacle lenses and should be considered in applicants with large refractive errors.

### **Anisometropia and aniseikonia**

11.3.50 Difference in refractive error between the two eyes is anisometropia. Correction of anisometropia produces a difference in retinal image size in the two eyes. When this difference in size is perceived by the person, it is called aniseikonia (from Gr. *eikon* = image, likeness, picture).

11.3.51 Large amounts of anisometropia can be fully corrected with spectacles in children, but in adults correction of more than 3 dioptres of anisometropia may be problematic. Tolerance of an anisometric spectacle correction and the induced aniseikonia varies greatly between individuals. Applicants with significant amounts of anisometropia should be evaluated by a vision care specialist.

### **Substandard vision in one eye**

11.3.52 It is common to see applicants in whom one eye meets the required standards of Annex 1 but whose other eye cannot be corrected to the required standards because of amblyopia or other eye disease.

*Such applicants require evaluation by a vision care specialist to determine the cause of the vision loss. They may be assessed as fit under the provisions of Annex 1, 1.2.4.8. In doubtful cases a medical flight test to evaluate visual performance during flight might be appropriate.*

### **Near visual acuity and accommodation**

11.3.53 In most modern aircraft a major part of the flying time is spent evaluating information displayed within the cockpit. Cockpit information systems become ever more complex and the need to see clearly at various distances inside the cockpit is just as important as the need for good distance acuity. Aeronautical charts, head-up displays, colour-coded warning lights, radio dials, topographical mapping and weather radar displays are some of the things which the aviator must see clearly and which require good visual acuity at close

and intermediate ranges.

11.3.54 In the young eye the lens is pliable and through the action of the ciliary muscle can easily increase its curvature so as to provide the necessary increase in power to focus on close objects. This ability to accommodate diminishes with age as the lens becomes increasingly rigid — a condition called presbyopia. The power of accommodation is measured while the applicant wears distance correction if prescribed. Small print which can just be read at arm's length is used and the applicant reads the print while the chart is moved towards the eyes until a point is reached when the print starts to become blurred. The applicant is encouraged to put maximum effort into the test. The distance from the eyes at which the print first becomes blurred is the near-point of accommodation. The reciprocal of this distance in metres is the accommodative amplitude in dioptres. Instead of using the ordinary near vision test card, a near-point rule can be used and has the advantage of allowing the examiner to read directly the distance from the subject's eyes to the chart. Table 11-4 shows the approximate relationship between age and accommodative power.

11.3.55 Presbyopia occurs in all eyes although there is considerable variation between individuals. For most emmetropic individuals reading becomes a little difficult in the middle to late forties. In uncorrected hyperopes the problem will occur at an earlier age because some of the eye's accommodative power must be used to overcome the hyperopia. Myopes, on the other hand, can simply remove their distance spectacles when presbyopia becomes significant, and many individuals with 3 or 4 dioptres of myopia never need any reading spectacles.

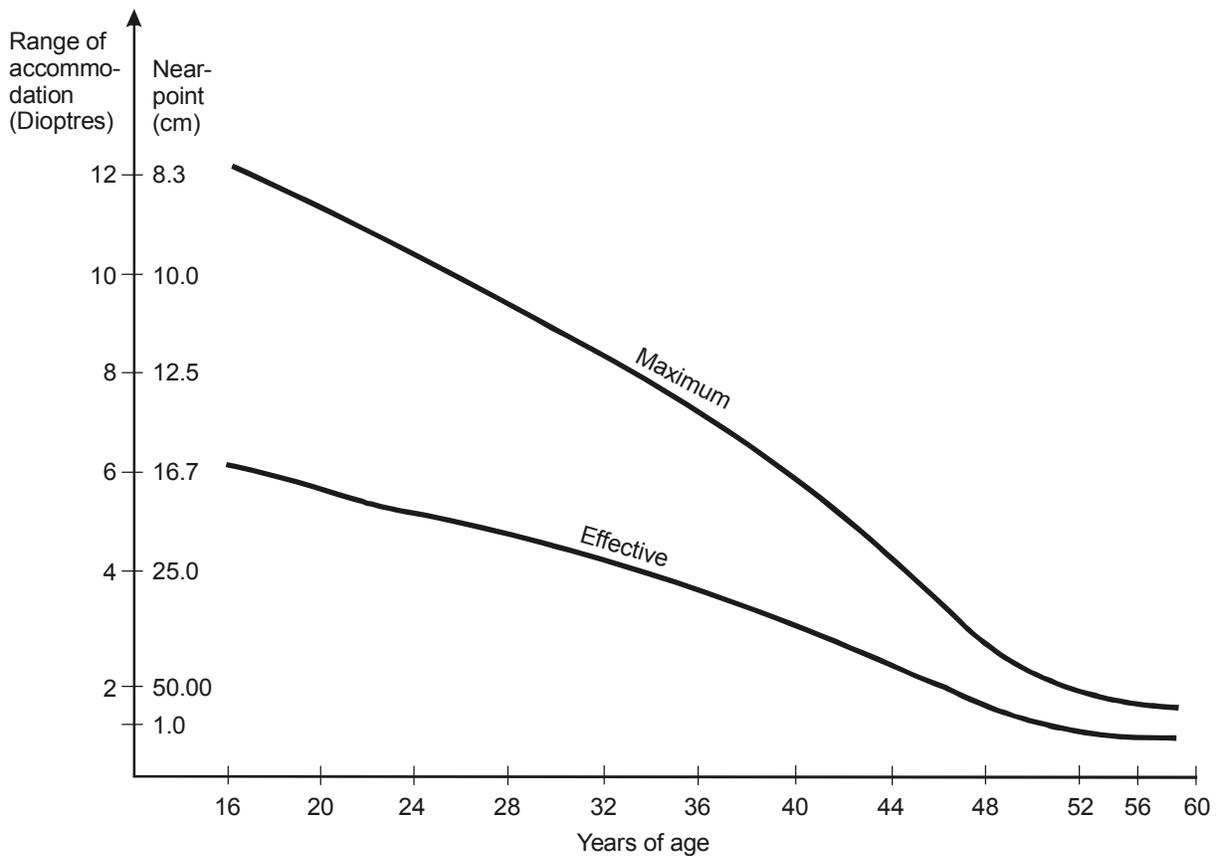
11.3.56 It is not acceptable for myopic flight personnel who are also presbyopic to simply remove their distance spectacles in order to read. Such individuals must have a spectacle correction which is satisfactory for both distance and near, that is to say, some type of multifocal correction.

11.3.57 The symptoms of presbyopia depend mainly on the amount of accommodation available but also to a considerable extent on illumination level, clarity and contrast of the print, pupil size, degree of fatigue, and general well-being of the subject. Most normal subjects are comfortable using up to half their accommodative amplitude. Figure 11-7 shows maximum and effective or comfortable amplitude of accommodation. Figure 11-8 shows how the amplitudes are affected by pre-existing refractive errors. When prescribing reading spectacles or a bifocal addition to distance spectacles one generally tries to leave about half the accommodative amplitude in reserve.

11.3.58 The increasing density of the lens, which is the basis of presbyopia, also results in generalized reduction of the brightness of the retinal image. This, together with the smaller pupils and steady loss of photoreceptors, explains why older persons generally need more light than younger persons for a given visual task.

**Table 11-4. Age and presbyopia**

<i>Age</i>	<i>Dioptres</i>	<i>Near-point (cm)</i>
15	12	8
25	10	10
35	7	14
45	4	25
55	1.5	67
65	1.1	91

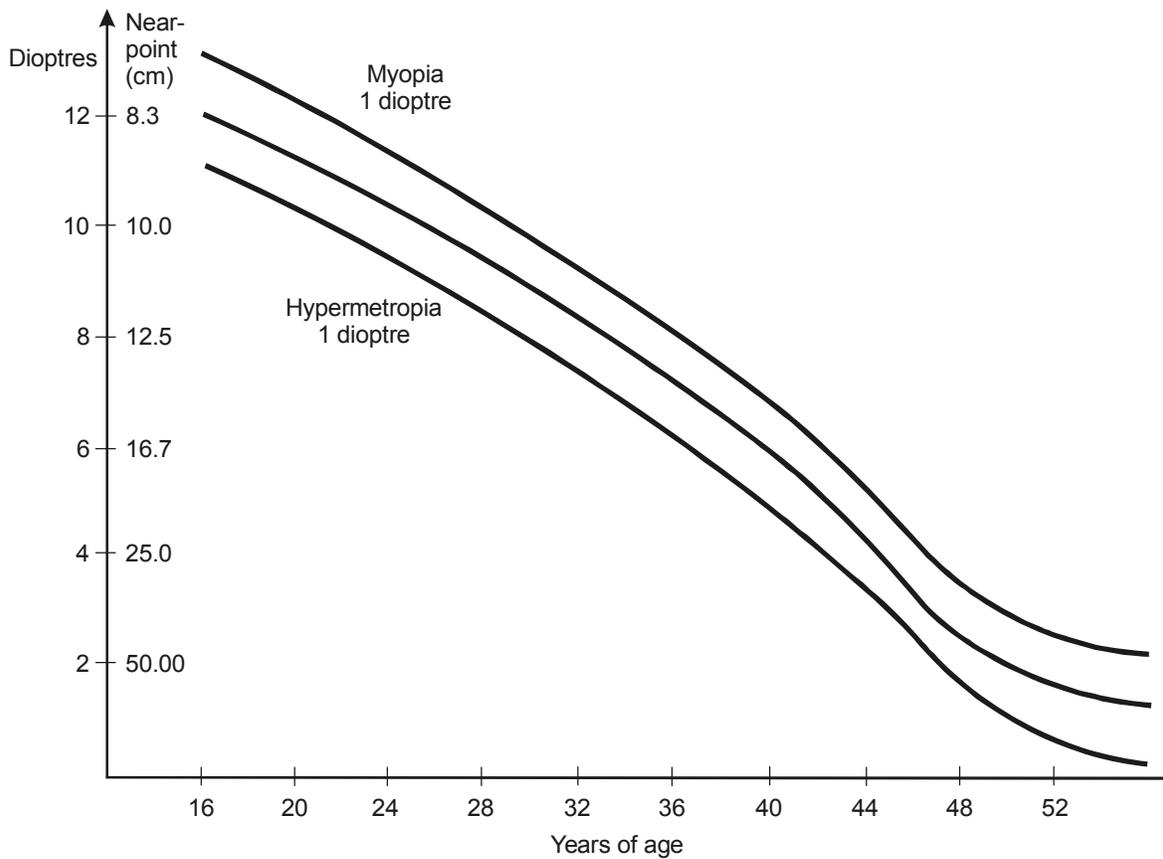


**Figure 11-7. Maximum and effective accommodation range**

### ***Impaired accommodation***

11.3.59 Diminished accommodation with the associated impairment of near vision can be caused by the following:

- a) Poor general health
- b) Severe mental stress
- c) Hypoxia
- d) High G-forces
- e) Cycloplegic drops



**Figure 11-8. Change of accommodation range by pre-existing ametropia**

- f) Ganglion blocking agents
- g) Atropine-like drugs
- h) Mood altering drugs and tranquilizers
- i) Disorders affecting the IIIrd cranial nerve
- j) Iritis and other disorders of the ciliary muscle.

### **Eye strain (asthenopia)**

11.3.60 Complaints of eye strain are very common and include blurring of vision, print running together, heavy or tired feeling of the eyes, burning sensation of the eyes, headaches, ocular pain, tearing, redness of the eyes, need to rub the eyes, increased light sensitivity and inability to do close work for any length of time.

11.3.61 Frequently, patients complaining of eye strain have completely normal ocular examinations and the cause of the symptoms may be general fatigue, stress or some systemic disease. Sometimes there are important ocular disorders needing treatment. These include blepharitis, conjunctivitis, dry eye syndromes, uncorrected refractive errors, including presbyopia, convergence insufficiency and other ocular muscle imbalance problems.

#### **Methods of assessing near visual acuity**

11.3.62 The wide variety of different test types used by Contracting States has made standardization of near vision testing difficult. For many years the Jaeger test types were in common use. The standard now adopted in Annex 1 is the font called "Times Roman". The size of the letters is based on the old printer's system in which one point is 0.35 mm (1/72 in). Thus 5-point type is one in which each letter is cast on a block 1.75 mm (5/72 in) tall. The point-numbers used are from N.5 to N.48. The N stands for near. An N.5 letter is slightly less than 1.75 mm in height and an N.48 letter is slightly less than 17 mm in height.

11.3.63 There is approximate correlation between the near visual acuity and the distance acuity provided the near testing is done at exactly the prescribed distance. For example the N.5 Times Roman lower case letters viewed at a distance of 40 cm (16 in) subtend an angle of 2 minutes of arc and correspond approximately to acuity of 6/12 (20/40, 0.5). Under the same conditions the N.14 notation is equivalent to 6/24 (20/80, 0.25).

11.3.64 In practice, a person's normal, comfortable reading distance depends on arm length and habit, so slavish adherence to a fixed reading distance is unrealistic.

#### **Guidance on practical procedures**

11.3.65 Near visual acuity should be determined and recorded with and without correcting lenses. The N-type Near Vision Acuity Test Chart or equivalent should be used (Figures 11-9 and 11-10). The examination should be conducted in a well-lighted room with illuminance of the test chart of approximately 500 lux. The applicant should hold the chart at a comfortable reading distance which will usually be between 30–50 cm (12–20 in) and should attempt to read the N.5 type. The same procedure is repeated with N.14 type held at a distance of about 100 cm (40 in) if intermediate distance acuity measurement is required. The near vision is recorded as the distance at which the applicant can read the N.5 type (e.g. N.5 at 40 cm and N.14 at 100 cm).

11.3.66 There is a difference between ability to read single optotypes on a near chart and ability to read text. The latter involves complex cognitive factors in addition to good acuity.

11.3.67 The near vision test cards should be made of a durable material such as plastic-covered cardboard which can be cleaned to maintain the proper contrast between the type and the background.

#### **Visual flight deck tasks**

11.3.68 The following main visual tasks concern the pilot and co-pilot (Figure 11-11):

- a) distance visual tasks — anything happening outside the cockpit
- b) intermediate and near visual tasks:
  - i) reading instruments on panel, pedestal and overhead displays
  - ii) reading hand-held printed and written material.



# NEAR VISION ACUITY

## SLOAN LETTERS

This chart should be held 16 inches (40 cm) from the eyes, at right angles to the line of vision, and illuminated with not less than 10 or more than 25 foot-candles of light (108–269 lux).

LINEAR  
SNELLEN  
SCALE

$\frac{20}{20}$

SOZCN      HRVOK      NOSCR  
KZVZH      DHZVN      FSORC

$\frac{20}{25}$

KNVRO      NVKDO      KNVRO  
VNKDZ      HOZVK      ROCNS

$\frac{20}{30}$

HSZVO      HZVOD      SRNHO  
KDCZN      KORHZ      NSVDZ

$\frac{20}{40}$

CVORD      OSKDR      RKSOD  
ROVDC      RCOSN      KVDZV

← Equivalent to N.5

$\frac{20}{60}$

HNZCO      SRVDK      RCOSN  
KVCHD      NHRVZ      NKRVD

$\frac{20}{80}$

S O C Z N H R V D K N Z C O ← Equivalent to N.14

$\frac{20}{100}$

R N H S O K D C Z V O S

$\frac{20}{200}$

D O N V R C K

## AERONAUTICAL CHART READING

Low altitude federal airways are indicated by centre line

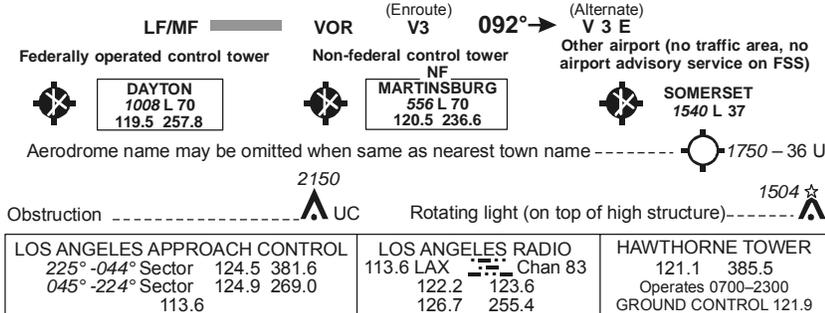


Figure 11-10. Examples of a near vision test provided with aeronautic symbols



(Courtesy: Boeing)

**Figure 11-11. Flight deck visual distances**

11.3.69 Factors which affect the visibility of objects within the cockpit include:

- a) the actual size of the instrument dials and their displayed data
- b) the size and contrast of printed symbols on charts, maps and other reading material
- c) the distance between the pilot's eyes and the object of regard
- d) the general illumination on the instrument panels and the brightness of illuminated instruments
- e) reflections from cockpit windows and instruments
- f) poor cockpit design and instrument placement
- g) the use of sunglasses.

11.3.70 As far as the flight crew are concerned the important factors are any refractive error present and the degree of presbyopia. Young individuals with ample accommodation available will require only their distance correction, if any. Older individuals or uncorrected hyperopic individuals, who must use some of their accommodative power to compensate for the hyperopia, will need reading spectacles of some sort. In general, the ordinary principles of prescribing for presbyopia will apply, and if reading spectacles are needed the prescribed power will be such as to leave the person using about half his power of accommodation.

11.3.71 Special problems arise for presbyopic flight crew needing bifocals when they have to read instruments located overhead. Management of this problem will be discussed in the next section.

## 11.4 VISUAL AIDS

11.4.1 The sections of Annex 1 dealing with visual requirements for licences state that where a standard of distant visual acuity can be obtained only with correcting lenses the applicant may be assessed fit provided that such correcting lenses are worn during the exercise of the privileges of the licence or rating applied for or held and a spare pair of suitable correcting spectacles is kept readily available. Annex 1 also states that when correcting lenses are needed to meet the intermediate or near vision requirements the applicant may be assessed fit provided that such lenses are available for immediate use during the exercise of the privileges of the licence or rating applied for or held. Again, a spare pair of suitable correcting spectacles must be kept readily available.

### Correcting lenses

11.4.2 In many persons there is a reluctance to wear spectacles because doing so suggests that there is "something wrong with the eyes" or that "one is getting old". This natural bias against the use of spectacles occurs in flight crew, particularly regarding the use of a distance correction. The ever increasing use of spectacles together with improvements in design and manufacture of spectacle frames and lenses and the advertising skills of those who make and sell them have made spectacles much more acceptable than was the case some years ago. Persons mature enough to hold a position of responsibility for control of an aircraft are usually mature enough to understand that good vision at both distance and near is essential for flight safety.

### Prescription spectacles

11.4.3 With normal uncorrected visual acuity and a good range of accommodation no visual aids are needed to carry out visual flight deck tasks. However, many flight crew, air traffic controllers and applicants for these positions do not meet the visual requirements without spectacles or contact lenses, so some knowledge of these optical devices is useful for the medical examiner. Modern spectacle lenses in the lower powers can provide excellent, distortion-free correction of the common refractive errors. Unfortunately, as the lens power is increased the optical aberrations found in all optical systems become significant. These aberrations include spherical aberration, chromatic aberration, coma<sup>3</sup>, astigmatism of oblique incidence, field curvature and distortion. The details of these aberrations are not important but one should know that the degradation of the imagery can become significant with lens powers greater than 5 dioptres and highly significant with lens powers greater than 10 dioptres. Apart from these aberrations there are problems which can arise from improper fitting of spectacles. These include:

- a) induced prism effects from tilting of the spectacles or decentration of the lenses so that the wearer is not looking through the optical centres of each lens
- b) incorrect placement of the reading segments in multifocal lenses
- c) incorrect distance of the lenses from the wearer's eyes. The effective power of a lens depends on its distance from the eye.

11.4.4 Not all refractive errors require correction. A young hyperope with ample accommodation may have excellent vision at distance and near and will need no correction. Small amounts of astigmatism may not need correction. Myopia of more than minimal degree will reduce visual acuity at far and require a distance correction. The decision to prescribe spectacles or contact lenses for an aviator should be made by a vision care specialist who is familiar with the visual requirements for aviation duties.

11.4.5 A young person requiring distance spectacles will have no problem reading with these spectacles but when significant presbyopia develops, a different prescription will be necessary for near work.

### **Management of presbyopia**

11.4.6 When the emmetropic subject develops presbyopia, reading spectacles are required. For flight crew ordinary full-sized lenses are not acceptable because they blur distance vision. The so-called half-spectacles or "look-over" spectacles are required. In many instances the reading spectacles will not need to be worn all the time but will be required for looking at charts and maps and during take-off and landing, especially at night. Such spectacles must be available for immediate use, as required in Annex 1.

11.4.7 A myopic person will develop presbyopia as anyone else, but can usually cope quite well by taking his (distant vision) spectacles off when he needs to read. As this is not acceptable for flight crew when flying, some sort of multifocal correction is required.

11.4.8 The hyperope will develop symptoms of presbyopia earlier than persons with other types of refractive error because some of the accommodative reserve is used to compensate for the hyperopia. This situation will require a multifocal correction.

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<sup>3</sup> Coma: an aberration of the image formed of a point-source off the principal axis of an optical system. It consists of a spreading out of the image in a plane roughly at right angles to the optic axis producing a comet-like tail.

11.4.9 It should be noted that, in accordance with Annex 1, a pilot shall demonstrate that one pair of spectacles is sufficient to meet the visual requirements. The use of separate distance and reading spectacles is not acceptable because of possible problems when having to change from one set to another during a critical phase of flight.

11.4.10 Multifocal lenses are well tolerated by most who try them and are available in many different forms. See Figure 11-12. Those most useful in the flying environment are the following:

- a) *Bifocals* — the top segment has the distance correction and the bottom segment the near correction. The size, shape and placement of the reading segment is best determined by a vision care specialist who is familiar with the requirements for medical certification.
- b) *Trifocals* — the top segment has the distance correction, the bottom segment the reading correction and the middle segment has a correction for intermediate distances such as instrument panels, which may be a metre or more from the pilot's eyes.
- c) *Progressive addition multifocals* — usually called *progressive add multifocals* — are also referred to as “invisible bifocals”. These are increasingly used for correction of presbyopia and are cosmetically popular because there is no visible line across the lens. The top part of the lens has the distance prescription. From near the centre of the lens the power increases progressively towards the lower part of the lens. The lowest part of the lens has the reading power so that there is a gradual transition from the distance portion to the near portion without a dividing line and without prismatic jump which is present in ordinary bifocals and trifocals. Theoretically there is a part of the lens which provides optimum correction for any distance between infinity and the distance required for reading. Unfortunately all progressive multifocals have peripheral areas of distortion at both sides of each lens making the so-called progression channel rather narrow, particularly in the higher reading add powers. When first introduced over thirty years ago, there was concern that the peripheral distortion areas in these multifocals would cause problems for pilots during take-off and landing. This has not been the case, and progressive add multifocals can be safely used by pilots, although some do not like the peripheral distortion and choose not to wear them.

11.4.11 In the early stages of presbyopia bifocals work well in the cockpit. The top part of the lens is used for distance and for the instrument panel and the bottom part of the lens for reading and any other visual task at near. As the presbyopia increases, the instrument panel is no longer clearly seen through the top of the bifocal lens and a correction is needed for this intermediate distance. The solution for this is a trifocal or a progressive add multifocal.

11.4.12 As a general rule, the strength of the intermediate portion of a trifocal is half the strength of the bottom portion or reading add. For example, if a given bifocal has a reading add of +2.00 dioptres, the strength of the intermediate add would be +1.00 dioptre. As the term “add”<sup>4</sup> indicates, these powers are simply added to whatever prescription is necessary in the top portion of the lens, i.e. the distance correction.

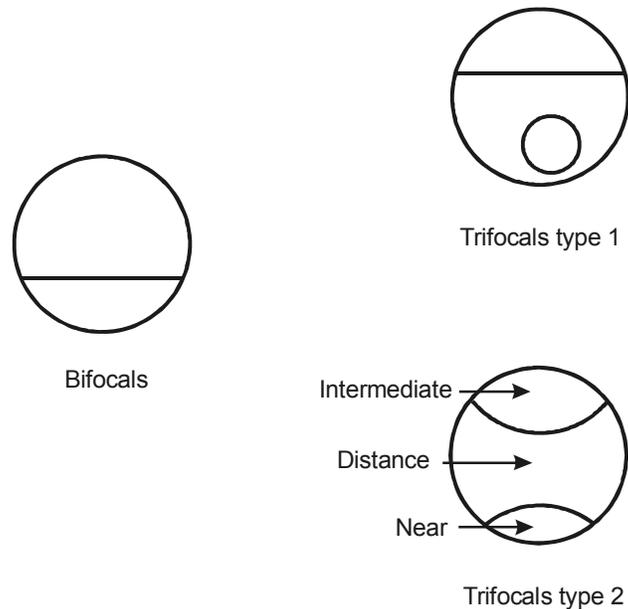
11.4.13 The standard bifocals and trifocals usually work well in the cockpit. If there are problems with the required focal distances, these distances should be measured in the aircraft or a simulator and the vision care specialist provided with the numbers so that the appropriate corrections can be prescribed. Correct fitting of the multifocals is critical. If the reading segment is too high, it will interfere with distance vision. If too low, the wearer will have to raise his chin uncomfortably high in order to read.

11.4.14 Although not ideal from a human engineering point of view, many modern aircraft are equipped

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<sup>4</sup> Add: abbreviation for L. *addetur* — let there be added, used in spectacle prescriptions.

with a great number of gauges and switches located on overhead panels. This may present a problem for the presbyopic pilot. If necessary a special “occupational multifocal” can be used with a small segment in the upper part of the lens with power appropriate for the distance of the overhead instrument panel.



**Figure 11-12. Examples of multifocal lenses useful in aviation**

11.4.15 In presbyopic flight crew who wear progressive add multifocals, the problem of seeing overhead instruments can be solved with the new stick-on bifocal segments in the upper part of the multifocal lens. Progressive add multifocals are not available with a progressive add in the upper portion of the lens.

11.4.16 It should be emphasized that almost all the visual requirements for the older flight crew can be met using ordinary multifocals. With proper communication between the flight crew member and the vision care specialist it is almost always possible to provide comfortable, functional spectacles.

11.4.17 Symptoms of presbyopia develop gradually and in the early stages an individual may only have difficulty when tired or in low light levels or when print quality is poor. A pilot with early presbyopia may have no trouble reading maps and charts in bright daylight but will have difficulty doing so as the light fails. Pilots should therefore be provided with reading spectacles as soon as they become presbyopic rather than waiting until they have difficulty reading small print in bright illumination.

11.4.18 The medical examiner should be aware that Annex 1 requires a flight crew member to have a spare set of suitable correcting spectacles readily available during the exercise of the privileges of the licence or rating applied for or held. Also when only near correction is required, a second pair of near-correction spectacles shall be kept available for immediate use.

