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“Diabetes mellitus : an Aviation Medicine point of view”

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CLASSIFICATION

□ TYPE 1

Genetically associated with T-cell dependent auto-immune disease and HLA factors. Very low or absent endogenous insulin. Liable to keto-acidosis. Onset typically under 25.

□ TYPE 2

Related to obesity and familial tendency. Endogenous insulin always present and often hyperinsulinaemic with insulin resistance. Rarely if ever ketotik. Onset 40+. There is a non obese subgroup displaying different aethiology and family aggregation

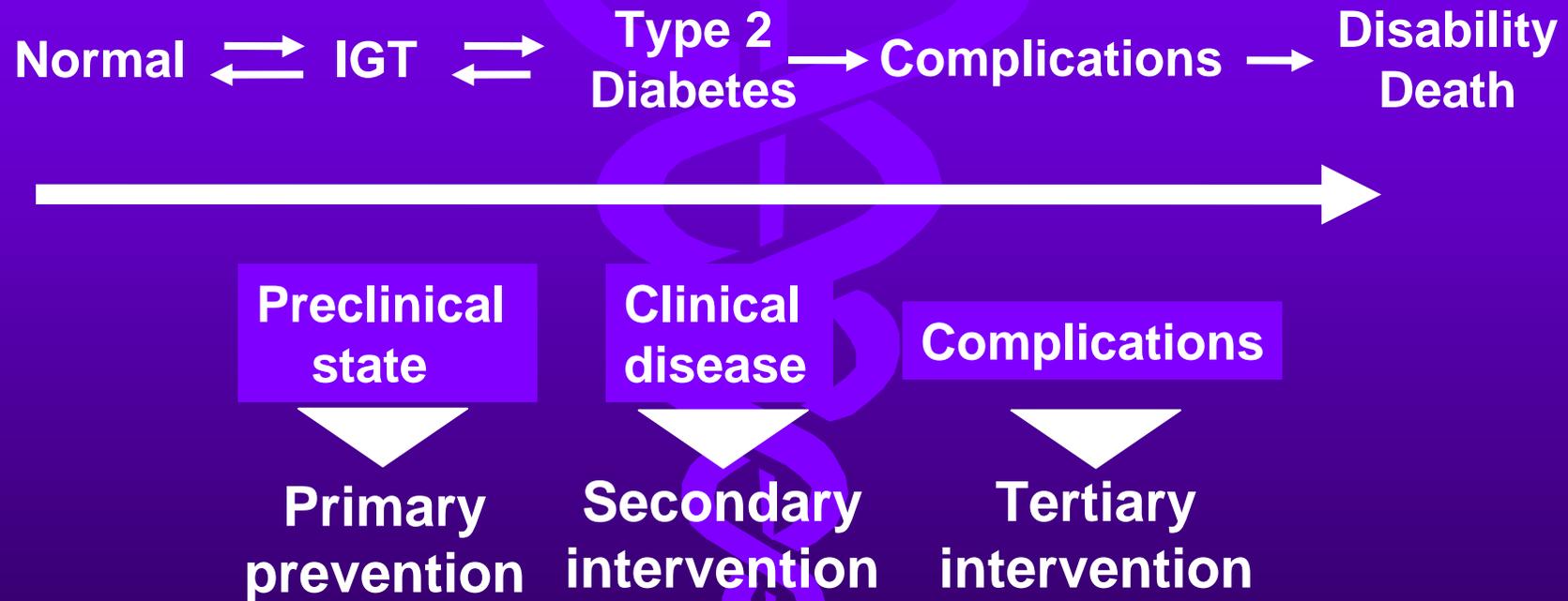
□ GESTATIONAL DIABETES MELLITUS

IMPAIRED GLUCOSE TOLERANCE IMPAIRED FASTING GLUCOSE

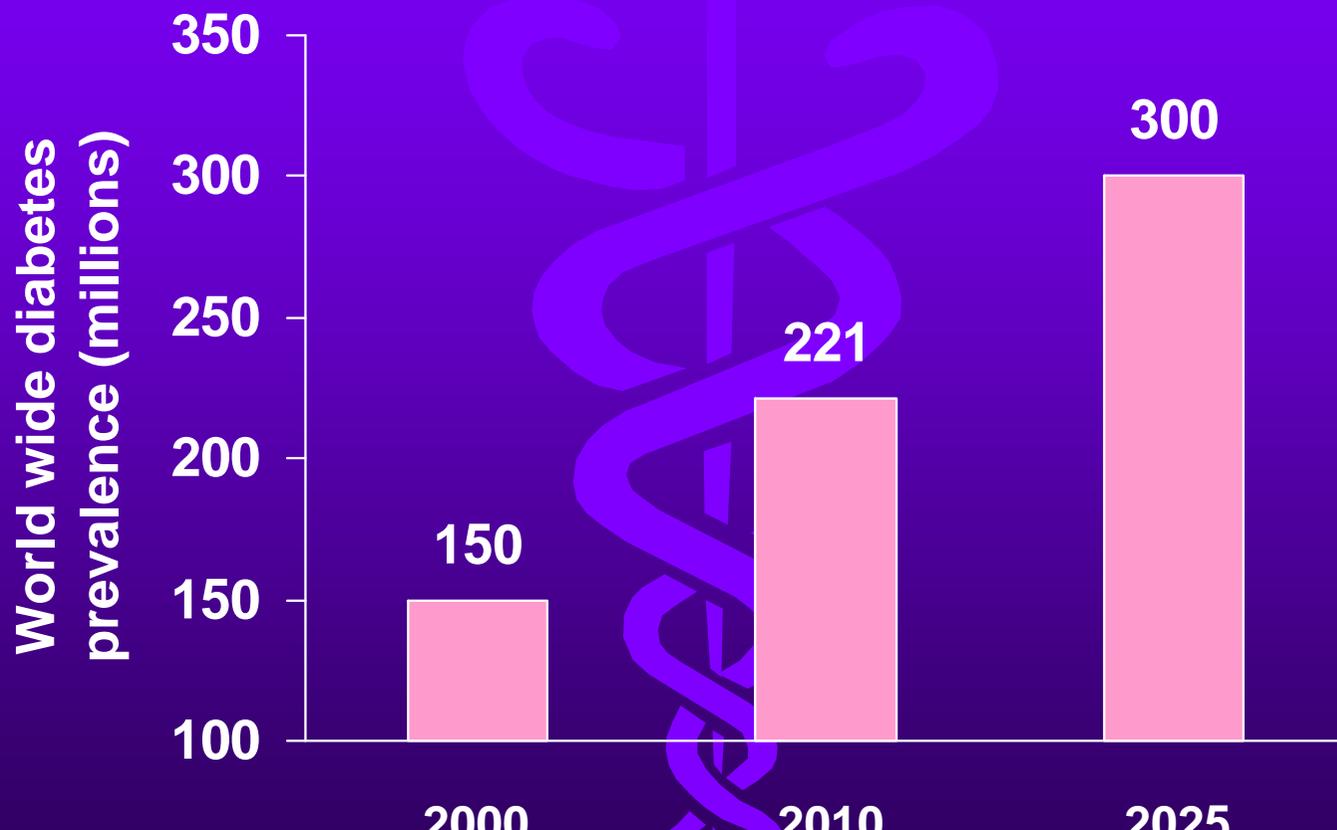
These conditions often represent a pre-diabetic state that may convert to the full disease at a rate of around 4% per year. Cases may need dietary treatment and will require prolonged and detailed follow up in order to continue aeromedical.

A remark: Glycosuria with normal glucose tolerance (low renal threshold) is acceptable for any certification

