Insulin-dependent diabetes and aeromedical certification — the Australian perspective

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ABSTRACT

- Whether pilots with insulin-dependent diabetes should be allowed to fly has long been a controversial issue.
- Hypoglycaemia remains a significant threat to flight safety, and a barrier for pilots with insulin-dependent diabetes to overcome.
- Some countries allow recreational pilots to fly while treated with insulin under strict conditions.
- Recent changes in aeromedical certification in Australia will give pilots with diabetes more freedom to exercise the privileges of their licence, while adopting mechanisms to ensure the safety of air navigation.

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The International Civil Aviation Organization defines aviation medicine as:

> a medical specialty which combines aspects of preventive, occupational, environmental and clinical medicine with the physiology and psychology of man in flight. It is concerned with the health and safety of those who fly, both crew and passengers, as well as the selection and performance of those who hold aviation licenses.[1]

It is also concerned with third-party risk on the ground. In Australia, civil aviation medicine — and in particular, the medical certification of pilots — is practised under the jurisdiction of the Civil Aviation Safety Authority (CASA). There are three levels of aeromedical certification in Australia

- Class 1 — for professional pilots;
- Class 2 — for private and recreational pilots; and
- Class 3 — for air traffic controllers.

In assessing fitness of pilots to fly, aviation medicine practitioners consider the overall risk that the applicant's medical condition presents to aviation safety, and the utility and reliability of risk mitigation efforts. Assessment takes into account a range of factors including the individual's age; amount and currency of experience; medical condition, treatment and possible side effects; and the type and extent of flying that he or she intends to undertake.

The steps involved in making aeromedical decisions include:

- assessing the pilot's functional capacity;
- determining the likelihood of a clinical event;
- determining the likelihood of an undesirable aviation outcome;
- determining the acceptability of the risk;
- determining the risk after likelihood modification; and
- managing the consequences and determining the risk after consequence modification.

In terms of aeromedical legislation, the clinical specialist helps to identify whether the condition is relevant to air safety and then contributes to the store of information about prognostic probabilities. This clinical information is vital in the next step of the process, which is to make an occupational risk management decision. This aeromedical decision requires a very different set of information, skills and expertise from that required for clinical decisions.

Diabetes and aviation

The relationship between diabetes and aviation has been emotive and controversial, with a perception of conflict between individual rights and the need for aviation safety. Traditionally, flying and the use of insulin have been considered incompatible. Primary concerns encompass the impact on performance of in-flight hypoglycaemia and aeromedically relevant complications such as ischaemic heart disease and diabetic retinopathy.

The consequences of gross hypoglycaemia with unconsciousness or confusion occurring during a flight are potentially catastrophic. In addition, studies such as those conducted in driving simulators confirm clinical observation that even mild to moderate hypoglycaemia (blood glucose level [BGL], 2.6–3.6 mmol/L) impairs cognition.[2] Such a situation could be disastrous in the context of flying.

In the past, CASA has limited certification of insulin-dependent pilots to Class 2 (private pilot) only, with a requirement that they always be accompanied by a safety pilot as a backup in case of hypoglycaemic events. Thirty-seven people have been issued Class 2 certification under these requirements. As of April 2010, only six of these have remained active pilots. To date, only one pilot with diabetes has been allowed to fly in Australia without a safety pilot, and only under strict conditions imposed following review by the Administrative Appeals Tribunal.[3] Other such appeals have been unsuccessful.[4]

Regulators in other countries have been more liberal in their certification. In the United States, the Federal Aviation Administration (FAA) allows a private pilot level of certification without the requirement for a safety pilot, as long as the pilot meets certain entry criteria and adheres to a strict regimen of pre-flight and in-flight monitoring, with ingestion of glucose snacks as required to keep in-flight BGLs in the 100–300 mg/dL (5.5–16.0 mmol/L) range. The aim of this protocol is to use a diabetic "sweet" to minimise the most acute risk to aviation safety posed by in-flight hypoglycaemia. However, this raises ethical issues in making a trade-off between the pilot's optimal health and the freedom to fly.

