Policy for the Management of: Insulin Pump Therapy In Children and Young Persons with Type 1 Diabetes

For use in:	Jenny Lind Children's Department
By:	Jenny Lind Diabetes Team
For:	Children on or considered for CSII therapy
Division responsible for document:	Women and Children's Services
Key words:	CSII, Insulin pump therapy,
Name and job titles of document author:	Dr.Vipan Datta, Consultant Paediatrician and Suzanne Lee, Paediatric Diabetes Specialist Nurse
Name and job title of document author's Line Manager:	Dr Mary-Anne Morris , Chief of Service
Supported by:	Joanna Gibbons, Louisa Fear and Faye Stubbs Paediatric Diabetes Specialist Nurses.
Assessed and approved by the:	Clinical Guidelines Assessment Panel (CGAP) If approved by committee or Governance Lead Chair's Action; tick here ✓
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To be reviewed by:	Dr.Vipan Datta, Suzanne Lee
Reference and / or Trust Docs ID No:	CA5021 - 1362
Version No:	4
Compliance links: *(is there any NICE related to guidance)*	NICE Guidance CSII for the Treatment of Diabetes Mellitus 2008 TA151
If Yes - does the strategy/policy deviate from the recommendations of NICE? If so why?	No

This guideline has been approved by the Trust's Clinical Guidelines Assessment Panel as an aid to the diagnosis and management of relevant patients and clinical circumstances. Not every patient or situation fits neatly into a standard guideline scenario and the guideline must be interpreted and applied in practice in the light of prevailing clinical circumstances, the diagnostic and treatment options available and the professional judgement, knowledge and expertise of relevant clinicians. It is advised that the rationale for any departure from relevant guidance should be documented in the patient's case notes.

The Trust's guidelines are made publicly available as part of the collective endeavour to continuously improve the quality of healthcare through sharing medical experience and knowledge. The Trust accepts no responsibility for any misunderstanding or misapplication of this document.

Trust Guideline for the Management of: Insulin Pump Therapy In Children with Type 1 Diabetes

Version and Document Control:

Version Number	Date of Update	Change Description	Author
4	10/03/2020	5 – 7 day Continuous Glucose Monitoring (CGM) or Libre device (14 days) may be offered (subject to equipment availability) to patients when deemed clinically necessary/appropriate, at the time of the pump start to facilitate basal rate adjustments.	Dr Vipan Datta and Suzanne Lee

Introduction

NICE has approved Insulin pump therapy (Continuous subcutaneous insulin infusion, CSII) in appropriately selected and motivated patients with Type 1 Diabetes.[1]

Objective/s and Rationale

This guideline covers the following:

- the process by which suitability for CSII will be determined
- The responsibilities of the diabetes team and families, to facilitate effective management of CSII.
- Criteria for discontinuing CSII where its use has not been effective in improving diabetes control and/or quality of life.

1. Eligibility for Insulin Pump Therapy

NICE guidance[1] identifies that patients with Type 1 diabetes, including children, should be considered for CSII therapy where:

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

[11] http://www.nice.org.uk/ta151

life
or

- HbA1c levels have remained high, (above 69 mmols/mol), on MDI therapy, (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care.

1.2 CSII therapy is recommended as a treatment option for children younger than 12 years with type 1 diabetes mellitus provided that:

- MDI therapy is considered to be impractical or inappropriate, and
- children on insulin pumps would be expected to undergo a trial of MDI therapy between the ages of 12 and 18 y

2. Assessment Process

Understanding pump therapy

Children/families interested in CSII will be shown the range of clinically appropriate insulin pumps and the principles of pump therapy will be explained.
This will include a discussion about linked CGM (CCG or Self funded) where clinically appropriate .
They will be encouraged to access available information, including internet resources and, if desired, discussion with a family whose child is on CSII.

