



BEST PRACTICE GUIDE:
**Continuous subcutaneous
insulin infusion (CSII) -
A guide to service requirements**

CONTENTS

	Page
Contributors	4
Foreword	5
Objectives	6
Introduction	6
Insulin pump service requirements	7
• List of desirable and essential criteria	7
Organisation and capacity	9
• Models of service delivery	10
• Capacity	12
• Clinical MDT meetings	12
• CSII Pathway	13
Pathway and programmes	14
• Access to type 1 education programmes	14
• Insulin Pump Annual Review	14
• Out of hours support pathway	14
• In-patient and emergency department support	14
• When insulin pump users move location	14
Informatics and data requirements	15
• Data download	15
• Pre-consultation questionnaire	15
• Insulin pump database	15
• National Insulin Pump Audit	15
• Clinic letters	15
Recommendations for future work	16
Conclusion	16
References	17
Appendix	18

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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 shows that the availability of CSII services, and the quality and outcomes of those using insulin pump treatment varies within 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 individualized 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.

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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, 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 (HbA1c) 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

HbA1c 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 6-15% 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

Here 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 (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, ante-natal 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 in-patients	(E)
Informatics and data requirements:	
• Insulin pump / meter/ sensor download facility	(E)
• Pre-consultation download (e.g. 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 HbA1c 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

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 dietitian 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, in-patient and ante-natal 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.



ORGANISATION AND CAPACITY

Organisation

The pump service should be integrated within the wider type 1 diabetes service.

The following range of patient contacts need 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 template list size and set up

Regardless of the clinic set up and structure, the essential criteria detailed on page 7 need to be met. This includes longer appointments for pump patients. The consensus from across the working group is:

- 30 minutes for follow-up
- 30-45 minutes for new patients

The precise list size and template is dependent on models used for the MDT clinic detailed below. Some models (e.g. models 3 and 4 below) 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 model 2 to 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 next page)

Clinic setup 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 e.g. young adult pump clinic, new referrals, etc.
2. Insulin pump patients mixed in with patients on MDI in specific multidisciplinary diabetes clinics e.g. 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.

	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 1-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	<ul style="list-style-type: none"> Joined up thinking MDT support for consultants Good team learning May not require post clinic meeting 	<ul style="list-style-type: none"> Clearly defined roles for each MDT member 	<ul style="list-style-type: none"> Efficient Allows multiple short contacts May allow second opinions and additional insights into care 	<ul style="list-style-type: none"> Enables MDT appointments and their advantages which are necessary for some patients Gives flexibility and efficiency 	<ul style="list-style-type: none"> Patient peer support Effective use of educator team time
✗ Cons	<ul style="list-style-type: none"> Resource heavy Can be intimidating for the patient 	<ul style="list-style-type: none"> Longer visit time for patient who may feel overwhelmed by having 3 appointments in 1 session Can result in unnecessary duplication 	<ul style="list-style-type: none"> Difficult to maintain relational continuity Patient may not be triaged to appropriate MDT member Post clinic MDT meeting required 	<ul style="list-style-type: none"> Patients need to be scheduled to the appropriate type of appointment in advance 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Possibly more appropriate for teams starting a new pump service with small patient numbers 	<ul style="list-style-type: none"> Intra-clinic communication between team members needed to make this work well 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Relies on a clinic list template to support the above 	<ul style="list-style-type: none"> 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

All models require a joint collaborative working relationship between the multi-disciplinary team and 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 (e.g. pump, warranty status, consumables) updated etc.

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.
- Hypoglycemia 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
- Re-inforce 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 (e.g. 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 (e.g. via Diasend, Libre link view, Medtronic carelink, Dexcom clarity, etc.)
- Administrator to help with download setup, 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 mins however additional time for administration (e.g. 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 health care professionals can improve diabetes control and reduce the risk of long term complications (DCCT group, 1993).

The pediatric 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, 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 6 contacts (3 face to face and 3 virtual per year) (Todd et al. 2017, Shah S et al. 2017).

