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Continuous subcutaneous insulin infusion (CSII) A clinical guide for adult diabetes services

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The working group includes 4 members who live with Type 1 diabetes managed with insulin pump therapy.

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FOREWORD

I am delighted to welcome the publication of the ABCD Diabetes Technology Network UK Insulin Pump Best Practice Guide. Insulin pump use in Type 1 diabetes is associated with improved quality of life and glycaemic control in addition to reductions in hypoglycaemia and is a fundamental part of the Type 1 diabetes care paradigm. NICE provides clear guidance on the use of insulin pumps and following the publication of NICE TA 151 in 2008 the uptake of insulin pumps in the UK improved.

However more recently this uptake has plateaued and we need to ensure we-as a nation- do not fall behind others as well as enable access to appropriate technology where warranted. The National Diabetes Insulin Pump Audit demonstrates lower HbA1c levels in insulin pump users vs non users; 20% more people with Type 1 diabetes on an insulin pump achieve an HBA1c < 58 mmol/mol (7.5%). Unfortunately in the UK there is too much variability in the provision of pump therapy, with some geographical locations with an uptake of >30% of their Type 1 diabetes population and some at <5%. This variation needs to be addressed if we are to improve outcomes in Type 1 diabetes and this publication will support that.

A key barrier to accessing insulin pump therapy, identified in the 2012 insulin pump service level audit, was staff training which has continued to be an area of concern. The development of this best practice guide which provides clear direction in a number of areas including pump optimisation, selection of candidates for pump therapy as well as indication for withdrawal will go a long way in equipping diabetes specialist teams with knowledge required to deliver pump services.

Many thanks to the authors of this guide who between them deliver care for over 7000 current insulin pump users in the UK.

Yours sincerely

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OBJECTIVES

This document aims to provide healthcare professionals with UK expert consensus on the best practice for managing and optimising CSII.

Introduction

Continuous subcutaneous insulin infusion (CSII or insulin pump therapy) is a mode of delivering intensive insulin therapy, which usually leads to improved glucose control and reduced hypoglycaemia.

What is CSII?

CSII employs a battery operated, portable, programmable pump to continuously deliver rapid-acting insulin via an infusion set inserted subcutaneously. The basal insulin infusion rate can be varied at least hourly and can be temporarily adjusted upwards or downwards by a fixed percentage. Several different basal rate profiles can be stored for use in different situations. Bolus doses can be given with meals as an immediate bolus, an extended bolus or a combination of the two. Most pumps incorporate bolus calculators which take account of insulin still active from previous boluses to provide advice to the user as to the bolus dose needed. CSII is used as a component of self-management of Type 1 diabetes supported by the Diabetes Specialist Team. This team should at a minimum include a pump-trained consultant diabetologist, diabetes specialist nurse and dietitian. The decision to start insulin pump therapy should be made by the pump multidisciplinary team.

What is the evidence that CSII is effective?

There is good evidence that CSII can reduce both HbA1c and hypoglycaemia frequency when used in place of MDI for intensive insulin therapy (Pickup and Sutton 2008). Additionally, CSII can reduce glycaemic variability and improve aspects of quality of life, particularly in relation to diet and physical activity (REPOSE study group 2017, Hoogma et al. 2006). Recent evidence has demonstrated an association between use of CSII and reduced mortality (Steineck et al. 2015).

A 2008 meta-analysis reported that severe hypoglycaemia was reduced by a ratio of 2.89 in RCTs and 4.34 for before/after studies. The reduction was greatest in those with initial high rates of hypoglycaemia. The mean HbA1c reduction was 0.21% (2.3 mmol/mol) in RCTs and 0.72% (7.9 mmol/mol) in before/after studies. Similarly, the greatest reduction in HbA1c was seen in those with the highest initial HbA1c (Pickup and Sutton 2008).

CSII is recommended by NICE Technology Appraisal 151 (TA151) as a treatment option for people with Type 1 diabetes who meet the clinical criteria specified in the TA and for whom it is clinically appropriate. CSII should be offered where glycaemic control issues persist despite optimised multiple daily injection therapy (MDI) which has been supported by a structured education programme fulfilling the criteria laid out in NICE clinical guideline NG17.

Integrated sensor augmented pump (SAP) therapy systems combine continuous glucose monitoring (CGM) with continuous subcutaneous insulin infusion and are intended to further improve glycaemic control and quality of life for people with Type 1 diabetes. Evidence suggests average HbA1c improvements of approximately 0.5% (5.5 mmol/mol) can be achieved with the addition of CGM to CSII when the CGM component is in use at least 60-70% of the time (Batellino et al. 2012, Bergenstal et al. 2011, Raccah et al. 2009)

There is more limited evidence for reduction in hypoglycaemia frequency with SAP (Choudhary et al. 2013, Ly et al 2013). However NICE clinical guideline NG17 has stressed the importance of alarmed CGM for protecting those with problematic hypoglycaemia. SAP systems which stop insulin delivery when hypoglycaemia occurs, or is predicted to occur, have been shown to significantly reduce the frequency and severity of hypoglycaemia (Choudhary et al. 2016).

Whilst CSII has evident benefits and modern insulin pumps are very safe, structured patient education at initiation of pump therapy in addition to ongoing support and refresher education to enable effective use of CSII are imperative to ensure that glycaemic control is optimised, and that the user is able to identify any failure of pump insulin delivery and take appropriate action to maintain safe glycaemic control.

Access to CSII across the four nations

The effectiveness of CSII is well established. However, CSII uptake in the UK continues to lag behind the USA and other European countries. Below is a summary of uptake in each of the four nations:

SCOTLAND

In Scotland just over 11% of individuals with Type 1 diabetes are on insulin pump therapy. This equates to approximately 35% of under 18s and 9% of over 18s. There is a commitment from Scottish government to ensure appropriate access to technology to improve diabetes care and £10M has been secured over the lifetime of this parliament to increase access to insulin pump therapy and establish continuous glucose monitoring services across Scotland. Challenges remain around timely access to structured education and ensuring staff are skilled in the use of these technologies. The appointment of a national co-ordinator to support clinical teams to upskill in these technologies will help ensure teams have the appropriate skill set to support individuals to manage their diabetes.

NORTHERN IRELAND

In Northern Ireland 10% of adults with Type 1 diabetes are on insulin pump therapy. Barriers to the uptake of insulin pump therapy include the availability of recurrent funding for devices and staff time to support optimal use of pump therapy. Northern Ireland has now established a Diabetes Network inclusive of a Technologies Subgroup to address these challenges.

ENGLAND

The percentage of adults with Type 1 diabetes on pumps in England has increased from 6% in 2012 to 15% in the 2016 National Diabetes Pump audit. However, with only ~40% of centres in England participating in the audit it is possible that this number is an overestimate. While the overall percentage on pumps is higher in England than the other 4 nations, there is huge variation between centres with some providing the technology to <5% while other centres have in excess of 30% on insulin pumps. DTN-UK is actively working with NHS England, NHS Digital and ABCD to investigate and address these variations in care.

WALES

In Wales NICE TA151 applies and therefore funding for insulin pumps should be mandatory. Currently 6% of adults with Type 1 diabetes are on insulin pump therapy but, again, there is great variation in uptake between centres. As part of the Wales Diabetes Delivery Plan the Welsh Government have identified CSII therapy as one of its core priorities to improve the uptake, decrease the inequalities to access and also ensure that services that are delivered are consistent and safe.