Parents and, where appropriate, children will be considered for CSII provided they

- Are engaged in managing their diabetes care.
- Have a good knowledge and understanding of diabetes including knowledge and management of illness ("sick-day rules"), including use of blood ketone measurement, insulin-adjustment, exercise management and problem-solving skills.
- Have knowledge of how exercise, insulin and food intake affect blood glucose levels.
- Understand the principles of Basal-bolus therapy and are proficient in carbohydrate counting (as assessed by the dietician after 3 day food diary)
- Be doing sufficient blood glucose checks (6-8)daily including pre meal and pre bedtime)

Teaching and support will be provided. Where appropriate this may include an inpatient admission

The diabetes team will explain:

- The limitations of CSII
- The process of selecting an appropriate insulin pump
- Training that would be provided. Including location and approximate timescale until pump start
- Expected family commitment to care including ; supporting their child in school , the circumstances when pump therapy may be discontinued and the requirement to sign written agreement

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3. Initiation of CSII

Choice of insulin pump

The diabetes team will give information regarding the choice of insulin pump, taking into account patient/family preferences provided there are no clinical contraindications for any preferred device. This will be reviewed periodically to take account of technological developments, level of support, including training and ease of ordering and obtaining pumps and consumables.

Initial pump training and support

Patients/families will attend pump training provided by a certificated pump trainer e.g. Nurse, dietician or company representative. A clinician must be present at all pump starts or upgrades. . A record of the pump start will be filed in the paper or electronic medical notes. Contact will be offered as outlined in Table 1.

4. On-going care

The family will attend outpatient clinics and pump education sessions on a regular basis, including periodic refreshers facilitated by the relevant pump provider or the diabetes team

Patients/families are expected to undertake adequate (minimum 6-8) blood glucose checks, or replace these when clinically indicated by CGM or flash glucose levels and use these values in accordance with the device to promote glucose stability , They will undertake fasting blood glucose profiles, as directed by the diabetes team for determination of basal rates of insulin and will also periodically undertake pre- and post-prandial testing to determine appropriateness of insulin: carbohydrate ratios, and nocturnal testing (3am).

A 5-7 day Continuous Glucose Monitoring (CGM) or Libre device (14 days) may be offered(subject to equipment availability) to patients where deemed clinically necessary/appropriate, at the time of the pump start to facilitate basal rate adjustments.

Families will ensure they can administer subcutaneous insulin with an insulin pen or syringe, in the event of pump failure. Families to keep insulin pen in fridge for emergency use at all times.

Emergency Care

- 24-hour medical support is provided through the Children's Assessment Unit
- Technical help for pump users is provided by company help lines
- Children and families have normal access to advice via telephone, email, fax etc., during office hours
- Open access follow-up is provided in the DSN-led Intensive Treatment Clinic

Support for CSII in schools

School staff will be given appropriate training to support the young person in school. Parents should be able to offer a period of supervised support for the staff if this is required. A

similar commitment is required for the support of children whilst they are at nursery, with relatives, carers or otherwise away from home. Training may be undertaken by parents or the diabetes team.

Older children may be able to generally manage their pump independently, but still require the support from school staff in some situations. All children with diabetes will be provided with a care plan for school which is agreed between Parents, the school and the healthcare team.

Transition to adult care
Patients starting on pump therapy or upgrading their pump after the age of 16 years should have their care-needs assessed collaboratively with the paediatric and adult teams and the patient level of knowledge assessed to ensure they can manage their care and the device primarily independent of parental support .

5. Discontinuation of CSII

The Children's Diabetes Team will periodically assess the appropriateness of continuing with pump therapy, depending on adherence to necessary minimum standards of care. Where necessary, the team will make a recommendation to withdraw pump therapy.

Criteria for discontinuing CSII

- Patient/family choice
- Recurrent site problems leading to infection skin trauma, or allergic reaction.
- Psychological distress, despite appropriate support and advice
- Family/personal difficulties in providing safe pump management, or inability to ensure safe pump management (e.g. at school)
- Inadequate self-care
    - inadequate blood glucose checks
    - Failure to respond to hyperglycaemia with appropriate blood and/or ketone testing, subcutaneous insulin administration and/or replacement of the insulin infusion set.
    - Failure to manage carbohydrate intake with appropriate insulin administration
    - Non-adherence with recommended care and/or clinic or other appointments including education.
    - Misuse of equipment
- Severe adverse events (e.g. episode of diabetic Ketoacidosis, insulin overdose, intentional non-administration of insulin)
- Failure to improve glycaemic control as assessed by HbA1c or episodes of severe hypoglycaemia, despite all efforts of the diabetes team and patient/family.

