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BEST PRACTICE GUIDE:
Continuous subcutaneous insulin infusion (CSII)
A clinical guide for adult diabetes services

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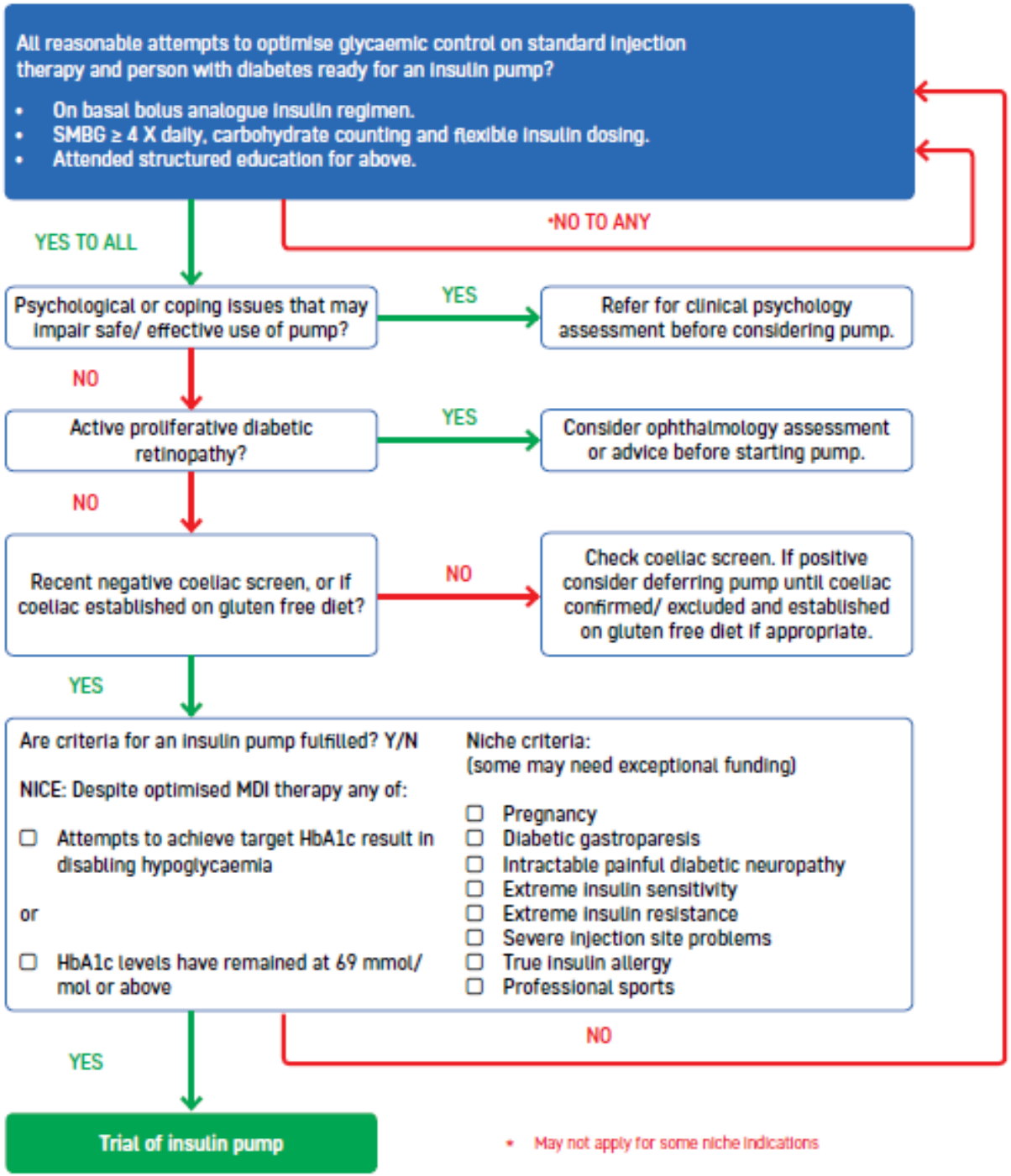
Overview of CSII: Clinical guide for adult diabetes services