In addition to this, referrals for consideration of pumps, pump initiation protocols, rapid reviews and fast track pump initiations (e.g. 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 Fig 1 CSII Pathway)

Clinical MDT meetings

Clinical MDT meetings are essential for discussing cases. For multi-site 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
- In-patient admissions and antenatal issues
- Cases requiring psychology or other MDT input
- Problematic hypoglycaemia (impaired awareness of hypoglycaemia or severe hypoglycaemia)

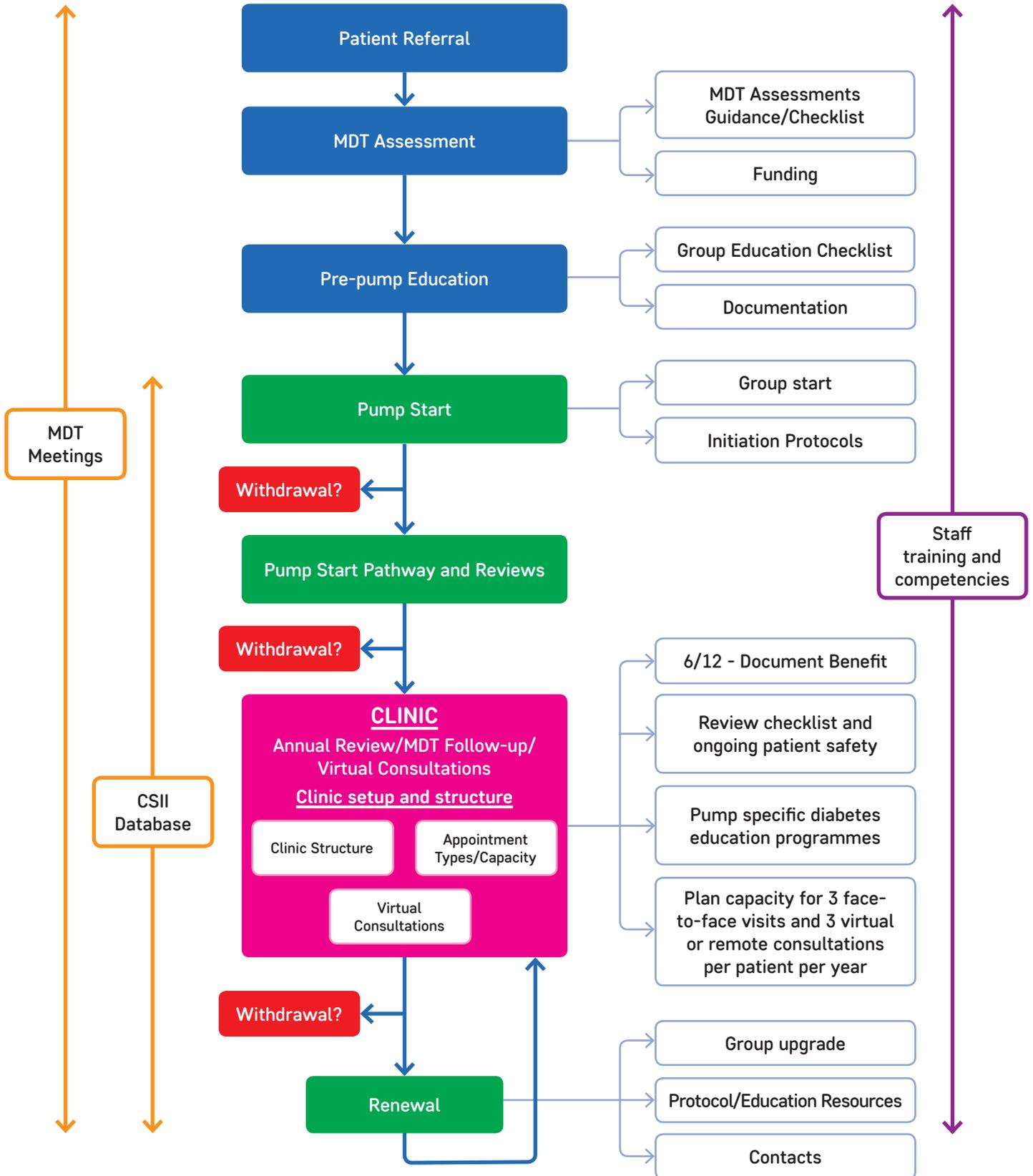
Depending on local service structures and health care professional skill set, other patient groups may need to be included such as pre-conception, pregnancy, transplant.

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 e.g. 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 (e.g. DAFNE). For those established on insulin pump therapy who have not had previous access to structured education there are pump specific courses available e.g. 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 manufacturers 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.

In-patient 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.

When insulin pump users move location

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 e.g. 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 with a structured review process in clinic and review of data downloads as detailed in the DTN-UK CSII best practice clinical guide.

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. Health care 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.



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APPENDIX

The online appendix containing useful resources for CSII services can be found at:

<https://abcd.care/dtn/appendices-dtn-service-best-practice-guide>



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