Managing Insulin Therapy in Ambulatory Care Settings

The Guiding Principles for Managing Insulin in Ambulatory Care Settings: A Quality Use of Medicines Strategy

Australian Diabetes Educators Association
Foreword

ADEA advises this is an interim document pending release of the final HWA Health Professional Prescribing Project (HPPP) report and recommendations due for publication in June 2013.
Acknowledgements

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The Working Group would like to acknowledge the contributions of the ADEA members and stakeholders during the draft consultation process.

Editing of the Interim National Standards for Developing and assessing the Quality of Services: Initiating Insulin Therapy in Ambulatory Settings (Standards) was undertaken by Giuliana Murfet and Tracy Aylen.
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## Acronyms and Definition of Terms

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<tr>
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<th>Definition</th>
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<tbody>
<tr>
<td>ABS</td>
<td>Australian Bureau of Statistics</td>
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<td>ADEA</td>
<td>Australian Diabetes Educators Association</td>
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<td>ADIPS</td>
<td>Australasian Diabetes in Pregnancy Society</td>
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<td>ADS</td>
<td>Australian Diabetes Society</td>
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<td>AHPRA</td>
<td>Australian Health Practitioner Regulatory Agency</td>
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<td>AIHW</td>
<td>Australian Institute of Health and Welfare</td>
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<td>Australian Medical Council</td>
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<td>ANF</td>
<td>Australian Nurses Federation</td>
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<td>APD</td>
<td>Accredited Practicing Dietitian</td>
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<td>APNA</td>
<td>Australian Practice Nurses Association</td>
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<td>DAA</td>
<td>Dietitians Association of Australia</td>
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<td>DCCT</td>
<td>Diabetes Control and Complications Trial</td>
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<td>DOHA</td>
<td>Department of Health and Aging</td>
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<td>EN</td>
<td>Enrolled Nurse</td>
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<td>GDM</td>
<td>Gestational Diabetes Mellitus</td>
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<tr>
<td>HbA1c</td>
<td>Haemoglobin A1c, glycosylated haemoglobin, A1c, glycated haemoglobin</td>
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<td>HMR</td>
<td>Home Medicines Review</td>
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<td>HRM</td>
<td>High Risk Medicine</td>
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<td>IDF</td>
<td>International Diabetes Federation</td>
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<td>IFG</td>
<td>Impaired Fasting Glucose</td>
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<td>IGT</td>
<td>Impaired Glucose Tolerance</td>
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<td>MI</td>
<td>Myocardial Infarction</td>
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<td>NDSS</td>
<td>National Diabetes Services Scheme</td>
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<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<td>NMBA</td>
<td>Nursing and Midwifery Board of Australia</td>
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<tr>
<td>NP</td>
<td>Nurse Practitioner</td>
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<td>NPS</td>
<td>National Prescribing Service</td>
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<td>NRAS</td>
<td>National Registration and Accreditation Scheme</td>
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<td>ODA</td>
<td>Oral Diabetes Agents</td>
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<td>RACGP</td>
<td>Royal Australian College of General Practitioners</td>
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<td>RN</td>
<td>Registered Nurse</td>
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<td>SMBG</td>
<td>Self - monitoring blood glucose</td>
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<td>T2DM</td>
<td>Type 2 diabetes mellitus</td>
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<td>T1DM</td>
<td>Type 1 diabetes mellitus</td>
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<td>UKPDS</td>
<td>United Kingdom Prospective Study</td>
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<td>UTI</td>
<td>Urinary tract infection</td>
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<td>QUM</td>
<td>Quality Use of Medicines</td>
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<td>VMAC</td>
<td>Victorian Medicines Advisory Committee</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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Definition of terms

Accredited Practising Dietitian
Accredited Practising Dietitians (APDs) are health care professionals who have been recognised by the DAA as having the qualifications and skills to assess an individual's eating behaviour in order to recommend the most appropriate medical nutritional therapy. Medical nutrition therapy involves assessing the biological and physiological parameters of diseases in relation to nutrition and assists in the management of a wide range of conditions including diabetes, heart disease, cancers, gastrointestinal diseases, food allergies, food intolerances as well as weight management issues. (See Appendix 1)

Accredited Exercise Physiologist
Accredited Exercise Physiologists are allied health care professionals who have been recognised by Exercise and Sports Science Australia (ESSA) as specialists in clinical exercise interventions for persons at high risk of developing or with existing chronic disease and complex medical problems or injuries. Interventions are provided by exercise delivery including health and physical activity education, advice and support and lifestyle modification with a strong focus on achieving behavioural change. (See Appendix 1)

Australian Health Practitioner Regulation Agency (AHPRA)
AHPRA’s operations are governed by the Health Practitioner Regulation National Law, as in force in each state and territory, which came into effect on 1 July 2010. This law governs 14 health professions regulated by nationally consistent legislation under the National Registration and Accreditation Scheme (NRAS).
AHPRA supports the 14 National Boards responsible for regulating the health professions. The primary role of the National Boards is to protect the public and they set standards and policies that all registered health practitioners must meet.

Ambulatory care
Ambulatory care is care that takes place as a day attendance at a health care facility, at the consumer’s home or other agreed location and includes care provided in general practice, private clinics, community health centres, home care services, district nursing services and outpatient services attached to hospitals. The term incorporates primary, secondary and tertiary level services provided to individuals or populations (Victorian Government Department of Human Services, 2005).

Carer
A carer is a person who provides unpaid care and support to family members and friends who have a disability, mental illness, chronic condition, terminal illness or who is frail aged (Carers Australia, 2012).

Competence/competencies
Competence is broadly defined as ‘…the state of having the knowledge, skills, energy, experience and motivation required to respond to the demands of one’s professional responsibilities.’ (Roach, 1992). Competencies help individuals achieve and maintain effective safe practice.

Competency framework
Competency framework refers to a group of inter-related competencies that are essential to effective, safe practice.

Credentialled Diabetes Educator
Credentialled Diabetes Educators (CDEs) are health care professionals who are recognised by the ADEA as having the qualifications, expertise and experience to integrate diabetes self-management education with clinical care as part of a therapeutic intervention to promote physical, social and psychological well-being in a variety of practice settings and roles, and across the intervention and care continuum within the five domains of Clinical Practice, Research, Education, Counselling and Leadership and Management. (See Appendix 1)
**Diabetes Educator**
Diabetes educators are health care professionals from differing disciplines who have a core body of knowledge and skill in the biological and social sciences, principles of teaching and learning, communication and counselling, as well as experience and advanced knowledge in the care of people with diabetes and those at risk of diabetes, and have diabetes education included in the scope of their employment. (See Appendix 1)

**Enrolled nurse**
The Enrolled Nurse (EN) is a health care professional recognised by the AHPRA as having the qualification, skills and knowledge to practice patient-centred care as an associate to the RN. Enrolled Nurses may apply to AHPRA for medication endorsement if they meet the required criteria. (See Appendix 1)

**Health capability**
Nutbeam defined health capability as: one that embraces actions directed at strengthening the skills and capabilities of people and also those directed towards changing social, environmental and economic conditions that create and sustain health (Nutbeam, 1998).

**Health Literacy**
Health literacy is the ‘degree to which individuals can obtain, process and understand the basic health information and services they need to make appropriate health decisions’ (Australian Commission on Safety and Quality in Healthcare, 2012).

**High risk medicine**
A High Risk Medicine (HRM) is a medicine that carries increased risk of causing significant or catastrophic harm when used in error and includes both low therapeutic index medicines that present a high risk when administered via the wrong route or when other systems errors occur. Insulin is classified as a high risk medicine.

**Medical Practitioner**
A Medical Practitioner (doctor) is a health care provider who has been recognised by the AHPRA as having the qualifications, knowledge and skills to practice medicine and has a current licence to practice. (See Appendix 1).

**Medicine management**
The definition of medicine management may depend on the circumstances and context in which the term is used. For example, a Department of Health may describe specific components such as clinical cost effectiveness and safe and secure handling of medicines. A simpler way of thinking about medicines management is that it is about enabling people to make the best possible use of medicines.

**Medicine-related adverse event**
Unwanted and usually harmful outcomes which may or may not be related to the medicine, adverse events can occur with high risk medicines even when the medicine is used as intended.

**Nurse Practitioner**
A Nurse Practitioner (NP) is a Registered Nurse educated and authorised by AHPRA to function autonomously and collaboratively in an advanced and extended clinical role within the context which the NP is licensed to practice.

**Person**
The term person in this document used to denote a person with diabetes and/or their family or carer(s).
Pharmacist
A Pharmacist is a health professional who has been recognised by AHPRA as having the qualification, skills and knowledge and skills assist members of the community to optimise health outcomes from use of medicines. (See Appendix 1)

Podiatrist
A Podiatrist is a health care practitioner who has been recognised by AHPRA as having the qualifications and skills to diagnose and treat specific foot and lower limb conditions. (See Appendix 1)

Prescribing
Prescribing is an iterative process involving the steps of information gathering, clinical decision making, communication, and evaluation that results in the initiation, continuation, or cessation of a medicine (Nissen et al 2010). The health professional prescribing or accepting such delegated responsibilities must have the relevant education and competency to perform the tasks, hold current licence/authorisation to practice and operate within National and State-based regulatory frameworks, including the relevant Drugs, Poisons and Controlled Substances Acts and regulations.

Quality Use of Medicines (QUM)
The definition of QUM applies equally to decisions about medicine use by individuals and decisions that affect the health of the population. The term ‘medicine’ includes prescription, non-prescription and complementary medicines and incorporates the following principles:
- Selecting management options wisely;
- Choosing suitable medicines if a medicine is considered necessary; and
- Using medicines safely and effectively.

Role
Prescribed or expected professional behaviour associated with a particular position or employment status.

Registered Nurse
A Registered Nurse (RN) is a health care professional recognised by AHPRA as having the qualifications, skills, and knowledge to independently and interdependently assume accountability and responsibility for the provision of nursing care and has a current licence to practice. (See Appendix 1)

Scope of Practice
Scope of practice defines the professional boundaries within which health care professionals may practice. Scope of practice is determined by standards and legislative frameworks, governance through professional registration and/or the employing organisation, together with the individual professional’s health care training, competencies, experience and level of expertise.

Specialist diabetes team
A team of diabetes health professionals working in both an interdisciplinary and multidisciplinary manner comprising medical specialists, nursing and allied health in a secondary or tertiary diabetes centre, whose focus is to provide care to people with diabetes who have acute and complex care needs, women with diabetes in pregnancy, those with T1DM and all children and young people with all types of diabetes (Australian Capital Territory Health, 2008).

Tertiary Diabetes Centre
A Diabetes Centre acknowledged as meeting the criteria for accreditation by the National Association of Diabetes Centre’s as a Tertiary Diabetes Centre and/or a hospital based Diabetes Centre that meets the accreditation requirements.
Executive Summary

The Guiding Principles for Initiating Insulin in Ambulatory Care Setting: a Quality Use of Medicines Strategy (Guiding Principles) was developed as a conceptual framework and guide to the National Standards for the Development and Quality Assessment of Services; Initiating Insulin in the Ambulatory Care Setting (Standards).

A DEA convened a Working Group with representation from within the ADEA and from external stakeholders involved in medication management and prescribing to review the 2004 Standards. The Working Group was tasked with reviewing and updating the Standards to ensure the revised document:
- conformed to relevant Australian Commonwealth, State and Territory legislation
- is informed by current evidence
- reflected the current diabetes education practice environment
- is consistent with Australian safety and quality frameworks and the Quality use of Medicines (QUM)

While the Standards address outcomes, process and structure of programs for insulin initiation in the ambulatory setting, the Guiding Principles were developed as a companion document to promote the quality use of insulin and to achieve optimal blood glucose management for people with diabetes, with particular focus on the use of insulin with T2DM.

