THE UNIVERSITY OF MELBOURNE

Stepping Up Study

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Insulin initiation and intensification in the general practice setting for adults with type 2 diabetes

A training manual for General Practitioners and Practice Nurses

Department of General Practice
The University of Melbourne
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Stepping Up Study

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Introduction

Type 2 diabetes mellitus (T2DM) is a chronic medical condition arising as a result of a combination of genetic and environmental factors. It occurs most commonly in people over 40 years of age and is characterized by reduced or less effective insulin, resulting in an increased concentration of glucose in the blood [1]. The AusDiab study (1999-2000) estimated that 7.1% of Australian adults over the age of 25 years had T2DM, a portion of which were undiagnosed [1] T2DM is common, is associated with a number of complications and has a high financial cost to the individual and the community (see Figure 1).

Figure 1: Diabetes Fast Facts

Prevalence

- Around 275 Australians develop diabetes every day
- Many cases of T2DM remain undiagnosed and it is estimated that 1.7 million Australians may have T2DM
- Up to 60% of cases of T2DM can be prevented.
- Australia's indigenous population suffers the fourth highest rate of Type 2 diabetes in the world

Complications

- People with diabetes are almost three times more likely to have high blood pressure, obesity or elevated blood fats e.g. cholesterol
- They are two to three times more likely to have cardiovascular disease, e.g. heart disease and stroke
- 65-80 percent of people with diabetes will die of coronary heart disease
- 15 percent of people with diabetes have heart disease compared to 2.5 percent without diabetes
- Renal disease accounts for 8-14 percent of deaths in people with diabetes
- 5 percent of people with diabetes will experience foot ulcers
- Of the 3000 amputations every year in people with diabetes, most are preventable

Financial costs

- Type 2 diabetes costs Australia $3 billion per year
- Average cost for a person with Type 2 diabetes who has no complications is $10,900
- If there are complications this cost almost doubles to $20,525
- The 4 percent of people who have diagnosed diabetes account for 12 percent of health costs in Australia

Currently the majority of care for people with T2DM occurs in the general practice setting. The BEACH program, a continuous national study of general practice activity, estimated that an average of 4.4 million type 2 diabetes encounters were managed in Australian general practice in the year 2010-11. Non-gestational diabetes was the third most frequently managed chronic medical condition in general practice behind hypertension and depressive disorder [3]. However, when insulin initiation is required it is generally not occurring in a timely manner [4, 5] and the majority of patients are referred to specialist care (endocrinologists and credentialed diabetes nurse educators (DNE))[6]. Indeed, people with diabetes represent the third most common group referred to specialists after that for malignant skin neoplasms and pregnancy [3].

There are a number of published guidelines which state the target for glycaemic control (as measured by HbA1c and capillary blood glucose levels) and the lifestyle and pharmacological means by which to achieve this. Depending on the presence of symptoms and degree of glycaemia, people with T2DM may utilise diet and exercise, oral hypoglycaemic agents (OHA), non-insulin injectibles or insulin to improve glycaemic control (see Figure 2). The target levels for HbA1c, fasting blood glucose and post prandial glucose are illustrated in Table 1. Meeting glycaemic targets early in the course of T2DM is important because of metabolic memory –the follow up to the United Kingdom Prospective Diabetes Study (UKPDS) demonstrated that there was an association between well controlled diabetes early in the course of the disease with a continued reduction in microvascular risk, myocardial infarction and death from any cause ten years later [7].

Table 1: Targets suggested by Guidelines

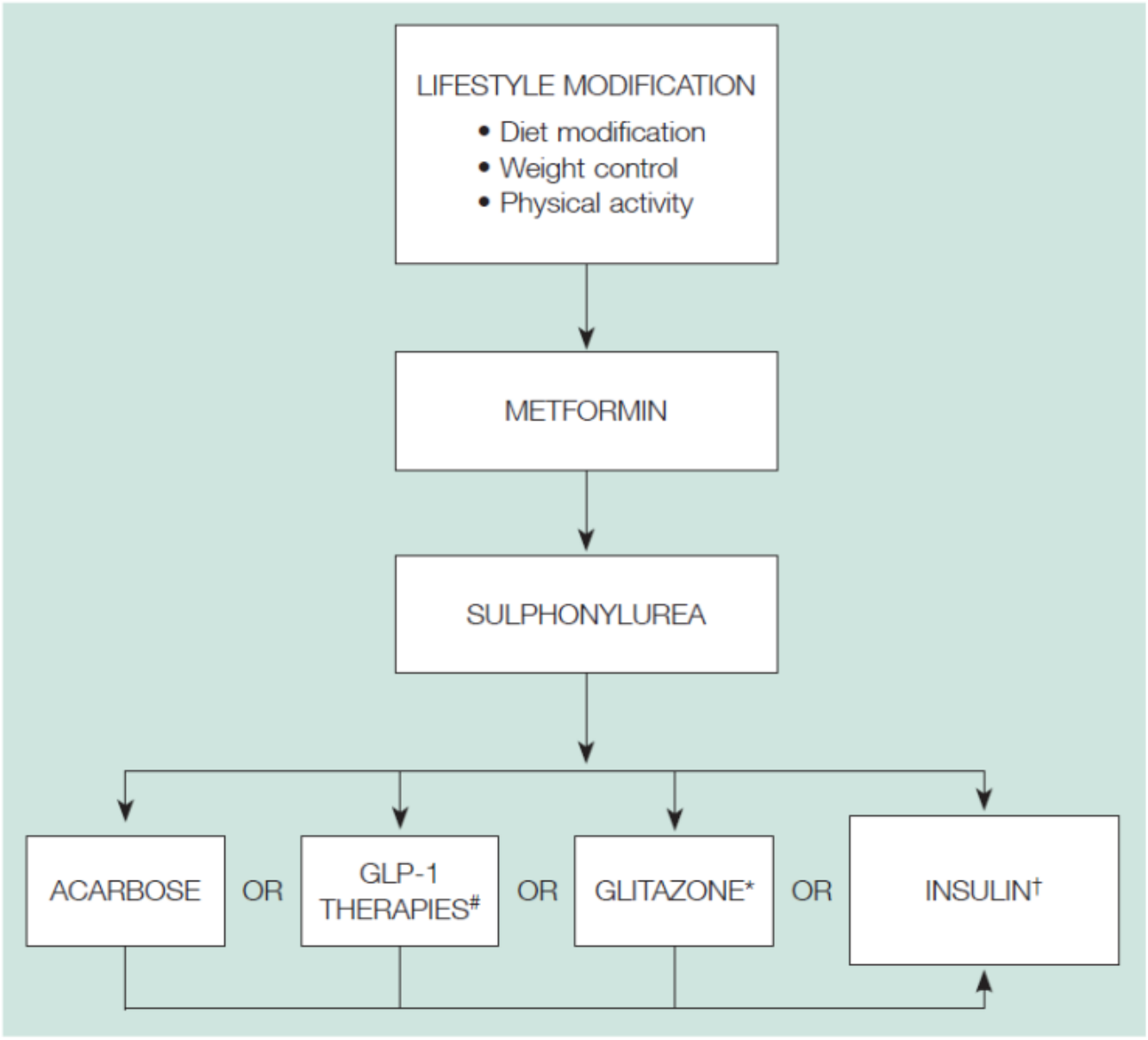
	Normal	Targets for diabetes patients			
		ADS/EASD	AACE	IDF	Stepping Up study
HbA1c % mmol/mol	<6.0 <42	<7.0 * <53*	≤6.5 ≤48	<6.5 <48	<7.0 <53
Fasting blood glucose (mmol/L)	<5.5	3.9-7.2	≤6.0	<6.0	<7.0
Post prandial blood glucose (mmol/L)	<7.8	<10	≤7.8	<8.0	<10.0

*This is the general ADS target for people on insulin therapy

Nevertheless, a gap exists between recommended care and real world practice. Many patients have an HbA1c over the recommended target. Less than 50% of people with T2DM have a HbA1c less than 7.5% (58mmol/mol) yet only 10-15% of people with T2DM are using insulin. In an Australian study the median duration of type 2 diabetes before commencing insulin was 8.1 years from diagnosis and the median HbA1c was 9.4% (79mmol/mol) [8].

Clinical inertia resulting in a delay in intensification of pharmacological therapy is an issue for both GPs and specialists, although studies suggest that GPs may delay insulin initiation longer than specialists (see Figure 3) Many patient and health professional barriers to insulin initiation have been identified (see Table 2) [9-12].

Figure 2: Treatment algorithm (PBS approved medications) for type 2 diabetes



Notes:

- *The algorithm is based on that published by the NHMRC.*
- *The algorithm includes only therapeutic agents available through the PBS.*
- *If HbA1c >7% consider intensifying treatment provided hypoglycaemia is not a problem.*

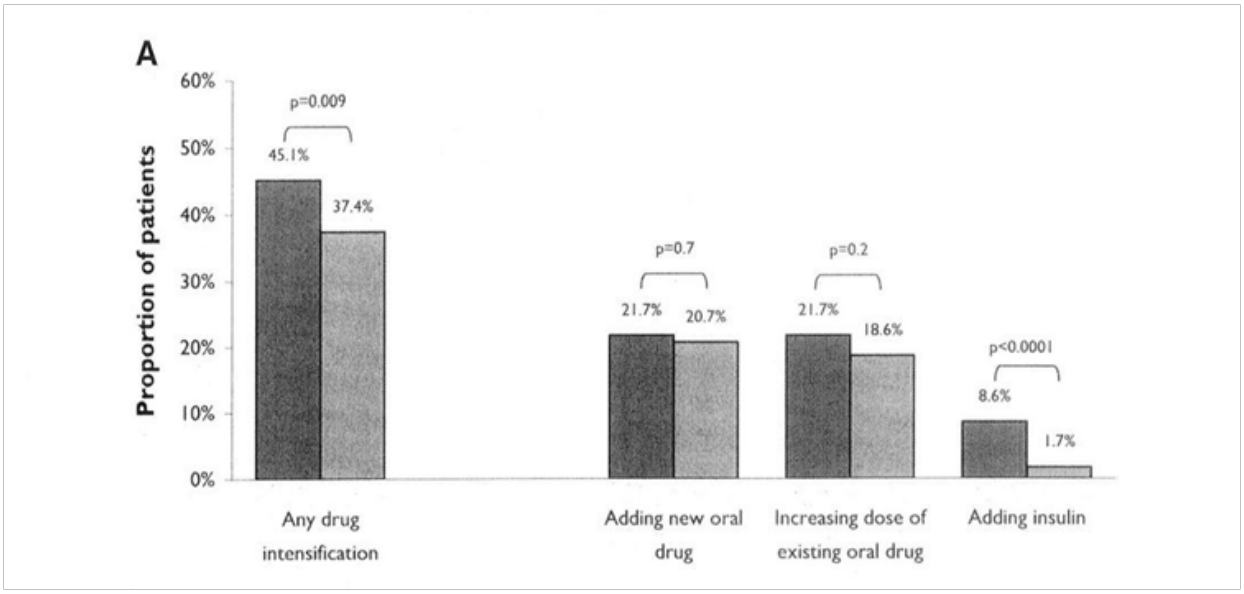
 # Saxagliptin, sitagliptin and vildagliptin are PBS subsidised only for dual therapy with metformin or sulphonylurea where combination therapy metformin and sulphonylurea is contraindicated or not tolerated. Exenatide is approved for use as dual or triple therapy with oral agents.

** Rosiglitazone is not authorised for triple therapy or for use with insulin but is approved only as dual therapy with metformin or sulphonylurea where combination metformin and sulphonylurea is contraindicated or not tolerated.*

† Insulin is frequently required for glycaemic control in people with type 2 diabetes and can be initiated as basal therapy or as premixed insulins, usually in combination with oral antidiabetic medications.

From RACGP [2]

Figure 3: Intensification of therapy: do specialists differ from GPs?