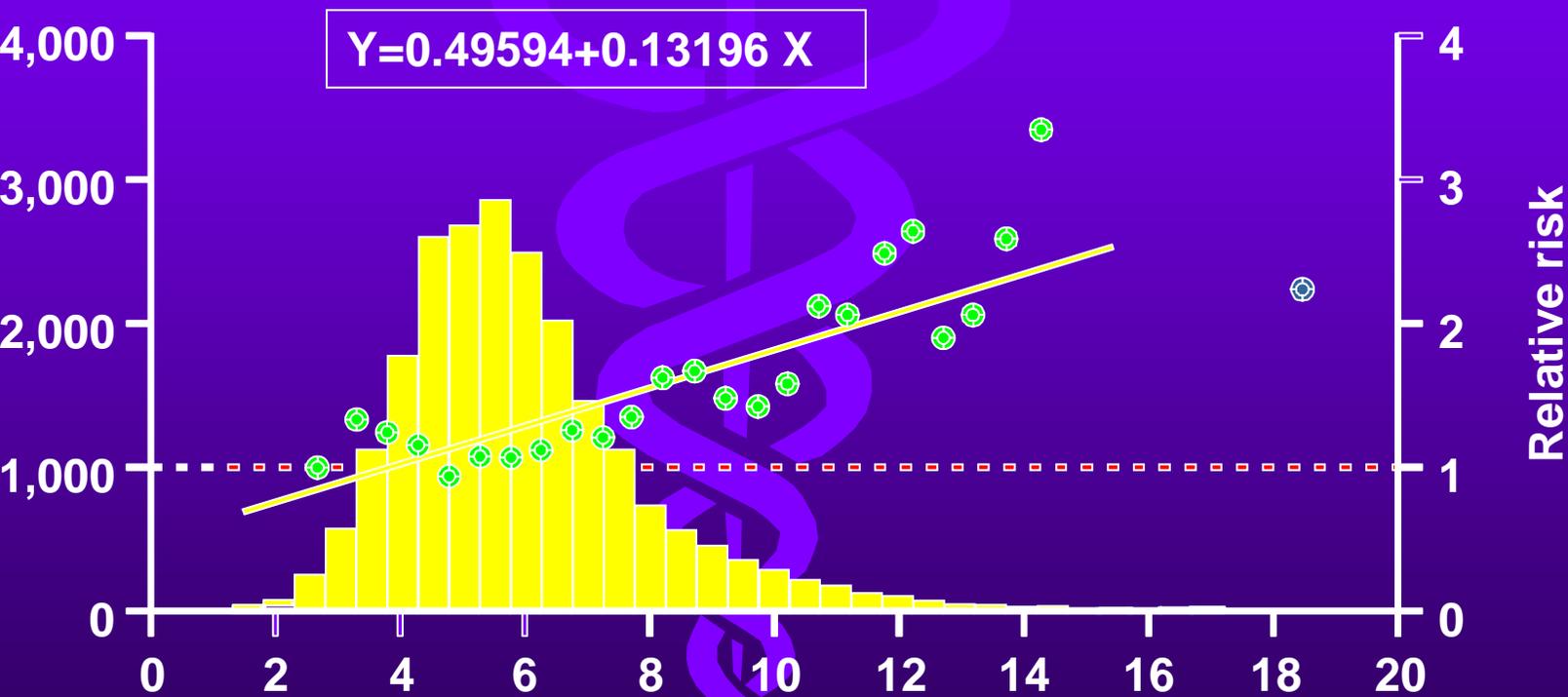
The continuum of glucose intolerance