Insulin is classified as a high-risk medicine because it can cause severe and adverse harm. Effective insulin initiation, education and management require the collaborative effort of an interdisciplinary team of health professionals working with the person with diabetes. In addition, the person with diabetes must have the relevant knowledge, skills and support to take responsibility for their day-to-day diabetes care.

In most cases, people with T1DM, especially children, require the involvement of specialist advice from a tertiary diabetes centre. There are NHMRC evidence based guidelines for T1DM in adults, adolescents and children. The Guiding Principles were designed to supplement (not replace) existing algorithms and targets for achieving optimal blood glucose control in people with T2DM.
The Australian Diabetes Educators Association

The Australian Diabetes Educators Association (ADEA) was formed in 1981 and is the leading Australian organisation for health care professionals providing diabetes education and care.

The Australian Diabetes Educators Association (ADEA) is committed to improving the health outcomes of people with diabetes by establishing and promoting evidence-based diabetes assessment, education, management and interdisciplinary care. In addition this approach engages people with diabetes and their families in deciding how these parameters translate to individual needs, targets and preferences to achieve holistic care.

Diabetes education and management are key therapeutic interventions that enable informed self-care, which is essential to achieving optimal health outcomes and appropriate service use. Health professionals require a specific core body of knowledge and competencies to deliver effective diabetes education and management.

The ADEA developed a Credentialling and Continuing Professional Development program denoting a Credentialled Diabetes Educator (CDE) as a health care provider who achieved a specialist level of practice in diabetes education through their academic qualifications, competence, commitment to professional development and duration of supervised clinical experience to perform the role of diabetes education and care.
Background to the Guiding Principles for Initiating Insulin in Ambulatory Care Settings: a Quality use of Medicines Strategy

Initially a philosophical framework was created to underpin the Guiding Principles for Initiating Insulin in Ambulatory Settings. The philosophical framework was derived from a review of the relevant literature, discussions with expert clinicians and with people with T2DM.

Philosophical Framework

1. The person with diabetes has a right to receive insulin-related education from health professionals accessing evidence based guidelines with relevant training in insulin initiation and self-management education and the ability to provide follow up advice and education.
2. Insulin is a high risk Schedule 4 medicine (see definition). Health professionals should only undertake insulin management tasks that fall within the level of their knowledge, competence, education, role and scope of practice and the legislation/regulations governing their practice.
3. Health professionals should only delegate insulin initiation, education and ongoing dose management responsibility to another health professional that has the appropriate knowledge, education, competency and scope of practice.
4. Safety and quality use of medicine (QUM) are of paramount importance.
5. Insulin initiation, education, ongoing dose management and review should be encompassed within QUM.
6. The medicine management plan must be individualised to suit the person with diabetes, considering their capabilities, preferences and individual circumstances (for example, cultural or diversity considerations, co-morbidities, polypharmacy).
7. The insulin regimen should be developed in collaboration with the person with diabetes.
8. Education, support and evaluation at follow up are essential.
9. Maintaining a healthy diet and regular physical activity, individualised to the person’s needs, is a key component of successful medicine management and prevention of complications.

Development of the Guiding Principles

The context

The prevalence and incidence of people diagnosed with T2DM is continuing to increase. Longer duration of T2DM is associated with beta cell destruction and increasing need to add insulin therapy to the management regimen. Initiation of insulin in T2DM is no longer considered last resort and more than 300,000 Australians with T2DM are now eligible to access insulin consumables through the NDSS.

With a focus on primary care services and the majority of people with T2DM already managed in the primary care sector, ambulatory initiation of insulin in T2DM is rapidly moving from outpatient care facilitated through diabetes specialist teams (usually located in a hospital) to being undertaken through community health, in general practice and through independently practicing health professionals.
The Working Group

ADEA convened a working group with representation from within the ADEA and from external stakeholders involved in medication management and prescribing. The Working Group was tasked with reviewing and updating the National Standards for the Development of Quality Assessment of Services Initiating Insulin in the Ambulatory Setting.

The process

A literature review focusing on ambulatory initiation particularly in T2DM was undertaken. The time period searched was from 2003 to 2010 (inclusive). The Working Group read relevant publications carefully and decided which information needed to be incorporated based on clinical need, the guiding principles and legislative requirements into the revised Standards. The following databases and search terms were used.

Databases: MEDLINE, PSYCHINFO, Cochrane database of Systematic Reviews, Joanna Briggs and hand searching the reference lists to identify relevant publications since 2004.

Search terms: standards, insulin, guidelines, safety, professional, practice, type 2 diabetes and combinations of these terms.

The Working Group was tasked with reviewing and updating the Standards to ensure the revised document:

- Conformed to relevant Australian Commonwealth, State and Territory legislation.
- Is informed by current evidence.
- Reflected the current diabetes education practice environment.
- Is consistent with Australian safety and quality frameworks and the Quality use of Medicines (QUM).

A total of nine (9) teleconferences were scheduled from February 2010 to April 2011. In addition, the Working Party met face-to-face for one day workshop in October 2010.

The final document, the Guiding Principles is the result of many hours of research, discussion, collaboration and voluntary contribution and was a collaborative effort of written feedback on drafts and revisions until consensus was reached. Prior to publication, major Australian guidelines were released on the management of T1DM in children, adolescents and adults. References to these guidelines and some additional publications from 2011 to 2012 have been included.
Guiding Principles

The Guiding Principles were developed to guide health professionals working in ambulatory health care settings to safely initiate insulin for people with diabetes. In most cases people with T1DM especially children, pregnant women with preexisting diabetes and women with GDM require specialist care and advice and it is strongly recommended that insulin initiation and management in these groups of patients occurs through, or in close liaison with, a specialist diabetes team at a tertiary diabetes centre.

These guiding principles represent the values that underpin the consensus recommendations and standards described in the document.

- Insulin should be initiated and monitored to provide consistent, safe and effective care in a legally and ethically appropriate manner.
- Choice of insulin regimen is determined according to the individual person’s circumstances, needs and management goals.
- The person should be involved in decisions about insulin. Their values, care preferences, and needs must be ascertained and respected and their dignity, privacy and autonomy maintained.
- Ambulatory initiation of insulin therapy requires a collaborative and interdisciplinary approach to provision of diabetes education and care by a team of health care professionals with specialist diabetes knowledge and experience.
- The person with diabetes is primarily responsible for managing their disease through applying self-care knowledge and daily self-care practices; therefore they are included in all aspects of diabetes management, care and education.
- Organisations and health care professionals have a responsibility to ensure that service delivery complies with standards, best-practice and legislative requirements.

Contextual setting

Medicine use in the Australian population is high. The Australian Bureau of Statistics (ABS) reported 70% of the overall population and 90% of people over age 65 used at least one prescription medicine (ABS 1999). The prevalence and incidence of people diagnosed with T2DM is continuing to increase and they often require multiple medicines to control high blood glucose levels and associated co-morbidities such as hypertension and dyslipidaemia. Longer duration of T2DM is associated with beta cell destruction and increasing need to add insulin therapy to the management.

Self-reported data on medicine use from the 2004–05 National Health Survey indicates that 21% of people with diabetes were using insulin and 68% were using other pharmaceutical medicines (Australian Institute of Health and Welfare, 2008). Initiation of insulin in T2DM is no longer considered last resort and more than 300,000 Australians with T2DM are now eligible to access insulin consumables through the NDSS. Insulin use increased three-fold between 1990 and 2004 (Australian Institute of Health and Welfare, 2006) and could reflect the move towards achieving optimal metabolic control (HbA1c less than 7% [53 mmol/mol]) following the release of the results of the Diabetes Control and Complications Trial (DCCT) in 1993 and United Kingdom Prospective Study (UKPDS) in 1998.

Insulin is a Schedule 4 medication and is classified as a high-risk medicine because it can cause severe and adverse harm to the user (Victorian Medicines Advisory Committee, 2008). Medicine related adverse events are prevalent and more likely in the setting of multiple medicine use, such as in diabetes management.

Initiating insulin in ambulatory settings has been common practice since the late 1980s (Hoskins, et al., 1985) (Bruce, Clark, Danesi, Campbell , & Chisholm, 1987) (Hayward, Manning, Kaplan, Wagner, & Greenfield, 1999). Ambulatory care refers to care delivered in outpatient or community settings and is
the preferred management approach for people with chronic diseases who are not acutely unwell. With a focus on primary care services and the majority of people with T2DM already managed in the primary care sector, ambulatory initiation of insulin in T2DM is now rapidly moving from outpatient care facilitated through diabetes specialist teams (usually located in a hospital) to being undertaken through community health, in general practice and through independently practicing health professionals.

Shared care for ambulatory insulin initiation and stabilisation in T2DM is ‘at least as effective as in outpatient settings’ (Rosendal, Vondeling, de Witte, Hutubessy, van Beekum, & Heine, 2002) and results in considerable cost savings. However, effective insulin initiation, education and management require the collaborative effort of an interdisciplinary team of health professionals working with the person with diabetes and their families. In addition, the person with diabetes must have the relevant knowledge, skills and support to take responsibility for their day-to-day diabetes management based on their level of understanding and physical and cognitive capability. For comparison, in newly diagnosed T1DM ambulatory, non-inpatient care is standard for adults who are not unwell, however in children and adolescents, both inpatient and ambulatory care are practiced. (Craig, et al., 2011)

Newer technologies for insulin injection and blood glucose monitoring have made self-management, safer, less time consuming and more user friendly, while recent insulin formulations have a more predictable onset and duration of action. However, hypoglycaemia remains a significant problem, is an under-recognised side effect of insulin therapy and is a source of unplanned hospital admissions.

Purpose and Scope of the Guiding Principles

The Guiding Principles for Initiating Insulin in Ambulatory Care Setting: a Quality Use of Medicines Strategy were developed within the quality use of medicine framework (QUM) (Australian Pharmaceutical Advisory Council, 2005) (Australian Pharmaceutical Advisory Council, 2002) (Australian Pharmaceutical Advisory Council, 2006). Their purpose and scope is to promote the quality use of insulin to achieve optimal blood glucose control for people with diabetes, with particular focus on the use of insulin with T2DM in ambulatory care settings.

As already noted in most cases, people with T1DM, especially children, require the involvement of specialist advice from a tertiary diabetes centre. In rural and remote areas some innovative models of multidisciplinary care may be available, for example the independent Gippsland paediatric practice located in Victoria (Goss, Paterson, & Renalson, 2009). There are existing NHMRC evidence based guidelines for T1DM in adults, adolescents and children (Craig, et al., 2011). The Guiding Principles were designed to supplement (not replace) existing algorithms and targets for achieving optimal blood glucose control in people with T2DM such as those widely used from the Diabetes Management in General Practice booklet (Harris, Mann, London, Phillips, & Webster, 2011) and the NHMRC Guidelines (Colagiuri, Dickinson, Girgis, & Colagiuri, 2009).

The Guiding Principles were designed to:
- Assist all health professionals to work collaboratively to achieve optimal insulin initiation in ambulatory settings within their training and competence and their relevant health discipline scope of practice.
- Enable people with T2DM to have access to timely insulin initiation.
- Enable people with T2DM requiring insulin to receive relevant medicines education and support to manage their insulin and other medicines.
- Guide health professionals to develop and evaluate safe, effective, evidence-based insulin initiation in ambulatory care settings.