AIM

- Facilitate access to pump therapy
- Improve outcomes for insulin pump users by describing what is required for successful use of insulin pump therapy
- The guide covers:
    - Initiation
    - Optimisation
    - Safety issues
    - Specific circumstances

Initiation

Advantages of pumps over MDI	Disadvantages of pumps over MDI
Fewer needle injections • No need to inject every time insulin delivery is required	**Constant attachment to pump** • Must be worn all the time, including when asleep • Constant visibility and reminder of diabetes • Can affect perceived body image
Insulin delivery can be conveniently varied so allowing more flexibility • Basal rates can be varied and programmed to match activity, shift work, changing requirements (eg pregnancy, hormonal changes, growth spurts, illness, travelling) • Bolus can be delivered over a varied time to help with other conditions eg malabsorption, gastroparesis or dealing with particular foods eg pizza • Temporary suspension or reduction of insulin delivery (activity and hypoglycaemia) • Allows pre-programming of insulin to deliver variable amounts insulin without constant input (e.g. whilst asleep or working) • The greater flexibility in insulin delivery and reduced variability in glucose levels can enhance quality of life	**No long-acting insulin depot** • Risk of rapid diabetic ketoacidosis development if technical failure or interruption in pump insulin delivery • Pumps should only be disconnected for short periods (eg swimming) **Complicated set up - infusion set changes** • Set changes are complicated compared to injections and infusion sets and cannulas need to be changed every 2-3 days
Small insulin doses • Deliver tiny doses (0.05-0.1 units) versus 0.5 -1 units from an insulin pen/syringe (useful for insulin-sensitive and young people)	**Infusion set problems** • Improper priming, air bubbles, tubing breaks and cannula kinks or slippages can interrupt delivery of insulin
Overcome variations in insulin absorption • Long-acting insulin can be absorbed differently in different people. Delivering programmed basal rates tailored to individual needs may overcome this problem, with the low volume of rapid-acting insulin at the infusion site resulting in a more consistent, reliable insulin absorption and hence circulating insulin profile (Bruntomesso et al. 2008)	**Infusion site problems** • Uncommon but risk of skin infections
Less snacks • Tailored insulin delivery and reductions in insulin delivery during activity reduces the need for snacking	**Increased education and training needed** • Requires higher level of education, understanding and motivation to get best use of pump and avoid problems
Improved patient experience and satisfaction • Improved self-management • Technology can motivate and improve engagement	**Increased health care provider training needed** • Health care providers need to have adequate knowledge and clinical systems in place to support pump therapy
Better integration with technology • Newer pumps can link with other technology such as meters, continuous glucose monitors, bolus advisors and diabetes information management systems	**Expense** • Pump costs as well as running costs (infusion sets, cannulas, batteries, accessories) are significantly more expensive than standard injections


All reasonable attempts to optimise glycaemic control on standard injection therapy and person with diabetes ready for an insulin pump?
• On basal bolus analogue insulin regimen.
• SMBG ≥ 4 X daily, carbohydrate counting and flexible insulin dosing.
• Attended structured education for above.
•NO TO ANY
YES TO ALL
Psychological or coping issues that may impair safe/ effective use of pump?
YES
Refer for clinical psychology assessment before considering pump.
NO
Active proliferative diabetic retinopathy?
YES
Consider ophthalmology assessment or advice before starting pump.
NO
Recent negative coeliac screen, or if coeliac established on gluten free diet?
NO
Check coeliac screen. If positive consider deferring pump until coeliac confirmed/ excluded and established on gluten free diet if appropriate.
YES
Are criteria for an insulin pump fulfilled? Y/N
NICE: Despite optimised MDI therapy any of:
☐ Attempts to achieve target HbA1c result in disabling hypoglycaemia
or
☐ HbA1c levels have remained at 69 mmol/ mol or above
Niche criteria:
(some may need exceptional funding)
☐ Pregnancy
☐ Diabetic gastroparesis
☐ Intractable painful diabetic neuropathy
☐ Extreme insulin sensitivity
☐ Extreme insulin resistance
☐ Severe injection site problems
☐ True insulin allergy
☐ Professional sports
NO
YES
Trial of insulin pump
• May not apply for some niche indications

Optimisation

Initial insulin setting at CSII initiation

Below is a summary flowchart to assist with dose calculation for CSII initiation, adapted from AACE (Consensus statement of AACE task force, 2014).