### Contact lenses

11.4.19 While the usual reason for wearing contact lenses is cosmetic, there are important visual advantages compared with spectacles. These include improved field of vision and abolition or marked reduction of the aberrations mentioned above. For applicants with large refractive errors, contact lenses generally provide better visual function than spectacles.

11.4.20 The modern soft (hydrophilic) contact lenses and the gas-permeable hard contact lenses can be satisfactorily worn by many persons with spherical and astigmatic refractive errors. The old polymethylmethacrylate (PMMA), non-gas-permeable hard contacts with their associated spectacle blur problems have almost disappeared. Bifocal contact lenses are available but their success rate is much lower than for ordinary single vision contacts and they are not acceptable for flight crew.

11.4.21 Even the best fitting contact lens is a foreign body in the eye and interferes somewhat with the normal physiology of the cornea. Wearing contact lenses is associated with slight but definite risks which include abrasion of the cornea, allergic reaction to the contact lens solutions, development of corneal neovascularization, conjunctivitis, corneal ulceration and eye infections.

11.4.22 Nevertheless, after establishing that an applicant has been properly fitted with contact lenses and that he can handle them and wear them comfortably for a period of time sufficient for the required flying duties, such an applicant may be allowed to use the contact lenses instead of spectacles.

11.4.23 The availability of high index materials allows individuals with large refractive errors to be fitted with spectacles which cause less distortion and less interference with the peripheral visual field than is the case with conventional spectacle lenses. Even so, there are applicants with high refractive errors such that the required spectacles would have unacceptable aberrations and/or cause visual field limitations. In such cases, the successful use of contact lenses may be a requirement, i.e. the applicant may fly wearing contact lenses but not wearing spectacles. In such a situation the applicant should have a spare set of contact lenses available whenever exercising the privileges of the licence. In addition to a spare set of contact lenses, applicants who meet the requirements with contact lenses but not with spectacles must have available a set of spectacles (preferably with high refractive index lenses) for use in an emergency situation when it may be impossible to insert the spare contact lenses.

11.4.24 Applicants who are successful contact lens wearers need not have their uncorrected visual acuity measured on a regular basis provided the recent history of the contact lens prescription is known. Stability of the contact lens prescription would indicate no significant change in the uncorrected distance visual acuity.

11.4.25 Monofit or monovision is a method of dealing with presbyopia in an individual who uses contact lenses for distance and does not wish to use reading spectacles while wearing the contact lenses. The method uses contact lens correction of the dominant eye for distance vision and of the non-dominant eye for near. This technique is not acceptable for flight crew because of the reduced distance visual acuity in the non-dominant eye.

11.4.26 In certain situations air traffic controllers may use contact lenses while working at their display screens and need a set of spectacles to correct their distance vision while wearing the contact lenses.

11.4.27 The low relative humidity in aircraft can affect soft contact lenses so that wearing time may be reduced. In some situations the use of non-preserved artificial tears may be desirable if the flight is prolonged. Artificial tears which contain preservatives may be irritating when used with contact lenses and are best avoided.

11.4.28 In all cases involving use of contact lenses, proper, regular monitoring by an appropriate vision care specialist is necessary.

## Sunglasses

11.4.29 Sunglasses are useful and often necessary to decrease glare and reduce discomfort in bright environments, particularly above clouds. In addition to reducing glare by cutting down transmission of the visible spectrum, sunglasses for general wear should provide protection from ultraviolet radiation (UVR).

11.4.30 UVR is somewhat arbitrarily subdivided into three bands according to wavelength: UVA, 400–320 nm; UVB, 320–290 nm; and UVC, 290–200 nm. Very little UVC is present in terrestrial sunlight except at high altitudes. Significant amounts of UVA and UVB reach the surface of the earth. UVB is the most important band as far as harmful effects on biological systems are concerned. The level of UVB is largely controlled by ozone in the atmosphere. Ozone (O<sub>3</sub>) is a gas present throughout the atmosphere but most concentrated in a layer (“the ozonosphere”) 15–50 km above the earth’s surface where its concentration reaches approximately one molecule per two million or 0.5 ppm.

11.4.31 Concern has been expressed that flight crew may be exposed to dangerous levels of UVR due to the chlorofluorocarbon (CFC)-induced depletion of stratospheric ozone at altitudes between 25 and 100 km where, otherwise, most of the UVR is absorbed. Measurements in aircraft cockpits have shown that aircraft windows provide excellent protection against UVR, even at high altitudes.

11.4.32 However, visible light at the blue end of the spectrum (400 to 500 nm) may cause some retinal damage, particularly in older individuals. The amount of blue light increases with altitude and 50 to 60 per cent of this light is transmitted through a 3-cm-thick flight deck window. Flight crew are thus exposed to more blue light than individuals on the ground. It is not known if this blue light exposure is harmful, but it is prudent to recommend that flight crew, especially when flying towards the sun at high altitude, wear sunglasses.

11.4.33 Harmful effects of UVR on the skin and the eyes are well recognized. Ocular damage from UVR (especially the UVB band) include: photokeratitis (snowblindness), pterygium, climatic droplet keratopathy, cataract and possibly intraocular melanoma. It should be stressed that the risks from UVR exposure are much greater on the beach than in any cockpit at high altitude.

11.4.34 The colour of sunglasses and the darkness of the tint are usually matters of personal preference. However, colour-tinted spectacles alter colour perception, and the only type of sunglasses acceptable in the aviation environment are neutral grey lenses which reduce overall brightness without altering the colour of viewed objects. Many different types of sunglasses are available including some with graded tint — dark in the upper portion of the lenses and clear in the lower part. In addition to the tint, good quality sunglasses absorb at least 95 per cent of UVB, while the highest quality sunglasses provide 99 per cent absorption of UVB and almost all the UVA.

11.4.35 The UVR absorbing properties are separate from the coloured tint in sunglasses so that it is possible to have very dark sunglasses with very little UVR protection and vice versa. In selecting sunglasses, the very dark tints should be avoided because these make it difficult to see the cockpit instruments (absorption of up to 85 per cent of visible light is suitable). Polarizing sunglasses are not acceptable for flight crew because of the disturbing reflections from certain glass and plastic laminates. Photochromic lenses darken rapidly and automatically depending on the brightness of the ambient light. The clearing process, however, is slow and they are therefore not recommended for flight crew because they do not increase light transmission sufficiently quickly when flying from bright to dull ambient lighting conditions.

11.4.36 Tinted spectacles, prescription or otherwise, are for daytime use only and result in severe reduction of visual performance if used in twilight or darkness.

## **Aphakia**

11.4.37 Aphakia is absence of the eye's crystalline lens. This is generally the result of cataract surgery but may rarely occur from non-surgical trauma. Removal of the lens reduces the refractive power of the eye by approximately 20 dioptres leaving it more or less hyperopic, depending on the original refractive error. In eyes with high degrees of myopia, removal of the lens reduces or abolishes the myopia and surgical removal of the normal, clear lens has been used as a treatment for high myopia. In most situations, the lens is removed because it is cataractous and optical correction will be required in the form of spectacles, contact lenses, intraocular lenses or a combination of these.

### ***Spectacle correction of aphakia***

11.4.38 In most patients the strength of aphakia spectacles is such that the induced magnification, distortion and loss of peripheral visual field precludes their use in the aviation environment. There may be some exceptions in persons previously highly myopic whose aphakia spectacles are of low or moderate power but, generally speaking, aphakia spectacles are not acceptable for flight crew or air traffic controllers.

### ***Contact lens correction of aphakia***

11.4.39 Almost all the optical problems associated with aphakia spectacles can be avoided by the use of contact lenses. Many aphakic patients obtain good or excellent distance vision with contact lenses and may need only reading spectacles worn in addition to the contact lenses. Some aphakic patients will need multifocal spectacles for optimum correction at distance and near.

11.4.40 With present cataract surgery techniques, wound healing and visual recovery are rapid and an eye may be ready for contact lens fitting six to eight weeks after surgery. Proper contact lens fitting procedures and appropriate follow-up examinations by a qualified vision care specialist are particularly important in aphakic contact lens wearers. As with ordinary contact lens wearers, the aphakic applicant must demonstrate satisfactory adaptation to the contact lenses before being considered for aviation duties.

11.4.41 Individuals who are aphakic in one eye, who use a contact lens in that eye and either spectacles or no correction in the other eye will not generally be able to wear spectacle correction for both eyes because of the large anisometropia. Such individuals should have a spare contact lens and a spare set of spectacles available when exercising the privileges of their licence.

### ***Intraocular lens correction of aphakia***

11.4.42 The condition in which an artificial lens is placed inside the eye after cataract removal is called pseudophakia. This is now the preferred method of treating cataracts in adults. The earliest intraocular lenses were used in the 1940s. Since then there have been numerous modifications in lens design and manufacture and in the surgical techniques for inserting these lenses. Usually the preferred lenses are placed behind the iris within the crystalline lens capsule after removal of the cataractous cortex and nuclear material. These posterior chamber intraocular lenses provide the best optical correction possible, and many patients have good distance vision without additional correction. Most patients who have intraocular lens implants do need spectacles, either reading spectacles or multifocals to achieve the best correction at distance and near. Multifocal intraocular lenses are available but visual results with these lenses are less satisfactory than with single vision intraocular lenses. Only single vision intraocular lenses are considered suitable for use in the aviation environment.

11.4.43 The success rate for cataract surgery with intraocular lens implantation is excellent, and the newer techniques using foldable lenses allow use of small incisions and no sutures so that surgically induced astigmatism is reduced and visual recovery is rapid. Many patients see well the day after their surgery, and most will have stable refraction six to eight weeks later.

11.4.44 The usual surgical complications which can occur following any operation that involves opening the eye are seen in intraocular lens surgery but their incidence is considerably less than with the older cataract surgery techniques. One of the most frequent problems following present day cataract surgery is opacification of the posterior part of the crystalline lens capsule which may occur weeks to years after the surgery. This results in reduction of vision but is usually easily treated by capsulotomy using a YAG<sup>5</sup> laser. Such laser treatment has a very low complication rate, is done in minutes with only topical anaesthesia and generally results in rapid return of vision.

11.4.45 The high success rate for cataract surgery with intraocular lens implantation has resulted in patients being offered surgery at an early stage in the development of their cataracts. Medical examiners will see increasing numbers of applicants who have had this surgery.

### **Refractive surgery**

11.4.46 Surgical correction of refractive errors is increasing dramatically. The aim is generally to allow the patient to do away with spectacles or contact lenses. However, refractive surgery is now widely used to correct refractive errors of a degree that previously prevented applicants from obtaining medical certification needed to work in the aviation environment.

11.4.47 There is, however, rarely any reason for an applicant to submit to refractive surgery in order to meet the visual requirement, and it is important that applicants understand this.

11.4.48 Details of the surgical techniques are not important for the medical examiner but some background knowledge may be useful. Refractive surgery is a rapidly changing field in which many different techniques have been tried. Some of the more widely used techniques are:

- a) Clear lens extraction (CLE)
- b) Radial keratotomy (RK)
- c) Astigmatic keratotomy (AK)
- d) Automated lamellar keratoplasty (ALK)
- e) Photorefractive keratectomy (PRK)
- f) Laser assisted in-situ keratomileusis (LASIK)
- g) Laser thermokeratoplasty (LTK)
- h) Intrastromal corneal ring (ICR).

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<sup>5</sup> YAG: yttrium-aluminum- garnate

**Clear lens extraction (CLE)**

11.4.49 The improved safety and excellent results from cataract surgery has led to increasing use of clear lens extraction together with the use of low power intraocular lenses in individuals with high myopia.

**Radial keratotomy (RK)**

11.4.50 Radial keratotomy is used to correct myopia and astigmatism. A diamond blade is used to make a series of radial incisions in the cornea. The incisions must be almost the full thickness of the cornea. The number and orientation of the incisions are determined by the refractive error. The central portion of the cornea is not treated, leaving an untouched optical zone of about 4 or 5 mm in diameter. The incisions and their subsequent healing leads to flattening of the cornea with reduction of the myopia and astigmatism.

**Astigmatic keratotomy (AK)**

11.4.51 This is similar to RK but placement of the incisions may be non-radial. It can be done as a primary procedure or as a secondary procedure to correct residual or induced astigmatism following other refractive surgery, cataract surgery or other corneal trauma.

**Automated lamellar keratoplasty (ALK)**

11.4.52 This procedure can be used to correct low to moderate degrees of hyperopia. A portion of the central cornea is removed with a microkeratome. The removed portion of cornea is reshaped then sutured back onto the eye.

**Photorefractive keratectomy (PRK)**

11.4.53 In this procedure an excimer laser operating in the ultraviolet portion of the electromagnetic spectrum is used to remove a portion of the central cornea. The size and shape of the disc of tissue to be removed are calculated from the pre-operative refractive error. Myopia and astigmatism are the most suitable cases for PRK but hyperopia can be treated successfully.

**Laser assisted in-situ keratomileusis (LASIK)**

11.4.54 Also called laser assisted intrastromal keratomileusis, this procedure is most useful for the higher degrees of myopia. A central corneal hinged flap is made with a microkeratome. The flap is raised and the excimer laser used to reshape the inner layers of the corneal stroma. When this has been done the corneal flap is replaced. Rapid visual recovery, better predictability and less trouble with glare are advantages of this procedure compared with PRK. Flap displacement, however, is a well-recognized complication of LASIK. It can occur months after the procedure, sometimes from the patient rubbing his eyes too vigorously. Often the flap can be surgically replaced. Bilateral simultaneous flap displacement is unlikely, but would be incapacitating. After successful laser surgery, corneas will appear normal on ordinary clinical examination, but the reshaping can be detected by measuring the corneal surface curvatures using keratography (corneal mapping).

### **Laser thermokeratoplasty (LTK)**

11.4.55 A holmium-YAG laser is used to induce shrinkage of the corneal stroma in a series of (usually eight) spots in a circle. The circle is placed close to the limbus when treating hyperopia and more towards the centre of the cornea when treating myopia.

### **Intrastromal corneal ring (ICR)**

11.4.56 A narrow strip of plastic material is threaded into the peripheral corneal stroma to form a ring which alters the corneal curvature without surgical invasion of the central cornea. This procedure has the advantage of being reversible.

### **Problems with refractive surgery**

11.4.57 Considerable experience with refractive surgery has been gained worldwide. The success rate is high, with some series reporting over 95 per cent of patients with low to moderate refractive errors achieving uncorrected visual acuity of 6/12 (20/40, 0.5) or better.

11.4.58 Complications following refractive surgery are infrequent but a formidable list of problems has been reported including post-operative infections, loss of best-corrected visual acuity, and blindness.

11.4.59 The most important risks, from an aviation standpoint, are loss of best-corrected visual acuity, undercorrection or overcorrection, fluctuation in vision at different times of the day, glare, "halo" or "starburst" effects due to corneal haze, loss of contrast sensitivity, loss of low-contrast visual acuity, and regression towards pre-operative refraction levels.

11.4.60 Significant changes in refraction during the course of the day have been reported in RK patients for as long as four years after the surgery but such problems are uncommon, and the great majority of patients see well within days or weeks after their surgery.

11.4.61 Visual recovery after PRK and LASIK is generally more rapid than after the other procedures, and these excimer laser procedures have to a large extent replaced RK although there are still specific indications for RK.

11.4.62 PRK and LASIK procedures usually leave no visible corneal scarring, so it is easy for an applicant to conceal the fact that he has had refractive surgery. Examiners should be aware of this because the usual visual acuity testing methods will not reveal the impaired low-contrast sensitivity, which may occur after refractive surgery and which might impair visual performance in the aviation environment.

11.4.63 The recovery rate, predictability and regression rate following refractive surgery depend to some extent on the pre-operative refractive error and on the type of surgery. The following is suggested as a guide to the minimum interval between withdrawal of eye drops after refractive surgery and the resumption of duties:

Pre-operative refractive error of up to 6.00 D spherical equivalent:

RK	3 months
PRK	3 months
LASIK	3 months

Pre-operative refractive error 6.00 to 10.00 D spherical equivalent:

RK 6 months  
PRK 6 months  
LASIK 3 months

Greater than 10.00 D spherical equivalent:

RK 6 months  
PRK 6 months  
LASIK 6 months

11.4.64 *It must be emphasized that applicants who have had refractive surgery and are being considered for medical certification or re-certification should meet the following criteria:*

- a) *The surgery is uncomplicated*
- b) *Vision is stable*
- c) *There is no corneal haze and no complaints of glare, halos or "ghosting"*
- d) *The result meets the visual requirements of Annex 1, and the assessment must be based on measurements made by a qualified vision care specialist acceptable to the Licensing Authority*
- e) *There should be follow-up examinations by a qualified vision care specialist six months after return to duty and yearly thereafter.*

11.4.65 Individuals contemplating refractive surgery must be made aware of the risks involved and should be told that having the surgery might result in a delay in return to duties as aircrew or air traffic controller or, if complications occur, in the permanent loss of medical certification.

## 11.5 VISUAL FIELDS

11.5.1 While good visual acuity is clearly a requirement for safe operations in the aviation environment, an adequate field of vision is also essential. The proper location of oneself in space and the location and assessment of movement of other objects in the surrounding space are necessary for safe operation of aircraft.

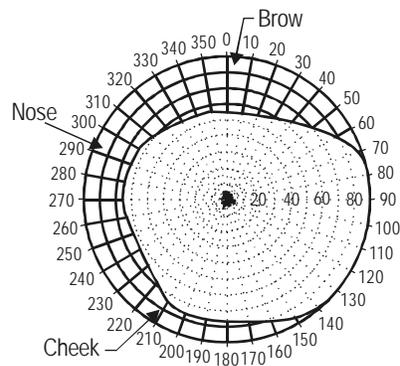
11.5.2 That portion of physical space visible to an eye in a given position looking straight ahead is the monocular visual field. The visibility of an object in the visual field depends on the size of the object, its brightness, the contrast of the object to its surround, and its location in the field of vision. Visual acuity diminishes rapidly as one moves away from the retinal fovea. Ten degrees eccentric from the fovea visual acuity is only 6/30 (20/100, 0.2).

11.5.3 The extent of the visual field can be measured using targets of different size and different brightness. In this way the (differential) sensitivity of the various parts of the retina can be determined and the results drawn on a chart. When targets of different size are used to determine the threshold of visibility and the points where each target just becomes visible are plotted on a chart, joining these points results in a series of concentric, approximately oval curves called isopters. Thus isopters are lines joining points of equal sensitivity.

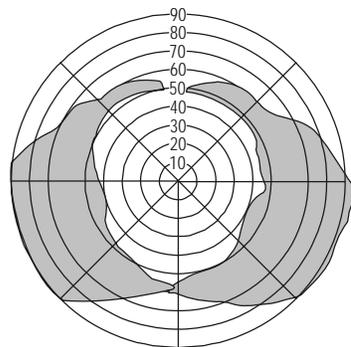
The larger an object the further out to the periphery of the field will it be perceived. In a normal eye the isopter for a 3-mm white test object will extend approximately 95 degrees temporally, 60 degrees nasally, 60 degrees upwards and 75 degrees downward. These values depend to some extent on the facial configuration of the subject. A large nose, deep-set eyes, and prominent eyebrows may influence the size of the field. Figure 11-13 illustrates the normal monocular and binocular visual fields.

11.5.4 In humans and all animals with forward-looking eyes, there is overlapping of the visual field of each eye so that the binocular field has a central area which is seen by both eyes simultaneously and temporal crescentic areas which are only perceived monocularly. The value of the binocular field is that it allows for improved depth perception and gets rid of the restriction of the monocular field caused by the nose.

11.5.5 The integrity of the visual field is of special importance to flight crew and air traffic controllers. A pilot must be aware of other aircraft and objects on the ground while scanning cockpit instruments or looking at charts. The “peripheral flow” of visual information during the landing flare is critical for this manoeuvre.



The useful monocular visual field.



The binocular field. The shaded area shows the lateral crescents on unocular vision.

**Figure 11-13. Extent of the visual field**

11.5.6 Apart from specific diseases causing visual field loss and covered in a later section, the following

factors may interfere with the visual field:

a) Mechanical factors

Aircraft windshield design, nose cone and wing design, headgear including helmets and oxygen masks and spectacle frames or multifocal segment lines are some of the impediments to vision.

b) Physiological factors

Sources of bright light, both natural and artificial (e.g. laser emitters<sup>6</sup>), may cause strong after-images with resulting temporary central scotomas. Some powerful lasers have the potential to cause permanent scotomas and other eye damage. Hypoxia may cause constriction of the peripheral visual field and enlargement of the normal blind spot, effects which can come on rapidly and may start at altitudes as low as 1 000 to 1 500 m (3 280 to 4 921 ft).

11.5.7 Depending on the size, location and density, a scotoma in the visual field of an applicant might represent a major safety risk.

### Methods of examination

#### **Confrontation**

11.5.8 The simplest but least accurate method of measuring the visual field is by confrontation (Donders' test<sup>7</sup>), in which the examiner compares the applicant's visual field with his own visual field. The examiner's visual field must be normal. The visual field is tested for each eye separately. The examiner and applicant are seated opposite each other about 1 m (3 ft) apart. The applicant's left eye is occluded. The examiner closes his right eye and each fixes the exposed eye of the other. The examiner moves a finger or a small white test object mounted on a handle from the extreme periphery towards the midline in a plane halfway between examiner and applicant and notes when it first comes into view. It should be seen simultaneously by the applicant. The test object should be brought into the centre of the field and any points of disappearance and emergence noted. All four quadrants of the visual field should be tested, exploring at least two different meridians in each quadrant. The applicant should have his back to the light, and the background behind the examiner should be uniform and dark, if possible. The test is repeated on the applicant's other eye using the examiner's other eye as the "control". Various modifications of this confrontation method can be used such as counting fingers in each quadrant of the visual field.

11.5.9 If the confrontation test suggests field loss or if there are other reasons to suspect field loss such as glaucoma, retinal or other ocular disease or neurological problems, more precise methods must be used.

#### **Tangent screen or campimetry**

11.5.10 This method is useful for detailed examination of the central 30 degrees of the visual field but cannot be used to evaluate the peripheral field. The tangent screen is usually black felt 1.5 to 2 m (5 to 6 ft)

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<sup>6</sup> For further information on laser emitters and their effect on the visual function, see *Manual on Laser Emitters and Flight Safety*, ICAO Doc. 9815

<sup>7</sup> After Franciscus Cornelius Donders, Dutch physician and ophthalmologist (1818-1889).

square with a central fixation point and the major meridians, 30 degrees apart, marked with stitching. The applicant is seated with the eyes 1 or 2 m from the centre of the tangent screen. If distance spectacles or contact lenses are normally used the applicant should wear these for the examination. Each eye is tested separately while the other eye is occluded.

11.5.11 The illuminance of the screen is usually between 200 and 300 *lux*. Test objects are circular discs from 1 to 50 mm in diameter, matt white on one side and matt black on the other. They are inserted in the end of a long wand painted matt black. Battery-illuminated test objects are also available and there are projection methods.

11.5.12 The examiner monitors the applicant's fixation on the central spot on the tangent screen while the test object is moved in at 30-degree intervals from the periphery towards the centre of the screen. The applicant indicates when he first sees the test object and if it disappears at any time during transit along each meridian tested. The normal blind spot is plotted first. This is about 6 degrees wide and is located in the temporal field between 12 and 18 degrees from the fixation point. As a screening test a 3-mm diameter white object is satisfactory and should be seen in all parts of the tangent screen except the normal blind spot. If a scotoma is detected it can be further examined using different sized white targets. During the test the examiner can check the applicant's attention from time to time by rotating the test disc so that the black (almost invisible) surface is presented. Failure to see a 3-mm white target in all parts of the tangent screen (except for the normal "blind spot") would be reasonable grounds for referral to an ophthalmologist.

### **Perimetry**

11.5.13 This test method examines the entire visual field by measuring its extent as delineated on multiple arcs of a circle approximately concentric with the eye. Several instruments have been devised ranging from simple, manually operated arc perimeters which can be rotated through 360 degrees so as to allow examination of multiple meridians using hand-held targets of different sizes to the large, expensive automated perimeters which use projection methods of displaying the targets and which have multiple, computer-driven test patterns and data base storage capability. The fixation of the examinee can be monitored during testing, and the size, brightness and colour of the test object together with the background illumination can be controlled. Instruments such as the Goldmann perimeter can be used with moving targets to determine the different isopters (kinetic perimetry), and other instruments use stationary targets the brightness of which is adjusted so as to determine the retinal sensitivity (static perimetry). In all cases the aim is to determine the sensitivity of the different parts of the retina. Detailed description of the different instruments and test methods is not necessary. The test results from modern automated perimeters are in general reliable and reproducible but they are not infallible and some experience is necessary to interpret the results correctly.

### **Medical factors**

11.5.14 Abnormalities in the visual fields should be distinguished from loss of peripheral vision resulting from impaired ocular motility. True field defects can be caused by a large number of neuro-ophthalmological disorders. Before outlining some of the more important causes of visual field defects it is worth mentioning the so-called pseudo-field defects which can occur in the following:

- a) Facial contours — prominent nose, eyebrows, cheekbones, and ptosis from any cause
- b) Opacities in cornea, lens or vitreous body
- c) Wearing strong spectacle prescription, especially aphakia correction

- d) Hysteria and malingering
- e) Mental deficiency, impaired cerebral function from drugs or disease, and poor understanding of the test procedures.

11.5.15 True visual field defects are seen in trauma and congenital or acquired diseases affecting any part of the visual pathway from the retina up to the occipital visual cortex. The location of the field defect, its shape and whether it is unilateral or bilateral help to determine the location of the damage and in some cases are characteristic of specific diseases or groups of diseases. Only the broadest generalizations can be mentioned:

- a) Retinal or choroidal disease will give field defects which match the site of the damage
- b) Macular disease will produce central scotomas while peripheral problems including retinal detachment will cause peripheral field defects
- c) Optic nerve disorders can cause central, sector or sometimes horizontal hemianopic defects.

11.5.16 The term hemianopia is widely used to describe visual field loss restricted to one half of the visual field. Strictly speaking the term means total loss of one half of the visual field. Clinically it is frequently the case that although the vision loss is restricted to one half of the field, the loss is neither total nor does it occupy the entire half field. In such cases the correct term is hemidysopsia. The term half-field defect covers all types of defects limited to one half of the visual field, but is rarely used.

11.5.17 Glaucoma is one of the most important causes of field defects. The earliest changes are usually nerve fibre bundle defects in the form of small, arcuate, paracentral scotomas which enlarge as the disease progresses. Sometimes nasal defects occur and in the later stages the visual field is reduced to a small central or temporal island. See Figure 11-14.

