Initiating Insulin Therapy in Ambulatory Care Settings

National Standards for Developing and Assessing the Quality of Services: Initiating Insulin in Ambulatory Settings
Key Words
1. Insulin
2. Ambulatory care
3. Quality use of medicines
4. Health Education – Australia
l. Australian Diabetes Educators Association

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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.
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The National Standards for Developing and assessing the Quality of Services: Initiating Insulin Therapy in Ambulatory Settings (Standards) was revised by a Working Group appointed by the Australian Diabetes Educators Association (ADEA). Members of the Working Group were:

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<tr>
<td>ADEA</td>
<td>Australian Diabetes Educators Association</td>
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<tr>
<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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<tr>
<td>APD</td>
<td>Accredited Practising Dietitian</td>
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<tr>
<td>BGL</td>
<td>Blood Glucose Levels</td>
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<tr>
<td>CALD</td>
<td>Culturally and Linguistic Diverse</td>
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<tr>
<td>DAA</td>
<td>Dietitians Association of Australia</td>
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<tr>
<td>DKA</td>
<td>Diabetic Ketoacidosis</td>
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<tr>
<td>GDM</td>
<td>Gestational Diabetes Mellitus</td>
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<tr>
<td>GPMP</td>
<td>General Practice Management Plan</td>
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<tr>
<td>HbA1c</td>
<td>Haemoglobin A1c, glycosylated haemoglobin, glycated haemoglobin</td>
</tr>
<tr>
<td>IHW</td>
<td>Indigenous Health Worker</td>
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<tr>
<td>NDSS</td>
<td>National Diabetes Services Scheme</td>
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<tr>
<td>NP</td>
<td>Nurse Practitioner</td>
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<tr>
<td>ODA</td>
<td>Oral Diabetes Agents</td>
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<tr>
<td>RN</td>
<td>Registered Nurse</td>
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<tr>
<td>SMBG</td>
<td>Self monitoring blood glucose</td>
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<tr>
<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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<tr>
<td>TCA</td>
<td>Team Care Arrangements</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 to assist 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.

**Ambulatory care**
Ambulatory care is care that takes place as a day attendance at a health care facility or at the consumer’s home 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)

**Ambulatory initiation of insulin**
The intensive process of initiating insulin undertaken in a community or outpatient setting that requires concurrent assessment, initiation of insulin therapy and subsequent insulin dose adjustment, education, skills development and support to introduce insulin therapy to the diabetes self-management regimen of a person with diabetes.

**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 wellbeing 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.

**Diabetes education**
Diabetes education is an interactive process that facilitates and supports the individual and/or their families, carers or significant social contacts to acquire and apply the knowledge; confidence; practical, problem-solving and coping skills needed to manage their life with diabetes to achieve the best possible outcomes within their own unique circumstances.
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.

Intervention
The term intervention in this context refers to initiation of insulin therapy in an ambulatory care setting.

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

Nurse Practitioner
A Nurse Practitioner (NP) is a Registered Nurse educated and authorised by the Australian Health Practitioner Regulation Agency (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).

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 delegated prescribing responsibilities must have the relevant education and competency to perform the tasks, hold current licence/authorisation to practice, practice prescribing within their scope of practice and operate within National and State-based regulatory frameworks, including the relevant Drugs, Poisons and Controlled Substances Acts and regulations.

Registered Nurse
A Registered Nurse (RN) is a health care professional recognised by the 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.

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).

Standard
Standards in this document refer to minimum requirements for the structure of ambulatory initiation of insulin therapy, the process to be used and expected outcomes for people with diabetes or their designated carers as a result of ambulatory initiation of insulin therapy.

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.
Tertiary Diabetes Centre
A Diabetes Centre acknowledged as meeting the criteria for accreditation with the National Association of Diabetes Centre’s as a Tertiary Diabetes Centre and/or a hospital based Diabetes Centre that is able to meet the requirements of this accreditation.
Executive Summary

The Working Group was tasked with reviewing the 2004 Standards to ensure they were consistent with current evidence, work practices, regulatory frameworks and legislation.

The Working Group:
- Critically reviewed the Standards to determine the areas that needed to be addressed.
- Undertook a literature review to determine trends in insulin management, insulin self-management education and insulin therapy.
- Consulted key experts.
- Incorporated relevant information into the Standards.

The Standards address outcomes, process and structure of programs for insulin initiation in the ambulatory setting and are intended to assist a planned intervention, increase consistency of practice and to promote the understanding of roles within interdisciplinary teams.

The Standards should be considered in conjunction with The Guiding Principles for Initiating Insulin in Ambulatory Care Setting: a Quality Use of Medicines (Guiding Principles) which has been developed as a conceptual framework and guide to the Standards.
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 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 care providers need a specific core body of knowledge and competencies to deliver effective diabetes education and management.

