

National Insulin Titration Guideline for Nurses working with People with Diabetes who require Subcutaneous Insulin Injections



Is this document a:

Policy ☐

Procedure ☐

Protocol ☐

Guideline ☒

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<https://www2.healthservice.hse.ie/organisation/national-pppgs/>

Table of Contents

Part A

Disclaimer	4
1.0 Introduction	5
2.0 Purpose of Policy	5
3.0 Scope of Policy	6
3.1 The role of Clinical Nurse and Midwife Specialist Diabetes	6
3.2 Scope of practice	7
3.3 Registration with HPRA	7
3.4 Continuous Professional Development	7
3.5 Competence	8
3.6 High alert medication	9
3.7 Serious reportable events	9
4.0 General Glucose targets for adults on Insulin therapy	9
4.1 Individual glucose target	9
4.2 Continuous Glucose monitoring / Flash Glucose monitoring	11
4.3 Driving guidelines	11
4.4 End of life care	11
5.0 General Principles of Insulin titration for persons with diabetes already prescribed Insulin	11
5.1 Practice points when discussing Insulin titration with the person with Diabetes	12
5.1.2 Insulin specific issues	13
5.1.3 Carbohydrate counting education programmes	14
5.1.4 Safe Insulin titration during the period of Ramadan	15
6.0 Hyperglycaemia	15
6.1 Titration of insulin for hyperglycaemia	15
6.1.1 General guidelines for titration of bolus/pre-meal titration	15
6.1.2 General guidelines for titration of once daily basal insulin	16
6.1.3 Ultra-long acting Insulins	16
6.1.4 Guidelines for titration of twice daily basal insulin	16
6.1.5 General guidelines for titration of twice daily mixed insulin	17
7.0 Hypoglycaemia	17
7.1 Classification of hypoglycaemia	17
7.1.1 Procedure to follow if patient displays signs of hypoglycaemia whilst consulting with them	18
7.2 Insulin titration for hypoglycaemia	18
7.2.1 General guidelines for titrating bolus/pre meal insulin	18
7.2.2 General guidelines for titrating once daily basal insulin (including Ultra long acting insulins)	19
7.2.3 General guidelines for titrating twice daily basal insulin	19
7.2.4 General guidelines for titrating twice daily mixed insulin	19

8.0 General guidelines for titration of insulin in combination with other agents	20
9.0 Insulin Omission	21
9.1 Omission of ultra-long acting insulins	21
9.1.2 Omission of twice daily mixed insulin regime	21
9.1.3 Omission of mixed insulin	21
10.0 Insulin prescribing and administration: Reducing errors	22
11.0 Insulin titration guidance for Diabetes in the Pregnancy care setting;	
Pre, ante, peri and post-natal period	22
11.1 Recommended nursing standard to undertake insulin titration	22
11.2 Glycaemic control and Insulin requirements in pregnancy	23
11.2.1 Pre pregnancy glucose targets	23
11.2.2 Targets for capillary blood glucose monitoring in pregnancy	24
11.3 Continual glucose monitoring	24
11.4 Falling insulin requirements >15%	25
11.5 Types of insulin used during pregnancy	25
11.5.1 Longer acting insulins	25
11.6 Carbohydrate counting	25
11.7 Breastfeeding	26
References	27
Appendices	30
Appendix 1	31
Appendix 2	32
Appendix 3	32
Appendix 4	35
Appendix 5	35

Part B **36**

Disclaimer

This updated policy represents the view of the National Clinical Programme for Diabetes and was arrived at following careful consideration and consultation with stakeholders. The expectation of the National Clinical Programme for Diabetes is that healthcare professionals will use clinical judgement, medical, nursing and midwifery knowledge in applying the general principles contained in this document. The principles may not be appropriate in all circumstances and decisions to adopt specific principles should be made at the discretion of the Diabetes Nurse/ Midwife.

A detailed clinical assessment of the individual's needs should take into consideration potential risks as well as benefits to the person with Diabetes.

1.0 Introduction

This policy (revised from the first edition 2016) aims to support and assist nurses and midwives who are deemed to be experienced in managing people with diabetes who attend adult services on how to safely titrate their insulin dosage in;

- Acute hospital settings and specialist Hospitals e.g. Maternity Hospitals
- Outpatient/ambulatory care departments
- Integrated community care settings (including ambulatory care hubs)

By conducting patient consultations in accordance with local and HSE/DOH, IT /GDPR policies through:

- Direct face to face consultation
- Virtual consultation including telephone and video platforms.
- Email
- A blended approach which includes remote monitoring including electronic platforms provided by commercial glucose meter companies to upload devices.

Blood & interstitial (from Real-Time CGM and FGM) glucose levels are influenced by many factors including illness, stress, activity and certain medication and pregnancy. The person with diabetes may seek expert advice to reduce the risks of hypoglycaemia, prolonged hyperglycaemia, Diabetic ketoacidosis and in the case of pregnancy, potential foetal abnormalities.

2.0 Purpose of the policy

The ethos of diabetes care is self-care and self -management, wherever possible. However, people with diabetes may require the support of a Diabetes nurse or midwife for periods of time or at different stages of their lives e.g. while they learn the skills of insulin titration some people will require ongoing support with insulin titration indefinitely. For the duration of pregnancy insulin titration will be required once or twice weekly.

The primary aim of this policy is to support the diabetes nurse / midwife, (recommended Clinical Nurse Specialists (CNS) Diabetes and Clinical Midwife Specialist (CMS)) who are non-Prescribers of Medicinal Products working in the specialist area of diabetes care.

Specific local circumstances not addressed in this policy should be guided by local PPGs

3.0 Scope of policy

These guidelines are applicable to diabetes nurses /midwife, CNS /CMS Diabetes/ Registered Nurse & Midwife Prescribers working in specialist area of diabetes care with people already with a diagnosis of diabetes, attending adult services and who have already been prescribed Insulin by a medical doctor or Registered Nurse prescriber. All must be deemed competent in titration of insulin & have a local signed PPPG with their Director of Nursing/Midwifery / DPHN & by their Clinical supervisor e.g. Consultant Endocrinologist.

This policy also supports the Diabetes CNS/CMS Nurse & Midwife Prescribers in the safe and appropriate titration of insulin during unscheduled care in pregnancy

The policy *DOES NOT* address the management of:

- Sick days and ketone management
- Steroids and other medications which may influence blood glucose levels
- Continuous subcutaneous insulin infusion pumps
- Children who receive their care in paediatric services;

In the event of a pregnancy where the mother is attending paediatric services for scheduled diabetes care it will be dealt with on a local case by case basis as to whether or not insulin may be titrated by the CMS/CNS Diabetes in pregnancy.

This guideline is designed to provide the basis of a local policy document which must be agreed and signed off with the employer including the local drugs and therapeutics committee.

3.1 Role of Clinical Specialist Nurse (CNS)/Midwife (CMS) Diabetes

The CNS/CMS role offers practitioners a career pathway incorporating professional development within an inter-professional team structure. Diabetes is the defined area of practice. This specialist practice encompasses a major clinical focus of care to patients or clients and their families in hospital, community and outpatient settings (ONMSD 2021).

The specialist CNS/CMS works with medical and para-medical colleagues and may make alterations in prescribed clinical options along agreed protocol, - driven guidelines. (National Council for the Professional Development of Nursing and Midwifery, 2008).

The CNS/CMS role centres on 5 core competencies:

- Clinical focus (direct care and indirect care)
- Patient/client advocate
- Education and training
- Audit and research
- Consultant

(National Council for the Professional Development of Nursing and Midwifery, 2008a)

3.2 Scope of Practice

An individual Nurse's and Midwife's scope of practice is dynamic; it will change and grow as they progress in their career. The scope of practice of the individual nurse and midwife is influenced by a number of factors including:

- The nurse's and Midwife's educational preparation, professional practice and competence
- Local, national and international guidelines, policies and evidence;
- The practice setting;
- Collaborative practice;
- Other factors, such as patient safety, patient needs and care outcomes. (NMBI 2015)

3.3 Registration with Health Products Regulatory Authority HPRA for safety notices

It is best practice that all Clinical Nurse Specialists CNS Diabetes and Clinical Midwife Specialist CMS Diabetes/ Registered Nurse Midwife Prescribers titrating insulin should register with the HPRA for safety notices regarding devices and treatments, the online registration system is available at <https://www.hpra.ie/homepage/site-tools/register>

3.4 Continuous Professional Development

Competence can be achieved by engaging in continuing professional development (NMBI 2015)

3.5 Competence:

The Nurses and Midwives Act, 2011, states that Nurses and midwives must maintain their “professional competence on an ongoing basis” (ISB 2011)

The attainment of knowledge, intellectual capacities, practice skills, integrity and professional and ethical values required for safe, accountable and effective practice as a registered nurse or registered midwife (NMBI 2015)

Appointment to a post within a diabetes service should not automatically assume competence in the area of insulin titration. Therefore recommendations for best practice have been developed.