A recurrent theme which limits access across all 4 nations is health care professional time and training (White et al. 2014). As such, this guide has been developed with the aim of sharing best practice from across the UK to support those who deliver, or would like to deliver, insulin pump services. A multidisciplinary team of healthcare professionals with a wealth of expertise in insulin pumps, responsible for providing care for over 7000 insulin pump users, have provided input into this guide. It is our hope that by providing clear clinical and service pathways that this document will support staff to deliver safe, effective, high quality insulin pump services.

BEST PRACTICE GUIDE

Indications for CSII

The National Institute for Health and Clinical Care Excellence (NICE) has published clear guidance on the use of continuous subcutaneous insulin infusion for adults with diabetes: **Technology Appraisal Guidance 151:**

1. Continuous subcutaneous insulin infusion (CSII or 'insulin pump') therapy is recommended as a treatment option for adults and children 12 years and older with Type 1 diabetes mellitus provided that:

   Attempts to achieve target haemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia. For the purpose of this guidance, disabling hypoglycaemia is defined as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life

   or

   HbA1c levels have remained high (that is, at 69 mmol/mol (8.5%) or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care.

2. It is recommended that CSII therapy be initiated only by a trained specialist team, which should normally be comprised of a physician with a specialist interest in insulin pump therapy, a diabetes specialist nurse and a dietitian. Specialist teams should provide structured education programmes and advice on diet, lifestyle and exercise appropriate for people using CSII.

3. Following initiation in adults and children 12 years and older, CSII therapy should only be continued if it results in a sustained improvement in glycaemic control, evidenced by a fall in HbA1c levels, or a sustained decrease in the frequency and severity of hypoglycaemic episodes. Appropriate targets for such improvements should be set by the responsible physician, in discussion with the person receiving the treatment or their carer.

4. CSII therapy is not recommended for the treatment of people with Type 2 diabetes mellitus, at present.

High level of care, as described in NICE TA151 includes:

- A high degree of motivation, commitment and competence;
- Estimating CHO consumption throughout every day
- Delivering multiple daily injections of insulin
- Regular glucose self-monitoring (≥4 times /per day)

NICE also recommends insulin pump therapy for use in pregnancy (NG3) and in the management of diabetic gastroparesis (NG17) (Sharma et al. 2011).

Other indications

Other indications for pump therapy, with anecdotal evidence of benefit are:

- Diabetic neuropathy, painful peripheral and autonomic with orthostatic hypotension (Boulton et al. 1982)
- Insulin allergy (Pratt E et al. 2001)
- Needle phobia
- Type 2 diabetes with high insulin requirements who are not achieving optimal glucose control despite insulin doses titrated to over 1.0 units / kg (Aronson et al. 2014)

Advantages and disadvantages of CSII

When offering CSII therapy it is important that consideration is given to the advantages and disadvantages as highlighted in table 1 (adapted from Hussain & Oliver: Insulin Pumps and Continuous Glucose Monitoring Made Easy, 1e, 2016, Elsevier Ltd)

✔ 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

Complications of CSII

User feedback on CSII has revealed some useful insights. In a survey of 92 insulin pump users with median duration of 3.3 years of CSII the following complications were described (Pickup at al. 2014)

- Infusion set kinking 64%, 12% frequent*
- Infusion set blockage 54%, 10% frequent*
- Lipohypertrophy 26%
- Site infection 17%
- 48% reported any pump malfunction, with 26% reporting a pump stop/no delivery

*frequent = > 5/year or > 10 for duration of CSII (median 3.3 years)

Any pump malfunction which results in hyperglycaemia carries a risk of metabolic decompensation. The pump only contains rapid acting insulin and if delivery is interrupted for any reason, hyperglycaemia will result. If this is not detected and acted on appropriately then ketosis progressing to DKA will result.

Pump failure rates of 16-17 per 100 patient years have been reported, with just under 10% resulting in hospital admission due to metabolic decompensation (Ross et al 2016). Accidental damage to pumps accounted for just under 30% of pump failures. The median pump 'life expectancy' is just under 3 years (Rabbone et al 2017). An ADA/EASD diabetes technology working group have made a statement on the safety of insulin pump therapy with recommendations for increasing safety (Heinemann et al 2015).

Reasons for CSII discontinuation

In the T1D Exchange registry 3% of pump users discontinued CSII within a year (Wong et al 2017). The reasons for discontinuation were:

- Problems with insertion/adhesive 60%
- Pump interfered with sports activities 42%
- Pump uncomfortable to wear 38%
- Pump interfered with intimacy 34%
- Problems with pump working properly 28%
- Problems with high blood glucose levels when using pump 28%

Data from a large UK pump service suggested that pump therapy was discontinued in 5% of users either due to lack of clinical benefit, technical issues, safety concerns or user choice (Beato-Vibora et al 2015).

STARTING PUMP THERAPY

Selection for CSII

To achieve optimal use of CSII, people with diabetes should be assessed for their suitability via a structured process involving the MDT. The following characteristics should be considered as part of this assessment:

1. **Education, understanding and implementation of the principles of intensive insulin therapy (carbohydrate counting, pre-meal injections, MDI ≥ 3 injections / day, ≥ 4 glucose measurements / day [SMBG or flash / continuous glucose monitoring])**

2. **Motivation to pursue CSII therapy and improve diabetes control**

3. **Engagement with diabetes services**

4. **Realistic expectations of CSII and clearly agreed individual expectations and targets**

5. **Absence of psychological factors that may impair safe CSII use (e.g., psychosis, severe anxiety, or severe depression). However, some psychological issues such as depression due to disease burden from hypoglycaemia or poor control may actually respond well to CSII and there is evidence that CSII can be safely used in this patient cohort (Rodrigues et al 2005)**

6. **Cognitive, visual and physical impairments may require a care partner to be co-trained in pump therapy, and should ideally be managed at more experienced centres, but should not be a contraindication to pump therapy.**

The MDT should continue to support people with diabetes who are unable to proceed with pump therapy in other ways e.g. through education, improved engagement or optimisation of their diabetes treatment to achieve targets or become candidates for CSII in the future.

Pump initiation pathway (Figure 1)

Type 1 diabetes teams should be encouraged to discuss the option of CSII with all people with diabetes who meet the NICE criteria for CSII. If CSII is an option the individual would like to pursue, the following pump therapy pathway describes the steps towards approval and initiation (Figure1) undertaken by the CSII MDT.

MDT assessment

The decision to initiate insulin pump therapy should only be made following agreement between the multidisciplinary insulin pump team and person with diabetes or their carer. The person with diabetes should have the opportunity to meet with the CSII trained diabetes educators to discuss the pros and cons of CSII and review the choice of available CSII devices used within the service so they are able to make an informed decision about which model best meets their needs. Teams should be reassured that in clinical practice, the model of pump is unlikely to impact on clinical outcomes so personal user choice is paramount (Leelarathna et al. 2017).

The team should agree with the user what the goals of therapy are (e.g. reduction in HbA1c and/or hypoglycaemia). These should be clearly documented in the notes.

Saline starts?