From Shah et al [13]

Table 2: Patient and Health Professional factors which act as barriers to insulin initiation

Patient factors	Health Professional factors
• Belief that diabetes is not a serious illness • Fear of addiction • Belief that insulin makes patient fat • Fear of hypoglycaemia • Belief that insulin would not help • Pain associated with insulin injection • Other fears regarding injection of insulin • Pain associated with blood tests • Lack of faith in doctor • Anxiety • Concern that they can never stop insulin • Life will be restricted as a result of starting insulin • Belief that insulin causes problems like blindness • Non-compliance with medical appointments • Non-compliance with medications	• Belief that patient wouldn't comply with treatment • Fear of hypoglycaemia in a specific patient • Belief that patient couldn't cope with pain involved in insulin injection • Patient too old or inadequate level of education • No experience with treatment • Not wanting to give to obese patients because insulin would result in further weight gain • Belief that a specific patient's diabetes is so severe that even insulin wouldn't help • Lack of resources in office based practice – drug cost, staff availability, skills of staff, time • Belief that insulin initiation is complex • Lack of motivation to improve clinical practice • Belief that insulin would impair patient quality of life • Patient co-morbidities

Stepping Up

The current challenge ahead is to develop a model of care for insulin initiation in Australian general practice which will overcome the current barriers, be acceptable to patients and health professionals and be able to be implemented into ongoing practice. Stepping Up is a new model of care which has four main components:

1. General practitioners and practice nurses working in partnership to identify patients requiring insulin
2. Simple, robust protocols and tools supporting insulin initiation in the Primary Care setting

3. GPs and PNs working in partnership to initiate and titrate insulin in primary care
4. Endocrinologists and diabetes educators acting as support resources in a hub and spoke manner

In this training manual education will be provided which will allow you to implement this model of care in your practice. The topics covered will be:

1. Identifying patients in your practice who may benefit from the initiation of insulin
2. Use of motivational interviewing to assist patients in making the transition to insulin
3. Introduction to insulin and its administration
4. Stepping Up protocol

Identifying patients in your practice who may benefit from the initiation of insulin

Potentially anyone with T2D can benefit from the addition of insulin to their management. Strong indications for insulin therapy include:

- HbA1c consistently ≥7.5% for more than 3 months
- Maximum oral therapy yet control not ideal
- Oral hypoglycaemic treatments not tolerated or contraindicated.

You can proactively identify these patients by generating a list through your pathology provider, using the PEN Clinical Audit Tool or your medical software.

Insulin therapy should be discussed as a treatment option at the time of diagnosis. ***It should not be used as a threatened punishment for poor compliance***. Treatment should start:

- As soon as there is evidence of deteriorating glycaemic control
- After exploring whether the person could change their lifestyle or current medication
- After full discussion of all the pros and cons of insulin therapy

Use of motivational interviewing to assist patients in making the transition to insulin

As discussed previously there are many potential barriers that may put people off starting insulin therapy. However, there are also many potential benefits such as symptom control and reduced risk of developing complications. Motivational interviewing is one tool that can be used to engage patients in making the decision to commence insulin.

Motivational interviewing is a patient-centred yet directive counselling style for helping people explore and resolve ambivalence about behaviour change. It is an approach designed to help patients build on their own motivation and reach a decision to change. The basic counselling skills that can be used by health professionals are: attending behaviours, focus, empathy, affirmation, reflection, open ended questions and summarising.

Figure 4: Essential Components of Motivational Interviewing

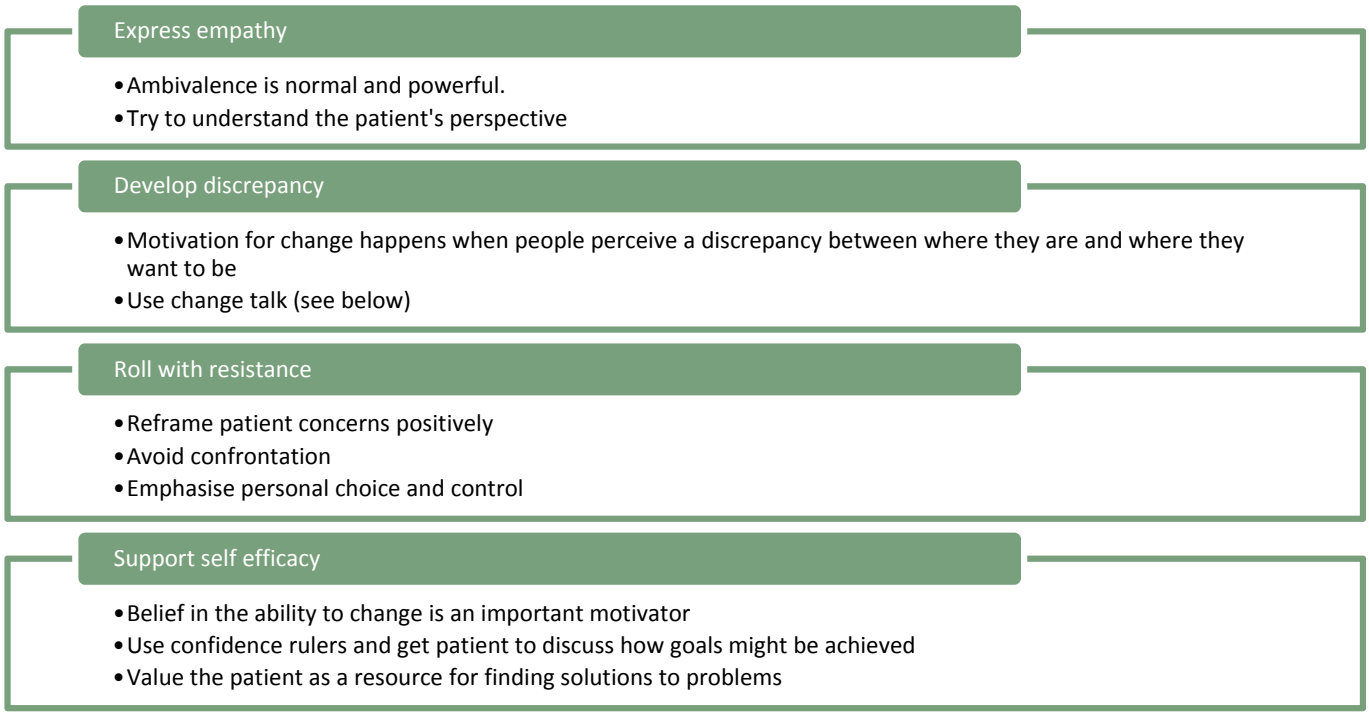
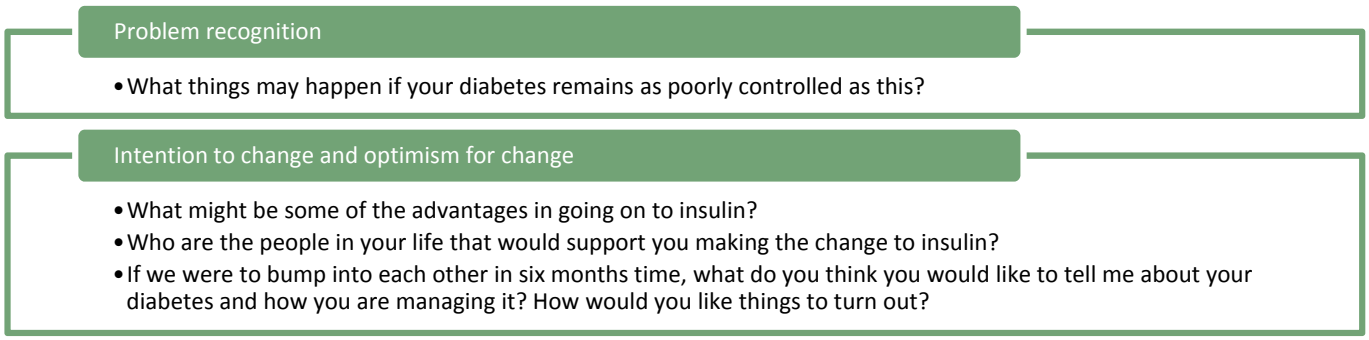


Figure 5: Change talk



In the appendix to this manual there are two papers by Sim et al which you might find helpful as a resource for motivational interviewing and assisting patients make behavioural changes.

Introduction to insulin and its administration

At the end of this section you will understand:

- What insulin is
- How insulin works and why it is needed in type 2 diabetes
- The different types and profiles of insulins available
- How insulin is delivered

What is insulin?

> *"We have obtained from the pancreas of animals a mysterious something which injected into totally diabetic dogs completely removes all the cardinal symptoms of the disease… If the substance works on the human, it will be a great boon to medicine"*
>
> J.B. Collip, January 8, 1922[14]

2012 marks 90 years since insulin was first extracted and used to treat humans with diabetes. Insulin is a protein hormone produced from the cleavage of a precursor (proinsulin) produced by the beta cells of the pancreas. In normal human adults, the pancreas secretes approximately 40 to 50 units of insulin per day. Basal insulin refers to the quantity of insulin secreted in the fasting state, whilst stimulated insulin secretion occurs in response to ingested meals [15]. The first insulins produced for use by people with diabetes were derived from beef and pork. Now human insulin is made using recombinant DNA technology and insulins with different time profiles, from ultra-short to long acting, have been produced.

How does insulin work?

Insulin receptors occur on many cells in the body but the main metabolic effects occur in fat, liver and muscle cells. The major function of insulin is to promote the storage of ingested nutrients. In the liver insulin promotes glycogen synthesis and storage and inhibits glycogen breakdown. It promotes protein synthesis in muscle and triglyceride storage in fat cells. The net result of these actions is to remove glucose from the blood and transport it into tissues [15].

The liver releases glucose at a relatively constant rate all the time, with a slight dip during the night and a surge before dawn. A steady release of insulin is therefore needed to maintain normal blood glucose levels. After meals (post prandial) there is a burst of insulin, often called the meal-time bolus (see Figure 6). Whenever glucose is released into the bloodstream from food, a matching release of insulin is required for up to two hours in order to move the glucose into the cells. How long this increased insulin level is needed depends on the type of carbohydrate, its glycaemic index, and the fat content of the meal.

Why is insulin therapy required in type 2 diabetes?

Type 2 diabetes is characterised by reduced or less effective insulin.

1. Less effective insulin (insulin resistance)

   Visceral fat (accumulated in central obesity) is more metabolically active than peripheral fat and releases large quantities of non-esterified fatty acids (NEFA) (see Figure 7). NEFA have several metabolic actions that can cause insulin resistance. Insulin resistance also develops with a cluster of clinical and biochemical features known as ***metabolic syndrome or the insulin resistance syndrome***. This consists of:

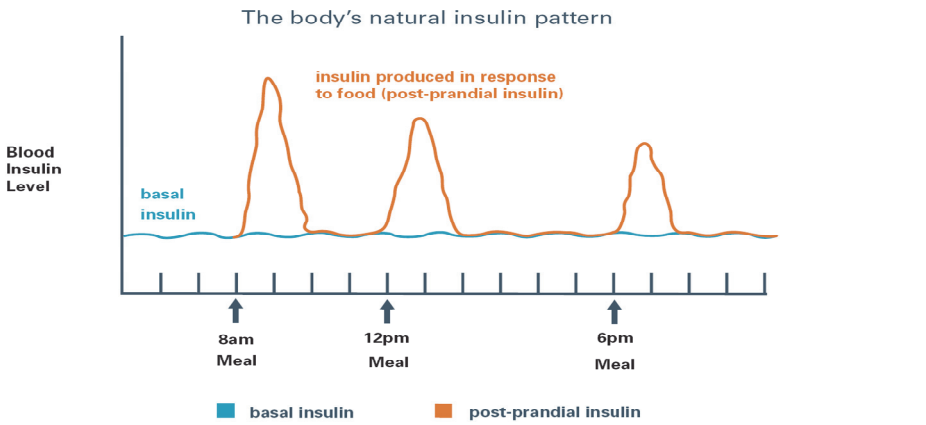
   - Glucose intolerance
   - Truncal obesity
   - Hypertension
   - Low HDL (high density lipoproteins or good cholesterol)
   - High LDL (low density lipoproteins or bad cholesterol)
   - High triglycerides

   Insulin resistance occurs when insulin receptors on the cells of muscle and fat tissue do not respond to the effects of insulin. Simply put, insulin cannot carry the glucose from the bloodstream into the cells resulting in a state of excess insulin and glucose in the bloodstream.

2. Reduced insulin

In response to increased blood glucose levels the pancreas continues to secrete insulin to try and provide the cells with energy. Over a period of time beta cells in the pancreas become exhausted and insulin production is reduced. ***By the time type 2 diabetes (T2D) is diagnosed, the pancreas has lost 50% of beta cell function*** (see Figure 8). As T2DM progresses, oral hypoglycaemic agents may not be sufficient to control blood glucose levels. Insulin therapy is an important adjunct to therapy to compensate for the body's decreased production of this hormone.