The recommended standard for insulin titration in non-pregnant adults.

- Ideally should be CNS level with relevant experience & have completed an appropriate level 8 / 9 qualification in diabetes care.
- Registered nurses who have appropriate experience/completed an appropriate qualification but who are employed at a grade other than CNS may titrate insulin where there is a local agreement by Director of Nursing /consultant endocrinologist/clinical supervisor.
- Nurses who are deemed not have clinical experience and /or an appropriate diabetes qualification should not routinely be titrating insulin in an unsupervised capacity. For nurses who are actively engaged in a training position and/or obtaining a higher level diabetes qualification any titration should be supervised when gaining experience in insulin titration as a locally agreed PPPG.

The recommended standard for insulin titration during pregnancy

- Scheduled care - Ideally CNS/CMS Diabetes with appropriate experience and a minimum level 8 or 9 qualification in diabetes care. They should also be a Registered Nurse/Midwife Prescriber as determined by the Nursing and Midwifery Board of Ireland and supporting legislation. Non prescribers should not regularly titrate within scheduled care.
- Unscheduled care - A CNS/CMS Diabetes in pregnancy who is a non-prescriber may have a locally approved PPPG for Insulin titration in unscheduled care. This should be in agreement with Director of Nursing/ Midwifery, Clinical Supervisor, Consultant Endocrinologist. (Within the local PPPG it is agreed the CNS/CMS to complete an appropriate programme and register as a prescriber with NMBI within two years of that agreement)

3.6 High-alert medications:

Insulin is identified as a high risk medicine. High risk medicines can cause significant patient harm or death when it is used in error (HIQA, 2019)

See www.ISMP.org or latest version of High –Alert medications in Acute Care and Ambulatory care settings.

The practitioner should be aware of Sound Alike Look Alike Drugs (SALADS) e.g Insulins including Humulin I, Humulin M3, Humulin S or Toujeo and Tresiba (Irish Medication Safety Network, 2019)

3.7 Serious reportable events:

‘Patient death or serious disability associated with a medication error by the healthcare provider but excluding reasonable differences in clinical judgement involving drug selection and dose’. Serious reportable events are a defined subset of incidents which are either serious or that should not occur if the available preventative measures have been effectively implemented by healthcare providers. Serious reportable events are mandatorily reportable by services to the Senior Accountable Officer (HSE 2015)

4.0 General blood targets for adults on insulin therapy

4.1 Individual Blood Glucose Target

- Glycaemic Recommendations for Non pregnant Adults with Diabetes (ADA 2022)

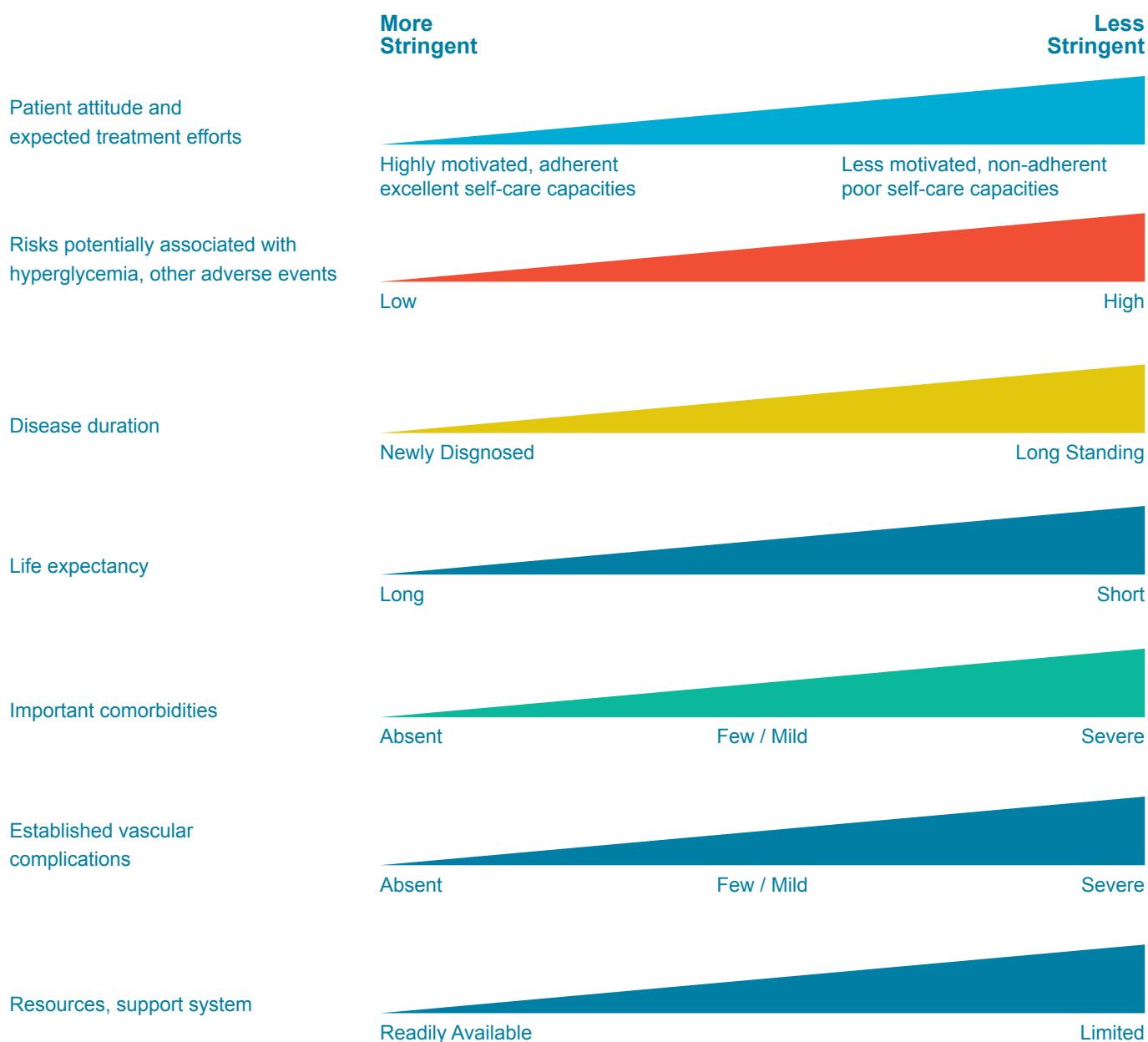
**More or less stringent glycaemic goals may be appropriate for individual patients. Goals should*

HbA1C	< 53 mmol/mol*
Pre-prandial capillary plasma glucose	4.4–7.2 mmol/L*
Peak postprandial capillary plasma glucose†	<10.0 mmol/L*

be individualized based on duration of diabetes, age/life expectancy, comorbid 9 conditions, known CVD or advanced microvascular complications, hypoglycaemia unawareness, and individual patient considerations.

†Postprandial glucose may be targeted if HbA1C goals are not met despite reaching pre-prandial glucose goals. Postprandial glucose measurements should be made 1–2 hours after the beginning of the meal, generally peak levels in patients with diabetes (ADA, 2022).

Approach to management of hyperglycemia



The National Clinical Programme for Diabetes has provided updated guidance on self-testing for people with type 2 diabetes available at;

<https://assets.hse.ie/media/documents/guide-to-blood-glucose-testing.pdf>

The HSE Medicines Management Programme has produced guidelines on preferred blood glucose strips. Further information available at;

<https://www.hse.ie/eng/about/who/cspd/medicines-management/blood-glucose-test-strips/>

4.2 Continuous Glucose Monitoring (CGM) / Flash Glucose Monitoring systems (FGM)

These devices have sufficient accuracy, reliability and robustness to permit use for adjustment of insulin doses without confirmation by blood glucose meter.

