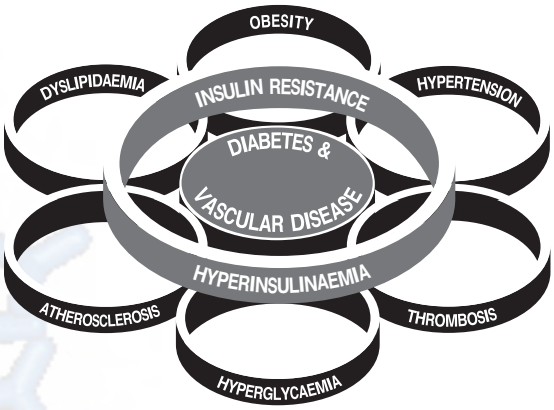
THE BRITISH JOURNAL OF
Diabetes
The Journal of the Association of British Clinical Diabetologists

JUNE 2020 VOLUME 20 SUPPLEMENT 1



DTN-UK Best Practice Guides

DTN UK
collaborate · evolve · support

THE BRITISH JOURNAL OF
Diabetes ABCD
The Journal of the Association of British Clinical Diabetologists

Formerly The British Journal of Diabetes & Vascular Disease

The peer reviewed journal linking specialists delivering diabetes care

Editorial office
Dr Marie-France Kong
The British Journal of Diabetes
ABCD (Diabetes Care) Limited
Miria House, 1683b High Street,
Knowle, Solihull, B93 0LL, UK
Email: editor@bjd-abcd.com
Twitter: @BJDVD_Editor

Authors instructions
See: www.bjd-abcd.com

Advertising, reprints, subscriptions
Tel +44 (0)1675 477602
Email: sales@bjd-abcd.com

Supplements and meeting reports
Br J Diabetes publishes supplements and meeting reports. These are subject to peer review and usual editorial control.
Contact the editors via the editorial office
Tel: +44 (0)1675 477602
Email: editor@bjd-abcd.com

Production and publishing
Br J Diabetes is produced on behalf of BJDVD Ltd (a wholly owned subsidiary of ABCD (Diabetes Care) Ltd) by
Red Hot Irons Ltd, Miria House,
1683b High Street, Knowle,
Solihull, B93 0LL, UK
Tel +44 (0)1675 475401
Email: sales@bjd-abcd.com

Annual subscriptions for 2020
Institutional rate
UK & Europe: GBP 284.00
Elsewhere: USD 524
Personal rate
UK & Europe: GBP 209.00
Elsewhere: USD 387

The British Journal of Diabetes is peer reviewed. It is published biannually but manuscripts are available on line as soon as they are accepted. The journal is distributed on a closed circulation to hospital diabetologists, endocrinologists, general physicians, surgeons, general practitioners and other professionals with a special interest in diabetes. The journal may be provided free, on request, to professionals who meet the journal's free circulation criteria.

ISSN 2397-6233 (Print)
ISSN 2397-6241 (Online)

Printed in the UK by Caric Press Ltd, in association with Stephens & George Magazines Ltd.
Printed on acid-free paper.

PEFC PEFC/16-33-254 PEFC Certified This product is from sustainably managed forests and controlled sources www.pefc.org

www.bjd-abcd.com

Members of the Medscape Publishers Circle®

DTN-UK Best Practice Guides

A group of clinicians with expertise in continuous subcutaneous insulin infusion (CSII) from across the UK have been meeting regularly to discuss and share their best practice. We have summarised the outcomes of these discussions in the published Best Practice Guides to follow. I am extremely grateful to Parth Narendran and Ali Karamat and team for developing the guide for those hospitalised on CSII and also to Peter Hammond and team for the development of the CSII clinical guide for adult services.

We hope that you find these guides useful in your day to day clinical practice.

Dr Emma Wilmot

Founding Chair ABCD Diabetes Technology Network UK

ACKNOWLEDGEMENTS

We would like to thank diabetes teams at North Bristol NHS Trust, Imperial College Healthcare NHS Trust, Royal Free Hospitals NHS Trust and Royal Bournemouth, Christchurch Hospital NHS Trust and King's College Hospital NHS Foundation Trust for material provided. We would also like to thank Insulin Pumps Wales and INPUT Diabetes for their contribution to the guide.

ABCD DTN-UK would like to give thanks to the following sponsors at the time of the Guides initially being produced: Roche, Medtronic, Abbott Diabetes Care, Animas, Cellnovo, Medtrum, Dexcom and Diasend. Without their support, the meetings and interactions between UK experts in CSII who contributed to the development of this document would not have been possible.


3:18
AM
5.1
mmol/L
Act Ins.
0.10 u
Bolus
Basal

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

CONTRIBUTORS

Leads

Dr Emma Wilmot, *Chair, ABCD Diabetes Technology Network UK, Consultant Diabetologist, Derby Teaching Hospitals NHS Foundation Trust, Derby*
Dr Peter Hammond, *Consultant Diabetologist, Harrogate and District Foundation Trust, Harrogate*

Working group

Dr Pratik Choudhary, *Senior Lecturer, King's College London, London*
Dr Rob Gregory, *Consultant Diabetologist, University Hospitals of Leicester, Leicester*
Geraldine Gallen, *Diabetes Specialist Nurse, King's College London*
Chris Headland, *Diabetes Specialist Nurse, Wales National Insulin Pump Co-ordinator, Wales*
Dr Sufyan Hussain, *Consultant Diabetologist, Guy's and St Thomas' NHS Trust, London*
Dr Peter Jennings, *Diabetes Specialist Nurse, Derby Teaching Hospitals NHS Foundation Trust, Derby*
Dr Lala Leelarathna, *Consultant Diabetologist, Manchester Royal Infirmary, Manchester*
Dr Alistair Lumb, *Oxford University Hospitals NHS Foundation Trust, Oxford*
Dr Dinesh Nagi, *ABCD Chair, Consultant Diabetologist, Mid Yorkshire NHS Trust, Yorkshire*
Prof Nick Oliver, *Wynn Professor of Human Metabolism & Consultant Diabetologist, Imperial College Healthcare NHS Trust, London*
Dr Vernon Parfitt, *Consultant Diabetologist, Southmead Hospital, Bristol*
Dr Neil Walker, *Consultant Diabetologist, Royal Devon and Exeter NHS Foundation Trust*

Contributions from

Dr Una Graham, *Consultant Diabetologist, Royal Victoria Hospital, Belfast*
Dr Brian Kennon, *Consultant Diabetologist, Queen Elizabeth University Hospital, Glasgow*
Dr Helen Partridge, *Consultant Diabetologist, Bournemouth*
Dr Julia Platts, *Consultant Diabetologist, National Clinical Lead for Diabetes, Wales*
Dr Andrew Solomon, *Consultant Diabetologist, East and North Hertfordshire NHS Trust*

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

CONTENT

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 TA151 in 2008,[1] 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 HbA_{1c} levels in insulin pump users versus non-users; 20% more people with type 1 diabetes on an insulin pump achieve an HbA_{1c} <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.

Partha Kar
Consultant in Diabetes & Endocrinology at Portsmouth Hospitals NHS Trust
Associate National Clinical Director of Diabetes with NHS England

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 HbA_{1c} and hypoglycaemia frequency when used in place of multiple daily injections (MDI) for intensive insulin therapy.[2] Additionally, CSII can reduce glycaemic variability and improve aspects of quality of life, particularly in relation to diet and physical activity.[3,4] Recent evidence has demonstrated an association between the use of CSII and reduced mortality.[5]

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 HbA_{1c} 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 HbA_{1c} was seen in those with the highest initial HbA_{1c}.[2]

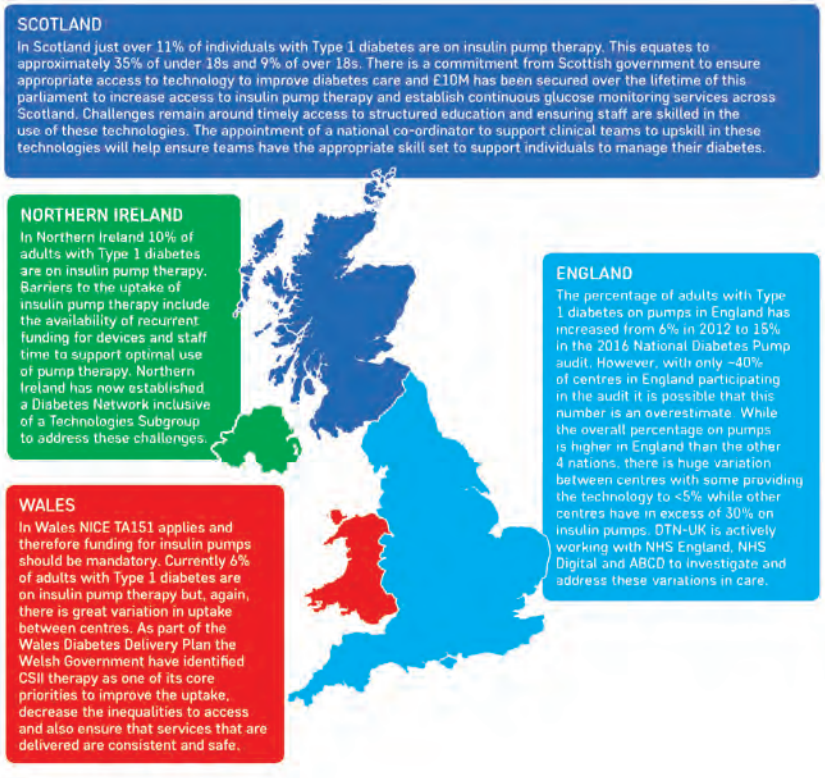
CSII is recommended by the National Institute for Health and Care Excellence (NICE) Technology Appraisal 151 (TA151)[1] as a treatment option for people with type 1 diabetes who meet the clinical criteria specified in the TA and for whom it is clinically appropriate. CSII should be offered where glycaemic control issues persist despite optimised MDI which has been supported by a structured education programme fulfilling the criteria laid out in NICE clinical guideline NG17.[6]

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 HbA_{1c} 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.[7-9]

There is more limited evidence for reduction in hypoglycaemia frequency with SAP.[10,11] 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.[12]

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.

Figure 1. Uptake of continuous subcutaneous insulin infusion (CSII) in the four nations of the UK



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. Figure 1 shows a summary of uptake in each of the four nations.

A recurrent theme which limits access across all four nations is healthcare professional time and training.[13] 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, this document will support staff to deliver safe, effective, high quality insulin pump services.

BEST PRACTICE GUIDE

Indications for CSII

NICE has published clear guidance on the use of CSII for adults with diabetes: Technology Appraisal Guidance 151.[1]

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 (HbA_{1c}) 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
   HbA_{1c} 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 comprise 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 HbA_{1c} 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,[1] 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)[14] and in the management of diabetic gastroparesis (NG17).[6,15]

Other indications

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

- Diabetic neuropathy, painful peripheral and autonomic with orthostatic hypotension[16]
- Insulin allergy[17]
- 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[18]

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.[19]

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:[21]

- 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

Table 1 Advantages and disadvantages of continuous subcutaneous insulin infusion (CSII). Adapted from Hussain and Oliver.[19]

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 such as pizza) • Temporary suspension or reduction of insulin delivery (activity and hypoglycaemia) • Allows pre-programming of insulin to deliver variable amounts of insulin without constant input (eg, 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[20]	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 healthcare provider training needed • Healthcare 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

appropriately, then ketosis progressing to diabetic ketoacidosis 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.[22] Accidental damage to pumps accounted for just under 30% of pump failures. The median pump 'life expectancy' is just under 3 years.[23]

An ADA/EASD diabetes technology working group have made a statement on the safety of insulin pump therapy with recommendations for increasing safety.[24]

Reasons for CSII discontinuation

In the T1D Exchange registry, 3% of pump users discontinued CSII within a year.[25] 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.[26]

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, ≥ glucose measurements/day [SMBG or flash / continuous glucose monitoring])
2. Motivation to pursue CSII therapy and improve diabetes control

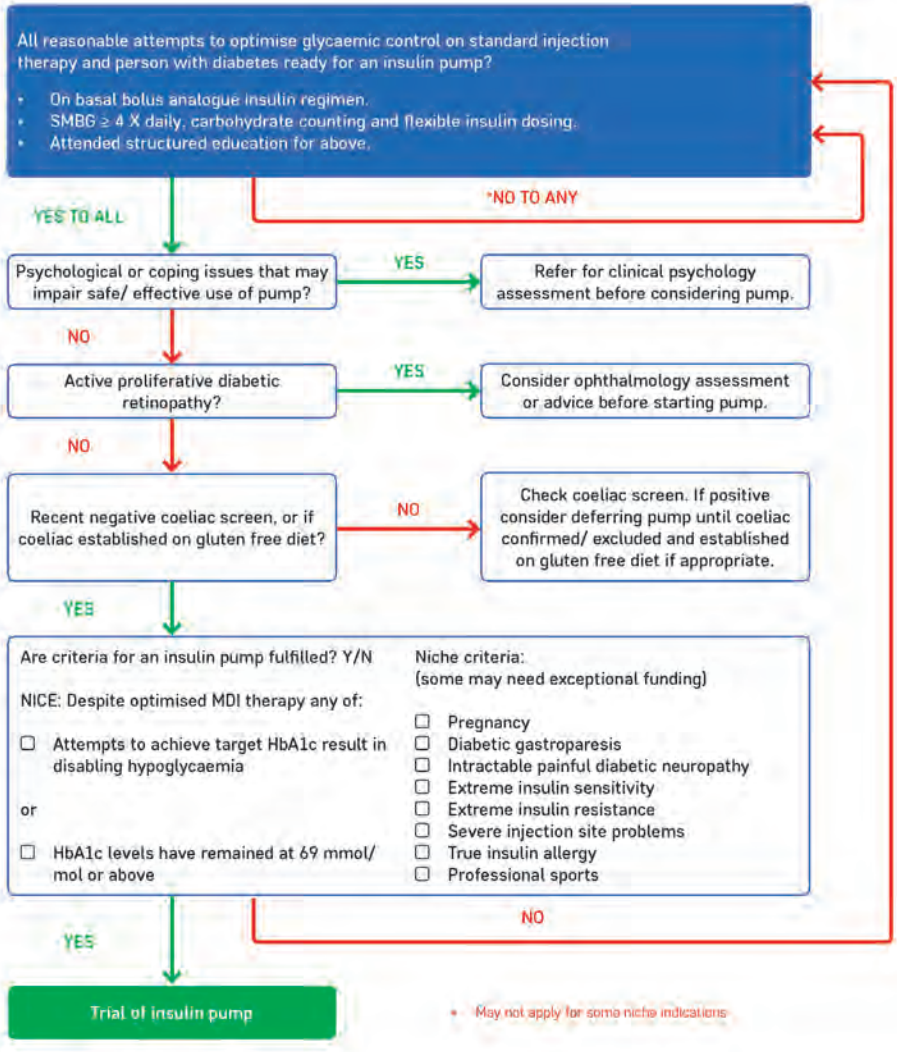
3. Engagement with diabetes services
4. Realistic expectations of CSII and clearly agreed individual expectations and targets
5. Absence of psychological factors that may impair safe CSII use (eg, psychosis, severe anxiety, or severe depression). However, some psychological issues such as depression 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[27]
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 2)

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 (Figure 2) undertaken by the CSII MDT.