The ADEA developed a Credentialling and Re-credentialling 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.
Regulation and Scope of Practice in relation to medicines

All health care professionals are required to practice within a regulatory framework (AHPRA, 2009) and/or the role and scope of practice and codes of conduct of their primary discipline 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).

Health professionals who become Credentialed Diabetes Educators must maintain registration with their primary health discipline and adhere to the requirements, regulations and scope of practice for their primary discipline. 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. ADEA does not endorse any health professional members, including CDEs, to undertake prescribing as defined below (see Guiding Principles Appendix 1 for information on primary discipline scope of practice, relevant regulations and standards).

Prescribing is an iterative process that results in the initiation, continuation, or cessation of a medicine (Nissen et al 2010). Initiation of insulin therapy, dose titration, dose adjustment and alteration of doses following a protocol are all prescribing practices. ADEA supports a nationally consistent approach to prescribing practice and management of medicines, recognising the Prescribing Competencies Framework (NPS, 2012) as the standard for competencies required to prescribe medicines safely and effectively in the Australian healthcare system.

Health professionals who independently prescribe or those accepting prescribing responsibilities through delegation or referral from an authorised prescriber must have the relevant education and competency to perform the tasks, hold a current authorisation to practice, practice prescribing within their scope of practice and operate within National and State-based regulatory frameworks. 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.

At the time of release of these interim Standards a national project (HWA HPPP) examining health professional prescribing was still to produce a final report and recommendations. It is expected that the recommendations of the HWA HPPP project will advocate significant changes for the regulatory frameworks and legislation governing prescribing and management of medicines, 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.
The Guiding Principles for Initiating Insulin in Ambulatory Care Setting: a Quality Use of Medicines Strategy

Quality use of Medicines (QUM) is an important Australian initiative, consequently, The Guiding Principles for Initiating Insulin in Ambulatory Care Setting: a Quality Use of Medicines Strategy (Guiding Principles) was developed to serve as the conceptual framework for the review of the Standards and as a guide to ambulatory insulin stabilisation in conjunction with the Standards.

The Guiding Principles was developed to promote the quality use of insulin to achieve a safe initiation of insulin therapy and optimal blood glucose control in the ambulatory care settings. It is recommended that the Guiding Principles be read in conjunction with the Standards.
Introduction to Standards

The standards and the quality indicators in this document lay the foundation for defining best practice. The standards in this document 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 process.
- 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 healthcare system.

Standards are set and interpreted according to local contexts and individual circumstances. Indicators infer a judgement about the quality of the care provided and identify potential problems. Due to limited available evidence, the standards and indicators in this document were determined through expert and consensus opinion following review of the National Standards developed by ADEA in 2004. Testing and validation of the Indicators in the clinical practice setting is recommended to strengthen the evidence for future review of the Standards.

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.

Outcome Standards

Describe the changes that are demonstrated as a result of the intervention.

**Outcome Standard 1**

The person with diabetes starts insulin therapy without requiring a hospital admission unless indicated for clinical or psychosocial reasons.

**Outcome Standard 2**

The person experiences a reduction in blood glucose levels (BGLs) and is progressing towards achieving optimal individual lipid and glycaemic targets without increasing the risk of acute diabetes complications.

**Outcome Standard 3**

The person demonstrates knowledge and skills needed for safe day-to-day self-management of insulin therapy.

**Outcome Standard 4**

The person accepts responsibility for the day-to-day management of insulin therapy by incorporating self-care practices in their diabetes self-management.
Outcome Standards

Describe the changes that are demonstrated as a result of the intervention.

Outcome Standard 1

The person with diabetes starts insulin therapy through ambulatory care without requiring a hospital admission unless indicated for clinical or psychosocial reasons.

Quality Indicators:

1.1 The person receives care in a community or outpatient setting throughout the planned intervention. The intervention includes:
   - A coordinated, planned program of concurrent clinical care, diabetes self-management education, skills training and support that involves the individual in decisions about his or her insulin regimen.
   - Comprehensive assessment of the person’s health status and well-being, diabetes self-management knowledge and practices, learning styles, social support systems, as well as cultural values and spiritual beliefs.
   - The collaborative efforts of an interdisciplinary team of health care providers working with the person.
   - Processes to enable the person to access advice from health care providers when needed during the intervention.

Outcome Standard 2

The person experiences a reduction in blood glucose levels (BGLs) and is progressing towards achieving optimal individual lipid and glycaemic targets without increasing the risk of acute diabetes complications.

Quality Indicators:

2.1 The person’s self-monitoring blood glucose (SMBG) results demonstrate an overall reduction in BGLs and blood glucose variability.

2.2 The person is free of signs and symptoms of hyperglycaemia including unintentional weight loss, polyuria, ketonuria, thirst and fatigue.