The Diabetes CNS/CMS needs to be aware of the guidelines and manufacturer's instructions for these devices. A high standard of continuous professional development should be maintained by the nurse / midwife to ensure the patient is educated on correct use of the appropriate device.

4.3 Driving Guidelines

Within scope of this document the Diabetes CNS/CMS should be familiar with driving guidelines for people with diabetes and advise appropriately. Individual patient assessment is always required.

For full guidance Health Care Professionals are advised to regularly review www.RSA.ie or www.ndls.ie

People with diabetes who are using insulin therapy must notify the National Driver Licence Service (NDLS 2017). Monitoring of glucose levels is mandatory for driver's prescribed Insulin therapy. People with hypoglycaemia unawareness must not drive and notify the RSA.

4.4 End of life care

In end of life care the aim is to keep the individual to be free of osmotic symptoms and not at risk of hypoglycaemia. Aim for readings of 6-15mmol/L (TREND 2018, HSE)

5.0 General principles of insulin titration for persons with diabetes already prescribed Insulin

- Observe patterns of glucose levels over a period of time (usually 3 – 4 days)
- Insulin doses should not be adjusted in response to a single high or low result.
- Discuss possible causes of out of target BGs refer to 6.1

- As per principles of medication administration establish that Insulin is being administered as prescribed i.e. the correct Insulin is being administered at the correct time (NMBI 2020)
- Insulin doses are usually increased or decreased in 10 % increments
- Insulin sensitivity can vary greatly from person to person. Where an individual dose is >50 Units, a 20% adjustment may be necessary
- Ideally, change one insulin dose at a time to avoid confusion and to allow time for results of adjustments to become apparent
- Preventing hypoglycaemia should always take priority over correcting hyperglycaemia; consider the issue of rebound hyperglycaemia.
- If nocturnal hypoglycaemia is suspected e.g. if a patient reports a poor night's sleep, headaches, night sweats, nightmares, talking, shouting or restlessness this would require confirmation by checking a 3am blood glucose level or by the use of CGMS/FGM.
- Documentation of any changes should be clear. Documentation should be as per local agreed PPPG's
- Insulins with their time action profiles in Appendix 1

5.1 Practice points when discussing insulin titration with the person with Diabetes.

- Identify the correct patient with name, address, telephone and date of birth.
- Establish that contact details such as telephone number/email address are up to date
- Identify type and duration of diabetes
- Review level of knowledge and current ability of Self-Management skills.
- Ascertain whether patient has received any recent advice regarding titration from another health care professional or has the patient made any changes to their insulin regimen themselves?

- If clinically appropriate ascertain if any recent change in renal, liver or pancreatic function
- Blood glucose monitoring: Identify if the correct technique was used when monitoring blood glucose levels i.e. hand washing prior to test, meter working correctly, test strips in date
- Review glucose levels over the previous 3 days to establish patterns
- Identify possible causes for abnormal blood glucose readings e.g.;
 - Discuss when did the patient last eat, has there been any change in diet including missed, delayed meals or change in carbohydrate content.
 - Has there been a change in physical activity from the norm/baseline for that person. Has there been less or more activity / exercise than is usual for them? Also enquire have they made any insulin adjustment themselves?
 - Have they taken any alcohol or other substances? Did the patient make any insulin and/or carbohydrate adjustment themselves.
 - Recent vaccinations
 - Has the patient commenced or discontinued any new medications e.g. /steroids?
 - Significant change in body weight
 - Inter-current illness (If the patient has Type 1 diabetes, have they tested for ketones?)
 - Is the patient feeling nauseated, vomiting or unable to tolerate fluids?
 - Special events such as travelling across time zones or fasting for Ramadan.
 - Risk of pregnancy if of reproductive age: Enquire if there is a possibility of pregnancy

5.1.2 Insulin specific issues:

- Establish current insulin regime, type, strength and usual dose(s) of insulin
- Establish has there been a recent change in the type of insulin?

- Consider any dose change guidelines that may have been followed. Think if switching to a biosimilar insulin e.g. Lantus to Abasaglar. Also consider bioequivalence of preparations e.g. Toujeo is not bioequivalent to Lantus
- If injection was missed why was that?
- Is Insulin being omitted regularly and if so why?
- Was the insulin administered as prescribed?
- Identify when the patient last took insulin (which insulin at what time if basal bolus)
- Identify any issues with visual acuity or dexterity
- Was the correct injection technique used?
- When was the needle last changed?
- Was the insulin stored correctly in keeping with manufacturer's guidelines?
- Was the insulin pen/cartridge/vial damaged?
- Is the patient rotating their injection sites on a regular basis? Is there any lipohypertrophy present? Advise as clinically appropriate. For guidance around Insulin injection please refer to the forum for injection technique guidelines (FIT) www.fit4diabetes.com

5.1.3 Carbohydrate counting education programmes for patients

- Any Diabetes CNS/CMS titrating insulin on a scheduled basis with patients who have completed any carbohydrate counting course e.g. DAFNE or BERGER ideally should have received the appropriate healthcare training in that specific course.
- In the case of unscheduled care where the CNS/CMS is not specifically trained in the appropriate course and titration takes place the changes should be documented and communicated to the appropriate team at the first possible opportunity.
- In the case of any person with diabetes who is trained in carbohydrate counting and not attending a centre which offers the appropriate expertise, every effort should be made to re-engage that person with the MDT in the appropriate centre.

5.1.4 Insulin titration for use in period of Ramadan

- Anyone with diabetes planning to fast during Ramadan should have a scheduled consultation with the diabetes team prior to the start of the fasting period to establish a care plan.
- Refer to IDF – DAR guidelines; https://dar-safa-storage-bahrain.s3.me-south-1.amazonaws.com/IDF_Da_R_Practical_Guidelines_2021_web_166f7cbf4f.pdf

6.0 Hyperglycaemia

- Refer to questions used in 5.1 to establish cause of hyperglycaemia
- If inter-current illness and /or ketones present, follow sick day rules in accordance with locally agreed and signed off PPPGs
- If patient is vomiting and unable to tolerate fluids, or is hyperglycaemic with ketones, please refer to your locally agreed PPPG on sick day rules for further management.

6.1 Titration of insulin for hyperglycaemia

6.1.1 General guidelines for titration of bolus/pre-meal insulin

Including insulins; Glulisine (Apidra), Aspart (Novorapid), Faster Acting Aspart- (Fiasp), Lispro (Humalog), Humulin S (soluble), Actrapid

Caution: Hyperglycaemia prior to meals is usually related to the previous bolus insulin or a snack between meals not matched appropriately with bolus insulin. However, if there is a long interval between meals, consider that hyperglycaemia is caused by an inadequate basal insulin dose.

High blood glucose /CGM/FGM readings	Titrate insulin dose
Pre-lunch	Increase morning bolus insulin by up to 10%
Pre-evening meal	Increase lunch-time bolus insulin by up to 10%
Pre-bed	Increase tea-time bolus insulin by up to 10%

6.1.2 General guidelines for titration of once daily basal insulin

Including Insulins; Glargine (Lantus & Abasaglar), Detemir (Levemir) Humulin

High blood glucose / CGM/ FGM readings	Titrate insulin dose
Pre-breakfast	Increase basal insulin by 10%

6.1.3 Ultra-long acting Insulins

Ultra-long acting Insulin formulations, Insulin Glargine (Toujeo) 300 units/ml and Insulin Degludec (Tresiba) 100 and 200 units/ml should be titrated less frequently. This is to minimise risk of hypoglycaemia from prolonged half-lives and a longer time to reach steady state; allow at least 5 days between titration of doses. (Kuritzky et al, 2019).