Except where it is the patient/family's choice to discontinue therapy or it is considered a risk to the patients immediate safety to continue on the pump, the Diabetes team will address the areas of concern with the patient/family, and an agreed care plan will be drawn up in conjunction with the patient/family. Appropriate additional support and education will be

provided. Failure to agree a care plan will lead to a recommendation to discontinue insulin pump therapy.

Where it proves impossible to effect satisfactory standards of care or control, despite an agreed care plan, which may include the option of a pump holiday , , within a reasonable period of time (eg 3-6 months), then the patient/family will be advised of the decision to discontinue insulin pump therapy . Re starting pump may be considered (after agreement by MDT) if child / family engages appropriately and diabetes control improves in the future

See table 1 for summary of process of pump assessment, initiation and on-going support.

Table 1. Summary of initiation of pump and post pump start support

Summary of Process		
Pre-pump Assessment		• MDT discussion and decision regarding patient suitability and agreement to proceed. • Appointment for discussion of pump pathway with patients and discussion re pump model • Consider team capacity to undertake pump start and follow up • Calculate pump doses from basal bolus TTD. • Trial of pump may be considered if appropriate and can be supported by company • Order supplies • Sign written agreement • Undertake initial pump training • Arrangement of clinic (keyworker or consultant led) appointments. Offer at least two clinic appointments within first three weeks and two further appointment within the following six weeks
Initial Pump Training & Pump Start [See Appendix 2: Record of Pump Start]	Day 1	• Pump set up and usage including use of software • Calculation of insulin basal rates, carbohydrate ratios and correction factor • Hypo/hyper management • Use of temporary basal rates • How to wear the pump / cannula insertion • Insertion of sensor and Using Libre or CGM (where clinically relevant). • Emergency clinical contact details and technical support/ re-ordering details
	First week	• Trouble-shooting • Exercise management • Fasting checks • Sick-day rules • Pump failure • Reversion to MDI • School care planning / staff training arrangements • Offer daily contact by phone / text/ email or face to face
Initial Support	First 2 weeks	• phone , text, email or face to face contact to “fine tune” pump settings • Managing hypo- and hyperglycaemia • Pre- and post-meal glucose testing • Fasting routine in order to adjust basal rates
	4 weeks	• Review of glycaemic control and pump settings • Infusion sites • Dietary review

		• Problem-solving • HbA1c
Ongoing support		• Nurse-led/ dietician clinic support or telephone / email support as required • Adherence to safe pump care (adequate glucose checks , cannula changes, responding to hyperglycaemia, fasting • Fasting checks in order to adjust basal rates
Transition	Age 16+	• Refresh knowledge & skills • Adherence to safe pump care • Transfer to adult physician by mutual agreement

JENNY LIND CHILDREN'S HOSPITAL

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Appendix 1: Patient Agreement Form for CSII

Paediatric Diabetes
Jenny Lind Children's Department
Norfolk & Norwich University Hospital
Colney Lane
Norwich
NR4 7UY

Patient/Parental Agreement for Continuous Subcutaneous Insulin Therapy (Pump Therapy)

I……..understand that the insulin pump I am being given to manage my/ my child's Diabetes is funded by , and remains the property of the NHS.

NHS funding for pump therapy is given providing the criteria in the NICE 2015 [NG18} guideline are met, with the aim to achieve and maintain safe and effective diabetes care. A copy of this guideline is available on request.

I understand that non-attendance of appointments and/ or not following clinical advice about my/ my child's diabetes care could result in this funding being withdrawn.

This may include not using the pump functions safely or correctly and / or not checking blood glucose the required number of times per day e.g. a minimum of 6-8 checks per day . In these circumstances I agree I/we will return the insulin pump. (Flash or CGM glucose readings may be used where clinically indicated).

I acknowledge that while we have the insulin pump we are responsible for its condition and will provide insurance against accidental damage or loss, including holiday insurance.

Patient……..

Date of Birth *(dd/mm/yyyy)*……

Signed (Parent)……...

Date *(dd/mm/yyyy)*……..