It is important to ensure there is adequate pre-pump education prior to initiating pump therapy. Saline starts are not routine practice in all adult centres. However, some teams may prefer insulin pump saline starts to allow individuals to familiarise themselves with the workings of the pump before starting to infuse insulin.

CSII Initiation

As far as possible, insulin pump therapy should be commenced at the start of the week. This is to ensure that the user has access to clinical support for the rest of the week. The diabetes team needs to ensure availability to respond quickly if contacted within the two week period following initiation.

We recommend:

1. CSII is commenced ideally in groups of 2-5 to maximize resources safely.
2. At the point of CSII initiation the team should record diabetes distress scale, hypoglycaemia awareness (Gold or Clarke) questionnaire and HbA1c to facilitate the longitudinal assessment of objective outcomes of pump therapy.
3. Users should be advised of the need to monitor glucose levels at least 4/day and keep in daily email or telephone contact with the team for the duration of the week.

Insulin pump assessment guideline

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.

YES TO ALL

***NO TO ANY**

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

Who should be present at CSII initiation

Individual teams should have skills and knowledge to undertake CSII initiation independently. Initiation is usually led by a specialist nurse or dietitian within the CSII team. The 2012 national insulin pump audit identified that CSII teams often relied on technology companies for CSII initiation and ongoing support. As teams become more confident with CSII, this reliance should reduce over time. Technology personnel should be experienced in both insulin pump initiation and optimisation. It is important that the team are comfortable and skilled in the products they are using and while this may on occasion lead to reduced choice of pumps available within a service, safety of the insulin pump user must be paramount. An insulin pump service should only offer a range of pumps which they feel their team are able to safely support.

Users may wish to have family or friends present at CSII initiation. This should be facilitated if possible to provide the individual with additional support.

Reviews after CSII initiation

Ideally the 1st year of pump initiation should include:

- Week 1 pump therapy – daily telephone or email contact with specialist team member
- Week 2 pump therapy – twice weekly telephone and/or email contact with specialist team member
- Week 4-5 pump therapy – face to face appointment with specialist team member for review and education. Pump downloads used to assess pump use, glucose levels, basal and bolus insulin requirements, alarm history and pump settings.
- Thereafter pump users are encouraged to have telephone or email contact with the diabetes specialist team as required by individual for clinical support.
- Appointments in consultant led pump clinic MDT as follows in the 1st year of pump therapy initiation:
  - 3 months after initiation of pump therapy
  - 6 months after initiation of pump therapy
  - 12 months after initiation of pump therapy

Factors for success on CSII

To achieve the best possible outcome on CSII, the expert group identified the following factors which should be discussed with the person with diabetes to have realistic expectations of the actions required to achieve their therapeutic goals:

- Regular glucose monitoring (≥4 /day)
- Use of the bolus calculator to calculate insulin doses
- Bolus doses for all carbohydrates intake
- Regular set changes every 2-3 days, ideally early in the day
- Use of advanced features: temporary basal rates and dual wave boluses
- Regular clinic attendance
- Regular downloads and review of data

(Scheiner et al. 2009, Wilkinson et al. 2010, Cukierman-Yaffe et al. 2011)

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).

Calculations for Insulin Pump Settings		
Pump TDD calculation		
Method 1 Pre-pump TDD Pre-pump TDD × 0.75		Method 2 Patient weight Weight: kg × 0.5
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		
Pump dose adjustment		
Basal Rate (Pump TDD × 0.5)/24 h	Carbohydrate Ratio (I:C) ratio 400/TDD	Insulin Sensitivity Factor (ISF) 130/TDD
• Start with one basal rate, adjust according to glucose values over basal rate testing • Add additional basal according to need (e.g. Dawn phenomenon)	• 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	• Correction insulin dose should bring glucose back to target range in 4-5 hours

Basal insulin

The basal rate is the amount of insulin infused per hour via CSII. The basal rate can be set hour by hour, facilitating flexible basal insulin delivery. The aim of the basal rate is to keep the glucose profile steady in the fasting state, with the aim of mimicking physiological requirements. It is important to recognise that basal requirements can vary significantly within the same person day-on-day, based on activity levels, illness and stress, and potentially changes in absorption from the insulin cannula (Ruan et al, 2016).

The basal insulin on the pump should be roughly 30-50% of the total daily dose, dependent on carbohydrate intake. Those with a high carbohydrate diet typically have a lower proportion of the total daily dose as basal insulin; those with a low carbohydrate diet have a greater proportion of their total daily dose as basal insulin.

The basal insulin can be adjusted to meet individual insulin requirements throughout the day.

Anticipated basal % of the total daily insulin dose:

- Basal 40-50% when:
  - carbohydrate intake 100 - 200g/day
- Basal < 30% when:
  - high carbohydrate intake (> 200 g/day)
  - > 10 micro-boluses/day
- Basal > 50% when:
  - low carbohydrate intake
  - inadequate bolus insulin
  - using predictive suspend in some cases
  - insulin resistant (TDD > 0.7u/kg)

Basal rate patterns

A range of basal profiles have been advocated for insulin pump initiation:

- Flat basal profile (50% of TDD over 24 hours)
- Modified basal profile (4-6 basal profiles) (Figure 2 and Table 2)
- Circadian Profile (Renner Scale, Wizemann et al. 2001)

Ultimately any initial basal profile is a starting point which will be adjusted over time in response to review of the glycaemic profile. Some experts have been advocating 'circadian rhythm' basal rate profiles which involve initiating users on a variable basal rate instead of a flat profile. However, the majority of the data underpinning circadian rhythm basal rates is from paediatric practice (Bachran et al. 2012) and it is not clear whether starting with a 'circadian rhythm' is superior to starting with a flat basal rate. Indeed, there is some evidence to suggest that high variability in the basal rate is associated with hypoglycaemia and ketoacidosis (Laimer et al. 2017). The best practice working group preferred a flat basal or modified basal rate over the circadian profile as the initial basal rate profile of choice. Regardless of the initial approach, the user must test and retest their basal rates to optimise control.