<table>
<tr><th colspan="3">Calculations for Insulin Pump Settings</th></tr>
<tr><th colspan="3">Pump TDD calculation</th></tr>
<tr><td colspan="2">Method 1 Pre-pump TDD
Pre-pump TDD × 0.75</td><td>Method 2 Patient weight
Weight: kg × 0.5</td></tr>
<tr><td colspan="3">Clinical considerations on pump TDD:
Average values from methods 1 and 2
Problematic hypoglycaemia: consider lower TDD
Hyperglycemic, elevated HbA1c, or pregnant, consider higher TDD</td></tr>
<tr><th colspan="3">Pump dose adjustment</th></tr>
<tr><td>Basal Rate
(Pump TDD × 0.5)/24 h</td><td>Carbohydrate Ratio (I:C) ratio
400/TDD</td><td>Insulin Sensitivity Factor (ISF)
130/TDD</td></tr>
<tr><td>Start with one basal rate, adjust according to glucose values over basal rate testing
Add additional basal according to need (e.g. Dawn phenomenon)</td><td>e.g. TDD 35 units = 400/35 = 11.4, I:C ratio 1 unit: 11g
Most adults require 1 unit: 8-15g
Acceptable post prandial rise is ~3mmol/l
Adjust based on low-fat meals with known quantity of carbohydrate</td><td>Correction insulin dose should bring glucose back to target range in 4-5 hours</td></tr>
</table>