Figure 2. Insulin pump assessment guideline



MDT assessment

The decision to initiate insulin pump therapy should only be made following agreement between the multidisciplinary insulin pump team and the 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.[28]

The team should agree with the user what the goals of therapy are (eg, reduction in HbA_{1c} 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 2-week period following initiation.

We recommend:

1. CSII is commenced ideally in groups of 2–5 to maximise resources safely.
2. At the point of CSII initiation the team should record the diabetes distress scale, hypoglycaemia aware-

ness (Gold or Clarke) questionnaire and HbA_{1c} 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.

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 is 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 first 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 the individual for clinical support.
- Appointments in consultant led pump clinic MDT as follows in the first 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

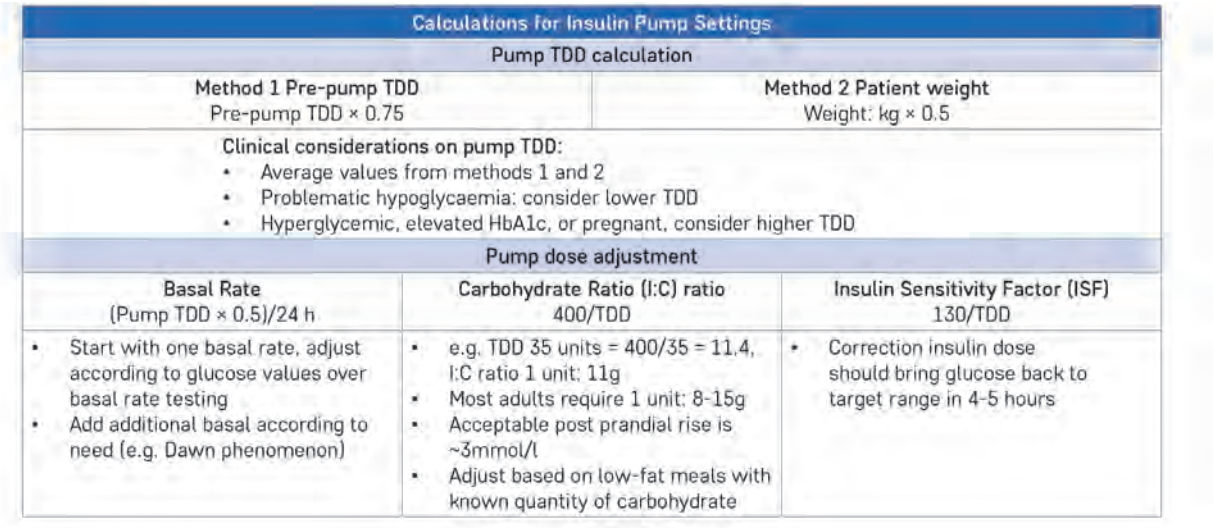
To achieve the best possible outcome on CSII, the expert group identified the following factors which should be discussed with the person with diabetes to have realistic expectations of the actions required to achieve their therapeutic goals:[29-31]

- 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

Initial insulin setting at CSII initiation

Figure 3 shows a summary flowchart to assist with dose calculation for CSII initiation, adapted from the American Association of Clinical Endocrinologists (AACE) (Consensus statement of AACE Task Force, 2014).[32]

Figure 3. Summary flowchart to assist with dose calculation for CSII initiation, adapted from the American Association of Clinical Endocrinologists (AACE) (Consensus statement of AACE Task Force, 2014).[32] TDD, total daily dose.



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.[33]

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 dose (TDD) of insulin:

- Basal 40–50% when:
  - carbohydrate intake 100–200 g/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 >0.7 u/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 4 and Table 2)
- Circadian profile (Renner Scale)[34]

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,[35] 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.[36]

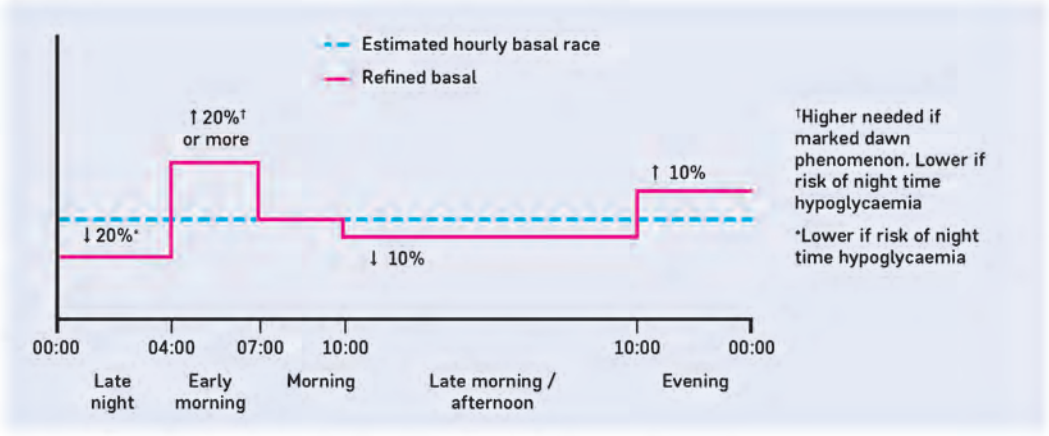
The best practice working group preferred a flat basal or modified basal rate over the circadian profile as the initial basal rate profile of choice. Regardless of the initial approach, the user must test and retest their basal rates to optimise control.

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 (eg, 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 through the day.[37] There is evidence that those with 3–6 basal rates have better outcomes.

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

Figure 4. Modified basal rate profile. Adapted from Hussain & Oliver.[19]



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,[38] 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 min before eating as this is associated with a lower postprandial glucose excursion.[39] The faster acting insulin analogue, Fiasp, is licensed for administration immediately pre or up to 20 min post meal.[40]

Insulin:carbohydrate ratio (ICR)

A number of centres have traditionally used the 500/100 rules to guide insulin dosing on pump therapy.[41] Following the publication of more recent data from King *et al*,[42] 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 (eg, 10 g vs 12 g) and also use inaccurate and rounded ratios such as 1 unit:10 g CHO or 1 unit:15 g CHO.[43] This practice reflects previous approaches used for manual calculations whilst on MDI therapy and, possibly, the preference of the healthcare 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 1 unit:10 g to 1 unit:9 g lowers the postprandial glucose by 1.8–2.9 mmol/L at each meal for an average individual consuming 60–100 g of carbohydrate.[43]

The consensus of the group was to routinely start with 400/TDD (Table 3). Some people may need more aggressive boluses, especially at breakfast with ratios 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] (Table 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 (eg, Medtronic), others correct to the mid range (eg, Roche), whilst others have a single target glucose value but define a threshold glucose above which a correction bolus will be calculated (eg, Omnipod). To overcome this, the expert group would advise an individualised narrow target range of ±1 mmol/L (eg 4.5–5.5 mmol/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 HbA_{1c} may need an initially higher target range as they may experience hypoglycaemia

Table 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 HbA_{1c} >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 HbA_{1c}. This is particularly important for those with retinopathy. Different pump bolus advisors calculate correction targets differently, the reason for suggesting single value or a narrow range (4.5–5.5 mmol/L) is that it overcomes issues with this.

Table 4 Predicted ICR and ISF based on insulin pump total daily dose

Total daily dose (TDD)	I:C ratio (ICR) 1 unit of insulin for X g of carbs	Insulin sensitivity factor (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:11 g 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 46 g 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 1 unit:11 g, so for sandwich needs 46 g / 11 = 4.2 units
ISF 1 unit:3.6 mmol/L, so to correct from 11.8 to 5 mmol/L: 11.8 – 5 mmol/L = 6.8 mmol/L /3.6 = 1.9 units. Total bolus insulin dose required = 4.2 + 1.9 = 6.1 units

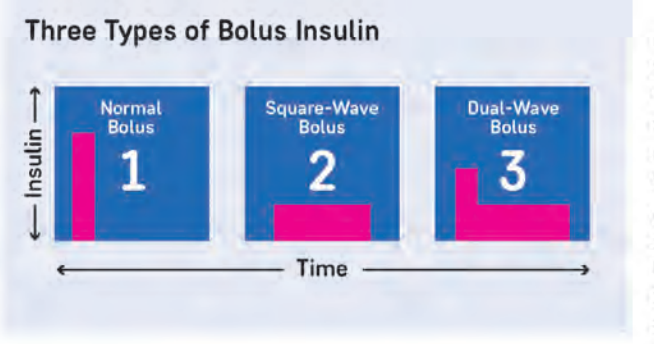
symptoms at normoglycaemic glucose values until they get accustomed to lower glucose values than they have been used to.

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 a good starting point and encourage thinking beyond simple rounded ratios (eg, 1 unit:10 g). 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 2–4 mmol/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):



- 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 once the user is established on their CSII therapy. Audit data and other surveys suggest that few people use these features routinely.[44]

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 post-prandial 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.[45-47] If the review of glucose profiles shows late (>3 hours) 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

Table 5 A guide to insulin pump download interpretation

Glucose

- What is the frequency of glucose monitoring?
  - Be aware that, in those achieving HbA_{1c} <58 mmol/mol (7.5%), the average BG tests per day is ≥ 5
- What is the mean glucose and therefore estimated HbA_{1c}?
- What is the glycaemic variability?
  - Standard deviation (SD) ≥ 3.5 mmol/L or CV (SD/mean) ≥36% suggests high variability[48]
- What percentage of time is spent in hypoglycaemia?
  - ≥10% in someone monitoring
    ≥4/day is a concern, so identify the cause.

Insulin

- 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 boluses/day

Pump settings

- 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 4.5–5.5 mmol/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

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. Table 5 details parameters which should be considered when reviewing a pump download.

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 6).[49]

Table 6 Possible causes of unexplained hyperglycaemia

Infusion set

- 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?

Insulin pump

- 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?

Insulin

- Is your insulin expired/inactive?
- Has your insulin been exposed to extreme temperatures?
- How long has the insulin been in the cartridge and tubing?

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.

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.

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 hypoglycaemia with validated tools such as:

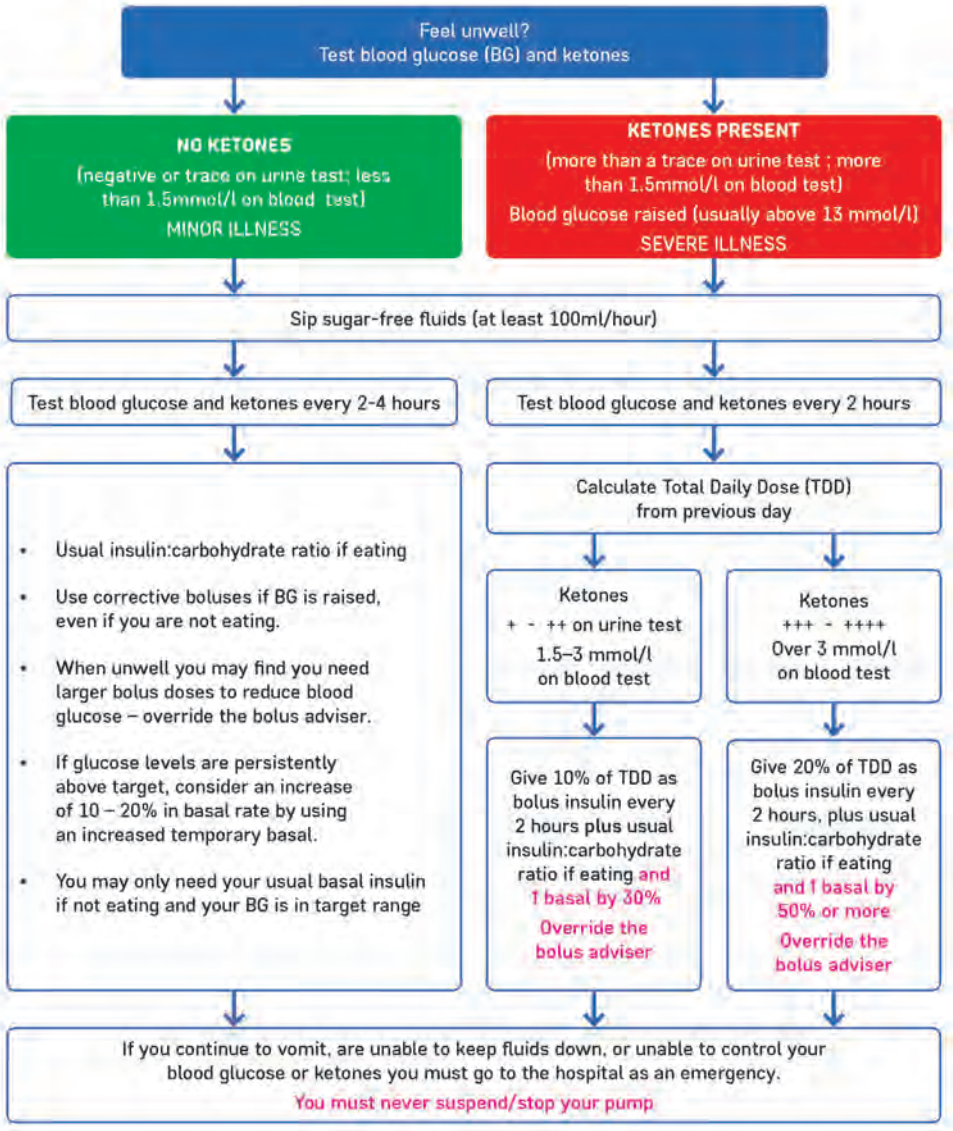
- Gold score
- Clarke Score

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)[50] have recently recommended that blood or sensor glucose readings <3.0 mmol/L should be considered as serious, clinically important hypoglycaemia. Problematic hypoglycaemia 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 SAP therapy and islet cell transplantation (see Figure 6). The MDT should consider whether the individual meets the NICE guidance (NG17, DG21) for sensor augmented pump therapy in the first instance.[6,51]

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



Sensor augmented pump therapy (NICE DG21)[51]

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.[12]

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).