Audit tools to assist health professionals and service providers evaluate their performance can be found on the ADEA web site as part of the Standards package.
Quality Use of Medicines

QUM is not a new concept. It was described by the World Health Organisation (WHO) in 1987 and implemented in Australia in 1992. Significantly, several countries have adopted Australian QUM strategies and processes. Quality use of medicines (QUM) is one of the main objectives of the National Medicines Policy, which defines medicines to include prescription medicines, non-prescription medicines, and complementary healthcare products’ (Department of Health and Aging, 2000). As part of the QUM program the Australian Pharmaceutical Advisory Council (APAC) developed Guiding Principles for Medication Management in the Community. These documents stipulate that ‘health care professionals, care workers and service providers all play an important role in making sure that consumers who live at home receive suitable information and/or assistance so that they take their medicines correctly’ (Australian Pharmaceutical Advisory Council, 2006).

A key QUM objective is to help health professionals and consumers make the best possible use of medicines to improve medication safety and health outcomes (Australian Pharmaceutical Advisory Council, 2005). Significantly, QUM recognises the central role of the consumer in safe medicines use, and that medicines may be needed for prevention as well as treatment. QUM is integral to initiating insulin; regardless of the setting in which insulin is commenced. More information on QUM can be accessed at www.nps.org.au

QUM encompasses:

- Regulatory processes such as approving medicines for use in Australia, codes and regulations concerning manufacturing, labeling, marketing, storing and disposing of medicines.
- Practitioners adopting appropriate assessment processes to determine the necessary information on which to base medicine-related decisions including whether medicines are indicated.
- Recommending non-medicine options first, if appropriate.
- Selecting appropriate medicine/s, doses, formulations, dose intervals and duration of treatment if medicines are indicated.
- Stopping medicines no longer required.
- Using medicines safely and effectively by accurate prescribing, monitoring the response and monitoring and reporting adverse events.
- Educating the patient and/or their families/carers about optimal medicines use including storage and disposal.
- Effectively communicating among health professionals and with patients. Effective communication encompasses documentation as well as education and listening skills.
- Recognising that lifestyle factors: diet, exercise and smoking cessation, are necessary to achieve optimal health outcomes, even when medicines are indicated (Australian Pharmaceutical Advisory Council, 2002).

Medication Safety

Medication safety is a significant issue in Australia with more than 1.5 million people experiencing a medicine-related adverse event each year. Such events result in additional service use across general practice and acute care, and account for 2-3% of hospital admissions (Roughead & Semple, 2009). Gandhi et al reported one quarter of outpatients they studied had an adverse drug event and of these events 39 percent were either ameliorable or preventable (Gandhi, et al., 2003). Older age groups in particular may experience problems with adverse medicine events. An Australian study conducted in people 75 years and older found 30.4% of unplanned hospital admissions were related to adverse drug events (Chan, Nicklason, & Vial, 2001).
Those responsible for clinical services within health organisations use structure and systems to improve the safety and quality of medicine use to reduce the risk of medication-related incidents. All health professionals and other members of the health workforce use these systems to manage medicines safely and in line with QUM principles. The National Safety and Quality Health Service Standards criteria (Australian Commission on Safety and Quality in Health Care, 2011) used to achieve standards of medications safety are:

- **Governance and systems for medication safety**
  Health service organisations have mechanisms for the safe prescribing, dispensing, supplying, administering, storing, manufacturing, compounding and monitoring of the effects of medicines.

- **Documentation of patient information**
  The clinical workforce accurately records a patient’s medication history and this history is available throughout the episode of care.

- **Medication management processes**
  The clinical workforce is supported for the prescribing, dispensing, administering, storing, manufacturing, compounding and monitoring of medicines.

- **Continuity of medication management**
  The clinician provides a complete list of a patient’s medicines to the receiving clinician and patient when handing over care or changing medicines.

- **Communicating with patients and carers**
  The clinical workforce informs patients about their options, risks and responsibilities for an agreed medication management plan.

A number of QUM resources and links are available (see Appendix 6)
Overview of the types of diabetes

Prevalence of diabetes

Diabetes is an increasingly common metabolic disorder. The prevalence of diabetes in all ages and both sexes has increased globally, with a steep rise occurring since the 1960s. The overall global prevalence in 2004 was 2.8% with a projected rise to 4.4% in 2030 (Wild, Roglic, Green, Sicree, & King, 2004). In Australia, if diabetes continues to rise at the current rates, up to 3 million people over the age of 25 years will have diabetes by the year 2025 (Shaw & Tanamas, 2012). Migrant populations are particularly at risk of developing T2DM. In addition, population subgroups, such as Aboriginal and Torres Strait Islander peoples (ATSI) and those who live in institutional care facilities, have a high prevalence of diabetes (Australian Institute of Health and Welfare, 2008). Therefore, prevention programs and regular screening to detect diabetes early are essential to support early intervention. The rising incidence of T1DM is also contributing to the growth of diabetes in Australia, and the prevalence of T1DM is predicted to increase by 10% between 2008 and 2013 (Shaw & Tanamas, 2012).

Diabetes is characterised by disturbed carbohydrate protein and fat metabolism due to insulin resistance, relative or absolute insulin deficiency. Both T1DM and T2DM lead to hyperglycaemia, hyperlipidaemia and glycosuria. When insulin is deficient or absent, glucose cannot be utilised for energy and accumulates in the blood. Fat stores, and in the longer term protein, are mobilised and act as substrates for gluconeogenesis in the liver.

Type 1 diabetes

Initiation and ongoing insulin therapy is required from the onset of diagnosis in T1DM. All people newly diagnosed with T1DM should be managed in an appropriately resourced multidisciplinary ambulatory care or inpatient setting. Although ambulatory initiation of insulin therapy may be undertaken in T1DM, the service and follow-up should be provided by and/or in close consultation with a specialist diabetes team from a tertiary diabetes centre. Multidisciplinary care is established practice for the management of individuals of all ages with T1DM diabetes. The specialist multidisciplinary diabetes care team includes:

- the person with diabetes and their family or carer
- a paediatric or adult endocrinologist or physician trained in the care of children, adolescents or adults with diabetes
- a diabetes educator
- an Accredited Practising Dietitian
- a psychologist or social worker

To optimise health care delivery in T1DM, access to high quality health care is required (Craig, et al., 2011). Each health professional in the multi-disciplinary team needs to have knowledge of T1DM and chronic conditions. The specialist diabetes team leads and takes responsibility for diabetes care, including initiation of and changes to diabetes management, regular reviews, screening for complications and management of diabetes ‘sick days’. In particular there are many facets that need to be considered in the management of a person with T1DM, for example, the risk of significant microvascular disease in rapid reduction of HbA1c.

More information about managing T1DM can be accessed at:

- National Health and Medical Research Council [NHMRC] 2011 National Evidence-Based Clinical Care Guidelines for Type 1 Diabetes in Children, Adolescents and Adults:
Latent Autoimmune Diabetes in Adults (LADA)

LADA is the term used to describe adults who have a slowly progressive form of autoimmune or T1DM that can be treated initially without insulin injections. The diagnosis of LADA is based on three criteria: being adult age at onset of diabetes, the presence of circulating islet autoantibodies and insulin independence at diagnosis. The prevalence of LADA in adults presenting with non-insulin-requiring diabetes is approximately 10% (Fourlanos, Dotta, Greenbaum, Rolandsson, Colman, & Harrison, 2005).

Gestational diabetes

The Australian Diabetes in Pregnancy Society recommends insulin therapy for the management of GDM when lifestyle interventions fail to achieve recommended glycaemic targets. Current targets are:

- Fasting capillary blood glucose (BG): ≤ 5.0mmol/L
- 1 hour BG after commencing meal: ≤ 7.4mmol/L
- 2 hour BG after commencing meal: ≤ 6.7mmol/L

These recommendations are based on self-measured capillary BG levels (Nankervis A., et al., 2012). The IDF Global Guidelines for Pregnancy and Diabetes (IDF Clinical Guidelines Task Force, 2009) provides a comprehensive overview of best practice management of GDM including insulin management in GDM. For the diagnostic criteria of GDM, see Appendix 4.

Although ambulatory initiation of insulin therapy may be undertaken in GDM the service should be provided by and/or in close consultation with specialist diabetes and obstetric teams. After delivery ongoing follow-up is required to identify and/or to reduce risk of T2DM in the future.

Type 2 diabetes

Progressive beta cell loss occurs in T2DM over time. Table 1 (see Appendix 4) indicates the stages involved in the progression of T2DM. People with diabetes managed with dietary modification and exercise alone are less likely to have other parameters such as blood pressure and cholesterol monitored and managed (Hippisley-Cox & Pringle, 2004). The majority of people with T2DM are older and more than 20% of people diagnosed with diabetes already have retinopathy and macrovascular disease at diagnosis (Australian Institute of Health and Welfare, 2008). Up to 80% of patients with T2DM will eventually develop macrovascular disease (Buse, Ginsberg, & Bakris, 2007). In addition to glycaemic control, management of other risk factors such as hypertension, dyslipidaemia and smoking are essential.

Within 6 years from diagnosis more than 50% of individuals with T2DM require the addition of insulin in conjunction with ODA to reach targets of fasting plasma glucose of less than 6mmol/L (Wright, Burden, Paisey, Cull, & Holman, 2002). Initiating insulin is an important stage in managing T2DM, but despite the evidence for progressive beta cell loss in T2DM, many health providers delay transitioning people with T2DM from oral agents to insulin (Henske, Griffiths, & Fowler, 2009).

To access the current national diabetes guidelines, visit the NHMRC website at http://www.nhmrc.gov.au/publications/subjects/diabetes.htm
Insulin and type 2 diabetes

Medicine management is a complex issue, particularly in T2DM where people often require multiple medications in complex regimens to manage primary diseases and comorbidities. Only approximately 15% of people with T2DM maintained an acceptable blood glucose range using dietary measures alone during the UKPDS (UK Prospective Diabetes Study, 1983) and most eventually require medicines to achieve targets and reduce risk associated with hyperglycaemia. Prior to introducing any new diabetes medicines and/or change in medicines, nutrition and dietary assessment including carbohydrate and alcohol intake should be completed. For older clients with frailty and/or cognitive issues the assistance of family or carers may be necessary in medicine management. In addition, the prevalence of T2DM is increasing in children and adolescents, some of whom require insulin. Thus, parental assistance may be required.

T2DM is associated with progressive beta cell failure; injected insulin is ultimately required to control blood glucose and reduce the risk of morbidity and mortality. Thus, beta cell failure and the subsequent failure of oral agents to control blood glucose levels represent a significant glycaemic burden and increased risk of complications. Glycaemic burden is a term often used in economic predictions and refers to an integrated measure of hyperglycaemia over time used to quantify risk of long term complications. Significantly, a US based prospective study using retrospective observational data indicates the average patient accumulates nearly five HbA1c years of excess glycaemic burden greater than 8% [64mmol/mol] from diagnosis until commencing insulin and about 10 HbA1c years of burden greater than 7% [53mmol/mol] (Brown, Nichols, & Perry, 2004). These findings suggested glucose-lowering medicines need to be optimised once the HbA1c reaches 7% [53mmol/mol] to prevent continuing deterioration and reduce the glycaemic burden.