High blood glucose/ CGM/ FGM readings	Titrate insulin dose
Pre-breakfast	Increase basal insulin by 10%

If a dose of ultra-long acting insulin is forgotten the missed dose may be administered when discovering the mistake, ensuring a minimum of 8 hours between doses. If the patient discovers at the time of the next regular scheduled dose that the previous dose was missed a double dose should not be taken. Please refer to the individual Insulin SPC which can be found at www.medicines.ie

6.1.4 General guidelines for titration of twice daily basal insulin

E.g. Detemir, Humulin I

High blood glucose /CGM/FGM readings	Titrate insulin dose
Pre-breakfast	Increase evening basal insulin by 10%
Pre-evening meal	Increase morning basal insulin by 10%

6.1.5 General guidelines for titration of twice daily mixed insulin

E.g. Novomix 30, Humulin M3, Humalog Mix 25, Humalog Mix 50

High blood glucose CGM/FGM readings	Titrate insulin dose
Pre-breakfast	Increase evening dose by 10%
Pre-evening meal	Increase breakfast dose by 10%

7.0 Hypoglycaemia

Hypoglycaemia is a well-documented side effect of insulin therapy. It can produce a range of symptoms which may manifest differently in each individual. Some people may lose their ability to recognise hypoglycaemia due to lack of counter regulatory hormones (this will require intervention not covered by these guidelines). Symptoms may range from mild such as hunger, anxiety or irritability, palpitations, sweating, or tingling lips, to more severe which can result in convulsions, loss of consciousness, and coma.

7.1 Classification of Hypoglycaemia

Level 1	Glucose <3.9 and >3.0mmols
Level 2	Glucose <3.0mmol/L
Level 3	A severe event characterised by altered mental and or physical status requiring assistance for treatment

ADA 2022

It is recommend for all people receiving insulin therapy they be provided with education and information about prevention, awareness and management of hypoglycaemia.

People receiving insulin therapy should always be advised to have available a fast acting source of glucose for the management of hypoglycaemia. In cases of severe hypoglycaemia where a person has a reduced level of consciousness, intramuscular glucagon given by another person is recommended (NICE 2017) or intravenous glucose as per locally agreed PPPGs in the hospital setting.

7.1.1 Procedure to follow if the patient displays signs of hypoglycaemia when consulting with them:

- For hypoglycaemic management in a face to face consultation refer to local PPPG
- Refer to Appendix 1 if phone or virtual consultation
- Once the hypoglycaemic event has been dealt with establish the reasons for hypoglycaemia;
 - Has the patient experienced recent weight loss?
 - Is the patient on a reducing dose of steroids?
 - Has there been a change in renal function?
 - Identify at what blood glucose level the patient normally recognises hypoglycaemia symptoms
 - Does the patient have hypoglycaemia unawareness?
 - Is the patient breast feeding?
 - Establish if there are any factors which could have impacted on insulin absorption. E.g. change in weather or areas of lipohypertrophy?

7.2 Insulin titration for hypoglycaemia

- If a patient has unexplained hypoglycaemia, insulin should be reduced
- If there is a reason for the hypoglycaemia, advise the patient to act to prevent it from happening again.
- If a patient has a severe unexplained hypoglycaemic event consider reducing the relevant insulin by 20%

7.2.1 General guidelines for titrating bolus / pre-meal insulin

E.g. Apidra – Insulin Glulisine, Novorapid or Fiasp - Aspart, Lispro - Humalog Humulin S, Actrapid

Caution: In general, hypoglycaemia prior to meals is usually related to the previous dose of bolus insulin. However, if there is a long interval between meals, or if there is hypoglycaemia before each meal consider that hypoglycaemia may be caused by excess basal insulin.

Low blood glucose/CGM /FGM readings	Titrate insulin dose
Pre-lunch	Decrease morning bolus insulin by 10%
Pre-evening meal	Decrease lunch-time bolus insulin by 10%
Pre-bed	Decrease tea-time bolus insulin by 10%

7.2.2 General guidelines for titrating once daily basal insulin (including ultra-long acting insulins)

e.g. Glargine (lantus /Abasaglar) Detemir (Levemir) Isophane, Humulin, Glargine 300iu/ml (Toujeo) and Degludec (Tresiba)

Low blood glucose /CGM/FGM/readings	Titrate insulin dose
Pre-breakfast	Decrease basal insulin by 10%

N.B. Caution with Insulins Degludec and Glargine 300/ml (Toujeo) Due to long half-life allow at least 5 days between titration of doses

7.2.3 General guidelines for titrating twice daily basal insulin

e.g. Detemir – Levemir, Humulin I

Low blood glucose reading	Titrate insulin dose
Pre-breakfast	Decrease evening basal insulin by 10%
Pre-evening meal	Decrease morning basal insulin by 10%

7.2.4 General guidelines for titrating twice daily mixed insulin

e.g. Novomix 30, Humulin M3, Humalog Mix 25, Humalog Mix 50

Low blood glucose readings	Titrate insulin dose
Pre-breakfast	Decrease evening dose by 10%
Pre-evening meal	Decrease breakfast dose by 10%

8.0 General Guidelines for titration of insulin in combination with GLP1 agonists

At the time of publishing these guidelines 2022, in Ireland the only insulin available in combination with another agent i.e. GLP-1 agonist is;

Insulin Degludec (Tresiba) in combination with Liraglutide (Victoza) otherwise known as Xultophy®.

Xultophy® is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus. There is no clinical experience with the use of Xultophy®, Insulin Degludec or GLP-1 agonist Liraglutide in pregnant women. If a patient wishes to become pregnant, or pregnancy occurs, treatment with Xultophy should be discontinued.

Xultophy® is administered in units but titrated as dose steps. One dose step contains 1 unit of insulin degludec and 0.036 mg of liraglutide. The pre-filled pen can provide from 1 up to 50 dose steps in one injection in increments of one dose step. The maximum daily dose of Xultophy is 50 dose steps i.e. 50 units of Insulin Degludec and 1.8 mg Liraglutide.

Dose adjustment after initiation of Xultophy® treatment is important and should be done in accordance with the individual patient's need. Optimise glycaemic control by adjusting the dose of Xultophy® twice weekly, based on fasting (pre-breakfast) plasma glucose (FPG). In the clinical trial programme the number of dose steps of Xultophy® was adjusted twice weekly by patients according to a pre-defined algorithm (see below), based on self-measured FPG (mean of 3 consecutive days), striving for a mean FPG concentration of 4.0-5.0 mmol/L or agreed patient target. (HPRA /Novo Nordisk, 2020)

Adjust dose according to FPG individualised target	
Above target	+2dose steps
At target	Maintain dose
Below target	-2dose steps

9.0 Insulin omission

Glucose control was negatively impacted on by level of missed, mistimed or reduced insulin doses being identified (Ellis et al 2018).

- Refer to point 5.1 for questions which may help establish reasons for insulin omission.
- Advise persons with diabetes that they may experience high blood glucose levels for 24 – 48 hours post omission of insulin.
- If ketones are present, treat as per 'sick day' rules in accordance with local approved PPG's
- If risk of HHS contact medical team/emergency service

9.1 Omission of Ultra long acting insulins

Manufacturer's guidelines state Insulin Degludec (Tresiba) may be taken at the time of discovering injection has been missed, however you must ensure there is more than 8 hours between injections. (Tresiba SPC, Medicines.ie)

Xultophy® "patients who forget a dose are advised to take it up on discovery and then resume their once daily dosing schedule. A minimum of 8 hours

9.1.2 Omission of Rapid acting bolus/pre meal insulin

Advice should be on the basis of clinical discretion. Factors influencing advice include type of diabetes; time elapsed since the last injection and time to the next scheduled injection.

9.1.3 Omission of mixed insulin

Advice should be on the basis of clinical discretion. Factors influencing advice include type of diabetes; time elapsed since the last injection and time to the next scheduled injection.

10.0 Insulin prescribing and administration: reducing errors

There are several high strength Insulin products available; the European Medicines Agency (EMA) provides guidance on preventing medication errors, with high strength insulins (EMA, 2015)

Other advice for healthcare professionals;

- Ensuring people with diabetes are provided with adequate information about their insulin.
- Prescribing insulin doses in units, ensuring that the word 'units' is spelled out in lower case and never as 'U' or 'iu'
- Only use insulin with the pre-filled pen it is supplied in, this is particularly important in high strength insulin.
- Insulin should never be drawn from a cartridge or a pre filled pen up via a separate syringe (James & Diggle 2016)
- Clear explanation of the appearance between different strength insulin preparations
- Advising people to closely monitor their blood glucose levels when starting high-strength insulin or making any insulin regimen changes.