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.

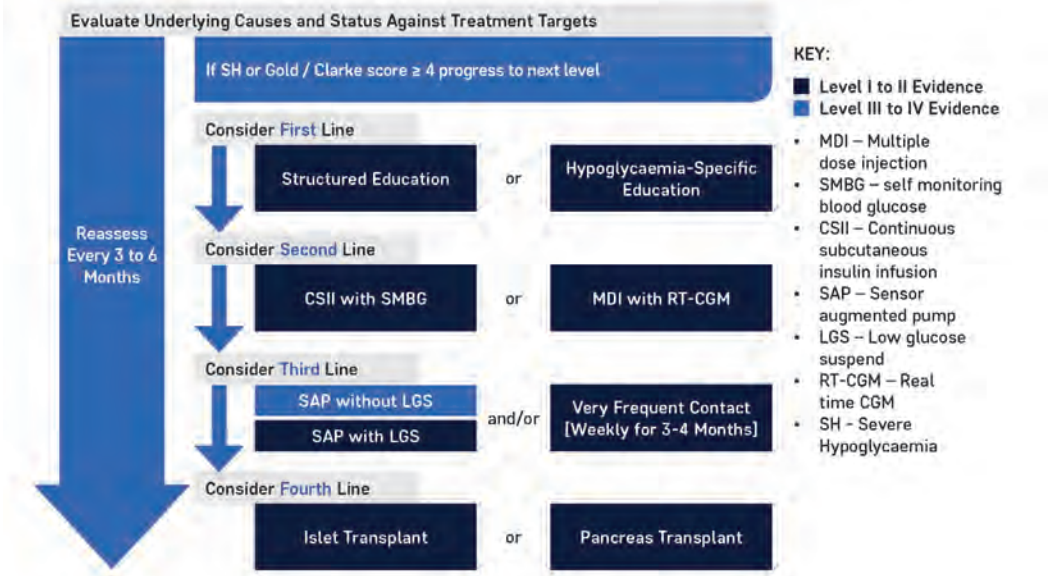
Discontinuation of insulin pump therapy

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

Figure 6. Approach to the person with problematic hypoglycaemia. Adapted from Choudhary *et al*, 2015.[52]



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, eg, 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 HbA_{1c} 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[53,54] 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 type 1 diabetes 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 type 1 diabetes 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, 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.[55] Responses to exercise are individual, 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 min 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 so, where possible, basal insulin should be reduced 60–90 min 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 min 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 min 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 with 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 water sports
- 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 (eg, for some water sports), 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, healthcare professionals will feel more confident to deliver and promote CSII therapy for those living with diabetes.

References

1. National Institute for Health and Care Excellence (NICE). Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. NICE, London, 2008. https://www.nice.org.uk/Guidance/TA151
2. Pickup JC, Sutton AJ. Severe hypoglycaemia and glycemic control in insulin dependent diabetes: meta-analysis of multiple daily insulin injections compared with continuous subcutaneous insulin infusion. *Diabet Med* 2008;**25**:765–74. https://doi.org/10.1111/j.1464-5491.2008.02486.x
3. REPOSE Study Group. Relative effectiveness of insulin pump treatment over multiple daily injections and structured education during flexible intensive insulin treatment for type 1 diabetes: cluster randomised trial (REPOSE). *BMJ* 2017;**356**:j1285. https://doi.org/10.1136/bmj.j1285
4. Hoogma RP, Hammond PJ, Gomis R *et al*. Comparison of the effects of

continuous subcutaneous insulin infusion (CSII) and NPH-based multiple daily insulin injections (MDI) on glycaemic control and quality of life: results of the 5-nations trial. *Diabet Med* 2006;**23**:141–7. https://doi.org/10.1111/j.1464-5491.2005.01738.x
5. Steineck I, Cederholm J, Eliasson B, *et al*. Swedish National Diabetes Register. Insulin pump therapy, multiple daily injections, and cardiovascular mortality in 18,168 people with type 1 diabetes: observational study. *BMJ* 2015;**350**:h3234. https://doi.org/10.1136/bmj.h3234
6. National Institute for Health and Care Excellence (NICE). NICE guideline [NG17]. Type 1 diabetes in adults: diagnosis and management. Last updated: July 2016. https://www.nice.org.uk/guidance/ng17
7. Batellino T, Conget I, Olsen B, *et al*. The use and efficacy of continuous glucose monitoring in type 1 diabetes treated with insulin pump therapy: a randomised controlled trial. *Diabetologia* 2012;**55**:3155–62. https://doi.org/10.1007/s00125-012-2708-9
8. Bergenstal RM, Tamborlane WV, Ahmann A, *et al,* STAR 3 Study Group. Sensor-augmented pump therapy for A1C reduction (STAR 3) study: results from the 6-month continuation phase. *Diabetes Care* 2011; **34**:2403–5. https://doi.org/10.2337/dc11-1248
9. Raccah D, Sulmont V, Reznik Y, *et al*. Incremental value of continuous glucose monitoring when starting pump therapy in patients with poorly controlled type 1 diabetes: the RealTrend study. *Diabetes Care* 2009; **32**:2245–50. https://doi.org/10.2337/dc09-0750
10. Choudhary P, Ramadamy S, Green L, *et al.* Real-time continuous glucose monitoring significantly reduces hypoglycemia in hypoglycemia-unaware patients with type 1 diabetes. *Diabetes Care* 2013;**36**:1460–2.
11. Ly TT, Nicholas JA, Retterath A, *et al*. Effect of sensor-augmented insulin pump therapy and automated insulin suspension vs standard insulin pump therapy on hypoglycemia in patients with type 1 diabetes: a randomized clinical trial. *JAMA* 2013;**310**:1240–7. https://doi.org/10.1001/jama.2013.277818
12. Choudhary P, Olsen BS, Conget I, *et al*. Hypoglycemia prevention and user acceptance of an insulin pump system with predictive low glucose management. *Diabetes Technol Ther* 2016;**18**:288–91. https://doi.org/10.1089/dia.2015.0324
13. White HD, Goenka N, Furlong NJ *et al*. The UK service level audit of insulin pump therapy in adults. *Diabetic Medicine* 2014:**31**:412–18.
14. National Institute for Health and Care Excellence (NICE). NICE guideline [NG3]. Diabetes in pregnancy: management from preconception to the postnatal period. Last updated: August 2015. https://www.nice.org.uk/guidance/ng3
15. Sharma D, Morrison G, Joseph F, *et al*. The role of continuous subcutaneous insulin infusion therapy in patients with diabetic gastroparesis. *Diabetologia* 2011;**54**:2768–70. https://doi.org/10.1007/s00125-011-2282-6
16. Boulton AJM, Drury J, Clarke B, *et al*. Continuous subcutaneous insulin infusion in the management of painful diabetic neuropathy. *Diabetes Care* 1982;**5**:386–90.
17. Pratt E, Miles P, Kerr D. Localized insulin allergy treated with continuous subcutaneous insulin. *Diabet Med* 2001;**18**:515–16. https://doi.org/10.1046/j.1464-5491.2001.00454-2.x
18. Aronson R, Cohen O, Conget I, *et al*. OpT2mise: a randomized controlled trial to compare insulin pump therapy with multiple daily injections in the treatment of type 2 diabetes. *Diabetes Technol Ther* 2014;**16**:414–20. https://doi.org/10.1089/dia.2013.0363
19. Hussain S, Oliver N. Insulin Pumps and Continuous Glucose Monitoring Made Easy, 1e, Elsevier, 2016.
20. Bruttomesso D, Crazzolari D, Maran A, *et al*. In type 1 diabetic patients with good glycaemic control, blood glucose variability is lower during continuous subcutaneous insulin infusion than during multiple daily injections with insulin glargine. *Diabet Med* 2008;**25**:326–32. https://doi.org/10.1111/j.1464-5491.2007.02365.x
21. Pickup JC, Yemane N, Brackenridge A, Pender S. Nonmetabolic complications of continuous subcutaneous insulin infusion: a patient survey. *Diabetes Technol Ther* 2014;**16**:145–9. https://doi.org/10.1089/dia.2013.0192
22. Ross P, Gray AR, Milburn J, *et al*. Insulin pump-associated adverse events are common, but not associated with glycemic control, socio-economic status, or pump/infusion set type. *Acta Diabetol* 2016;**53**:991–8. https://doi.org/10.1007/s00592-016-0897-2
23. Rabbone I, Minuto N, Bonfanti R, *et al.* Insulin pump failures in Italian children with type 1 diabetes: retrospective 1-year cohort study. *Diabet Med* 2017;**34**:621–4. https://doi.org/10.1111/dme.13294
24. Heinemann L, Alexander GF, Petrie JR, *et al*. Insulin pump risks and benefits: a clinical appraisal of pump safety standards, adverse event reporting and research needs. A Joint Statement of the European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group. *Diabetologia* 2015;**58**:862–70. https://doi.org/10.1007/s00125-015-3513-z
25. Wong JC, Boyle C, DiMeglio LA, *et al*. Evaluation of pump discontinuation and associated factors in the T1D Exchange Clinic Registry. *J Diabetes Sci Technol* 2017;**11**:224–32. https://doi.org/10.1177/1932296816663963
26. Beato-Vibora P, Yeoh E, Rogers H, *et al*. Sustained benefit of continuous subcutaneous insulin infusion on glycaemic control and hypoglycaemia in adults with type 1 diabetes. *Diabet Med* 2015;**32**:1453–9. https://doi.org/10.1111/dme.12869
27. Rodrigues IA, Reid HA, Ismail K, Amiel SA. Indications and efficacy of continuous subcutaneous insulin infusion (CSII) therapy in type 1 diabetes: a clinical audit in a specialist service. *Diabet Med* 2005;**22**:842.
28. Leelarathna L, Roberts SA, Hindle A, *et al*. Comparison of different insulin pump makes under routine care conditions in adults with type 1 diabetes. *Diabet Med* 2017;**34**:1372–9. https://doi.org/10.1111/dme.13412
29. Scheiner G, Sobel RJ, Smith DE, Pick AJ, *et al*. Insulin pump therapy: guidelines for successful outcomes. *Diabetes Educ* 2009;**35**(S2):29S–41S.
30. Wilkinson J, McFann K, Chase HP. Factors affecting improved glycaemic control in youth using insulin pumps. *Diabet Med* 2010;**27**:1174–7. https://doi.org/10.1111/j.1464-5491.2010.03068.x
31. Cukierman-Yaffe T, Konvalina N, Cohen O. Key elements for successful intensive insulin pump therapy in individuals with type 1 diabetes. *Diabetes Res Clin Pract* 2011;**92**:69–73. https://doi.org/10.1016/j.diabres.2011.01.002
32. American Association of Clinical Endocrinologists/American College of Endocrinology Insulin Pump Management Task Force consensus statement. *Endocr Pract* 2014;**20**:462–89. https://doi.org/10.4158/EP14145.PS
33. Ruan Y, Thabit H, Leelarathna L, *et al*. Variability of insulin requirements over 12 weeks of closed-loop insulin delivery in adults with type 1 diabetes. *Diabetes Care* 2016;**39**:830–2. https://doi.org/10.2337/dc15-2623
34. Wizemann E, Renner R, Hepp K. Prospective evaluation of a standardized basal rate distribution for CSII in type 1 diabetes over 6 months. *Diabetologie und Stoffwechsel* 2001;10:57.
35. Bachran R, Beyer P, Klinkert C, *et al*. Basal rates and circadian profiles in continuous subcutaneous insulin infusion (CSII) differ for preschool children, prepubertal children, adolescents and young adults. *Pediatr Diabetes* 2012;**13**:1–5. https://doi.org/10.1111/j.1399-5448.2011.00777.x
36. Laimer M, Melmer A, Mader JK, *et al*. Variability of basal rate profiles in insulin pump therapy and association with complications in type 1 diabetes mellitus. *PLoS One* 2016;**11**:e0150604. https://doi.org/10.1371/journal.pone.0150604
37. Chico A, Tundidor D, de Leiva A. Changes in insulin requirements from the onset of continuous subcutaneous insulin infusion (CSII) until optimization of glycemic control. *J Diabetes Sci Technol* 2014;**8**:371–7. https://doi.org/10.1177/1932296813520205
38. McAuley SA, Ward GM, Horsburgh JC, *et al*. Asymmetric changes in circulating insulin levels after an increase compared with a reduction in insulin pump basal rate in people with type 1 diabetes. *Diabet Med* 2017;**34**:1158–64. https://doi.org/10.1111/dme.13371
39. Cobry E, McFann K, Messer L, *et al*. Timing of meal insulin boluses to achieve optimal postprandial glycemic control in patients with type 1 diabetes. *Diabetes Technol Ther* 2010;**12**:173–7. https://doi.org/10.1089/dia.2009.0112
40. Slattery D, Amiel SA, Choudhary P. Optimal prandial timing of bolus insulin in diabetes management: a review. *Diabet Med* 2018;**35**:306–16. https://doi.org/10.1111/dme.13525
41. Davidson PC, Hebblewhite HR, Bode BW, *et al.* Statistically based CSII parameters: correction factor (CF) (1700 rule), carbohydrate-insulin ratio