Other diabetes medications

Sulphonylureas and metformin are the most commonly used ODAs and are frequently used in combination. Increasingly other PBS subsidised therapy combinations are being considered, especially where issues such as weight gain or hypoglycaemia are a concern. Most people with diabetes will require increasing doses and additional medications as their diabetes progresses (Harris, Mann, London, Phillips, & Webster, 2011). Sulphonylureas reduce both basal and prandial blood glucose. Metformin predominantly affects the basal blood glucose but has some effect on post prandial levels. Newer agents might provide some benefit in older people considering their benefits, risks, indications, contraindications and precautions such as renal failure.

Other available glucose lowering medicines include:

- **Acarbose**, reduces HbA1c by about 0.5%, could be considered if only small improvements in HbA1c are needed. Acarbose is primarily a prandial agent.
- **Thiazolidinediones** can reduce the HbA1c by 1–2% [11 - 22mmol/mol]. However, the risk related to heart failure and propensity to cause oedema need to be considered particularly with rosiglitazone. Thiazolidinediones increase the sensitivity of peripheral tissues to insulin and decrease hepatic glucose output (Rossi, 2012)
- **Dipeptidyl peptidase - 4 inhibitors (DPP4)** are relatively recent additions to the oral anti diabetic agents in Australia. These agents inhibit DPP-4 thereby increasing the concentration of the incretin hormones glucagon-like peptide-1 and glucose-dependent insulinotropic polypeptide; glucose-dependent insulin secretion is increased and glucagon production reduced (Rossi, 2012): this results in HbA1c reduction through improved fasting and post prandial blood glucose levels.
Incretin mimetics (exenatide) is also an anti-diabetic agent administered by subcutaneous injection. This agent enhances glucose-dependent insulin secretion and suppresses inappropriate glucagon secretion. It also delays gastric emptying, which reduces the rate of glucose absorption, and decreases appetite.

Basic insulin action

Insulin is a hormone secreted by the beta cells of the pancreas. Normal requirements vary between 0.5 and 1.0 unit/kg/day. Insulin synthesis and secretion are primarily stimulated by the increase in the blood glucose level after meals. Insulin release is augmented by release of the incretin hormones, glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide (GLP-1) in the gastrointestinal tract. Once released, insulin attaches to insulin receptors on cell membranes and facilitates the passage of glucose into the cell via a number of mechanisms. Inside the cells glucose is used as energy or stored as glycogen.

In addition, insulin:
- reduces hepatic glucose production
- stimulates the storage of fatty acids and amino acids
- facilitates glycogen formation and storage in the liver and skeletal muscle, and
- limits lipolysis and proteolysis.

Therefore, if insulin is deficient, normal protein, fat and carbohydrate metabolism are altered producing hyperglycaemia and hyperlipidaemia, which increases the risk of short and long term diabetes complications.

Insulin is a very effective medicine, unfortunately people with T2DM are often given the impression that insulin is a 'last resort' when all else fails and they are to blame for the failure. Hence, the possible need for insulin therapy should be discussed early in the diabetes education process so the person understands that commencing insulin is common and expected. Insulin is also the medicine of choice if significant renal or liver impairment is present (Gavin, Peragallo-Dittko, & Rodgers, 2010).

Despite the benefits of early insulin initiation, insulin can be an added self-care burden especially if more than one dose is needed per day and the individual requires assistance to prepare and administer the dose because their health capability is compromised, for example by limited manual dexterity, cognitive deficits, or visual impairment. Family members or other care arrangements will be needed in these instances. It is important to reassure people with T2DM and their carers that, although improving glycaemic control is very important, it will not be achieved 'overnight.'

Rapid improvement in glycaemic control can result in adverse outcomes; for example, exacerbating or causing a retinal bleed from proliferative retinopathy, significant hypoglycaemia including relative hypoglycaemia, and treatment dissatisfaction, which can compromise medicine self-management (Henske, Griffiths, & Fowler, 2009). Relative hypoglycaemia is defined as the experience of hypoglycemic symptoms even when plasma glucose is above the normal range and is associated with release of counter-regulatory hormones, usually in the setting of long term elevation of HbA1c (Briscoe & Davis, 2006).

Despite the documented benefits and safety of insulin for T2DM and the risks associated with hyperglycaemia, health professionals and people with T2DM are often reluctant to commence therapy until HbA1c is around 9% [75mmol/mol] (Brown & Nichols, 2003). One of the many challenges for health professionals working in ambulatory settings is deciding on which insulin/s to use, how to manage ODAs and what dose regimens to use.
**Objectives of insulin therapy**

After considering the individual’s particular circumstances and available social and other support, physiology, medicine regimen, mental health, health capability and safety the objectives of insulin therapy are to:

1. Achieve blood glucose and lipid levels in an acceptable range by replacing absent insulin secretion in T1DM and supplementing insulin production in T2DM.
2. Minimise episodes of hypoglycaemia and their severity.
3. Approximate physiological insulin requirements.
4. Maintain or improve quality of life and reduce progression and effects of long term complications by achieving appropriate metabolic control.
5. Continue diet and activity management to maximise the effect of the insulin.
6. Meet blood glucose and lipid targets.

Targets need to be individualised and may change over time depending on health status. Some people e.g. the old and frail, children, or people with chronic renal failure are at risk of adverse events such as hypoglycaemia and consequent trauma. In these cases HbA1c targets are generally set at a higher range (Cheung, et al., 2009). For evidenced based targets refer to recognised resources as mentioned below:

- NHMRC Adult, Paediatric and Adolescent Type 1 Guidelines
- NHMRC Type 2 Guidelines
- RACGP and Diabetes Australia – Diabetes Management in General Practice 2011/12
- ADIPS Pregnancy and GDM Guidelines
- ADEA Guidelines for the Management and Care of Diabetes in the Elderly

**When to initiate insulin**

The decision to commence insulin depends on the type of diabetes, the HbA1c level, complication risk and patient willingness and self-care capability. Usually insulin is not required at initial diagnosis of T2DM. In circumstances where the individual presents with unexplained weight loss, is lean, severely hyperglycaemic with symptoms or has ketonaemia, a differential diagnosis should be considered and insulin may be required. If insulin is being contemplated as an initial treatment option then the health professional should consider involving a specialist diabetes team or referral to a tertiary diabetes centre. Antibody testing can establish the diagnosis of T1DM.

Secondary causes of hyperglycaemia, such as intercurrent illness, thyroid disease and diabetogenic medicines need to be identified and managed before deciding to transfer the person from ODAs to insulin permanently. For example, a person may require only temporary insulin support during short-term steroid therapy. Later, review of ODA and cessation of insulin may achieve acceptable HbA1c targets in some, especially if they experience frequent hypoglycaemia.

More commonly, insulin is initiated in T2DM due to ‘secondary failure’ after some years on ODAs. Secondary failure refers to significant hyperglycaemia and HbA1c greater than 7% [53mmol/mol] despite maximal ODA therapy. As noted earlier, T2DM is a slow progressive disease of beta cell failure. Several guidelines/algorithms describing how to initiate insulin are available, but individual factors must be considered and the decision made with the person/s concerned. The consideration of insulin therapy may occur earlier the treatment of younger people with the aim of reducing glycaemic burden and complications risk. Generally, younger people on maximal ODAs and lifestyle modification benefit from early insulin use to reduce the glycaemic burden because the lifetime risk of diabetes-related complications is greater in younger people.
Older people are more likely to have comorbidities and disabilities that may complicate diabetes management. Management of diabetes in those aged over 65 should remain focused on maintaining wellbeing, glycaemic control and prevention of acute and chronic complications (Australian Diabetes Educators Association, 2003). For frail older people HbA1c targets need to be individualised, taking into consideration the presence of CVD, diabetes duration, diabetes medication regimen, comorbidities, problems with severe hypoglycaemia and life expectancy. HbA1c > 7% may be more acceptable however the avoidance of symptomatic hyperglycaemia is important (Cheung, et al., 2009).

The prognosis in this group is more likely to be affected by macrovascular complications, which are not greatly influenced by glycaemic control. However, strategies to reduce macrovascular complications such as lifestyle, reducing/stopping smoking and optimising blood pressure and controlling lipids remain important (Kalofoutis, Piperi, Kalofoutis, Harris, Phoenix, & Singh, 2007). The decision regarding the type of insulin and frequency of dosing is based upon individualised need.

Educating the person to self-manage insulin

Diabetes education and management are key therapeutic interventions that enable informed self-care, which is essential to achieving optimal health outcomes and appropriate service use. A wide range of health care providers provide some form of diabetes education. Such providers include general practitioners and practice nurses, other generalist nurses, allied health professionals and Indigenous health workers. In addition, all members of the multidisciplinary diabetes team provide discipline specific diabetes education to support their clinical intervention (Australian Diabetes Educators Association, 2007).

People with T2DM often want to know what other options are available before they agree to commence insulin. Sometimes it is important to give people with T2DM a trial on triple oral therapy, but insulin treatment should not be overly delayed if glycaemic levels remain above target. A trial period could be negotiated; this is dependent on therapeutic time frames. The added medicine burden and, increased risk of medicine interactions and mismanagement needs to be considered in the context of the individual's situation and health capability.

When the addition of insulin therapy is contemplated, many people are reluctant to commence for a number of reasons including; weight gain, needle fears and phobias, fear of hypoglycaemia, beliefs that insulin is a medication of last resort, that they have 'done the wrong thing' in self-management, or that they may experience discrimination at work and/or in social situations. Health professionals sometimes contribute to the myth that diet and ODA controlled diabetes is a milder form of diabetes than insulin-treated diabetes (Dunning & Martin 1999). In addition, some health professionals still use insulin as a threat to motivate patients to comply with diet or ODAs.

Practical considerations for diabetes educators and clinicians include strategies for early insulin initiation, addressing peoples’ psychosocial barriers, quality of life concerns, understanding pharmacokinetic properties of insulin formulations, selecting appropriate patient based therapy regimens and intensifying glycaemic control (Gavin, Peragallo-Dittko, & Rodgers, 2010). Algorithms related to diabetes management and insulin are readily available for clinical consideration and guidance, such as those released by Diabetes Australia in conjunction with RACGP (Harris, Mann, London, Phillips, & Webster, 2011), and the American Diabetes Association and European Association for the Study of Diabetes (Nathan, et al., 2008).

Recognising and addressing low health literacy is another key component of successful initiation of insulin in the ambulatory setting. The traditional view of health literacy focused on the skill level of the patient however the more recent approach is to look at strategies that focus on activities that minimise the complexity of healthcare in addition to improving individual skills. Approximately 60 per cent of
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Australians have poor health literacy and are not able to effectively exercise their ‘choice’ or ‘voice’ when it comes to making health care decisions (Australian Commission on Safety and Quality in Healthcare, 2012).

Health literacy cannot be predicted from education level alone, therefore all health professionals are encouraged to assess the individual's learning needs, styles and preferences. Recognition of the health literacy status of individuals and population groups informs interventions such as the development and use of appropriate health information to support the self-management of chronic disease. This is especially significant in the management of diabetes which requires complex and ongoing self-care and often is associated with poly-pharmacy and multiple service provider involvement.

Health care providers need a specific core body of knowledge and competencies to deliver effective diabetes education and management (Funnell, Brown, Childs, Haas, & Hosey, 2007). Standards and quality indicators for diabetes education relating to ambulatory insulin therapy lay the foundation for defining best practice. The National Standards for the Development and Quality Assessment of Services; Initiating Insulin Therapy in the Ambulatory Care Setting are specifically intended to provide a platform to benchmark and influence service delivery and programs for ambulatory initiation insulin therapy and are designed to promote:

- Safety, by avoiding and minimising inadvertent harm in the care delivery processes.
- Effectiveness through health care providers adopting and routinely using best - practice principles that produce desired health outcomes.
- Quality care that is planned to meet the individual person's needs, is timely, reviewed and adapted as the condition progresses along the person's life cycle and as new technology/evidence is released.
- Accessible care based on a comprehensive assessment of the person's needs.
- Utilisation of resources in a manner that provides maximum benefit for both the person with diabetes and the health care system.