Overall, many users tend to require an increase in the basal rate early in the morning, to counteract the 'dawn-phenomenon', and lower rates between mid-morning and mid-afternoon. Some users also require an increase in basal insulin in the evening, the 'dusk-phenomenon', which may be related to a reduction in physical activity later in the day. If fixed periods of activity occur at the same time every day, such as walking or cycling to and from work, these can be accommodated for in the basal rate with reductions ~60-90 minutes prior to the activity. A variety of basal rate patterns can be stored for different patterns (e.g. shift work, menstrual cycle etc.). Blood insulin levels settle into a steady state approximately 2-3 hours after a basal rate change, so it is desirable to change the basal rate in blocks of hours. Most users will require multiple basal rates, usually several though the day (Chico et al. 2014). There is evidence that those with 3-6 basal rates have better outcomes.
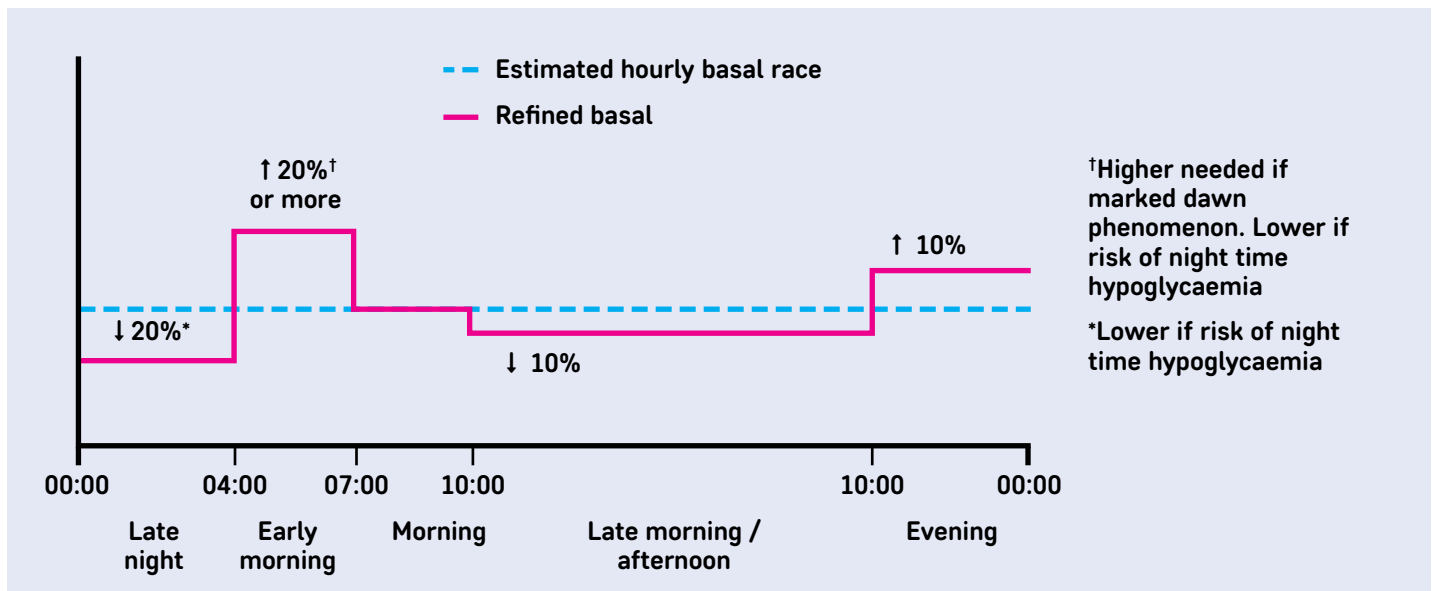

**Figure 2. Modified Basal Rate Profile
(Adapted from Hussain & Oliver: Insulin Pumps and Continuous Glucose Monitoring Made Easy, 1e, 2016, Elsevier Ltd)**

Table 2. King's Modified Basal Circadian Profile

Time of day	Basel rate
Midnight to 3 hours before waking	80-100% of calculated units/hours
3 hours before waking to waking up	100%-120% of calculated units/hours
Waking up to lunch	80-100% of calculated units/hours
Lunch to evening meal	80-100% of calculated units/hours
Evening meal to bedtime	100%-120% of calculated units/hours

Basal rate optimisation

Basal insulin requirements can vary from day to day in Type 1 diabetes. However, it can be useful to ensure that CSII basal rates are close to the individual's physiological requirements. To achieve this, basal rate assessment should be performed on a 'normal' day for the individual when there are no preceding external or internal factors which will change usual insulin requirements, such as stress, illness, exercise, hypoglycaemia, alcohol intake, menstruation or sleep deprivation. It can be challenging to perform basal rate testing, and some may find this easier using CGM or flash glucose monitoring to gain more detailed insight into glucose patterns.

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.

If the basal insulin is appropriate for that individual, then the glucose should not increase or decrease by more than 1.5 mmol/l in the fasting state. If it does, then the basal insulin should be increased or decreased as necessary 2 hours before the fluctuation in glucose values is identified. Once changes have been made, basal rate testing can be repeated to ensure the new basal insulin pattern is appropriate.

Temporary basal rates

Temporary basal rates allow users the option of changing the basal insulin delivery for a fixed period of time. It should be noted that following a change in basal insulin it can take anything from 2-6 hours for the insulin to reach steady state, therefore temporary basal rates are generally recommended if a longer term (hours) change in insulin delivery is required (McAulay et al 2017), although can be useful for exercise provided the change is made early enough. The change in basal insulin delivery should be made 1-2 hours before the desired change in blood glucose.

Indications for temporary basal rate increase:

- Illness
- Stress
- Pre-menstruation
- Reduced physical activity

Indications for temporary basal rate decrease:

- Increased physical activity
- Following alcohol

Bolus insulin

Insulin timing

Rapid-acting insulin (Novorapid, Humalog, Apidra) bolus doses for meals should be administered 15-20 minutes before eating as this is associated with a lower postprandial glucose excursion (Cobry et al 2010). The faster acting insulin analogue, Fiasp, is licensed for administration immediately pre or up to 20 minutes post meal (Slattery et al 2018).

Insulin:carbohydrate ratio (ICR)

A number of centres have traditionally used the 500/100 rules to guide insulin dosing on pump therapy (Davidson et al, 2003). Following the publication of more recent data from King et al (King et al. 2016), there is a suggestion that more aggressive bolus doses and less aggressive corrections may be beneficial. The below recommendations are the consensus of a group of UK clinicians working with people with diabetes who use CSII. It should be noted that calculated ICR and insulin sensitivity factor (ISF) are a starting point which may require adjustment following review of downloaded insulin pump data.

Accurate carbohydrate estimation is a limiting factor in achieving excellent diabetes control. Although CSII does not remove the potential for human error in this calculation, it does allow for accurate insulin to carbohydrate ratios, to the nearest gram of carbohydrate. However, despite this, many CSII users continue to input rounded carbohydrate amounts (e.g. 10g vs 12g) and also use inaccurate and rounded ratios such as 1unit:10g CHO or 1unit:15g CHO (Walsh et al. 2010). This practice reflects previous approaches utilised for manual calculations whilst on MDI therapy and, possibly, the preference of the health care provider. However, such an approach prevents the delivery of accurate insulin therapy which has implications for short and long term glycaemic control. For instance, changing the ratio from 1unit:10g to 1unit:9g lowers the post-prandial glucose by 1.8-2.9 mmol/l at each meal for an average individual consuming 60-100g of carbohydrate (Walsh et al, 2010).

The consensus of the group was to routinely start with 400/TDD (Figure 3). Some people may need more aggressive boluses, especially at breakfast with ratios of of up to 300/TDD.

To calculate the ICR, 400 is divided by the total daily insulin dose to provide an indication of how many grams of carbohydrate 1 unit of insulin will cover (see example). Some users may require different ICR and ISF for different times in the day dependent on factors such as individual diurnal variation and activity levels.

The calculated ICR and ISF are useful when troubleshooting potential causes of hypoglycaemia and hyperglycaemia. If hyperglycaemia is persistent once other factors have been excluded, then the TDD can be increased by 5-10% and the ratios re-calculated.

Insulin sensitivity factor (ISF)

The ISF, or correction factor, is a guide to the reduction in blood glucose, in mmol/l, which can be expected when giving 1 unit of insulin. It is important to get this ratio correct as users will rely on this to reduce unexpectedly high blood glucose values. Those previously on MDI will have been used to crude corrections of 1 unit:2-3 mmol/l which would often have prevented them from correcting glucose values <10 mmol/l, due to a fear of hypoglycaemia. However, CSII allows for the delivery of correction doses to the nearest 0.1 unit of insulin which, combined with the reduced variation in the absorption of insulin allows for accurate corrections of near normal glucose values without the fear of hypoglycaemia.