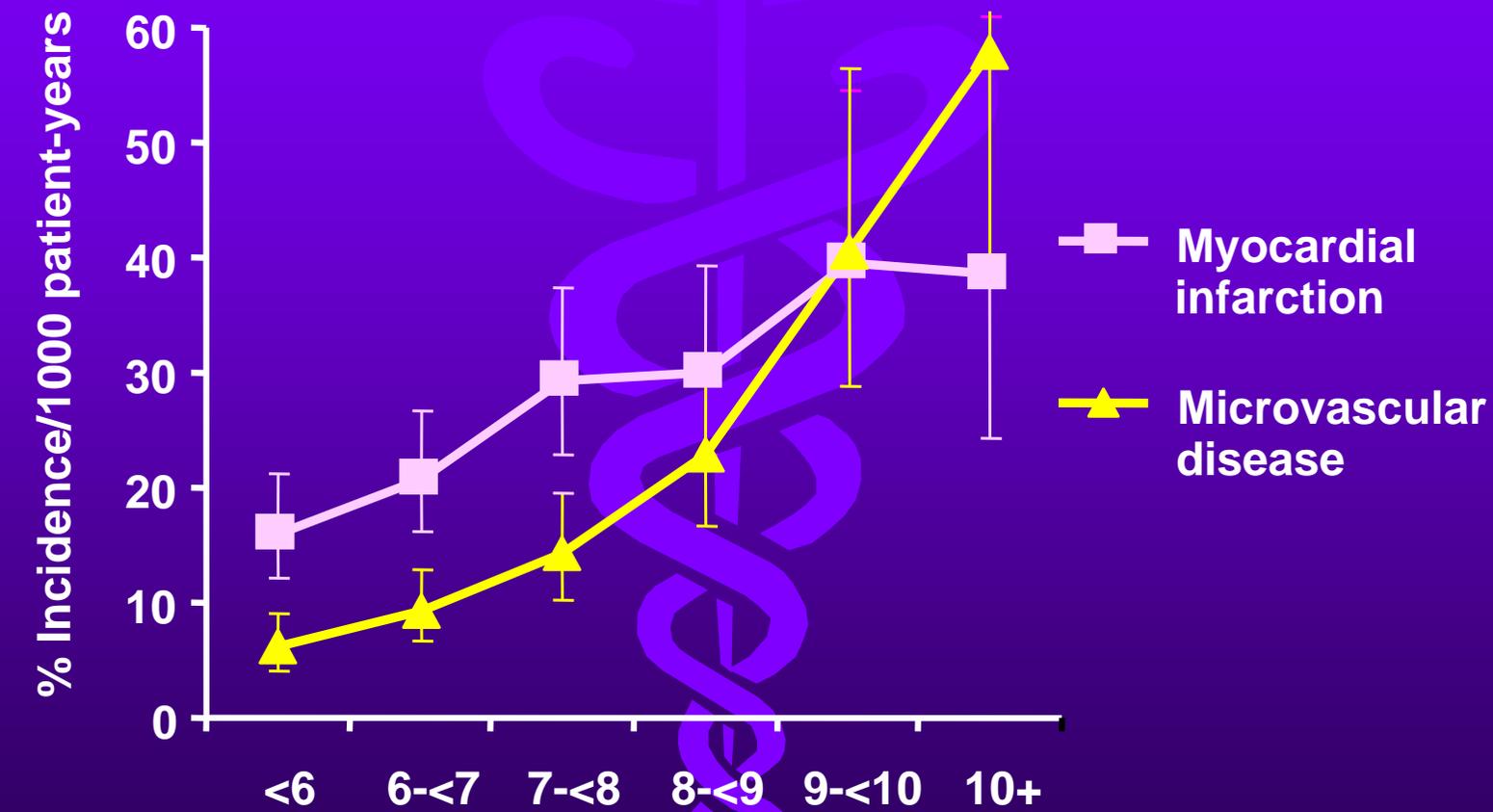
The worldwide pandemic of type 2 diabetes