2.3 The person does not experience moderate and/or severe hypoglycaemic events during the intervention.

2.4 The person reports improved well-being.
Outcome Standard 3

The person demonstrates knowledge and skills needed for safe day-to-day self-management of insulin therapy.

Quality Indicators:

3.1 The person describes to the best of their ability:

- The type of diabetes they have.
- The reason(s) for starting insulin therapy.
- Personal blood glucose targets and SBGM regimen.
- The inter-relationships between insulin, other current medications, nutrition (including meal/carbohydrate [CHO] distribution), physical activity and exercise, illness and stress.
- The correct method of administering insulin.
- Their insulin type and action profile.
- The recommended time(s) to administer insulin.
- Preferred injection sites, a site rotation plan and factors influencing insulin absorption.
- Recommended storage and handling of insulin including use-by date.
- Use of chosen insulin injection device and SMBG equipment.
- Unit size of syringe and gauge of needle of syringe and/or for insulin delivery device.
- Safe handling and disposal of sharps.
- Side effects of insulin, for example, hypoglycaemia and weight gain.
- How to access insulin delivery devices and related injection and SMBG consumables from the National Diabetes Services Scheme (NDSS).
- Strategies for prevention, recognition and management of hypoglycaemia and hyperglycaemia.
- Strategies for managing illness such as vomiting, diarrhoea and infection in accordance with individual sick-day plan.

3.2 The person demonstrates:

- Correct preparation of insulin injection e.g. drawing up and mixing insulin if relevant, using an insulin syringe and/or priming and dialling up insulin dose using an insulin delivery device.
- Correct storage, handling, operation, maintenance and care of insulin delivery devices.
- Correct disposal of used equipment.

3.3 A family member, carer or significant other of a person with T1DM demonstrates or describes how to recognise severe hypoglycaemia, the correct administration of glucagon, its correct storage and use to manage severe hypoglycaemia, and the management of an unconscious person.

3.4 The person with T1DM describes the indications of testing for and appropriate actions to take if ketones are detected in blood (preferable) or urine.
3.5 The person demonstrates the correct technique for obtaining and recording SMBG results and interpreting patterns.

3.6 The person describes the function, capabilities and specific calibration and/or maintenance procedures for their blood glucose meter.

3.7 The person describes the process for obtaining and maintaining adequate supplies of insulin, pen needles and/or lancet devices.

**Outcome Standard 4**

The person accepts responsibility for the day-to-day management of insulin therapy by incorporating self-care practices in their diabetes self-management.

**Quality Indicators:**

4.1 The person:
- states safe diabetes self-management practices around insulin and describes how these are applied in their self-care practice (for example; balancing CHO intake and insulin requirements)
- describes the implications of insulin therapy on aspects of diabetes care and self-care options
- describes how to apply SMBG results and diabetes self-management knowledge to achieve glycaemic targets and reduce the risks of acute and chronic diabetes complications
- demonstrates knowledge and understanding of long-term self-management planning including follow-up appointments with the treating/referring practitioner and other members of the diabetes health care team.

4.2 The person:
- states the importance of carrying personal medical identification noting their condition of insulin treated diabetes
- describes the importance of always having easily digested high Glycaemic Index (GI) CHO available to treat hypoglycaemia
- can identify signs and symptoms of hypo unawareness and states actions to be taken, including review by a diabetes health professional
- describes the importance of maintaining adequate supplies of insulin, insulin related consumables and blood glucose testing equipment
- describes the importance of planning and preparation for times when access to required diabetes self-management supplies may be limited (for example; CHO, monitoring equipment or medications) such as extended travel or visiting remote locations.
- describes the process for obtaining diabetes self-management supplies, is registered with NDSS and has notified NDSS of commencing insulin therapy or has appropriate alternative arrangements if NDSS registration is declined.

4.3 The person states the requirement to have their driver’s licence endorsed in accordance with their state or territory road traffic authority in which they reside.

4.4 The person demonstrates active problem-solving in all aspects of their day-to-day diabetes self-management decisions e.g. with respect to diet and exercise, interpreting and managing their blood glucose results, physiological demands including breast feeding, personal...
relationships and family roles and responsibilities, social and community life, school, employment and leisure activities.
Process Standards

Process standards describe the intervention and its appropriateness, timeliness and effectiveness.

**Process Standard 1**
The treating/referring practitioner provides a written referral containing identifying and clinical information to the interdisciplinary diabetes service or the health care provider performing the intervention.

**Process Standard 2**
The person has timely access to the intervention as determined thorough clinical and psychosocial assessment and according to individual needs and circumstances.

**Process Standard 3**
The intervention is determined by clinical and psycho-social assessments together with stated preferences the individual person.

**Process Standard 4**
The person’s care plan for the interventions is flexible, accommodates individual needs, goals and the ability to achieve confidence in self-management over time and is developed in collaboration with the person and the diabetes care team.