The Standards will assist diabetes educators, general practitioners and other members of interdisciplinary diabetes care teams throughout Australia to initiate insulin effectively and safely, and in a manner consistent with quality diabetes care. The Standards complement recommendations, standards of practice and competencies adopted by ADEA (Australian Diabetes Educators Association, 2001) (Australian Diabetes Educators Association, 2007) (Australian Diabetes Educators Association , 2008) (Australian Diabetes Educators Association Association, 2012 [in process]) (Australian Diabetes Educators Association, 2003) (Australian Diabetes Educators Association, 2008) (Australian Diabetes Educators Association, 2010). Further information can be found in the:

- National Standards for the Development and Quality Assessment of Services; Initiating Insulin Therapy in the Ambulatory Care Setting
- Australian Medicines Handbook
- Diabetes Australia / Royal Australian College of General Practitioners - Diabetes Management in General Practice: Guidelines for Type 2 Diabetes 2011/12

Enhancing insulin self-management

Psychosocial Issues

Providing diabetes education to enhance insulin self-management is more complex than just teaching self-care practices and skills. Addressing psychosocial support is an essential component of diabetes education and care. Studies show that 57% people with diabetes worry about starting insulin and up to 48% of people with T2DM believe starting insulin means they have failed in their self-management
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(Penkallo-Dittko, 2007). Further, more than one quarter of people were unwilling to start insulin (Polonsky, Fisher, Guzman, Villa-Caballero, & Edelman, 2005).

Research into people with diabetes’ perception of their Quality of Life (QoL) reveals that many find insulin therapy a burden (Rubin & Peyrot, 1999). In addition, although some people recognise their QoL increases with improved glucose control, this only occurs when there is not perception of increased treatment burden (Huang, Brow, Ewigman, Foley, & Meltzer, 2007).

The psychosocial issues around insulin therapy are complex and should not be generalised or trivialised. Assessing perception of and adjustment to insulin therapy is the responsibility of all health care providers involved in ambulatory insulin initiation. Similarly, providing staged diabetes education meeting the individual person’s specific needs and concerns is also the responsibility of all health care providers. Referrals for counselling to assist adjustment and acceptance of diagnosis and treatment, and to deal with grief and stress, can occur through specialist diabetes services or through General Practice Management Plans (GPMP) and Team Care Arrangements (TCA) in general practice where required.

**Empowerment**

Most diabetes education, including, insulin initiation, will focus on helping the person with diabetes develop their self-care capacity by actively engaging them in their care and decisions about their care (Funnell, et al., 1991). This process is commonly known as empowerment and is central to optimal diabetes care. The person is seen as the expert on their own life, and the health professional’s expertise serves as a resource. The role of the educator is to help patients to achieve skills and to overcome barriers through education, self-exploration, and emotional support (Funnell, et al., 1991).
Health Professional Roles and Scopes of Practice relevant to these Guiding Principles

“Diabetes has been a pathfinder in multidisciplinary, or what is more correctly termed interdisciplinary care, to the extent that there is substantial overlap in the function of the various disciplines involved. For example, diabetes (nurse) educators initiating and adjusting insulin, nurse run complications screening, the operation of nonmydriatic fundus cameras by Aboriginal health workers, the provision of advice to patients about clinical aspects of care by dietitians, and the self-care education of patients by medical staff. Despite these exemplars, there is still much resistance to breaking down traditional dominance among health disciplines and it is justifiably argued that changes to current roles could compromise the quality of care provided to consumers unless adequate attention is paid to training, experience and competence, accreditation and accountability issues.”

(Colagiuri, Colagiuri, & Ward, National Diabetes Strategy and Implementation Plan, 1998)

The scope of practice of a health professional, working within the field of diabetes care, management and education encompasses a broad framework and context. The range of roles include:

1. Functions and responsibilities
2. Practice in an ethical manner and within the legal boundaries of the profession
3. Decision making capacity which the professional performs in the context of their practice
4. Management of work issues and interpersonal relationships.

Health care providers’ engagement in a person’s interdisciplinary diabetes care team is determined by the individual person’s need as well as health system factors e.g. age, type and duration of diabetes, availability and accessibility of services. Some members of the team more commonly provide continuity of diabetes management and care throughout a person with diabetes’ lifespan such as GPs and Endocrinologists/Diabetes Specialists, CDEs, Dietitians, Nurses, Nurse Practitioners, Pharmacists, Podiatrists and Psychologists.

Similarly to what occurs in other areas of health care, the practice and roles of members of the interdisciplinary care team can cross traditional professional boundaries. However, all members are obliged to practice within their knowledge and competency frameworks, according to professional codes and guidelines, and as mandated under regulatory standards and legislation.

Primary disciplines, diabetes educators and CDEs

Diabetes educators are health care professionals with a primary qualification in a range of health disciplines, e.g. nursing, dietetics, pharmacy, podiatry, medicine and exercise physiology who have a core body of knowledge and skills in the biological and social sciences, principles of teaching and learning, communication and counselling. Diabetes educators have experience and knowledge in the care of people with diabetes and those at risk of diabetes, practice in accordance with the National Standards for Diabetes Educators, and have diabetes education included in their position descriptions and the scope of their employment.

The ADEA is the regulatory agency for Credentialled Diabetes Educators and is a self-regulating body, independent of the NRAS and AHPRA systems. A CDE is a diabetes educator who has been recognised by the ADEA as having the academic qualifications, advanced knowledge, expertise and experience to integrate diabetes self-management education with clinical care as part of a therapeutic intervention. All CDEs must remain authorised to practice in their primary disciplines and commit to practicing diabetes education according to standards, codes and guidelines set by ADEA.
Although ADEA is a self-regulatory body, the majority of ADEA members and CDEs have primary discipline registration with an AHPRA National Board (Medical Practitioners; Pharmacists; Podiatrists; Registered Nurses). Scope of practice and related information for the six health professions eligible to seek recognition by ADEA as CDEs is as follows:

**Dietitians**

The dietitian/ Accredited Practising Dietitian (APD) is an allied health professional and central member of the diabetes care team. Dietitians recommend a diet relevant to the requirements of the persons’ health conditions (medical nutrition therapy) and may include specific advice on carbohydrate awareness and manipulation, meal planning, and eating for activity, growth and/or weight management. People with diabetes may also have other medical conditions that require alternative dietary advice than what is usually recommended for a conventional ‘healthy’ diet. Dietitians support the person with diabetes to adapt their eating habit to meet their individual nutritional needs and achieve improved glycaemic control whilst incorporating personal and cultural food preferences in their food choices. Dietitians belong to a self-regulated professional organisation, the Dietitians Association of Australia (DAA), which is independent of the NRAS / AHPRA systems. DAA sets the standards and competency framework for dietetic practice, is the regulatory body for APDs and Advanced APDs (AAPD) and grants this recognition following demonstration of experience and continuing professional development in their field of practice. (See Appendix 1)

**Exercise physiologists**

Exercise physiologists are allied health professionals who specialise in the delivery of exercise, lifestyle and behavioural modification programs for the prevention and management of chronic diseases and injuries. EPs provide physical activity and behaviour change support for clients with conditions such as cardiovascular disease, diabetes, osteoporosis, depression, cancer, arthritis, COPD and other conditions. Exercise and Sports Sciences Australia (ESSA) provides the national accreditation program for exercise physiologists, is self-regulatory and independent of the NRAS / AHPRA systems. (See Appendix 1)

**Medical Practitioners**

All medical practitioners demonstrate their competence by practicing in accordance to Commonwealth, State and Territory legislation and codes and guidelines of the Medical Board of Australia. Medical practitioners are authorised to practice by AHPRA by adhering to mandated professional registration standards. (See Appendix 1)

People with diabetes frequently require consultation, treatment and ongoing management by specialist medical practitioners e.g. endocrinologists, paediatricians. Registration as a specialist medical practitioner is granted following assessment by an AMC accredited Specialist College. Recognition of specialty practice and titles are approved by Ministerial Council and the title is protected by law.

General practitioners are medical practitioners who follow standards set by the Royal Australian College of General Practitioners (RACGP). The standards outline the aspects of general practice that support high quality and safe comprehensive care, including attention to the services practices provide, the rights and needs of patients, quality improvements and education processes, practice management, and the physical aspect of the practice. These standards are based on evidence from clinical trials or large-scale research, and where there is no other evidence from current professional consensus. The standards are flexible, independent and owned by the profession and are appropriate to general practice regardless of changes in government policy.
Registered nurses

Registered nurses demonstrate their competence through successfully completing educational requirements and by practicing in accordance to Commonwealth, State and Territory legislation and codes and guidelines of the Nursing and Midwifery Board of Australia. Registered nurses are authorised to practice by AHPRA by adhering to mandated professional registration standards.

Registered nurses provide nursing care within the context of their practice or practice site e.g. Practice Nurses (PNs) provide nursing care in the general practice to people with basic diabetes care requirements and coordinate care and manage referrals pathways for people with more complex diabetes care requirements.

The registered nurse (RN) demonstrates competence within the context of their practice and within the framework of four (4) domains; Professional Practice, Critical Thinking and Analysis; Provision and Coordination of Care; Collaborative and Therapeutic Practice.

Registered nurses practice independently and interdependently, and assume accountability and responsibility for their practice and for their delegation of care to enrolled nurses (ENs) and health care workers. (See Appendix 1)

Pharmacists

Pharmacists provide services within the community across Australia and are frequently consulted by people with diabetes and the wider community about a range of health and health care issues. Pharmacists dispense medicines including insulin and ODA’s to the person with diabetes, and conduct medication reviews. Pharmacies provide NDSS consumables and other diabetes self-management equipment and health related products. Thus, the pharmacist’s role encompasses advice to ensure correct use of health related products.

Pharmacists are health professionals authorised to practice by AHPRA through adhering to mandated professional registration standards and having the qualifications, skills and knowledge to assist members of the community to optimise health outcomes from use of medicines.

Pharmacists demonstrate their competence through successfully completing educational requirements and by practicing in accordance to Commonwealth, State and Territory legislation and codes and guidelines of the Pharmacy Board of Australia. (See Appendix 1)

Podiatrists

Podiatrists are responsible for the prevention, diagnosis, treatment and rehabilitation of medical and surgical conditions of the feet and lower limbs of people with diabetes. Podiatrists diagnose and treat any complications resulting from neurological and vascular complications of diabetes as well as joint disorders such as arthritis and soft tissue and muscular pathologies. Podiatrists establish and maintain collaborative relationships with other members of the interdisciplinary diabetes care team to facilitate enhanced clinical care and health outcomes for people with diabetes.

Podiatrists demonstrate their competence through successfully completing educational requirements and by practicing in accordance to Commonwealth, State and Territory legislation and codes and guidelines of the Podiatry Board of Australia. Podiatrists are authorised to practice by AHPRA by adhering to mandated professional registration standards. (See Appendix 1)
Regulation and Scope of Practice in relation to medicines

As noted earlier, all health care professionals are required to practice within regulatory frameworks (AHPRA, 2009) (AHPRA, 2010), the role and scope of practice and codes of conduct of their primary discipline, employing organisation guidelines and further, according to other relevant legislation such as State and Territory Drugs, Poisons and Controlled Substances Acts and regulations (see Appendix 2 for a list of the Acts and suggested links).