There are a number of 'rules' in the literature, none of which have been compared head to head. The most widely used is the 100 rule [ISF = 100/TDD], although many now advocate a more gentle correction of 120-130/TDD. The consensus of the group was to routinely start with the 130 rule [ISF = 130/TDD] (Figure 3). To achieve the optimal ISF 130 is divided by the TDD to provide an estimate of how much 1 unit of insulin will reduce the blood glucose by in mmol/l.

It should be remembered that the ICR and ISF rules are not absolute and should be used as rough starting points which should be adjusted based on subsequent glucose readings. Any adjustments to ICR and ISF need to be tested and revised accordingly. The ISF should bring the glucose into target after 4-5 hours. Ideally the ISF should be tested when the last bolus was more than 5 hours ago, carbohydrate was consumed more than 3 hours ago and the user can wait 4-5 hours until they next eat.

Target ranges

Choosing an appropriate glucose target range when using CSII is of paramount importance. Some devices correct to the higher figures in the target range (e.g. Medtronic), others correct to the mid range (e.g. Roche), whilst others have a single target glucose value but define a threshold glucose above which a correction bolus will be calculated (e.g. Omnipod). To overcome this, the expert group would advise an individualized narrow target range of +/- 1mmol/l (e.g. 4.5-5.5mmol/l target range, or target glucose of 5.0 mmol/l) for all pumps to minimise the risk of user error.

Targets should be individualised to a level the user is comfortable with. For instance, those with a high HbA1c may need an initially higher target range as they may experience hypoglycaemia symptoms at normoglycaemic glucose values, until they get accustomed to lower glucose values than they have been used to.

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**

*   For TDD <30 units per day consider reduced insulin active time

*   Consider longer active insulin time in renal failure (GFR<45), or bolus size>10 or TDD>60

** Targets need to be individually tailored. For HbA1c >86 mmol/mol (10%) consider a BG target 9-10 with the plan to reduce target every month by 1 mmol/l to create a gradual fall in HbA1c. This is particularly important that those with retinopathy. Different pump bolus advisors calculate correction targets differently, the reason to suggesting single value or a narrow range (4.5-5.5mmol/l) is that it overcomes issues with this.

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

Example: calculating the desired insulin

John has a total daily insulin dose of 36 units.
Using the '400 rule' to calculate ICR
Insulin:CHO ratio = 400/TDD = 400/36 = 11.1 = 1 unit:11g CHO
Using the '130 rule' to calculate ISF
ISF= 130/TDD = 130/36 = 3.6 = 1 unit reduces glucose by 3.6 mmol/l

John is going to eat a sandwich which contains 46g of carbohydrate. His target glucose is 5 mmol/l. His glucose before lunch is 11.8 mmol/l. How much insulin should he administer?
ICF 1unit:11g, so for sandwich needs 46g / 11 = 4.2 units
**ISF 1unit:3.6 mmol/l so to correct from 11.8 to 5 mmol/l: 11.8 - 5mmol/l = 6.8mmol/l /3.6 = 1.9 unit**
Total bolus insulin dose required = 4.2 + 1.9 = 6.1 units

Such calculations are complex. It is important that users are encouraged to use their bolus calculator to facilitate accurate insulin delivery. An accurate insulin bolus should bring the glucose close to target 4-5 hours after administration. If this is not the case, the ratios will need to be reassessed and altered as necessary.

While these rules may not work perfectly for every person with diabetes, they are good starting point and encourage thinking beyond simple rounded ratios e.g. 1unit:10g. Modern pumps have integrated bolus calculators, allowing the user to programme their ratios, saving them from performing complex arithmetic at mealtimes. In consultation with CSII users it is worth ensuring that they are using the bolus calculator and that the settings are appropriate and up to date. Pump users often report mistrust of the bolus calculator settings as a reason for not using it, so they should be made aware that this is an indication for adjusting the settings, in conjunction with a member of the diabetes team if needed, not rejecting the calculator function. An adequate insulin:CHO ratio should control the post-prandial glucose. A rise of 2-4mmol/l at 2 hours would be considered reasonable except in pregnancy when a lower increment would be desirable.

Advanced bolus features

Insulin pumps have the ability to deliver a bolus of insulin in a variety of options (see below):

Three Types of Bolus Insulin
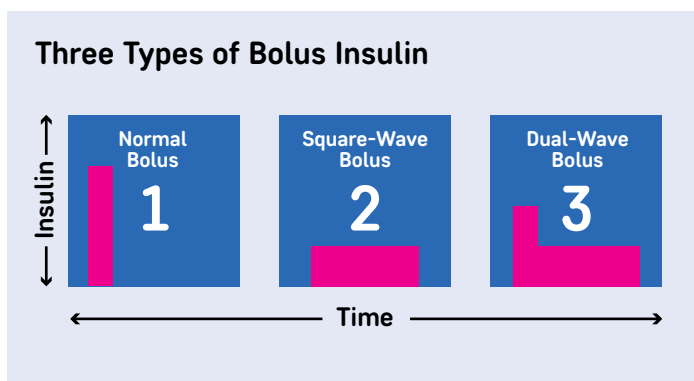
- A square wave or extended bolus delivers insulin over a fixed extended period
- A dual or combination bolus delivers a percentage of the insulin as a normal bolus and the remainder over a fixed period.

The aim of these advanced bolus options is to better match insulin delivery to dietary intake and minimise the post prandial glucose excursion. These advanced features can be added to therapy once the user is established on their CSII therapy. Audit data and other surveys suggest that few people use these features routinely (Groat et al, 2017).

Meals high in fat and/or protein can be associated with prolonged raised glucose values, particularly overnight, leading to morning hyperglycaemia. Common examples of these meals might include Indian or Asian cuisine, pizza, cheese with pasta or fish and chips. However considerable inter-individual differences exist in the impact of fat, protein and GI index of carbohydrates on postprandial glucose levels, making it very difficult to come up with uniform algorithms for dose advice. Based on published literature, we recommend that for high protein and high fat meals (>40 g fat, >25 g protein), individuals with Type 1 diabetes should initially consider increasing the insulin dose calculated from their ICR by 25%–30% and using a dual wave (combination) bolus with 50%–70% given initially and the remainder over 2–6 hours depending on the individual's experience (Bell et al. 2015, Bell et al. 2016, Lopez et al. 2017). If the review of glucose profiles shows late (>3 h) hyperglycemia or early hypoglycaemia, then for subsequent meals of similar composition the insulin delivered in the immediate and extended period should be adjusted.

Guide to download interpretation

All CSII centres should routinely download insulin pumps and interrogate the data obtained. We recommend review of the download as an essential part of the consultation with the person with diabetes. Users should also be encouraged to review their data prior to clinic attendance. Pumps can be downloaded using proprietary software such as Medtronic Carelink, Roche 360, or general software such as Diasend/Glooko. Most clinicians will develop their own preference for the order in which they review these aspects, but ultimately all aspects should be covered. The following should be considered when reviewing an insulin pump download:

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.