**Process Standard 5**
The insulin type and regimen is matched to the person’s individual needs and determined by the treating/referring practitioner in collaboration with the person.

**Process Standard 6**
The person’s insulin is supplied according to State and Territory Drugs and Poisons legislation and handled according to manufacturer’s guidelines.

**Process Standard 7**
The person’s established medical record complies with accepted legislation and standards and documents an agreed care plan for concurrent educational and clinical management at each contact.

**Process Standard 8**
All members of the diabetes care team contribute to the person’s progress according to agreed clinical and educational goals through regular communication.

**Process Standard 9**
Each member of the diabetes care team evaluates and documents the person’s progress towards developing the skills, confidence and knowledge required to complete the intervention.

**Process Standard 10**
The effectiveness and quality of the program/content for the intervention are evaluated regularly and revised according to the outcomes.
Process Standards

Process standards describe the intervention and its appropriateness, timeliness and effectiveness.

Process Standard 1

The treating/referring practitioner decides nature of the care requested (delegation, referral or handover) and provides the required written documentation containing identifying and clinical information to the interdisciplinary diabetes service or the health care provider performing the intervention.

Quality Indicators:

1.1 Information includes:

- Person’s name, address and day time contact details.
- Date of birth.
- Type and duration of diabetes.
- Reason for referral for the intervention.
- Relevant laboratory test results e.g. current HbA1c, recent BGLs, lipids, eGFR, microalbumin, ketones.
- Recent abnormal and/or unusual signs and symptoms e.g. blurred vision.
- Weight history.
- Current and previously trialled treatment for diabetes and other medical/surgical conditions.
- Cultural background and need for interpreter.
- Contact details of treating/referring practitioner.
- Case management arrangement, roles and communication for the team.
- The name of the health care provider undertaking the intervention.

1.2 Where the treating/referring practitioner is an independent practitioner who has not endorsed the insulin management protocols and/or related policies of the diabetes service or health care provider who is undertaking the intervention, the written referral instructions for the intervention must include:

- The starting insulin type, dose, time, route and regimen.
- The process for and/or units of incremental insulin dose adjustments.
- The person’s individual fasting and post prandial blood glucose range target.
- Any reason for delaying rapid improvement toward glycaemic targets, for example; active retinopathy, hypoglycaemia unawareness.
- The maintenance, reduction and/or cessation date and time of any current ODAs.

Appendix 1 provides a referral template with the suggested fields included.
Process Standard 2

The person has timely access to the intervention as determined by a thorough clinical and psychosocial assessment, and according to individual needs and circumstances.

Quality Indicators:

2.1 People newly diagnosed with T1DM who are symptomatic and have blood ketones greater than 1.5 mmol/L or moderate to large urine ketones have an urgent clinical assessment by a medical practitioner (doctor) or an endorsed nurse practitioner (NP) and commence the intervention immediately under supervision of a specialist diabetes care team, or are alternatively referred to the hospital emergency department for immediate admission for insulin initiation.

People newly diagnosed with T1DM who are mildly symptomatic and have blood ketones less than 1.5 mmol/L or small urine ketones have a clinical assessment by a doctor or an NP and commence the intervention within 24 hours under supervision of a specialist diabetes care team.

Refer to the NHMRC National Evidence-Based Clinical Care Guidelines for Type 1 Diabetes for Children, Adolescents and Adult (2011).

2.2 People newly diagnosed with T2DM or with established T2DM who manifest symptoms of severe hyperglycaemia including severe dehydration, disturbed consciousness and shock and who are assessed by a doctor or NP as requiring insulin therapy, commence the intervention immediately at the hospital emergency department or under the supervision of a specialist diabetes care team. (Harris, Mann, Phillips, Bolger-Harris, & Webster, 2011)

People with T2DM not responding to maximal ODAs who are well hydrated, not experiencing severe symptomatic hyperglycaemia and who do not have inter-current illness or medicines causing elevation of glycaemic levels, commence insulin therapy as determined by metabolic status within two (2) to four (4) weeks.

2.3 Women with GDM who have BGLs above target despite attempted lifestyle modification (healthy dietary intake, appropriate CHO modification and recommended physical activity), commence the intervention within one (1) to five (5) working days and should be referred to a specialist diabetes care team.

2.4 Women with T2DM treated with ODAs [with the exclusion of metformin] and who are found to be pregnant commence insulin therapy within 48 hours and should be referred to a specialist diabetes care team.

2.5 People with steroid or antipsychotic induced hyperglycaemia, or an inter-current illness, who manifest symptoms of hyperglycaemia, commence the intervention according to the clinical assessment undertaken by doctor or NP, commonly within 48 hours.