ADEA supports a nationally consistent approach to quality use of medicines and prescribing practices. The Prescribing Competencies Framework (NPS, 2012) utilizes the following prescribing definition, “an iterative process involving the steps of information gathering, clinical decision making, communication and evaluation that results in the initiation, continuation, or cessation of a medicine” (Nissen, Kyle, Stowasser, Lum, Jones, & McLean, 2010). In terms of managing insulin in the ambulatory setting, prescribing may include activities such as:

- writing a prescription (by hand or electronically) on a prescription pad or inpatient medication chart
- recording insulin dose adjustments in an individual's medicine record, blood glucose record book, medical record or inpatient medication chart
- writing a letter concerning initiation of insulin, where the type, dose, intervals and/or dose adjustments are specified.

Health professionals may be independent prescribers or accept prescribing responsibilities through delegation or referral from an authorised prescriber. The Medical Board of Australia (2010) understands delegation as a medical practitioner asking another health care professional to provide care while retaining overall responsibility for the patient’s care, referral as sending a patient to obtain opinion or treatment from another doctor or health care professional with partial transfer of responsibility for the patient's care (usually for a defined time and specific purpose) and handover as transferring all responsibility to another health care professional.

The ADEA grants status as a CDE in recognition of demonstrated experience and expertise in diabetes education and commitment to professional development and ongoing learning that meet the ADEA’s expected standards. Recognition as a CDE is ADEA’s assurance to people with or at risk of diabetes, their families, carers and health care providers that they can expect to receive quality diabetes education and advice. Whilst health professionals from various primary disciplines undertake an ADEA accredited post-graduate course, successful completion of the course and the achievement of CDE status does not entitle any health professional to work outside their scope of practice in relation to medicines.

ADEA does not provide endorsement to any health professional member, including CDEs, to undertake prescribing practices. Refer to Appendix 1 for information on primary discipline scope of practice, codes, relevant regulations and standards. Provision of care outside the scope of practice has serious implications which can include invalidation of professional indemnity insurance cover, contravention of Codes of Conduct and the regulations and standards for registration or accreditation by the governing primary health discipline body.

At the time of release of these interim Standards a national project examining prescribing among health professionals registered through AHPRA National Boards is still to produce a final report and recommendations. It is expected that the recommendations of the national project by the HWA HPPP will advocate changes for the regulatory frameworks and legislation governing prescribing, as well as provide direction for registration, accreditation, professional, educational, and other organisations on issues around prescribing. These interim ADEA Standards will be finalised after the final HWA HPPP recommendations are published.
Best practice for managing insulin in ambulatory care

A best practice approach for the initiation and management of insulin therapy reflects the principles of QUM. Underpinning this approach are the regulations governing health professional practice and the prescription and use of insulin (S4 medicine). In addition, a health service must have the necessary processes in place to support the person commencing insulin therapy (including arrangements for ‘out of hours’ support).

Assessment includes:
- Indications for commencing insulin.
- Physical, mental, social, spiritual and environmental
- Individual capability to self-manage insulin.
- Education needs.

Implementation includes:
- Strategies for communicating the need for insulin to the person with diabetes.
- Collaborative care planning.
- Selecting the appropriate insulin formulation, dose, and dose interval for commencement
- Individualised diabetes self-management education
- Documentation and communicating the insulin initiation process.
- Appropriate titration of insulin dosing.

Monitoring includes:
- Self-monitoring of blood glucose patterns.
- Diabetes symptoms.
- Injection sites and insulin related knowledge.

Ongoing review once initiation and stabilisation is completed includes:
- Regular review with GP (at least quarterly).
- Review with prescribing practitioner if not the GP.
- Completion of all recommended diabetes medical assessments (HbA1c, lipids, blood pressure, renal function, eyes, feet)
- Diabetes self-management practices and update of skills and knowledge.
- Further referral to health care team members as required

For detailed description of standards and quality indicators for managing insulin in ambulatory care please refer to the companion Standards document.

Team care and interdisciplinary practice

Diabetes management and care is an interdisciplinary sphere of practice as the person with diabetes needs advice and support from a range of providers from different health care disciplines throughout the continuum of their disease and their lifespan. Interdisciplinary diabetes practice is collaborative and underpinned by mutual acceptance of each other’s discipline specific skills, training, attributes and contribution to diabetes care and shared leadership, accountability and responsibility for achieving the best possible outcome for the person with diabetes.

The team approach to diabetes care enables different health care providers to integrate their knowledge and skills with those of the person with diabetes and offers continuous, supportive, holistic, comprehensive and integrated management across the lifespan. A team approach incorporates shared decision-making by valuing and respecting the contributions of each member of the team and includes the person with diabetes as the central member of the team. Team care can improve planning, treatment and coordination of services when supported by structured information sharing and team
communications processes (Zwar, Hermiz, Comino, Shortus, Burns, & Harris, 2007) (Colagiuri, Girgis, Eigenmann, Gomez, & Griffiths, 2009).

**Diabetes care team members**

The range of health professionals participating in the diabetes care team is determined by the type of diabetes, the services available in the particular location, the health care setting (primary care or tertiary sector), and the individual’s stage of diabetes, lifespan and individual circumstances. In addition to the person with diabetes, the following health professionals are commonly long term members of the interdisciplinary diabetes care team:

- General Practitioner.
- Practice nurse [Registered or Enrolled Nurse]
- Endocrinologist.
- Nurse Practitioner
- Registered Nurse - CDE/ RN-Diabetes Educator
- Dietitian/± CDE.
- Podiatrist/± CDE.
- Pharmacist/± CDE.
- Exercise Physiologist/± CDE

Other health care providers that frequently participate include:

- Specialist medical practitioners e.g. Paediatrician, ophthalmologist, obstetrician, gastroenterologist, nephrologist.
- Physiotherapist.
- Optometrist.
- Indigenous health worker.
- Midwife.
- Psychologist and/or social worker
- Drug and Alcohol team.
- Mental Health team.

**Indications for referral to an endocrinologist / diabetologist**

Generally, a referral will be made to an endocrinologist / diabetologist for the following situations:

- Pre-existing diabetes and pregnancy
- Children and transitioning young adults
- Differential diagnosis of LADA
- Annual review [T1DM or complex T2DM]
- When not achieving outcomes or metabolic / HbA1c targets
- Diabetes complication(s)
- Related conditions such as coeliac or thyroid disease
- New or intensified steroid therapy
- Complex medical needs
- Commercial or heavy vehicle license
Indications for referral to a Credentialled Diabetes Educator

The goals for diabetes education are optimal adjustment to living with diabetes, optimal physical health and cost effectiveness for the person with diabetes. It is recommended to seek diabetes education when:

- Newly diagnosed
- Commencing blood glucose monitoring
- Changing medications, including commencement of insulin therapy**
- Difficulties experienced in reaching treatment targets and management goals such as blood glucose, weight or blood pressure
- Having episodes of severe hypo/hyperglycaemia
- Hospitalised for diabetes or related conditions
- Lifestyle or life stage changes such as when starting an exercise program, planning to travel, starting high school or having symptoms of menopause
- Planning pregnancy, during pregnancy and after delivery
- Experiencing psychological stress or ‘burnt out’ by diabetes self-care
- For the latest diabetes new and information, at least every 1-2 years
- Review and update of hypo and sick day action plan is required

** When referring a person for support with initiation or management of insulin in the ambulatory setting, the health professional making the referral should be satisfied that the CDEs primary discipline, scope of practice and employer guidelines enable their participation in this type of prescribing intervention. (See Appendix 1 for further information)

Indications for pharmacist HMR

The Home Medicines Review (HMR) is designed to assist individuals living at home to maximise the benefits of their medicine regimen and prevent medication related problems. A general practitioner must assess that a review of a patient living at home is clinically necessary to ensure the quality use of medicines or to address a patient’s needs. A home medicines review is indicated when a person:

- is currently taking five or more regular medicines
- is taking over 12 doses of medicine per day
- has significant changes to their medicine regimen in the last three months, including recent discharge from hospital
- is taking medicine with a narrow therapeutic index or required therapeutic monitoring
- has symptoms suggestive of an adverse drug reaction
- is having problems managing their own medicines because of literacy or language or other difficulties
- is attending a number of different doctors (Department of Human Services, 2012)

Indications for APD/dietitian

The DAA recommends that all people with diabetes should have access to an Accredited Practising Dietitian in order to achieve optimal nutritional management as part of their diabetes care. Medical Nutrition Therapy is essential for the following:

- T1DM
- T2DM on insulin
- Major changes to treatment e.g.; starting of continuous subcutaneous insulin infusion (CSII)
- Carbohydrate counting skills for CSII and multiple daily injection regimens
Indications for Exercise Physiologist

Current evidence supports physical activity and exercise as an integral treatment for both primary and secondary prevention and the treatment of chronic disease. Exercise prescription is a major component of diabetes management. Accredited exercise physiologists (AEPs) are physical activity and exercise specialists within healthcare and play an important role in developing individualised exercise programs for people with diabetes. AEPs work within multidisciplinary teams in a range of locations from hospital based to private practice. AEP services can be accessed through the Medicare supported Allied Health initiatives.

Exercise physiology should be considered for:

- patients at high-risk of developing or currently with chronic disease;
- patients at risk of developing, or currently with existing injury, that require rehabilitation to improve physical function; and
- patients in need of lifestyle change through risk factor modification, at all levels of readiness to behavioural change (Exercise and Sports Science Australia, 2012).

Diabetes management and care in relation to ambulatory initiation of insulin will usually involve a core team of health professionals during the commencement and titration phases. For this reason the figure below does not include an exercise physiologist or members of the extended diabetes care team. This does not preclude their involvement when required and referrals should be based upon assessment of clinical need.

The following two pages (Figure 1) summarise some of the key responsibilities of the diabetes care team. The figure should be utilised in conjunction with the Standards:
Referral Criteria
New diagnosis T1DM & T2DM:
Severe hyperglycaemia with symptoms, significant weight loss, ketonaemia, GAD antibodies present → refer to endocrinologist and/or specialist diabetes services.

Gestational diabetes:
Not achieving glycaemic targets with dietary modifications → refer to endocrinologist and/or specialist diabetes services.

Established T2DM
Not achieving glycaemic targets (HbA1c < 7%) despite appropriate lifestyle modification and maximal ODAs. Note that glycaemic targets differ if very young / pregnant / frail elderly and care should be individualised, balancing benefit and risks.

Ambulatory Initiation of Insulin

Monitoring outcomes by team
- BGLs
- HbA1c
- Lipids
- Weight history
- Eating behaviour
- Injection sites
- Adverse events e.g. hypo / DKA
- Complication screening
# Note: When delegating, referring or handing over care for insulin initiation and titration (with appropriate medical authority or agreed protocol) the referrer should verify the primary discipline and scope of practice for the health professional accepting their referral, including those of CDEs. Refer to Appendix 1 of these Guidelines for Health Professional Scope of Practice, Guidelines, Code statements and related regulations.