All-cause mortality has a linear relationship with 2-hr plasma glucose



Hyperglycemia and complications in type 2 diabetes



Intervention to effect better control means fewer complications

EVERY 1%

reduction in HBA_{1c}

Reduced Risk*

Deaths from diabetes

-21%

Heart attacks

-14%

Microvascular complications

-37%

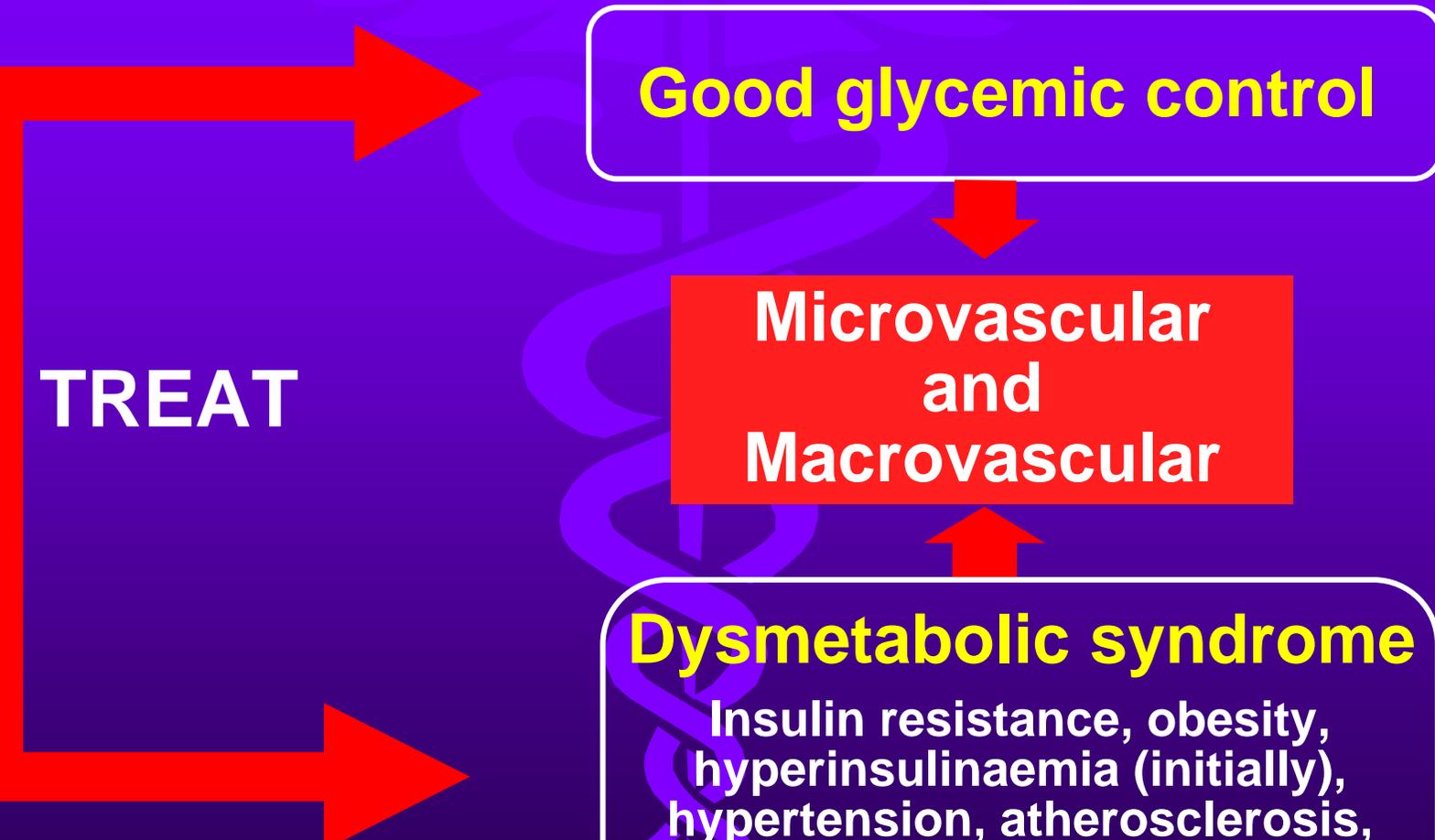
Peripheral vascular disorders

-43%

1%



**A HOLISTIC ATTITUDE AGAINST GLOBAL CV RISK:
treating both type 2 diabetes hyperglycemia and
metabolic syndrome**



DIABETES MELLITUS

This carbohydrate metabolic disorder is associated with many complications which may produce sudden incapacitation or grossly reduced performance and thus cause a serious risk to air safety.

Micro-angiopathic vascular damage is the common background for the coronary, brain and peripheral arterial disease which may contribute to a major aeromedical risk and may be related to the hyperlipidaemic effects of diabetes.

Diabetes-related cardiovascular risk varies depending on different estimates but is clinically significant and increases with the duration of the disease.