(CIR) (2.8 rule), and basal-to-total ratio. *Diabetes Technol Ther* 2003; **5**:237–42.
42. King AB, Kuroda A, Matsuhisa M, Hobbs T. A review of insulin-dosing formulas for continuous subcutaneous insulin infusion (CSII) for adults with type 1 diabetes. *Curr Diab Rep* 2016;**16**:83–90. https://doi.org/10.1007/s11892-016-0772-0
43. Walsh J, Roberts R, Bailey T. Guidelines for insulin dosing in continuous subcutaneous insulin infusion using new formulas from a retrospective study of individuals with optimal glucose levels. *J Diabetes Sci Technol* 2010;**4**:1174–81. https://doi.org/10.1177/193229681000400516
44. Groat D, Grando MA, Soni H, *et al*. Self-management behaviors in adults on insulin pump therapy. What are patients really doing? *J Diabetes Sci Technol* 2017;**11**:233–9. https://doi.org/10.1177/1932296816666538
45. Bell KJ, Smart CE, Steil GM, *et al*. Impact of fat, protein, and glycemic index on postprandial glucose control in type 1 diabetes: implications for intensive diabetes management in the continuous glucose monitoring era. *Diabetes Care* 2015;**38**:1008–15. https://doi.org/10.2337/dc15-0100
46. Bell KJ, Toschi E, Steil GM, Wolpert HA. Optimized mealtime insulin dosing for fat and protein in type 1 diabetes: application of a model-based approach to derive insulin doses for open-loop diabetes management. *Diabetes Care* 2016;**39**:1631–4. https://doi.org/10.2337/dc15-2855
47. Lopez PE, Smart CE, McElduff P, *et al*. Optimizing the combination insulin bolus split for a high-fat, high-protein meal in children and adolescents using insulin pump therapy. *Diabet Med* 2017;**34**:1380–4. https://doi.org/10.1111/dme.13392
48. Danne T, Nimri R, Battelino T, *et al*. International consensus on use of continuous glucose monitoring. *Diabetes Care* 2017;**40**:1631–40. https://doi.org/10.2337/dc17-1600
49. Ponder SW, Skyler JS, Kruger DF, *et al*. Unexplained hyperglycemia in continuous subcutaneous insulin infusion: evaluation and treatment. *Diabetes Educ* 2008;**34**:327–33. https://doi.org/10.1177/0145721708315682
50. International Hypoglycaemia Study Group. Glucose concentrations of less than 3.0 mmol/L (54 mg/dL) should be reported in clinical trials: a joint position statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care* 2017;**40**:155–7. https://doi.org/10.2337/dc16-2215
51. National Institute for Health and Care Excellence (NICE). NICE diagnostics guidance [DG21]. Integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes (the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system). February 2016. https://www.nice.org.uk/guidance/dg21
52. Choudhary P, Rickels MR, Senior PA, *et al*. Evidence-informed clinical practice recommendations for treatment of type 1 diabetes complicated by problematic hypoglycemia. *Diabetes Care* 2015;**38**:1016–29. https://doi.org/10.2337/dc15-0090
53. National Institute for Health and Care Excellence (NICE). NICE guideline [NG18]. Diabetes (type 1 and type 2) in children and young people: diagnosis and management. Last updated: November 2016. https://www.nice.org.uk/guidance/ng18
54. National Institute for Health and Care Excellence (NICE). NICE quality standard [QS125]. Diabetes in children and young people. Published July 2016. https://www.nice.org.uk/guidance/qs125
55. Riddell MC, Gallen IW, Smart CE, *et al*. Exercise management in type1 diabetes: a consensus statement. *Lancet Diabet Endocrinol* 2017;**5**:377–90. https://doi.org/10.1016/S2213-8587(17)30014-1
56. 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**:697–703.
57. 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**:517–22.

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.

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 *et al*.[56]

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 hypoglycaemia 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 hypoglycaemic 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

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)

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

Four or more R responses = impaired hypoglycaemia awareness

Adapted from Clarke *et al*.[57]

Guidelines for managing continuous subcutaneous insulin infusion (CSII, or 'insulin pump') therapy in hospitalised patients

COMMITTEE

Kate Evans, *Consultant Diabetologist, Plymouth*
Emma Green, *Patient representative, antenatal and diabetes nurse*
Barbara Hudson, *Diabetes Specialist Nurse, Birmingham*
Martha Stewart, *Diabetes Specialist Nurse, Birmingham*
Mark Evans, *Consultant Diabetologist, Cambridge*
Rob Gregory, *Consultant Diabetologist, Leicester*
Emma Wilmot, *Consultant Diabetologist, Derby*
Andrew Solomon, *Consultant Diabetologist, Hertfordshire*
Muhammad Karamat, *Consultant Diabetologist, Birmingham (co-Chair)*
Parth Narendran, *Consultant Diabetologist, Birmingham (Chair)*

CONTENT

FOREWORD

The authors are to be congratulated on producing this much needed and comprehensive guideline which should improve the care and experience of inpatients with diabetes treated by subcutaneous insulin infusion (CSII) pump therapy. Though multi-professional, it has been produced with a high level of user involvement ensuring that the guideline is firmly grounded in patient experience. It will be of great value to diabetes inpatient teams as well as to the large variety of other healthcare professionals who care for this group of inpatients.

Insulin pump therapy in the UK is almost exclusively confined to people with type 1 diabetes, of which 10–15% are treated by CSII. Only 7% of the inpatient diabetic population has type 1 diabetes thus, at most, only 1% of inpatients with diabetes are treated with CSII. Over 90% are admitted for a variety of non-diabetes related reasons and, as such, they will be primarily under the care of non-diabetes specialist teams with little or no experience of insulin pump therapy. Indeed, given the rarity of this group, most healthcare professionals will not have seen an insulin pump and almost certainly not be familiar with all of the many different pumps and 'pods'. Under these circumstances, non-specialists will often discontinue pump therapy in favour of familiar therapies such as variable rate intravenous insulin infusion or intermittent boluses of subcutaneous insulin, much to the frustration of patients, particularly if this destabilises their glucose control. Furthermore, the return to pump therapy can be tricky, often prolonging the inpatient stay.

This guidance supports the continued use of CSII during the inpatient stay and, where appropriate, encourages healthcare professionals to allow the person with diabetes to manage their own pump therapy. The most important messages are the early involvement of the inpatient diabetes team in all scenarios and the recognition that most pump users are more than capable of managing their insulin pump therapy provided they are well enough to do so.

The document highlights what can go wrong and what to look out for to prevent harms from happening. It also addresses for both specialists and non-specialists common but not often considered scenarios such as what to do with the pump during MRI scanning, safe disconnection from the pump, insulin therapy during the pump-free period, managing hypoglycaemia on insulin pump therapy, safe storage of a removed pump and safe re-establishment of pump therapy. There is increasing use of CSII in pregnancy as its benefits are being increasingly recognised. In this context, there is a very useful section on CSII in pregnancy including during steroid treatment and in labour.

I have no doubt that this comprehensive guideline will be welcomed by healthcare professionals and patients as it will help promote improvements in the care, outcomes and experience of people with diabetes on insulin pump therapy..

Professor Gerry Rayman
Consultant Diabetologist, Ipswich Hospital NHS Trust
Clinical Lead of the National Diabetes Inpatient Audit
Co-Lead for the Diabetes GIRFT project, NHS I

STATEMENT, IMPLEMENTATION AND AUDIT

Continuous subcutaneous insulin infusion (CSII, Insulin pump) therapy is used by 10–15% of people with type 1 diabetes, and by some patients with type 2 diabetes. It is an effective option for day to day insulin delivery, but one that may not be familiar to healthcare professionals caring for these people in an inpatient hospital setting. Therefore, patients on CSII therapy are often unnecessarily switched to alternative modes of insulin delivery on admission to hospital, or alternatively, CSII therapy may be mismanaged.

There are currently no national level guidelines for the inpatient management of CSII in the UK.

These guidelines are designed to support the inpatient care of people with type 1 diabetes managed on CSII therapy. They were developed by a multi-disciplinary group of healthcare professionals and a patient on behalf of the Diabetes Technology Network and the Association of British Clinical Diabetologists. It has been further reviewed by national diabetes societies. It conforms to other national guidelines for diabetes/pregnancy care.

It is intended that the guideline will be useful to clinicians and service commissioners in planning, organising and delivering high quality diabetes inpatient care. There remains, however, an individual responsibility of healthcare professionals to make decisions appropriate to the circumstance of the individual patient. When implementing this guideline, full account should be taken of the local context and in line with statutory obligations required of the organisation and individual.

Quality Indicators

- Every Trust should have a local management plan in place based on these or other authoritative guidelines. These guidelines should be current and should not be used if the review date has expired.
- Every Trust should have a healthcare professional leading the implementation of these guidelines, and performance indicators should be used to assess the quality of care given.
- The purpose of standards is to maximise patient safety, improve patient satisfaction, support best clinical practice, reduce cost to the Trust relating to litigation and complaints, and contribute to reduced length of stay.
- Performance indicators will include
  - adverse events relating to insulin pump use (hypoglycaemia, DKA)
  - delayed discharge due to conversion onto/off CSII
  - patient satisfaction with inpatient management of CSII therapy
  - 'loss' of insulin pumps removed from patients

OVERVIEW OF CONTINUOUS SUBCUTANEOUS INSULIN INFUSION (CSII) THERAPY

Continuous subcutaneous insulin infusion (CSII, also known as 'insulin pumps') is used by people with type 1 diabetes (T1DM) (and some with type 2 diabetes) to improve glucose control and/or reduce the risk of hypoglycaemia.[1,2] Modern CSII are portable and discrete, and utilise smart technologies, such as bluetooth transmission of capillary glucose level from glucometer to CSII and the ability to download CSII data to a computer for analysis. Examples of commonly used 'pumps' are provided in Appendix 4. Contrary to the hopes of many individuals with T1DM, CSII is not a fully automatic "artificial pancreas", and therefore requires a high level of user involvement.

How it works

CSII involves a continuous basal infusion of short acting insulin (the hourly rate typically varies over a 24-hour period), in combination with meal-time boluses of the same insulin. Both basal and bolus insulin are delivered by CSII, which infuses insulin through a catheter (tubing) or directly via a pod. Both the tubing and pod attach to a fine bore subcutaneous cannula.

The cannula is typically sited in the abdomen, although other sites (arms, legs, buttocks) can also be used, and is changed every 2–3 days. Any short acting insulin can be used (Novorapid/insulin aspart, Humalog/insulin lispro, Apidra/insulin glulisine, Fiasp/faster acting insulin aspart/). The basal infusion rate is pre-programmed by the patient (or their diabetes specialist team) and will continue to run until the insulin cartridge is empty. The basal rates can be temporarily increased/decreased to accommodate fluctuations in blood glucose levels (eg, as a consequence of increased activity or ill health). Boluses are delivered under the patient's direction to cover carbohydrate intake and to correct for high blood glucose levels. Most CSII users make use of an inbuilt 'bolus calculator' which uses known variables for that individual (insulin: carbohydrate ratio, insulin sensitivity and target blood glucose range) in conjunction with situation-specific data (current capillary glucose level, estimated carbohydrate intake and time since last insulin bolus). Some CSII work in conjunction with a continuous glucose sensor to temporarily suspend insulin delivery if hypoglycaemia is developing.

What can go wrong

People on CSII do NOT take any long acting insulin so, if there is

any interruption to insulin delivery (eg, if the cannula is blocked/ dislodged/removed), hyperglycaemia and then ketoacidosis can develop very quickly.

In these situations, the problem has to be identified and rectified, e.g. by re-siting the cannula, changing the tubing, or starting alternative insulin such as an intravenous infusion. Technical problems can occur; the CSII manufacturing companies offer round-the-clock telephone support and are typically able to provide a replacement pump within 24 hours if required. All patients using CSII are advised to retain a supply of their pre- CSII insulin pens for use in an emergency situation, for example, in case of 'pump failure' or damage.

The CSII user in hospital

Unless incapacitated, most people using CSII are safest remaining on CSII if admitted to hospital.[3]

If he/she is unable to manage the CSII and no specialist advice is immediately available, remove the CSII and start a conventional intravenous insulin infusion or s/c basal-bolus insulin regimen. CSII is expensive and steps should be taken to ensure they are not lost when a patient is admitted to hospital. CSII should only be adjusted by its owner (who has received extensive training) or a member of the diabetes team in possession of the correct knowledge and skills.[4] Please discuss all CSII patients with a member of the Diabetes Team.

CSII MANAGEMENT FOR DKA AND THE UNCONSCIOUS/INCAPACITATED PATIENT

See Appendix 1 for summary

It is usually best for the patient to continue to self-manage their diabetes with CSII except:

- If unconscious, confused or incapacitated (eg, if illness/pain prevents self-management)
- If undergoing major procedures under general anaesthetic lasting >2 hours
- Diabetic ketoacidosis (DKA)

The unconscious or incapacitated patient

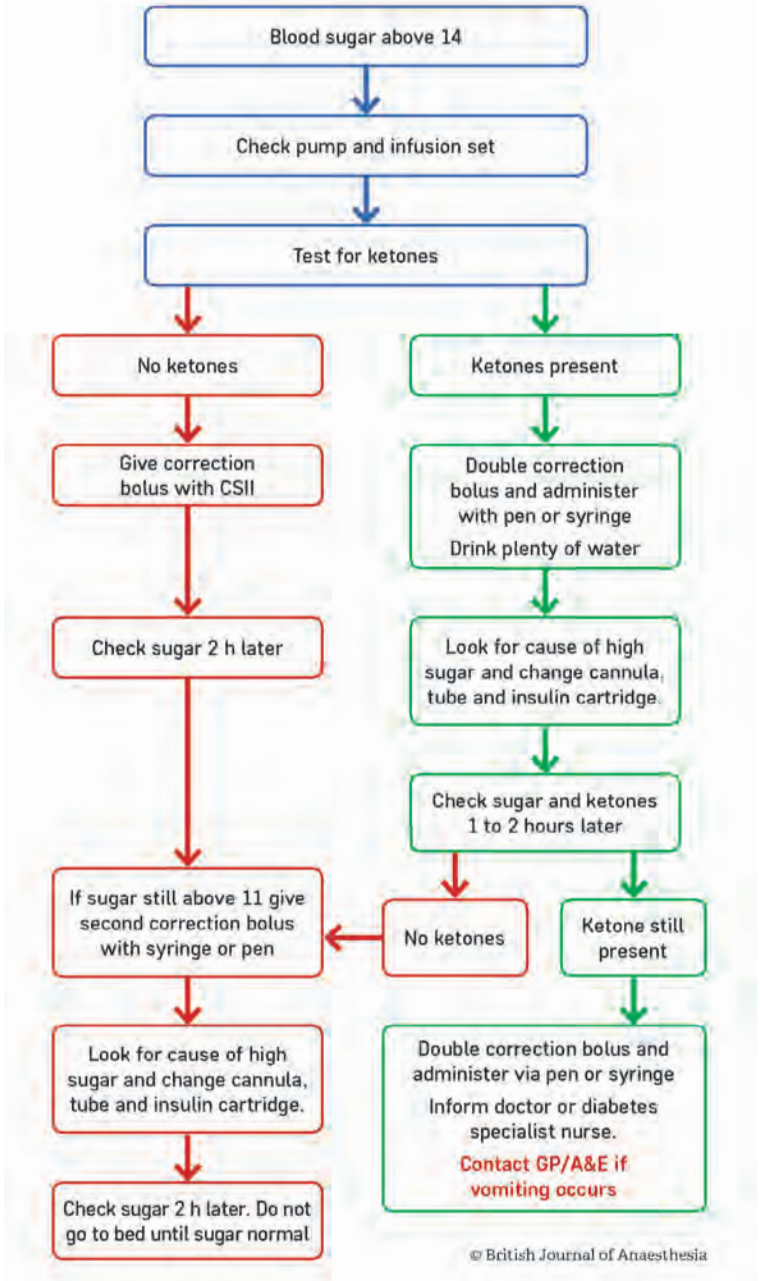
If the patient is unable to self-manage their CSII: detach pump and tubing. Place pump in a safe place and document.