### CDE
- Provide concurrent comprehensive clinical and self-management assessment and review
- Provide comprehensive self-management and diabetes skills education#
- Support achieving clinical targets and individual education goals
- Support problem-solving and diabetes self-determination
- Collaborate with the interdisciplinary diabetes team
- Authorise NDSS registration for insulin consumables
- Support long term self-management planning for review and risk reduction
- Matching insulin to carbohydrate content where relevant

### RN / RN DE
- Assess self-management capability*
- Basic insulin self-management education
- Collaborate with family carers where relevant *
- SMBG technique revision
- NDSS membership check*
- Care coordination and referral to interdisciplinary diabetes care team*
- May be Practice Nurse, Community Nurse, District Nurse

### GP / Endo / NP
- Insulin formulation:
  - Dose
  - Dose regimen
  - Continue/discontinue ODA
- Determine glycaemic targets
- Medicines review including self-management, diabetogenic medicines and complementary medicines

### APD / Dietitian
- Diet history / food frequency
- Eating and drinking patterns
- Behaviours and preferences
- Nutritional status
- Weight history
- Medical nutrition therapy and meal planning [including matching CHO to insulin]

### Pharmacist
- Dispense prescription
- Medicines education
- Medicines reconciliation
- Medication review

**Key:** CDE (Credentialled Diabetes Educator); APD (Accredited Practising Dietitian); RN (Registered Nurse); DE (Diabetes Educator); GP (General Practitioner); NP (Nurse Practitioner); *these items may relate to all members of the health care team; ODA (oral diabetes agents)
References


Australian Diabetes Educators Association. (2012 (in process)). *Credentialling and Re-Credentialling Program*. Canberra: ADEA.


Managing Insulin in the Ambulatory Care Setting: A Quality Use of Medicine Strategy


Managing Insulin in the Ambulatory Care Setting: A Quality Use of Medicine Strategy


Appendices

Appendix 1: Scope of Practice, Guidelines and Codes of Health Practitioners

Accredited Practising Dietitian

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<thead>
<tr>
<th>Scope of Practice, Guidelines and Codes</th>
<th>Legislation and professional registrations standards</th>
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<tbody>
<tr>
<td><strong>Scope of Practice:</strong></td>
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<tr>
<td>An Accredited Practising Dietitian (APDs) is a health care practitioner who has been recognised by the Dietitians Association of Australia (DAA) as having the qualifications and skills to assess an individual's diet in order to help treat a wide range of conditions including diabetes, heart disease, cancers, gastrointestinal diseases, food allergies, food intolerances as well as overweight and obesity and to provide expert nutrition and dietary advice to both groups and individuals.</td>
<td>The APD® is a recognised trademark registered by the DAA and protected by law. As the regulatory body for APD recognition is granted according to the criteria determined by the DAA.</td>
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<tr>
<td><strong>Guidelines and Codes:</strong></td>
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<tr>
<td>• Statement of Ethical Practice¹</td>
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<tr>
<td>• Code of Professional Conduct²</td>
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<tr>
<td>• Complaints and Disciplinary Procedure³</td>
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<tr>
<td>• Scope of Dietetic Practice Framework⁴</td>
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<tr>
<td>• The National Competency Standards for Entry Level Dietitians⁵</td>
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<tr>
<td><strong>Legislation:</strong></td>
<td></td>
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<tr>
<td>• By-law: Accredited Practising Dietitians⁶</td>
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<tr>
<td>• Accredited Practising Dietitian Program⁷</td>
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## Enrolled Nurse

### Scope of Practice, Guidelines and Codes

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<th>Guidelines and Codes</th>
<th>Legislation and Professional Registrations Standards</th>
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<td>- Competency Standard for Nurses in General Practice[^9]</td>
<td>- State and Territory Drugs, Poisons and Controlled Substances Legislation[^9]</td>
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<tr>
<td>- Code of Ethics[^10]</td>
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<tr>
<td>- Principles for the Assessment of National Competency Standards Decision Making Framework[^12]</td>
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<tr>
<td>- Nursing Practice Decision Summary Guide[^13]</td>
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<td>- Nursing Practice Decision Flowchart[^14]</td>
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<tr>
<td>- Nursing and Midwifery Guidelines for Advertising of Regulated Health Services[^15]</td>
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<tr>
<td>- A Nurses Guide to Professional Boundaries[^16]</td>
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<tr>
<td>- Nursing and Midwifery Guidelines for Mandatory Notifications[^17]</td>
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<td>- Principles for the Assessment of National Competency Standards Decision Making Framework[^12]</td>
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## Exercise Physiologist

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<td><strong>Scope of Practice:</strong></td>
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<tr>
<td>The Accredited Exercise Physiologist is a university qualified allied health professional recognised by ESSA who specialises in the delivery of exercise, lifestyle and behavioural modification programs for the prevention and management of chronic diseases and injuries.</td>
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<tr>
<td><strong>Guidelines and Codes:</strong></td>
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<tr>
<td>- Code of Professional Conduct and Ethical Practice&lt;sup&gt;24&lt;/sup&gt;</td>
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<tr>
<td>- Dealing with Complaints in Respect of Members: The Role of ESSA in Complaints Resolution&lt;sup&gt;25&lt;/sup&gt;</td>
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<tr>
<td>- Social Media Policy for ESSA Members&lt;sup&gt;26&lt;/sup&gt;</td>
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<tr>
<td>- Accredited Exercise Physiologist Scope of Practice&lt;sup&gt;27&lt;/sup&gt;</td>
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<tr>
<td><strong>Legislation:</strong></td>
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<tr>
<td>- Terms and Conditions for the use of ESSA intellectual property</td>
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<tr>
<td><strong>Professionals Registrations Standards:</strong></td>
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<tr>
<td>- ESSA Constitution and By-laws</td>
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<tr>
<td>- Accredited Exercise Physiologist CPD program</td>
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**Credentialled Diabetes Educator**

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<td><strong>Scope of Practice:</strong></td>
<td><strong>Legislation:</strong></td>
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<tr>
<td>A Credentialled Diabetes Educator (CDE) is a health care practitioner who has been recognised by the Australian Diabetes Educators Association as having the qualifications, expertise and experience to practice within the scope of their primary discipline to integrate diabetes self-management education with clinical care as part of a therapeutic intervention to promote physical, social and psychological well-being in a variety of practice settings and roles and across the intervention and care continuum within the five domains of Clinical Practice, Research, Education, Counselling and Leadership and Management.</td>
<td>• The CDE® is a recognised trademark registered by the ADEA and protected by law. As the regulatory body for CDEs recognition is granted according to the criteria determined by the ADEA.</td>
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<tr>
<td><strong>Guidelines and Codes:</strong></td>
<td><strong>Professionals Registrations Standards:</strong></td>
</tr>
<tr>
<td>• The Credentialled Diabetes Educator in Australia - Role and Scope of Practice(^{28})</td>
<td>• Credentialling Program(^{32})</td>
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<td>• National Core Competencies for Credentialled Diabetes Educators(^{29})</td>
<td>• Re-Credentialling Program(^{32})</td>
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<tr>
<td>• National Standards of Practice for Diabetes Educators(^{30})</td>
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<td>• National Standards for Diabetes Education Programs(^{31})</td>
<td>• By-laws(^{37})</td>
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<td>• Client Centred Care(^{32})</td>
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<td>• Code of Conduct(^{33})</td>
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Medical Practitioner

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<td><strong>Scope of Practice:</strong></td>
<td><strong>Legislation:</strong></td>
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<tr>
<td>A Medical Practitioner is a health care provider who has been recognised by the Australian Health Professional Regulation Agency (APHRA) as having the qualifications, knowledge and skills to practice medicine.</td>
<td>Health Practitioner Regulation National Law Act[^41]</td>
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<tr>
<td><strong>Guidelines and Codes:</strong></td>
<td>State and Territory Drugs, Poisons and Controlled Substances Legislation[^47]</td>
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<tr>
<td>• Good Medical Practice[^38]</td>
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<td>• Medical Guidelines for Advertising of Regulated Health Services[^40]</td>
<td>• Criminal History Registration Standard[^44]</td>
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<td>• English Language Skills Registration Standard[^45]</td>
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<td>• Limited registration for area of need Registration Standard[^46]</td>
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<td>• List of specialties, fields and related titles Registration Standard[^38]</td>
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<td>• Recency of Practice Registration Standard[^50]</td>
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<td>• Limited Registration for Teaching or Research Registration Standard[^51]</td>
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<td>• Limited Registration in Public Interest Registration Standard[^52]</td>
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Pharmacist

Scope of Practice, Guidelines and Codes

- **Scope of Practice:**
  A Pharmacist is a health professional who has been recognised by the Australian Health Professional Regulation Agency (APHRA) as having the qualification, skills and knowledge and skills assist members of the community to optimise health outcomes from use of medicines.

- **Guidelines and Codes:**
  - Pharmacy Guidelines on responsibilities of pharmacists when practising as proprietors
  - National Competency Standards Framework for Pharmacists in Australia
  - Pharmacy Guidelines for dispensing of medicines
  - Pharmacy Guidelines on practice-specific issues
  - Pharmacy Guidelines on practice-specific issues - Guideline 1 (List of References)
  - Pharmacy Guidelines on specialised supply arrangements
  - Pharmacy Guidelines on Continuing Professional Development
  - Pharmacy Guidelines for Mandatory Notifications
  - Pharmacy Guidelines for Advertising of Regulated Health Services
  - Pharmacy Code of Conduct for Registered Health Practitioners

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<th><strong>Professionals Registrations Standards:</strong></th>
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<tr>
<td>- Pharmacy Criminal History Registration Standard</td>
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<td>- Pharmacy Professional Indemnity Insurance (PII) arrangements standard</td>
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<td>- Pharmacy Continuing Professional Development Registration Standard</td>
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<td>- Pharmacy Examinations for General Registration Standard</td>
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<td>- Pharmacy English language skills Registration Standard</td>
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Nurse Practitioner

**Scope of Practice, Guidelines and Codes**

**Scope of Practice:**

A Nurse Practitioner (NP) is a health care practitioner recognized and endorsed by AHPRA as having the qualifications, skills, and knowledge to work autonomously and independently in an advanced manner.

**Guidelines and Codes:**

- Registered Nurses Competency Standards
- Code of Ethics
- Code of Professional Conduct for Nurses in Australia
- Principles for the Assessment of National Competency Standards Decision Making Framework
- Nursing Practice Decision Summary Guide
- Nursing Practice Decision Flowchart
- Nursing and Midwifery Guidelines for Advertising of Regulated Health Services
- A Nurses Guide to Professional Boundaries
- Nursing and Midwifery Guidelines for Mandatory Notifications

**Legislation and Professional Registrations Standards**

**Legislation:**

- Health Practitioner Regulation National Law Act
- State and Territory Drugs, Poisons and Controlled Substances Legislation

**Professionals Registrations Standards:**

- Nursing and Midwifery Continuing Professional Development Standard
- Nursing and Midwifery Criminal History Registration Standard
- English Language Skills Registration Standard
- Nursing and Midwifery Professional Indemnity Insurance Registration Standard
- Nursing and Midwifery Regency of Practice Registration Standard

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Podiatrist

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<td><strong>Scope of Practice:</strong></td>
<td><strong>Legislation:</strong></td>
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<tr>
<td>A Podiatrist is a health care practitioner who has been recognised by the Australian Health Professional Regulation Agency (APHRA) as having the qualifications and skills to diagnose and treat specific foot and lower limb conditions.</td>
<td>• Health Practitioner Regulation National Law Act[^88]</td>
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<tr>
<td><strong>Guidelines and Codes:</strong></td>
<td>• State and Territory Drugs, Poisons and Controlled Substances Legislation[^88]</td>
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<tr>
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<td><strong>Professionals Registrations Standards:</strong></td>
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<td>• Podiatry Guidelines for continuing professional development[^90]</td>
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<td>• Australian Guidelines for the Prevention and Control of Infection in Healthcare[^92]</td>
<td>• Podiatry English Language Skills Registration Standard[^102]</td>
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<td>• Podiatry Guidelines for Endorsement for Scheduled Medicines[^95]</td>
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<td>• Podiatry Guidelines for advertising of regulated health services[^96]</td>
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</tbody>
</table>

[^104]: Australian Diabetes Educators Association | ADEA advises this is an interim document pending release of the final HWA Health Professional Prescribing Project (HPPP) report and recommendations due for publication in June 2013.
Registered Nurse

Scope of Practice, Guidelines and Codes

Scope of Practice:
A Registered Nurse (RN) is a health care practitioner recognised by the Australian Health Practitioner Regulation Agency (AHPRA) as having the qualifications, skills, and knowledge to independently and interdependently assume accountability and responsibility for the provision of nursing care as specified by the registering authority’s license to practice, educational preparation, relevant legislation, standards and codes, and context of care within the context of their practice and the four domains of Professional Practice, Critical Thinking and Analysis, Provision and Coordination of Care, Collaborative and Therapeutic Practice.