Sick day management in adults with T2DM may require the temporary addition of insulin to current therapy. Considerations include that the person with diabetes and their carer must be able to safely undertake insulin therapy and ideally will have been educated on this approach in advance as part of a sick day management plan. (Harris, Mann, Phillips, Bolger-Harris, & Webster, 2011)
2.6 Ambulatory insulin initiation is not recommended in the following circumstances:

- people with newly diagnosed T1DM, who are severely metabolically compromised [pH less than 7.3] and require intravenous (IV) fluid replacement and/or insulin infusion;
- initial presentation of T1DM where access to a specialist diabetes care team is essential but not immediately available;
- children aged younger than 2 years
- in any person under 18 years of age it is highly recommended that insulin initiation is performed within a hospital setting and/or in conjunction with a diabetes specialist service (Harris, Mann, Phillips, Bolger-Harris, & Webster, 2011)
- people with T2DM who have severe hyperglycaemia and dehydration;
- in any person with a metabolic disorder, for example; renal disease;
- in pregnancy in pre-existing diabetes, gestational or any circumstances where access to specialist diabetes care team is necessary, but not readily available;
- people who have physical or psychosocial difficulties that preclude him/her from taking responsibility for safe administration, recognition and treatment of hypoglycaemia and appropriate insulin dose adjustment, e.g. physical or intellectual disability, dementia or poorly controlled psychiatric disorder, and who do not have a suitable carer;
- people who live a significant distance from the service provider and who have no or poor access to communication facilities (telephone, internet), transport and emergency medical services;
- People who are unwilling or unable to commit to attending scheduled appointments or additional appointments as deemed necessary by the person undertaking the intervention and who cannot be visited by the care team.

Process Standard 3

The intervention is determined by clinical and psycho-social assessments together with stated preferences of the individual.

Quality Indicators:

3.1. The clinical and psycho-social assessment is conducted with the person with diabetes prior to the intervention and involves other team members in the evaluation as appropriate.

3.2 The clinical and psychosocial assessment includes:

- Health and well-being history including weight and family history.
- medical/surgical history, known chronic diabetes complications and co-morbidities
- Current hyperglycaemic symptoms and hydration status.
- Current medications including "over the counter" medications, complementary alternative therapies and vitamins.
- Biomedical parameters including weight, Body Mass Index (BMI), waist circumference, HbA1c, Blood Pressure (BP), lipid profile, electrolytes and ketones in T1DM.
- Diabetes self-care practices e.g. SMBG, eating habits, physical activity/exercise patterns, foot care.
- Preconceptions and fears about diabetes, insulin treatment and injections.
- Diabetes self-management knowledge and previous diabetes education.
Understanding of dietary management in diabetes.

Previous nutritional assessment and medical nutritional therapy of diabetes and related conditions.

Social history including support network.

Education and literacy level.

Demands from occupation, work patterns [e.g., shift worker], lifestyle, leisure activities and family responsibilities.

Learning style and preferences.

Psychological and emotional state.

Other physical and individual factors e.g. hearing, mobility, visual acuity, cognitive functioning, manual dexterity.

Other relevant individual needs e.g. social circumstances, cultural, spiritual and socio-economic.

3.4 The person with diabetes has a carer to provide assistance with self-management activities, which he/she is unable to perform independently.

3.5 People with T2DM and modifiable risk factors contributing to the hyperglycaemic state are referred for further assessment and intervention prior to a final decision to commence insulin therapy.

3.6 The person has access to support services according to individual needs e.g. community nursing, interpreter services, to ensure a safe and individualised intervention process.

3.7 Children aged over two (2) years are managed in consultation with a specialist paediatric diabetes care team or a specialist diabetes team with paediatric intervention.

3.8 People of Aboriginal or Torres Strait Islander background have access to the additional support of indigenous health care providers, such as an Aboriginal Liaison Officer and/or Indigenous Health Worker (IHW) when required or requested and are eligible for additional services and incentives for helping establish good diabetes self-management.

3.9 Language support through a NAATI qualified interpreter is offered to the person of CALD background if required and other care options are explored, such as referral to a diabetes service with interpreter access, if qualified interpreting services are not available in the treating/referring health care provider setting.

3.10 The person has access to a psychologist, social worker or counselling service when required or requested.

3.11 The health care provider discusses alternative management options with person, the treating/referring practitioner and other members of the diabetes care team when/if the intervention is deemed to be unsafe or unsuitable.
Process Standard 4

The person's care plan for the interventions is flexible, accommodates individual needs, goals and the ability to achieve confidence in self-management over time and is developed in collaboration with the person and the diabetes care team.

Quality Indicators:

4.1 Health care providers work with the person to facilitate development of an individualised care plan including, self-management goals, education content and process of achieving their goals.

4.2 The person agrees to a schedule of appointments and/or a schedule of visits by the diabetes care team that are mutually acceptable.

4.3 The person is provided with the following minimum information until the subsequent visit/s when the intervention is urgent and immediate:
   - SMBG technique and testing times.
   - Initial advice regarding intake of carbohydrate containing foods and referral for more detailed information and meal planning.
   - How to recognise and treat of hypoglycaemia.
   - Contact details to health care providers for diabetes advice as needed.