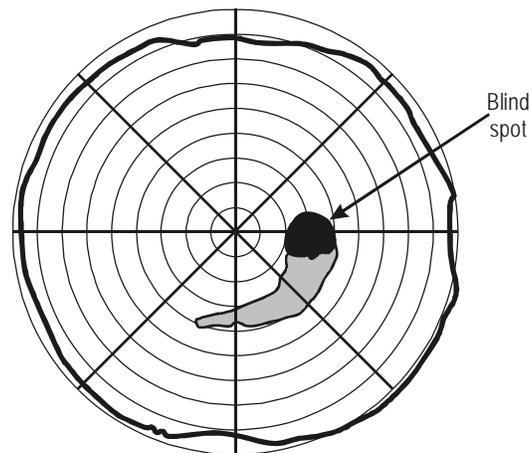
11.5.18 The pigmentary retinopathies (retinitis pigmentosa) and other tapeto-retinal degenerations tend to affect the mid-peripheral portion of the retina first and cause ring scotomas which enlarge and eventually leave only a small island of central vision.

11.5.19 Lesions involving the centre of the optic chiasm classically cause bitemporal hemianopias, while those involving the optic tracts and optic radiations produce contralateral homonymous hemianopic defects, which may be partial or complete. The shape, location and symmetry of these hemianopic defects help in localizing the causative lesion.

11.5.20 *Not all visual defects will disqualify an applicant from flying or from air traffic control duties but any applicant with a visual field defect requires neuro-ophthalmological evaluation.*

## 11.6 MONOCULARITY

11.6.1 One eye provides about 140 degrees of vision in the horizontal plane. Even allowing free movements of the head, a monocular pilot can never have as extensive a field of vision at any given moment as a normal binocular individual. The question of depth perception is also of concern in a monocular individual. It is important to understand that while a monocular individual has no stereopsis, he does not lack depth perception. At a distance beyond 10 m (30 ft) stereopsis becomes less important than monocular clues in judging depth. Monocular individuals cannot perform tasks such as photo-interpretation which requires stereopsis, and they have difficulty performing visual tasks requiring fine detail discrimination at close range but they usually have good depth perception at distance which is provided by the following monocular clues:



**Figure 11-14. Typical glaucomatous scotoma (right eye)**

- a) Aerial perspective — distant objects appear bluish with blurring of their contours due to preferential scattering of the short wavelength light by the atmosphere.
- b) Distribution of light and shade including shadows — conveys much information as to shape and solidity of objects.
- c) Overlapping of contours — an object partially concealed by another is interpreted as being behind it.
- d) Geometrical perspective — horizontal planes appear to intersect in the plane of the horizon, and this produces a foreshortening and alteration in the images of all objects of any significant size in the visual field.
- e) Apparent size — the apparent size of a known object allows designation of a distance of that object from the observer.
- f) Parallax — parallactic displacement of objects relative to each other when the eye is moved is one of the most important monocular clues in depth perception. When a middle plane is regarded, objects beyond it appear to move in the same direction as the observer, while objects in near planes appear to move in the opposite direction.

11.6.2 *The Annex 1 requirement for normal visual fields precludes licensing of monocular pilots except under the flexibility clause (Standard 1.2.4.8).*

11.6.3 Before assessing a monocular applicant's fitness under this flexibility clause, an adaptation period of at least six months should be allowed following the loss of vision. The assessment should include practical flight testing in the case of a pilot or practical testing in the air traffic control environment in the case of an air traffic controller and should be conducted by a suitably qualified person in consultation with the Aviation

Medicine Section of the Licensing Authority.

11.6.4 *The following points should be considered by a Contracting State prior to granting a licence to a monocular pilot or air traffic controller:*

- a) *The nature of the flying operation — airline transport, charter, agriculture, private, recreational, air traffic control.*
- b) *The type of aircraft — fixed or rotary wing, cockpit layout including seating position of the pilot, single or multi-crew arrangement.*
- c) *The applicant — which eye is affected, what is the status of the other eye, and does the applicant have full range of head, neck and eye movements.*
- d) *Special tasks — helicopter slung-load operations, hoisting, search and rescue, supply drops, nap-of-the-earth flying, crop-spraying, power-line inspection, multiple aircraft aerobatics and display flying. Operations involving close proximity to the ground, other aircraft, ships or people constitute high-risk flying activities.*

11.6.5 In general, monocularity does not pose a significant problem for air traffic controllers. For those working at electronic display terminals, care must be taken to ensure that fixed secondary displays such as map boards and weather radar screens are located comfortably inside the operator's monocular field of vision.

11.6.6 Monocular individuals can perform many flying tasks safely, particularly in multi-crew situations where visual tasks can be shared. For single-seat operations it is sometimes possible to adjust seating or provide aids such as rear-view or downward-looking mirrors to compensate for the loss of peripheral vision.

11.6.7 In monocular individuals it is obviously important to provide optimum vision for the normal eye (correcting spectacles, sunglasses) and to minimize the risk of injury to that eye during high-risk flying activities, e.g. by use of helmet with visor to minimize injury from bird strike.

11.6.8 Substandard vision in one eye has been dealt with in an earlier section of this chapter.

*In many applicants with a small visual field defect in the central 50 degrees of the visual field in one eye, the extent of the binocular visual field will be normal and medical certification may be considered.*

## 11.7 OCULAR MUSCLE BALANCE

11.7.1 With the evolutionary migration of the eyes from the sides of the head to the front, there came the need for accurate alignment of the two eyes so as to achieve single, binocular vision throughout the entire visual field. Binocularity or binocular vision results from the coordinated movement of the two eyes in a way that produces a single mental impression. The blending of the visual information gathered from each eye into a single, unified perception is called fusion. Fusion has two components: 1) a motor component which steers the eyes in the proper direction; and 2) a sensory component which serves the integration of the electrical data arriving at the two halves of the occipital visual cortex.

11.7.2 In the normal individual who looks at an object in space, the images of this object in each eye will fall on what are called corresponding retinal points. These are points in each eye which have the same "visual direction". For example, each of the foveae have the "straight ahead direction". An object in the left half of the

visual field will form its image somewhere on the nasal half of the left retina and somewhere on the temporal half of the right retina. These will therefore be corresponding retinal points.

11.7.3 For any given position of the eyes, i.e. with the eyes focused at any given distance, the locus of those points in space the images of which fall on corresponding retinal points form an imaginary curved plane in space which is called the horopter (from Gr. *horos* = limit). Objects located on the horopter will be seen as single. Objects which are not on or close to the horopter will be seen as double. This is the physiological diplopia ("double vision") which we all have but which is usually unnoticed. There is an infinite number of horopters in space depending on where the eyes are focused. At the centre of the horopter, that is at the projection of the two foveae, even slight displacement of an object from the plane of the horopter will result in diplopia. As one moves further away from the fovea the amount by which an object can be displaced behind or in front of the horopter before inducing diplopia, increases. The boundary of the space in which single vision is maintained is called Panum's fusional area.

11.7.4 Thus rather than corresponding retinal points there is for every point in one retina a corresponding area in the other retina. The further into the periphery of the retina, the larger the corresponding area in the fellow eye. This explains the shape of Panum's fusional area<sup>8</sup>.

11.7.5 Measuring ocular muscle balance in applicants is important to detect conditions which might cause diplopia. The paucity of visual clues when flying at night or at high altitude and the physiological stresses of hypoxia, vibration and high G-loading can interfere with normal fusion mechanisms so that ocular misalignment is more likely than in the normal terrestrial environment.

11.7.6 Before discussing examination methods, some explanation of the terms used to describe ocular muscle balance is appropriate. The innervation and coordination of the twelve extraocular muscles so as to keep the object of regard accurately imaged on the two foveae at all times is complex, and it is not surprising that in many individuals the ocular alignment is less than perfect.

### **Definitions**

11.7.7 **Normal binocular vision** is vision in which images from each eye are blended into a single, unified perception so that there is no diplopia. For this to happen, the eyes must be accurately aligned with each other. The mechanism for maintaining this alignment involves a motor component in which the extraocular muscle innervation is precisely adjusted so that both eyes are pointing at the object of regard. It also involves a sensory component in which the data from each eye are integrated in the cerebral visual cortex. This motor component together with the sensory component constitute the mechanism called fusion.

11.7.8 **Stereopsis (stereoscopic vision)** is a special type of binocularity in which small differences in the retinal images from each eye are used to assign "depth" or position of objects in space. Good stereopsis is evidence of binocular vision and indicates normal binocular function. However, stereopsis is not essential for binocular vision, and some individuals with minimal ocular misalignment and/or minimal amblyopia have binocular vision and use peripheral fusion to maintain ocular alignment without having good stereopsis.

11.7.9 **Orthophoria** means perfect alignment of the eyes with no tendency for deviation of the visual axes even when fusion is prevented by covering one eye or by any of the various tests to be described.

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<sup>8</sup> Panum's fusional area: the region of binocular single vision. It is the area on the retina of one eye over which a point-sized image can range and still provide a stereoscopic image with a specific point of stimulus on the retina of the other eye. Outside Panum's fusional area, physiological diplopia occurs. After Peter Ludvig Panum, Danish physiologist (1820-1885).

11.7.10 **Tropia** is a manifest deviation of the visual axes. The amount may be large or small but the eyes are misaligned even when there is no mechanical obstruction to fusion. In a tropia, fusion is not happening so that covering one eye or interposition of any of the test instruments to prevent fusion does not make any difference to the deviation.

11.7.11 **Phoria** is a latent deviation which means that there is a tendency for the eyes to become misaligned but this tendency is held in check by the normal fusion mechanisms. When fusion is permitted, the eyes are straight. When fusion is prevented, such as by covering one eye or by interposition of a Maddox rod<sup>9</sup>, the visual axes become misaligned. As soon as the obstruction to fusion is removed, the deviating eye will align itself correctly.

11.7.12 The distinction between phorias and tropias is important. Persons with long-standing non-paralytic tropias rarely have diplopia. On the other hand, persons with a phoria may “break down” and become tropic if the fusion mechanisms are impaired by such things as fatigue, stress, high G-loading or sedative drugs, including alcohol. Such a person will be asymptomatic while phoric but may have diplopia when the deviation becomes a tropia and therefore be at risk of developing double vision during the course of a prolonged or difficult flight.

11.7.13 Ocular misalignments may be classified according to the direction of the deviation. Collectively these are called heterophorias or heterotropias:

Inward deviation	esophoria esotropia	or
Outward deviation	exophoria exotropia	or
Upward deviation	hyperphoria hypertropia	or
Downward deviation	hypophoria hypotropia	or
Rotational deviation	cyclophoria cyclotropia	or

11.7.14 Most phorias are well controlled by fusion and cause no symptoms. In some individuals the compensation is less satisfactory, and they may have symptoms such as headaches, eye discomfort and fatigue together with tearing and redness of the eyes and eyelids, all of which are generally worse during periods of fatigue, stress or general debility from any cause.

11.7.15 It should be noted that the ocular misalignment may not be present at all distances. For example, a person may be orthophoric at distance and esophoric or esotropic at near. Another individual may be exotropic or exophoric at distance and orthophoric at near.

11.7.16 There is no absolute correlation between the amount of ocular deviation and symptoms. Some persons with large phorias are entirely asymptomatic while others with a much smaller deviation have

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<sup>9</sup> Maddox rod: a set of parallel cylindrical glass rods used in testing for heterophoria. The rods, placed before the eye, distort the image of a point source of light into a long streak perpendicular to the axis of the rods, interfere with fusion, and break up binocular vision (see also under Examination techniques). After Ernest Edmund Maddox, English ophthalmologist (1860-1933).

significant problems. In some individuals the ocular misalignment worsens over time so that a small phoria becomes larger, then progresses to an intermittent tropia and finally a constant tropia. This is particularly likely in exo-deviations (outward deviation of the visual axes).

11.7.17 Ocular deviations are measured using prisms which are designated by the deviation they produce in the light passing through them. This deviation can be measured in degrees but the unit most often used clinically is the prism dioptre ( $\Delta$ ). One prism dioptre is an angle whose tangent is 1/100. A prism having a power of 1  $\Delta$  produces an apparent shift of 1 cm of a object located 1 m distant from the prism. A 5  $\Delta$  prism produces an apparent displacement of 5 cm of an object 1 m from the prism.

11.7.18 As a general rule, symptoms may be expected when the deviations exceed the following:

esophoria	10 prism dioptres
exophoria	5 prism dioptres
hyper or hypophoria	2 prism dioptres
cyclophoria	1 prism dioptre

11.7.19 *Applicants whose ocular deviations exceed these values should be referred for evaluation by an appropriate vision care specialist.*

### **Strabismus**

11.7.20 Manifest or latent misalignment of the visual axes is called strabismus and may be classified into:

Paralytic — due to injury or disease affecting the extraocular muscles or their nerve supply;

Non-paralytic — due, probably, to some poorly understood disorder of the fusional mechanisms or to the central nervous system centres controlling eye movements.

11.7.21 Paralytic strabismus of recent onset is always associated with diplopia and is not acceptable in flight crew or air traffic controllers.

11.7.22 Non-paralytic strabismus may be congenital or acquired. In the acquired types when fusional ability is exceeded there may be symptoms which have been mentioned above. In congenital or early onset strabismus the central nervous system is presented with the problem of resolving intolerable diplopia. Three adaptations are possible:

- a) suppression of the central vision in one or other eye depending on gaze direction. This avoids diplopia while maintaining good visual acuity in each eye. It occurs in alternating strabismus;
- b) continued suppression of the central vision in one eye only. This avoids diplopia but leads to failure of development of the visual potential in the deviating eye. This probably occurs in the central nervous system rather than in the eye itself and is called amblyopia ex anopsia. A similar loss of development of visual potential may occur when there is a large difference in the refractive error between the two eyes. This is amblyopia ex anisometropia; and
- c) a readjustment in the directional values of the various parts of the retina. This is called anomalous retinal correspondence and avoids diplopia but generally with some sacrifice of

visual acuity.

### **Examination techniques**

11.7.23 The following examination techniques enable the examiner to detect some of the ocular misalignments which have been described above and to decide on referral to the appropriate vision care specialist whenever the screening standards are not met or if significant pathology is suspected.

11.7.24 Abnormal head posture is sometimes an indication of an extraocular muscle weakness. Head turn to one side is seen in homolateral sixth nerve weakness and head tilt to one side in contralateral fourth nerve weakness. These abnormal positions are adopted to get rid of diplopia. Examining ocular excursions may disclose impaired muscle function, but additional testing is often necessary to evaluate ocular misalignments. The most useful screening tests are cover tests and Maddox rod or Maddox wing.

### **Cover testing**

11.7.25 This is the most useful screening examination to determine ocular alignment. No special equipment is required. It allows the examiner to distinguish between phorias and tropias, to estimate the magnitude of the deviation and to get some idea about the applicant's fusional ability. The test can be done at distance and near although for most screening examinations a distance measurement is all that is required. Cover testing is often poorly done because the following points are not understood:

- a) If a spectacle correction or contact lenses are required for the applicant to see properly at the test distance, this correction must be worn during the test.
- b) Accommodation must be controlled by having the applicant read symbols at a known distance (generally 6 m, or 20 ft). The ordinary visual acuity charts are used. It is incorrect and may be misleading to do cover testing by asking the applicant to look at a light because accommodation is then not controlled.
- c) When checking for horizontal deviations the applicant is asked to read vertical columns of symbols, and when checking for vertical deviations the applicant should read horizontal rows of symbols. Cover testing cannot be used to evaluate cyclo-deviations.
- d) The test should be done in such a way that the examiner can observe both of the applicant's eyes.

11.7.26 For screening examinations it is generally sufficient to do the cover testing in the primary position i.e. with the applicant looking straight ahead into the distance with his head straight. For more detailed evaluation of strabismus, the testing is also done in the eight cardinal positions of gaze — left, right, up, down and into each of the four corners.

11.7.27 There are two parts to the cover test — alternate cover and cover/uncover.

### **Alternate cover test**

11.7.28 With the distance spectacle correction (if any) in place, the applicant is asked to read the Snellen letters (or other suitable optotype) in columns, vertically. A cover, which can be the examiner's hand or a

suitably shaped piece of cardboard or plastic, is placed in front of the applicant's right eye, held there for a few seconds then rapidly moved across to cover the left eye. After another few seconds the cover is shifted back to the right eye. The cover is moved back and forth several times until the examiner is satisfied with his observations.

11.7.29 If the eyes are straight (orthophoria) there will be no movement of either eye other than the slight vertical movement as the applicant looks from one symbol down to the next. Repeat the test with the applicant reading the letters horizontally. If the eyes are straight there will be no vertical movement of either eye. No shift of the eyes on alternate cover testing indicates orthophoria.

11.7.30 If the applicant is not orthophoric, there will be movement of the eyes during the alternate cover test. If the eye behind the cover abducts when uncovered it must have been turned inwards indicating an esodeviation. If it adducts when uncovered it must have been turned outwards indicating an exodeviation. If the eye makes a downward movement when uncovered it must have been hyperdeviated and if it makes an upward movement when uncovered it must have been hypodeviated. These correcting movements are made to "take up fixation", and this is why it is essential to have the applicant reading symbols.

11.7.31 The alternate cover test prevents fusion and tells the examiner if the applicant is orthophoric or if there is a deviation. It indicates the direction of the misalignment but it does not distinguish between a phoria and a tropia. For this, the following test is needed.

#### **Cover/uncover test**

11.7.32 In this test the applicant does exactly the same thing as in the alternate cover test but this time the examiner simply covers then uncovers each eye in turn. The cover is held in place for a few seconds so as to prevent fusion while the eye position is observed. When the cover is removed fusion is permitted and again the movement of the eyes is observed. The test is repeated several times until the examiner is satisfied that he has observed what happens to each eye when it is covered and when it is uncovered.

11.7.33 If there is a tropia, covering the fixating eye (the one which is not deviated) will make the applicant look with the deviated eye, which will have to move to see the letters on the chart. If the eye must **abduct** there is an **esotropia**, if it must **adduct** there is an **exotropia**, if it must move **downward** there is a **hypertropia** and if it must move **upwards** there is a **hypotropia**. The examiner will be able to tell if the tropia is left, right or alternating.

11.7.34 When the cover/uncover test is done on the deviating eye there will be no shift of either eye because the non-deviating eye is already properly aligned and reading the letters.

11.7.35 In an applicant with a tropia, the examiner will note that during the cover/uncover test the two eyes move in unison. When one eye adducts the other abducts and vice versa. This maintenance of the misalignment of the visual axes is the essence of a tropia.

11.7.36 If the deviation is a phoria, by definition the eyes are straight when fusion is allowed. As soon as one eye is covered, fusion is prevented. There will be no shift in the uncovered eye because it is already looking at the letters on the chart but the eye behind the cover will drift into its misaligned position. It may take a few seconds for the misalignment to occur, so the examiner should not hurry the test. When the cover is removed, the deviated eye will straighten out because fusion is now possible. In applicants with good fusion, the recovery movement will be rapid. In those with less efficient fusion the recovery will be slower and may require the patient to blink or make a conscious effort to bring the eyes together.

11.7.37 This drift into the deviated position behind the cover and the recovery movement (fusional

movement) is the essence of a phoria. Throughout the cover/uncover test in an applicant with a phoria there is no shift of the uncovered eye. This is the distinction between a phoria and a tropia. The direction of the drift into the deviation shows if the phoria is eso, exo, hyper or hypo.

11.7.38 *The amount of the ocular deviation can be measured using prisms but in most situations it will be sufficient for the examiner to detect that there is a significant deviation and then refer the applicant to the appropriate vision care specialist.*

### **Maddox rod**

11.7.39 The Maddox rod is a device which prevents fusion by presenting completely different images of a light source in each eye. It is a ribbed glass which can be fitted into a frame having markers, which show how the eyes are aligned, and a calibrated rotary prism (Herschel prism) to measure the deviation of the visual axes in prism dioptres. Looking at a small light source through the device, one eye sees the light and the other eye sees a straight line which can be horizontal or vertical depending on the orientation of the ribbed glass in the Maddox rod. When the ribs are horizontal, the perceived line is vertical and vice versa.

11.7.40 With the ribbed glass horizontal (the perceived line will be vertical), the applicant looks at a small light source 5 to 6 m (16 to 20 ft) distant and adjusts the rotary prism until the line runs through the centre of the light. The examiner reads the number indicated on the scale of the instrument which indicates the deviation, if any, whether it is eso or exo, and how much. The ribbed glass is rotated 90 degrees so that it is vertical (the perceived line will be horizontal), and the applicant again adjusts the rotary prism so that the line runs through the centre of the light. The scale reading gives the vertical deviation, if any, in prism dioptres.

11.7.41 A simple Maddox rod with no rotary prism can be used and will indicate orthophoria or a deviation. The amount of the deviation can be measured with loose prisms or a prism bar. If a simple Maddox rod is used, the examiner must remember that eso deviation will cause displacement of the vertical line to the same side as the eye looking through the ribbed glass (uncrossed diplopia), and exodeviation will cause displacement of the line to the opposite side (crossed diplopia). For vertical deviations, the rod is placed in front of the right eye in which case an upward deviation of the horizontal line indicates a left hyperdeviation, a downward displacement indicates a right hyperdeviation.

11.7.42 The Maddox rod can be used to test ocular alignment at near by holding the light source at 1/3 m (1 ft) or a Maddox wing can be used. This is a hand-held instrument with a vertical partition separating the vision from the two eyes thus preventing fusion. One eye sees red and white arrows and the other eye sees a graded cross. The applicant looks through the device with both eyes open and reports the positions of the arrows. The figure at which the white arrow is pointing is a measure of the horizontal deviation. The red arrow indicates the vertical deviation.

11.7.43 The Maddox rod and wing are ingenious instruments, useful for screening examinations, but they have shortcomings. First, they are entirely subjective, second they cannot distinguish between phoria and tropia, third it is possible for the applicant to move the vertical line by exerting voluntary convergence, and finally they present entirely abnormal viewing conditions for the visual system and may indicate non-orthophoria when in the real world situation fusion occurs when similar images are presented to each eye.

### **Testing the sensory status in strabismus**

11.7.44 The presence of fusion, diplopia or suppression can be determined with the Worth four-dot test (W4D) which uses a box illuminated from the inside and presenting four dots — a red one at the top, a green dot at either side and a white dot at the bottom (Figure 11-15). The test can be done at 6 m (20 ft) or at near,

and small flashlight Worth four-dot tests are available.

11.7.45 The applicant wears spectacles having a red lens on one side and a green lens on the other. These lenses can be reversed. With the red lens in front of the applicant's right eye and the green in front of his left eye the following results may be described:

- a) Five dots – two red and three green = diplopia
- b) Four dots with the bottom one described as being a combination of red and green or changing from red to green and back = fusion
- c) Two red dots only = suppression of the left eye
- d) Three green dots only = suppression of the right eye

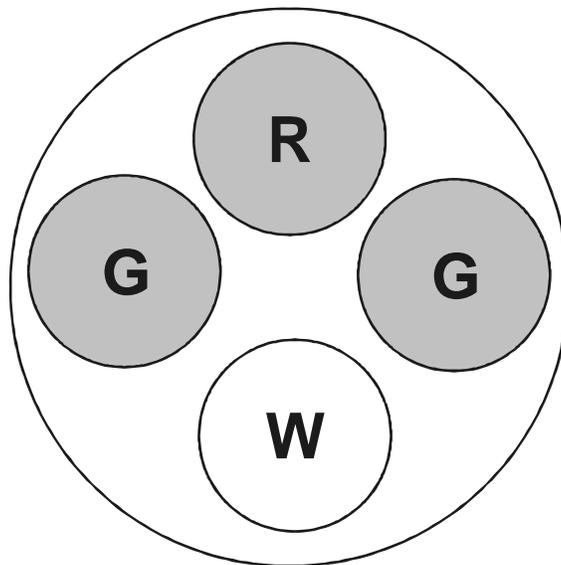


Figure 11-15. Worth four-dot presentation

### **Convergence**

11.7.46 Convergence is an act by which the eyes are turned towards each other in order to maintain binocular vision when near objects are regarded. There is an approximate relationship between convergence and accommodation. The unit of convergence is the metre angle which is the amount of convergence required to view an object 1 m away. In ordinary clinical work it is usually sufficient to measure convergence by having the applicant focus on a small target which is brought progressively closer to the eyes until diplopia is reported or the examiner sees that fusion cannot be maintained and one eye deviates outwards. As an approximate value, this "near point of convergence" is measured in cm. Normal values are usually between 6 and 8 cm. If the near point is 10 cm or more, the convergence is insufficient.

### **Evaluation of significant defects of binocular vision**

11.7.47 The proper evaluation of an applicant with significant ocular muscle imbalance who does or who might experience diplopia, asthenopia or both, requires referral to an appropriate vision care specialist for an orthoptic evaluation to determine the applicant's fusional amplitudes. This is done by measuring the applicant's ability to maintain fusion when the retinal image in one eye is moved either with prisms or with a major amblyoscope (synoptophore).

11.7.48 More detailed advice on the evaluation of significant defects of binocular vision is given in the Attachment to this chapter.

## **11.8 COLOUR VISION**

### **Introduction**

11.8.1 The increasing use of colour-coded information in flight information display systems means that adequate colour perception continues to be important for flight crew and air traffic controllers.

11.8.2 The traditional conventions "red for danger or stop" and "green for safety or go" are in common use worldwide and unlikely to change in the foreseeable future.

11.8.3 In addition, aviation personnel need to be able to distinguish colours on charts and in the terrain.

11.8.4 The colours most widely used on the flight deck, in the aircraft cabin, on external airborne lighting, in air traffic control instruments and on aerodrome runways are red, green, yellow, orange, blue, cyan, magenta and white.

11.8.5 Deficient colour vision is often referred to as colour blindness, but this is an inaccurate use of a term which refers to monochromatic vision. Colour-blind individuals are very rare and, in addition to their monochromatic vision, they generally have poor visual acuity, nystagmus and photophobia.

11.8.6 Individuals with less severe colour vision defects are common — some eight per cent of all males and about 0.8 per cent of all females will fail the more stringent colour perception tests. More than 99 per cent of these will have red-green deficiencies.

11.8.7 While it is unfortunate that the ability to distinguish red and green is the most common variety of colour vision defect, it does not mean that every applicant with a red-green colour deficiency must be denied a licence.

11.8.8 Because colour perception is a purely subjective phenomenon, it is impossible to know exactly what sensation an individual has when viewing light of a particular wavelength. What can be demonstrated is that individuals with colour vision defects are unable to distinguish variations in colour that are readily apparent to a person with normal colour vision.

11.8.9 There are all grades of colour vision defect from subtle to severe, and the question which arises is how much of a colour vision defect can be allowed before an individual must be considered unable to operate safely in the aviation environment.

11.8.10 The section of Annex 1 dealing with colour perception states that the applicant shall be required to

demonstrate ability to perceive readily those colours the perception of which is necessary for the safe performance of his duties. Precise physical and physiological criteria cannot be given because of the large number of variables in different viewing situations.

11.8.11 Simple practical tests such as the ability to name correctly signal flare or signal light colours give information only about the specific test situation and are of limited value.