Macroangiopathy is associated with progressive retinal and renal damage. Neuropathy is also related to the long

DIAGNOSTIC CRITERIA

6 WHO + 2009 International Expert Committee Report
recommendations for the diagnosis of DM and disglycemia

BETES

fasting plasma glucose
plasma glucose*

>7.0 mmol/l – 126 mg/dl
> 11.1 mmol/l – 200 mg/dl

IMPAIRED GLUCOSE TOLERANCE

fasting plasma glucose
plasma glucose*

>7.0 mmol/l – 126 mg/dl
>7.8 mmol/l and <11.1 mmol/l
140 mg/dl and 200 mg/dl

When plasma glucose is not measured, status is uncertain as diabetes
IGT cannot be excluded

IMPAIRED FASTING GLUCOSE

fasting plasma glucose

5.6 mmol/l to 6.9 mmol/l
100 mg/dl to 125 mg/dl

7.0 mmol/l – 126 mg/dl

TYPE 1 Assessment

JAA Manual of Civil Aviation Medicine 1 June 2009

It should be noted that an apparent remission of insulin invariably ends in relapse and the applicant should not be neither certificated during such a remission or “honeymoon” period.

Type 1 diabetics are unfit to fly. The intrinsic risks of the disease itself are further increased by that of hypoglycaemia. No present injection regime or insulin infusion pumps are sufficiently efficient to act as an artificial pancreas.

Nevertheless, progress in such developments as islet transplantation or stem cells may require re-consideration in the future.

JAR-FCL 3.175 Class 1 - 3.295 Class 2 Amendment 5

(d) Applicants with diabetes requiring insulin shall be assessed as unfit.

**THIS IS THE “EUROPEAN” WAY TO
DIABETES CERTIFICATION...**

BUT

**THERE IS AN “AMERICAN” WAY TO
DIABETES CERTIFICATION!**

Medical Certification Guidelines for Pilots with Insulin-treated Diabetes FAA - USA

(very similar in Canada and Australia)

Terms and conditions have been adapted to European Organization

Restrictions on medical certification

Individuals may exercise only the privileges of a student, leisure, or private pilot certificate.

Individuals are prohibited from operating an aircraft as a required crewmember on any flight outside the airspace of the United States of America.

Exceptionally low risk ITDM who already holds a Class 1 medical certificated licence, may be considered for fitness for flight restricted to "as or with co-pilot", also as Airline Pilot in Command.

Evaluation of Individuals With Insulin-Treated Diabetes Mellitus

Individuals with ITDM who have no otherwise disqualifying conditions, especially significant diabetes-related complications such as arteriosclerotic coronary or cerebral disease, retinal disease, or chronic renal failure, will be considered as fit if they:

1. They had no recurrent (two or more) hypoglycemic reactions resulting in a loss of consciousness or seizure within the past 5 years. A period of 1 year of demonstrated stability is required following the first episode of hypoglycemia;

2. They had no recurrent hypoglycemic reactions requiring intervention by another person within the past 5 years. A period of 1 year of demonstrated stability is required following the first episode of hypoglycemia;

er to provide an adequate basis for an individual medical determination, the person with ITDM
g special issuance of a medical certificate must submit the following to CAA - AMS:

s of all medical records concerning the individual's diabetes diagnosis and disease history and
of all hospital records, if admitted for any diabetes-related cause, including accidents and injuries.

s of complete reports of any incidents or accidents, particularly involving moving vehicles, whether
the event resulted in injury or property damage, if due in part or totally to diabetes;

ts of a complete medical evaluation by an endocrinologist or other diabetes specialist physician
able to the AMS. This report should detail the individual's complete medical history and current
al condition. The report must include a general physical examination and, at a minimum, the
wing information:

Two measurements of glycated hemoglobin (total A1 or A1C concentration and the laboratory
nce normal range), the first at least 90 days prior to the current measurement;

A detailed report of the individual's insulin dosages (including types) and diet utilized for glucose
l;

Appropriate examinations and tests to detect any peripheral neuropathy or circulatory insufficiency
extremities;

Confirmation by an ophthalmologist of the absence of clinically significant eye disease. The eye
nation should assess, at a minimum, visual acuity, ocular tension, and presence of lenticular
ies, if any, and include a careful examination of the retina for evidence of any diabetic retinopathy
cular edema. The presence of microaneurysms, exudates, or other findings of background
opathy, by themselves, are not sufficient grounds for disqualification unless it prevents the subject
meeting visual standards. However, individuals with active proliferative retinopathy or vitreous
rhages will not be considered for special issuance of a medical certificate until the condition has
zed and this has been confirmed by an ophthalmologist; and

ication by a specialist that the individual has been educated in diabetes and its control and has been
ughly informed of and understands the monitoring and management procedures for the condition
e actions that should be followed if complications of diabetes, including hypoglycemia, should

ITDM individual applying for special issuance of a medical certificate should have been receiving appropriate insulin treatment for at least 6 months prior to submitting a request for special issuance of a medical certificate.

special medical flight test. If the AMS determines that there is need for an ITDM applicant to demonstrate his or her ability to comply with the medical protocol, it may require a special medical examination and/or medical flight test prior to a determination of the applicant's eligibility for special issuance of a medical certificate.