4.4 The person receives self-management review, education and skills training of the following prior to insulin initiations when the intervention is not immediate or urgent:
   - SMBG technique and times.
   - General nutrition and the ability to identify carbohydrate containing foods.
   - Preparation of insulin injection device.
   - Recognition and treatment of hypoglycaemia.

4.5 The person is provided with a staged skills training and education program concurrently with clinical assessment.

4.6 A gradual timeline for achieving individual glycaemic targets is discussed and decided in collaboration with the person.

4.7 The progress is discussed with the person at each contact and regularly reviewed by members of the diabetes care team as part of their care plan.
Process Standard 5

The insulin type and regimen is matched to the person’s individual needs and determined by the treating/referring practitioner in collaboration with the person.

Quality Indicators:

5.1. Factors considered when determining choice of insulin, type, insulin delivery device and insulin with the person include:

- Type and duration of diabetes.
- Age of person.
- Metabolic status.
- Other medications.
- General health and well – being.
- Comorbidities, presence of chronic diabetes complications and individual risks associated with acute diabetes complications.
- Cognitive and functional status, and physical characteristics (for example; a vision problem).
- Usual meal/eating behaviour and beverage pattern.
- Lifestyle and physical activity pattern, including work, school and study.
- Glycaemic profile and individual targets.
- Individual preferences and diabetes self-management aspirations.
- Psycho-social factors.

5.2 The person’s initial dose is determined by:

- Weight.
- Age.
- Degree of hyperglycaemia.
- Severity of symptoms.
- Ketone levels.
- The level of insulin resistance present in the person.

5.3 The person’s glycaemic response to the insulin therapy is monitored and the insulin dose is adjusted accordingly.

5.4 The person’s weight change following initiation of insulin is monitored at each visit during the intervention and is a factor when determining incremental insulin dose adjustment.

5.5 The person’s insulin doses are adjusted either by:

- the treating/referring practitioner
- the health care provider undertaking the intervention who has accepted delegation of insulin dose adjustment,

in accordance with the relevant State and Territory Drugs and Poisons legislation.

5.6 The health care provider checks with the person that other ancillary diabetes supplies and equipment (for example needles [pen or syringe], syringes, single use delivery cartridges, glucagon injection kits, BG test strips, lancets) are in date and appropriate to persons diabetes care needs.
Process Standard 6

The person’s insulin is supplied according to State and Territory Drugs and Poisons legislation and handled according to manufacturer’s guidelines.

Quality Indicators:

6.1 The health care provider undertaking the intervention checks the expiry date and integrity of the prescribed or supplied insulin.

6.2 The health care provider undertaking the intervention confirms that the insulin delivery device’s compatibility with the prescribed or supplied insulin.

6.3 The health care provider undertaking the intervention ensures the insulin is supplied in accordance with State and Territory Drugs and Poisons Acts for Schedule 4 medications from either:
   - The service’s or provider’s pharmaceutical stocks in accordance with the provider/organisation’s policies for issuing a Schedule 4 medication.
   - The person who has submitted their prescription to a pharmacist who supplies the insulin and appropriately labels the vial or disposable insulin delivery device.

Process Standard 7

The person’s established medical record complies with accepted legislation and standards and documents an agreed care plan for concurrent educational and clinical management at each contact.

Quality Indicators:

7.1 The clinical and psychosocial assessment, care planning, self-care skills and initial and adjusted insulin doses are documented at each contact.

7.2 All adverse events e.g. hypoglycaemia that occurs throughout the intervention period are documented.

7.3 All adjustment of insulin dose, type and/or regimen are authorised or delegated in accordance with State and Territory Drugs and Poisons acts for prescription of Schedule 4 medications and documented in writing and with insulin dose units written in full.

7.4 Outcomes are evaluated against agreed goals and documented in the person’s medical record.

7.5 The health care provider undertaking the intervention reports to the treating/referring practitioner in writing outlining the process and outcomes.

7.6 Referral letters, laboratory results and copies of letters to referring/treating practitioners are held in the person’s paper or electronic medical records or other means of shared communications such as General Practice Management Plan (GPMP) and Team Care Arrangements (TCA).

7.7 The person’s confidentiality is maintained as per Australian legislation.
Process Standard 8

All members of the diabetes care team contribute to the person’s progress according to agreed clinical and educational goals through regular communication.

Quality indicators:
8.1 All members of the diabetes care team:
- Contribute towards achieving the agreed goals specified in the care plan and demonstrate a collaborative approach respecting each other’s discipline specific skills, training, attributes and contributions to providing diabetes self-management education and care.
- Share the responsibility for leadership, accountability and responsibility for comprehensive, holistic and individualised care planning and delivery.
- Are responsible for communication and sharing of relevant information that may influence management, process and progress.
- Demonstrate an understanding of the specific challenges faced by the person as a result of the intervention.
- Arrange access to other interventions and support services that may assist in addressing any individual, socio-economic and psycho-social needs.