Figure 6: The body's physiologic insulin pattern



The body's normal insulin secretory response is biphasic

White JR, 2003, Porte D & Kahn S, 1995

Figure 7: Central obesity

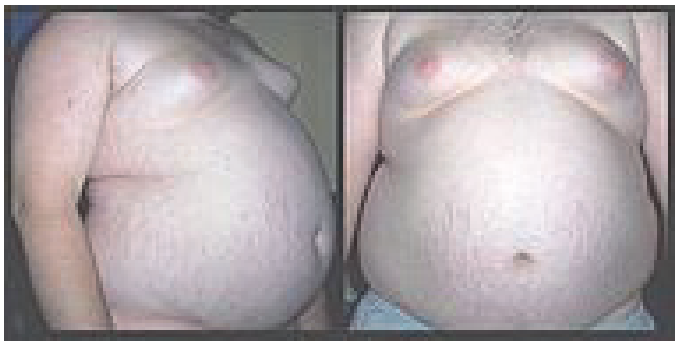
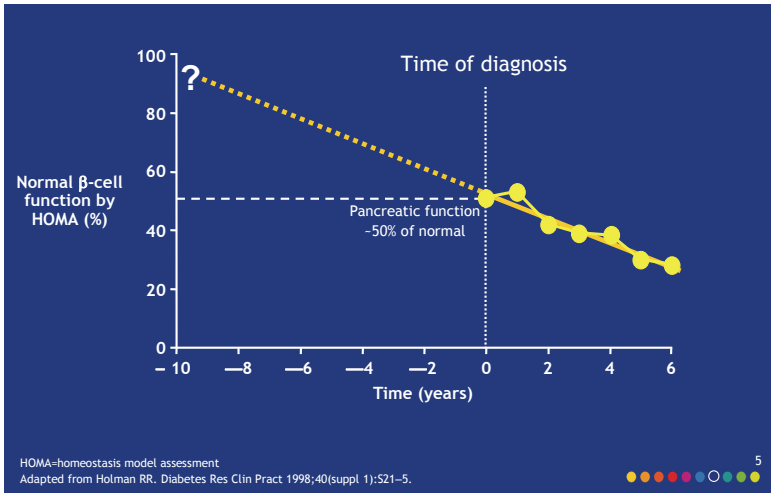


Figure 8: Decreasing beta cell function as part of the progression of T2DM



The different types and profiles of insulins available

Manufactured insulin aims to mimic natural patterns. Current insulins used for the treatment of type 2 diabetes are listed in Table 3. The number of injections, type and dose of insulin varies between individuals and should be tailored to their lifestyle and eating habits and will be decided on the basis of their blood glucose pattern throughout the day and before and after meals.

Figure 9: Time profile of insulins

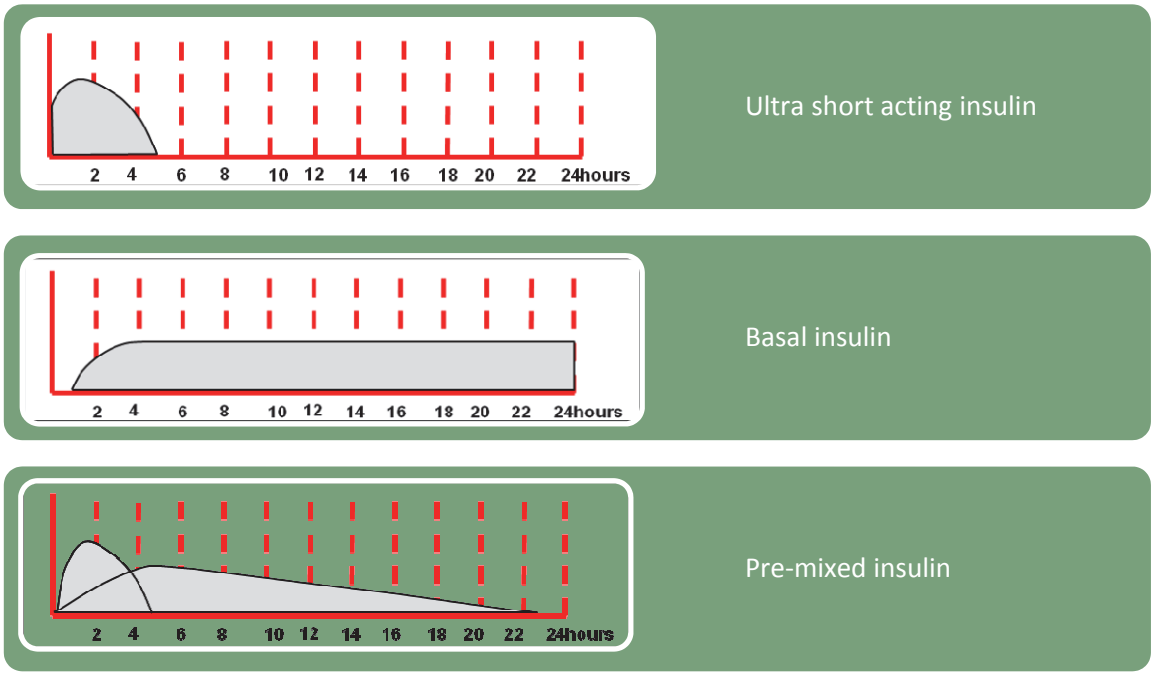


Table 3: Current insulins available

Type	Brand Name	Manufacturer	Nature
ULTRA SHORT ACTING (peak at 1hr, last 3.5–4.5 hrs)			
Insulin lispro	Humalog+	Lilly	Analogue
Insulin aspart	NovoRapid+	Novo Nordisk	Analogue
Insulin glulisine	Apidra+	sanofi-aventis	Analogue
SHORT ACTING (peak at 2–5 hrs, last 6–8 hrs)			
Neutral	Actrapid	Novo Nordisk	Human
	Humulin R	Lilly	Human
	Hypurin Neutral	Aspen	Bovine
INTERMEDIATE ACTING (12–24 hrs)			
Isophane	Humulin NPH	Lilly	Human
	Protaphane	Novo Nordisk	Human
	Hypurin Isophane	Aspen	Bovine
LONG ACTING			
Insulin detemir **(up to 24 hrs)**	Levemir	Novo Nordisk	Analogue
Insulin glargine **(24 hrs)**	Lantus	sanofi-aventis	Analogue
PRE MIXED INSULINS			
Lispro 25% Lispro protamine 75%	Humalog Mix 25+	Lilly	Analogue
Lispro 50% Lispro protamine 50%	Humalog Mix 50+	Lilly	Analogue
Insulin aspart 30% Insulin aspart protamine 70%	NovoMix 30+	Novo Nordisk	Analogue
Neutral 30% Isophane 70%	Humulin 30/70 Mixtard 30/70	Lilly Novo Nordisk	Human Human
Neutral 50% Isophane 50%	Mixtard 50/50	Novo Nordisk	Human

From RACGP [2]

The two insulins which will be used in the Stepping Up study are glargine (Lantus) and glulisine (Apidra)

Glargine (Lantus)

Glargine (Lantus) is a long acting basal analogue insulin. This insulin is peakless, and as a result is associated with less hypoglycaemic episodes. It has less impact on weight gain, has been associated with significant improvements in health related Quality of Life measures and is administered once per day. This is usually given in the evening, but the time of day the injection is given can be altered depending on patient preference provided that it is given at the same time each day.

After injection Lantus insulin clumps under the skin, and releases from there very slowly and evenly over 24 hours, therefore an increase of 4 units is spread over the 24 hours (i.e. 0.16 units increase of this insulin per hour, a very small increment!)

Figure 10: Glargine (Lantus)

Glulisine (Apidra)

Glulisine (Apidra) is a rapid acting insulin analogue which is given at mealtimes. It is generally commenced when target fasting blood glucose levels have been attained using glargine (Lantus) but postprandial blood glucose levels remain high (>10mmol/L).

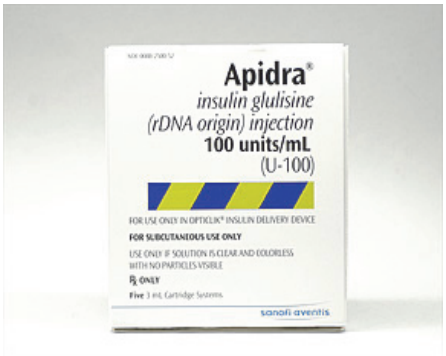
Because of its rapid onset of action (within 10 minutes of injection) the patient needs to be advised to inject this insulin just as they are sitting to eat the meal or just after starting the meal (either eat and inject or inject and eat). Rapid acting insulins are more likely to cause hypoglycaemia and so the patient needs to be educated about the symptoms and management of this potential side effect.

If the pre-meal injection is forgotten, it is NOT to be given an hour or two later when a high glucose is detected, but rather ask them to record in their BG diary that it was missed. The following day they can return to the planned schedule and inject prior to the designated meal.

In contrast to glargine (Lantus) which acts for 24 hours, glulisine (Apidra) acts almost immediately and is inactive within 2 to 4 hours. Therefore the carbohydrate content of the actual meal is the only target of this insulin, which results in a lowered risk of hypoglycaemia compared to the extended tails of other fast acting insulins, such as Actrapid. Every increased dose of Apidra insulin can result in a significant effect on the post meal BGL.

No matter how high the BGL is, the first (starting) dose of 4 units Apidra should be adhered to, until it is established how sensitive your patient is to this insulin. In some patients one unit of Apidra may drop the blood glucose level 4 to 6mmol/l, in others 4 units may only drop them 1mmol/l. Until the effect on each individual patient is established it is important to maintain frequent contact in relation to dose adjustment of Apidra.

Figure 11: Glulisine (Apidra)



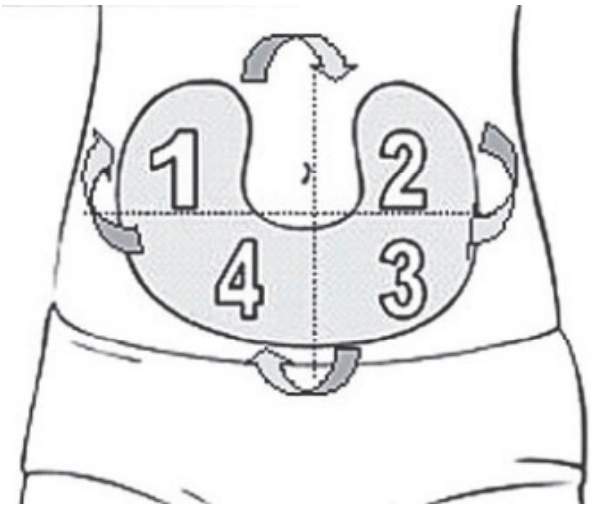
Delivery of insulin

In this section you will learn how to choose an injection site and how to teach the patient how to inject.

Choosing an injection site

In the Stepping Up study we recommend that the abdomen is used as the site for all injections (see Figure 12)

Figure 12: Injection sites for insulin administration

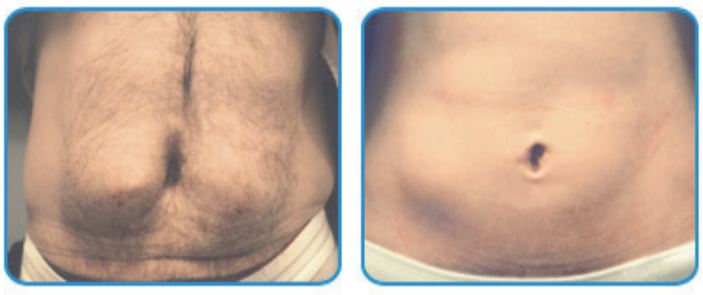


Abdominal rotation pattern by quadrants (Diagram courtesy of Lourdes Saez-de Ibarra and Ruth Gaspar, Diabetes Nurses and Specialist Educators from La Paz Hospital, Madrid, Spain).