This is the ideal because it allows the diabetes team to subsequently 'interrogate' and adjust the pump. Alternatively, ask a relative to take the pump home for safe keeping. Immediately start alternative insulin e.g. variable rate IV insulin (refer to local guidelines) or subcutaneous insulin (see below:"Alternatives to CSII") unless hypoglycaemic. If hypoglycaemic, start alternative insulin once hypoglycaemia is treated. CSII can be restarted once patient is recovered (see below: "Stopping and restarting CSII").

Diabetic ketoacidosis (DKA)

The altered tissue perfusion in DKA affects insulin absorption, making CSII unreliable. CSII should be temporarily discontinued in patients presenting in DKA: remove cannula/detach pump/pod. For further management, follow standard

Figure 1. Sick Day Rules' algorithm for managing high blood sugar on CSII[5]



DKA protocol. CSII can be restarted once DKA is treated (see below: "Stopping and restarting CSII"). All patients should have specialist diabetes input before discharge to review CSII settings which may need adjusting to prevent subsequent DKA and to re-enforce 'Sick Day Rules'.

Managing high glucose levels

Patients admitted to hospital often have elevated blood glucose levels due to illness and stress. They should use their standard 'Sick Day Rules' to manage these glucose values. If they do not have their own system, or are too unwell to manage them, then a simple algorithm is outlined in Figure 1.

CSII AND RADIOLOGY INVESTIGATIONS

Current manufacturer's guidelines state that CSII must be suspended and removed along with any metal cannulae prior to MRI, CT scan, X-ray or any other type of exposure to radiation, and should not be taken into the scanning room. However, it is likely that some of this advice is based on lack of evidence rather than evidence of harm. Therefore, these guidelines should be individualised by each centre. Many centres continue the use of CSII for non-magnetic imaging such as X-ray and CT scans.

The patient should reconnect CSII immediately following any radiological investigation. CSII can be safely suspended/removed for up to an hour at a time without needing alternative insulin. A correction bolus may be needed on reconnecting the pump (see below: "Stopping and re-starting CSII").

CSII MANAGEMENT FOR SURGERY

See Appendix 2 for summary

Fasting is not usually a problem for CSII users, so being 'nil by mouth' does not necessarily mean removal of CSII or need for IV insulin.[6] Most patients will be able to manage their CSII post sedation/anaesthesia as safely as any patient using standard insulin pen injection therapy, and are more likely to achieve stable glucose control. Hence it is not necessary to admit day-case patients overnight for variable rate IV insulin infusion simply because they manage their diabetes by CSII. However, some patients will feel unable to self-manage post-procedure and should discuss this with their diabetes team in advance; they may require alternative management such as prior conversion back to insulin pens (see below: "Alternative insulin regimens") or hospital admission. If continuing on CSII, patients should ensure SC CSII cannula is sited away from the operative site and accessible to the healthcare team.

Major surgical procedures (>2 hours duration, or where they are likely to miss more than one meal, or surgery requiring diathermy)

Patients should remove their CSII for these procedures, and this should be stored safely. Once the CSII is removed, start variable rate IV insulin infusion immediately (refer to local guidelines). CSII can be restarted once the patient has recovered and able to manage it (see below: "Stopping and restarting CSII").

Minor procedures (<2 hours and expected to eat/drink within 2–3 hours) under general anaesthetic or sedation

Patients should ensure blood glucose is in the acceptable range pre-procedure – that is, ideally 6-10 mmol/L but 4–12 mmol/L is acceptable with more frequent testing. If glucose is not in the acceptable range, then one round of bolus correction via the CSII is allowed before starting variable rate IV insulin (as for major surgical procedures). Whilst on CSII (or VRII), the healthcare team must monitor the patient's capillary glucose levels at least hourly. Post-procedure, the patient on CSII should also use a correction bolus if capillary glucose is >10 mmol/L. Consider starting VRII if BG is >12 mmol/L.[7]

If the CSII alarms during the procedure, do not attempt to rectify; monitor blood glucose every 30 min and start IV insulin if >12 mmol/L. If the CSII alarm becomes intrusive, remove CSII plus cannula, allow CSII to continue to run (the amount of insulin 'lost' is minimal) and store safely.

If VRII is used during the procedure, see below for transferring back to CSII ("Stopping and restarting CSII"); a correction bolus is less likely to be required in this situation.

Minor procedures without sedation

The CSII can be continued with regular glucose monitoring as for any person with diabetes.

CSII MANAGEMENT FOR PREGNANT WOMEN

See Appendix 3 for summary

Introduction

The goal of insulin therapy in diabetes management during pregnancy is to maintain blood glucose levels as close to normal as possible in order to improve the outcome of pregnancy and reduce the risk to both mother and baby. The aim of glycaemic control for delivery is to safely maintain near-normal glucose levels until delivery and to safely manage the transition to post-delivery when insulin requirements fall and there is an increased risk of hypoglycaemia.[8]

Antenatal and postpartum care

Obstetric care will follow established protocols for patients with diabetes. The diabetes team are responsible for CSII management including glycaemic control and addressing any educational needs.

Inpatient use of CSII

Please inform the Diabetes Specialist antenatal team of any pregnant woman using CSII therapy admitted to hospital.

CSII may continue providing the patient or partner is able to self-manage the CSII and perform the required blood monitoring.

Inpatient use of steroids during pregnancy

- Please inform the Diabetes Specialist antenatal team before (or as soon as possible after) steroids are started.
- CSII may continue. The Diabetes Specialist antenatal team will instruct the patient regarding any change in CSII settings. A temporary increase in basal rate of 30% or more may be required, and needs to be individualised based on patient requirements
- Patients will be responsible for the management of CSII and glucose testing.
- Patients will be required to test their glucose levels 1–2 hourly; levels of 4–7.8 mmol/L should be aimed for.
- If glycaemic targets are not achieved, midwifery or obstetric staff should contact a DSN or Diabetes Consultant. Consider commencing VRII (without IV glucose). This should be prescribed in advance where possible. Note: CSII may be continued alongside VRII in this situation.

Managing glycaemic control through delivery in women with type 1 diabetes on CSII

Women on CSII may be converted to VRII plus glucose for delivery (traditional management). Women who choose may continue to use their CSII through delivery, provided their blood glucose levels are within the target range of 4–7 mmol/L and the patient/partner is able to manage their CSII. The decision regarding the patient's suitability to self-manage CSII through delivery will be made by the diabetes specialist antenatal team and documented in the patient's case sheets. The diabetes team will educate the woman and her partner and provide written instructions regarding cannula siting, guidelines for using CSII through delivery, and situations where CSII treatment may need to be discontinued and traditional management instigated with VRII plus IV glucose. The individualised VRII should be prescribed in advance.

Staff responsibilities

While the woman remains on CSII, the patient and her partner are responsible for checking glucose hourly, giving corrections via CSII, adjusting basal rates and other pump settings as required including at delivery. The midwife is responsible for ensuring the patient/partner remains able and willing to manage their CSII, that glucose is checked and documented hourly and that, if glucose is persistently (see below) above 7mmol/L, VRII plus IV glucose is started and the CSII stopped.

Once the patient is on VRII plus glucose, the midwife is responsible for checking glucose hourly and adjusting VRII rates as prescribed.

Protocol for managing glycaemic control through delivery using CSII

Measure and record blood glucose levels hourly using approved hospital blood glucose meter. The patient should continue her usual basal infusion rates, aiming to keep blood glucose levels between 4 and 7mmol/L. Bolus correction doses should be made by the patient via CSII to maintain target blood glucose levels of 4–7mmol/L.

If the patient/partner is unable to manage CSII or if blood glucose >7mmol/L for >2 hours despite correction doses, switch from CSII to individualised VRII plus IV glucose. (Remove CSII and tubing and place in suitable container; no need to turn off CSII or to remove SC cannula).

Correction doses during labour

If blood glucose is >7mmol/L, a correction bolus dose should be given via CSII, aiming for a blood glucose of 5mmol/L, using the patient's personal correction factor (also known as "ISF" = insulin sensitivity factor) or, if not known, calculate 1 unit of insulin to reduce blood glucose levels by 2.5mmol/L e.g. if blood glucose 10.0 mmol/l, give 2 units bolus. After 1 hour, if that correction bolus is ineffective (ie, blood glucose still above 7.0 mmol/L), another correction bolus dose should be given via CSII (using the same calculation advice as above). After a further half hour, if blood glucose levels still not below 7.0 mmol/L, then switch to VRII plus IV glucose as above.

Hypoglycaemia during labour

If blood glucose <4.0 mmol/L, treat hypoglycaemia as per hospital policy. If the woman has one unexplained hypoglycaemic event, she should reduce her current basal rate by 25–50% using a temporary basal rate setting. If having further episodes of hypoglycaemia despite original reduction, she should reduce by another 25% or more as required. A lower basal rate is usually required throughout the rest of labour. After delivery, the basal rate should change to the post-delivery basal rate which should have been defined.

Post-delivery

Planned post-delivery CSII settings should be determined towards the end of pregnancy, in conjunction with the diabetes team, and documented. The basal profile is typically the same as the pre-pregnancy basal profile, often with a 10–20% reduction, or if CSII started during pregnancy, 50% of pre-delivery basal rates. This post-delivery basal profile can be entered into the pump memory in advance. The planned post-delivery insulin:carbohydrate ratio, ISF and targets will need to be programmed after delivery but before the first bolus dose.

If there is no documentation of post-partum doses, then the basal rate can be set to 0.5 units/hour, insulin:carbohydrate ratio 1:15 g, ISF 4mmol/L and BG targets 6–8 mmol/L. These should be reviewed and adjusted in conjunction with the diabetes specialist team before discharge.

If the women continues on CSII for delivery, the basal rate should be changed to the planned post-delivery basal rate immediately at delivery and the bolus calculator settings changed as soon as possible but before the first bolus dose.

If managed with VRII, CSII can be recommenced once the patient is able to self-manage the pump. Ensure all pump settings are changed to post-delivery settings as above. The VRII should continue for 60 minutes after restarting CSII.

For women who are breastfeeding, settings may need reducing by a further 10–20% or even more as feeding is established.

HYPOGLYCAEMIA IN PATIENTS ON CSII

Patients able to manage their CSII

Treat hypoglycaemia according to local protocol, and this is likely to include rapid acting carbohydrates (eg, dextrose tablets). Unlike patients on long acting insulin, follow-up with long acting carbohydrates is not usually needed. CSII infusion rates may need adjustment, especially if there is a history of recurrent hypoglycaemia: consult diabetes team.

The unconscious/incapacitated patient

Initial treatment of hypoglycaemia is as standard local protocol. If persistent hypoglycaemia occurs, remove cannula and pump. Once normoglycaemic, re-start insulin, either CSII if patient now alert and able to self-manage or alternative regimen (see below); this is needed to prevent the development of ketoacidosis.

STOPPING AND RE-STARTING CSII

Stopping

The pump together with its tubing may be removed leaving only the SC cannula in place, unless the cannula site is infected or in the surgical field. Clearly this will not apply to CSII without external tubing such as the Omnipod®. It is important not to cut tubing or disconnect the pump from the tubing as the remaining insulin in the tube may infuse quickly risking hypoglycaemia. Place the CSII into a suitable container and do not attempt to turn off; the amount of insulin 'lost' into the container will be minimal. Document where the CSII is stored, or to whom it has been given. The insulin in a CSII is very short acting therefore alternative insulin must be started immediately i.e., within an hour (see below) to avoid risk of ketoacidosis. If the patient is able to do so, he/she should make a record of their current basal and bolus settings as the data may be lost if the pump is stopped for any significant length of time.

Re-starting

The person with diabetes is ideally best placed to re-start the CSII because they will have received training in this process and will be experienced. If this is not possible, and CSII has been only temporarily removed or suspended (ie, no IV insulin infusion has been required) and the SC cannula is still in position, the patient should perform a 'fixed prime' to refill the dead space within the tubing, then simply reconnect the CSII and re-start basal infusion. If capillary glucose is >10 mmol/L, he/she should bolus a correction dose once the CSII is re-connected using their personal correction ratio or ISF (insulin sensitivity factor).

If transferring from IV insulin infusion: ask the patient to insert a new cannula and re-start the CSII after performing a fixed prime (there is no need to wait until a meal); wait 60 minutes before discontinuing IV insulin.

If transferring from SC insulin: the patient inserts a new cannula, performs a fixed prime and re-starts the CSII. The CSII settings may need to be re-programmed. The patient may need to temporarily reduce the background insulin infusion rate (eg, drop to a 70% temporary basal rate for 24 hours) while long acting SC insulin is still active; increased glucose monitoring may be required. No further SC insulin doses should be required once CSII is re-started. Re-check blood glucose 1–2 hours after CSII re-start. Contact the Diabetes Team for further advice.