11.0 Insulin titration guide for the Diabetes in Pregnancy care during the pre, ante, peri and postnatal setting

11.1 Recommended nursing standard to undertake titration

Women in pregnancy attend regularly for scheduled care with RAMP /Consultant; The Clinical Midwife / Nurse Specialist CMS/CNS in diabetes in pregnancy may titrate insulin for unscheduled care to avoid hypoglycaemia and treat hyperglycaemia requiring immediate titration. This can be done by 10-20% of the Total Daily Dose (TDD) of Insulin adjusted for unscheduled emergency care ensuring the woman has an appointment with the Consultant Endocrinologist or the Registered Advanced Midwife Practitioner Diabetes for a scheduled routine appointment. This appointment may occur in a virtual, telephone/video call or a face to face outpatient/ inpatient consultation.

Due to the complexity of insulin management in pregnancy, escalation of Diabetes care from the CNS/ CMS as per local guidelines to the Registered Advanced Midwife Practitioner Diabetes and/or Consultant

Endocrinologist is recommended if the woman has co existing conditions, comorbidities of her diabetes or the CMS Diabetes/RAMP considers the Diabetes care is outside her scope of practice as per (NMBI 2015). The recommended acceptable standard is clearly set out in section 3.5 'Competence'

Guidelines should be adopted & adapted locally; exclusion criteria for insulin titration by the CMS/RNP should be agreed among the Senior Midwifery Management, the Consultant Endocrinologist and the CMS Diabetes/Registered Nurse Midwife Prescriber.

Any CNS/CMS caring for women with Diabetes in Pregnancy who is not currently a registered prescriber must have a minimum of 1 year of active supervised experience (this should not just be a year of employment in the post) of titrating insulin under the endocrinologist or RAMP, plus a minimum of 40 separate case titrations before they can be considered competent & signed off to titrate independently. An agreement should be undertaken that the prescribing programme will be completed within a 2 year time frame.

Any post holder who does not have a minimum qualification of post graduate diploma (or equivalent qualification) level 8 or 9 & therefore does not fit the criteria for CNS/CMS should NOT be titrating insulin in pregnancy.

11.2 Glycaemic control and Insulin requirements in pregnancy

'Glucose control remains paramount in later stages of pregnancy for women diagnosed with GDM, type 1 diabetes, or type 2 diabetes. Hyperglycaemia after organogenesis is a risk factor for large-for-gestational-age babies, macrosomic babies (>4,500 g), shoulder dystocia (birth injury), neonatal hypoglycaemia, hyperbilirubinemia, and admission to the neonatal intensive care unit. Maternal outcomes include a higher risk for preeclampsia, primary caesarean section, and preterm labour. Finally, long-term effects of maternal hyperglycaemia on the child include a higher risk of childhood obesity and adult diabetes. Tight glycaemic control before conception and throughout pregnancy can decrease the prevalence of these outcomes in women with any type of diabetes' (Blum 2016).

Women with type 1 diabetes may experience increased or occasionally reduced insulin sensitivity in the first trimester, with predictable increasing resistance in the second and third trimesters, requiring additional testing for the treatment of low blood glucose levels. The physiology of pregnancy requires frequent titration of insulin to match changing requirements. In the first trimester, there is often a decrease in total daily dose of insulin. In the second trimester, rapidly increasing insulin resistance requires weekly or biweekly increase in insulin dose to achieve glycaemic targets. Insulin requirements change dramatically during pregnancy, Insulin resistance and therefore insulin requirements rise in

the second and third trimesters (Buschur 2021). Rapid implementation of tight glycaemic control in the setting of retinopathy is associated with worsening of retinopathy therefore any changes noted from baseline should be urgently escalated for the appropriate medical attention. Most women with T1DM require 1.5 to 2 times the pre-pregnancy insulin requirement in the third trimester. Insulin requirements during pregnancy can be increased in certain clinical scenarios including multiple pregnancy. Gestational insulin requirements may be reduced for some women with T1DM who have longer diabetes duration, with renal or hepatic dysfunction (Buschur 2021). 'Insulin resistance decreases dramatically immediately postpartum and insulin requirements need to be evaluated and adjusted as they are roughly half the pregnancy requirements for the initial few days post-partum' (ADA,2022). Insulin sensitivity increases in the immediate postpartum period and then returns to normal over the following 1–2 weeks, and many women will require significantly less insulin at this time than during the pre-partum period.

11.2.1 Pre pregnancy targets

Prior to conception it is recommended that HbA1c levels should be <48mmols

(ADA 2022) A target of up to 53mmols/mol may be recommended in certain circumstances

11.2.2 Targets for capillary Blood Glucose Monitoring in pregnancy

Pre-prandial and pre-bed:	<5.3 mmol/L
1-hour post prandial	<7.8 mmol/L
2 hours post prandial	<6.7 mmol/L

Whilst avoiding excessive hypoglycaemia. If hypoglycaemia cannot be avoided consider less stringent targets (ADA 2022)

Accurate and timely adjustments depend on accurate blood glucose testing, type of insulin used, and consistent carbohydrate levels for meals. Fasting, pre-prandial, 1-hour postprandial, and bedtime blood glucose levels are all important to monitor all types of diabetes during pregnancy. Maintaining tight control throughout pregnancy will require close and frequent monitoring to titrate appropriate doses of insulin treatment

11.3 Continuous Glucose monitoring

It is agreed that CGM-based glycaemic targets must be personalised to meet the needs of everyone with diabetes. CGM targets of 3.5– 7.8 mmol/L have been recommended during pregnancy, along with a time in target of 70 % for women with type 1 diabetes.

11.4 Falling insulin requirements >15% in pregnancy

This is an important clinical sign, among women with diabetes, that should alert the CNS/CMS /RAMP to immediate escalation to the Consultant Obstetrician for investigation of underlying placental dysfunction and pre-eclampsia (Padmanabhan 2017).

11.5 Types of Insulin Used in Pregnancy services

The type of insulin used is to be decided by the diabetes in pregnancy team under the clinical supervision of the Consultant Endocrinologist

11.5.1. Longer acting insulins

Insulin Degludec (Tresiba) should be omitted on day one postnatal if it was administered in the 24 hours before the birth due to its long duration of action of 42 hours (Keller et al 2019).

11.6 Carbohydrate Counting

When women with diabetes who have received carbohydrate counting education e.g. DAFNE/BERGER training are pregnant and attending a Diabetes in Pregnancy service, at the start of the pregnancy the CNS/CMS in the Diabetes in Pregnancy service doing unscheduled insulin titrations, should develop an individual plan for insulin titrations in collaboration with the RAMP/Consultant Endocrinologist for each woman, and escalate any concerns to the RAMP/Consultant Endocrinologist during the pregnancy.

In a centre which is receiving referrals of mothers from multiple locations; in the interests of safety carbohydrate ratios should be expressed as 1:10g. Carbohydrate portions (CP's) should not be used however dietetic support may be required to facilitate the change from CP's to grams. This is to take into account different methods of carbohydrate counting e.g. DAFNE & BERGER that are used in different referring centres and avoid confusion.

11.7 Breastfeeding

“All women including those with diabetes should be supported in attempts to breastfeed.... Lactation can increase the risk of overnight hypoglycaemia and insulin dosing may need to be adjusted”. (ADA 2022)

Hypoglycaemia is a concern in the breastfeeding period among women with type 1 diabetes and ketoacidosis may also occur. The usual goals for glucose values for persons with diabetes also apply during breastfeeding. The recommended minimum daily carbohydrate intake is 210 g during breastfeeding, and this may contribute to prevention of hypoglycaemia and ketoacidosis while aiming for gradual weight loss (if necessary/advised) Insulin requirements are approximately 20% lower during breastfeeding than before pregnancy (Ringholm 2020)

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Appendices

Appendix 1

Insulin preparations chart

Appendix 2

What to do if a patient shows signs of hypoglycaemia during a telephone / virtual consultation

Appendix 3

Glossary of terms

Appendix 4




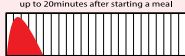













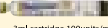














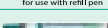

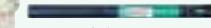


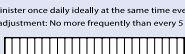







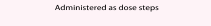
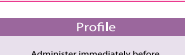