CSII AND SPECIFIC SCENARIOS

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

Insulin pump users should be encouraged to explore the reasons why the high glucose has occurred (see table 5) (Ponder et al. 2008).

All CSII users should be advised to perform set changes early in the day, not in the evening.

Insulin pump therapy users must carry, or have access to, an alternative means of insulin delivery (pens or syringe). They should also have access to long acting insulin and know the dose to take in the event of pump failure.

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.

Table 5 Causes of unexplained hyperglycaemia

Possible causes of unexplained hyperglycaemia		
Infusion Set	Insulin Pump	Insulin
• Is the tubing primed or filled with insulin? • Is there air in the tubing? • Did you remember to fill the cannula with insulin after inserting new set? • Is the tubing connected to the cartridge? • Is the set connected to your body? • Are there any leaks? • Is the cannula dislodged or kinked? • Has the infusion set been in longer than 2-3 days? • Is there redness or discomfort at the site? • Is there blood on/at the site?	• Did you forget your last bolus? • Have you received any recent alarms? • Is your cartridge empty? • Is the date and time correct? • Are your basal rates programmed correctly?	• Is your insulin expired/inactive? • Has your insulin been exposed to extreme temperatures? • How long has the insulin been in the cartridge and tubing?

Sick day rules

Insulin pump therapy users should be provided with sick day rules and access to in date blood ketone monitoring. They should be advised to check for ketones if they feel unwell. Figure 5 details sick day rules for pump therapy.

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.
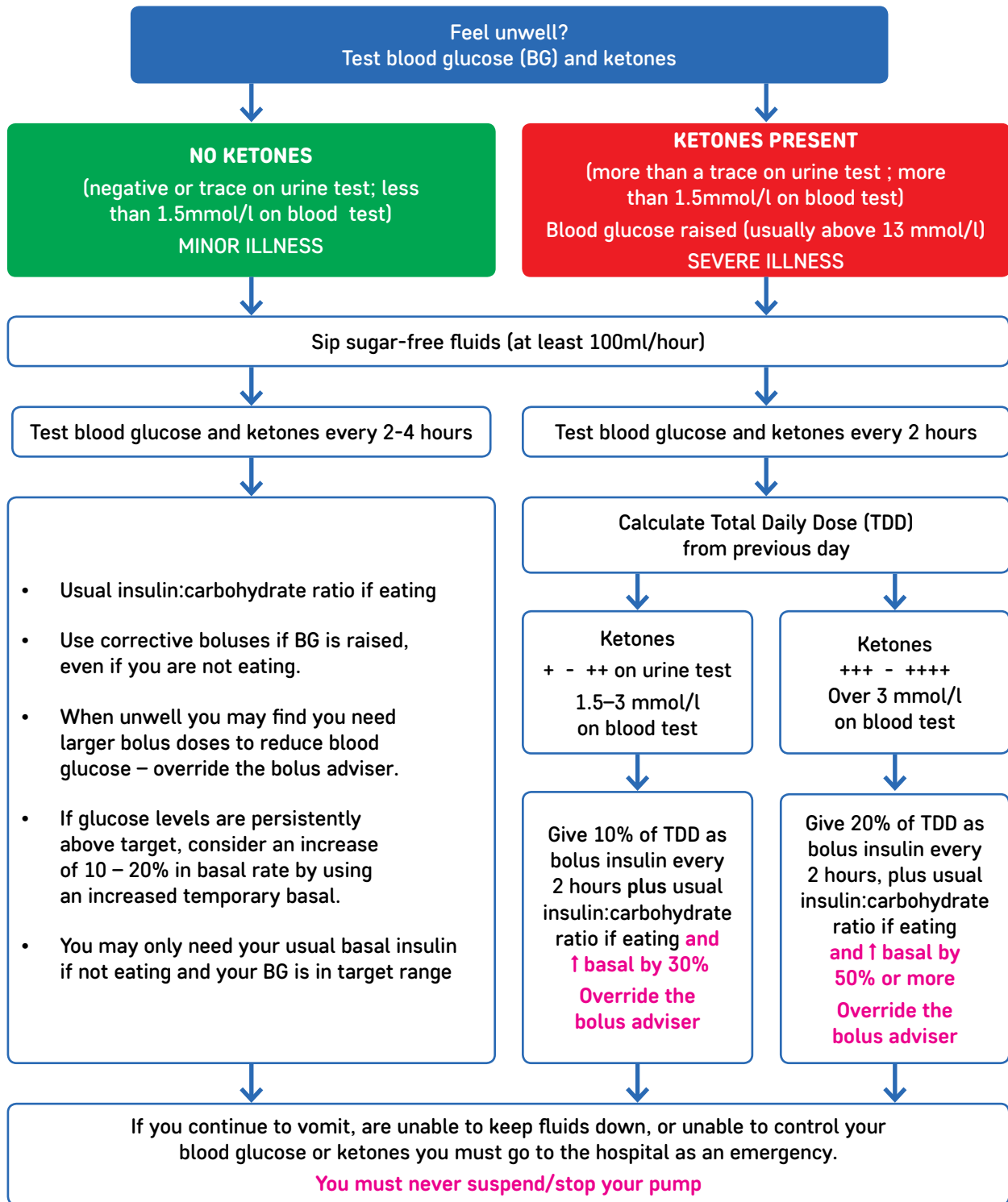**You must never suspend/stop your pump**

Figure 5: Pump sick day rules (copyright DAFNE UK)

Problematic hypoglycaemia

Disabling hypoglycaemia is defined as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life.

All people with Type 1 diabetes should have annual screening for impaired awareness of hypoglycemia with validated tools such as

- Gold score
- Clarke Score

These tools show consistency between them and identify those with increased risk of severe hypoglycaemia events (SHE). On a meter download, if there are >10% of readings < 4 mmol/l, or >3 readings <3 mmol/l per week, this may also be considered as increased frequency of hypoglycaemia that may identify those at increased risk of SHE.

The International Hypoglycaemia Study Group (IHSG, 2017) have recently recommended that blood or sensor glucose readings <3.0 mmol/l should be considered as serious, clinically important hypoglycaemia. Problematic hypoglycemia should be considered as frequent readings below this level (> 2/week).

CSII should result in improvements in hypoglycaemia. If it does not, then next steps need to be considered which include sensor augmented pump therapy (SAP) and islet cell transplantation (see figure 5). The MDT should consider whether the individual meets the NICE guidance (NG17, DG21) for sensor augmented pump therapy in the first instance.

Sensor Augmented Pump Therapy NICE DG21

NICE recommendations:

- The MiniMed Paradigm Veo system is recommended as an option for monitoring blood glucose levels in people with Type 1 diabetes who:
  - have repeated and unpredictable episodes of disabling hypoglycaemia despite optimal management with continuous subcutaneous insulin infusion or
  - feel ongoing anxiety about these episodes happening again.

The Medtronic Paradigm Veo system has been superseded by the Medtronic 640G system with Predictive Low Glucose Management and now has evidence demonstrating reduction in hypoglycaemia frequency (Choudhary et al. 2016).