ALTERNATIVE INSULIN REGIMENS FOR HOSPITALISED PATIENTS UNABLE TO CONTINUE ON CSII

All the guidance below should be used in accordance with local guidelines and protocols

The appropriate alternative insulin regimen depends on the clinical scenario:

- For patients with DKA, use a fixed rate IV insulin infusion as per local guidelines.
- For patients who are fasted and/or have unstable glucose levels (but not DKA), use aVRII as per local guidelines.
- For patients who are unable to self-manage their CSII but do not have unstable blood glucose levels and are not NBM, a basal bolus insulin regimen is preferable to VRII.

How to calculate multiple daily injection insulin requirements

Calculate appropriate starting doses based on the patient's recent (e.g. 7 day) average total daily insulin dose (TDD); this information can be obtained by the patient or DSN from the pump.

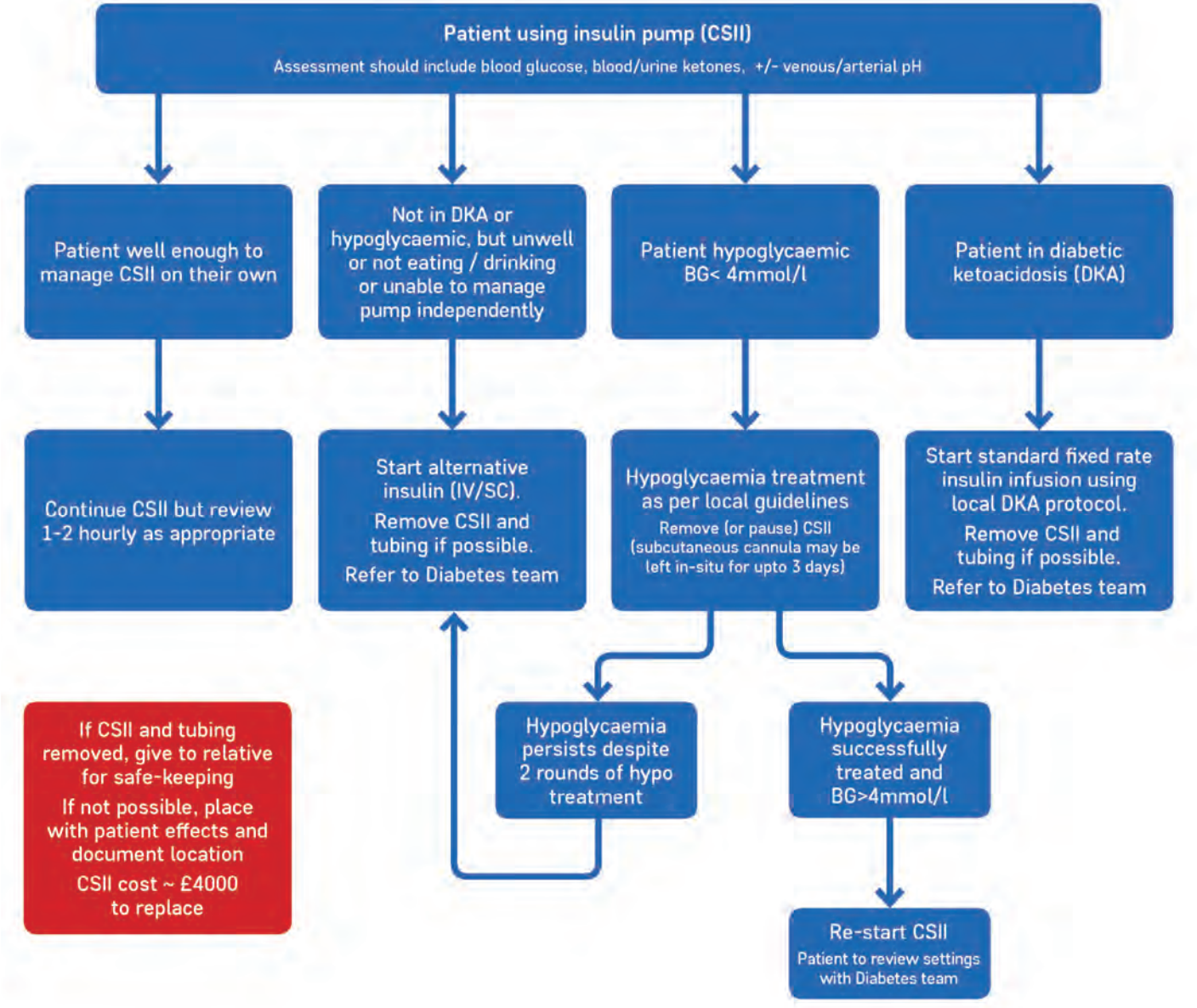
- Prescribe 50% of the TDD as Levemir insulin (as per NICE guidelines), initially split equally in a bd insulin regime
- For meal-time (rapid acting) insulin dose: 50% of TDD/3 plus a safety adjustment (e.g. minus 30%) to minimise risk of hypoglycaemia. Titrate doses according to response. Alternatively, if the patient is able to continue to carbohydrate count, prescribe a variable dose for self-administration.
- E.g. a patient's average CSII insulin TDD for last 7 days is 48 units/day. 50% of 48 units = 12 units bd daily Levemir® insulin. 50% of 48 units/3 = 8 units of rapid acting insulin with each meal: after safety adjustment = 6 units. If the patient is trained in carbohydrate counting (and they often are), it would be preferable for them to inject insulin doses according to their insulin: carbohydrate ratio.

References

1. NICE. Diabetes Insulin Pump Therapy–Continuous subcutaneous insulin infusion for the treatment of diabetes. TA151 2008
2. Diabetes UK. Insulin Pump Therapy Position Status. 2011
3. Noschese ML, DiNardo MM, Donihi AC, *et al*. Patient outcomes after implementation of a protocol for inpatient insulin pump therapy. *Endocr Pract* 2009;**15**(5):415–24. doi: 10.4158/EP09063.ORR
4. Anstey J, Yassaee A, Solomon A. Clinical outcomes of adult inpatients treated with continuous subcutaneous insulin infusion for diabetes mellitus: a systematic review. *Diabet Med* 2015;**32**(10):1279-88. doi:10.1111/dme.12740. Epub 2015 Mar 31.
5. Partridge H, Perkins B, Mathieu S, Nicholls A, Adeniji K. Clinical recommendations in the management of the patient with type 1 diabetes on insulin pump therapy in the perioperative period: a primer for the anaesthetist. *Br J Anaesth* 2016;**116**(1):18–26.
6. Boyle M, Seifert K, Beer K, *et al*. Guidelines for application of continuous subcutaneous insulin infusion (Insulin Pump) therapy in the perioperative period. *J Diabetes Sci Technol* 2012;**6**:184–90.
7. Sobel SI, Augustine M, Donihi AC, Reider J, Forte P, Korytkowski M. Safety and efficacy of a peri-operative protocol for patients with diabetes treated with continuous subcutaneous insulin infusion who are admitted for same-day surgery. *Endocr Pract* 2015;**21**(11):1269–76. doi: 10.4158/EP15727.OR
8. Drever E, Tomlinson G, Bai AD, Feig DS. Insulin pump use compared with intravenous insulin during labour and delivery: the INSPIRED observational cohort study. *Diabet Med* 2016;**33**(9):1253-9. doi: 10.1111/dme.13106

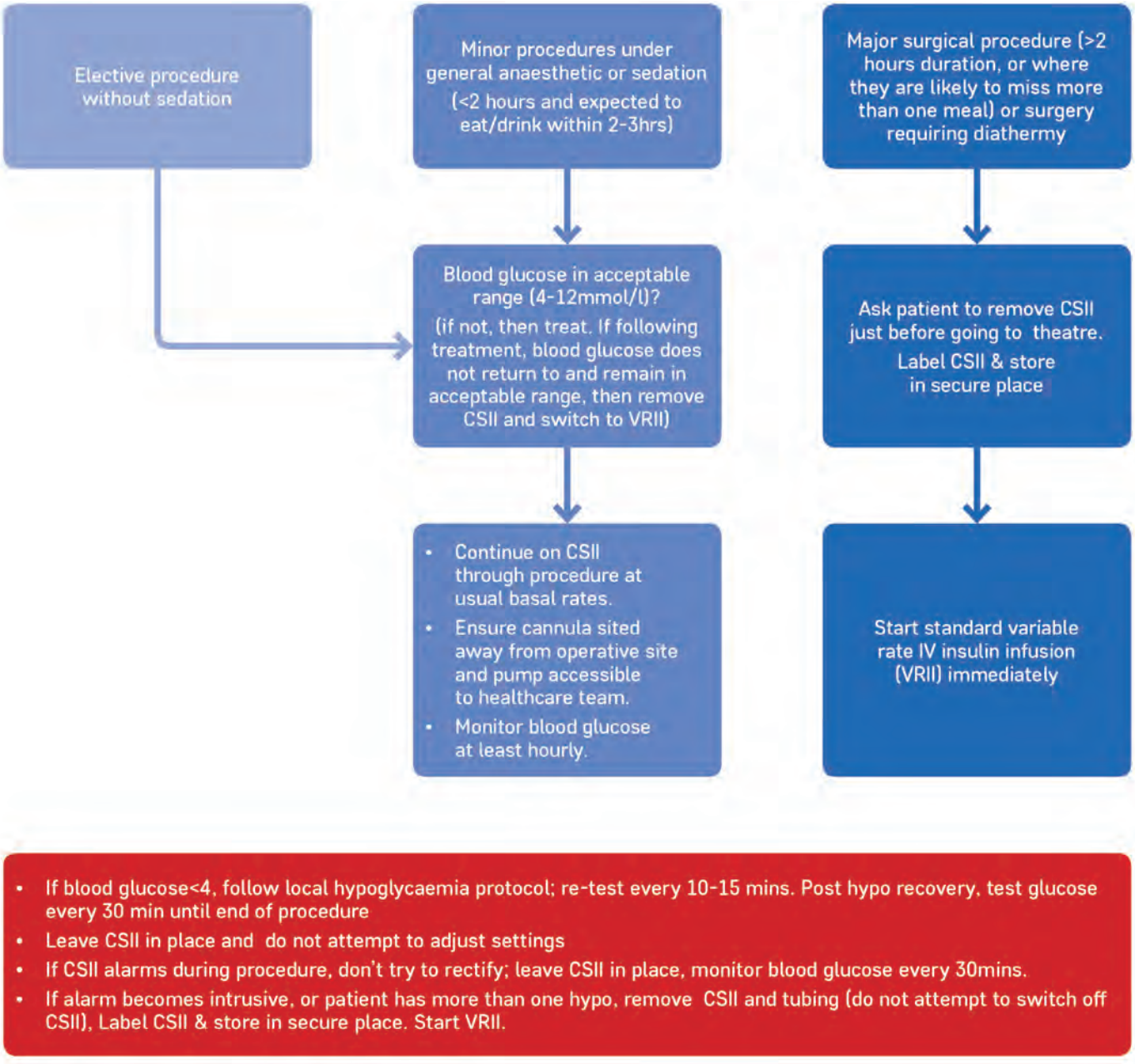
APPENDIX 1

EMERGENCY ADMISSIONS AND CSII MANAGEMENT:



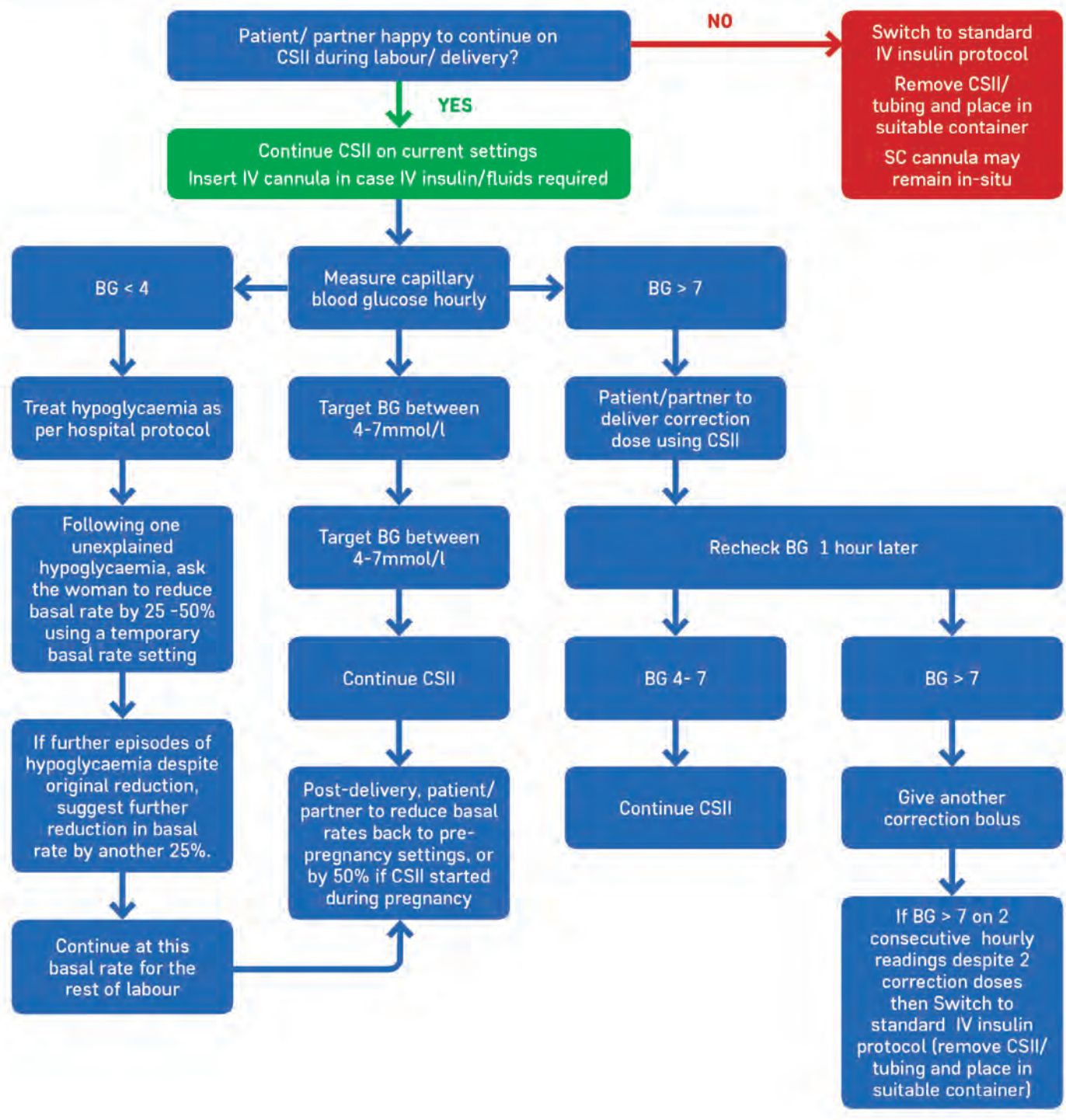
APPENDIX 2

CSII MANAGEMENT FOR ELECTIVE SURGICAL PROCEDURES UNDER SEDATION OR ANAESTHESIA



APPENDIX 3

WOMEN USING CSII ADMITTED IN LABOUR OR FOR ELECTIVE CAESAREAN SECTION



APPENDIX 4

COMMONLY USED PUMPS

Information subject to change but correct at time of printing

Medtronic 640/670G pump with linked Contour meter

Omnipod Dash pump and handset

Tandem t:slim X2 pump

Roche Accu-Chek Insight pump and handset

Dana Diabecare RS pump

Roche Accu-Chek Combo pump

*Sensor augmentation option

Continuous subcutaneous insulin infusion (CSII) A guide to service requirements

CONTRIBUTORS

Leads

Dr Sufyan Hussain, *Consultant Diabetologist, Guy's and St Thomas' NHS Trust, London*
Dr Vernon Parfitt, *Consultant Diabetologist, Southmead Hospital, Bristol*
Dr Emma Wilmot, *Chair, ABCD Diabetes Technology Network UK, Consultant Diabetologist, Derby Teaching Hospitals NHS Foundation Trust, Derby*