Paediatric Diabetes:
Jenny Lind Children's Department, Norfolk & Norwich University Hospital, Colney Lane, Norwich, NR4 7UY

Diabetes Consultants:

Dr Vipan Datta
vipan.datta@nnuh.nhs.uk

Dr Emma Webb
Emma.webb@nnuh.nhs.uk

Dr Ravi Alanoor
Ravi.alanoor.nnuh.nhs.uk

Consultant Clinical Psychologist:
Dr Jo Derisley
Secretary: Linda Fish
Email: linda.fish@nnuh.nhs.uk
Tel: 01603 287545

Dr Jo-Anne Veltman
(speciality doctor)
Joanne.veltman@nnuh.nhs.uk

Secretaries:
Caron Leftley

Tel: 01603 286357 Fax: 01603 286318
caron.leftley@nnuh.nhs.uk

Paediatric Diabetes Specialist Dietitians:
Lucy Findlay
lucy.findlay@nnuh.nhs.uk

Paediatric Diabetes Specialist Nurses:

Suzanne Lee
Jo Gibbons
Faye Stubbs

Tel: 01603 287504
Email: pdsn@nnuh.nhs.uk

In an emergency contact the
Children's Assessment Unit
Tel: 01603 289774

Appointments:
Tel: 01603 286557

Patient/Parental Agreement for Continuous Subcutaneous Insulin Therapy (Pump Therapy)

Patient's name	
Consultant name	
Unit/Hospital number	
Paediatric diabetes specialist nurse (PDSN)	

Indication for treatment aged <12 years	
MDI therapy is considered to be impractical or inappropriate	
Attempts to achieve target HbA1c levels with multiple daily injections results in disabling hypoglycaemia.	
HbA1c remains high (69 mmol/mol or above) on MDI therapy.	

Indication for treatment aged >12 years	

Attempts to achieve target HbA1c levels with multiple daily injections results in disabling hypoglycaemia.	
HbA1c remains high (69 mmol/mol or above) on MDI therapy.	

You have been given an Insulin pump and the Diabetes Team expect you to take responsibility for using it correctly.

I/We agree to:

- Attend the recommended pump training with annual education updates
- Perform a minimum of 6-8 glucose checks/day and to enter these values into the pump.
- Attend appointments regularly
- Attend the annual dietetic review
- Have a trial off the insulin pump between the ages of 12 and 18 years

I/We understand that the pump may no longer be provided if:

- Blood glucose tests are carried out less than six times per day
- I do not attend appointments including the annual dietetic review
- Appropriate actions, as advised by the diabetes team are not carried out.
- In children aged >12 years the results below have not been achieved by the six-month review or improvement is not maintained at each annual review.
    - Improved hypo awareness
    - A reduction in the number of hypoglycaemic events
    - HbA1C remains high (that is, at 8.5% [69 mmol/mol] or above)
- Any decision to stop pump therapy will only be made after team discussion involving the child / young person's consultant and keyworker and a dietician.

In these circumstances I agree I will return the insulin pump.

I……..understand that the insulin pump I am being given to manage my/ my child's Diabetes is funded by , and remains the property of the NHS. NHS funding for pump therapy is given providing the criteria in the NICE 2015 [NG18} guideline are met, with the aim to achieve and maintain safe and effective diabetes care. A copy of this guideline is available on request.

I acknowledge that while we have the insulin pump we are responsible for its condition and will provide insurance against accidental damage or loss, including holiday insurance.

I have been given and have signed the data sharing information form to enable the pump company to supply pump consumables.

Patient……..

Date of Birth *(dd/mm/yyyy)*…….

Signed (Parent)…… ……..

Signed (patient) where applicable ……

Signed (on behalf of diabetes team) ……. ……..

Date *(dd/mm/yyyy)*…….

Clinical audit standards

Individual elements of the policy will be subject to audit and patient satisfaction surveys.

Summary of development and consultation process undertaken before registration and dissemination

The policy was developed by the Jenny Lind Diabetes Team through a process of consensus. Comments were invited from nursing and medical staff, and the policy has been adapted in the light of ongoing developments over time.

This version has been endorsed by the Clinical Guidelines Assessment Panel.

Distribution list / dissemination method

Trust Intranet

References / source documents

- NICE Guidance CSII for the Treatment of Diabetes Mellitus 2008 TA151.
- DoH Insulin pump Services: Report of the Insulin pumps Working Group. 2007.
- Diabetes UK Insulin pumps Services. 2007.
- Pickup, J. ed. Insulin Pump Therapy and Continuous Glucose Monitoring. 2009. Oxford press