If the team has little experience in managing problematic hypoglycaemia and the use of sensor augmented pump therapy, then consider referral onto a specialist hypoglycaemia 'hub' centre. Similarly, if the user has a trial of SAP with no improvement, they should be referred to a dedicated hypoglycaemia service for review and consideration for islet cell transplantation and/or pancreas transplant (figure 6).
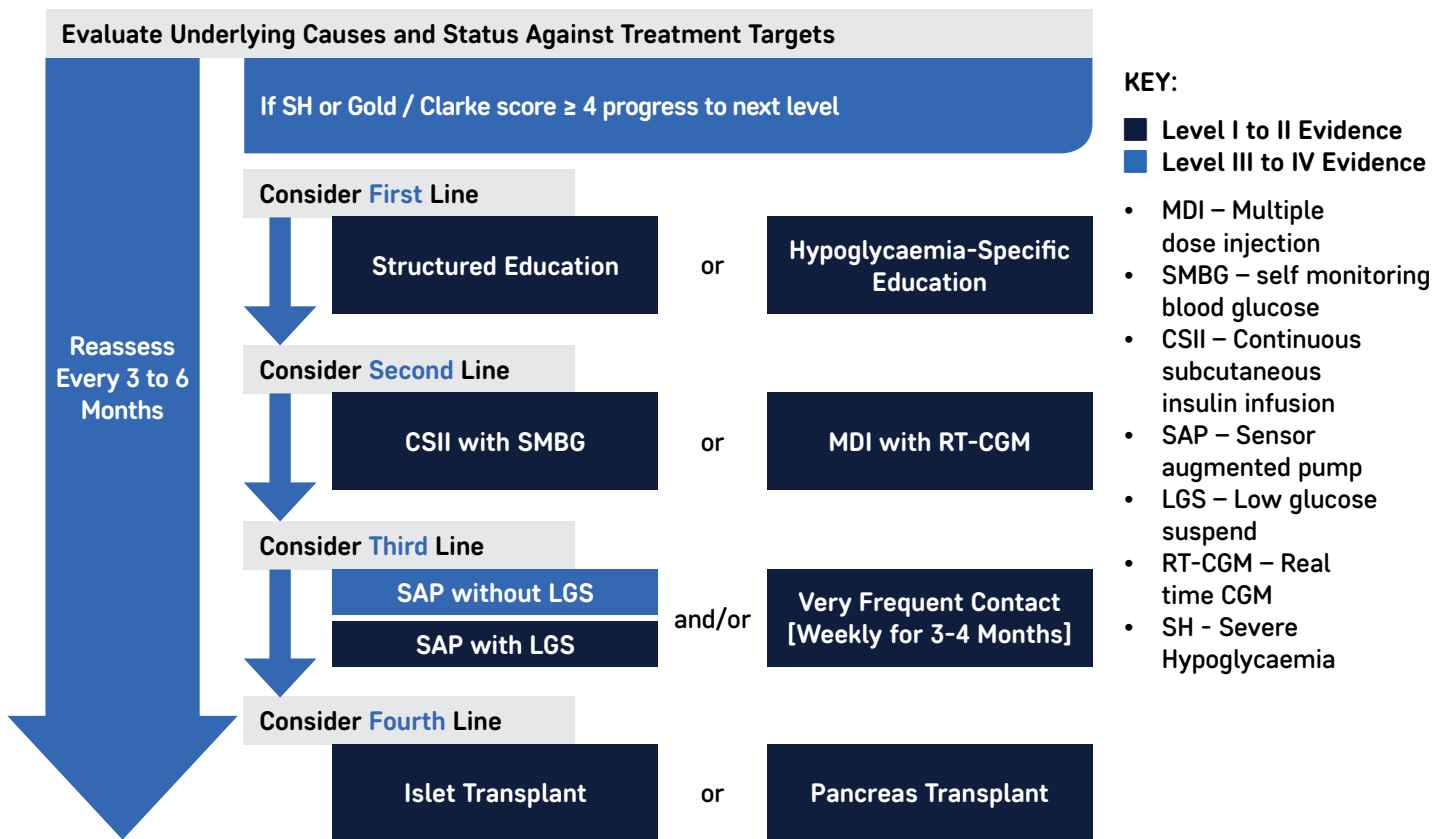
Evaluate Underlying Causes and Status Against Treatment Targets

Reassess Every 3 to 6 Months

If SH or Gold / Clarke score ≥ 4 progress to next level

Consider First Line

| Structured Education | or | Hypoglycaemia-Specific Education |

Consider Second Line

| CSII with SMBG | or | MDI with RT-CGM |

Consider Third Line

| SAP without LGS | | |
| SAP with LGS | and/or | Very Frequent Contact [Weekly for 3-4 Months] |

Consider Fourth Line

| Islet Transplant | or | Pancreas Transplant |

KEY:

- ■ Level I to II Evidence
- ■ Level III to IV Evidence

- MDI – Multiple dose injection
- SMBG – self monitoring blood glucose
- CSII – Continuous subcutaneous insulin infusion
- SAP – Sensor augmented pump
- LGS – Low glucose suspend
- RT-CGM – Real time CGM
- SH - Severe Hypoglycaemia

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

Insulin pump renewal

Prior to CSII renewals there should be documented evidence of ongoing clinical benefit as demonstrated over the previous 4 years.

Most centres routinely replace insulin pumps when the warranty expires. Advantages include access to holiday 'loan' pumps and reassurance that the company will quickly replace the pump in the event of a fault.

Some centres may choose not to routinely replace insulin pumps when the warranty expires. While this reduces costs, there is a potential risk of pump failure beyond the warranty period and as such there is a need, in this situation, to ensure the local hospital can supply an emergency pump in the event of pump failure. The decision on policy for 'out of warranty pumps' should be decided at a local Trust level and clearly communicated to people with diabetes.

The point of pump renewal is an important time to review and assess the benefit of pump therapy over the 4 years to ensure that the aims of pump therapy have been achieved.

Discontinuation of insulin pump therapy

In some circumstances the MDT may feel it is appropriate to consider discontinuation of insulin pump therapy: either when insulin pump therapy is not safe or there is an absence of clinical benefit. In some cases, such as the absence of adequate glucose testing, this can be a temporary discontinuation until the user is safe to use insulin pump therapy again.

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

If pump therapy is withdrawn due to safety concerns, this should be done in a supportive way, with a plan to provide educational and psychological support to be able to move towards being able to restore pump therapy again if appropriate. This should be done with MDT input.

Transition

The principles of best practice for transition of care from paediatric care to adult services (NG18; NICE QS125) should apply to adolescents with Type 1 diabetes on insulin pumps. There are typically a higher proportion of the paediatric population using insulin pump therapy than in adult services (28% paediatric vs 15% adults with T1DM using pumps in the 2016 national audit) because the NICE criteria allow access to pump therapy for a greater breadth of indications for those with T1DM aged 11 and under. These pump users will be transitioning into adult services in the years to come. It is imperative that the adult team looking after young adults have both the skills and capacity to continue to support young people using insulin pump therapy. Paediatric and adult services should liaise to ensure that the insulin pump equipment used is familiar to both teams.

Paediatric best practice tariff allows a minimum follow-up of 3 monthly consultant led MDT clinic appointments plus telephone contacts, significantly more than that typically available in adult services. Young adult services need to be aware of this and attempt to maintain contact and reinforce contact points and safe pump use. There is the potential for adolescent pump users to miss out on the benefits of transition diabetes services because they are transferred from paediatric to adult pump service. Ideally these adolescent pump users should be seen in both a transition clinic and pump clinic, but if this is not an option follow up in a transition clinic with pump specialist input should be the default arrangement.