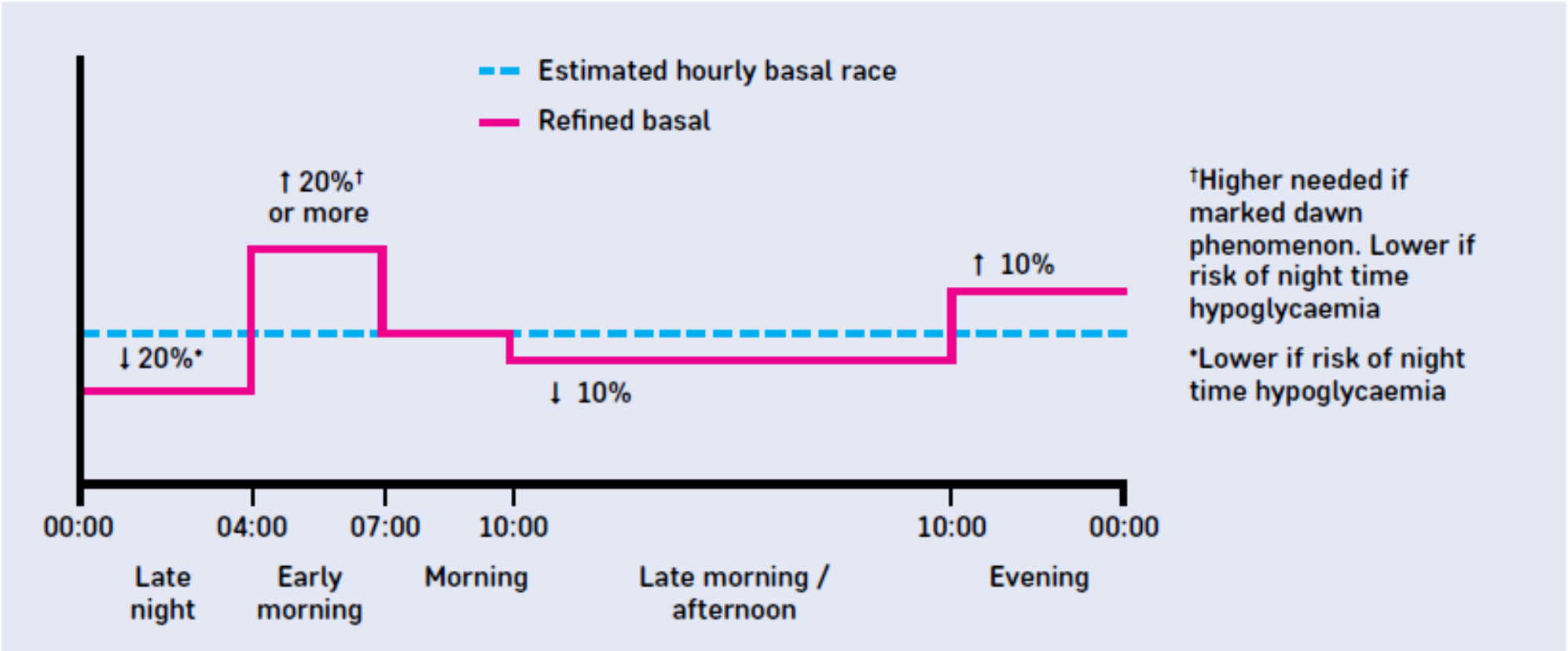


Figure 2. Modified Basal Rate Profile
(Adapted from Hussain & Oliver: Insulin Pumps and Continuous Glucose Monitoring Made Easy, 1e, 2016, Elsevier Ltd)

Basal rate testing

There are a few strategies that can be used to optimise and adjust basal rates:

1. **Formal basal rate testing.** This is particularly useful for overnight/dawn phenomenon or troubleshooting or to help user understanding and engagement. See Appendix 1 for basal rate testing protocol.
2. **Opportunistic basal rate testing.** This is easier to conduct using continuous or flash glucose monitoring to capture and assess glucose values in the fasting state >4 hours since last meal/bolus during day to day living.
3. **Download review.** If the user is unable/unwilling to perform basal rate testing then the download can be interrogated to assess the appropriateness of basal insulin; although more challenging, this is probably the most common approach in clinical practice.

Settings

Figure 3 Insulin pump settings

	Settings
Total Daily Dose (TDD)	If problematic hypoglycaemia consider a 10% reduction
Insulin:Carbohydrate ratio	300-400/TDD
Insulin Sensitivity Factor (ISF)	130/TDD
Insulin active time	4 hours*
Blood glucose target	5 mmol/l**

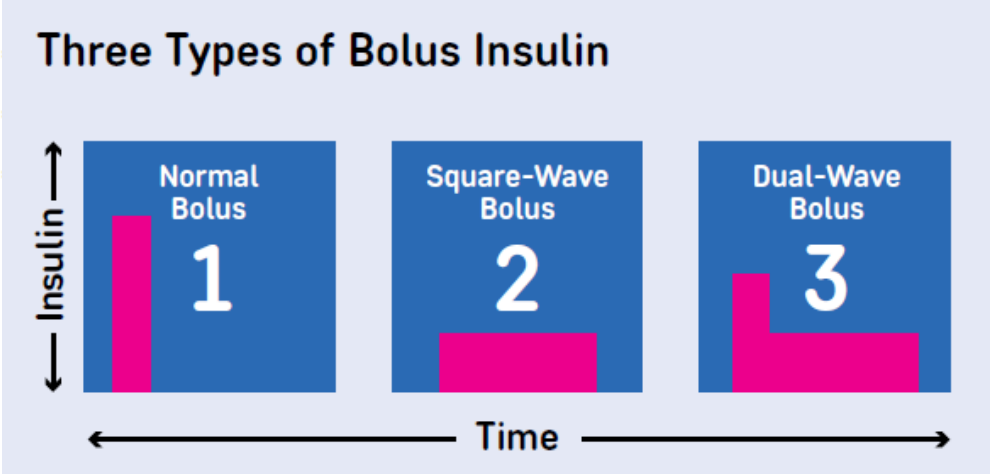


Table 3: Predicted ICR and ISF based on insulin pump total daily dose (TDD)