Working group

Dr Pratik Choudhary, *Senior Lecturer, King's College London, London*
Dr Rob Gregory, *Consultant Diabetologist, University Hospitals of Leicester, Leicester*
Geraldine Gallen, *Diabetes Specialist Nurse, King's College London, London*
Chris Headland, *Diabetes Specialist Nurse, Wales National Insulin Pump Co-ordinator, Wales*
Dr Peter Hammond, *Consultant Diabetologist, Harrogate*
Dr Peter Jennings, *Diabetes Specialist Nurse, Derby Teaching Hospitals NHS Foundation Trust, Derby*
Dr Lala Leelarathna, *Consultant Diabetologist, Manchester Royal Infirmary, Manchester*
Prof Nick Oliver, *Wynn Professor of Human Metabolism & Consultant Diabetologist, Imperial College Healthcare NHS Trust, London*
Dr Neil Walker, *Consultant Diabetologist, Royal Devon and Exeter NHS Foundation Trust*

CONTENT

FOREWORD

Since the advent of CSII in the management of diabetes several decades ago, the UK has seen a remarkable growth in the use of CSII in routine clinical management of people with type 1 diabetes. This has been largely possible due to the availability of robust technological advances and also evidence gathering supporting the use of this technology for the benefit of people with type 1 diabetes. The role of CSII in the management of the sub-category of people living with diabetes who meet the NICE guidance is now well established. At the same time, we have seen an expansion in the availability of CSII in the UK; it is quite comforting to know that most, if not all, specialist diabetes teams in the UK are able to provide care to people who are treated with CSII. However, the data gathered through the National Diabetes Insulin Pump audit clearly show that the availability of CSII services and the quality and outcomes of those using insulin pump treatment varies within the UK. Clearly, further progress needs to be made in addressing these inequalities in the provision of CSII services in the UK.

The availability of the current guidance produced by the "Insulin Pump Experts" under the guidance of the DTN- UK represents an important first step in improving the quality of CSII services. This document, which is comprehensive in its scope, not only provides a way forward for teams and clinicians in starting the CSII services in their patch but also in benchmarking their services so that further progress and improvements can be made where CSII services are already established.

As someone who has provided CSII services in my own patch, I welcome and commend this excellent document. I feel this guidance will go a long way in improving the quality of care we provide to people with type 1 diabetes, which they richly deserve and when other methods of treatment such as MDI have failed to achieve individualised targets and improve quality of life further.

All of us, as specialists in diabetes, should thank the lead authors and the working party for producing this excellent document.

Dinesh Nagi
Consultant in Diabetes & Endocrinology, The Mid Yorkshire Hospitals NHS Trust Chairman, Association of British Clinical Diabetologist (ABCD)

OBJECTIVES

This guide is based on consensus from clinicians looking after more than 7000 adult insulin pump patients in the UK. It aims to define the requirements and principles for setting up and running a high quality and efficient insulin pump (CSII) service.

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.

The indications for CSII, as recommended by NICE TA151,[1] are: 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 (HbA_{1c}) levels with multiple daily injections (MDIs) result in the person experiencing disabling 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)
> or
> HbA_{1c} levels have remained high (that is, at 69 mmol/mol (8.5%) or above) on MDI therapy despite a high level of care.

The use of insulin pumps in the UK adult diabetes services ranges between 6% and15% and has increased considerably following the introduction of the NICE recommendations in 2008.

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.

This guide explores the service requirements of CSII therapy including essential and desirable service requirements, organisation and capacity considerations, pathways, programmes and data requirements.

INSULIN PUMP SERVICE REQUIREMENTS

Table 1 is a summary of the essential (E) and desirable (D) requirements for an adult insulin pump service based on consensus of the working group and taking into account variations in resources, skillset and staff.

Workforce requirements

The core multidisciplinary team (MDT) providing the pump service should include pump trained:

- Consultant diabetologist
- Diabetes specialist nurse*
- Diabetes specialist dietitian*
- Access to clinical psychology services with interest and experience of diabetes-related issues. In addition to direct referrals, this should include case-discussions with an integrated member of the psychology team.

* A diabetes educator role (trained in structured education and pump therapy with intensive insulin management skills) can be fulfilled by either a diabetes specialist nurse or dietician or both. The nurse and dietitian should ideally be trained so that both can function as diabetes educators and are competent to see pump patients independently.

There is a requirement for a wider framework of 'pump-aware' team members who have training in the management of pump-specific problems such as set failures, pump failures, inpatient and antenatal support.

Competencies

The pump service MDT should be formally trained in the use of insulin pump therapy and other diabetes technologies. Staff competencies need to be continually updated. Routine in-house pump updates are recommended to ensure the whole team remains up to date.

Table 1 Summary of essential (E) and desirable (D) requirements for an adult insulin pump service

Workforce (staff) requirements:	
• Dedicated consultant-led multidisciplinary team trained in the use of pump therapy	E
• Psychology link via MDT	E
• Access to wider diabetes team e.g. podiatry, renal, ophthalmic, antenatal services	E
• On-going staff training in diabetes technology	E
• Diabetes Coordinator/Technician/Administrator	D
Organisation and capacity of pump service:	
• 30 min follow-up, 30–45 min new patient appointment slots for both consultant and educator (nurse/dietician)-led clinics	E
• 15 min virtual clinic slots educator (nurse/dietician) clinics	E
• Capacity of at least 3 face-face appointments per pump user per year with extra provision for 3 virtual appointments per pump user per year	E
• Regular planned pump MDT meetings	E
• Rapid access facility	E
Pathway, protocols and programmes:	
• Access to type 1 diabetes-specific education programmes	E
• MDT pathway for referral for consideration of pump therapy	E
• Insulin pump initiation and follow-up protocol	E
• Insulin pump renewal process	E
• Access to insulin pump-specific education programmes	E
• Topic specific education groups*	D
• Fast track insulin pump initiation for select cases	E
• Out of hours clinical support pathway	E
• Peer support groups	D
• Protocols for inpatients	E
Informatics and data requirements:	
• Insulin pump/meter/sensor download facility	E
• Pre-consultation download (eg, via Diasend/Carelink)	D
• Pre-consultation patient questionnaire (see online appendix)	D
• Database to capture clinical and pump-related information (see online appendix)	E
• Structured template for letters (see online appendix)	D
• IT infrastructure to enable virtual consultations (telephone, email, webcam)	E
Consultation and support tools:	
• Individual targets and holistic goals	E
• Structured review process in clinic (see online appendix)	D
• Guide to downloads and reviewing downloads for people with diabetes	D
• Point of care HbA_{1c} testing	D
Funding agreements and contractual arrangement:	
• Access to several pump types	D
• Funding agreements in place for all patients fulfilling NICE criteria	E

* Topics include exercise, carb-counting refreshers, technology updates, advanced pump and sensor use, psychology and diabetes

ORGANISATION AND CAPACITY

Organisation

The pump service should be integrated within the wider type 1 diabetes service. The following range of patient contacts needs to be provided:

1. Face to face appointments: Attendance at consultant-led clinics, reviews by diabetes educators (nurse/dietitian) or psychologist outside these clinics.
2. Remote consultations: Usually with the diabetes educators via telephone, webcam appointments or email.

Clinic set-up and structure

There are two main clinic sub-types for face to face consultant-led clinics. The most appropriate one depends on the size of the pump service, healthcare professional skillset and other local circumstances. Many services have both:

1. Dedicated consultant-led multidisciplinary insulin pump clinic. This can include specific clinic types (eg, young adult pump clinic, new referrals, etc).
2. Insulin pump patients mixed in with patients on MDI in specific multidisciplinary diabetes clinics (eg, intensive type 1 diabetes, complex diabetes, young adult, antenatal, etc).

In larger centres and with the proliferation of a range of diabetes technologies as well as increased uptake of pumps, there is a shift towards insulin pump patients being seen in clinics with patients on MDI.

Clinic template list size and set-up

Regardless of the clinic set-up and structure, the essential criteria detailed in Table 1 need to be met. This includes longer appointments for pump patients. The consensus from across the working group is:

- 30 min for follow-up
- 30–45 min for new patients

The precise list size and template is dependent on the models used for the MDT clinic shown in Table 2. Some models (eg, Models 3 and 4) will require extra capacity for ad hoc reviews by more than one MDT member to deliver the desired efficiencies. The clinic list template must also take into account time needed for post-clinic MDT meetings (essential requirement for Models 2–5).

Models of CSII service delivery

Having every appointment multidisciplinary is very resource intensive, so single clinician appointments should be used when appropriate. The service should try and use their resources appropriately to match the right person to the right consultation. The team must retain mechanisms to communicate updates on patients within and outside the clinic (see Table 2).

All models require a joint collaborative working relationship between the multidisciplinary team and

Table 2 Models of CSII service delivery

	MODEL 1	MODEL 2*	MODEL 3*	MODEL 4*	MODEL 5*
	All patients seen simultaneously in a joint MDT appointment (doctor, nurse, dietician)	All patients seen by each member of the MDT individually and sequentially in a one-stop shop fashion	Patients seen by one or more MDT team members at each appointment matched according to need	Mixture of MDT and single clinician appointments	Group diabetes educator sessions with individual scheduled appointments
Pros	• Joined up thinking • MDT support for consultants • Good team learning • May not require post-clinic meeting	• Clearly defined roles for each MDT member	• Efficient • Allows multiple short contacts • May allow second opinions and additional insights into care	• Enables MDT appointments and their advantages which are necessary for some patients • Gives flexibility and efficiency	• Patient peer support • Effective use of educator team time
Cons	• Resource heavy • Can be intimidating for the patient	• Longer visit time for patient who may feel overwhelmed by having 3 appointments in 1 session • Can result in unnecessary duplication	• Difficult to maintain relational continuity • Patient may not be triaged to appropriate MDT member • Post-clinic MDT meeting required	• Patients need to be scheduled to the appropriate type of appointment in advance	• Personal matters difficult to discuss in group setting • Not all patients are supportive of having group appointments • Targeted reviews and education cannot be delivered
Suggestions	• Possibly more appropriate for teams starting a new pump service with small patient numbers	• Intra-clinic communication between team members needed to make this work well	• Matching correct MDT skills to correct patient may require pre-clinic triage process • All team members need to be able to function as diabetes educators and see pump patients independently	• Relies on a clinic list template to support the above	• Group sessions can be used as an adjunct to shorten appointment duration in MDT reviews • For reasons above they may not be a replacement for MDT reviews

* Post-clinic meeting and capacity for brief 'ad hoc' intra-clinic reviews or discussions essential.

flexibility to share or switch patients between individual lists. As most hospital electronic health record systems have not reached a maturity to support this set-up, for large clinics we recommend an administrator. This is to maintain aspects of clinical governance, follow-up appointment coordination, capturing activity, keeping patient details (eg, pump, warranty status, consumables) updated.

Joint (Model 1) or Sequential (Model 2) MDT appointments are recommended for the following:

- New patients referred for an assessment for an insulin pump
- New patients already on a pump transferring from another centre or transitioning from a paediatric service
- Patients approaching 4-year warranty renewal, to review the appropriateness of continuing
- When considering withdrawal of pump therapy
- Where the skillset within a team is developing as in Model 1 above.
- Hypoglycaemia unawareness
- Complex cases

Virtual clinics

Virtual clinics or remote consultations utilise telemedicine to deliver patient care. The benefits include:

- Improved engagement, quality of care and support to patients
- Easily accessible appointments where burden of travel and waiting time are reduced
- Reinforce patient self-management and behaviour change by increasing patient contact and thereby improve quality of care and support
- Reduced overhead costs of running a clinic (eg, does not require receptionist staff, pre-clinic assessments or clinic space)
- Potentially reduce the number of visits needed per year

Requirements

- Dedicated clinic space for webcam and telephone clinic (noise proof)
- IT set-up for downloads, email and webcam clinics
- Remote downloads by patient (eg, via Diasend, Libre link view, Medtronic carelink, Dexcom clarity, etc).

- Administrator to help with download set-up, consistency, email administration and clinical governance including capturing activity for remuneration
- Support for documentation in letter as for face to face clinic contacts
- Use can be formally scheduled as part of a virtual telephone or Skype clinic or occur individually as required
- Telephone or webcam consultations would typically take 15 min; however, additional time for administration (eg, time for set-up, capturing activity, documentation, etc) and review of downloads will be required

Job planning

For all disciplines involved, this should account for time spent on the following activities:

- Outpatient clinics and administration time
- Additional or ad-hoc face to face contacts
- Virtual clinics and remote consultations including telephone, emails and administration time for these activities
- Reviewing and analysing pump and meter downloads
- Preparing, supporting and running patient group education sessions
- Clinical and service MDT meetings
- Ongoing staff training

Capacity

Frequency of contact

The Diabetes Control and Complications Trial has demonstrated that intensive therapy with regular contact with healthcare professionals can improve diabetes control and reduce the risk of long-term complications.[2]

The paediatric best practice tariff is based on 3 MDT clinics and 8 contacts per year, and the award winning Diabeter model from Rotterdam uses an average of 8–10 contacts per year and achieves outstanding results.