When injecting rapid and long-acting analogue insulin, each injection should be administered within a different site, even if injected at different times during the day. For the patient's ease of memory we suggest "Lantus on the left; rapid (Apidra) on the right". In the diagram above Lantus would be rotated within sites 2 and 3 and Apidra within sites 1 and 4. [16]

It is recommended that insulin injection sites are rotated as repeatedly injecting into the same small area results in lumps (lipohypertrophy) which hinder insulin absorption and can be unsightly. Alternate between the left and right side on a weekly basis, and rotate sites within the same area. Each injection should be at least a fingers breadth away from the last one. Check for lumps on a regular basis. If lipohypertrophy (see Figure 13) is found, that area should not be used for injection until it has become soft again. This may take weeks or even months, depending on the severity of the lipohypertrophy.

Figure 13: Lipohypertrophy



Some points to remember

- Temperature – heat also speeds up the absorption of insulin. People should therefore avoid injecting immediately before or after a hot bath or shower.
- Injecting through clothing – people sometimes feel they need to do this, for example while traveling or in social situations, but it should be discouraged especially considering the very short 4 mm needles being used.

Teaching injection technique

Teaching insulin injection technique is a key role for the practice nurse.

Glargine (Lantus) and glulisine (Apidra) both come in a completely disposable, ready made up pen which only requires the needle to be inserted at the tip of the pen. This is the easiest way for patients to commence insulin. Both pens are used according to the instructions below (see Figure 14). The patient must always check they are injecting the correct insulin at the correct time (eg Lantus = grey pen = inject in the evening; Apidra = blue pen = inject with meals).

The key points for this task are:

1. Make sure the person attaches the needle, dials the dose and gives the injection themselves. You may need to guide them – but don't do it for them. Advise the patient to use a new needle for every injection.
2. Do an 'air shot' before each injection. An air shot will make sure the plunger is connecting, and expel air from the pen.
3. Ensure hands and the skin that will receive the injection are clean. Alcohol wipes are not required. They are an astringent and can make the injection more painful.
4. To 'pinch up' or not to 'pinch up'? Insulin should be injected into soft fat, not muscle. To avoid intramuscular injection, slim people, or those using injection sites without much subcutaneous fat, may need to 'pinch up' and /or use a shorter needle length. *Pinch up is not usually required for people with type 2 diabetes* (See Figure 15)
5. Insert the needle at a 90° angle and push the needle in to the hilt
6. Inject the insulin
7. After the injection, leave the needle in the skin for 5 -10 seconds to avoid leakage. With large doses, it many need to be left in for longer.
8. Occasionally, there may be bleeding after the needle is withdrawn. Reassure the person, and advise them to apply gentle pressure for a couple of minutes to minimize bruising. They should not rub the area, as this may increase the rate of absorption.

Advise the patient that needles and syringes are free for people registered with the National Diabetes Services Scheme (NDSS). Ensure patient is a member and that the NDSS is advised when they commence insulin (form is available in patient encounter pack in the practice or via the NDSS website).

Figure 14: Quick reference guide to SoloStar pens (Lantus and Apidra)

SoloSTAR®

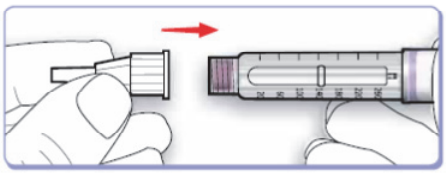
QUICK REFERENCE GUIDE

These instructions are supplied as a guide only. Always read the full instruction leaflet before you use SoloSTAR® for the first time. If you have any questions, ask your healthcare professional or call 1800 LANTUS (1800 526 887).

Before you start, check you have the right insulin

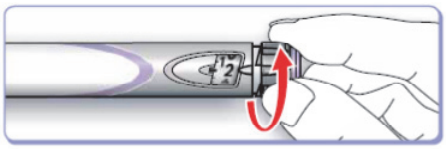
1 Attach a new needle

Keep the needle straight as you attach it.

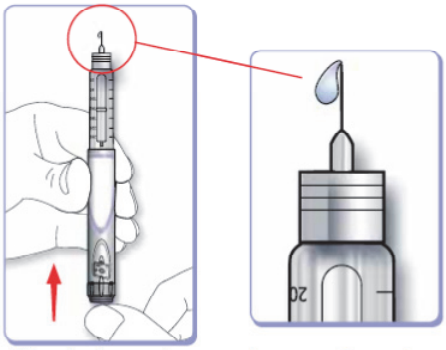


2 Perform a safety test

This removes air bubbles and ensures that the pen and needle are working properly. Select a dose of 2 units.



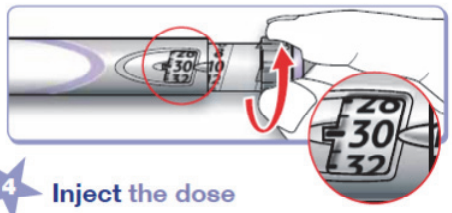
Remove the needle caps.
Hold the pen with the needle pointing upwards and press the injection button all the way in.
Check if insulin comes out of the needle.



If insulin does not come out, you must repeat the test until it does.
If no insulin comes out after doing the test 3 times, replace the needle with a new needle and try again.

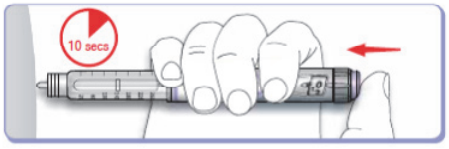
3 Select the dose

Check the dose shows "0". Select your required dose. (This example shows 30 units).



4 Inject the dose

Using the injection method instructed by your healthcare professional, insert the needle into the skin. Press the injection button in all the way. Keep the injection button pressed and slowly count to 10. Then withdraw the needle.



5 Remove the needle

Replace the outer needle cap and use it to unscrew the needle from the pen. Dispose of the needle safely. Put the cap on the pen.

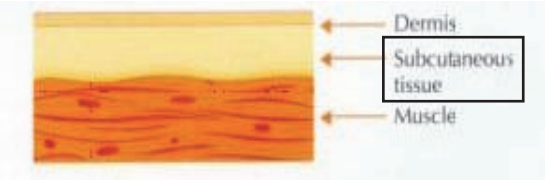
IF YOU CAN'T dial to the dose you want, check if you have enough insulin in the reservoir.
IF YOU HAVE any other problems with the pen, first try replacing the needle and repeating the safety test.
EACH SoloSTAR® is for use by one person only.

SANOFI DIABETES

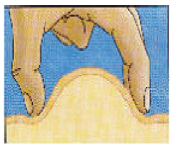
sanofi-aventis australia pty ltd trading as
Sanofi, 12–24 Talavera Road, Macquarie Park NSW 2113
ABN 31 008 558 807 AU.DMP.12.01.001

Figure 15: Pinch up for slim people or those using injection sites without much subcutaneous fat

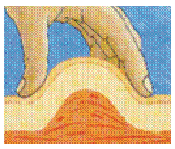
To ensure the reliable absorption of insulin, injections must be made into the subcutaneous tissue.



Pinch up a mound of clean skin between thumb and index finger before gently pushing the needle into the mound at an angle of 90°. Release the grip on the skin fold once the needle has been removed as releasing too soon can provoke an intramuscular injection.



Correct pinch-up



Incorrect pinch-up

There are some instances where patients can't pinch-up, eg arthritis. If thin patients choose not to pinch-up they should inject at 45° to decrease the chances of giving an intramuscular injection.

Insulin Dosing

Glargine (Lantus)

All patients are commenced on 10 units of glargine (Lantus). The first injection will occur in the clinic with the practice nurse. The patient can then continue insulin at a time convenient to them, provided it is at approximately the same time each day. Evening or pre-bed administration is recommended. The insulin dose is titrated every three days using the Accu-chek®360° Insulin Adjustment Tool for basal insulin glargine (see Figure 16) until the fasting blood glucose target of 4.0-7.0mmol/L is achieved.

Figure 16: Accu-chek®360° Insulin adjustment tool for use with basal insulin glargine (Lantus)

CAUTION: INVESTIGATIONAL DEVICE. FOR INVESTIGATIONAL USE IN THE STEPPING UP STUDY ONLY.

ACCU-CHEK® 360° Insulin Adjustment Tool
For use with insulin glargine (Lantus®)

Patient Name _____
Healthcare Professional Name _____
⚠ Warning: Do not use this form without first consulting your healthcare professional

Oral Diabetes Medications	Dose	Time/Day

Insulin Starting Dose (units) ☐
Daily Dose Time _____

	Period ____	Adjustment	Period ____	Adjustment	Period ____	Adjustment
Start Date						
Daily Dose (units)	☐ units	+ ☐ =	☐ units	+ ☐ =	☐ units	+ ☐ = ☐ → Record as new Daily Dose on your next sheet
Fasting Blood Glucose (mmol/L) finger prick	Day 1 ☐ + Day 2 ☐ + Day 3 ☐ mmol/L		Day 1 ☐ + Day 2 ☐ + Day 3 ☐ mmol/L		Day 1 ☐ + Day 2 ☐ + Day 3 ☐ mmol/L	
3-Day Total	= ☐		= ☐		= ☐	
Average Blood Glucose	÷3 = ☐		÷3 = ☐		÷3 = ☐	
Notes Use this space to record details of hypoglycaemia						

Handling Hypoglycaemia

If you feel Hypoglycaemic or have blood glucose below 4 mmol/L at any time since your last insulin dose:

1. Treat immediately by following instructions given to you by your healthcare professional
2. Cross out any remaining blood glucose or calculation fields in current Period
3. Reduce your daily insulin dose by -2 to -4 units and start a new Period

Find Your Dose Adjustment Before Dosing on Day 3**

If you were NOT hypoglycaemic at this dose, use this table to find your Adjustment.

	Target range			
Average Blood Glucose (mmol/L)	4.0-7.0	7.1-8.0	8.1-10.0	Over 10
Adjustment (units)	+0*	+2	+4	+6

* Dose Adjustment is complete when your Average Blood Glucose falls within the target range. Continue monitoring your fasting blood glucose daily as directed by your healthcare professional

Bring this form and your Accu-Chek blood glucose monitoring system to your next appointment.

Based on O'Neal DN et al. INITIATION STUDY: a pilot study examining a model of care for initiating patients with Type 2 Diabetes on a basal +/- prandial insulin regimen in primary care with adjunct Continuous Glucose Monitoring. http://www.diabetesccre.unimelb.edu.au/professionals/documents/Sanofi_Meeting_INITIATION_ONeal_et_al_Oct-2011.pdf [accessed May 30th, 2012]
** Modified according to the STEPPING UP study protocol from Davies M et al. Improvement of Glycemic Control in Subjects with Poorly Controlled Type 2 Diabetes. Diabetes Care 28:1282–1288, 2005

CAUTION: INVESTIGATIONAL DEVICE. FOR INVESTIGATIONAL USE IN THE STEPPING UP STUDY ONLY.

ACCU-CHEK® 360° Insulin Adjustment Tool
For use with insulin glargine (Lantus®)

Instructions and Examples

Why use this form
You have been diagnosed with Type 2 diabetes and your healthcare provider has recently prescribed insulin as part of your treatment. This form will help you adjust your Daily Dose of insulin to achieve an average *fasting blood glucose* that falls within the target range specifed by your healthcare provider.

Definition: A *fasting blood glucose* is one where you do not eat food or drink liquids – except water - for at least 8 hours before testing. The most convenient time to measure your fasting blood glucose is when you wake up each day—and before your first meal of the day.

Before using this form:
- Read all instructions.
- Complete the User Information section with your healthcare professional.
- Confirm that your healthcare professional has supplied you with an Insulin Starting Dose and Daily Dose Time.
- Record the Start Date for each week.

Completing your Dose Adjustment:
- Dose Adjustment is complete when your fasting blood glucose falls within the Target Range.
- Continue monitoring your fasting blood glucose daily as directed by your healthcare professional.

Steps

Fasting
- Test and record your fasting blood glucose using your Accu-Chek blood glucose meter.
- If hypoglycaemic, see Handling Hypoglycaemia.

Before Dosing Day 3
- Add blood glucose values for days 1, 2 and 3 to find the 3 Day Total.
- Divide the Total by 3 to find the Average Blood Glucose.
- Enter your Adjustment using the Dose Adjustment table. Note: Dose Adjustment is complete when your Average Blood Glucose falls within the Target Range. Continue with the current dose of insulin according to your healthcare professional's instructions.
- Add your current Daily Dose and the Adjustment to find your new Daily Dose.

Handling Hypoglycaemia
If you feel hypoglycaemic at any time, refer to the Handling Hypoglycaemia instructions.