TDD	I:C Ratio 1 unit of insulin for X g of carbs	ISF 1 unit reduces glucose by...
	400 rule	130 rule
10	40	13
20	20	6.5
30	13	4.3
40	10	3.3
50	8	2.6
60	7	2.2
70	6	1.9

Table 4. A guide to insulin pump download interpretation

Glucose	Insulin	Pump settings
• What is the frequency of glucose monitoring? - Be aware that in those achieving HbA1c < 58mmol/mol (7.5%) the average BG tests per day is ≥ 5 • What is the mean glucose and therefore estimated HbA1c? • What is the glycaemic variability? - Standard deviation (SD) ≥ 3.5 mmol/l or CV (SD/mean) ≥ 36% suggests high variability (Danne et al. 2017) • What percentage of time is spent in hypoglycaemia? - ≥ 10% in someone monitoring ≥ 4/day is a concern, so identify the cause.	• What percentage of the total daily dose is basal? - ~40-60% expected - but take number of boluses and carbohydrate intake into account • Is the basal insulin adequate? - Is the glucose stable overnight and fasting at times when there are no other confounding factors? • What is the frequency of boluses? - Is all carbohydrate covered with a bolus? - Optimal glucose control often requires ≥ 5 bolus /day	• What is the total daily dose? • Do the I:C ratio and ISF fit with expectations taking into account the 400 and 130 rules? • If more insulin resistant at certain points of the day, are I:C and ISF in keeping with this? • Are set changes occurring at least every 3 days? • Is the bolus calculator used for the majority of boluses? - Is bolus calculator advice being over-ridden? • What is the target range? - Remember Medtronic pumps correct to the upper level so consider using 4.5-5.5mmol/l for most to overcome this - but do individualise targets following discussion with users. • If settings are way off those expected, with ineffective basal rates and bolus ratios, and sub-optimal control, consider resetting insulin pump settings based on weight calculations. Note that this will require close contact thereafter for further optimisation.

Safety concerns & specific circumstances

Management of unexplained hyperglycaemia

Set failure can occur and if not detected can potentially result in the development of ketosis/ketoacidosis within a matter of hours. All people with diabetes who use insulin pump therapy should be aware of the potential for set failure and how to manage this.

Rules for the management of **unexplained** hyperglycaemia:

- If glucose >13 mmol/l, take a correction bolus by the pump
- Check BG in 2 hours - if no change or glucose is higher, take a correction injection with a syringe or pen, check for ketones
- Change infusion set and reservoir
- Check glucose and blood ketones in 2 hours and take a correction bolus via the pump if required, check for ketones if glucose still high
- Follow sick day rules if ketones are positive
- Do not go to sleep:
  - with unexplained hyperglycaemia which has not resolved
  - or, within 2 hours of a new set change

Back up insulin pens

Pump users should have some long acting insulin available to them which they can use in the event of CSII failure. This is particularly important if they are travelling away from home. Users should carry a note of their ICR, ISF and basal insulin requirements. In the event of CSII failure, the emergency basal insulin would be the same as the total daily basal insulin on the pump and the ICR/ICF would be the same as on the pump.

In the event that a user experiences pump failure but they do not have long acting insulin with them, they should check glucose and take an injection of rapid acting insulin every 3 hours.

Some users may wish to plan a temporary return to multiple daily injections for holidays; they should be supported to do this. Some pump companies offer a holiday loan pump.