To date, Australia has not adopted such a protocol. One reason for this is that, although the FAA protocol has been in place for some time, it has not been extensively monitored or reviewed regarding whether it reliably ensures safe in-flight BGLs. The only published outcome measures have been the number of accidents in the cohort of pilots with diabetes flying by the protocol. In CASA's view, this is an inadequate measure, as it relies on the occurrence of serious outcomes that it is CASA's role to prevent. There have been no published data to confirm that the FAA protocol does in fact keep in-flight BGLs within the parameters as designed, nor are there any data analysing the frequency of in-flight hypoglycaemic episodes of the cohort.

Australian protocol for monitoring BGLs during flight operations

When the pilot must measure his or her BGL	BGL	Action that the pilot must take
30 minutes before flight*	> 15 mmol/L	Cancel flight
	5–15 mmol/L	Undertake flight
	< 5 mmol/L	Ingest a 15 g glucose snack and measure BGL 30 minutes later
30 minutes after glucose snack, when first measurement < 5 mmol/L	> 15 mmol/L	Cancel flight
	5–15 mmol/L	Undertake flight
	< 5 mmol/L	Ingest a 15 g glucose snack and measure BGL 30 minutes later
30 minutes into the flight, at each successive hour of flight, and within 30 minutes of landing†	> 15 mmol/L	Land at the nearest suitable airport; resume flight when BGL can be maintained in the 5–15 mmol/L range
	5–15 mmol/L	No action required
	< 5 mmol/L	Ingest a 30 g glucose snack and arrange to land at the nearest suitable airport; resume flight when BGL can be maintained in the 5–15 mmol/L range

BGL = blood glucose level. * The pilot should not commence flight within 90 minutes of administering insulin. † When determining BGLs during flight, the pilot must use judgement in deciding whether measuring concentrations or the operational demands of the environment (eg, adverse weather conditions) should take priority. If the pilot decides that operational demands take priority, he or she must ingest a 15 g glucose snack and measure BGL 1 hour later. If measurement is not practical at that time, the pilot must ingest a 30 g glucose snack and land at the nearest suitable airport to measure his or her BGL. ◆

The Australian protocol

In mid 2009, CASA, in conjunction with the Civil Aviation Authority of New Zealand, convened a workshop that was attended by aviation medicine experts from both countries, occupational medicine specialists, endocrinologists and other members of the industry. The aim was to design a protocol for Australian pilots with diabetes that would satisfy CASA's responsibility for regulating aviation safety while allowing increased freedom for such pilots. The workshop used the FAA design as a basis for the Australian protocol, with some modifications to increase the assurance of reliability and safety. The basic protocol that emerged from the workshop was then modified further, particularly regarding its operational application.

Some significant safety caveats have been incorporated into the Australian protocol. In particular, given the wide individual variability in insulin treatment and diabetic control, the Australian protocol requires each individual pilot to submit to a lead-in period of at least 15 flights with a safety pilot. This will allow CASA to assess the pilot's ability to comply with the protocol and maintain safe in-flight BGLs before he or she can fly solo. The requirement for 15 supervised flights will give CASA an *individualised* evidence base that recognises individual variability and ensures that each pilot is capable of maintaining BGLs within safe parameters.

As the protocol will be assessed on an individual basis, the pilot will need to discuss the protocol with his or her treating physician and obtain advice on the best combination of food intake and medication to optimise glycaemic control without adversely affecting safety.

Another significant safety requirement of the Australian protocol is that if an in-flight BGL reading is lower than 5 mmol/L, the pilot should, at the same time as attempting to rectify the hypoglycaemia with glucose, divert the flight to the nearest operationally suitable aerodrome until the BGL can be once again maintained in the 5–15 mmol/L range.