Examples

Starting Dose is 10 units

Period 1
- User is not hypoglycaemic
- Average Blood Glucose calculated on Day 3 = 8.6 mmol/L
- Adjustment is +4
- New Daily Dose is 14 units

Period 2
- User is hypoglycaemic on Day 2 with a Fasting Blood Glucose of 3.1 mmol/L
- Adjustment is -2 and a new Period is started with Daily Dose 12 units

Period 3
- User is not hypoglycaemic
- Average Blood Glucose calculated on Day 3 = 7.5 mmol/L
- Adjustment is +2
- New Daily Dose is 14 units (carried forward as new Daily Dose on next sheet)

	Period 1	Adjustment	Period 2	Adjustment	Period 3	Adjustment
Start Date	04/03/2011		07/03/2011		09/03/2011	
Daily Dose (units)	10 units	+ 4 =	14 units	+ -2 =	12 units	+ 2 = 14 → Record as new Daily Dose on your next sheet
Fasting Blood Glucose (mmol/L) finger prick	Day 1 8.3 + Day 2 8.9 + Day 3 8.7 mmol/L		Day 1 7.8 + Day 2 3.1 + Day 3 ☒ mmol/L		Day 1 8.6 + Day 2 7.7 + Day 3 6.3 mmol/L	
3-Day Total	= 25.9		= ☒		= 22.6	
Average Blood Glucose	÷3 = 8.6		÷3 = ☒		÷3 = 7.5	
Notes Use this space to record details of hypoglycaemia			Fasting Blood Glucose hypoglycaemia on 08/03/2011 Adjusted Daily Dose by -2			

Handling Hypoglycaemia #
If you feel Hypoglycaemic or have blood glucose below 4 mmol/L at any time since your last insulin dose:
1. Treat immediately by following instructions given to you by your healthcare professional
2. Cross out any remaining blood glucose or calculation fields in current Period
3. Reduce your daily insulin dose by -2 to -4 units and start a new Period

Find Your Dose Adjustment Before Dosing on Day 3**
If you were NOT hypoglycaemic at this dose, use this table to find your Adjustment.

	Target range			
Average Blood Glucose (mmol/L)	4.0-7.0	7.1-8.0	8.1-10.0	Over 10
Adjustment (units)	+0*	+2	+4	+6

* Dose Adjustment is complete when your Average Blood Glucose falls within the target range. Continue monitoring your fasting blood glucose daily as directed by your healthcare professional

Roche

Figure 17: Accu-chek®360° 3 day profiling tool

CAUTION: INVESTIGATIONAL DEVICE. FOR INVESTIGATIONAL USE IN THE STEPPING UP STUDY ONLY.

PATIENT NAME	INSULIN NAME	DOSE (UNITS)	TIME OF DAY	ORAL DIABETES MEDICATIONS	DOSE	TIMES/DAY	HEALTHCARE PROFESSIONAL NAME
PATIENT PHONE							HEALTHCARE PROFESSIONAL PHONE

Accu-Chek 360° View 3-day Profiling Tool

	Day 1 Date _____							Day 2 Date _____							Day 3 Date _____						
	Before breakfast	2 hours after breakfast	Before lunch	2 hours after lunch	Before dinner	2 hours after dinner	Before bed	Before breakfast	2 hours after breakfast	Before lunch	2 hours after lunch	Before dinner	2 hours after dinner	Before bed	Before breakfast	2 hours after breakfast	Before lunch	2 hours after lunch	Before dinner	2 hours after dinner	Before bed
Time																					
Insulin Units																					
Meal Size S M L	–	S M L	–	S M L	–	S M L	–	–	S M L	–	S M L	–	S M L	–	–	S M L	–	S M L	–	S M L	–
Activity Level*	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
BLOOD GLUCOSE																					
BLOOD GLUCOSE RANGE# HIGH >14,0 mmol/L																					
HIGH 12,1–14,0 mmol/L																					
HIGH 10,1–12,0 mmol/L																					
HIGH 8,1–10,0 mmol/L																					
HIGH 7,1–8,0 mmol/L																					
4,5–7,0 mmol/L																					
4,0–4,4 mmol/L																					
LOW 3,1–3,9 mmol/L																					
LOW <3,0 mmol/L																					

After Meal Goal

Before Meal Goal

*ACTIVITY LEVEL					
What is your activity level?	1 Very Low	2 Somewhat Low	3 Moderate	4 Somewhat High	5 Very High

WARNING: Do not adjust your prescribed oral medication or insulin therapy without first consulting your healthcare professional.

YOUR COMMENTS

_____

_____

Bring this form and your Accu-Chek blood glucose monitoring system to your next healthcare professional appointment.

* According to the STEPPING UP study protocol, Furler J et al, Starting basal insulin and addition of pre-meal insulin if required in adults with type 2 diabetes. The University of Melbourne, Department of General Practice, Melbourne, Australia.

ACCU-CHEK®

Instructions to patient:
Complete this form over
3 consecutive days.

Step 1
Fill in the **dates** for the days on which you will track your blood glucose results.

Step 2
Test your **blood glucose** using your Accu-Chek blood glucose monitoring system at the times indicated to the left.

Step 3
Enter the **time** of the test in the first row of the chart.

Step 4
If you use insulin, enter your insulin dose (units).

Step 5
Based on your normal eating habits, describe this **meal size** by circling **Small**, **Medium** or **Large** in the second row.

Step 6
Rate your **activity level** on a scale of **1 (very low) to 5** (very high) and circle that score.

Step 7
Enter your **blood glucose value** in the fifth row for that day.

Step 8
Graph your **blood glucose level** (from Step 7) by placing an **X** in the corresponding row of the chart. Then connect the Xs. See other side for example.

FOOD DIARY

Use this space to fill in what you eat and drink over 3 days.

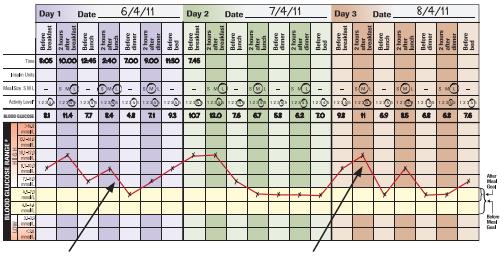
Day 1	Day 2	Day 3
Breakfast	**Breakfast**	**Breakfast**
Snack	**Snack**	**Snack**
Lunch	**Lunch**	**Lunch**
Dinner	**Dinner**	**Dinner**
Drinks (soft drinks, hot beverages, alcohol, etc)	**Drinks (soft drinks, hot beverages, alcohol, etc)**	**Drinks (soft drinks, hot beverages, alcohol, etc)**

Accu-Chek 360° View 3-day Profiling Tool

Data can show you:

- Trends in blood glucose levels
- The relationship between blood glucose values and
  - Time of day
  - Meal size
  - Activity level
  - Diabetes medication (if prescribed)

Accu-Chek 360° View 3-day Profiling Tool



By drawing a line through the recorded results, you can easily identify trends in blood glucose.

Out-of-range blood glucose values can indicate a need for better blood glucose control, and might suggest the need to adjust and/or change therapy.

www.accu-chekacademy.com.au
Roche Diagnostics Australia Pty Ltd
31 Victoria Avenue, Castle Hill NSW 2154
ABN 29 003 001 205
Accu-Chek Enquiry Line: 1800 251 816

ACCU-CHEK®

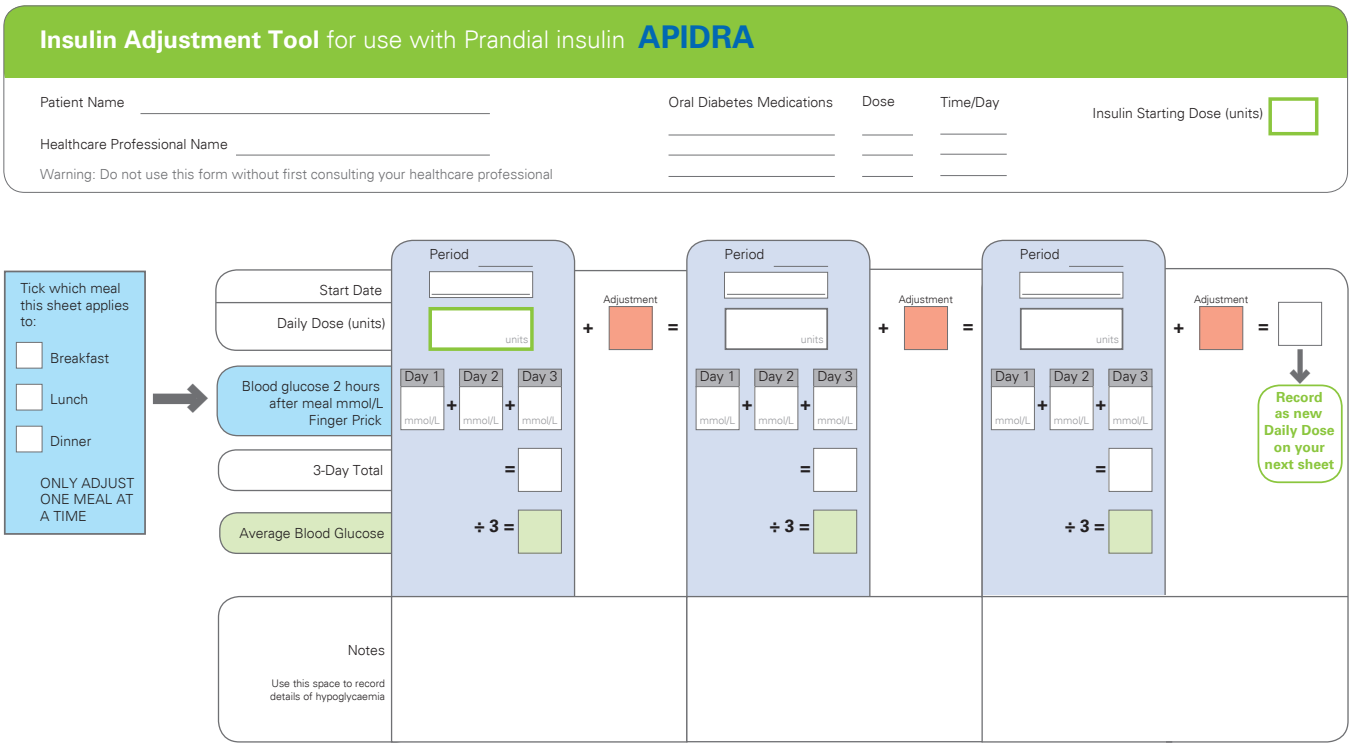
Glulisine (Apidra)

Initiation of glulisine (Apidra) is indicated when the patient has achieved the target fasting blood glucose of 4.0-7.0 mmol/L but have postprandial blood glucose readings of above 10mmol/L. If there is more than one meal at which this occurs, target the one with the greatest post-meal excursion first. The 3 day profiling tool will assist you in determining this (see Figure 17). The starting dose for Apidra is 4 units.

Remember: No matter how high the BGL is, the first (starting) dose of 4 units APIDRA should be adhered to, until it is established how sensitive your patient is to this insulin. In some patients one unit of Apidra may drop the blood glucose level 4 to 6mmol/l, in others 4 units may only drop them 1mmol/l. Until the effect on each individual patient is established it is important to maintain frequent contact in relation to dose adjustment of Apidra. If the pre-meal injection is forgotten, it is NOT to be given an hour or two later when a high glucose is detected, but rather ask them to record in their BG diary that it was missed. The following day they can return to the planned schedule and inject prior to the designated meal.

Glulisine (Apidra) is titrated using the Insulin adjustment tool for use with prandial insulin glulisine (Apidra) (see Figure 18) every three days until the target of 4.5 – 7.0mmol/L two hours after the meal is attained (note: for some patients the GP may aim for a target of up to 10mmol/L – this is at the discretion of the clinician).

Figure 18: Insulin adjustment tool for use with prandial insulin glulisine (Apidra)



Handling Hypoglycaemia

If you feel Hypoglycaemic or have blood glucose below 4mmol/L at any time since your last insulin dose:

1. Treat immediately by following instructions given to you by your healthcare professional
2. Cross out any remaining blood glucose or calculation fields in current Period
3. Reduce the dose of the last insulin given by 2 to 4 and start a new Period

Find Your Dose Adjustment Before dosing on Day 3

If you were NOT hypoglycaemic at this dose, use this table to find your Adjustment.