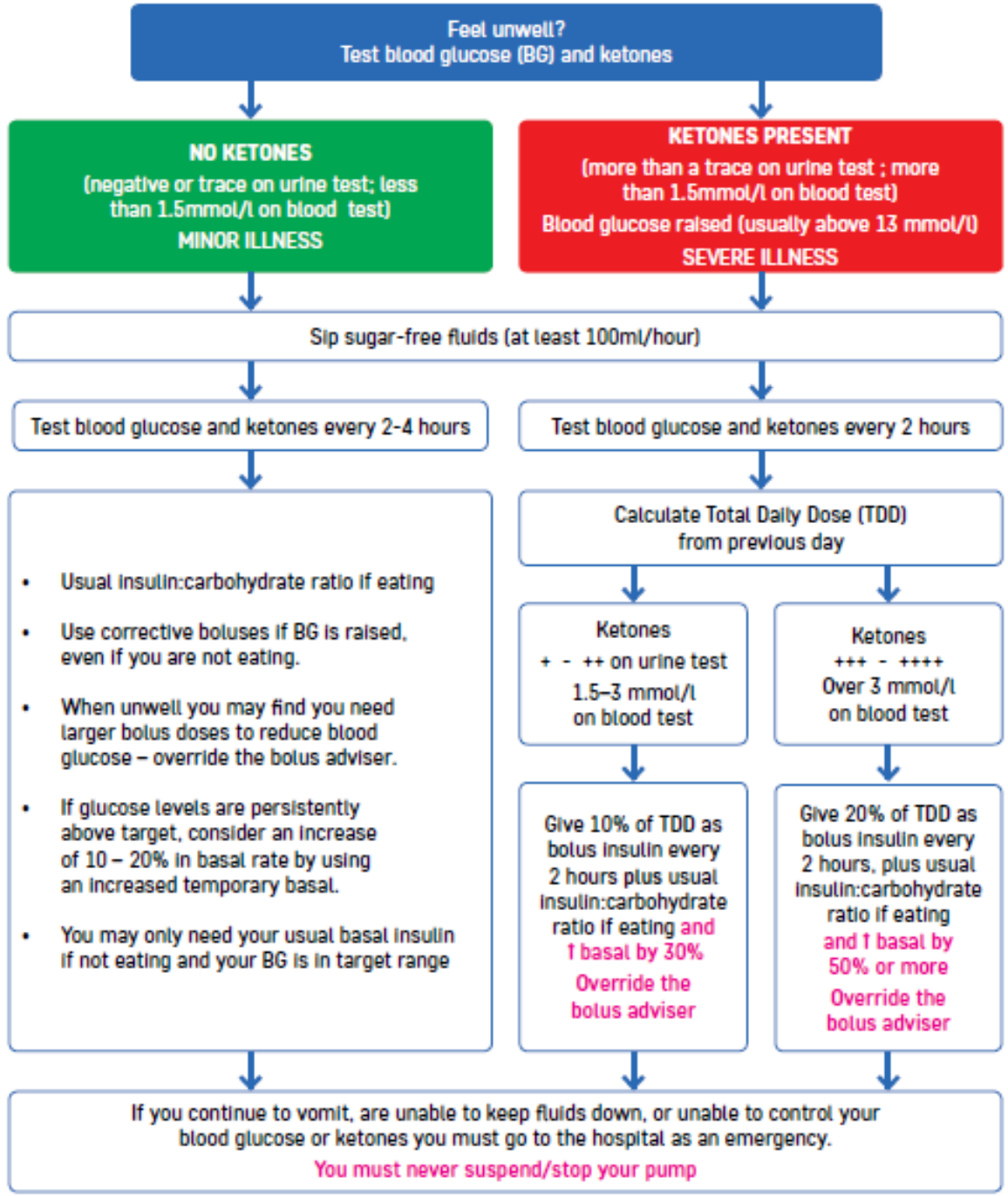
Consider CSII discontinuation in the following circumstances:

1. User choice
   User would prefer MDI

2. Safety concerns
   a. Admission with ketosis/diabetic ketoacidosis related to unsafe insulin pump use
   b. Inadequate glucose monitoring (<4 / day on download)
      i. If monitoring <2 per day, consider temporary immediate withdrawal on the basis of safety concerns

      ii. If monitoring 2-4 times per day, consider withdrawal if unable to increase to >4 times per day
   c. Unable to self-manage CSII safely (user or carer, e.g. cognitive impairment)
   d. Non-attendance at clinic for review