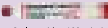

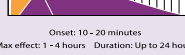





Further reading

Appendix 5

Governance Group

Appendix 1

Insulin preparations chart

INSULIN PREPARATIONS CHART									
ULTRA RAPID INSULIN		Vial	Refill Pen	Cartridge	Pre-filled Pen	Profile			
Fiasp® (Insulin Aspart)	NOVO NORDISK	 10ml Vial 100units/ml	NP5 NPE	 3ml cartridge 100units/ml for use with refill pen	 Pre-filled FlexTouch Pen 100units/ml	Administer immediately before a meal or up to 20minutes after starting a meal  Onset: 5 minutes Max effect: 1-3hrs Duration: 3-5hrs			
RAPID ACTING INSULIN		Vial	Refill Pen	Cartridge	Pre-filled Pen	Profile			
	Apidra® (Insulin Glargine)	SANOFI	 10ml Vial 100units/ml	AS JS	 3ml cartridge 100units/ml for use with refill pen	 Pre-filled SoloStar Pen 100units/ml	Administer immediately before a meal  Onset: 10-20 minutes Max effect: 1-3 hours Duration: 3-5 hours		
	Humalog® (Insulin Lispro)	EULIPLY	 10ml Vial 100units/ml	HS	 3ml cartridge 100units/ml for use with refill pen	 Pre-filled KwikPen 200units/ml			
NovoRapid® (Insulin Aspart)	NOVO NORDISK	 10ml Vial 100units/ml	NP5 NPE	 3ml cartridge 100units/ml for use with refill pen	 Pre-filled FlexPen 100units/ml				
SHORT ACTING INSULIN		Vial	Refill Pen	Cartridge	Pre-filled Pen	Profile			
	Actrapid® (Insulin Soluble)	NOVO NORDISK	 10ml Vial 100units/ml	N/A	N/A	N/A	Administer 30 minutes before a meal  Onset: 30 minutes Max effect: 2-4 hours Duration: 6-8 hours		
Humulin S® (Insulin Soluble)	EULIPLY	 10ml Vial 100units/ml	S	 3ml cartridge 100units/ml for use with refill pen	N/A				
MEDIUM ACTING INSULIN		Vial	Refill Pen	Cartridge	Pre-filled Pen	Profile			
	Humulin I (Insulin Human)	EULIPLY	 10ml Vial 100units/ml	HS	 3ml cartridge 100units/ml for use with refill pen	 Pre-filled KwikPen 100units/ml	Administer once daily at the same time each day OR Twice daily 30 minutes prior to breakfast and evening meal. Mix to form a uniform cloudy or milky suspension before each use  Onset: 1.5 hours Max effect: 4-12 hours Duration: Up to 24 hours		
Insulatard (Insulin Human)	NOVO NORDISK	 10ml Vial 100units/ml	NP5 NPE	 3ml cartridge 100units/ml for use with refill pen	 Pre-filled Innolet device 100units/ml				
LONG ACTING INSULIN		Vial	Refill Pen	Cartridge	Pre-filled Pen	Profile			
	Abasaglar® (Insulin Glargine)	EULIPLY	 N/A	N/A	N/A	 Pre-filled KwikPen 100units/ml	Administer once daily at the same time each day (Lantus and Abasaglar) Administer once or twice daily at the same time each day (Levemir)  Onset: 1-2 hours Max effect: From 2 and up to 24 hours Duration: Up to 24 hours		
	Lantus® (Insulin Glargine)	SANOFI	 10ml Vial 100units/ml	AS JS	 3ml cartridge 100units/ml for use with refill pen	 Pre-filled SoloStar Pen 100units/ml			
Levemir® (Insulin Detemir)	NOVO NORDISK	 N/A	NP5 NPE	 3ml cartridge 100units/ml for use with refill pen	 Pre-filled Innolet device 100units/ml  Pre-filled FlexPen 100units/ml				
INSULIN PREPARATIONS CHART									
LONGER ACTING INSULIN		Vial	Refill Pen	Cartridge	Pre-filled Pen	Profile			
	Toujeo® (Insulin Glargine)	SANOFI	 N/A	N/A	N/A	 Pre-filled SoloStar Pen 300units/ml	Administer once daily ideally at the same time every day Dose adjustment: No more frequently than every 5-7 days  Onset: Takes at least 3 days to reach steady state Duration: Toujeo up to 36 hours / Tresiba up to 42 hours		
Tresiba® (Insulin Degludec)	NOVO NORDISK	 N/A	N/A	N/A	 Pre-filled FlexTouch Pen 200units/ml  Pre-filled FlexTouch Pen 100units/ml				
LONGER ACTING Insulin combinations		Vial	Refill Pen	Cartridge	Pre-filled Pen	Profile			
Xultophy® (Insulin Degludec / Liraglutide)	NOVO NORDISK	 N/A	N/A	N/A	 Administered as dose steps	Xultophy is administered as 'dose steps' 1 dose step = 1unit of insulin degludec (Tresiba) and 0.036mg of liraglutide (Victoza)			
BIPHASIC INSULIN		Vial	Refill Pen	Cartridge	Pre-filled Pen	Profile			
	Humalog Mix 25 (Insulin Aspart and Insulin Glargine)	EULIPLY	 N/A	HS	 3ml cartridge 100units/ml for use with refill pen	 Pre-filled KwikPen 100units/ml	Administer immediately before breakfast and evening meal. Mix to form a uniform cloudy or milky suspension before each use.  Onset: 10-20 minutes Max effect: 1-4 hours Duration: Up to 24 hours		
	Humalog Mix 50 (Insulin Aspart and Insulin Glargine)	EULIPLY	 N/A	HS	 3ml cartridge 100units/ml for use with refill pen	 Pre-filled KwikPen 100units/ml			
	NovoMix 30 (Insulin Aspart and Insulin Glargine)	NOVO NORDISK	 N/A	NP5 NPE	 3ml cartridge 100units/ml for use with refill pen	 Pre-filled FlexPen 100units/ml			
Humulin M3 (Insulin Aspart and Insulin Human)	EULIPLY	 10ml Vial 100units/ml	HS	 3ml cartridge 100units/ml for use with refill pen	 Pre-filled KwikPen 100units/ml	Administer 30 minutes before breakfast and evening meal. Mix to form a uniform cloudy or milky suspension before each use  Onset: 30-60 minutes Max effect: 2-8 hours Duration: 12-24 hours			
REFILL PENS FOR USE WITH 3ML CARTRIDGES									
AS		JS		HS		NP5		NPE	
PLEASE NOTE: In order to reduce Insulin errors it is recommended to prescribe all insulins using their trade names.									
INSULIN STORAGE: All insulins should be stored in the fridge prior to use. Once opened insulin vials, cartridges and pens should be stored at room temperature in a locked drug trolley. All insulins in use should have opening date recorded and not be in use for more than 4 weeks. Insulin pens in use should be labelled with Insulin patient name and Hospital Number.									
PLEASE NOTE: All insulins are administered S/C. Insulins marked with an 'm' may also be administered IV. Insulin should only be drawn up from a vial using an insulin U100 syringe. Insulin MUST NOT be drawn up from cartridges or disposable pens. Administration advice is a general guideline only. For specific product instructions refer to summary of product characteristics.									
All trademarks, product names, company names and logos appearing on this poster are registered and protected by their respective owners.									
PRODUCED BY: DIABETES NURSE SPECIALISTS SLIGO UNIVERSITY HOSPITAL MAY 2020 The cost associated with the original printing of this poster were sponsored by NovoNordisk Novo Nordisk Ltd, have had no input into the content of this publication. The costs associated with printing of this updated version of this poster have been sponsored by the Irish Diabetes Nurses and Midwives Specialist Association.									

Appendix 2

What to do if a patient shows signs of hypoglycaemia during a telephone / virtual consultation

- Instruct the patient to check for & correct hypoglycaemia. Consider how patient is feeling / assess cognitive ability before continuing the consultation.
- If the patient is unable to check blood glucose levels and correct it themselves a third party will need to help. If this is a virtual consultation check someone is there to help.
- If patient is alone and unable to check their own glucose level or administer treatment to themselves then the emergency services should be called immediately.
- Patient safety should be maintained at all times.
- Only when the blood glucose level is above 4.0mmol/L and the patient is feeling well should the assessment be continued, if the patient does not feel they wish to continue the consultation should be postponed to another suitable time.
- If a patient has a severe hypoglycaemic event the consultation should be postponed to another suitable time (this is to allow for the time it takes for the brain to recover from hypoglycaemia)

Appendix 3

Glossary of terms

Bioequivalent

The property where 2 drugs with identical active ingredients possess similar bioavailability and produce the same effect at the site of physiological activity

Biosimilar

A biological medicine that is highly similar to another biological medicine (known as the reference medicine) which already has a marketing authorisation and has been approved for use in patients.