		Target range				
Average Blood Glucose (mg/dL)	Less than 4.5	4.5-7.0	7.1-10.0	10.1-12.0	12.1-14.0	More than 14
Adjustment (units)	-2-4 units	0*	+0 to 2 units	+2 units	+4 to 6 units	+6 to 8 units

*Dose Adjustment is complete when your Average Blood Glucose Falls within the target range. Continue monitoring your fasting blood glucose daily as directed by your healthcare professional.

Side effects of insulin

Insulin is very safe when used with the guidance of health professionals and at the correct dose. The main side effect is hypoglycaemia (low blood glucose level). Mild hypoglycaemia can be treated very quickly by the person with diabetes without too much disruption to their day. Very low blood glucose levels can be dangerous and must not be ignored. In order to keep the patient symptomatic of hypoglycaemia at a reasonable level (around 3.5 to 3.8mmol/l) stress the importance of rapid, appropriate treatment of the hypoglycaemia as soon as symptoms are detected. Regularly delaying treatment for 10 to 15 minutes will result in hypoglycaemia unawareness at that level, and symptoms will progressively not manifest themselves until lower and lower glucose levels are reached.

Some people may experience a slight reaction where the injection was given. This usually goes away within a few days. Very rarely, a person may experience a reaction to the insulin that requires them to stop it and start another type of insulin. If they experience any side effects please discuss with the GP.

Weight gain can occur after starting insulin therapy. Often, the longer people wait before starting insulin, the more weight they gain. This can be curbed by increasing exercise and reducing energy intake. The benefits of better blood glucose control with insulin outweigh the risks of increased weight.

Hypoglycaemia

Hypoglycaemia is the main potential side effect of insulin therapy and it is essential that the person starting insulin, and their immediate family, know what symptoms to expect, how to reduce the risks of hypos and how to treat them.

Hypoglycaemia can be caused by one of a number of events such as:

- Delaying or missing a meal
- Unplanned physical activity
- Not eating enough carbohydrate
- More strenuous exercise than usual
- Too much insulin or diabetes tablets

While symptoms vary from person to person, common feelings are:

- Weakness, trembling or shaking.
- Light headedness
- Dizziness
- Tearfulness/crying
- Hunger
- Sweating
- Headache
- Lack of concentration/behaviour change
- Irritability
- Numbness around the lips and fingers

Treatment of hypoglycaemia

The first thing to do is ensure safety. For example if driving a car, pull over to the side of the road. Then, advise the patient to have some quick acting carbohydrate that is easy to consume, for example;

- ½ can regular soft drink, or
- ½ glass of fruit juice, or
- 3 teaspoons of sugar or honey, or
- 6-7 jelly beans, or glucose tablet equivalent to 15 grams of carbohydrate

The following steps are also recommended. The order and timing of these steps depends on the severity of the 'hypo' and time and circumstances.

- Wait 10-15 minutes. If it isn't rising, repeat treatment with a quick acting carbohydrate as described above.
- If the next meal is more than 20 minutes away, eat some longer acting carbohydrate. This could be one of the following:
  - A sandwich **OR**
  - 1 glass of milk or soy milk **OR**
  - 1 piece of fruit **OR**
  - 2-3 pieces of dried apricots, figs or other dried fruit **OR**
  - 1 tub of natural low fat yoghurt **OR**
  - 6 small dry biscuits and cheese

If consciousness is impaired oral intake of carbohydrate should not be attempted and caregivers should be advised to seek emergency medical care. Treatment will include management of hypoglycaemia and review of diabetes medications.

Storage of insulin and sharps disposal

Unopened insulin should be stored in the fridge, between 2 and 8 degrees Celsius. Once opened, insulin may be kept at room temperature (between 25 to 30 degrees Celsius) for one month and then discarded.

Insulin can be damaged by extreme temperatures. It must not be left where temperatures reach over 30 degrees, e.g. in the car or in direct sunlight. Insulin should not be allowed to freeze as it will lose its potency, and must be discarded. Discard the insulin if lumps or flakes are seen in the insulin or on the inside of the cartridge and are not able to be dissolved by gently rotating the pen.

Used syringes, pen needles and lancets must be disposed of in an Australian Safety Standards-approved sharps container which is puncture proof and has a secure lid. These are usually yellow in colour and are available through pharmacies, your local municipal council and DA–VIC.

Stepping Up protocol

Blood glucose monitoring

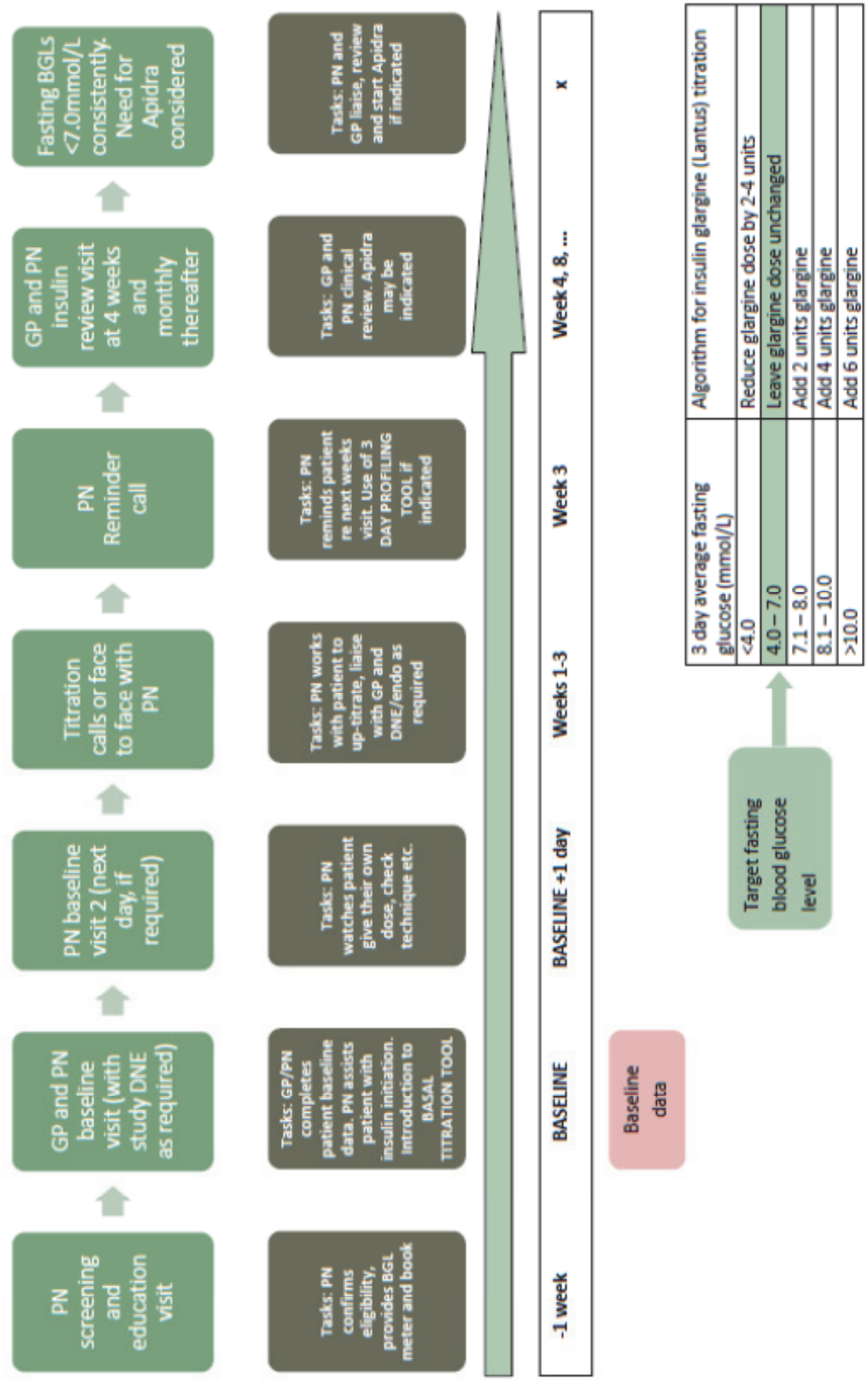
All patients participating in the Stepping Up study will be supplied with a Roche Performa Nano blood glucose meter.

Patients should be directed to monitor blood glucose levels at least twice daily - before breakfast and at another time (preferably about 2 hours after a meal). The second reading can be rotated. When considering the addition of Apidra, the patient will be requested to complete the 3 day profile tool which requires seven blood glucose readings per day for three days (see Figure 17, Page 17).

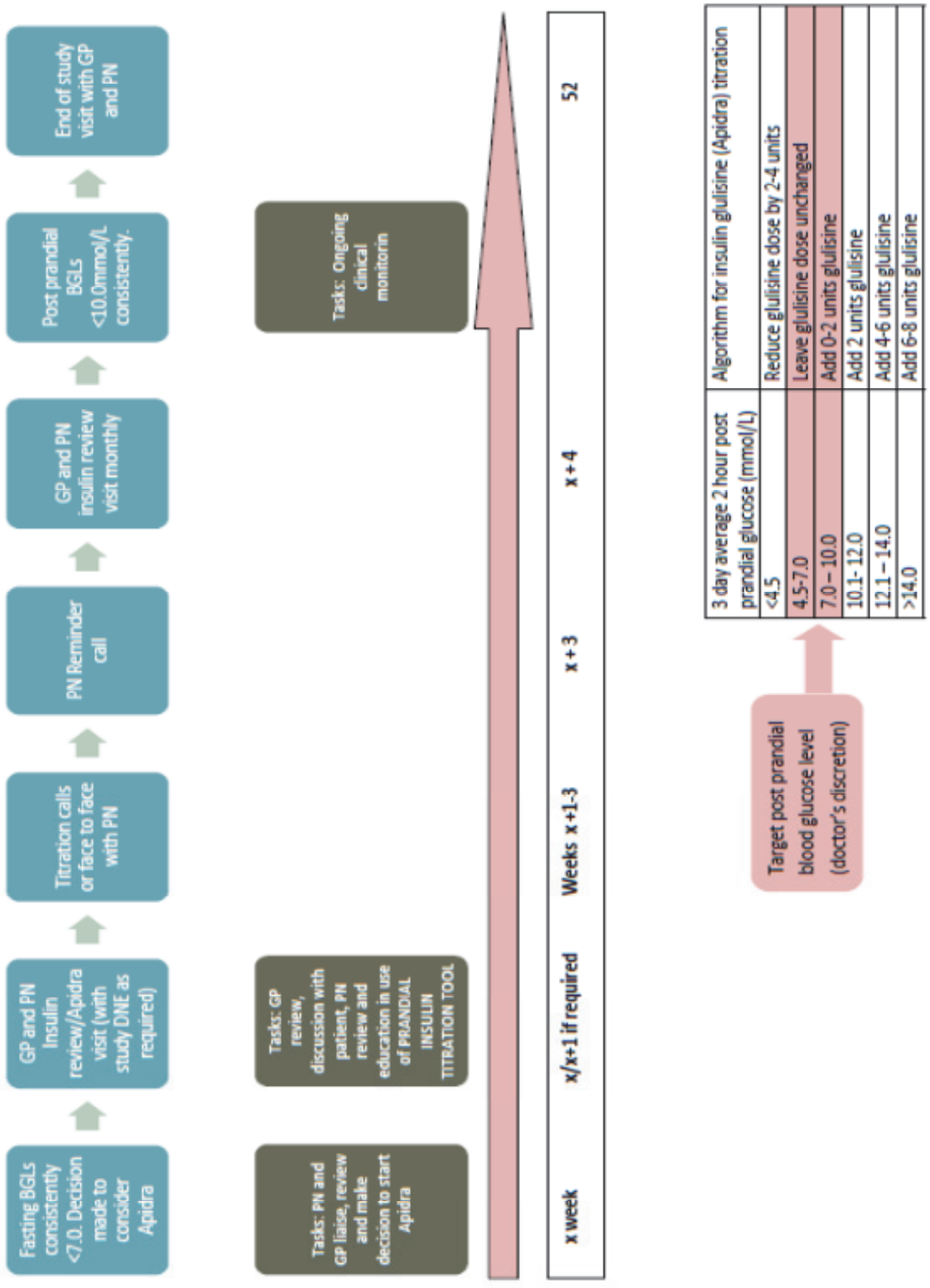
Times and readings are to be recorded in the blood glucose monitoring diary and tools provided. Any symptomatic hypoglycaemic episodes are to be recorded in the diary and any episodes of severe hypoglycaemia (requiring assistance from a third party) are to be reported to the study team within 24 hours.