### Physiology of colour perception and colour deficiency

11.8.12 Colour is a subjective phenomenon. The three subjective attributes of colour vision are:

*Hue* this is an attribute associated with the dominant wavelengths of the spectrum and refers to how we perceive an object's colour, e.g. red, yellow, blue.

*Saturation* also called "chroma", this refers to the vividness or dullness of a colour and indicates the degree of absence of whiteness.

*Lightness* also called "value", this refers to the luminous intensity of a coloured light or the amount of light the colour reflects, and it distinguishes between the lightness and darkness of a colour.

These three attributes are not mutually independent.

11.8.13 Like other visual functions, colour perception is only possible when certain stimulus thresholds are reached. To be identified, a coloured object must be large enough and bright enough to exceed those thresholds. Location in the visual field, duration of exposure and contrast with the surround are also important. During normal bright illumination (photopic vision) the peripheral retina is less colour-sensitive than the central retina. In dim illumination (scotopic vision) only the retinal rods are functioning, and colour perception is not possible.

11.8.14 Under normal circumstances the human eye responds to the part of the electromagnetic spectrum between 380 nm (violet) and 750 nm (red) although at very high intensities this range may be increased. This is the visible spectrum. The ability of the eye to distinguish between different wavelengths is the basis of that part of colour vision called hue discrimination, i.e. what colour is the object. This ability to distinguish between different hues varies in different parts of the visible spectrum. Near the limits of the spectrum, particularly at the red end, large differences in wavelength are necessary to produce a perceptible change in hue. Near the centre of the spectrum the sensitivity of the eye is maximal and in the regions around 495 nm (blue-green) and 595 nm (orange-yellow) wavelength differences as small as 1 nm can be detected.

11.8.15 In 1895, Johannes von Kries (1853-1928), professor of physiology at Freiburg (Germany), elaborated on the work of his predecessors to lay down the principles of the duplicity theory of vision which suggests two distinct types of visual activity in the retina — a rod-mediated mechanism which operates at low light-levels and is achromatic, and a cone-mediated mechanism which operates at high light-levels and is responsible for colour perception. Low light-level vision is called scotopic, and high light-level vision is called photopic. Most of our normal viewing activity takes place between these extremes, involves both rods and cones and is called mesopic vision.

11.8.16 Colour perception, like other visual functions, is a complex process involving both retinal and

occipital visual cortical activity. The traditional trichromatic theory (the Young-Helmholtz theory<sup>10</sup>), while it does not explain certain things like colour constancy, coloured shadows and some coloured after-images, does explain most of the observed facts about colour vision and is useful in understanding colour vision defects. The theory was proved in a 1983 experiment when microspectrophotopic readings of single eye cone cells were obtained. [http://en.wikipedia.org/wiki/Young%E2%80%93Helmholtz\\_theory\\_-\\_cite\\_note-0](http://en.wikipedia.org/wiki/Young%E2%80%93Helmholtz_theory_-_cite_note-0)

11.8.17 There are three populations of retinal cones. One contains a visual pigment with maximum sensitivity in the red portion of the spectrum, the second contains a pigment with maximum sensitivity in the green portion of the spectrum and the third group has pigment with maximum sensitivity in the blue portion of the spectrum.

11.8.18 There is some overlap in the spectral sensitivity curves but basically one can think of red sensitive cones, green sensitive cones and blue sensitive cones. By appropriate stimulation of these three types of cones, all spectral colours can be perceived.

11.8.19 Colour vision defects occur when there is deficiency in one or more of the three cone pigments, and there are all grades of severity of the defects.

11.8.20 Normal individuals have all three types of cones with normal amounts of their respective pigments and use all three mechanisms in colour perception and colour matching. Such individuals are normal trichromats. A normal trichromat is able to match any given hue by using an appropriate mixture of red, green and blue light.

11.8.21 The commonest type of colour vision defect is one in which the individual has all three types of cones but one type is deficient to some degree (Table 11-5). Such individuals are anomalous trichromats. They fall into three groups:

- a) red deficient = protanomalous trichromat
- b) green deficient = deuteranomalous trichromat
- c) blue deficient = tritanomalous trichromat.

11.8.22 In dichromatism the affected individuals have only two colour-sensing mechanisms and can match any coloured or white light by a mixture of two other coloured lights taken from near the two ends of the spectrum. They accept colour-matches made by normal observers but they also make matches unacceptable to the trichromat. There are three types of dichromats:

- a) Protanopes — who lack the retinal long-wavelength sensitive pigment; have a reduced sensitivity to red light (that is black for them). They see no colour in red and blue-green.
- b) Deuteranopes — who lack the mid-wavelength sensitive pigment. They have normal sensitivity to light and for them green and red-purple are seen achromatic.
- c) Tritanopes — a rare type where probably the short-wavelength pigment is missing. Blue-violet is achromatic to them.

**Table 11-5.**

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10 After Thomas Young, English physician and physicist (1773-1829) and Hermann Ludwig Ferdinand von Helmholtz, German physiologist (1821-1894).

Classification of colour vision
Normal trichromatism (normal colour vision)
Congenital colour vision defects
Dyschromatopsia
Anomalous trichromatism
Protanomaly
Deuteranomaly
Tritanomaly
Dichromatism
Protanopia
Deuteranopia
Tritanopia
Achromatopsia
Rod monochromatism
Cone monochromatism
Acquired colour vision defects

11.8.23 The third group consists of monochromats who may be rod monochromats or cone monochromats. Both deficiencies are extremely rare, are associated with severe visual problems and need not be considered further in an aeromedical context.

11.8.24 Congenital deficiencies in the blue sensitive mechanisms — tritanopia and tritanomaly are also rare and are seldom of practical importance.

#### **Prevalence and distribution of colour vision defects**

11.8.25 There are interesting variations in the prevalence of colour vision defects. Caucasians have the highest prevalence. African Americans, Japanese and Chinese have about half this prevalence, and the lowest rate is found in native Africans.

11.8.26 The breakdown of the various defects in Caucasian men is approximately as follows:

- a) deuteranomalous trichromatism — 4.6 per cent
- b) protanomalous trichromatism — 1.0 per cent

- c) deuteranopia — 1.4 per cent
- d) protanopia — 1.2 per cent.

11.8.27 Persons with colour vision defects have difficulty distinguishing colours which are easily distinguished by normal persons. The degree of difficulty varies with the severity of the defect.

11.8.28 These difficulties will be worse when light levels are low and when the colours are unsaturated. The main concern in the aviation environment is the risk of confusion between red, white (yellow) and green signals.

11.8.29 The problem with colour vision standards for pilots and air traffic controllers is that there is very little information which shows the real, practical implications of colour vision defects on aviation safety. Ideally one would select only applicants with normal colour vision as measured by the most discriminating tests. This policy would deny licences to a significant number of individuals who might be able to function safely in the aviation environment. The question is where to draw the line. Many Contracting States simply define as acceptable those applicants who obtain a certain score with an authorized set of pseudo-isochromatic test plates, others accept as “colour safe” colour-deficient applicants who pass certain additional tests.

#### **Tests for colour vision**

11.8.30 Tests for colour vision fall into three categories:

- a) chromatic confusion plates or discs
- b) colour lantern tests
- c) anomaloscopes.

11.8.31 The first group includes pseudo-isochromatic plates (PIP) such as those designed by Ishihara, Stilling-Velhagen, Dvorine, Boström & Kugelberg, and Hardy, Rand and Rittler. The Ishihara plates<sup>11</sup> or variations of these are widely available and have gained general acceptance. For accurate work these plates should be viewed in daylight (but not in sunshine) or with a special light source — International Commission on Illumination (CIE) illuminant “C” or “D65”. It should be noted that the American Optical Hardy-Rand-Rittler plates are not very useful for detecting congenital colour vision defects but are excellent for detecting acquired defects.

11.8.32 There are different criteria for “pass” and “fail” in each of the different series of test plates so it is important to adhere strictly to the test guidelines for each series.

11.8.33 The plates are placed in front of the applicant at normal reading distance (approximately 50 cm, or 20 in). The applicant should wear spectacles if these are normally used for reading at this distance, and his response to each coloured plate should be given without hesitation. Tinted lenses must not be used, and the use of “colour correcting” contact lenses is not allowed. A second attempt may be allowed if the examiner suspects carelessness or lack of concentration. Loose plates are preferred to books of plates because the plates can be rearranged so as to prevent the applicant from learning the sequence by heart. Care must be taken to avoid touching the surface of the colour plates, and when not in use they should be kept in the dark to avoid fading of the colours.

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11 After Shinobu Ishihara, Japanese ophthalmologist (1879-1963)

11.8.34 A problem with colour plates is that they detect very mild colour vision defects which might not be significant in the aviation environment. In other words, they are rather too discriminating.

11.8.35 Variations of the pseudo-isochromatic plates are tests using a series of coloured discs which must be arranged in correct sequence. The simplest of these is the Farnsworth D-15 test. This is supplied with forms on which the applicant's score is recorded and which indicate the type of colour vision defect. A more complex test is the Farnsworth-Munsell 100 hue test which consists of four trays containing a total of 85 removable reference caps. The colour caps have incremental hue variation on one side and are numbered on the reverse. Colour vision anomalies are detected by the ability of the subject to place the colour caps in hue order. A score sheet yields numerical and graphical results.

11.8.36 For applicants who fail the colour plate tests, colour lanterns can be used to screen for the more serious red-green colour deficiencies. Several different lanterns have been used by Contracting States, but there is no consensus on any particular one as a universal standard. Some of the lanterns which have been used and are still used include the Spectrolux lantern, the Beyne lantern, the Eldridge-Green lantern, the Farnsworth lantern, the Giles-Archer lantern, the Holmes-Wright lantern, the Royal Canadian Air Force lantern, and the Optec 900 lantern. These lanterns vary in their complexity and price, but none is clearly to be preferred and several are no longer available for purchase.

11.8.37 Following a request from ICAO to several Contracting States with highly developed aeromedical facilities detailed studies have been carried out in recent years to determine the importance of colour perception and to what extent deficient colour perception can be allowed without affecting aviation safety. Vision testing software programmes have been developed for use on personal computers and on more sophisticated equipment and such programmes are designed to test colour vision and other visual functions. It is likely that in the next few years some of the traditional tests of colour vision will be replaced with more modern equipment.

11.8.38 Anomaloscopes are instruments which utilize a method of mixing light of two wavelengths so as to match a given hue. In the Nagel anomaloscope<sup>12</sup> one half of the screen can be adjusted by varying the proportions of red and green light so as to match the other yellow half of the screen. Dichromats accept all red-green mixtures if the yellow brightness is properly adjusted. Anomalous trichromats accept only abnormal mixtures; the deuteranomalous use more green and the protanomalous more red. Anomaloscopes give both qualitative and quantitative assessment of the colour vision deficiency. These instruments are difficult to use, expensive, and not generally available but may be found in major clinics and research centres.

11.8.39 The above remarks apply to the common, congenital colour vision defects. These are genetic defects, present from birth and not progressive. The red-green types are inherited as a sex-linked recessive trait which is typically manifest in men and transmitted by women. There is less information available about tritanopia which may be polygenetic and inherited as an irregular dominant trait.

11.8.40 Some States use the term "colour vision defective **safe**" or "colour safe" to refer to individuals who fail the colour plate tests but can pass testing with an anomaloscope or an accepted colour lantern test or both, and the term "colour vision defective **unsafe**" or "colour unsafe" to refer to those individuals who fail both plates and anomaloscopy and lantern tests. Despite all the work undertaken concerning colour vision, a challenge remains to determine exactly where the cut-off between "safe" and "unsafe" should be placed with respect to an initial applicant who chooses aviation as his career or hobby.

### Acquired colour vision defects

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12 After Willibald A. Nagel, German physiologist (1870-1911)

11.8.41 Although much less common than congenital defects, acquired colour vision defects do occur. These may affect one eye more than the other and may be progressive. The more important causes include:

- a) Tapeto-retinal degenerations and pigmentary retinopathies
- b) Chorioretinitis from any cause including macular lesions
- c) Optic neuropathy from any cause including advanced glaucoma
- d) Drug toxicity affecting the macula or the optic nerve.

11.8.42 Most drug-induced impairment of colour vision, for example that caused by hydroxychloroquine (Plaquenil®), digitalis and ethambutol (Myambutol®), is long-lasting or permanent. Sildenafil (Viagra®) is a drug which is widely used in the treatment of erectile dysfunction in males that has been shown to cause light sensitivity and bluish colour tinge of viewed objects in 3 to 11 per cent of users. These effects may last up to five hours or longer and could be dangerous in situations where correct colour identification of blue or green light is required.

11.8.43 There is no internationally agreed, standardized method for evaluating colour vision in persons working in the aviation environment. Some Contracting States test all flight crew and air traffic controllers on a regular basis and test each eye separately using a method which screens for yellow-blue defects in addition to the more common red-green defects. This allows detection of the uncommon but important acquired colour vision defects. Suitable tests would be the Japanese SPP plates or the American Optical H-R-R plates or one of the coloured-chip sorting tests using the principle of the Farnsworth D-15 test.

11.8.44 Aircraft accidents in which colour perception defects have been cited as a contributing factor are rare but have occurred. One example is the crash of FedEx flight 1448 (a Boeing 727) in Tallahassee in 2002 during a night visual approach to land, where the first officer's colour deficiency interfered with his ability to discern the red and white lights of the PAPI<sup>13</sup>. Studies of colour perception in the aviation environment have so far been limited. Further research in this area is required to determine precisely the importance of colour perception and what defects can be allowed without affecting safety.

## 11.9 ASSESSMENT OF PATHOLOGICAL EYE CONDITIONS

11.9.1 One of the requirements for obtaining a Medical Assessment is that the eyes and adnexa are healthy. According to Annex 1, 6.3.3.1, 6.4.3.1 and 6.5.3.1, the function of the eyes and their adnexa shall be normal. There shall be no active pathological condition, acute or chronic, nor any sequelae of surgery or trauma of the eyes or adnexa likely to reduce proper visual function to an extent that would interfere with the safe exercise of the applicant's licence and rating privileges.

11.9.2 The following conditions are usually associated with reduced visual performance and applicants with them would normally be assessed unfit pending thorough ophthalmic evaluation by an accredited ophthalmological specialist. In many cases the problems will be treatable, allowing the applicant to reapply after successful therapy.

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<sup>13</sup> PAPI: Precision Approach Path Indicator, a series of white and red lights that aid flight crews in determining if they are on a proper glide slope to the runway.

### **Eyelids and lacrimal system**

- a) Destruction or malfunction of the lids which impairs protection of the eye or which results in corneal irritation from in-turned lashes
- b) Scars and adhesions of the lids to each other or to the eyeball
- c) Ptosis interfering with the visual field
- d) Growth or tumour of the eyelids other than small, benign, non-progressive lesions causing no symptoms
- e) Obstruction of the lacrimal drainage system sufficient to cause tearing

### **Cornea**

- a) History of recurrent keratitis, corneal ulcers, corneal scars or vascularization which interferes with vision
- b) Corneal dystrophy of any type including keratoconus

### **Uveal tract**

- a) History of anterior uveitis except on a single occasion and without sequelae. Any history of posterior uveitis (choroiditis) or signs of chorioretinal scars except minor scars not affecting central or peripheral vision when tested by ordinary clinical methods
- b) Coloboma of iris or choroid

### **Retina and optic nerve**

- a) Any of the tapeto-retinal degenerations of the retina including pigmentary retinopathies
- b) Significant macular lesions from any cause
- c) Retinal detachment or retinoschisis
- d) History of optic neuritis from any cause
- e) Optic atrophy from any cause

### **Lens**

- a) Lens opacities (cataract) affecting visual acuity, visual field or causing glare
- b) Aphakia, unilateral or bilateral

- c) Dislocation or subluxation of lens

### **Miscellaneous defects and diseases**

- a) Glaucoma — dealt with in detail below
- b) Tumour of eye, adnexa or orbit
- c) Fracture of orbit impairing ocular motility or with any communication between orbit and nasal sinuses or intracranial cavity
- d) Pathological nystagmus from any cause
- e) Loss of normal pupillary reflexes from any cause
- f) Retained intraocular foreign bodies
- g) Night blindness (nyctalopia)
- h) Any other injury, disease or disorder of the oculo-visual system which, in the opinion of the examiner, might interfere with safe performance as flight crew or air traffic controller.

## **11.10 GLAUCOMA**

11.10.1 Although glaucoma is more common in older persons, it can occur at any age and measurement of intraocular pressure (tonometry) should be part of the ocular screening examination in all applicants.

11.10.2 The diagnosis of glaucoma is not always easy. Increased intraocular pressure is only one of the risk factors. Above normal intraocular pressure not accompanied by demonstrable optic nerve damage does occur (ocular hypertension). Other cases occur in which typical glaucomatous damage to the optic nerve with associated visual field loss — the hallmark of glaucoma — is seen in spite of intraocular pressure measurements generally considered to be normal (normal pressure or low pressure glaucoma). Such cases are difficult to diagnose and manage.

### **Methods of screening intraocular pressure**

11.10.3 Estimation of ocular pressure by palpation is highly inaccurate and only useful in detecting marked increase in intraocular pressure such as might occur in acute angle closure glaucoma.

### **Tonometry**

11.10.4 Measurement of intraocular pressure is called tonometry and there are two methods used clinically. The most accurate method is by applanation or flattening of the cornea utilizing a contact tonometer mounted on a slit-lamp. Such instruments are expensive and not usually available to non-specialist physicians. Hand-held instruments such as the Perkins tonometer are satisfactory, less expensive and may be practical in

situations where fairly large numbers of screening examinations are done.

11.10.5 Air-puff applanation tonometers are available and are reasonably accurate. They have the advantage of not requiring topical anaesthesia.

11.10.6 The second method of tonometry is the indentation method. Indentation instruments such as the Schiøtz tonometer are widely available and reasonably accurate if they are properly maintained and correctly used. Schiøtz tonometry is done with the applicant lying supine. The appropriate weight is placed on the tonometer plunger. A drop of topical anaesthetic (such as proparacaine hydrochloride 0.5 per cent) is placed in the applicant's eye. After ten to fifteen seconds to allow the anaesthetic to work, the examiner uses thumb and forefinger or middle finger to hold the eyelids open without pressing on the eye. The applicant is instructed to look straight upwards (looking at his own finger held up in front of the eyes is helpful) while the tonometer is lowered gently onto the centre of the cornea, care being taken to keep the instrument vertical. Gentle fluctuation of the tonometer needle is a good indication that the instrument is correctly positioned and is transmitting the normal ocular pulsations. The scale reading is noted and the tonometer removed. Standard tables (Friedenwald tables) are used to determine the intraocular pressure. For a given scale reading the ocular pressure will depend on which tonometer weight was used.

11.10.7 *If consistent values of intraocular pressures of 24 mm Hg or more are recorded, or if there is a difference of 5 mm Hg or more between the two eyes, the applicant should be referred to an ophthalmologist who will investigate further with gonioscopy, funduscopy, visual field studies and any other tests necessary to determine the type and severity of the glaucoma and make the decision as to whether or not treatment is required.*

### Treatment

11.10.8 This depends on the type of glaucoma. If the glaucoma is secondary to some underlying disease such as anterior uveitis, the treatment will be that of the underlying disease.

11.10.9 Angle closure glaucoma, which is much less common than open angle glaucoma, is generally managed with either laser iridotomy or surgical iridectomy.

11.10.10 Primary open angle glaucoma is by far the commonest type of glaucoma. It can be treated with laser or conventional surgery but in most parts of the world topical drug therapy is the initial treatment of choice. Laser therapy or filtering surgery is used for patients whose glaucoma cannot be satisfactorily controlled with medications.

11.10.11 Numerous medicines are available for treating glaucoma, and this is a rapidly changing therapeutic field. The main groups of pharmaca used for treating primary open angle glaucoma are the following:

- a) *Epinephrine derivatives*. These are used as drops. Potency is low. They act by reducing the production of aqueous humour. They are useful in flight crew because they produce no significant blurring of vision but can cause local irritation of the eyes and also systemic effects such as cardiac arrhythmia. Dipivefrin is an example.
- b) *Miotics*. These are used as drops. Potency is high. They act by increasing the outflow of aqueous humour from the eye. They include pilocarpine, carbachol, eserine and phospholine iodide. They induce miosis and accommodative blurring of vision, especially in young individuals and for this reason are generally not allowed in flight crew.

- c) *Beta-blocking agents.* These are used as drops. They act by reducing the production of aqueous humour. They are potent, but may have numerous systemic side effects including bradycardia, central nervous system effects, and aggravation of asthma. They are useful in flight crew provided the systemic effects present no problems. Examples are timolol, metipranolol, carteolol, levobunolol and betaxolol.
- d) *Carbonic anhydrase inhibitors.* Topical and systemic preparations are used. They have moderate potency. They act by reducing the production of aqueous humour. The systemic preparations include acetazolamide and methazolamide. Systemic side effects generally limit their use to short-term therapy. Drops can be used in flight crew as they rarely have systemic side effects. Examples of topical carbonic anhydrase inhibitors include dorzolamide and brinzolamide.
- e) *Prostaglandin analogues.* These are used as drops. Potency is high. They act by increasing uveoscleral outflow of aqueous humour. Side effects are few so they can be used in flight crew. Latanoprost (Xalatan<sup>®</sup>) is an example.
- f) *Alpha 2 agonists.* These drugs work by reducing aqueous humour production and by increasing uveoscleral outflow. Apraclonidine and brimodine are used as drops. They may cause allergic reactions in some patients.
- g) *Combinations.* Mixtures of the above groups of medicines are available. These are useful because they simplify the treatment regimen and lead to better patient compliance. Such mixtures have the side effects of their components, and those containing pilocarpine will not be suitable for most flight crew. Examples of available combinations are dipivefrin/levobunolol, pilocarpine/ timolol, and dorzolamide/timolol.

11.10.12 *The medical treatment of primary open angle glaucoma must be tailored for each individual. Fitness for flying will depend on what medications are required to control the disease and what side effects, if any, these produce.*

11.10.13 *Applicants whose ocular pressures are well controlled with medications which do not produce serious side effects and whose visual acuity and visual fields are satisfactory may meet the visual requirements of Annex 1 and can be granted a Medical Assessment.*

11.10.14 *Regular follow-up examinations which must include measurement of visual acuity, ocular pressures, evaluation of the optic discs, visual field studies and assessment of side effects of the medications are mandatory for glaucoma patients and for individuals with ocular hypertension.*

## 11.11 CONCLUSION

11.11.1 As in all technical fields, the developments in aviation as well as medicine accelerate with each passing year. New generations of aircraft and navigation systems together with improved instrumentation and new ways to manage increasingly crowded airspace bring with them challenges to flight crew, ground support staff, air traffic controllers and those charged with supporting the health of aviation workers and improving the comfort and safety of their workplace. Improved surgical techniques and better medical management of many disorders enable individuals who might have had to stop working in the aviation environment to continue safely and effectively.

11.11.2 The inevitable delay between writing and publishing means that some of the information presented in this chapter may already be or soon will be out of date. This is most likely to occur in the sections dealing with refractive surgery and with glaucoma medications. Updating will be required in a few years to keep pace with further developments in medical science and to make new adjustments to the changing occupational demands of flight crew and air traffic controllers, the paramount concern remaining the safety of aviation.

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## **ATTACHMENT**

### **EVALUATION OF SIGNIFICANT DEFECTS OF BINOCULAR VISION**

1. A significant defect of binocular vision implies either the presence of or increased risk of visual symptoms incompatible with safe flying. In a traditional ophthalmological meaning of the terms, an applicant may show anomalous or absent binocular vision without demonstrating symptoms significant for safe flying. On the other hand, an applicant may demonstrate apparently normal binocular vision, which in some situation may decompensate, resulting in symptoms incompatible with safe flying. Evaluating binocular vision in relation to aviation medicine thus implies establishment of how the two eyes cooperate and an assessment of the stability of this cooperation.

#### **Normal binocular vision**

2. In normal binocular vision, a viewed object is imaged in the observer's two retinas on corresponding retinal points, which means points having identical directional values. After this, cerebral integration of the two images (sensory fusion) occurs so that the observer sees the object as single, at a given distance and in a particular direction. Traditionally, the normal binocular vision is considered to have three elements: simultaneous perception, fusion, and stereopsis.

3. The presence and maintenance of normal binocular vision requires precise coordination of the movements of the two eyes to ensure that the object of regard is imaged on corresponding retinal points. This is the motor component of fusion. Fusion is the blending of the visual information from the two eyes into a single, unified perception and, as mentioned, has both sensory and motor components. The motor component can be measured by determining the ability to overcome prismatic displacement of the retinal image in a given direction. Such measurements of the fusional reserve are called fusional amplitudes and normally are greater at near than at distance and much greater horizontally than vertically.

#### **Stereopsis**

4. Stereopsis is the perception of the third dimension obtained from fusible but slightly dissimilar retinal images. It is very important for depth perception at close range but much less important at distances beyond about 30 m and is not a requirement for safe flying.

#### **Adaptive mechanisms**

5. In manifest strabismus an object is imaged on non-corresponding retinal points and may be seen as double (diplopia). In persons with an immature central nervous system (less than eight years of age) cerebral adaptation generally develops to overcome the diplopia. Sensory adaptations to strabismus include suppression (disregarding the image from the deviating eye) and anomalous retinal correspondence (assignment of new directional values to retinal points in the deviating eye).

#### **Suppression**

6. Suppression is a positive inhibitory reflex developed to allow the visual cortex to ignore the visual information coming from a deviating eye so as to avoid diplopia. In alternating strabismus the suppression changes from one eye to the other depending on which eye is being used. In unilateral strabismus the

suppression is always in the deviating eye. The size, shape and density or depth of the suppression scotoma is different in different types of strabismus.

7. In most squinting persons with suppression, the whole area of the visual field of the deviating eye that overlaps the fixing eye is suppressed. The remainder of the visual field of the deviating eye is not suppressed. Thus, the deviating eye always contributes to the overall binocular field of vision in a strabismic patient in two ways. Neither the area corresponding to the blind spot of the fixing eye nor the peripheral temporal crescent area in the deviating eye is suppressed. The binocular field is smaller (narrower) in esotropic patients and larger (wider) in exotropic patients.

8. The retinal midline divides the temporal retina and one side of the brain from the nasal retina and the other side of the brain. When the image of the fixation target crosses the midline from the nasal side to the temporal side or vice versa, it operates a “trigger” mechanism (the hemiretinal trigger mechanism) that determines whether diplopia or suppression occurs. Suppression develops in the visually immature patient in order to avoid diplopia. The image of the fixation object always falls on the same side of the retina of the deviating eye and is suppressed. If, however, the deviation is changed from esotropia to exotropia or vice versa, this is a new situation and diplopia is triggered. It is the change in position of the retinal image from one half of the retina to the other half that triggers the change from suppression to diplopia and vice versa whenever the visual fields overlap. Thus the risk to get outside the suppression area and become diplopic is the risk to change from esotropia to exotropia or vice versa.