3. Absence of clinical benefit
   Failure to meet the objectives of CSII described at pump start eg failure to improve HbA1c and / or reduce hypoglycaemia frequency in absence of extenuating circumstances


Feel unwell?
Test blood glucose (BG) and ketones
NO KETONES
(negative or trace on urine test; less than 1.5mmol/l on blood test)
MINOR ILLNESS
KETONES PRESENT
(more than a trace on urine test ; more than 1.5mmol/l on blood test)
Blood glucose raised (usually above 13 mmol/l)
SEVERE ILLNESS
Sip sugar-free fluids (at least 100ml/hour)
Test blood glucose and ketones every 2-4 hours
Test blood glucose and ketones every 2 hours
• Usual insulin:carbohydrate ratio if eating
• Use corrective boluses if BG is raised, even if you are not eating.
• When unwell you may find you need larger bolus doses to reduce blood glucose – override the bolus adviser.
• If glucose levels are persistently above target, consider an increase of 10 – 20% in basal rate by using an increased temporary basal.
• You may only need your usual basal insulin if not eating and your BG is in target range
Calculate Total Daily Dose (TDD) from previous day
Ketones
+ - ++ on urine test
1.5–3 mmol/l
on blood test
Ketones
+++ - ++++
Over 3 mmol/l
on blood test
Give 10% of TDD as bolus insulin every 2 hours plus usual insulin:carbohydrate ratio if eating and ↑ basal by 30%
Override the bolus adviser
Give 20% of TDD as bolus insulin every 2 hours, plus usual insulin:carbohydrate ratio if eating and ↑ basal by 50% or more
Override the bolus adviser
If you continue to vomit, are unable to keep fluids down, or unable to control your blood glucose or ketones you must go to the hospital as an emergency.
You must never suspend/stop your pump