Patients are to be advised to bring the diary and meter in with them at every visit to the clinic. The diary will be collected at the conclusion of the study. The Roche SmartPix tool will be available to clinics to upload blood glucose readings directly from the meter to a computer so that information can also be viewed visually. *Patients still need to record their readings in the diary and tools provided.*

Starting glargine (Lantus)



Starting glulisine (Apidra)



3 day average 2 hour post prandial glucose (mmol/L)	Algorithm for insulin glulisine (Apidra) titration
<4.5	Reduce glulisine dose by 2-4 units
4.5-7.0	Leave glulisine dose unchanged
7.0 – 10.0	Add 0-2 units glulisine
10.1- 12.0	Add 2 units glulisine
12.1 – 14.0	Add 4-6 units glulisine
>14.0	Add 6-8 units glulisine

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Appendix

Motivational Interviewing Resources

CLINICAL PRACTICE

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Influencing behaviour change in general practice

Part 1 – brief intervention and motivational interviewing

Background
Behaviour change toward achieving a healthy lifestyle is important for all Australians, and general practitioners have a key role to play in assisting patients to make these changes.

Objective
This is the first of a two part series which provides the background to approaches to influencing behaviour change in general practice, from brief interventions to motivational interviewing (MI). The second part of the series will explore motivational interviewing in more detail.

Discussion
General practitioners have a key role in changing their patients' health behaviours. There are a range of tools GPs can use to help enhance their patients' motivation to achieve their health goals.

Instigating behaviour change in patients to help them achieve a healthy lifestyle is a critical component of general practice to combat rising chronic disease in the community. An individual's health behaviour is determined by a complex interplay between their knowledge and understanding of health and disease, the personal meaning and relevance of that knowledge, their confidence in their ability to make changes, and a range of other factors acting as facilitators and barriers to change.[1]

Brief interventions

Brief interventions (provision of information and advice) by general practitioners are successful in promoting healthy behaviour in relation to smoking, alcohol, physical activity and nutrition.[2,3] General practitioners develop therapeutic relationships with patients over time, are respected, and have multiple opportunities to provide brief advice in a range of health behaviours. Furthermore, GPs can tailor information to the individual, which is more effective than generic information.[4,5]

A framework that has been widely promoted for brief intervention is the 5As approach – Ask, Assess, Advise, Assist and Arrange follow up. Initially developed for managing tobacco dependence, it has subsequently been applied to many other health behaviours.[6] With this approach, all patients are screened for unhealthy behaviours (ask). All those identified by screening are assessed for their readiness to change (assess) and advised to alter their behaviour (advise). Those who agree to change are provided with practical help to make the change (assist) and followed up to provide support (arrange). This can include practical strategies such as the use of a decisional balance sheet,[7] which compares the pros and cons of change, setting dates and times for action and support medication.

Brief interventions in general practice usually take a few minutes and are incorporated into routine care. While there is strong evidence

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to support brief interventions, they are sometimes insufficient to alter behaviour.[7] When positive outcomes are not apparent, the sense of inability to change behaviour can be associated with frustration, a lack of confidence and negative attitudes toward attempting to change health behaviours.[8,9]

Transtheoretical model of change

The transtheoretical model (TTM) of change, commonly known as the 'cycle of change' or 'stages of change', was originally developed by Prochaska and DiClemente in 1982 in relation to tobacco use.[10,11] It has since been applied to many behaviours and helps to explain why attempts to change behaviour may not work.[11] There have been many versions of this model. In its original form, it consisted of five stages:

- precontemplation (not thinking about change)
- contemplation (thinking about change)
- preparation/decision making (actively planning change)
- action (changing or recently changed and new behaviour not established), and
- maintenance (new behaviour established and working on maintenance).

Relapse was not considered to be a stage as it was seen as an event that terminates the action or maintenance phase, prompting a movement back into an earlier phase. Later, the authors proposed a 'spiral of change' which suggests that most relapsers do not revolve endlessly in circles regressing back to the beginning, but instead learn from each attempt and progress with each cycle[11] (*Figure 1*). While the cycle of change is frequently associated with MI, Miller and Rollnick specifically point out that they are not the same thing and that MI was never based upon TTM. The transtheoretical model of change is a model of how and why changes occur, while MI is a specific clinical method to enhance motivation for change. It is not necessary to assign a stage of change in order to apply MI.[12]

Another model that evolved from the original stages of change is the 'contemplation ladder',[20,21] in which the clinician asks people to identify where they are on a ladder (*Figure 2*).

Ambivalence, resistance and defence mechanisms

Ambivalence is a normal aspect of human nature and is a natural transition phase in the process of change.[7] For example, a person who is dependent on a drug can have a 'love-hate relationship' with the drug, ie. intensely positive feelings toward the drug together with an intense dislike of the problems associated with use of the drug and the control it has over the person. Change and resistance to change are seen as two sides of a coin.[7]

Giving brief advice, regardless of the stage of change, may be effective; this advice may trigger consideration of, or a decision to, change. On the other hand, advice can increase resistance to change[7] in the same way that someone who feels they are being nagged might become resentful and less willing to change.

Another brief intervention approach that has a stronger emphasis on empathy and therapeutic interaction is the use of the acronym FRAMES – Feedback about risk, emphasis on personal Responsibility, Advice to change, a Menu of options, Empathy and facilitation of Self efficacy.[13] While the 'brief interventions' for which FRAMES was developed referred to a few short term counselling sessions and not the brief interventions that occur in general practice, the components can still be relevant to the longitudinal interaction that occurs in general practice over multiple consultations.

Figure 1. The spiral of change

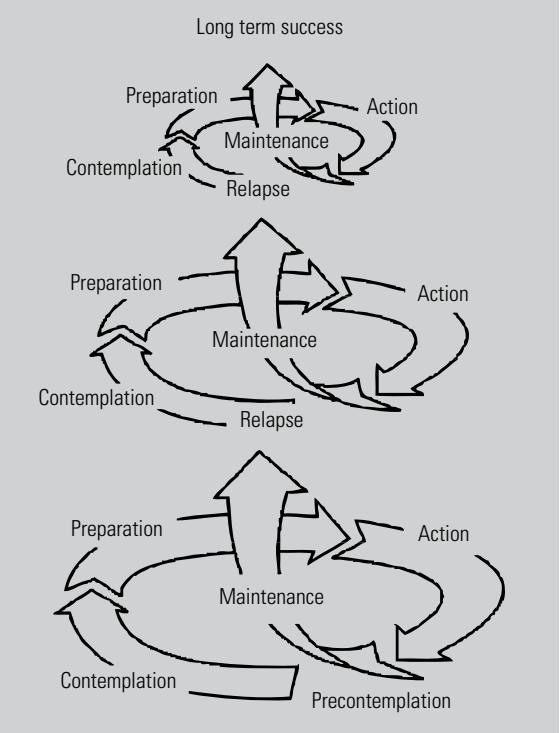

Figure 2. The contemplation ladder[20,21]

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Motivational interviewing

Motivational interviewing is a collaborative, person centred way of guiding the patient to elicit and strengthen motivation to change.[12] The goal is to increase intrinsic motivation rather than to impose it externally. Involving a flexible blend of informing, asking and listening, it works to evoke the patient's own values, goals, insights, motivation and resources for change.[14] The approach to MI is expressed in the acronym GRACE: Generate a gap, Roll with resistance, Avoid arguments, Can do, and Express empathy. These are summarised in *Table 1*.[15]

Table 1. Using GRACE in all stages of change

Generate a gap

The goal is to increase intrinsic motivation by generating a gap (between what the patient wants and what is) rather than to impose it externally

Roll with resistance

If resistance is encountered, alter the strategy used. Ambivalence is viewed as normal, not pathological, and is explored openly

Avoid arguments

Arguing increases resistance to change. It should be the individual and not the therapist who voices the arguments for change. The goal is to encourage the patient to hear themselves say why they want to change

Can do

Encourage self efficacy and hope. A person may perceive a serious problem but still will not move toward change unless there is hope for success

Express empathy

Listen, communicate acceptance and support and gently persuade while respecting personal views and choice

Motivational interviewing has been applied to many aspects of behaviour change ranging from alcohol and drug dependence, smoking cessation, weight loss, physical activity, the treatment of asthma and diabetes, adherence to treatment and follow up, and criminal activity. A systematic review and meta-analysis of randomised controlled trials using MI as the intervention found 74% of trials demonstrated a positive effect of MI. Measures of clinical relevance that improved with MI included body mass index, cholesterol, blood pressure, blood alcohol concentration, blood glucose, and length of hospital stay. The number of encounters and length of follow up was more important than the length of each encounter, with 64% of studies using brief encounters of 15 minutes being effective. Both psychologists and physicians obtained an effect in 80% of the studies.[16]

In a trial comparing GPs who were randomised to MI training to those who were not, the GPs trained in MI evaluated it to be more effective and no more time consuming than 'traditional advice giving'.[17]

Changing behaviour in general practice

General practitioners manage many health issues within a limited period of time in each consultation. It is relatively simple to integrate brief interventions consisting of the provision of information and advice relevant to the health issues being dealt with. This may be triggered by the presenting complaint or from routine screening for risk factors. Patients who are ready to change can be provided with further assistance and follow up. Brief advice from a respected person such as a medical practitioner may be effective regardless of the stage of change.[3] However, by recognising different needs at each stage of change, approaches

Table 2. Stages of change using brief intervention and motivational interviewing approaches

	Precontemplation (Not considering change)	Contemplation (Considering change)	Preparation (Planning change)	Action (Recent change)	Maintenance (Change established)
5As	• Ask • Assess • Advise	• Ask • Assess • Advise • Assist	• Ask • Assess • Advise • Assist • Arrange	• Ask • Assist • Arrange	• Ask • Arrange
FRAMES	• Feedback • Responsibility • Advice • Menu (options) • Empathy • Self efficacy	• Feedback • Responsibility • Advice • Menu (options) • Empathy • Self efficacy	• Feedback • Responsibility • Advice • Menu (options) • Empathy • Self efficacy	• Feedback • Responsibility • Advice • Menu (options) • Empathy • Self efficacy	• Feedback • Responsibility • Advice • Menu (options) • Empathy • Self efficacy
GRACE	• Build motivation	• Build motivation and strengthen commitment	• Strengthen commitment	• Strengthen commitment	• Strengthen commitment

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can be tailored to the individual's stage.[18,19] This is illustrated in *Table 2*, which maps the stages of change against some brief intervention and MI approaches.

A simple question that can help the GP to assess readiness to change and the right approach to use is: 'How do you feel about your smoking/drinking/lack of exercise?' The answer to this question will quickly establish if the person is ready to be given brief advice, or needs a gentler explorative approach using MI principles.

Medical practitioners are usually confident in helping people who have made a decision and commitment to change. Motivational interviewing fills the gap in providing strategies to explore ambivalence, build motivation and strengthen commitment in those who are uncertain or not yet considering change.

Conclusion

General practitioners are respected, see the majority of the population and have continuity of care, which means they play an important role in enhancing health outcomes through changing behaviour. Each GP develops a personal communication style; while this personal style might be effective in changing behaviour in a proportion of patients, having a range of tools increases the GP's repertoire, allowing them to facilitate more change.

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CLINICAL PRACTICE

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Influencing behaviour change in general practice

Part 2 – motivational interviewing approaches

Background
Behaviour change toward achieving a healthy lifestyle is important for all Australians, and general practitioners have a key role to play in assisting patients to make these changes.

Objective
This is the second of two articles on influencing behaviour change in general practice. This article deals with the 'how to' of motivational interviewing in the general practice setting.

Discussion
Motivational interviewing can help build motivation, commitment and confidence to change. General practitioners can use motivational interviewing to help their patients achieve their health goals. Motivational interviewing is not about a set of techniques and questions; it is about creating a climate that facilitates change; it is more about listening than telling, evoking rather than instilling. Motivational interviewing can be done in the brief periods available in consultations over time.