CGM

Continual glucose monitoring

Clinical Nurse/Midwife Specialist (CNS/CMS) Diabetes

A nurse or midwife who is registered with the Nursing and Midwifery Board of Ireland/An Bord Altranais agus Cnáimhseachais na hÉireann and who has undertaken the required level of educational preparation as verified by the Nursing and Midwifery Planning and Development Unit (HSE) to practice as a CNS/CMS in the specialist area of Diabetes. He/She is employed as a Clinical Nurse Specialist / Clinical Midwife Specialist in Diabetes.

Diabetic ketoacidosis (DKA)

DKA is a life threatening condition characterised by uncontrolled hyperglycaemia, metabolic acidosis and increased total ketone body concentration

FGM

Flash glucose monitoring

HbA1c

(Glycated Haemoglobin) a stable glycoprotein formed when glucose binds to Haemoglobin A in the blood. Measuring Hba1c levels in the blood determines average blood glucose concentration in the preceding 2 – 3 months.

Hyperglycaemia

Elevation of blood glucose levels above the normal range.

Hypoglycaemia: Hypoglycaemia is a condition characterized by abnormally low blood glucose, which in extreme cases can lead to unconsciousness and death

Hypoglycaemia unawareness

The onset of neuroglycopenia before the appearance of autonomic warning symptoms. Clinically it is manifested as the inability to recognise hypoglycaemia by symptoms.

Insulin

Insulin is a protein pancreatic hormone secreted by the beta cells of the Islets of Langerhans that is essential for metabolism of carbohydrates and regulation of glucose levels in the blood

Ketone bodies

Three related compounds (acetone, acetoacetic acid and beta-hydroxybutyric acid) two of which are used a source of energy instead of glucose produced during the metabolism of lipids. They accumulate in blood and urine in abnormal amounts in conditions of impaired metabolism such as diabetes mellitus

MDT

Multi disciplinary team. Members of the wider team involved in the persons care which may include; medical staff, nurses, podiatrists, dietitians and other associated health care professionals

NMBI

Nursing and Midwifery Board of Ireland / An Bord Altranais agus Cnáimhseachais na hÉireann

PPPG's

Policies, procedures, protocols and guidelines

Registered Nurse

A person whose name is entered in the relevant division of the live register of nurses and midwives with the Nursing and Midwifery Board of Ireland.

Registered Nurse Prescriber

A nurse or midwife who is registered in the relevant division of the register of nurse prescribers of NMBI

Registered Advanced Nurse/ Midwife Practitioners (RANPs/RAMPs)

Advanced nursing practice is defined as a career pathway for registered nurses committed to continuing professional development and clinical supervision, to practice at a higher level of capability as independent, autonomous and expert practitioners. Registered Advanced Nurse Practitioners (RANPs) have met the board's criteria to enter the advanced practice division of the register.

Registered Advanced Midwife Practitioner RAMP

Advanced midwifery practice is carried out by autonomous experienced practitioners who are competent, accountable and responsible for their own practice through caseload management of acute or chronic illness (National Council for the Professional Development of Nursing and Midwifery 2008b). The Registered Advanced Midwife Practitioner RAMP utilises advanced clinical midwifery knowledge and critical thinking skills to provide optimum care and improved clinical outcomes for women and their babies through higher levels of critical analysis, problem solving and senior clinical decision-making as a lead healthcare professional who is accountable and responsible for their own practice (NMBI, 2018).

Registered Nurse/ Midwife Prescriber RNMP

Prescribing is an expansion of a registered nurses or midwife's scope of practice, beyond the skills, competence and knowledge an individual practitioner possesses at the point of registration (NMBI, 2019). Nurses and midwives prescribe within the confines of robust legislation and professional regulation and their scope of practice. Improving client care is core to this extended role.

Scope of practice

The range of roles, functions, responsibilities and activities in which a registered nurse is educated, competent and has autonomy to perform.

Titration

Where medication has been prescribed within a range of dose, it is acceptable for registrants (nurses, midwives and specialist community public health nurses) to titrate doses according to patient response and symptom control and to administer within the prescribed range.

Unscheduled care

This can be defined as health care which cannot reasonable be foreseen or planned in advance of contact with the relevant professional.

Type 1 diabetes

Type 1 diabetes is characterised by autoimmune, cell-mediated, selective destruction of the insulin-producing beta cells of the pancreatic islets in genetically predisposed individuals

Type 2 diabetes

Type 2 diabetes is characterised by a relative deficiency of endogenous insulin in the presence of impaired insulin action, leading to increased hepatic glucose production and decreased insulin-mediated glucose uptake due to post-receptor defect in muscle.

Appendix 4

Further reading

The Nursing management of adults with type 2 diabetes. HSE Land

Appendix 5

Governance Group

Joanne Lowe – CNS Integrated care /lead nurse National Clinical Programme for Diabetes

Ciara Coveney- RAMP

Yvonne Moloney- RAMP

National Clinical Programme Diabetes

Richard Walsh – Director of Nursing Integrated Care

Integrated care nurses for Diabetes national group

IDNMSA

OMNSD

National Clinical Programme for Diabetes Clinical Advisory Group

Part B

B1.0 Initiation – this national policy has been developed in partnership with key stakeholders to comply with HSE statutory obligations and to give practical effect to the governing. Legislation and NMBI guidance documents

B1.1 Purpose

This guideline was developed and has been revised to provide information and guidance to support the health service provider undertaking the process of titration of Insulin which has already been prescribed.

B1.2 Scope

The scope of this PPPG identifies what will (and will not) be covered by the PPPG

1.2.1 Target users; identify who the intended audience is and how they may use the PPPG.

1.2.2 Population to whom it applies; identify who will (and will not) be covered by the PPPG, age range, sex, (clinical) description, comorbidity (if applicable).

These guidelines are applicable to diabetes nurses /midwife, CNS /CMS Diabetes/ Registered Nurse & Midwife Prescribers working in specialist area of diabetes care with people with a diagnosis of diabetes already, attending adult services and who have already been prescribed Insulin by a medical doctor or Registered Nurse prescriber. All must be deemed competent in titration of insulin & have a local signed PPPG with their Director of Nursing/Midwifery/DPHN & by their Clinical supervisor e.g. Consultant Endocrinologist.

This policy also supports the Diabetes CNS/CMS Nurse & Midwife Prescribers in the safe and appropriate titration of insulin during unscheduled care in pregnancy.

The policy DOES NOT address the management of:

- Sick days and ketone management
- Steroids and other medications which may influence blood glucose levels
- Continuous subcutaneous insulin infusion pumps
- Children who receive their care with in paediatric services;

In the event of a pregnancy where the mother is attending paediatric services for scheduled diabetes care it will be dealt with on a local case by case basis as to whether insulin may be titrated by the CMS/ CNS Diabetes in pregnancy or not.

This guideline is designed to provide the basis of a local policy document which must be agreed and signed off with the employer including the local drugs and therapeutics committee.

B1.3 Objective(s) support best practice in insulin titration, support safety of patients and staff.

B1.4 Outcome(s) this national policy will provide information and guidance to promote and enhance evidence based practice in nurses and midwives who are responsible for titrating insulin

B1.5 PPPG Development Group National clinical programme diabetes, CAG, IDNMSA, ONMSD

B1.6 PPPG Governance Group

The national nurse lead co-ordinated the revision of this document.

See Appendix 5

B1.7 Supporting Evidence

1.7.1 List relevant legislation/PPPGs. See part A

1.7.2 List PPPGs that are being replaced by this PPPG –
This will replace the Insulin titration guidelines 2016 version 1

1.7.3 List related PPPGs.

Management of Hyperglycemia in Type 2 Diabetes, 2022. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)
<https://diabetesjournals.org/care/article/45/11/2753/147671/Management-of-Hyperglycemia-in-Type-2-Diabetes>

B1.8 Glossary of Terms Appendix 3

B2.0 Development of pppg

B2.1 Clinical/non-clinical questions addressed in PPPG

Identify areas of new and emerging evidence or areas where there is variation in practice, which will form the basis of the PPPG and the type of evidence being gathered. In order to identify the evidence required to address the PPPG topic it is essential to define

one or more key questions. Where applicable, clinical questions should be broken down into PICO(T) format (Population, Intervention, Comparison, Outcome, Time). The clinical questions should be clear, unambiguous, focused and concise (NCEC, 2013).