9. The monofixation syndrome is characterized by a minor heterotropia with paracentral fixation and good peripheral fusion. There is suppression of the macula of the deviating eye only. The risk of diplopia is minimal and depends on the peripheral fusional amplitude, which maintains ocular alignment.

10. Suppression is not equally deep in all patients. To make a patient aware of the images perceived by the deviated eye, one must reduce the retinal illuminance in the fixating eye until the patient sees double. This is best done with a series of red filters of increasing density in the form of a ladder (Sbisa bar<sup>14</sup>). The patient fixates a small light source, and the filters are placed in front of the fixating eye. Some patients see double with a light density filter; others require a heavier-density filter before they recognize their diplopia. The lighter the density of the filter needed to produce diplopia the more superficial is the suppression indicating an increased risk of diplopia. In individuals with normal fusion, placing graduated neutral-density filters in front of either eye will, at a certain density level, prevent fusion and induce two lights either together (orthophoria) or apart from each other (diplopia with heterophoria).

### **Anomalous retinal correspondence**

11. Anomalous retinal correspondence (ARC) is a neural adaptation to eye misalignment in which non-corresponding retinal points are linked in the visual cortex to provide binocular fusion. When both eyes are used, ARC works by using a change in the visual direction of the retinal points in the deviating eye so that an extrafoveal point in that eye corresponds with the fovea in the straight eye. As with suppression, ARC can exist in either eye in alternating strabismus. In some individuals the fusion mechanism is weak, the ARC may be unstable, and there is a risk of diplopia. Other persons with ARC have peripheral fusion (including some motor fusion reserve) and even gross stereopsis. In such cases, diplopia is very unlikely.

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14 Sbisa bar: a Bagolini filter bar, manufactured by Sbisa Industriale SpA, Italy.

## SYMPTOMS

### Asthenopia

12. Symptoms of asthenopia include redness, dryness, discomfort, a feeling of heaviness in the eyes and inability to use the eyes for more than a short period of time. In some cases there may be ocular pain or headaches. The symptoms may indicate decreased accommodation, ametropia or heterophoria, sometimes with reduced fusional amplitudes and are usually more pronounced while doing close work. Other conditions such as conjunctivitis and anterior uveitis may cause similar symptoms.

*Patients with asthenopia require full ocular examination including refraction, measurement of accommodation and evaluation of ocular alignment and binocular status.*

### Diplopia

13. Double vision (diplopia) means that a single object is seen in two different locations.

*Diplopia, even if intermittent, it is generally incompatible with safe flying. Single vision in gaze straight ahead, down and to the sides is required for safety. Some individuals who have diplopia only in the extremes of up-gaze to the sides may be acceptable for flying duty. Monocular diplopia from any cause is disqualifying.*

### Shift in location

14. Persons with alternating strabismus may note a shift in the apparent position of objects when they alternate fixation and be disturbed by this.. This seems more likely to cause problems in large angle strabismus.

*Location shift is incompatible with safe flying. Alternating strabismic patients who always fixate with the same eye for distance and the other eye for near will not experience shift in location and may be fit for flight. Changes in refraction may result in an unstable fixation pattern incompatible with safe flying.*

### Binocular vision

15. The evaluation of binocular vision can be considered under *screening* tests and detailed *assessment*.

### Screening

16. The applicant who is asymptomatic and has no past history of strabismus treatment with patching, orthoptics or surgery should be evaluated with regard to visual acuity, refraction, ocular motility and general health of the eyes. Ocular alignment should be tested with cover testing using the appropriate spectacle correction or contact lens correction. Sensory testing with the Worth four-dot test, measurement of stereopsis and measurement of fusional amplitudes are useful in evaluation of the binocular status.

### Assessment

17. *Applicants who do not normally pass the screening tests mentioned ought to be examined by an eye specialist. Based on a full sensory and motor evaluation of the applicant, the specialist may be able to estimate the risk of diplopia or shift in location.*

*Symptoms of diplopia or location shift or a high risk of these would disqualify the applicant for class 1 and 2 certificates. Moderate risk of these symptoms may be acceptable for class 2 certificate. Minor risk of these symptoms may be acceptable for class 1 certification.*

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## Part III

### Chapter 12. OTORHINOLARYNGOLOGY

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## INTRODUCTION

This chapter is devoted to the principles of assessment of the otorhinolaryngological system in relation to aviation duties. The medical examiner should be familiar with the demands likely to be imposed upon hearing, equilibrium and speech during flight and other aviation duties.

This guidance material does not have any regulatory status and its main purpose is to aid in the implementation of Annex 1 provisions. It contains methods for comprehensive assessment of applicants in whom there is a suspicion or overt manifestation of ear, nose and throat pathology. It further serves as a guide in the assessment of normal, presumably healthy, applicants for aviation personnel licences. The examiner must make certain that the functions of hearing, equilibrium and speech required for the safe performance of aviation duties can be reliably carried out by the applicant.

The aim is also eventually to achieve international uniformity of procedures and comparable results in the assessment of borderline certification cases.

The ENT requirements in Annex 1 are as follows:

6.3.2.25 The applicant shall not possess any abnormality or disease of the ear or related structures which is likely to interfere with the safe exercise of the applicant's licence and rating privileges.

6.3.2.26 There shall be:

- a) no disturbance of vestibular function;
- b) no significant dysfunction of the Eustachian tubes; and
- c) no unhealed perforation of the tympanic membranes.

6.3.2.26.1 A single dry perforation of the tympanic membrane need not render the applicant unfit.

6.3.2.27 There shall be:

- a) no nasal obstruction; and
- b) no malformation nor any disease of the buccal cavity or upper respiratory tract which is likely to interfere with the safe exercise of the applicant's licence and rating privileges.

6.3.2.28 Applicants with stuttering or other speech defects sufficiently severe to cause impairment of speech communication shall be assessed as unfit.

In addition, Annex 1 contains provisions related to hearing test requirements, which are described later in this chapter.

## THE EXTERNAL EAR

Usually a disease of the external ear and canal, such as otitis externa or furuncles, may temporarily but will not permanently disqualify an individual from flying. When the examiner is unable to visualize the tympanic membrane and where the hearing is markedly impaired due to obstruction, an applicant should obtain proper treatment and present himself later for completion of the examination.

## THE TYMPANIC MEMBRANE

The topography of the tympanic membrane should be well recognized. The tympanic membrane is slightly cone-shaped, like the diaphragm of a loudspeaker. It is also slightly inclined so that the upper part is more external or closer to the examiner's eye than the lower part. Both the concavity of the tympanic membrane and its position relative to the auditory canal normally vary somewhat and may be greatly altered in disease.

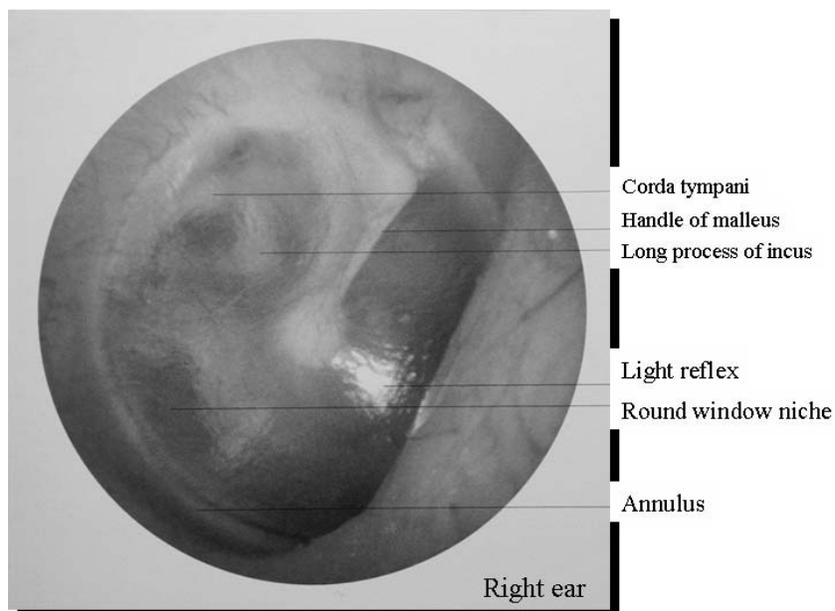


Fig. 12-1: Normal tympanic membrane

The colour of the normal tympanic membrane is usually pearly grey. Embedded in the tympanic membrane are the long and short processes of the malleus. The short process stands out like a tiny knob at the upper end of the long process (or handle). The malleus is the key structure in dividing the tympanic membrane into its four quadrants. A line drawn down through the malleus gives the anterior and posterior halves. A line drawn perpendicular to the malleus at the level of the umbo (lower end of the malleus) gives four quadrants: anterior superior, anterior inferior, posterior superior and posterior inferior. These are important reference areas in reporting abnormal findings.

If the light reflex (cone of light) points to the chin, one can assume that the tympanic membrane is in a normal position. Any retraction of the tympanic membrane will displace the cone of light inferiorly. Position-wise this would be from 4 o'clock to 6 o'clock (right ear). Findings should be recorded in reference to the clock dial, and by quadrants (see Figure 12-2).

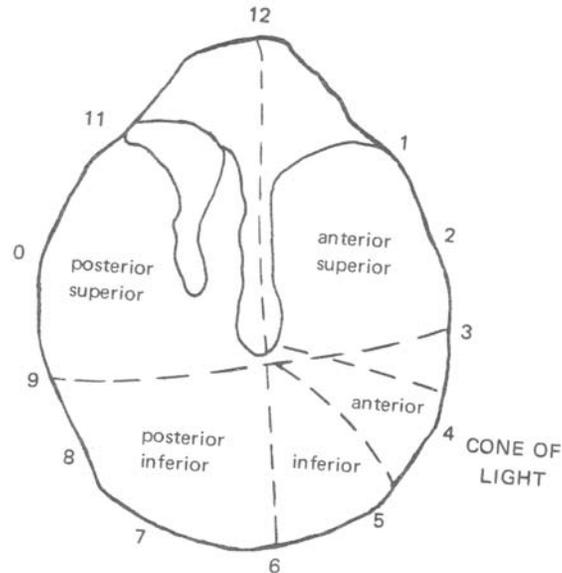


Fig.12-2: Right tympanic membrane – quadrants and clock numbers

Injuries of the tympanic membrane may result from suppurative disease, from direct trauma such as careless instrumentation, or indirect injury such as from a slap on the ear or from aerotitis. The evidence of injury may vary from slight hyperaemia to a ragged perforation of the tympanic membrane.

When examining the ears, the medical examiner should note perforations and healed perforations. Perforations usually heal but the healed area is thinner, more transparent and also more flaccid when alternating positive and negative pressures are produced, as with a pneumatic otoscope. Any perforations should be described as small or large, marginal or central, and its location given by quadrant or as numbers on the clock. The type of discharge should be described, e.g. thin, odourless, mucoid or thick, purulent with a foetid odour. Atrophic parts of the tympanic membrane are of special concern as they may rupture when exposed to even a small increase in differential pressure. A sudden perforation during descent may cause alternobaric vertigo and lead to acute incapacitation. Because of their fragility, atrophic areas should be treated aeromedically as if they were true perforations. Grey white masses of debris may be a sign of cholesteatoma which also can lead to acute incapacitation with vertigo and/or hearing loss. Granulation tissue in the general area of the tympanic membrane usually indicates protrusion of the tissue from the middle ear through a small perforation in the tympanic membrane. This will often be found in the upper part of the tympanic membrane: pars flaccida or Shrapnell's membrane<sup>1</sup>. An applicant should not be declared fit until all of these conditions have been fully examined and evaluated.

## THE MIDDLE EAR

Many conditions and diseases of the middle ear reflect their presence by alterations in the colour, position, or integrity of the tympanic membrane.

Aerotitis media (otitic barotrauma, barotitis) is an acute or chronic pathological condition caused by the pressure difference between the ambient air and that of the middle ear. It is characterized by fullness, deafness, pain, tinnitus and sometimes vertigo. It is the most common otitic disorder among flying personnel today. The

<sup>1</sup> After Henry J. Shrapnell, English anatomist (1761-1841)

otoscopic findings of the aerotitis media can be classified into 5 or 6 levels according to Teed<sup>2</sup>. In the 6-level Teed classification grade 0 is a condition with subjective symptoms but no otological signs, grade 1 diffuse redness and retraction of the tympanic membrane, grade 2 slight haemorrhage and retraction of the tympanic membrane, grade 3 gross haemorrhage and retraction of the membrane, grade 4 free blood or fluid in the middle ear, and grade 5 perforation of the tympanic membrane. In the 5-level classification grade 2 and 3 has merged. An exact description of the findings is of importance when determining the prognosis. Also other findings should be taken into account (pain, hearing loss, vertigo). Signs and symptoms of aerotitis media are not compatible with active flying.

Because of fairly rapid changes in atmospheric pressure during flight, it is essential that there be a ready interchange of air between the middle ear and the environment, in order to maintain equal pressure on the inside and outside of the tympanic membrane. Under normal conditions this equilibrium is maintained through the Eustachian tube<sup>3</sup>. The pharyngeal end of the tube is slit-like in shape and acts as a one-way flutter valve. The lumen is closed except during the acts of swallowing, yawning, chewing, etc.

During ascent, the air in the middle ear expands. The Eustachian tube is forced open by excess pressure in the tympanic cavity, middle ear pressure equalizes and the tympanic membrane snaps or "clicks" into its normal position. During descent from altitude, when the atmospheric pressure increases, a totally different effect is produced. The collapsed pharyngeal end of the Eustachian tube then acts as a flutter valve preventing entry of air. The flight crew member must remember to swallow, yawn or perform Valsalva manoeuvres<sup>4</sup> while descending. While swallowing, the lips of the tubal opening are pulled apart and air rushes into the middle ear, equalizing pressure.

When an applicant is unable to equalize the pressure, if necessary by conscious effort during descent, there is a rapid onset of deafness, tinnitus and pain in the ear. In exceptional cases, severe vertigo may occur due to inner ear barotrauma. A rupture of the fenestral membrane at the round or oval window may take place. If the differential pressure reaches 200-500 mm Hg, the tympanic membrane might rupture. It should be noted that aerotitis media may occur at low altitudes, even in the pressurized cabins of modern jets. Relevant altitude pressure values are indicated in Table 12-1.

Altitude in metres	Altitude in feet	Pressure (mm Hg)
0	0	760
600	2 000	706
1 200	4 000	656
1 850	6 000	609
2 450	8 000	564
3 050	10 000	522
3 960	13 000	460

Table 12-1. Altitude-pressure relationship

In 85 per cent or more of the cases, failure to equalize the pressure (and the injury that follows) is all secondary to disease of the upper respiratory tract. Obstruction of the Eustachian tube, as by congestion of the mucous

<sup>2</sup> After R.W. Teed, American otologist (20<sup>th</sup> century)

<sup>3</sup> Eustachian tube: pharyngotympanic (auditory) tube or *tuba auditiva*. After Bartolommeo Eustachio, Italian anatomist (1524-1574).

<sup>4</sup> Valsalva manoeuvre: Forced expiratory effort with closed lips and nostrils. After Antonio Valsalva, Italian anatomist (1666-1723).

membranes when suffering from common cold, is followed by absorption of the air in the middle ear. The symptoms are stuffiness in the ear, loss of hearing (conductive type) and sometimes pain. If not treated at this stage, transudation of fluid into the middle ear follows - acute serous otitis media. The entire tympanic membrane may be amber coloured, or the lower half may be amber coloured and the upper half normal in appearance due to the presence of the transudate in the middle ear. Often a fine black line will be seen across the tympanic membrane - the meniscus of a fluid level. Sometimes air bubbles can be seen through the tympanic membrane.

Many cases of serous otitis media recover spontaneously or after inflation of the Eustachian tube. If the condition is neglected and the fluid remains in the middle ear for weeks or months, it may thicken and organize to cause permanent hearing loss. These cases should be referred to ear, nose and throat (ENT) specialists for evaluation and treatment. If infection follows, the middle ear cavity may fill with pus - acute or chronic suppurative otitis media. If untreated, the tympanic membrane commonly ruptures and pus drains into the external canal. Suppurative otitis media must still be considered a form of abscess and surgical drainage (myringotomy) may be indicated, especially when one considers the aspects of future hearing. Once drainage is established, resolution may proceed rapidly.

<b>Aerotitis media</b>	<b>Otitis media</b>	<b>External otitis</b>
Due to barometric pressure changes	Inflammatory	Inflammatory
Retraction of tympanic membrane	Bulging of tympanic membrane	View of tympanic membrane may be obstructed
Tympanic membrane landmarks accentuated	Tympanic membrane landmarks obliterated	
Rupture of vessels	Diffuse erythema	
No thickening of tympanic membrane	Thickening of tympanic membrane	May be thickening of tympanic membrane if visible
Usually no fever	Fever usually present	May be fever
White blood cell count normal	White blood cell count elevated	White blood cell count elevated
Serosanguineous fluid in middle ear	Serous or seropurulent fluid in middle ear	No fluid in middle ear
Hearing normal or slightly reduced	Deafness profound	Hearing normal if canal not obstructed
No pain on pressure over tragus and movement of auricle	No pain on pressure over tragus and movement of auricle	Pain on pressure over tragus and movement of auricle
No swelling of canal	Slight if any swelling of canal	Swelling of canal

Table 12-2. Differential diagnosis of aerotitis media, otitis media, and external otitis

Chemotherapeutic agents and broad-spectrum antibiotics often prove effective in treating diseases of the middle ear. Serious complications such as mastoiditis, sinus thrombosis and brain abscess are now rarely seen. However, the incidence of deafness has not decreased since the advent of antibiotics. Antibiotics may not resolve these infections completely and a "smouldering" otitis may persist for weeks, with the only symptoms being stuffiness in the ear and deafness.

Before an applicant for flight training is selected, it is essential that the function of the Eustachian tubes be examined by clinical means, such as the Valsalva manoeuvre. Applicants with chronic inflammatory diseases of the nose or paranasal sinuses should be carefully screened. Any chronic suppurative disease of the middle ear should be carefully evaluated. A slow but progressive erosion of the bony labyrinthine capsule resulting from an expanding cholesteatoma - the so-called fistula-symptom - should be excluded. An applicant may be assessed as fit following an acute process once it has completely subsided and the examination reveals no signs of the disease. Table 12-2 presents a differential diagnosis for aerotitis media, otitis media and external otitis.

## POST-SURGICAL ASSESSMENT

Ear surgery may affect fitness for aviation duties. After an uncomplicated simple myringotomy and simple mastoidectomy, if the applicant is free of vertigo and his hearing is in accordance with Annex 1 requirements, there should be no restrictions. A post-operative radical mastoidectomy should be carefully assessed as it causes severe monaural hearing loss and carries a risk of subsequent infection, vertigo and intracranial complications. The examiner should refer the applicant for a complete otological consultation before a final assessment is made.

Otosclerosis is one of several causes of conductive hearing loss in adults. The medical examiner will face the problem as to whether an applicant who has had ear surgery for otosclerosis may be assessed as fit. The physical examination may show no evidence of previous ear surgery. A careful history and possible otological examination should be in order before an assessment is made. After about 1960, nearly all surgery for otosclerosis has consisted of a procedure referred to as stapedectomy. The stapes is removed and a prosthesis is placed, re-establishing a connexion between the incus and the open oval window. The prosthesis most often used is a stainless steel wire with one end attached to the incus and the other end extending into the oval window. It has a gel foam or fat pad attached and fits into the oval window. In selected cases the percentage of success is high. More recently, stapedectomy has been superseded by a “small fenestra technique.” This is a stapedotomy where a small hole is drilled or made with a laser, and a small piston prosthesis is attached to the long process of the incus. A “close-window-technique” is common, involving a sealing of the shaped fistula using vein or fascia graft to avoid lateral displacement at an accidental opening during a sudden decompression which might induce incapacitating vertigo.

*Applicants should not fly for a period of one to three months following stapes surgery to allow complete healing to take place. Thereafter, a specialized ENT assessment should be made to ascertain Eustachian tube patency and the absence of vertigo, past pointing, nystagmus or unsteadiness during the Valsalva manoeuvre and while blowing the nose forcibly.*

*An applicant who, after this three-month period, has not had vertigo and has post-operative acceptable hearing may be allowed to fly only under operational restrictions such as flying with or as a co-pilot only or with a safety pilot for a two-year observation period. The final decision to remove these restrictions should then be considered..*

It is essential that such a pilot be told of the potential hazards of upper respiratory tract infections or other conditions which may interfere with ventilation of the middle ear.

A surgical reconstruction referred to as tympanoplasty has been known since 1956. The aims are twofold - firstly to improve hearing and secondly to close small or large perforations of the tympanic membrane and rebuild the middle ear structures. Once again a careful history must be obtained.

*If the hearing is within Annex 1 provisions, there is no vertigo, and the new tympanic membrane is intact and*

*free of disease, there should be no restrictions on the applicant's ability to fly.*

## HEARING ASSESSMENT

Most applicants have fairly good or serviceable hearing. There are, however, borderline cases, and there are changes in the hearing of applicants with time. Consequently, hearing must be re-examined at specified intervals. The hearing test requirements and the hearing requirements are detailed in Annex 1 as follows:

### 6.2.5 Hearing test requirements

6.2.5.1 Contracting States shall use such methods of examination as will guarantee reliable testing of hearing.

6.2.5.2 Applicants shall be required to demonstrate a hearing performance sufficient for the safe exercise of their licence and rating privileges.

6.2.5.3 Applicants for Class 1 Medical Assessments shall be tested by pure-tone audiometry at first issue of the Assessment, not less than once every five years up to the age of 40 years, and thereafter not less than once every two years.

6.2.5.3.1 Alternatively, other methods providing equivalent results may be used.

6.2.5.4 Applicants for Class 3 Medical Assessments shall be tested by pure-tone audiometry at first issue of the Assessment, not less than once every four years up to the age of 40 years, and thereafter not less than once every two years.

6.2.5.4.1 Alternatively, other methods providing equivalent results may be used.

6.2.5.5 **Recommendation.**— *Applicants for Class 2 Medical Assessment should be tested by pure-tone audiometry at first issue of the Assessment and, after the age of 50 years, not less than once every two years.*

6.2.5.6 At medical examinations, other than those mentioned in 6.2.5.3, 6.2.5.4 and 6.2.5.5, where audiometry is not performed, applicants shall be tested in a quiet room by whispered and spoken voice tests.

*Note 1.— The reference zero for calibration of pure-tone audiometers is that of the pertinent Standards of the current edition of the Audiometric Test Methods, published by the International Organization for Standardization (ISO).*

*Note 2.— For the purpose of testing hearing in accordance with the requirements, a quiet room is a room in which the intensity of the background noise is less than 35 dB(A).*

*Note 3.— For the purpose of testing hearing in accordance with the requirements, the sound level of an average conversational voice at 1 m from the point of output (lower lip of the speaker) is c. 60 dB(A) and that of a whispered voice c. 45dB(A). At 2 m from the speaker, the sound level is 6 dB(A) lower.*

*Note 4.— Guidance on assessment of applicants who use hearing aids is contained in the Manual of Civil Aviation Medicine (Doc 8984).*

*Note 5.— Attention is called to 2.7.1.3.1 on requirements for the issue of instrument rating to applicants who hold a private pilot licence.*

#### Class 1 Medical Assessment:

##### 6.3.4 Hearing requirements

6.3.4.1 The applicant, when tested on a pure-tone audiometer, shall not have a hearing loss, in either ear separately, of more than 35 dB at any of the frequencies 500, 1 000 or 2 000 Hz, or more than 50 dB at 3 000 Hz.

6.3.4.1.1 An applicant with a hearing loss greater than the above may be declared fit provided that the applicant has normal hearing performance against a background noise that reproduces or simulates the masking properties of flight deck noise upon speech and beacon signals.

*Note 1.— It is important that the background noise be representative of the noise in the cockpit of the type of aircraft for which the applicant's licence and ratings are valid.*

*Note 2.— In the speech material for discrimination testing, both aviation-relevant phrases and phonetically balanced words are normally used.*

6.3.4.1.2 Alternatively, a practical hearing test conducted in flight in the cockpit of an aircraft of the type for which the applicant's licence and ratings are valid may be used.

#### Class 2 Medical Assessment:

##### 6.4.4 Hearing requirements

*Note.— Attention is called to 2.7.1.3.1 on requirements for the issue of instrument rating to applicants who hold a private pilot licence.*

6.4.4.1 Applicants who are unable to hear an average conversational voice in a quiet room, using both ears, at a distance of 2 m from the examiner and with the back turned to the examiner, shall be assessed as unfit.

6.4.4.2 When tested by pure-tone audiometry, an applicant with a hearing loss, in either ear separately, of more than 35 dB at any of the frequencies 500, 1 000 or 2 000 Hz, or more than 50 dB at 3 000 Hz, shall be assessed as unfit.

6.4.4.3 **Recommendation.**— *An applicant who does not meet the requirements in 6.4.4.1 or 6.4.4.2 should undergo further testing in accordance with 6.3.4.1.1.*

#### Class 3 Medical Assessment:

##### 6.5.4 Hearing requirements

6.5.4.1 The applicant, when tested on a pure-tone audiometer, shall not have a hearing loss, in either ear separately, of more than 35 dB at any of the frequencies 500, 1 000 or 2 000 Hz, or more than 50 dB at 3 000 Hz.

6.5.4.1.1 An applicant with a hearing loss greater than the above may be declared fit provided that the applicant has normal hearing performance against a background

noise that reproduces or simulates that experienced in a typical air traffic control working environment.

*Note 1.— The frequency composition of the background noise is defined only to the extent that the frequency range 600 to 4 800 Hz (speech frequency range) is adequately represented.*

*Note 2.— In the speech material for discrimination testing, both aviation-relevant phrases and phonetically balanced words are normally used.*

- 6.5.4.1.2 Alternatively, a practical hearing test conducted in an air traffic control environment representative of the one for which the applicant's licence and ratings are valid may be used.

Before discussing hearing to any extent, it is necessary to have a basic knowledge of sound. The frequency of a sound wave determines pitch and is expressed in cycles per second or hertz (Hz). The wave form of a pure tone is sinusoidal. The amplitude of the sine wave determines its intensity.

The weakest sound pressure,  $p$ , detected by an average young person with undamaged hearing in quiet conditions, the sound perception threshold, is generally reported as the sound pressure level (SPL) of 20  $\mu$ Pa (micropascals) =  $2 \times 10^{-5}$  Pascal (Pa) at 1000Hz. When considering different sound (noise) levels and their effect on human hearing, it is more convenient to use a relative unit for sound (noise) intensity measurements, namely the decibel (dB), which is defined as 20 times the common logarithm of the ratio between two sound pressure levels:

$$20 \log (p_2/p_1) \text{ dB}$$

## ANATOMY AND PHYSIOLOGY

Hearing involves the transmission of sound to the inner ear, the change of the sound wave to a neural impulse, its transmission to the brain and perception of the impulse by the brain. Every individual has a hearing threshold in each frequency audible to him. This varies considerably among individuals and changes in the same individual with age.