Motivational interviewing (MI) is a collaborative person centred guidance strategy to elicit and strengthen motivation to change.[1] It evolved from Carl Roger's client centred counselling approach which focuses on the person's interests and concerns, but differs by being consciously directive toward resolving ambivalence and moving toward change.[2] The goal is to increase intrinsic motivation rather than to impose it externally.[3] It was initially developed from work with problem drinkers, where in comparison with confrontational directive styles, motivational reflective styles were associated with lower levels of resistance and a higher likelihood of long term change.[4]

The 'spirit' of MI is collaborative (a partnership between the patient and the clinician), evocative (evoking from the patient's own values, goals, insights, motivation and resources for change), and honouring patient autonomy (acceptance that the patient makes his/her own choices).[5] It is particularly useful for those who are reluctant to change or ambivalent about changing behaviour.[6]

Motivation is seen not as a personal trait, but as an interpersonal process that results from the interaction between the practitioner and the patient. How the practitioner acts influences motivation to change. Resistance to change and denial is considered a signal to the therapist to alter strategies.[3]

Ready, willing and able to change

For behaviour change to occur, a person has to want to change, feel that they can change, and feel it is the right time to prioritise this action.[3] Motivational interviewing can help build motivation, commitment and confidence to change. Simply knowing that change is needed is not enough. Even if a person wants to change, they need to believe that they can before they take action. According to the protection motivation theory (PMT) developed by Rogers,[7] if a person believes there

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is a serious health threat but does not believe that anything can be done about it, the results are defence mechanisms and denial to reduce the emotional arousal associated with this knowledge of threat[8] (*Figure 1*).

The guiding principles of motivational interviewing

The acronym 'RULE' summarises the principles of MI:[5]

- Resisting the righting reflex – resisting the need to solve problems or tell patients what to do. This may seem at odds with the philosophy of brief intervention in which GPs are encouraged to advise patients to change their behaviour. However, repeatedly advising behaviour change in those who are not ready to change may increase their resistance and therefore be counterproductive
- Understand and explore the patient's own motivations – humans tend to believe what we hear ourselves say.[5] Bem's self perception theory suggests that what we say and do influences our own attitudes.[9] Hearing someone else say something is not as powerful as hearing ourselves say it. The goal of MI is to increase intrinsic motivation rather than to impose it externally
- Listen with empathy – in achieving behaviour change a key task is to listen in a way that will draw out the patient's issues so that it can be heard by both the patient and the doctor
- Empower the patient by encouraging hope and optimism – patients know better than anyone else how to change their own behaviour but may sometimes lack confidence in their own ability. A skilled practitioner encourages patients to vocalise why and how they intend to change during the consultation, knowing that this both reinforces the patient's own expertise in their own actions and influences the patient's attitudes.

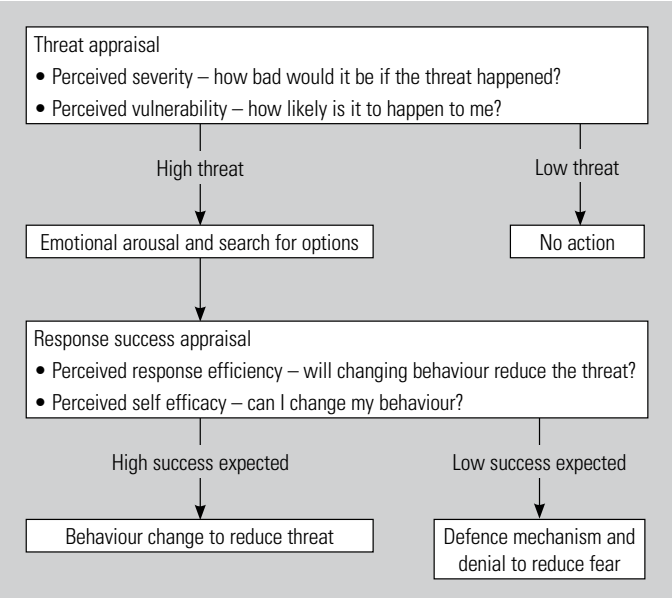
Asking instead of telling draws out the patient's thoughts, feelings, understanding and motivations. For example, 'Your blood sugar is high. What do you think of that? Does that worry you? Why do you think it's gone up? What can you do about that? Do you think you can manage that? How have you managed to do it before?' The answers to questions give us insights to the person's level of knowledge and beliefs, helping us to provide more relevant information and an appropriate response.

A second acronym, which provides useful strategies during consultations, is 'GRACE'.[10]

- Generate a gap – motivation for change happens when people perceive a discrepancy between where they are and where they want to be.[11] Raising awareness of the adverse consequences of behaviours by exploring experiences, values and attitudes nonjudgmentally can help generate this gap
- Roll with resistance – if the individual perceives an attack, defensiveness ensues, which evokes resistance. The patient's resistance is not challenged, instead MI 'rolls with' the momentum, viewing ambivalence as normal. In this way resistance is decreased and new perspectives are invited by exploring ambivalence openly.[11] For example: 'Oh no, you're not going to have a go about my smoking again!' can be met with, 'Has someone been giving you a hard time over this? What do you think of that?' These questions can evoke consideration toward change from the individual
- Avoid arguing – it should be the individual and not the clinician who voices the arguments for change.[3] The goal of MI is to encourage the individual to hear themselves say why they want to change. If the doctor is perceived as challenging the patient's position and not listening, then the patient will work harder to try to convince the doctor of the arguments for not changing. In the process of vocalising the reasons against change, they reinforce their own resistance to change since humans tend to move toward congruence between external actions (speech and action) and internal attitudes (beliefs and values).[9,12] Avoid the 'yes, but...' arguments where you and the person argue over change. Instead try, 'I'm wondering if you have any ideas about how you can exercise more, even when you're very busy?' Or, 'It sounds like my ideas aren't very good. Do you have any ideas?'
- Can do – a person convinced of a need to change will not move toward change without self efficacy (belief that they can succeed).[13] Without this, they are likely to adopt defensive coping (eg. rationalisation, denial) to reduce discomfort instead of behaviour change.[11] There is no 'right way' to change, and all previous attempts and learning, as well as pharmacotherapy and psychotherapy options, can be explored
- Express empathy – listening and communicating acceptance, understanding of ambivalence and respect for the individual's decisions.[11] Active listening is encapsulated by the acronym 'OARS' (open ended questions, affirmations, reflective listening, summaries).[3]

Each clinician develops a unique style, which might involve a blend of empathy, humour, 'straight talk', encouragement and other personal touches which can be adapted to the individual consultation.

Figure 1. Protection motivation theory[8]



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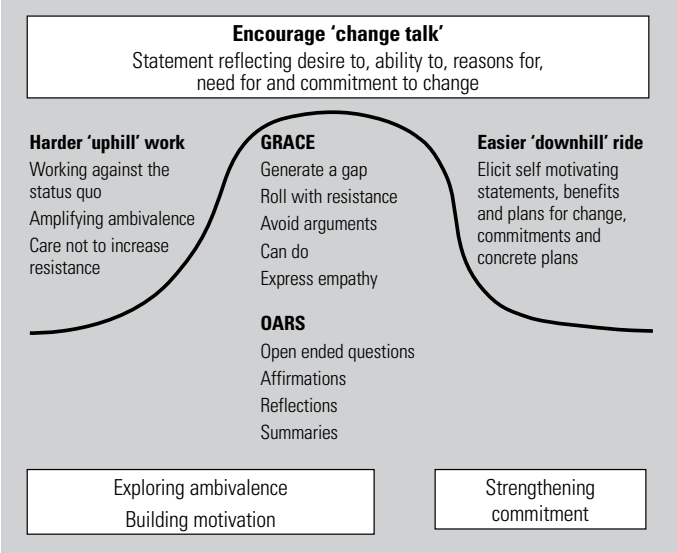
Eliciting 'change talk'

Motivational interviewing can be divided into two phases: building motivation and strengthening commitment.[3] Miller and Rollnick use the term 'change talk' to refer to statements from the individual that reinforce the movement toward change. The aim is to elicit 'change talk' statements through skilful questioning and reflection which express the following desire, ability, reasons, need and commitment (DARN-C)[14,15]:

- Desire – I want, I so want, I wish
- Ability – I can, I could, it's possible, I know I can
- Reasons – because, since, I'm sick of, I hate it
- Need – I must, I need, important, got to, really have to
- Commitment – I will, I'm going to, it's time now.

In eliciting change talk, instead of giving information, we ask questions and invite comments that draw out the patient's expressions of what, why, how and when to change. Among the 'change talk' statements, 'commitment talk' is the most predictive of change. *Figure 2* demonstrates the uphill process of exploring ambivalence and building motivation while encouraging change talk. Building commitment becomes easier as resistance decreases and motivation increases.

Figure 2. Encouraging change talk: stages and tools[18]



Changing behaviour in general practice

People are often ambivalent about health behaviours and resistance and change are two sides of a coin.[1] It is important to stress that MI is not about a set of techniques and questions; it is about creating a climate that facilitates change; it is more about listening than telling, evoking rather than instilling; and communicates, 'You have what you need, and together we will find it'.[16] Motivational interviewing can be done in the brief periods available in consultations over time[1] (*Table 1, Case study*).

Relapse management

Lapses (a brief return to the earlier behaviour) and relapses (a sustained return to the earlier behaviour) are common. It is important to stress that a lapse is different to a relapse and can result in new behaviour. Both clinicians and patients will often feel a sense of failure when relapses occur. This can be reframed, eg. 'I'm a failure' can be viewed as a partial success in a person who knows what needs to be changed, who is motivated to keep going despite adversity, and is willing to accept

Table 1. Questions to facilitate discussion in motivational interviewing in general practice

Brief: The following questions can be used within a 5 minute discussion	
Question	**Rationale**
'What do you like about (your smoking or other behaviour)?'	This question is unexpected as most would be expecting a lecture. It gives an opportunity to listen and build rapport. It also gives valuable information that helps to understand the context of the behaviour. It may also be important to consider how to replace this function if the behaviour were to stop
'What don't you like about...?'	This question is critical as it draws out the internal motivation for change
If appropriate you can add your own concerns	If you believe that adding your own concerns about the behaviour might help to tip the balance toward change and not increase resistance, this can be done
Summarise: 'So you like... but you don't like..., so where does that leave you?'	It is up to the patient to decide what needs to be done
Summarise, agree on a plan	Aim to get commitment to a plan which might range from action to change, an agreement to return to discuss further or an agreement for the issue to be raised again later
Briefer: The following questions can be used within a 1–2 minute discussion	
'On a scale of 1–10 where 10 is a lot, how much do you want to... (make the change)?'	The patient will usually pick a number higher than 2. Regardless of the answer, you can usually ask the next question. If the answer is 2 you can ask, 'Why so high, why is it not 1?'
'Why so high?'	The patient then tells you why (s)he wants to change, ie. argues for change
'So what do you want to do about it?'	The patient then states how to move toward change. Again aim to get a commitment to a plan which might range from action to change, an agreement to return to discuss further or an agreement for the issue to be raised again later

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help to achieve this goal.[17] The goal is to build self efficacy, strengthen commitment and to support. Behaviour change takes time and people may move backward and forward before achieving longer term change.

Case study

Dr M is running late, trying to get on to her next appointment. Her exiting patient, Kyle, hesitates with his hand on the doorknob, and says, 'I know you've been on at me forever but I think I need to stop smoking'. [Heartsink – 'I do need to deal with this now, but I don't have time'.] Dr M says, 'Tell me the most important reason you need to stop smoking now'. When Kyle answers, she notes these (now understanding his internal motivation), agrees they are very important reasons (reinforcing his motivations) and says she'd like to work with him on this. She asks, 'Are you willing to commit to coming back to talk to me next week to set up a Quit plan?' (builds commitment). That conversation took less than 1 minute and leaves the patient with enhanced motivation and a commitment to return to discuss the change plan.

Note: Providing the patient with a decisional balance sheet to consider at home can help some people to see their dilemma more clearly but the decisional balance technique differs from MI in that it gives equal weight to pros and cons, while MI deliberately aims to influence the direction of change by strengthening internal motivation for change and avoiding reinforcing reasons against change.[1]

Conclusion

General practitioners are in a strong position to make a difference to population and individual health outcomes in Australia as they provide continuing primary health care. Each GP develops a personal communication style, which is effective in changing behaviour in a proportion of patients, but having a range of tools such as MI helps achieve greater change.

Resource

The October 2009 issue of The Royal Australian College of General Practitioners' **check** Program, contains case studies that illustrate the practical application and complements the theoretical discussion in this series of articles. Available at www.racgp.org.au/check.

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Stepping Up Study