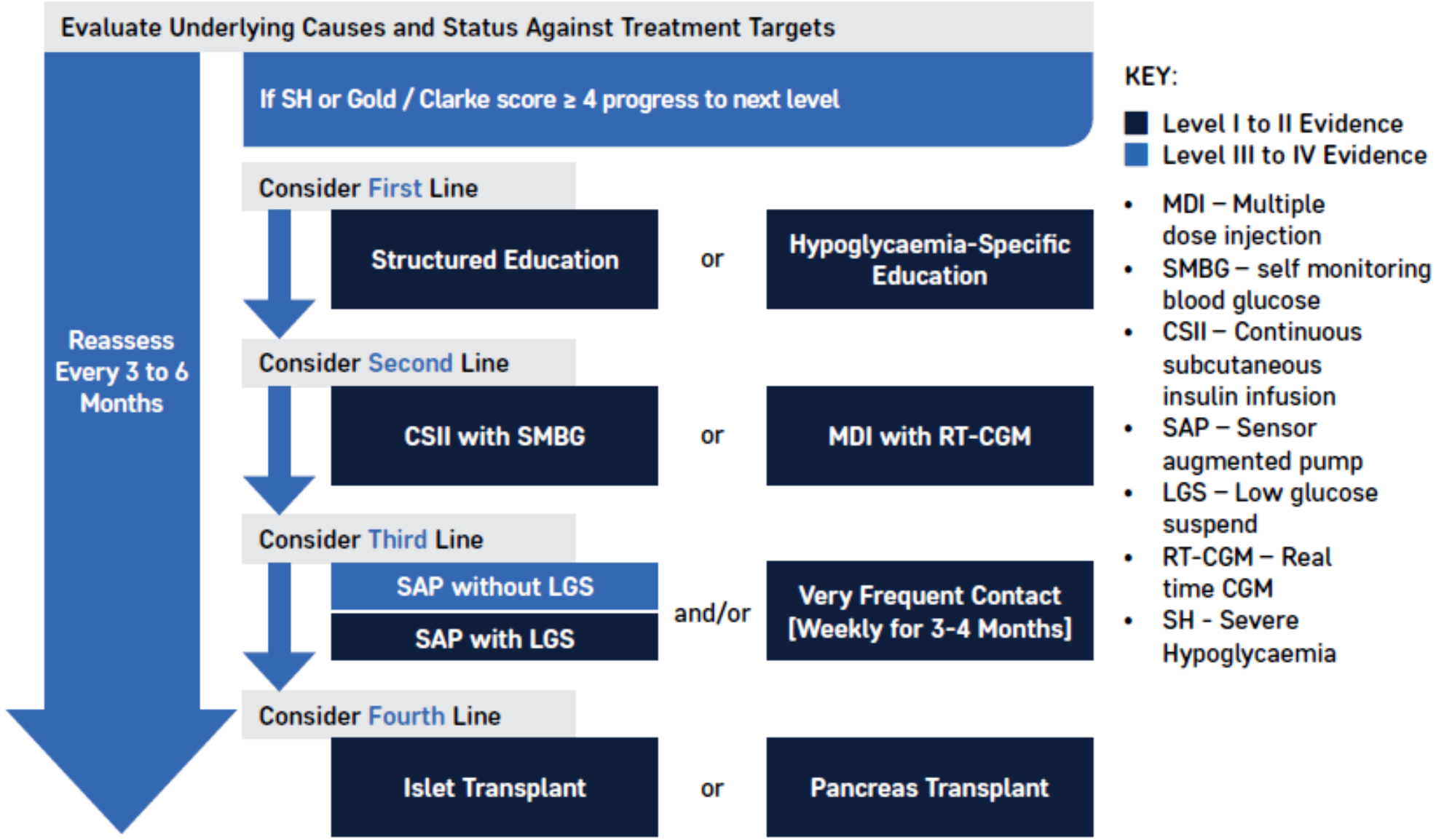


Figure 6 Approach to the person with problematic hypoglycaemia (adapted from Choudhary et al 2015)

Exercise

The flexibility in insulin delivery which is available through insulin pump therapy can help to reduce the dysglycaemia associated with exercise in Type 1 Diabetes (Riddell MC et al. 2017). Responses to exercise are individual and so all adjustments recommended here should be used as a starting point and are likely to need adjustment based on glucose trends.

Aerobic exercise

The most common type of exercise people will undertake is aerobic exercise. This is exercise (often running, cycling, swimming) at an intensity which can be maintained for around 30 minutes or longer. In Type 1 diabetes, this is associated with the possibility of hypoglycaemia during, soon after, or some hours post exercise completion. Higher circulating insulin at the start of activity is associated with a higher risk of hypoglycaemia, and so where possible basal insulin should be reduced 60-90 minutes before activity starts. The optimal reduction in basal insulin is likely between 50 and 100% (total suspension), with a reduction of 80% a useful starting point. Basal insulin can be returned to the usual rate at the end of exercise, although extending the temporary reduction for longer may be necessary depending on glucose trends. Where exercise is within 90-120 minutes after food, a 50% reduction in bolus insulin is likely to be more effective in reducing the risk of hypoglycaemia.

Anaerobic exercise

Anaerobic (high intensity) exercise is associated with a counter-regulatory response which can result in a rise in blood glucose. Where this is observed, a temporary increase in basal insulin may be helpful, ideally starting 30-60 minutes prior to the activity. Initially an increase of 20% may be helpful, although this should be adjusted based on glucose trends. An alternative is to correct any hyperglycaemia which does arise using 50% of the correction dose calculated using the usual ISF.

Combined exercise

Where anaerobic exercise is mixed with aerobic exercise (such as in many exercise classes) the overall result is usually a fall in glucose which is attenuated compared to the fall in glucose seen with aerobic exercise alone. In this instance a reduction in basal insulin should be used as above, with the starting point a reduction in basal insulin of 50%.

Nocturnal Hypoglycaemia

Nocturnal hypoglycaemia is commonly associated with exercise in Type 1 diabetes, particularly when the exercise has been of unusual intensity or duration, or when it has happened later in the day. The risk of this can be reduced by making a 20% reduction in basal insulin to last for 4-6 hours from the time of going to bed.

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