Guidelines for individuals with ITDM who have been granted special issuance of medical Certificates

Individuals with ITDM who are granted special issuance must:

Submit to a medical evaluation by an AMC every 3 months. This evaluation must include a complete physical examination and a report of glycated hemoglobin (total A1 or A1C) concentration. This evaluation shall also contain an assessment of the individual's continued knowledge and willingness to monitor and manage properly his or her diabetes and of whether the individual's diabetes or its complications could reasonably be expected to adversely affect his or her ability to safely control an aircraft.

Buy and use a digital whole blood glucose measuring device with memory that is acceptable to the CAA. Provide records of all daily blood glucose measurements for review by the specialist at each 3-month evaluation required above and, if required, to the CAA at the time.

Provide to the CAA, on an annual basis, written confirmation by a specialist that the individual's diabetes remains under control and without significant complications and that the individual has demonstrated reasonable accuracy and recordation of his or her blood glucose measurements with the above described device.

Provide to the CAA, on an annual basis, confirmation by an ophthalmologist of the absence of any clinically significant disease that would prevent the individual from meeting current FAA standards.

Provide to the CAA, immediately, a written report of any episode of hypoglycemia associated with cognitive impairment, whether or not it resulted in an accident or adverse event.

Provide a written report to the CAA, immediately, of involvement in any accidents, incidents, including those involving aircraft and motor vehicles, or other significant adverse events, whether or not they are believed related to an episode of hypoglycemia.

Provide to the CAA, immediately upon determination by a specialist or other physician, any

Glucose Management Prior to Flight, During Flight, and Prior to Landing

Individuals with ITDM shall maintain appropriate medical supplies for glucose management at all times while preparing for flight and while acting as pilot-in-command (or other flightcrew member). At a minimum, such supplies shall include:

• FAA-acceptable whole blood digital glucose monitor with memory;

• Supplies needed to obtain adequate blood samples and to measure whole blood glucose; and

• Amount of rapidly absorbable glucose, in 10 gram (gm) portions, appropriate to the potential duration of the flight.

All disposable supplies listed above must be within their expiration dates.

The individual with ITDM, acting as pilot-in-command or other flightcrew member, shall establish and document a

blood glucose concentration equal to or greater than 100 milligrams/deciliter (mg/dl) but not greater than 300 mg/dl

within 1/2 hour prior to takeoff. During flight, the individual with ITDM shall monitor his or her blood glucose

concentration at hourly intervals and within 1/2 hour prior to landing. If a blood glucose concentration range of 100-300

mg/dl is not maintained, the following action shall be taken:

Before flight

The individual with ITDM shall test and record his or her blood glucose concentration within 1/2 hour prior to takeoff. If

blood glucose measures less than 100 mg/dl, the individual shall ingest an appropriate 10 gm glucose snack (minimum 10

grams) and recheck and document blood glucose concentration after 1/2 hour. This process shall be repeated until blood

glucose concentration is in the 100-300 mg/dl range. If blood glucose concentration measures greater than 300 mg/dl, the

individual shall follow his or her regimen of blood glucose control, as provided to the CAA by his or her attending

physician, until the measurement of blood glucose concentration permits adherence to this protocol.

During flight

One hour into the flight, at each successive hour of flight, and within 1/2 hour prior to landing, the individual shall

measure and document his or her blood glucose concentration. Listed below are blood glucose concentration ranges and

actions to be taken when they occur during flight:

1) Less than 100 mg/dl: The individual shall ingest a 20 gm glucose snack and recheck and document his or her blood

glucose concentration after 1 hour.