The mixture of face to face and virtual clinics can be individualised depending on patient needs.

We would recommend the clinic bases capacity requirements on an average of 3 face to face visits per patient per year and 3 virtual or remote consultations per year.

For example, for patients who are well controlled and do not have increased care needs an annual follow-up may be sufficient, and for those who need extra support, more frequent follow-up and virtual support will be required.

Using HbA_{1c}, hypoglycaemia risk and diabetes distress scoring can help stratify those needing more support. A recent study from King's College London showed that those with high HbA_{1c} had higher diabetes distress. Allowing them more contacts was associated with reductions in diabetes distress as well as HbA_{1c}. These patients had an average of six contacts (three face to face and three virtual per year).[3,4]

In addition to this, referrals for consideration of pumps, pump initiation protocols, rapid reviews and fast track pump initiations (eg, in pregnancy) all need to be factored in when planning a service. For example, in the first year after starting a pump, frequent contact and support will be required over the first few months, plus several virtual/remote consultations to support effective use of pump therapy (see CSII Pathway in Figure 1).

Clinical MDT meetings

Clinical MDT meetings are essential for discussing cases. For multisite services we recommend a single MDT to ensure ongoing quality improvement, accountability, promoting good and consistent working standards whilst offering high-level expertise to all patients. For larger services this should be held separately to clinics with cases emailed to an MDT coordinator. Trainee or junior staff cases can be supervised by the lead clinician as part of routine intra- or post-clinic discussions and referred to the MDT as per criteria for discussion.

Examples of patients to be discussed at the MDT meeting:

- Discuss referrals for pump initiation
- MDT review 3–6 months after starting pump therapy
- Prior to renewal of pump warranty
- When considering withdrawal of pump therapy
- Complex, challenging and difficult cases, problems or situations
- Inpatient admissions and antenatal issues
- Cases requiring psychology or other MDT input
- Problematic hypoglycaemia (impaired awareness of hypoglycaemia or severe hypoglycaemia)

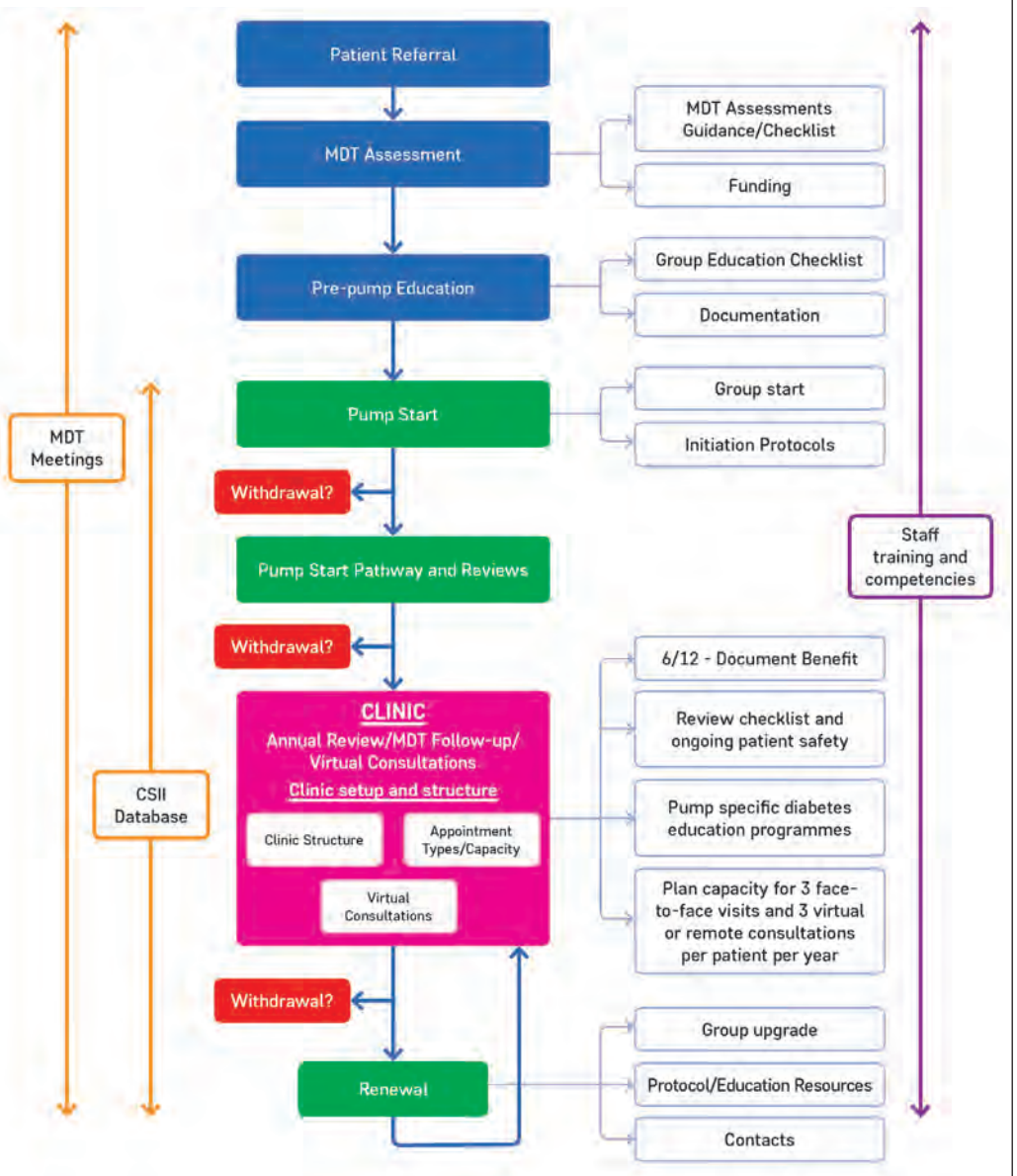
Depending on local service structures and healthcare professional skill set, other patient groups may need to be included such as pre-conception, pregnancy, transplant.

Service development MDT meetings (specific for type 1 services)

Service development meetings specific to the type 1 service should also discuss the following pump-related service issues regularly (eg, quarterly). These should be held separately to clinical MDT meetings with involvement of service managers:

- Audit planning and reflection
- Service development
- Safety: individual patient safety concerns, device concerns, mortality and morbidity
- Staff development: sharing of best practice, guideline development, education, mentorship and quality assurance

Figure 1. CSII Pathway



PATHWAY AND PROGRAMMES

Access to type 1 education programmes

This is an essential requirement for any service looking after people with type 1 diabetes. People with type 1 diabetes referred for consideration of pump therapy must demonstrate adequate diabetes education, experience and understanding of functional insulin therapy (carbohydrate counting principles) and will usually have completed structured education (eg, DAFNE). For those established on insulin pump therapy who have not had previous access to structured education, there are pump-specific courses available (eg, DAFNE Pump curriculum).

Insulin pump annual review

Pump (and CGM) download should be reviewed, printed and given to the insulin pump user annually to ensure they have a complete record of all settings necessary to programme a new pump. Care processes, risk management and long-term care planning should also be included. A checklist and template for annual review is included in the online appendix.

Out of hours support pathway

All pump users should be educated on how to deal with clinical diabetes emergencies or technical pump problems out of hours, with written algorithms based on the local service model available and advice on when to attend the emergency department. They should be given emergency contact details which they should carry with them at all times. This should be reviewed and revised annually. For technical pump problems out of hours, patients should be advised to use the insulin pump manufacturer's 24-hour technical support line.There should be a clear point of contact for any clinical problems during working hours.

Some larger centres may be able to provide a 24-hour, 7-day emergency advice service to deal with clinical problems and offer support out of hours. This is an ideal solution. It may not be feasible to offer this from a single centre for most services, however working with other local centres and a commissioning structure could enable this.

Inpatient and emergency department support

Diabetes teams should ensure that pathways and algorithms are in place in emergency departments to manage patients on pumps presenting as emergencies out of hours. Regular

education on this is also desirable. Emergency departments must have a mechanism to inform the diabetes team of any emergency department patient encounters. This will allow the diabetes team to contact the patient during working hours. Further details can be accessed from the DTN-UK Guide for Managing CSII Therapy in Hospitalised Patients.[5]

When insulin pump users move locatione

When a pump user moves to another part of the country they should be encouraged to obtain 6 months of pump consumables prior to the move so they have adequate supplies while they arrange transfer to their new service. They should be supported to enquire with their pump company which services support their specific pump in their new locality.

INFORMATICS AND DATA REQUIREMENTS

Data download

Access to software and IT infrastructure to download and display data from pumps, glucose meters and CGM devices in clinic is essential.

Pre-consultation questionnaire

Patients should be helped to gather all the relevant information and be prepared for pump appointments.

They should be set up with personal accounts for the data software relevant to their devices and advised to download their pumps and meters before their appointments. Ideally, they should be given pre-clinic preparation forms to complete prior to the appointment. This process can be done after checking in for clinic appointments, but experience demonstrates pre-appointment downloads and questionnaires lead to more efficient and appropriate use of clinic time and resources. An example of such a questionnaire is available in the online appendix.

Insulin pump database

A bespoke pump clinic record sheet and database is recommended to help structure the appointment and collect the relevant information for clinical use and for audit. This can be set up on a hospital's existing diabetes database or in an Excel spreadsheet or visual basic/Microsoft access to aid data capture. Structuring appropriately may also allow automated flags (eg, for patients approaching end of their pump warranty). A more comprehensive database can also help business planning for the service. A suggested minimum dataset is detailed in the online appendix.

Clinic letters

A structured clinic letter should provide a comprehensive up-to-date summary of all details about the pump, settings and clinical issues so that a new clinician unfamiliar with the patient could continue their care. The letter should usually be addressed to the patient, copy to GP and other relevant parties. Examples of structured letter templates are available in the online appendices.

Consultation tools

Individual targets and holistic goals should be set for each patient (see online appendix for goal setting tools). This must be accompanied by a structured review process in clinic and review of data downloads as detailed in the DTN-UK CSII best practice clinical guide.[6]

National Insulin Pump Audit

All CSII centres in England and Wales are encouraged to submit data to the National Insulin Pump Audit which is run annually. This allows centres to benchmark their data and outcomes.

RECOMMENDATIONS FOR FUTURE WORK

Competency framework for diabetes technology

The group highlighted a national need for training the workforce in type 1 diabetes and diabetes technologies, both for established therapies such as CSII and continuous glucose monitoring and also emerging therapies such as hybrid closed loop systems, for example. To help support this we recommend the development of competency frameworks for diabetes technology applicable to different disciplines, grades and teams. Consideration should also be given to the concept of individual and centre accreditation in diabetes technology as the range and breadth of available devices grows.

Minimum staffing levels

Whilst it would be very helpful to define minimum staff to patient ratios to help with service planning and development, due to variations in clinical set-up and job roles, precise staff to patient ratios are difficult to establish. A national type 1 diabetes service audit is planned which should hopefully establish the national average staffing ratios.

Conclusion

The use of CSII in the UK continues to expand. Healthcare professionals involved in the care of people with type 1 diabetes have a duty to ensure that their services support the user to optimise their chosen technology.

Services should meet the essential requirements as set out in this document as well as striving to secure adequate capacity for their expanding CSII service.

It is the hope of the working group that this guide will support teams to reflect on current practice and consider how they will continue to deliver care which best meets the needs of their CSII users.

References

1. National Institute for Health and Clinical Excellence (NICE). Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. NICE, London, 2008. https://www.nice.org.uk/Guidance/TA151
2. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med* 1993;**329**:977–86.
3. Todd PJ, Edwards F, Spratling L, *et al*. Evaluating the relationships of hypoglycaemia and HbA1c with screening detected diabetes distress in type 1 diabetes. *Endocrinol Diabetes Metab* 2017 Dec 23;1(1):e00003. https://doi.org/10.1002/edm2.3
4. Shah S, Todd P, Choudhary P. *Diabetologia* 2017;**60**(Suppl 1):P138; S64.
5. ABCD Diabetes Technology Network. CSII Best Practice Guide. Guidelines for managing continuous subcutaneous insulin infusion (CSII) therapy in hospitalized patients. https://abcd.care/dtn-uk-best- practice-guides (last accessed 16 April 2018).
6. ABCD Diabetes Technology Network. CSII Best Practice Guide. Continuous subcutaneous insulin infusion (CSII) A clinical guide for adult diabetes services. https://abcd.care/dtn-uk-best-practice-guides (last accessed 16 April 2018).

Further Sources of Useful Information

American Association of Clinical Endocrinologists/American College of Endocrinology. Insulin Pump Management Task Force consensus statement. *Endocr Pract* 2014;**20**:462–89.

Cukierman-Yaffe T, Konvalina N, Cohen O. Key elements for successful intensive insulin pump therapy in individuals with type 1 diabetes. *Diabetes Res Clin Pract* 2011;**92**:69–73.

Hussain S, Oliver N. Insulin Pumps and Continuous Glucose Monitoring Made Easy, 1e, 2016, Elsevier Ltd

National Institute for Health and Clinical Excellence (NICE). NICE guideline [NG3]. Diabetes in pregnancy: management from preconception to the postnatal period. Last updated: August 2015. https://www.nice.org.uk/guidance/ng3

National Institute for Health and Clinical Excellence (NICE). NICE guideline [NG17]. Type 1 diabetes in adults: diagnosis and management. Last updated: July 2016. https://www.nice.org.uk/guidance/ng17

Scheiner G, Sobel RJ, Smith DE, Pick AJ, *et al*. Insulin pump therapy: guidelines for successful outcomes. *Diabetes Educ* 2009;**35**(S2):29S–41S.

APPENDIX 1

The online appendix containing useful resources for CSII services can be found at:
https://abcd.care/dtn/appendices-dtn-service-best-practice-guide