Process Standard 9

Each member of the diabetes care team evaluates and documents the person’s progress towards developing the skills, confidence and knowledge required to complete the intervention.

Quality Indicators:
9.1 The person’s individual care plan is evaluated by each diabetes care team at each contact against agreed goals.

9.2 Communication occurs between the person with diabetes, the case manager and the health care provider undertaking the intervention regarding progress towards achieving agreed clinical and educational goals.

9.3 Written communication documenting the diabetes self-care skills, competencies, knowledge, practices and current glycaemic profile is forwarded within five (5) working days to the referring/treating practitioner after the person has completed the intervention.
Process Standard 10

The effectiveness and quality of the program/content for the intervention are evaluated regularly and revised according to the outcomes.

Quality Indicators:

10.1 The program for the intervention is reviewed and evaluated at a minimum every three (3) years including:
- Program objectives.
- Curriculum, instructional methods and materials.
- Timely access and waiting times.
- Follow-up mechanisms and programs.
- Program resources e.g. space, personnel, support material and budget.
- Program effectiveness using validated tools.
- Program outcomes against agreed targets using validated tools.
- Audit of documentation and reporting.
- Review of adverse events at the time of occurrence.
- Audit of adverse events.
- Post intervention arrangements for follow up and care.

10.2 The program for the intervention is amended and updated according to results of evaluations and more frequently to align with new best-practice evidence.

10.3 Policies, procedure manual and protocols are updated every three (3) years following evaluation or more frequently to align with new best-practice evidence.
Structure Standards

Structure standards describe the human and physical resources required to support the processes and outcomes.

**Structure Standard 1**

The intervention is provided through the collaborative efforts of an interdisciplinary team of health care providers with demonstrated specialist knowledge, skills and experience in managing insulin therapy.

**Structure Standard 2**

All health care providers who participate in insulin initiation intervention practise according to legislation and standards governing registration within their primary discipline, scope of practice and according to their organisational duty statement.

**Structure Standard 3**

People with diabetes have access to a range of education support materials reflecting best-practice.

**Structure Standard 4**

The consultation environment is conducive to clinical care and teaching and learning, and meets occupational health and safety and infection control legislation and standards.

**Structure Standard 5**

An organisational manual which documents all policies, processes and procedures relevant to the intervention and the interdisciplinary team members involved is reviewed every three (3) years.
Structure Standard 1

The intervention is provided through the collaborative efforts of an interdisciplinary team of health care providers with demonstrated specialist knowledge, skills and experience in managing insulin therapy.

Quality Indicators:

1.1 The interdisciplinary diabetes care team consists of, but is not limited to:
   - Doctor or NP;
   - Registered nurse (RN);
   - Diabetes educator (DE or CDE); and
   - Dietitian.

1.2 There are established referral pathways and protocols in place to ensure the person has access to other diabetes health care providers when required.

1.3 There are established protocols for communications between the diabetes care team members’ e.g. organisational policies, GPMP and TCA.

1.4 Communication between members of the diabetes care team is documented in the person’s medical records.

1.5 The person’s written referral from the treating/referring practitioner is maintained as part of the person’s medical record.

1.6 The person’s care plan includes evidence of:
   - nutrition assessment and planning
   - individual education goals and clinical targets identified collaboratively with the person with diabetes and the diabetes care team
   - lifestyle assessment
   - diabetes self-management skills assessment and training.
   - Diabetes self-management assessment and education.

1.4 Access to counselling and psychosocial support by qualified health professionals is available.

1.5 Professional interpreters are available.

1.6 Protocols are in place for the person with diabetes to access to advice about insulin therapy from health care providers when needed throughout the intervention.

1.7 All health care providers who undertake a coordinating and primary role in the intervention have the relevant training and endorsement to initiate insulin and have participated in professional development related to insulin initiation and management within the last three (3) years.
Structure Standard 2

All health care providers who participate in insulin initiation intervention practise according to legislation and standards governing registration within their primary discipline and, where not operating as a self-employed health care provider, according to their organisational duty statement.

Quality Indicators:

2.1 All health care providers involved in the intervention have their specific clinical practice responsibilities documented in organisational policies and duty statements.

2.2 All health care providers involved in the intervention maintain their competence through peer review and participation in professional development activities specifically addressing issues related to insulin initiation and therapy.

2.3 Evidence-based policies and protocols that meet the requirements of State and Territory Drug and Poison Acts are in place where insulin dose adjustments are delegated by the Medical Practitioner to a Registered Nurse via for example; hospital or organisational protocol or standing order.