In man, the auricle does little to increase the sensitivity of hearing. Its occasional absence in congenital or traumatic conditions is not associated with an appreciable loss of hearing. Occlusion of the external auditory meatus affects hearing seriously. Hard impacted cerumen (earwax) is a good example.

When the good ear is turned toward the sound source, monaural hearing is only slightly less acute than binaural hearing. But, if the head is turned in the opposite direction, hearing may be reduced by as much as 20 dB in some frequencies. A more serious handicap of unilateral deafness is the patient's difficulty in localizing a sound source.

If the auditory canal of an applicant with normal hearing is occluded tightly by the examiner's finger, the resultant hearing loss in that ear is generally no greater than 40 dB. This loss still permits the applicant to hear a low or slightly raised voice. A common mistake in testing hearing is to assume that one ear is adequately masked by the finger when actually it is not. The applicant then receives credit for better hearing than is present.

Perforations of the tympanic membrane exert a variable effect on hearing depending upon their size and location and whether or not there are associated changes in the middle ear. An intact tympanic membrane is

not absolutely essential for normal hearing. Any interference with the ossicular chain, however, is very likely to result in some hearing loss.

Uncomplicated tympanic perforations reduce hearing by about 10-15 dB. Some people with almost complete loss of the tympanic membrane can still understand a loud whisper.

Hearing is divided into two separate functions: sound conduction in the external ear, the tympanic membrane and the ossicles, and sound perception in the cochlea, the auditory nerve, its nuclei and the complex cerebral connexions of the auditory pathway. Any condition causing interference with the conductive mechanism would result in a conduction deafness. Similarly, a lesion of the perceptive mechanism would result in a perceptive (often referred to as sensorineural) deafness. Lesions in both the conductive and perceptive systems result in a mixed type of deafness. In conductive deafness, the hearing loss is more marked in the lower tones but speech discrimination may be normal. In the sensorineural type of deafness, various types of hearing loss may occur, some with reduced speech discrimination.

## NOISE

Noise may be defined as unwanted sound. An exposure to high noise intensity will cause harmful effects, e.g. hearing loss or even the rupture of the tympanic membrane. The effects will depend basically on noise intensity level, its quality (frequency spectrum), and exposure time. For aviation personnel particularly, two considerations need to be examined: the risk of temporary or permanent hearing damage, and interference with speech communications. Temporary hearing loss may occur through exposure to noise above 80 dB. High-frequency sounds produce greater impairment than low-frequency sounds, thus the noise spectrum needs to be considered before deafening effects can be determined.

Noise-induced hearing loss of the sensorineural type occurs first as a temporary threshold shift (TTS) as measured audiometrically. This is considered due to fatigue of cochlear cells. Noise-induced temporary threshold shifts can become permanent. The medical examiner should be concerned with temporary and permanent threshold shift in aviation personnel. The TTS duration and magnitude depends on noise intensity and exposure time. With intermittent exposure, TTS is reduced. It is normally not produced below 78 dB. After two hours' exposure, resulting in a TTS of 50 dB, recovery will be complete after about sixteen hours. Complete recovery of a 60 dB shift will take several days and tends to be slowest in the 4 000 Hz range. TTS is a criterion for the determination of permanent noise damage risks. The possibility of its effect upon audiograms should be kept in mind when studying audiograms of applicants who have been examined without a sufficient time lapse after being exposed to aircraft noise.

The interference by noise on speech and communications is basically a masking process. Background noise increases the hearing threshold. The extent to which the hearing threshold is increased is called speech interference level, expressed in decibels. It is the average of the sound pressure levels in dB, in the octave bands 600-1 200, 1 200-2 400 and 2 400-4 800 Hz and indicates the degree of interference with the ability of people to communicate and to understand speech. Intermittent noise often causes less interference as interpolation may compensate for gaps in what is actually heard in partly masked speech. An accurate and comprehensive method for expressing speech intelligibility in noise is the articulation index, which is described in the section dealing with speech audiometry. Maximum speech interference levels have been laid down for predicting to what degree understanding of speech and communications is possible under noise conditions.

Aircraft noise originates principally from propellers (for piston and turbo-prop aircraft), the engines and exhaust (with different characteristics for jet, turbo-fan, turbo-prop and piston engines), and aerodynamic flow or slipstream (speed, take-off, landing). The intensity of sound (noise) decreases proportionally to the

square of the distance.

The noise background for speech and communications is primarily the flight-deck noise. Communication equipment might be an additional noise source, although static and radio beams, which used to be disturbing for flight crews in the earlier days of air transport, have now practically disappeared with improved equipment. Flight-deck noise intensities for a number of aircraft are given in Table 12-3 and its dependence on speed will be noted.

Centre-cockpit SIL, in dB

Aircraft	Cruise	High-speed descent
DC-6	78	85
F-27J	78	78
B-707	80	82
B-720	74	74
B-727	78	82
DC-9	74	74
DC-10-30	67	
MD-80	68	
B-747-300	70	
B-737-500	72	
B-737-600/800	77	
A-320	74	
B-737-436	74	76
B-757-236	71	73
B-767-336	70	72
BAe ATP (advanced turboprop)	72	74
Concorde	74	78

Table 12-3. Cockpit noise levels of representative older and current airline aircraft in terms of speech interference levels (SIL)

## PERSONAL EAR PROTECTION

Without control and protection, the hearing mechanism can become impaired permanently and/or speech communication affected adversely. In many instances, use of ear protectors is the most practical means of shielding man from these noise effects. The main function of an ear protector is to reduce the sound pressure level of the noise reaching the sense organ by serving as an acoustical barrier between the source of the noise and the inner ear.

### Ear protectors

There are two basic types of ear protectors - the insert type and the muff type. The efficiency of a protector is usually expressed in terms of the amount of noise reduction provided through 300 to 3 000 Hz, a frequency range critical for the hearing of speech. Generally ear protectors are more effective for the higher frequencies of this range.

The insert-type protector reduces the noise level reaching the inner ear by plugging the external ear canal. It

may be made of rubber, neoprene, plastic, silastic or cotton impregnated with wax. The effect of commercially available plugs of differing materials and shapes varies little, except for user acceptance. New features are being introduced regularly. Polyethylene tubes through the longitudinal dimension of the ear plug have been used. Slit valves and other modifications are being tried for pressure equalization between the ambient air and the parcel of air contained between the ear plug and the tympanic membrane. The best ear inserts are those which are flexible enough to conform to the variations in the shape of the ear canal. However, these ear inserts can be dislodged by jaw movements which occur in talking, chewing or yawning and require readjustment to assure an air-tight seal. If the ventilation channel is blocked by for instance earwax, significant pressure-induced ear pain can occur, especially if the pressure change occurs fast. Therefore, it is very important that the ventilation channel in insert-type ear protectors is checked by the pilot before every flight and that the pilot's ear canal is frequently inspected for cerumen and skin irritation (external otitis).

The ear-muff type reduces the noise level by enclosing the auricle of the ear, providing an acoustical seal against the head. This may be prefabricated or custom fitted from such materials as rubber or soft plastic. The external ear is covered completely. The muffs, mounted on an adjustable headband or on a protective helmet, consist of rigid cups with cushions of soft sealing material placed around their rims. There are those who feel that muffs usually provide more protection (attenuation) than insert devices. The average attenuation for muffs is 35 dB. Although the ear muffs are generally easier to fit, care must be taken to ensure that a seal is made between the side of the head and the muff cushion. Modifying the muff for reasons such as for wires to ear phones, a pressure relief, or for ventilation, impairs its efficiency to reduce sound. Efficiency can be reduced also when wearing glasses which create a leak where the stems of the glasses pass under the ear cushion. This can be rectified by wrapping a piece of foam rubber around the stems where they go under the muff.

The simultaneous use of an ear insert and a muff offers more reduction of noise than either one alone and provides the potential for the maximum reduction of sound transmitted through the external ear before sound transmission by bone takes place. The perfect protector cannot provide more than about 55 dB of noise reduction, for above this level sound begins to reach the inner ear through the vibration of the bones of the skull. Whatever the type of ear protector, insert or muff, its effectiveness depends on its ability to obtain and maintain an air-tight seal, and accompanying directions should be followed to assure a proper fit and acoustic seal.

In recent years Active Noise Reduction (ANR) has become widespread. The mechanism is, in short, that noise is removed by emission of a sound wave of the exact same frequency as that of the incoming sound wave but in the opposite phase, thus eliminating the noise. The technique is limited to lower frequencies (up to 1200 Hz), it is therefore important to use additional passive noise protection.

Generally, ear protectors have no adverse effects on understanding speech in noise, provided the voice is raised above background noise level, either in face-to-face communication, loudspeaker communication or communication under a headset (insert protectors used with communication earphones or earphones incorporated into ear muffs). Problems in speech communication depend on the type and the amount of noise, the type of ear protector, and the hearing status of the individual.

Ear protectors may cause medical problems in various ways. The materials from which the ear protectors are made may cause allergic or toxic reactions. Cases of external otitis are rare when the material is inert, such as neoprene, polyvinyl plastic or rubber. Stiff ear inserts may cause injuries if a blow on the ear causes the insert to penetrate more deeply. Inserts with too tight a fit may contribute to barotrauma. Pressure-reducing ear inserts are ineffective and should be avoided. Insertion of ear plugs may result in impacted cerumen in the ear canal. Failure to keep ear protectors clean can result in disease. Ear protectors should not be worn when there is existing external otitis or skin infection.

## HEARING TESTS AND FUNCTIONAL EXAMINATIONS

The examiner is actually testing the hearing throughout the examination. Questions should be asked in a low voice and instructions given while the examinee has his back turned to the examiner. A few specific questions whispered in alternate ears will give excellent leads as to the hearing ability.

The purpose of the hearing tests is to determine as nearly as possible the degree and type of any hearing loss and functional impairment and to ascertain whether hearing function is satisfactory for the safe performance of aviation duties as required in Annex 1. Hearing tests are useful for the diagnosis of certain diseases of the ear and to separate disturbances of sound conduction from those of sound perception.

Hearing tests commonly employed include the use of whispered and spoken voice and tuning forks. These methods yield much knowledge for the assessment of hearing if they are employed intelligently. However, the results obtained are likely to be more qualitative than quantitative when assessed by inexperienced examiners. Quantitative determinations are made with the electrically calibrated audiometer, which produces sound of known intensity - either pure tone signals (at various frequencies) or actual speech (recorded or "live").

### Whispered and spoken voice tests

The examiner who uses his voice to test an applicant's hearing must know how well his own voice is heard at different distances and how to vary the intensity of his own voice so that each applicant is tested under similar conditions. One can begin testing with a very low whisper, the lips about half a metre from the applicant's ear and directed toward the ear. The examiner exhales and then whispers. In a quiet room an applicant with normal hearing can repeat what is said to him. If he cannot understand a low whisper, the examiner uses a medium whisper and finally a loud whisper. The examiner gradually increases the intensity of his voice until the applicant responds correctly.

Hearing requirements for the issue and renewal of flight crew and air traffic controller licences in international civil aviation are contained in Annex 1, Chapter 6, 6.3.4 - Hearing requirements (for Class 1 Medical Assessment), 6.4.4 (for Class 2 Medical Assessment) and 6.5.4 (for Class 3 Medical Assessment). For Class 2 Medical Assessment, it is stated, *inter alia*, that the applicant must have the ability "to hear an average conversational voice in a quiet room, using both ears, at a distance of 2 metres (6 feet) from the examiner, with the back turned to the examiner."

Care must be taken in the choice of word material used to test hearing. Questions which can be answered by "yes" or "no" should be avoided. It is better to have the applicant repeat familiar bisyllabic words (known as "spondee<sup>5</sup> words") such as snowball, cowboy and mousetrap or to ask a question such as "How many singers constitute a quartet?" It is important to be certain that the applicant cannot read the examiner's lips.

Applicants with sensorineural hearing loss may hear a spoken voice much better than a whisper, even a loud one. The reason is they tend to have a greater loss in high than in low frequencies and the whisper contains more high frequencies than does the spoken voice.

### Tuning fork tests

Tuning fork tests for hearing remain an important part of the hearing examination. The most useful tuning fork for testing hearing is the 512 Hz fork. The examiner should understand and be able to do a Weber<sup>6</sup> and a

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<sup>5</sup> Spondee: having two long syllables ( — — )

<sup>6</sup> After Friedrich Eugen Weber, German otologist (1832–1891)

Rinne<sup>7</sup> test (*vide infra*). The 512 fork is selected because it is not felt as a vibration and higher frequencies are heard by air conduction.

A tuning fork should be stroked between the thumb and index finger, gently tapped on the knuckle, or carefully activated with a rubber reflex hammer. Striking the fork too hard produces overtones as well as too intense a sound. When tuning forks are used for testing, masking may be necessary. A simple improvised mask is a sheet of glazed paper rubbed rapidly over the ear to be masked. Forks are particularly useful in the differentiation between conductive and sensorineural hearing losses.

### **The Weber test**

The 512 Hz fork is used most frequently. A vibrating tuning fork is placed on the mid-line of the forehead. The incisor teeth can also be used. The examiner asks the patient whether the sound is heard more distinctly in the right or left ear (lateralization). If a conductive deafness is present, the tone will be heard more distinctly in the deafer ear. If one ear suffers from a sensorineural type of impairment, the tone will be heard by bone conduction in the normal ear and not in the nerve-deafened ear.

### **The Rinne test**

This test compares air and bone conduction and determines whether bone conduction is dominant, indicating a conductive-type deafness, or decreased, indicating a sensorineural-type deafness. The hilt of a 512 Hz vibrating tuning fork is first pressed against the mastoid bone behind the ear. When the applicant indicates that it is no longer audible by bone conduction (record the time in seconds) the fork is instantly removed and the vibrating tines held directly in front of the open ear canal. If it is still audible, wait until it is no longer heard, and then record the time. The normal ear hears a tuning fork about twice as long by air conduction as by bone conduction. If the fork is heard by air conduction after it has ceased to be audible by bone conduction, the test is said to indicate a Positive Rinne. If the fork is audible for a shorter period by air conduction than by bone conduction, the test result is termed a Negative Rinne. The results should be recorded in actual time heard - for instance, air conduction 62 seconds; bone conduction 30 seconds.

## **MALINGERING**

Young applicants rarely feign deafness. They are more likely to claim much better hearing than they actually have. Older air crew and individuals exposed to aircraft noise will at times claim hearing loss. They rarely claim bilateral loss. Usually they insist that they have total loss of hearing on one side. Several tests have been devised to help detect the malingerer. The outstanding findings are the inconsistencies. Cases of malingering and psychogenic deafness should be referred to the specialist.

### **The Lombard test<sup>8</sup>**

This test to detect malingering depends upon the reflexive increase in loudness of the voice of a speaker with normal hearing in the presence of loud background noise or masking sounds. The applicant is given easy reading material and requested to read out loud and to continue no matter what happens. A Barany noisemaker<sup>9</sup> is then placed next to the supposedly good ear of the applicant while he continues to read. A test

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<sup>7</sup> After Friedrich Heinrich Rinne, German otologist (1819-1868)

<sup>8</sup> After Etienne Lombard, French physician (1868-1920)

<sup>9</sup> Barany noisemaker: a noise-producing device like a small alarm clock with a button to be inserted into the ear canal of the patient. After Robert Bárány, Austrian-Hungarian otologist and Nobel laureate (1876-1936)

subject who is truly deaf in the other ear will automatically raise the intensity of his voice as he continues to read, but the malingerer will continue to read in an even or very slightly elevated tone.

The method of delayed speech auditory feedback is, however, better as it makes it impossible for a malingerer to speak without stuttering.

## AUDIOMETRY

Quantitative measurements of hearing are made using the pure-tone audiometer which produces pure tones that can be varied according to frequency and intensity. Plotting the intensity against the frequency provides an audiogram.

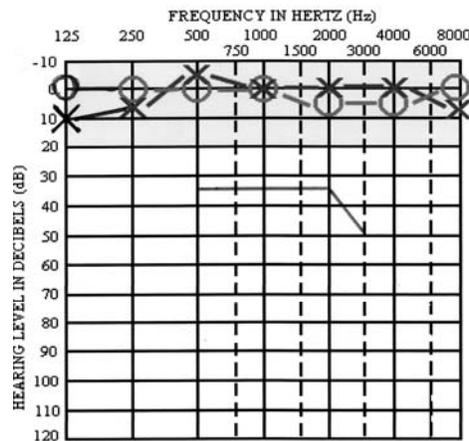


Fig. 12-3: Normal audiogram

□ = right ear; × = left ear; the green line indicates the ICAO hearing requirements

A number of frequencies in the range 125 Hz to 8 000 Hz are tested by presenting a tone loud enough for the applicant to hear distinctly, and then the threshold level for each frequency is determined. The examinee signals by finger signs or by pressing a button when a tone is heard and when it is no longer heard.

The zero (0) reference level of a clinical audiometer refers to that sound intensity which can just be detected by the average normal ear. Most audiometers show decibels in minus as well as plus values. When a person can hear a given frequency at -10 dB, he can hear that frequency better than average person. Similarly, when the threshold of an ear is no more than 15 dB above zero, the hearing is considered to be normal though not quite as good as average. A threshold of 30 dB at a given frequency means that this tone must be made 30 dB more intense than for the average normal person in order to be heard. This person is then said to have 30 dB hearing loss at the test frequency.

The young unimpaired human ear can detect sounds from 20 Hz to 20 000 Hz. The most important range for speech perception is between the frequencies of 500 and 3 000 Hz, and the hearing requirements of Annex 1 are confined to this range. It is, however, not sufficient to test for the 500 to 3000 Hz range only. For diagnostic reasons, testing is done above and below these frequencies to more thoroughly map the ability of the ear to perceive sound and to indicate minimal losses of which the examinee is unaware but which may be early symptoms of inner ear disease.

Hearing in the human ear is most acute at about 1 000 Hz. After finding the threshold for 1 000 Hz, the higher frequencies are tested in the same manner and in ascending order (2 000, 3 000, 4 000, 6 000 and 8 000 Hz). The 1 000 Hz frequency may then be re-checked, followed by the low frequencies in descending order (500,

250 and 125 Hz). Then the ear selector switch is turned to the opposite ear and the sequence is repeated.

## **Masking**

While one ear is being tested, the opposite ear must be masked to exclude it from the test. Failure to mask the good ear is a very common error which leads the examiner to believe that the signal is being perceived in the poor ear (which is under test). Masking is especially important in taking bone conduction measurements, and it should be used with both tuning fork and audiometer examinations. The greater the discrepancy in hearing between the ears, the greater the need for masking the better ear. Audiometers are equipped with a masking sound (a mixture of frequencies, sometimes called "white" noise). The intensity can be varied. Determining the proper amount of masking to use presents a serious problem. Although numerous systems of determining the proper level have been suggested, all require knowledge of how much the threshold for a particular pure tone will be shifted by a given amount of the masking tone. The following simple method can be used.

In air conduction testing, 50-60 dB of effective masking has been found to be sufficient to rule out the better ear without being loud enough to interfere with measurements on the poorer ear. Bone conduction testing is accomplished in the same manner as air conduction testing, except that the tone is delivered through the bone oscillator positioned behind the ear on the mastoid bone. Octave frequencies tested in this manner are 250 Hz to 4 000 Hz.

## **Audiogram**

The audiogram (Figure 12-2) is a graph having two dimensions, intensity along the ordinate and frequency along the abscissa. The intensity generally ranges from -20 to +100 dB, and the frequency ranges from 125 to 8 000 Hz.

Since the intensity (hearing loss) scale refers to average normal hearing, the (0) indicates no deviation from normal. Any positive (plus) number (normally plotted from the zero line downwards) indicates a degree of hearing loss - the farther down on the audiogram chart, the poorer the threshold and the greater the intensity required to reach it.

The applicant's threshold at each frequency is tested and plotted on the audiogram for each ear separately at the appropriate 5 dB steps, using different symbols for air and bone conduction. In addition, the threshold is drawn in red standard symbols (□) for the right ear and in blue symbols (×) for the left ear.

## **Calibration of audiometers**

The need for international standardization of audiometers has been generally recognized. An international standard was agreed upon in 1964. As stated in Note 1 to 6.2.5, the reference zero for calibration of pure tone audiometers can be found in the current edition of the Audiometric Test Methods, published by the International Organization for Standardization (ISO).

Audiometers must be tested at regular intervals and the calibration corrected as necessary by the manufacturer. When such checks create difficulties, the reliability of audiometric testing procedures can be verified on the basis of the mean hearing threshold for the various frequencies of at least 20 ears of healthy young persons with normal tympanic membranes and without past ear disease or known exposure to high noise intensity levels. Pure tone audiometry should be carried out in a quiet room in which the background noise intensity is less than 35 dB(A), i.e. measured on "slow" response of an "A"-weighted sound-level meter (Annex 1, 6.2.5, Note 2).

Hearing requirements for Class 1 and Class 3 Medical Assessments require an applicant tested on a pure-tone audiometer not to have "a hearing loss, in either ear separately, of more than 35 dB at any of the frequencies 500, 1 000 or 2 000 Hz, or more than 50 dB at 3 000 Hz".

### **Speech audiometry**

A speech audiometer is essentially the same instrument as the pure-tone audiometer. It produces the spoken voice rather than pure tones at controlled intensity levels. The spoken voice may be a "live voice" but is normally a recorded voice, preferably by a selected speaker (air traffic controller). Speech audiometry is basically a speech intelligibility test. The percentage of words correctly perceived, independently of the type of material used, gives the intelligibility rate (articulation score). This rate, even in normal persons, will depend considerably on the test word material used, predominantly spondee words (already discussed under whispered voice tests) and phonetically balanced words.

Annex 1, 6.3.4.1.1, Note 2, indicates that "in the speech material for discrimination testing, both aviation-relevant phrases and phonetically balanced words are normally used". Tests should aim at an assessment of strictly auditory functions and not depend on the ability to grasp the meaning of codes and sentences heard incompletely, as in unfamiliar situations dangerous misunderstandings from incorrect interpretation might occur. The following material is used in several States for testing speech intelligibility, listed in order of increasing difficulty:

Short sentences: lists of simple sentences, subject, object and verb corresponding closely to normal speech and R/T messages presented at various intensity levels. They might be supplemented by lists of two-digit numbers. With normal hearing 100 per cent of this material is correctly understood.

Spondee words such as "aircraft, baseball, iceberg". The threshold is determined for a discrimination of 50 per cent.

Phonetically balanced (P-B) words: these are familiar monosyllabic (sometimes bisyllabic) words such as "at, tree, by, ice" selected so as to approximate the distribution of sound in ordinary conversation. The maximum P-B score is established at the individually optimal intensity level. Lists of phonetically balanced words have been established for many languages.

Speech audiograms can be produced by varying the intensity levels at which the test material is presented (abscissae) and plotting them against the speech intelligibility in percentages (ordinates). Separate curves may be presented on the speech audiogram for spondees, P-B words, figures and short sentences as appropriate. Although there appears to be a satisfactory degree of equivalence for the intelligibility of P-B lists in various languages, better uniformity of testing procedures should be aimed at internationally, referring particularly to the application of background noise (see Tables 12-4 and 12-5).

An applicant with normal hearing will hear and correctly repeat 95-100 per cent of these words at individually suitable intensity levels. A discrimination score lower than 80 per cent should not be accepted. Those with sensorineural loss may fail to achieve a satisfactory score. No matter how loud P-B words are presented, the examinee with severe inner ear hearing loss fails to make an adequate score. In fact, if the intensity is increased beyond the range of his most comfortable loudness, his score may even become worse. This is poor discrimination ability.

In contrast, persons with conductive loss score high on this test. All that is required for them to hear well is amplification. Thus, they can use hearing aids very satisfactorily.

Certain frequencies are more important than others in the interpretation of speech. The most important frequencies are 500, 1 000, 2 000 and 3 000 Hz. Speech is essentially compressed into this range, which is sufficient for fairly complete understanding. In persons whose audiogram curves exhibit an abrupt drop, the average of the best two frequencies may give better correlation. Discrimination is usually bad when the drop affects speech frequencies. This is the person who will often remark, "I can hear you, but I can't understand you." These individuals have difficulty in group conversation or when listening against a background of noise.

### **EXAMINATION PROCEDURE FOR APPLICANTS WITH A POTENTIAL HEARING DISORDER**

The examination may be conducted in the following way:

- a) Any extraneous material in the auditory canals (cerumen, purulent material, debris), which may impede the passage of sound waves or prevent the tympanic membrane or middle ear from being seen, is removed.
- b) Whispered and conversational voice tests are carried out. A 512 Hz fork is used to do a Weber and a Rinne Test.
- c) An audiogram is taken, showing both air and bone conduction graphs for each ear and indicating what fraction (percentage) of the hearing range has been rendered inaudible.
- d) The examinee is asked to state the effect of noisy surroundings, his ability to understand telephone conversation, and in addition, his reaction (pain, distress) to loud noises. His statements are recorded.
- e) The tympanic membrane is carefully examined and its mobility observed with a Siegle-type otoscope<sup>10</sup> (pneumatic).
- f) In cases of conductive deafness, an attempt is made to introduce air into the middle ear (Valsalva manoeuvre, Politzer method<sup>11</sup>, Eustachian catheter). An observation (or history) of appreciable improvement in hearing (even though transient) following the introduction of air is recorded.

With the exception of the audiogram, all of the above information can be obtained in a few minutes, and designated medical examiners should possess the apparatus used in obtaining it. The use of an impedance meter for tympanometry and reflex measurements can be of great value.

#### **Speech-in-noise test**

If an applicant fails to meet the pure-tone audiometry hearing requirement, he may be declared fit if he has "normal hearing performance against a background noise that reproduces or simulates the masking properties of flight deck noise upon speech and beacon signals" (Annex 1, 6.3.4.1.1). In the assessment of applicants for air traffic control duties, 6.5.4.1.1 indicates that the applicant may be declared fit provided that he has "normal hearing performance against a background noise that reproduces or simulates that experienced in a typical air traffic control working environment."

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<sup>10</sup> Siegle otoscope: an otoscope with a bulb attachment by which the air pressure in the external auditory canal can varied. After Emil Siegle, German otologist (1833-1900).

<sup>11</sup> Politzer method: inflation of the Eustachian tube and tympanon by forcing air into the nasal cavity at the moment when the patient swallows. After Adam Politzer, German otologist (1835-1920).