This guideline was developed and revised with a view to standardising the practice of Insulin titration nationally.

B2.2 Literature search strategy (attach Appendix as appropriate)

Based on the key question(s) defined, a literature search strategy should be developed. The literature search strategy should be documented explicitly in order that it can be replicated. The following should be included: Databases searched, search terms, search limits, inclusion and exclusion criteria. If undertaking searches, utilise a librarian or other information specialist who has expertise and experience in this area (NCEC, 2013).

The terms 'insulin' and 'titration' were searched in national and international peer reviewed journals. Specific product characteristics (SPC) from the appropriate pharmaceutical companies were accessed for specific insulin information pertaining to that product.

The terms 'diabetes', 'insulin' 'titration' and 'glycaemic targets' were searched in national and international peer reviewed journals.

For the pregnancy section in addition the terms pregnancy, pre peri & post-natal, gestational diabetes and breast feeding were also used.

Specific product characteristics (SPC) from pharmaceutical companies were accessed for specific insulin information pertaining to that product.

Publications in the last 5 years were prioritised to give the latest evidence. Non English speaking journals were excluded.

B2.3 Method of appraising evidence (attach Appendix as appropriate)

Critically appraise the quality, validity and relevance of all evidence gathered as part of your search. As a first step, studies can be categorised according to the 'hierarchy of evidence' (e.g. meta-analyses and systematic reviews are a higher level of evidence than randomised controlled trials, which are a higher level of evidence than cohort or case-control studies (NCEC, 2013).

There are various critical appraisal tools available (e.g.):

SIGN: <https://www2.healthservice.hse.ie/organisation/national-pppgs/>

AGREE II appraisal tool:

http://www.agreetrust.org/wp-content/uploads/2013/10/AGREE-II-Users-Manual-and-23-item-Instrument_2009_UPDATE_2013.pdf

These tools can be used to appraise the strengths and weaknesses of the research. There are three main points considered when appraising all research evidence:

- Are the results valid?
- What are the results?
- Are the results applicable/generalisable to the population of the PPPG?

Evidence was not formally appraised for the revision of this guideline as following internationally agreed guidelines

B2.4 Formulation of recommendations

Recommendations may be formulated through a formal structured process whereby the following may be considered and documented:

- What evidence is available to answer the clinical questions?
- What is the quality of the evidence
- Is the evidence applicable to the Irish population and healthcare setting?
- What is the potential benefit verses harm to the population/patient?

Evidence is covered in part A

B2.5 Summary of the evidence from the literature

Outline a summary of the supporting evidence from the literature for the PPPG.

Glycaemic targets should be set and insulin titration should be carried out following a detailed assessment of each individual person with diabetes. Sub optimal glucose control may lead to well documented long term complications of diabetes.

B2.6 Resources necessary to implement the PPPG recommendations

Are there resource implications? Outline same.

There needs to be protected time for nurses in the dissemination, reading, understanding and local adaptation/sign off of this updated guideline.

B2.7 Outline of PPPG Steps/Recommendations

An outline of the steps and recommendations to be followed are in Part A of this PPPG.

B3.0 Governance and approval

B3.1 Formal Governance Arrangements

3.1.1 Refer to Appendix 5 for Membership of the Approval Governance Group.

B3.2 Method for assessing the PPPG in meeting the Standards outlined in the HSE National Framework for developing PPPGs.

Consultation with appropriate stakeholders

B3.3 Copyright/permission sought

Permission was sought from Sligo diabetes nurses for replication of Insulin preparations chart

B3.4 PPPG Checklist

Standards for developing Clinical PPPG	Checklist
Stage 1 Initiation	
The decision making approach relating to the type of PPPG guidance required (policy, procedure, protocol, guideline), coverage of the PPPG (national, regional, local) and applicable settings are described.	<input type="checkbox"/>
Synergies/co-operations are maximised across departments/organisations (Hospitals/Hospital Groups/Community Healthcare Organisations (CHO)/ National Ambulance Service (NAS)), to avoid duplication and to optimise value for money and use of staff time and expertise.	<input type="checkbox"/>
The scope of the PPPG is clearly described, specifying what is included and what lies outside the scope of the PPPG.	<input type="checkbox"/>
The target users and the population/patient group to whom the PPPG is meant to apply are specifically described.	<input type="checkbox"/>
The views and preferences of the target population have been sought and taken into consideration (as required).	<input type="checkbox"/>

The overall objective(s) of the PPPGs are specifically described.	<input type="checkbox"/>
The potential for improved health is described (e.g. clinical effectiveness, patient safety, quality improvement, health outcomes, quality of life, quality of care).	<input type="checkbox"/>
Stakeholder identification and involvement: The PPPG Development Group includes individuals from all relevant stakeholders, staff and professional groups.	<input type="checkbox"/>
Conflict of interest statements from all members of the PPPG Development Group are documented, with a description of mitigating actions if relevant.	<input type="checkbox"/>
The PPPG is informed by the identified needs and priorities of service users and stakeholders.	<input type="checkbox"/>
There is service user/lay representation on PPPG Development Group (as required).	<input type="checkbox"/>
Information and support is available for staff on the development of evidence-based clinical practice guidance.	<input type="checkbox"/>

Stage 2 Development	Checklist
The clinical question(s) covered by the PPPG are specifically described.	<input type="checkbox"/>
Systematic methods used to search for evidence are documented (for PPPGs which are adapted/adopted from international guidance, their methodology is appraised and documented).	<input type="checkbox"/>
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).	<input type="checkbox"/>
The health benefits, side effects and risks have been considered and documented in formulating the PPPG.	<input type="checkbox"/>
There is an explicit link between the PPPG and the supporting evidence.	<input type="checkbox"/>

PPPG guidance/recommendations are specific and unambiguous.	<input type="checkbox"/>
The potential resource implications of developing and implementing the PPPG are identified e.g. equipment, education/training, staff time and research.	<input type="checkbox"/>
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	<input type="checkbox"/>
Budget impact is documented (resources required).	<input type="checkbox"/>
Education and training is provided for staff on the development and implementation of evidence-based clinical practice guidance (as appropriate).	<input type="checkbox"/>
Three additional standards are applicable for a small number of more complex PPPGs: Cost effectiveness analysis is documented. A systematic literature review has been undertaken. Health Technology Assessment (HTA) has been undertaken.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Stage 3 Governance and Approval	Checklist
Formal governance arrangements for PPPGs at local, regional and national level are established and documented.	<input type="checkbox"/>
The PPPG has been reviewed by independent experts prior to publication (as required).	<input type="checkbox"/>
Copyright and permissions are sought and documented.	<input type="checkbox"/>

Stage 4 Communication and Dissemination	Checklist
A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.	<input type="checkbox"/>
Plan and procedure for dissemination of the PPPG is described.	<input type="checkbox"/>
The PPPG is easily accessible by all users e.g. PPPG repository.	<input type="checkbox"/>

Stage 5 Implementation	Checklist
Written implementation plan is provided with timelines, identification of responsible persons/units and integration into service planning process.	<input type="checkbox"/>
Barriers and facilitators for implementation are identified, and aligned with implementation levers.	<input type="checkbox"/>
Education and training is provided for staff on the development and implementation of evidence-based PPPG (as required).	<input type="checkbox"/>
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	<input type="checkbox"/>

Stage 6 Monitoring, Audit, Evaluation	Checklist
Process for monitoring and continuous improvement is documented.	<input type="checkbox"/>
Audit criteria and audit process/plan are specified.	<input type="checkbox"/>
Process for evaluation of implementation and (clinical) effectiveness is specified.	<input type="checkbox"/>

Stage 7 Revision/Update	Checklist
Documented process for revisions/updating and review, including timeframe is provided.	<input type="checkbox"/>
Documented process for version control is provided.	<input type="checkbox"/>

I confirm that the above Standards have been met in developing the following:

Title of PPPG: _____

Name of Person signing off on the PPPG Checklist:

Name: _____

Signature: _____

Title: _____

Date: _____

This signed PPPG Checklist must accompany the final PPPG document in order for the PPPG to be approved.