Entry criteria

To apply for entry to the protocol, pilots will need to provide medical information to CASA, including:

- medical records and history of any accidents or incidents related to diabetes;
- up-to-date reports from their treating endocrinologist detailing current treatment, control and presence of any complications;
- a record of their serial glycated haemoglobin (HbA_{1c}) levels;
- a BGL diary in electronic format;
- certification that they have completed their diabetes education; and
- if aged > 40 years, a stress electrocardiogram test result.

Some indicative entry criteria to the protocol include an HbA_{1c} level between 6.5% and 8.0%, and blood glucose analysis (over a 3-month period immediately before the time of application) with no more than 5% of readings below 4 mmol/L, and 80% of readings between 5 mmol/L and 15 mmol/L.

Individuals with more frequent hypoglycaemic episodes and those with demonstrated hypoglycaemic unawareness are considered at higher risk of impairment and will be unlikely to meet the criteria for entry to the protocol. Individuals with significant complications, such as diabetic retinopathy, ischaemic heart disease, advanced renal disease or autonomic neuropathy, may also be assessed as unfit.

At entry stage, certification will only be considered for private pilot-level (not commercial) operations under conditions where day visual flight rules apply (ie, when there is clear visibility without lights). Individuals will be assessed on a case-by-case basis.

If accepted into the cohort, the applicant will initially receive Class 2 certification valid for flight with a safety pilot only. To remove the safety-pilot requirement, the applicant must carry out the in-flight requirements of the protocol (Box) in a two-pilot situation for at least 15 flights — CASA will tailor the types of flights and durations to meet individual requirements. The applicant must then provide the on-ground and in-flight data to CASA for assessment. CASA will review the in-flight data, and if BGL control is deemed adequate to prevent in-flight hypoglycaemia or hyperglycaemia, the pilot will be allowed to fly solo.

Monitoring BGLs during flights

During flight, pilots accepted into the protocol must:

- carry two BGL recording devices (a primary and a backup);
- have computer download facilities;
- monitor their BGLs regularly; and
- administer glucose and take operational action if their BGL falls below 5 mmol/L (Box).

A flight should not be commenced within 90 minutes of insulin administration. The full protocol in its current form is available on the CASA website at http://www.casa.gov.au/wcmswr/_assets/main/avmed/download/casainsulinprotocol.pdf.

Follow-up and ongoing certification

Under the protocol, pilots with diabetes must be reviewed by their treating endocrinologist at regular intervals and rigorously monitor their BGLs. Each year, in conjunction with their standard aeromedical examination, pilots will need to submit their in-flight BGL results for the year, which CASA will scrutinise. If a pilot fails to maintain safe in-flight BGLs or to meet the requirements of the protocol, CASA may review the pilot's certification and modify the specific requirements for the individual, so as to optimise safety. In serious cases, CASA may remove the pilot from the protocol cohort.

Aeromedical certification will be restricted to 12 months, and renewal will depend on the pilot's yearly aeromedical assessment, as well as endocrinology reports, serial HbA_{1c} measurements and regular ophthalmological and cardiological assessments. At each annual assessment, the pilot must also provide CASA with a record of all in-flight measurements and log book entries for all flights undertaken since the last certificate.

Any significant hypoglycaemic episodes requiring assistance and any accidents or incidents related to diabetes must be reported immediately to CASA.

CASA aims to review and publish relevant data from the insulin-dependent cohort regularly as a mechanism for review of the safety of the elements of the protocol, at both an individual and a cohort level. Data to be kept and reviewed will include:

- the number of pilots in the cohort;
- the total number of hours flown;
- the number of in-flight BGL readings outside the 5–15 mmol/L range;
- the number of pilots removed from the cohort and reasons for removal; and
- accident and incident rates.

CASA is taking positive, evidence-based steps to increase the freedom of pilots with diabetes to exercise the privileges of their licences. At the same time, to meet its responsibility as Australia's aviation regulator, CASA will regard the safety of air navigation as the most important consideration.

The protocol outlined has been devised for aviation, and has many aviation-specific requirements. However, the principles can apply to any safety-sensitive workers with type 1 diabetes, and the protocol could be suitably modified for use in any safety-sensitive industry.

Competing interests

None identified.

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