Guidelines and Codes:
- Registered Nurses Competency Standards
- Competency Standard for Nurses in General Practice
- Code of Ethics
- Code of Professional Conduct for Nurses in Australia
- Principles for the Assessment of National Competency Standards Decision Making Framework
- Nursing Practice Decision Summary Guide
- Nursing Practice Decision Flowchart
- Nursing and Midwifery Guidelines for Advertising of Regulated Health Services
- A Nurses Guide to Professional Boundaries
- Nursing and Midwifery Guidelines for Mandatory Notifications

Legislation and Professional Registrations Standards

Legislation:
- Health Practitioner Regulation National Law Act
- State and Territory Drugs, Poisons and Controlled Substances Legislation

Professionals Registrations Standards:
- Nursing and Midwifery Continuing Professional Development Standard
- Nursing and Midwifery Criminal History Registration Standard
- Nursing and Midwifery Endorsement scheduled medicines
- English Language Skills Registration Standard
- Nursing and Midwifery Professional Indemnity Insurance Registration Standard
- Nursing and Midwifery Regency of Practice Registration Standard

Appendix 1

## Appendix 2: AHPRA Listing of Drugs and Poisons Acts

**Australian Health Practitioner Regulation Agency**  
Links to State and Territory Drugs and Poisons Legislation

**Australian Capital Territory**  
Medicines, Poisons and Therapeutic Goods Act 2008  

**New South Wales**  
Poisons and Therapeutic Drugs Act 1966  

Poisons and Therapeutic Goods Regulation 2002  

**Northern Territory**  
Poisons & Dangerous Drugs Act  

**Queensland**  
Health Act 1937  

Health (Drugs and Poisons) Regulation 1996  

**South Australia**  
Controlled Substances Act 21984  

Controlled Substances (Poisons) Regulations 1996  

**Tasmania**  
Poisons Act 1971  
http://www.thelaw.tas.gov.au/tocview/index.w3p;cond=all;doc_id=81%B%2B1971%2BAT%40EN%2B20100214000000;histon=;prompt=;rec=;term=poisons%20act

**Victoria**  
Drugs, Poisons and Controlled Substances Act 1981  

**Western Australia**  
Poisons Act 1964  

Poisons Regulations 1965  
Appendix 3: Key ADEA documents

Key ADEA documents relevant to initiating insulin in ambulatory care settings include:

- The Credentialled Diabetes Educator in Australia - Role and Scope of Practice (2007) ADEA, Canberra.
- Client Centred Care; Position Statement, (2008), ADEA Canberra
- Code of Professional Conduct for Diabetes Educators in Australia (2010) ADEA, Canberra
- ADEA Clinical Recommendations-Subcutaneous Injection Technique for Insulin and Glucagon-like Peptide 1 (2011), ADEA.

Other relevant documents include:

- National Competencies for Registered Nurses (2008), Australian Nursing and Midwifery Board of Australia (NMBA), Melbourne.
- National Standards for Practice Nurses (2005), Australian Practice Nurses Association (APNA) and Australian Nurses Federation (ANF), Melbourne.
- Registration standard for endorsement for scheduled medicines registered nurses (rural and isolated practice) (2010), ANMB, Melbourne.
- Guiding Principles for Medication Management in the Community (2006), Australian Pharmaceutical Advisory Council (APAC) Canberra. (these are being revised)
- Insulin High Risk Medicine Alert (2008) [10].
- GP Insulin Stabilisation Program (undated), Diabetes Alliance Group, Melbourne Division of General Practice.
- Prescribing Competency Framework documents NHS National Prescribing Centre. (Date)
- Registration standard for endorsement for scheduled medicines registered nurses (rural and isolated practice) (2010). AHPRA (“Note: Medication endorsement status not recorded on National Register”)

ADEA advises this is an interim document pending release of the final HWA Health Professional Prescribing Project (HPPP) report and recommendations due for publication in June 2013.
Appendix 4: Diagnostic Criteria of Diabetes

Type 2 diabetes

Fasting plasma glucose is preferred for diagnostic purposes: however, random plasma glucose or oral glucose tolerance tests (OGTT) are needed in some cases. Venous plasma glucose values are shown in this table. Glucose in capillary blood is about 10-15% higher than in venous blood. The diagnosis is confirmed when the diagnostic values are confirmed on another day (Colagiuri, Davies, Girgis, & Colagiuri, 2009). At the time of preparation of the Guiding Principles the use of HbA1c as a diagnostic test was being explored in Australia.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Fasting plasma glucose</th>
<th>Random plasma glucose</th>
<th>OGTT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>Less than 5.5 mmol/L</td>
<td>Less than 5.5 mmol/L</td>
<td>Less than 7.8 mmol/L at 2 hours</td>
</tr>
<tr>
<td>IGT is possible.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes cannot be</td>
<td>5.5 to 6.9 mmol/L</td>
<td>5.5 to 11 mmol/L</td>
<td>Above 7.8 and less than 11.1 mmol/L at 2 hours - IGT</td>
</tr>
<tr>
<td>excluded.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repeat the test. If the</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>repeat test is abnormal, do</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>an OGTT.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes present.</td>
<td>Above or equal to</td>
<td>Above or equal to</td>
<td>Above or equal to</td>
</tr>
<tr>
<td></td>
<td>7.0 mmol/L</td>
<td>11.1 mmol/L and</td>
<td>11.1 mmol/L at 2 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td>symptoms</td>
<td></td>
</tr>
</tbody>
</table>
Table 1: The five stages of the progression of type 2 diabetes.

Each stage can be distinguished by changes in the beta cell mass, phenotype and function (Holst et al. 2008).

<table>
<thead>
<tr>
<th>Stage</th>
<th>Distinguishing features</th>
</tr>
</thead>
<tbody>
<tr>
<td>One</td>
<td>Increased glucose stimulated insulin secretion and beta cell mass. The changes may be a response to insulin resistance (IRS).</td>
</tr>
<tr>
<td>Two</td>
<td>The beta cells are in a stable state of adaptation but first phase insulin secretion is lost. The second phase of insulin secretion is largely preserved. Blood glucose levels are elevated due to a decline in beta cell function or IRS or both. Stage two is often referred to as ‘prediabetes’ and can last for years. However, at some point the beta cells are no longer able to cope and the blood glucose rises above the normal range.</td>
</tr>
<tr>
<td>Three</td>
<td>Blood glucose levels fluctuate in response to the variable beta cell function and inefficient insulin secretion.</td>
</tr>
<tr>
<td>Four</td>
<td>The fasting plasma glucose is elevated and the beta cell mass is reduced to approximately 50% of normal possibly due to beta cell apoptosis, despite normal beta cell formation and replication. Usually enough insulin is secreted to prevent ketoacidosis but not enough to maintain blood glucose within the normal range. People with T2DM can remain in stage four for many years.</td>
</tr>
<tr>
<td>Five</td>
<td>Beta cell failure and persistent hyperglycaemia. Hyperlipidaemia, particularly elevated triglycerides, high LDL and low HDL, also often present. May present in a HHS or rarely, diabetic ketoacidosis (DKA).</td>
</tr>
</tbody>
</table>

Type 1 diabetes

The diagnostic values for T1DM are also a fasting plasma glucose equal or above 7mmol/L or a random plasma glucose of equal or above 11.1mmol/L. However, confirmation of the diagnosis on a subsequent day is rarely required as hyperglycaemia with acute metabolic decompensation and/or obvious symptoms are usually present.
Gestational diabetes

**Note:** GDM is defined as glucose intolerance of variable severity with onset or first recognition during pregnancy. The diagnosis of GDM will therefore include those women with previously undiagnosed abnormalities of glucose tolerance, as well as women with glucose abnormalities related to the pregnancy alone. A definitive diagnosis of non-gestational diabetes cannot be made until the post partum period.

- **Early testing for GDM of women with high risk factors**
- **75 g OGTT at the first opportunity after conception**
- **Normal result**
- **One or more of the following results:**
  - FG ≥ 5.1mmol/L
  - 1-hr glucose ≥ 10.0mmol/L
  - 2-hr glucose ≥ 8.5mmol/L
- **GDM**

All women not known to have GDM (24–28 weeks gestation) → 75g oral glucose tolerance test → One or more of the following results:
- FG ≥ 5.1mmol/L
- 1-hr glucose ≥ 10.0mmol/L
- 2-hr glucose ≥ 8.5mmol/L

**High risk factors:**
- Previous GDM
- Previously elevated BG level
- Ethnicity: Asian, Indian, Aboriginal, Torres Strait Islander, Pacific Islander, Maori, Middle Eastern, non-white African
- Maternal age ≥40 years
- Family history DM (1st degree relative with diabetes or a sister with GDM)
- Obesity, especially if BMI > 35 kg/m2
- Previous macrosomia (baby with birth weight > 4500 g or > 90th centile)
- Polycystic ovarian syndrome
- Medications: corticosteroids, antipsychotics

OGTT=oral glucose tolerance test
FG=fasting glucose
BG=blood glucose

Source: (Nankervis A., et al., 2013)
Glycosylated haemoglobin

Glycosylated haemoglobin (HbA1c) is considered to be the ‘gold standard’ for assessing blood glucose control. Circulating blood glucose attaches to the haemoglobin in the red blood cells and undergoes an Armadori reaction whereby the glucose becomes permanently fixed to the haemoglobin (glycolysis). The glycolysated haemoglobin can be quantified to give an indication of the average blood glucose concentration over the preceding three months. The rate of haemoglobin glycolysis is influenced by chronic hyperglycaemia. Tests are usually performed at least three months apart but can be done sooner to gauge the effect of a treatment modification. HbA1c complements but does not replace capillary blood glucose testing or the clinical assessment of the patient.

**It is very important that the HbA1c is interpreted in the context of the individual’s health status rather than relying on the laboratory result. For example, HbA1c can be within an acceptable level in the following circumstances: frequent hypoglycaemic episodes, anaemia, recent blood loss, blood transfusion, and some haemoglobinopathies. However, actual blood glucose control may be inadequate putting the person at risk of hyperglycaemia-related long term diabetes complications. Therefore, the HbA1c should be considered as part of the total clinical picture and not viewed in isolation.**
Appendix 5: Insulin information sources

Insulin Information sources


- *Australian Prescriber* – accessible information electronically at [http://www.australianprescriber.com/content/indexing_subject](http://www.australianprescriber.com/content/indexing_subject).


Appendix 6: QUM Resources

Quality Use of Medicine Resources


- Medicines Information Line where patients can access a pharmacist for advice about all kinds of medicines (1300 633 424) from anywhere in Australia for local call cost (mobile may cost more) Mon-Friday 9am to 5pm