NICE guidance states that children initiated on insulin pump therapy should expect a trial of MDI between the ages of 12 and 18. In practice this is not a policy supported by UK practice. However, it is important to recognise that often pump education has been directed at parents rather than children, and so as the adolescent pump user becomes more autonomous in managing their diabetes they may not have the education, and hence skills to optimise pump therapy. Transition services should make sure that adolescent pump users are offered appropriate education to develop the necessary skills for optimal usage of CSII and should allow adolescent pump users a pump holiday where they can try MDI without perceiving this as a failure on their part.

It is good practice for paediatric teams, who already have a relationship with the young person with diabetes and family, to discuss about possible future pump holidays/ trials of MDI prior to transition rather than leaving these potentially difficult conversations to the new adult team.

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.

Considerations when exercising using an insulin pump:

- Not all pumps are waterproof – some may need to be removed for swimming or other watersports
- It may not be possible to wear an insulin pump for some contact sports
- Activity can increase the risk of cannula displacement, so careful monitoring of glucose (and ketones) is advised
- Any heated room, or exercising in warm weather may accelerate insulin absorption and/or magnify the effect of the infusion rate for any given pump setting

Exercising when pump is removed or basal insulin suspended

A time limit of 2 hours is recommended for the suspension of basal insulin infusion and/or the removal of the insulin pump. Should the activity last longer than this one option is to re-connect the pump hourly and administer a bolus of 20-50% of the basal insulin which would have been given during that hour. Where this is not practical (e.g. for some watersports), and especially where the removal is likely to last for a longer period, an alternative is to remove the insulin pump for 6-12 hours and administer basal insulin using a single dose of NPH insulin or Levemir. The required dose will depend on the nature of the activity and individual glucose responses but a starting point would be 50% of the missed basal insulin.

Signposting

Longstanding pump users can provide a useful 'buddying' service to those starting insulin pump therapy. Several centres have pioneered this.

Those keen to find out more about insulin pump therapy can be pointed towards the following resources and support networks:

- INPUT Patient Advocacy www.inputdiabetes.org.uk
- Twitter #GBDOC
- JDRF www.jdrf.org.uk
- Diabetes UK www.diabetes.org.uk
- Type 1 resources www.t1resources.co.uk
- Insulin Pumps Wales www.insulinpumpswales.org.uk

Conclusion

In summary, insulin pump therapy is an effective self-management tool for people living with Type 1 diabetes. Insulin pump use is associated with improvements in glucose control, hypoglycaemia and quality of life. The uptake of insulin pumps across the UK has demonstrated unacceptable variation which must be addressed. It is the hope of the authors of this guide that by providing consensus on UK Best Practice that health care professionals will feel more confident to deliver and promote CSII therapy for those living with diabetes.

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APPENDIX 1

Basal rate testing protocol:

Basal rates should be tested where there is an indication that the rates are running too high, too low or to confirm a dawn phenomenon.

Basal rates can be tested at any of the four time blocks:

- Overnight
- Morning
- Afternoon
- Evening

When carrying out basal testing the user should bolus normally prior to the testing period, avoiding unusual meals or exercise, eliminating any snacks. For example if testing during the afternoon period the user would have breakfast with their normal bolus and then fast avoiding snacks and corrections. For 4 hours after breakfast blood glucose measurements should be taken 2 hourly during the day, unless using a glucose sensor or flash monitoring which provide continuous glucose data.

If at any time during the fasting period the patient experiences a hypoglycaemic episode or blood glucose levels go above 14.0mmol/l they should treat and abandon the test.

If there is a change in the blood glucose of more than 1.5mmol/l during any time block then the basal for that time block is adjusted up or down by 0.05-0.1 unit per hour (or 10-20%) two hours prior to that glucose change.

APPENDIX 2

Gold score for hypoglycaemia awareness

Please indicate on the scale how aware you are of when your hypos are commencing?

Always 1	2	3	4	5	6	Never 7

A score of ≥ 4 = impaired hypoglycaemia awareness

Adapted from: Gold AE, MacLeod KM, Frier BM. Frequency of severe hypoglycemia in patients with type I diabetes with impaired awareness of hypoglycemia. Diabetes Care. 1994; 17(7):697-703

APPENDIX 3

Clarke hypoglycaemia awareness questionnaire

1. **Check the category that best describes you:**
   (check one only)

   - ☐ I always have symptoms when my blood sugar is low (A)
   - ☐ I sometimes have symptoms when my blood sugar is low (R)
   - ☐ I no longer have symptoms when my blood sugar is low (R)

2. **Have you lost some of the symptoms that used to occur when your blood sugar was low?**

   - ☐ Yes (R)
   - ☐ No (A)

3. **In the past six months how often have you had moderate hypoglycemia episodes?**
   (Episodes where you might feel confused, disoriented, or lethargic and were unable to treat yourself)

   - ☐ Never (A)
   - ☐ Once or twice (R)
   - ☐ Every other month (R)
   - ☐ Once a month (R)
   - ☐ More than once a month (R)

4. **In the past year how often have you had severe hypoglycemic episodes?**
   (Episodes where you were unconscious or had a seizure and needed glucagon or intravenous glucose)

   - ☐ Never (A)
   - ☐ 1 time (R)
   - ☐ 2 times (R)
   - ☐ 3 times (R)
   - ☐ 4 times (R)
   - ☐ 5 times (R)
   - ☐ 6 times (R)
   - ☐ 7 times (R)
   - ☐ 8 times (R)
   - ☐ 9 times (R)
   - ☐ 10 times (R)
   - ☐ 11 times (R)
   - ☐ 12 or more times (R)

5. **How often in the last month have you had readings < 3.9 mmol/l with symptoms?**

   - ☐ Never;
   - ☐ 1 to 3 times;
   - ☐ 1 time/week;
   - ☐ 2 to 3 times/week;
   - ☐ 4 to 5 times/week;
   - ☐ Almost daily

6. **How often in the last month have you had readings < 3.9 mmol/l without any symptoms?**

   - ☐ Never;
   - ☐ 1 to 3 times;
   - ☐ 1 time/week;
   - ☐ 2 to 3 times/week;
   - ☐ 4 to 5 times/week;
   - ☐ Almost daily

   R = answer to 5 ≤ answer to 6
   A = answer to 5 > answer to 6

7. **How low does your blood sugar need to go before you feel symptoms?**

   - ☐ 3.3-3.9 mmol/l (A)
   - ☐ 2.8-3.3 mmol/l (A)
   - ☐ 2.2-2.8 mmol/l (R)
   - ☐ < 2.2 mmol/l (R)

8. **To what extent can you tell by your symptoms that your blood sugar is low?**

   - ☐ Never (R)
   - ☐ Rarely (R)
   - ☐ Sometimes (R)
   - ☐ Often (A)
   - ☐ Always (A)

> **Four or more R responses = impaired hypoglycaemia awareness**

Adapted from: Clarke WL, Cox DJ, Gonder-Frederick LA, Julian D, Schlundt D, Polonsky W. Reduced awareness of hypoglycemia in adults with IDDM. A prospective study of hypoglycemic frequency and associated symptoms. Diabetes Care. 1995; 18(4):517-522

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