2) 100-300 mg/dl: The individual may continue his or her flight as planned.

3) Greater than 300 mg/dl: The individual shall land as soon as practicable at the nearest suitable airport.

The individual, as pilot, is responsible for the safety of the flight and must remain cognizant of those factors that are

important in its successful completion. Accordingly, in recognition of such elements as adverse weather, turbulence, air

traffic control changes, or other variables, the individual may decide that a scheduled, hourly measurement of blood

glucose concentration during the flight is of lower priority than the need for full, undivided attention to piloting. In such

cases, the individual shall ingest a 10 gm glucose snack. One hour after ingesting of this glucose snack, the individual

shall measure and document his or her blood glucose concentration. If the individual is unable to perform the

measurement of his or her blood glucose concentration for the second consecutive time, the individual shall ingest a 20

**GUIDANCE MATERIAL TO SUPPORT THE PROPOSED CHANGE
TO THE MEDICAL PROVISIONS CONTAINED IN
ANNEX 1 – Personnel Licensing
ICAO State letter AN 5/22-08/33, dated 5 May 2008**

**Risk of severe hypoglycaemia among ID diabetics :
0.05 – 0.27 cases per patient per year; Bott & C. 1997**

**Incapacitation risk:
using the extrapolation for the pilot group one may estimate the rate
to be between 1 and 2 per cent per annum; O’Neill – Silberman 2008**

**Risk of subtle impairment of performance:
0.85 episodes/patient/week; Pramming 1991 – McLeod 1992**

From the literature review, the ID risk assessment is outside that which
would be acceptable in terms of the “1 per cent rule”. But taking into account the
that groups are highly selected, well motivated and meticulous in managing their
diabetes, some Contracting State certificate **Class 1 ID professional pilots limited
multicrew operation following selection criteria and monitoring procedures**

TWO COMPLETELY DIFFERENT APPROACHES

INDIVIDUAL RIGHT

VS

COMMON GOOD

PATIENT

VS

DISEASE

TYPE 2 Assessment

JAA Manual of Civil Aviation Medicine 1 June 2009

Periodic medical examination of type 2 diabetics involves:

regular weight measurements;

(excellent Body Mass Index less than 25);

control of diet and hypoglycaemic drugs use (insulin in occasional resistant cases is disqualifying);

control of blood glucose, lipids, urine test, blood pressure and any other risk factor (e.g. smoking);

careful examination to exclude common complications of diabetes

TYPE 2 Assessment

JAA Manual of Civil Aviation Medicine 1 June 2009

crew should undergo careful review of the following in addition to the periodic medical examination:

regular ophthalmoscopy after pupillary dilation to check for retinopathy and lens or vitreous opacities;
CNS examination for evidence of neuropathy;
cardiological review with consideration of exercise electrocardiography;
periodic blood tests including glycosylated haemoglobin (HbA1: <6.5%) or serum fructosamine, renal function, liver function and plasma proteins, fasting blood lipids;
periodic urinary test for early renal damage detection

TREATMENT AND CERTIFICATION

DIRECTLY OR INDIRECTLY INCREASE INSULIN SENSITIVITY

biguanides (Metformin)

Class 1 OML
Class 2 unrestricted

thiazolidinediones (Glitazones)

rosiglitazone – at present suspended by UE
(rosiglitazone)

Class 1 OML
Class 2 unrestricted

glucocorticoid receptor agonists:
(glucocorticoid agonists)

in the horizon

Will probably have an important
role in managing Type 2 diabetes
within a few years like glitazones

ALPHA-GLUCOSIDASE INHIBITORS

use

TREATMENT AND CERTIFICATION

INCREASE CIRCULATING INSULIN

thonylureas

Not acceptable Class 1
Acceptable Class 2 OSL

inides (nate- or repaglinide)

Not acceptable Class 1
Acceptable Class 2 OSL
may require re-consideration in
the future

agon-like peptide-1 (GLP1) analogues/mimetics

Not easily not acceptable due to parenteral administration
May require re-consideration in the future

ptidase IV inhibitors (DPP4-I)

Oral administration.

May require re-consideration in the future

*Thank you
for your
attention!*