The significance of speech-in-noise tests rests on the finding that aviation personnel with hearing loss, generally caused by exposure to aircraft noise during many years of service, may be able to understand communications under flight deck noise as well as those with normal hearing. This apparent improvement of hearing under noise is called recruitment. Flight safety under these conditions is not impaired as long as it is made certain in each case that intelligibility of speech and perception of signals under background noise, as well as hearing on the ground for briefing and check-list procedures is satisfactory (Annex 1, 6.3.4.1.1, Note 1). Such a test can be performed under different conditions for reproducing or simulating flight deck noise: white noise, tape recordings in flight, flight simulators or flight tests may be used. However, flight-deck noise levels and spectra differ between aircraft types (Table 12-3). A high noise level is not considered an essential factor as tests may also be carried out at lower noise levels (70-110 dB have been used, taking into account conditions prevailing in some aircraft, including take-off and landing).

The speech-in-noise test is further a screening procedure aimed at ensuring that applicants can reliably perceive radio communications and acoustic signals (beacons, warning signals); they must also hear aerodynamic flow (speed, approaching stall), engine performance and sounds associated with aircraft systems and instruments. Voice communications between crew members in the cockpit including instructions and routine check-list operations must be clearly understood, also during approach, landing and emergency operations.

The distances between pilots in the average airline flight deck varies from 0.6 to 1.2 m (2 to 4 ft), while the pilot-to-flight engineer distance is 0.6 to 1.8 m (2 to 6 ft).

Instrument landing system (ILS) modulation frequencies are: inner marker 3 000 Hz, middle marker 1 300 Hz, outer marker 400 Hz (Annex 10, Vol. I, 3.1.6.4). NDB (non-directional beacon) modulating tone for identification is 1 020 Hz  $\pm$  50 Hz or 400 Hz  $\pm$  25 Hz.

The characteristics and intensity of flight-deck noise largely depend on the various types of aircraft and their engines (piston, turbo-prop, turbo-jet, turbo-fan) but also considerably on aerodynamic noise and the speed of the aircraft. The basic problem is the effect of flight-deck noise upon speech perception, i.e. speech interference levels. It is complicated by acoustically significant differences in the use of earphones or overhead speakers for listening to R/T signals. Earphones are often not designed for hearing protection, thus little sound attenuation is provided. Whether earphones or loudspeakers are used on the flight deck, the signal-to-ambient noise ratio can be varied through volume control.

As the speech-in-noise test is relevant for the final assessment of auditory fitness for applicants who have failed to meet the pure-tone audiometry requirements, these tests, as well as practical assessment in flight if necessary, should be carried out so as to produce reliable results and to convey confidence on an international basis, considering their importance for flight safety. An applicant who fails to pass the pure-tone audiometry test should not be declared unfit because of hearing loss, if his speech and signal perception has been demonstrated to be within acceptable limits at the appropriate masking noise level.

The background noise, regulated at the desired intensity levels, can be presented to the ear on separate loudspeakers. The volume of the test material should be controllable by the applicant in a manner representative of the aircraft communication equipment.

## TYPES OF HEARING LOSS

### Monaural Hearing Loss

The risk of sudden loss of hearing during flight is negligible. Head-shadow effects, brought about by the head in certain positions, cause poorer discrimination during monaural reception and might affect efficient communication between crew members and should be taken into account. The question of whether the affected individual is a pilot-in-command or co-pilot is relevant because of the seating arrangements. The differences in signal-to-noise ratio necessary for equivalent monaural and binaural perception are usually 3-4 dB. Annex 1, 6.3.4.1 and 6.5.4.1, specify a hearing ability "in each ear separately". In addition, 6.3.2.25 requires an applicant to "not possess any abnormality or disease of the ear". Monaural hearing in both private pilots and professional flight crews should therefore always be investigated and evaluated in accordance with best medical practice as well as assessed under 6.3.4.1.1. It should be noted that under the provisions of Annex 6, multi-crew aircraft are required to have intercom and radio equipment which can be effectively used in these cases.

Individuals with monaural loss complain about their inability to localize sound, to understand speech in noisy situations, and to hear or understand speech directed to their poor side (shadowing). A so-called CROS-arrangement - contralateral routing of the signal - may sometimes be used advantageously for the person with normal hearing in one ear and essentially no hearing in the other ear. Here the auditory signals are picked up by a microphone placed beside the poor ear and shunted across, either electrically or acoustically, to the good ear. A non-occluding-type ear mould is used in the good ear which permits the direct reception of auditory stimuli in that ear. Persons fitted with this arrangement report a decided improvement in their ability to understand speech directed to their bad ear as well as some improvement in their ability to understand speech in noisy situations.

### Presbycusis

As a pilot grows older, there will be a gradual deterioration of hearing. This sensorineural hearing loss is called presbycusis. The age of onset of presbycusis may occur as early as the thirties and Figure 12-4 shows the high frequency hearing loss synonymous with the aging process. Repeat audiograms will detect the situation. The vast majority of individuals with sensorineural hearing impairment can gain significant improvement through the use of a wearable hearing aid.

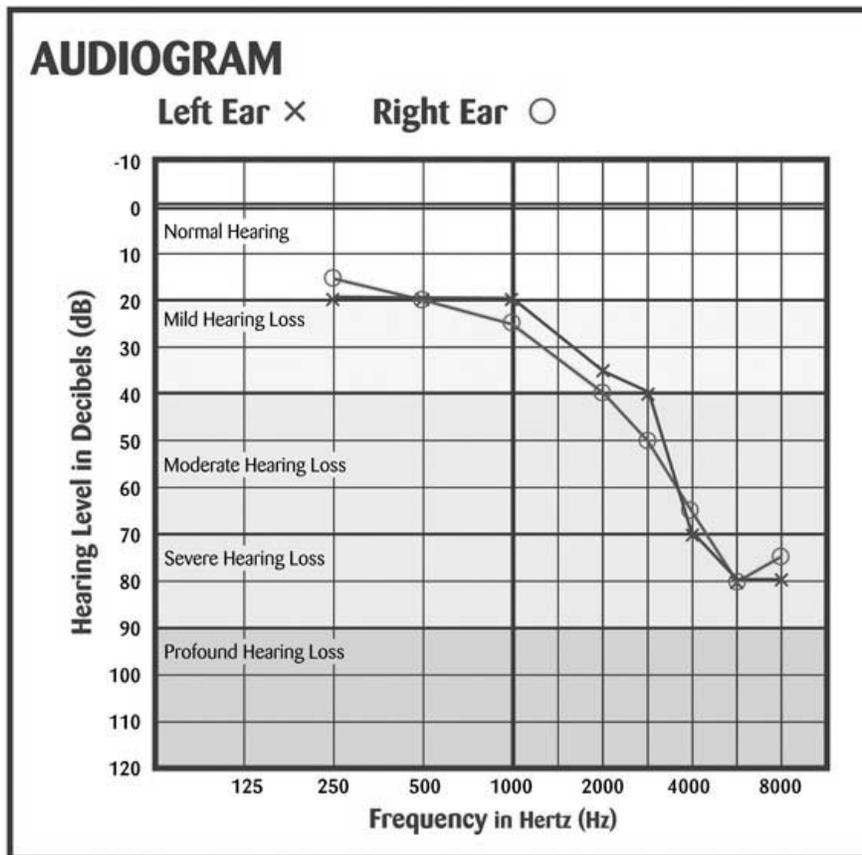


Fig. 12-4: Audiogram showing presbycusis

## HEARING AIDS

Few applicants present themselves for a medical examination wearing a hearing aid. There are, however, quite a number of flight crew who can benefit, particularly socially, by an aid. When an applicant can communicate better with the hearing aid than without it, consideration should be given for its use for aviation duties on the ground.

The first hearing aids were made in the late 1920s and early 1930s. These carbon-type aids were responsible for the prevalent notion that only persons with conductive hearing loss could benefit from hearing aids.

In the 1930s the vacuum-tube aid came into usage. There was still much doubt concerning the efficiency of a hearing aid for the person with sensorineural hearing loss. The development of the transistor and the transistor hearing aids opened up a new era in design and fitting. No longer was it necessary to have a bulky, inefficient instrument. Significant advances and refinements in hearing aids can be expected to continue.

If an applicant requires an aid, counselling in the selection of an aid to meet individual needs is necessary. Weight, size and concealment of the aid are secondary. By testing appropriately powered aids with frequency response characteristics deemed suitable for the particular hearing loss involved, it is often possible to demonstrate clear-cut and significant improvements in performance.

The degree of hearing loss and the discrimination scores, as well as the ear that is habitually used on the

earphones, are factors to consider in the initial selection. In many instances, it may be necessary to test hearing-aid use in each ear separately and binaurally to determine the most appropriate fitting.

The use of personal hearing aids is usually not accepted during flight performance of professional flight crews. Arguments against the use of hearing aids for licensing purposes centre around their delicate nature, their relatively low reliability, and their suboptimal acoustic performance. However, personal hearing aids are not normally required in flight because of the mandatory aircraft intercom and radio equipment. The best aids presently available provide a maximum of approximately 70 per cent of normal speech perception in environments of even relatively low ambient noise. This results from the frequency-response characteristic of aids, which is not "flat" in the 500-3 000 Hz range (as in the normal ear's response) and which above 3 000 Hz shows deep "valleys" in which ambient noise intrudes, masking adjoining frequencies. The point is made that the use of hearing aids is by no means functionally analogous to the use of correcting lenses for a refractive error.

Consideration of the technical characteristics of hearing aids for other than professional pilots leads to the recommendation that they should not be used in flight unless approved following a full investigation and assessment taking into account all of the operational implications under Annex 1, 1.2.4.8.

## **NOSE AND PARANASAL SINUSES**

### **Nose**

It is important for a pilot to have a normal-functioning nose. Impairment of the sense of smell may cause the first faint odour of gas, oil or smoke to go unnoticed. A malfunctioning nose can cause serious problems in regard to aeration of the sinuses and the Eustachian tube with resultant middle ear pathology.

A careful examination of the nose can and should be done. In some cases, where the mucosa of the septum and the turbinates are swollen, it is impossible to examine it carefully unless a shrinking agent, such as neosynephrine or xylometazolin solution is used. Most examinees do not object to a flat pledget of cotton (soaked) placed in each nostril.

### **Paranasal sinuses**

The sinuses are somewhat difficult to examine, but there are definite procedures that are useful. Deep palpation (pressure) over the maxillary sinus may elicit discomfort or pain. The same is true with pressure over the anterior surface of the frontal or deep digital pressure over the floor of the frontal. This can be done by placing the finger under the superior bony rim of the orbit and having the examinee flex the head. If this produces pain, the examinee will tilt the head away from the pressure.

If there is a purulent exudate in the nose, examine carefully and determine where the maximum accumulation is. A useful tool in the sinus examination is transillumination. It should be pointed out, however, that this technique may be misleading on account of the numbers of false positives and negatives found. This investigation can be done easily and requires only a dark room and any type of bright light. To examine the frontal sinuses place the light under the superior bony orbital rim and shield the light from your eyes. If the frontals are both clear, one can assume that they are essentially normal. If one is clear and one fails to transmit light (remains dark) then the condition should be examined further. The maxillary sinuses are transilluminated in a similar manner, placing the light in the mouth, near the hard palate, with lips tightly closed. If any abnormality or gross difference is noted or if any clinical doubt arises, additional diagnostic procedures, such as X-ray or better CT-scan is required. If the frontal and maxillary sinuses are all transilluminated clearly, do not assume that the examinee cannot have sinus trouble. The reason for this is that no one can transilluminate

the sphenoid or ethmoid sinuses.

Few applicants are assessed as unfit because of nasal sinus findings during a routine physical examination. The aviation examiner must, however, be alert, examine carefully, counsel and advise the examinee. If needed, the applicant must complete further examinations (X-ray or CT-scan) and treatment before being assessed as fit for aviation duties.

## **PATHOLOGICAL CONDITIONS**

### **The common cold**

Usually an applicant will state that the symptoms of a cold have been present for just one or two days. There may be marked nasal obstruction, thick yellow discharge, cough and a slight temperature. Withhold a final decision until a second examination seven to ten days later. Complications can occur in the paranasal sinuses, the Eustachian tube, the middle ear, larynx, trachea and bronchi. The common cold can be the direct cause of aerotitis media, inner ear barotrauma and of aerosinusitis.

*Pilots should be advised not to fly when they have a cold or nasal stuffiness.*

### **Allergies**

The examiner must be alert for the detection of allergic conditions. Be wary of the person who states, "I have a little hay fever." During the examination of the nose, ask the examinee, "What nose drops do you prefer? Have you used any antihistamines?" Individuals with severe allergies should be advised early of the possible complications of allergic reactions while piloting aircraft; the dangers of medication should also be pointed out.

The outstanding symptoms of allergic rhino-sinusitis are sneezing, marked nasal obstruction, discharges, watering of the eyes, and a bothersome itching of the nose.

Asthma is often merely a manifestation of allergy in the lower respiratory tract. A careful pulmonary examination must be done where a definite allergic rhinitis is noted. Persons with "bronchial asthma" frequently suffer from infections of the paranasal sinuses.

### **Aerosinusitis (Sinus barotrauma)**

Many pilots have at times been bothered with aerosinusitis. Like aerotitis it is caused by pressure differences between the sinus and the ambient air. This condition causes headache and at times severe pain over the sinus involved. Any obstruction to drainage of the sinuses results in absorption of the oxygen, stagnation of the secretion in the sinus, followed by bacterial growth and the formation of pus. Like aerotitis, aerosinusitis usually develops during descent from higher altitudes. Aerosinusitis in the sphenoid gives rise to headache in the back of the head, whereas aerosinusitis located in the other sinuses gives pain near the sinus involved.

Choncha bullosa is a cystic distention in the middle nasal concha (choncha media) with entrapped air, which in some cases can cause aerosinusitis. Choncha bullosa is usually diagnosed by CT-scanning (see Fig. 12-5).

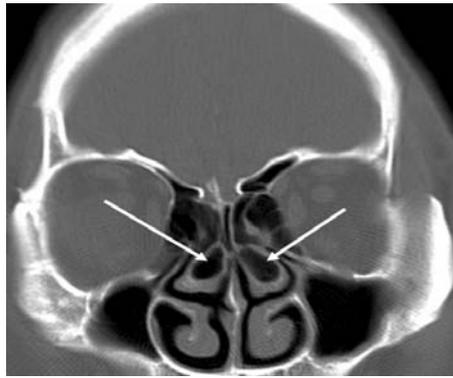


Fig. 12-5: CT-scan of sinuses showing concha bullosa

Relief can be obtained, usually in minutes, by using a mild nasal vasoconstrictor which will decrease nasal and Eustachian swelling and oedema. One can assume that a pilot with the above symptoms is taking some form of medication.

*If antibiotics and antihistamines are prescribed and if they are being used, the applicant should be aware of possible side effects and not fly while under treatment.*

## THE LARYNX

It is essential that a flight crew member has understandable speech. A husky, rough or croaking type of voice requires a thorough examination of the larynx. Any abnormality should be noted. If further investigation is required, the pilot should be assessed as temporarily unfit. An acute laryngitis with hoarseness is frequently seen and will usually subside when the allied infection clears up.

Chronic laryngitis should make the examiner alert for possible causes. Smoking and excessive use of alcohol as well as tuberculosis and cancer are frequent aetiological factors. Hoarseness lasting longer than two weeks demands visualization of the larynx and, if indicated, a biopsy of the larynx, which should be done by an ENT specialist. If a cancer is found, the pilot must receive proper treatment before being considered for certification. If treated with radiation, special attention must be paid to any post-radiation swelling in the larynx the following half year. In addition, the pilot must take the inconvenience of a dry mucosa into account. Frequent moistening of the mouth becomes necessary, especially in the dry air of airliners.

## VESTIBULAR SYSTEM

### **Spatial disorientation**

Few applicants for initial issue of a licence will admit to vertigo or dizziness and disorientation but a careful history and physical examination might confirm such a finding. The term 'vertigo' has different meanings to different people. To earthbound individuals it usually means dizziness. To a pilot it means, in simple terms, disorientation, i.e. loss of frame of reference and loss of orientation in space.

Disorientation in the air is described in Part III, Chapter 9 of this manual as a condition of importance in aviation medicine which has its basis in physiological mechanisms but which may be perpetuated by psychological factors.

In the absence of a visual reference, e.g. when flying in clouds or darkness without instruments, the vestibular information can be confusing or misleading. Distortion of the hair cells in the vestibular system sets up a chain of reflexes which produce postural, proprioceptive and oculomotor responses. Thus the examiner's interest lies in such important reactions as nystagmus, past pointing, and falling.

A pilot with spatial disorientation (SD) has an incorrect mental impression of the position, attitude and movement of the aircraft; SD during flight can have fatal consequences. Many pilots have had episodes of disorientation in various environments. They may accept these as normal or believe them to be symptoms of abnormality in themselves or in their aircraft. Whether they report disorientation, even under direct questioning, is influenced by:

- a) their recognition that they were disoriented;
- b) their ability to assess potential dangers in such episodes and their willingness to report them;
- c) social and economic pressures:
  - 1) will their admission have desired consequences, e.g. a medical excuse to give up a no longer desired career?
  - 2) will their admission have undesired consequences, e.g. groundings, loss of pay, status, career?
- d) their confidence (or lack of it) in those to whom they might turn for help, e.g. their medical examiner.

## **HISTORY**

The most important consideration is to determine whether the pilot actually had experienced true vertigo (a sensation of turning or spinning of oneself or one's surroundings) or merely a feeling of tridimensional instability, giddiness, light-headedness or faintness. The time spent in clarifying this point is wisely invested. When no true vertigo is present, the aetiology must be sought somewhere other than in the vestibular apparatus.

Disorientation may be related to many flight conditions. One of these is rapid changes in altitude, which may produce pressure-induced vertigo, mainly during descent due to blockage and clearing of the middle ear. Pilots who experience this condition repeatedly or severely should be referred to an experienced aviation ENT specialist, who is able to determine whether it is a case of simple alternobar vertigo or a perilymphatic fistula (inner ear barotrauma). In general, pilots should be warned that disregarding the signs of a common cold and flying with an upper respiratory infection may result in acute incapacitation caused by pain in the ears or sinuses and, in some cases, an additional non-reversible vertigo and hearing loss which may lead to permanent grounding.

Occurrence of vertigo in circumstances other than flight or the persistence of a particular pattern of disorientation (such as spinning or tilting, or position dependent vertigo) suggests labyrinthine disease. Vestibular neuronitis (and acute labyrinthitis), Menière's disease<sup>12</sup>, benign paroxysmal position nystagmus and other miscellaneous causes of vertigo, should be taken into account and applicants assessed accordingly.

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<sup>12</sup> Menière's disease: an affection characterised clinically by vertigo, nausea, vomiting, tinnitus, and fluctuating and progressive sensory hearing loss associated with endolymphatic hydrops. After Prosper Menière, French physician (1799-1862).

## PHYSICAL EXAMINATION

The physical examination, as outlined earlier in this manual, must be carefully done and recorded for each pilot having a history of vertigo. The examiner should have the results of the cardiopulmonary evaluation; blood pressure determinations may lead to a diagnosis of orthostatic hypotension as the cause of dizziness. Hearing loss accompanying vertigo is often associated with localized labyrinthine disease. In patients with true vertigo and perceptible hearing loss, two sites of involvement must be suspected: the end organ and the eighth cranial nerve. Audiometry is the more satisfactory method of localizing the lesion. Pure-tone audiometry, while able to distinguish conductive and sensorineural hearing losses, will not aid in this localization. End organ disease is indicated by the presence of recruitment. Eighth nerve disease is indicated by low speech discrimination, abnormal tone decay time, and abnormal brainstem-evoked response audiometry (BRA). More advanced methods of investigation, such as computed tomography (CT) or better magnetic resonance imaging (MRI) are now routine in most hospitals.

The presence of a vestibular pathology (central or peripheral cause) may be indicated by a few essential clinical tests. Romberg test<sup>13</sup>, Bárány's rotatory chair test<sup>14</sup>, Dix-Hallpike test<sup>15</sup>, test for spontaneous nystagmus, the ability to walk a straight line, heel-to-toe with eyes blindfolded (or Unterberger's stepping test<sup>16</sup>) are sensitive indicators and easy for the examiner to perform. Also placing the finger to the nose and then to the examiner's finger rapidly back and forth with the eyes blindfolded will demonstrate a drift (past pointing) in acute labyrinthine disturbances and make apparent any latent ataxia. In case of irregular vestibular test results the pilot should be referred for further evaluation using more sophisticated test methods such as electro-nystagmography (ENG), video-nystagmography (VNG), caloric testing, vestibular autorotation test (VAT), vestibular evoked myogenic potential (VEMP), equilibrium platform testing (EPT), etc.

## CALORIC TESTING

Applicants with a history or evidence of vertigo should have caloric studies or other equivalent testing done. In the caloric test, the lateral semi-circular canal is stimulated by introducing fluid into the external auditory canal. If the fluid temperature differs from body temperature, the temperature difference will be conducted to a sector of the lateral semi-circular canal. Endolymph in this sector will differ in density from the remainder of the endolymph. If the plane of the semi-circular canal is aligned with gravity, this density difference will cause the endolymph to fall if the fluid is colder, or to rise if the fluid is warmer than body temperature. Since the caloric stimulus can produce a convection current which will rotate the endolymph in either direction, each ear can be tested independently.

Many articles have been written on technique, modification and interpretation of tests with hot and cold water stimulation of the semi-circular canals. A simple formula for the examiner to remember is ←**COWS**→. When

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<sup>13</sup> Romberg's test: station test or Romberg's sign. The test is positive when a patient, standing with feet approximated, becomes unsteady, or much more unsteady with eyes closed. After Moritz Romberg, German physician (1795-1873).

<sup>14</sup> Bárány's rotatory chair test: A test to measure vestibular function by rotating the patient in a swivel-chair and observing the duration of the nystagmus produced under Frenzel's glasses.

<sup>15</sup> Dix-Hallpike test: A test to determine whether vertigo is triggered by certain head movements. After Margaret R. Dix, English physician, and Charles Skinner Hallpike, English neuro-otologist (both 20<sup>th</sup> century).

<sup>16</sup> Unterberger's stepping test: A test for vestibular pathology; the test is positive if the patient turns while walking on the spot with eyes closed. Rotation to one side indicates labyrinthine disease on that side. After A. Unterberger, German otologist (20<sup>th</sup> century).

cold (C) water is used, the resultant nystagmus is to the opposite (O) side; when warm (W) water is used, the nystagmus is to the same (S) side. One refers to nystagmus to the right or left according to the direction of the fast component. The speed of the slow component of the nystagmus and its direction are the parameters. A unilateral weakness of less than 20 per cent is considered normal. A directional preponderance of less than 25 per cent is within accepted normal limits. The test procedure uses water at 30°C and 44°C i.e. 7°C below and above body temperature. This procedure is somewhat complicated and time-consuming for the non-specialist medical examiner.

A more attractive way of inducing vestibular responses is by means of natural head movements and the vestibular-ocular reflex (VOR). The vestibular autorotation test, or VAT, is a computerized test that has been developed to measure the VOR during high-frequency head rotations (2-6Hz), using active head movement that is cued by an auditory stimulus, instead of passive rotation in a chair. The test is an aviation relevant replacement of caloric testing and is the preferred test in several aviation medical centres in Contracting States.

### **ELECTRONYSTAGMOGRAPHY/VIDEONYSTAGMOGRAPHY**

The major drawback in the use of the caloric test in examination of vestibular function lies in the fact that the induced nystagmus must be judged by direct observation and is, therefore, subject to the personal judgement and experience of the examiner. An observation of nystagmus reaction can easily vary from one observer to the next. This has made a comparison of results unsatisfactory unless the tests were consistently performed by the same person. Other properties of nystagmus, in addition, could not be properly assessed. Factors such as amplitude of nystagmus, maximum frequency and speed of the nystagmus beat could not be obtained with any accuracy. To overcome these difficulties and to eliminate fixation (the examinee's eyes are kept closed), electronystagmography/videonystagmography (ENG/VNG) has been developed, whereby one is able to electronically record the induced nystagmus in a manner similar to recording the cardiac action with electrocardiography. Also spontaneous and positional nystagmus can be quantified with ENG/VNG.

#### **Technique**

A difference in potential exists between the cornea and the retina, the retina being negative and the cornea being positive. This corneal-retinal potential allows the eye to act as a dipole. The movements of the eye which occur with nystagmus, cause the corneal-retinal potential to be displaced laterally, causing a recordable change in the potential at the outer canthus. In the ENG these changes are recorded by electronic equipment and can be then analysed both qualitatively and quantitatively. In VNG a video camera is fixated on the pupil and records the movements of the eye. The subject is placed recumbent with the head elevated 30 degrees, thus placing the horizontal canal in a position for maximum stimulation. Active electrodes are placed lateral to the outer canthus of the eye with the ground placed on the forehead; the eyes are closed to prevent fixation. The hot and cold caloric stimuli are applied and the induced nystagmus is automatically recorded by the electronic apparatus.

Very few aviation medical examiners will have an electronystagmograph in the office. The examiner should, however, know that these tests are available at aviation medical centres or in well-equipped otology clinics and audiology centres.

### **REFERENCES**

Rayman, Russell B., et al.: Clinical Aviation Medicine, fourth edition, 2006.  
Manual of Civil Aviation Medicine, Joint Aviation Authorities (JAA), 2006.

## **PART III**

### **Chapter 13. HUMAN IMMUNODEFICIENCY VIRUS (HIV)**

*(This part is currently undergoing a review.)*

## **PART III**

### **Chapter 14. HAZARDS OF MEDICATION AND DRUGS**

*(This part is currently undergoing a review.)*

## Part III

### Chapter 15. MALIGNANT DISEASE

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*Note.— This chapter has been adapted from Chapter 17 of the Joint Aviation Authorities Manual of Civil Aviation Medicine, 2006.*

## INTRODUCTION

Every applicant who has been treated for malignant disease will need an individual assessment before exercising licence privileges, and although this chapter is concerned with pilot certification, many principles also apply to other categories of licence applicants. Recovery from surgery or radiotherapy should be assessed. Current curative or adjuvant chemotherapy is incompatible with certification, and recovery from the effects of such treatments will demand a period of unfit assessment after it has finished. If the pilot has recovered from the primary treatment and, as far as can be assessed with available techniques, there is no residual tumour, then the level of certification will depend on the likelihood of recurrent disease. This chapter of the guidance material will explore methods that enable the risk to flight safety posed by air crew who have received treatment for malignant disease to be assessed.

In addition to ensuring that treatment has been effective, pre-requisites for certification after treatment for malignant disease include satisfactory haematological parameters and no on-going side effects from therapy.

## PRIMARY TREATMENT FOR MALIGNANT DISEASE

### Surgery

Surgery is the commonest primary treatment for malignant disease, and is frequently the only treatment. A return to flying, from the purely surgical aspect, depends on the extent of the surgical operation, and this can be conveniently broken down into minor, intermediate and major surgery. Examples of minimum times assessed as unfit for various types of surgery are shown in Table 1. It is stressed that these are minimum times, and more extensive procedures or any complications with, for example, wound healing will extend these times.