Structure Standard 3

People with diabetes have access to a range of education support materials reflecting best-practice.

Quality Indicators:

3.1 Educational support material is:

- Reviewed for accuracy and currency in accordance to documented organisational policies.
- Provided in a timely manner as part of a planned learning intervention.
- In a format appropriate for the person.
- Culturally acceptable and at an appropriate literacy level.
- Where possible, offered in languages other than English when required.
- In a suitable format that accommodates specific cognitive, developmental or physical impairment needs.
- Affordable.

3.2 Health care providers undertaking the intervention have a wide range of insulin delivery devices and blood glucose monitoring equipment available for demonstration.

3.3 There is local access to a wide range of complimentary and/or ‘for purchase’ insulin delivery devices and blood glucose monitoring equipment.
Structure Standard 4

The consultation environment is conducive to clinical care and teaching and learning, and meets occupational health and safety and infection control legislation and standards.

Quality Indicators:

4.1 Individual consulting area is private and allows the presence of family members and/or carer(s).

4.2 Individual physical examination space is private and allows the presence of support persons.

4.3 Toilet and hand-washing facilities are available and meet infection control guidelines.

4.4 Disabled access is available to all facilities.

4.5 If kept on premises, insulin and glucagon are stored as per manufacturer’s recommendations and quality control mechanisms for both medicines and storage are in place.

4.6 Approved sharps and waste disposal facilities are available.

4.7 Organisational infection control policies and procedures, for example management of needle stick injury, meet best-practice guidelines.

4.8 A quality management process is in place for maintenance of medical assessment and other equipment and supplies.

4.9 The health care provider has access to telephone, facsimile and computer systems.

4.10 Storage of paper based medical records and access to electronic records meets privacy standards and legislative requirements.

Structure Standard 5

An organisational manual which is reviewed every three (3) years documents all policies, processes and procedures relevant to the intervention and the interdisciplinary team members involved.

Quality Indicators:

5.1 The manual states the roles and scope of practice for all members of the interdisciplinary diabetes care team.

5.2 All members of the interdisciplinary diabetes care team adhere to the policies, process and procedures approved by the organisation.

5.3 In organisations where incremental insulin dose adjustment is delegated, Standing Orders:

- Are included in the organisation’s manual.
- Meet the requirements of all State or Territory drugs and poisons legislation and health authority regulations.
- Are endorsed by the employing organisation and treating/referring practitioner.
- Document the process and parameters of incremental insulin dose adjustments during the intervention period.
- Document the expected skills and knowledge levels of the staff concerned as well as how and how often the skills and knowledge is assessed.
5.4 In organisations, where there are no standing orders for the intervention and subsequent incremental insulin dose adjustment, the treating/referring practitioner provides orders, in writing, for the health care provider undertaking the intervention.
Appendix 1

PRO-FORMA REFERRAL:

INITIATION & STABILISATION OF INSULIN THERAPY IN AN AMBULATORY SETTING

Referral to: _______________________________ [Organisation/Individual]

Date of referral: ___________________________ UR/ID: ___________________________

Patient Details
Name: ____________________________________ DOB: ___________________________
Address: __________________________________

H: ______ M: ______ W: ______ Email: ______________________________________

Carer Details: ___________________________
Carer Contact: ___________________________

Interpreter Required [ ] Language __________

Type of diabetes: Type 1 [ ] Type 2 [ ] Gestational [ ] Date of Diagnosis: ___________________________

HbA1c: ___________________________ **Please attach other relevant test results

Current treatment: ___________________________

In Type 2 diabetes, is current oral therapy to be continued as combination therapy?
Yes [ ] No [ ] If yes, please state type of oral agent and dosage:

Case Management for Patient Commencing Insulin Therapy in an Ambulatory Setting:
Please indicate by ticking appropriate section otherwise referral is INVALID -

[ ] The referrer wishes the CDE-RN / RN / _______________ to undertake insulin dose adjustment.
[ ] The referrer will manage ongoing insulin dose adjustment.

(Continues over page)
Insulin Therapy Order [and regime]:

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<th>Name</th>
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Size of incremental adjustments (Please indicate):

- [ ] As per the __________________________ (insert facility name) Protocols.
- [ ] Increments by set size; ______________ Maximum ___________ units per day.

Target blood glucose range:

- [ ] As per levels within set protocols listed above
- [ ] Fasting [____ mmol/L] Pre Prandial [____ mmol/L] Post Prandial [____ mmol/L].

Expectations for progress reports: Weekly [ ] Monthly [ ] 3 Monthly [ ] 6 monthly [ ]

Other Information:

Referring Doctor Signature:

Print Name/ Stamp: __________________________ Provider Number __________________________
Appendix 2

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%2B%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*
References


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ADEA. (2007). *The Credentialled Diabetes Educator in Australia - Role and Scope of Practice*. Canberra: ADEA.