Extent of surgery	Operation example	Minimum time assessed as unfit
Minor	Excision of mole Biopsy of lymph node	One week
Intermediate	Orchidectomy for testicular cancer	Four weeks
Major	Hemicolectomy for carcinoma of colon	Twelve weeks

Table 1.— Minimum periods of unfitness after surgery

The medical assessor may consider earlier recertification if recovery is complete, the applicant is asymptomatic, and there is a minimal risk of complications.

### Radiotherapy

Radiotherapy treatment for malignant disease is usually given as an intensive course. The aim of this may be curative, for example when given to an isolated group of lymph nodes which have proved by biopsy to contain lymphoma; or as adjuvant treatment, for example to the abdominal nodes following orchidectomy for a seminoma of the testis, on the assumption that they may contain metastatic tumours. Since most

courses are intensive, there is little time to fly even if the pilot wished to, but many patients undergoing radiotherapy suffer non-specific systemic effects (tiredness, malaise and nausea) which make it inadvisable for any pilot to fly whilst receiving such treatment.

*Apart from physical symptoms, there are often psychological effects and worries associated with radiotherapy, which, in common with chemotherapy, may also affect flying ability. Consequently, pilots should be assessed as unfit during any course of radiotherapy.*

### **Chemotherapy**

*Pilots should be assessed as unfit during any period of treatment with cytotoxic chemical agents.*

These medicines are toxic to normal cells, and in particular to rapidly dividing cells in the bone marrow. During chemotherapy the patient is routinely tested for normal blood levels of red blood cells and haemoglobin, and this should serve as a reminder both to the pilot and the medical examiner that there are potential risks when entering a hypoxic environment.

An unfit assessment applies both to *curative* chemotherapy, for example, treatment of disseminated lymphoma, and to *adjuvant* chemotherapy, for example when given to prevent the possible recurrence of colorectal cancer following surgical excision. The latter treatment may extend over a prolonged period of time, and there may well be a conflict between the medical advice to have the adjuvant treatment and the pilot's desire to regain medical certification to fly.

*The only exception to an unfit assessment during adjuvant treatment for malignancy is endocrine therapy. Certain adjuvant hormone and anti-hormone treatments following (for example) breast or prostate cancer treatment may be acceptable if there are no side effects.*

### **Stem cell transplantation**

*It is possible to return to flying after stem cell transplantation if there is sustained remission.*

## **CERTIFICATION AFTER PRIMARY TREATMENT**

### **Defining acceptable risk**

In this discussion the assumption is made that the primary treatment, be it surgery, radiotherapy, chemotherapy or a combination of these, has removed all signs of tumour "X" when measured clinically or by investigation. The risk to flight safety is now the possibility that local or metastatic recurrence will cause sudden or insidious incapacitation whilst the pilot is flying.

The concept of "acceptable risk" or "the one per cent rule" has been discussed elsewhere in this manual. Much work in aviation cardiology has defined a risk of incapacitation of one per cent per year or less to be acceptable for two-crew professional operations as well as unrestricted private flying. This can also be applied to certification after treatment for malignant disease. One difference between cardiology (a topic that is well-suited to the application of objective risk assessment) and oncology is that with the former, once the risk has been defined and certification achieved, the pathological condition is not likely to go away. After treatment of malignancy, however, the prognosis improves with recurrence-free time after the original episode. Thus to consider the full range of certification possibilities, from no certificate to unrestricted Class 1, and including Class 2 certification for private flying, acceptable incapacitation risk levels have to be defined.

In this discussion, the following annual incapacitation risks will be used to define the appropriate certification. It should be noted that the exact levels of acceptable risk for restricted Class 2 certification (restricted private flying<sup>1</sup>) have not been defined. For single-crew professional flying a figure of 0.1 per cent has been empirically quoted and is a reasonable basis, given that it is an order of magnitude less than the maximal acceptable multi-crew figure and is the approximate cardiovascular risk of men in their 40s (see Table 2).

For the purpose of these calculations, a five per cent annual incapacitation risk has been taken as the upper limit for restricted private flying.

<b>Incapacitation risk per year</b>	<b>Acceptable level of certification</b>	<b>Licence</b>
Less than 0.1 per cent	Any	Any
Between 0.1 and 1 per cent	Class 1 restricted Class 2 unrestricted	Multi-crew only Private
Greater than 1 per cent	No Class 1 Possibly Class 2 restricted	No professional Private with restriction

Table 2.— Certification possibilities according to acceptable risks of incapacitation

Thus if an incapacitation rate per year can be derived for “tumour X” at any particular time following its original treatment, then an acceptable level of certification for that pilot, at that time, can be calculated from the table above.

Following “successful” primary treatment, the risk that tumour X will cause an insidious or sudden incapacitation depends on two factors. The first is the actual risk of recurrence, which will depend on the pathological stage of the tumour or its TNM classification<sup>2</sup>. The second is the site of that recurrence, and this will depend on the primary tumour type. These two factors will now be discussed individually, again in relation to a hypothetical tumour X.

### **Defining the risk of recurrence**

The annual recurrence rate of tumour X can be calculated from survival curves. Ideally these should be “recurrence free” survival curves, but those are often not available, and thus simple survival data will need to be used. However, unless it is possible to cure many patients once their tumour has recurred (not a common situation) then the two curves will be very similar in shape.

Figure 1 shows a hypothetical five year survival curve for tumour X, and is used to show the usual representation of this type of data. It includes percentage figures along the curve showing the recurrence rates for each of the five years following treatment.

<sup>1</sup> Restricted Class 2: For private flying, limitations in use in many Contracting States include “without passengers”, “outside controlled airspace”, and “with safety pilot.”

<sup>2</sup> TNM classification: staging of tumours according to three basic components – primary tumour (T), regional nodes (N) and metastasis (M). Numbers denote size and degree of involvement, e.g. 0 means “undetectable”, and 1, 2, 3, and 4 a progressive increase in size and involvement. Thus a tumour can be described as T1N2M0.

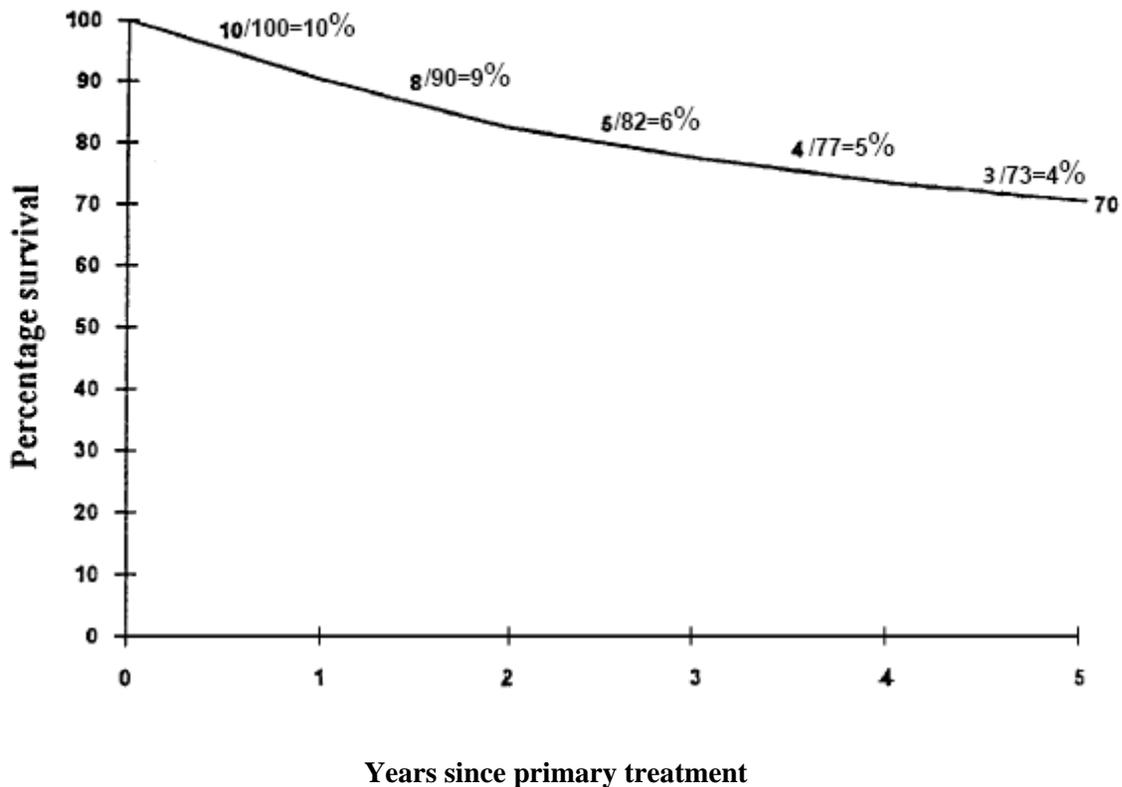


Figure 1.— Overall five year survival after primary treatment of tumour X.

The graph represents the recurrence rates for all cases of tumour X. These data, however, include a large spectrum of recurrence rates from very low (early stage disease) to very high (late stage disease). To illustrate the effect of different stages on prognosis, it is assumed that tumour X lesions can be divided into three types, or stages, based on the pathological examination of the resected specimen.

Studies have shown that the prognosis following surgical treatment for tumour X is related positively to the stage of the tumour at operation. Thus the previous overall five year survival curve of tumour X can be broken down into three separate curves relating to the three separate stages as shown in Figure 2. As would be expected, the more advanced stage tumours (stages 2 and 3) have a worse prognosis than early lesions.

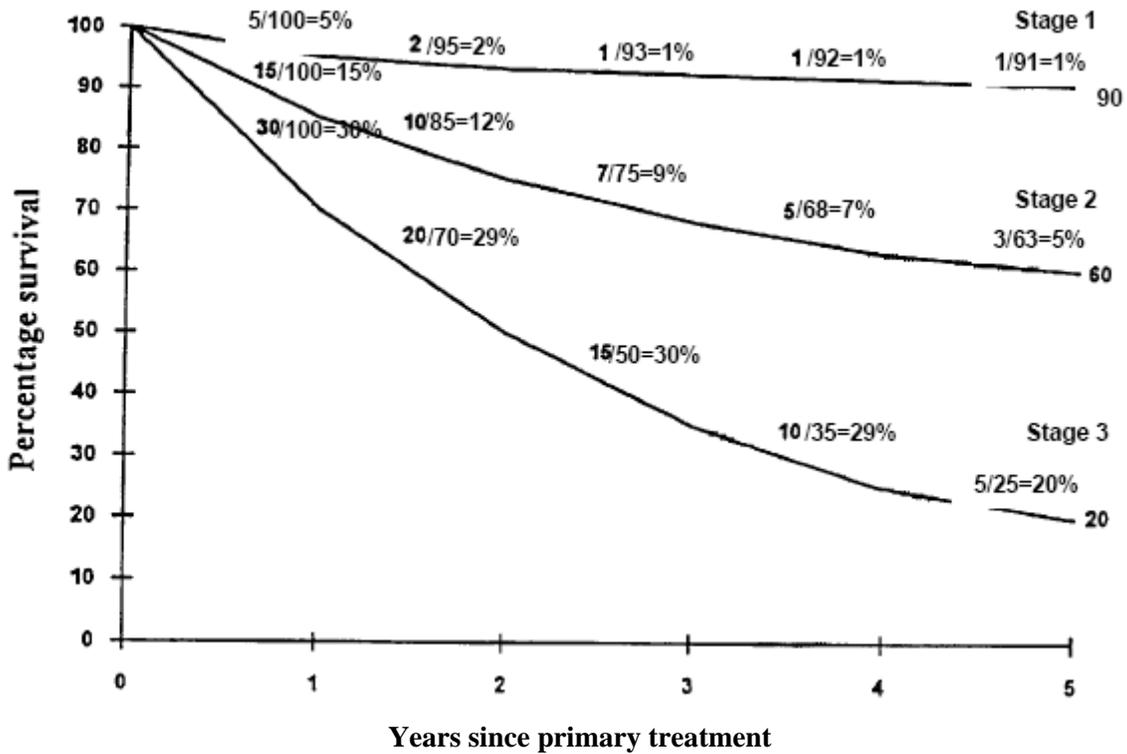


Figure 2.— Five year survival for tumour X divided into pathological stages

From the data in Figure 2 it is possible to derive a yearly percentage risk of recurrence for any stage of tumour X. For instance, the risk of a recurrence between two and three years after surgery for a stage 2 tumour is nine per cent

### Defining the site of recurrence

Each tumour has its own particular sites of recurrence, and these have been recorded in pathology textbooks since they were first written. Although metastases can occur in any part of the body, the majority are found in lymph nodes, lungs, bones, bone marrow and brain. For any particular tumour the risk of first recurrence at each of these sites can be determined from available data sources. However, these data are often difficult to find in the medical literature. Figures for the incidence of metastases in various organs at post-mortem are more easily obtained, and in some tumours an extrapolation from such data may be necessary to obtain a “first recurrence” incidence.

Table 3 provides an example of the percentage incidence figures of first recurrence at different sites for a hypothetical tumour.

Site incidence	Per cent
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Local and regional lymph nodes	60
Liver	20
Brain	10
Lung	5
Bone	5
Bone marrow	0

Table 3.– Incidence of metastasis by site for a hypothetical tumour

### Defining the risk of a particular metastasis causing incapacitation

A first recurrence in a regional lymph node carries a very small risk of incapacitation. A brain metastasis, on the other hand, as the first indication of recurrent disease, must be assumed to carry a 100 per cent potential for sudden incapacitation in the form of a fit or seizure or another neurological event such as paresis, sensory loss or headache. Metastatic disease in bone marrow can cause anaemia and bleeding disorders. Rarely metastases erode major vessels with catastrophic consequences (lungs and liver).

The risk of subtle incapacitation is harder to quantify, but it must be assumed that any recurrence of any tumour will degrade the operational abilities of aircrew to some extent. Thus a table of “incapacitation weighting” can be constructed to give an estimate of the potential for sudden and insidious incapacitation by a recurrence at each metastatic site. This is shown in Table 4.

Site	Incapacitation “weighting” in per cent
Local and lymph nodes	5
Liver	5
Lungs	5
Bone	5
Bone marrow	20
Brain	100

Table 4.– Incapacitation weighting

### Defining the total risk of incapacitation

Three parameters may be known about tumour X, and these can be used to estimate a “total” risk of incapacitation. They are:

- a) The recurrence rate per year for any stage of tumour X (as a percentage)
- b) The frequency of metastatic disease in a particular organ (as a percentage)
- c) The risk that a metastasis in a particular organ will cause incapacitation (as a percentage)

A formula can now be derived to calculate the total risk of a particular metastasis causing incapacitation in any year after completion of primary treatment. The example below is for brain metastases.

$$(\text{Tumour X recurrence rate}) \times (\text{Incidence of brain metastases}) \times (\text{Risk of brain metastasis causing incapacitation}) = \text{risk of incapacitation from brain metastases in tumour X}$$

Using the figures that we have obtained, numbers can be put to this formula. The tumour recurrence rates per year are from Figure 2.

Year 1 / Stage 1 :  $1/20$  (5%)  $\times$   $1/10$  (10%)  $\times$   $1/1$  (100%) =  $1/200$  = 0.5% risk of incapacitation

Year 1 / Stage 2 :  $3/20$  (15%)  $\times$   $1/10$  (10%)  $\times$   $1/1$  (100%) =  $3/200$  = 1.5% risk of incapacitation

Year 1 / Stage 3 :  $3/10$  (30%)  $\times$   $1/10$  (10%)  $\times$   $1/1$  (100%) =  $3/100$  = 3.0% risk of incapacitation

In the first year, therefore, the average risk of incapacitation due to brain metastases ranges from 0.5 per cent to 3.0 per cent, depending on the staging of the tumour. This would allow a range of certification as shown in Table 5.

#### YEAR 1 – BRAIN METASTASES

Year 1 – brain metastases			
Stage	Incapacitation risk	Professional certification	Private certification
1	0.5%	Multi-crew restriction	Unrestricted
2	1.5%	None	Restricted
3	3.0%	None	Restricted

*Table 5.– Range of certification possible in first year after completion of treatment*

By year 5 the prognosis has improved and the incapacitation risks have decreased. Again the tumour recurrence rates are taken from Figure 2.

Year 5 / Stage 1 :  $1/100$  (1%)  $\times$   $1/10$  (10%)  $\times$   $1/1$  (100%) =  $1/1000$  = 0.1% risk of incapacitation

Year 5 / Stage 2 :  $1/20$  (5%)  $\times$   $1/10$  (10%)  $\times$   $1/1$  (100%) =  $1/200$  = 0.5% risk of incapacitation

Year 5 / Stage 3 :  $1/5$  (20%)  $\times$   $1/10$  (10%)  $\times$   $1/1$  (100%) =  $1/50$  = 2% risk of incapacitation

In the fifth year the risk of incapacitation has now fallen to between 0.1 and 2%. The range of acceptable certification has also increased, as shown in Table 6:

#### YEAR 5 – BRAIN METASTASES

Year 5 – brain metastases			
Stage	Incapacitation risk	Professional certification	Private certification
1	0.1%	Unrestricted	Unrestricted
2	0.5%	Multi-crew restriction	Unrestricted
3	2.0%	None	Restricted

*Table 6.– Range of certification possible in fifth year after completion of treatment*

Other types of recurrence are possible (and indeed more likely) than brain metastases, but because of the “incapacitation weighting” given to each anatomical recurrence, brain lesions contribute most to the total risk of incapacitation. The combined risks of several sites of recurrence may need to be taken into account.

### Presenting the total risk of incapacitation

A table can be used to show the type of certification possible depending on time since completion of primary treatment and stage (Table 7):

Stage	Year since completion of primary treatment				
	1	2	3	4	5
1	0.5% (5%×10%×100%) (1/20×1/10×1/1×100%)	0.2% (2%×10%×100%)	0.1% (1%×10%×100%)	0.1% (1%×10%×100%)	0.1% (1%×10%×100%)
2	1.5% (15%×10%×100%)	1.2% (12%×10%×100%)	0.9% (9%×10%×100%)	0.7% (7%×10%×100%)	0.5% (5%×10%×100%)

Table 7.– Certification possibilities according to stage and time since completion of treatment

This can be displayed graphically in a chart as shown in Figure 3:

Stage	Years since completion of treatment				
	1	2	3	4	5
1					
2					

 Unrestricted Class 1

 Class 1 with multi-crew restriction or unrestricted Class 2

 No Class 1 – restricted Class 2

Figure 3.– Chart indicating certification possibilities according to stage and time since completion of treatment

### Using certification assessment charts

It must be emphasized that charts are only for guidance. Flight crew with tumours that have a number of additional good prognostic factors may be returned to flying earlier than the “average” example demonstrated by the chart. Conversely, if adverse prognostic factors are present, further delay may be necessary before recertification.

Charts are based on published survival statistics following treatment for a particular type of tumour and may need revision if new therapy is introduced or the results of new studies become available. States can develop their own charts as guidance for the more common tumours based on the local prognostic factors and treatments used. Studies used to calculate the certification assessment figures may use overall, event-free or disease-free survival, and may include subjects unrepresentative of a pilot population (in terms of age, sex, country of residence, lifestyle and other variables) and may include cases where curative treatment has not been attempted. Individual case assessment therefore remains paramount.

Charts are useful for tumours that have a prognosis that improves with time. Some malignancies have a long median survival time of ten years or more but the rate of progression remains relatively constant with time. In such a situation it may be possible to maintain certification for several years provided the licence holder remains asymptomatic, is not on active treatment, and is reviewed regularly.

### **Tumour Markers**

The relapse or active progression of certain tumours may be effectively followed by measuring tumour markers. The most common example in pilots and controllers is adenocarcinoma of the prostate where levels of Prostate Specific Antigen (PSA) can be tracked over a period of time.

Analysis of the tumour marker is very useful in determining the risk of relapse for an individual. It is inappropriate to use a certification assessment chart where this alternative type of specific risk assessment is possible.

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## Part III

### Chapter 16. ADDITIONAL CONSIDERATIONS RELATED TO AIR TRAFFIC CONTROL OFFICERS

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## **INTRODUCTION**

Air Traffic Control (ATC) has developed rapidly since the 1950s. From simple beginnings, it is now a sophisticated system in which the controller is in charge but in which the machine (i.e. the computer) plays an important part. The controller processes some of the information but a proportion is processed by the machine. Technical equipment such as the radar screen, closed-circuit television or visual display unit (VDU) presents information in a convenient and usable form but it is the controller who has the final decision as to how this information will be used.

Some Contracting States have been giving increasing importance to medical facts relating to controllers and their tasks, recognizing that technological progress has been rapid but that the controller as the final arbiter has not changed. The controller must still make many and varied decisions, sometimes under considerable stress, to produce a safe, orderly and expeditious flow of traffic.

## **SELECTION AND SUPERVISION**

To carry out the job effectively, the Air Traffic Control Officer (ATCO) must meet the Standards specified for a Class 3 Medical Assessment as laid down in Annex 1. It should be noted that the differences between Class 1 (applicable to professional pilots) and Class 3 (applicable to ATCOs) are minimal. Medical procedures should include a full history, including family history, and a full physical examination carried out in accordance with 6.5 in Chapter 6 of Annex 1. Controllers are to be examined every four years until the age of 40, then every two years (and after age 50 preferably once per year), and it is important to exclude, so far as is possible, any cause for incapacitation during this time. A baseline 12-lead resting ECG, and a pure tone audiogram are required at initial examination, and thereafter at intervals determined by the age of the applicant.

The Designated Medical Examiner (DME) is responsible for determining the physical and mental fitness of the applicant. However, the assessment of aptitude is not done by the DME and is not part of the Class 3 assessment. Research generally supports the value of psychological testing as a measure of such aptitude, aiming at predicting adequate performance during the controller's career, although the most appropriate tests are subject to ongoing debate.

Subsequent loss of licence, on medical grounds, amongst active controllers appears not to be excessive which suggests that the validity and interpretation of present medical standards are correct.

## **JOB-RELATED STRESS**

Air traffic control has been widely perceived as being a stressful occupation. Research conducted in one Contracting State has shown a higher incidence of stress-related illness such as hypertension and peptic ulceration as compared with a control population. However, other reports fail to substantiate this and a more recent study encompassing all ATCOs in a Contracting State indicates that controllers enjoy better health than the background population and have a lower prevalence of stress-related conditions.

There is even less agreement on what is the nature of this stress, and little supporting evidence that such stress is harmful. One study of a group of ATCOs in a Contracting State suggests that the generally preconceived factors thought to be stressful are not necessarily so. For example, responsibility for safety and lives was not a stressor whereas being overloaded was. High work load was not, but boredom was. Failure of pilots or other controllers to conform to standard operating procedures was, but shift working was

not. Research continues.

Stressful factors	Non-stressful factors
Being overloaded	Responsibility for safety and lives
Boredom	High work load
Failure to conform by others	Shift working

In order to predict and/or prevent job-related stress interfering with performance and/or producing loss of licence on medical grounds, the DME should attempt to establish close rapport with ATCOs. A good occupational health programme is clearly of value and, as an example, close attention should be paid to short-term trivial sickness absence as a good indicator for stress.

### CORONARY HEART DISEASE

This is still responsible for significant loss of licence, according to figures published by some Contracting States.

*ICAO SARPs permit recertification of ATCOs who have suffered a myocardial infarction or undergone cardiac surgery, provided the controller's cardiac condition has been investigated and evaluated in accordance with best medical practice and is assessed not likely to interfere with the safe exercise of his or her licence and rating privileges.*

*The length of time considered necessary before the controller can be allowed back on duty after a cardiac event might be shortened by the inclusion on the licence of an endorsement calling for a "similarly qualified controller to be in close proximity while the licence holder is exercising the privileges of the licence".*

### PSYCHIATRIC DISORDERS

These illnesses are responsible for a significant number of ATCOs having licences withdrawn on medical grounds, but their prevalence does not differ significantly when compared to other licence-holders. In solving problems of this nature, peer and family support appears to be significant and the opportunity to discuss such problems with sympathetic management or a designated colleague or personnel officer or, more particularly, with an understanding DME, is important. Experience has shown, however, that some controllers still report a build-up of stress because apparently none of these channels is available to them.

### PREGNANCY

The relevant requirements in Chapter 6 of Annex 1 are as follows:

6.5.2.22 Applicants who are pregnant shall be assessed as unfit unless obstetrical evaluation and continued medical supervision indicate a low-risk uncomplicated pregnancy.

6.5.2.22.1 **Recommendation.**— *During the gestational period, precautions should be*

*taken for the timely relief of an air traffic controller in the event of early onset of labour or other complications.*

**6.5.2.22.2 Recommendation.**— *For applicants with a low-risk uncomplicated pregnancy, evaluated and supervised in accordance with 6.5.2.22, the fit assessment should be limited to the period until the end of the 34th week of gestation.*

6.5.2.23 Following confinement or termination of pregnancy the applicant shall not be permitted to exercise the privileges of her licence until she has undergone re-evaluation in accordance with best medical practice and it has been determined that she is able to safely exercise the privileges of her licence and ratings.

There is no published evidence to suggest that there is increased risk to mother or foetus as a result of working with radar screens or VDUs.

## VISUAL PROBLEMS

### *Refractive errors*

Air Traffic Controllers should be able to read radar screens, visual displays and written or printed material and also to make use of distant vision through control tower windows. If correction is needed to perform one or more of these tasks, one pair of glasses should meet the requirements, so that it is unnecessary to remove or change the glasses when operating. Contact lenses may be appropriate if tolerance has been achieved.

It is an advantage if the optician who dispenses the glasses for the ATCO is familiar with the working environment, particularly with regard to operating distances and ambient lighting.

### *Presbyopia*

Controllers report a high incidence of problems with vision as they get older. Today's sophisticated equipment requires the ATCO to operate at near and intermediate distances and often change quickly between these and long distance. Special correcting spectacles, suitable only for the work place, may be necessary. "Look-over", bifocals or multifocals may be the answer, and often these will correct for near and intermediate distances while leaving long distance uncorrected. Varifocal lenses are a good solution for many although they may cause some peripheral distortion and often require several days of familiarization before they can be used on duty. Single-vision near correction (full lenses of one power only, appropriate for reading) may be acceptable for certain air traffic control duties (whereas they are not for pilots). However, it should be realized that single-vision near correction significantly reduces distant visual acuity.

## FLEXIBILITY

In some specific cases of ATCOs not meeting the medical Standards in Chapter 6 of Annex 1, it may be desirable to exercise flexibility in accordance with 1.2.4.8. In such cases, as mentioned under the section on coronary heart disease, the licence may be endorsed as follows: "Subject to a similarly qualified controller being in close proximity while the licence holder is exercising the privileges of the licence".