

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

A clinical guideline recommended for use

In:	Jenny Lind Children's Department
By:	Jenny Lind Diabetes Team
For:	Children on CSII therapy
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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.
- guidance on management of
 - sick day rules for patients on CSII
 - insulin pump failure

1. Eligibility for Insulin Pump Therapy

NICE guidance¹ identifies that patients with Type 1 diabetes, including children, should be considered for CSII therapy where:

Children under 12y

- The diabetes team consider that the child and family have the necessary commitment and competence to use CSII effectively.

Children 12y and over

- The diabetes team consider that the child and family have the necessary commitment and competence to use CSII effectively, AND
- The child or young person is experiencing disabling hypoglycaemia², OR
- Satisfactory glycaemic control (HbA1c < 70mmol/mol) has not been achieved with multiple daily injection therapy, despite taking appropriate measures

Note: Children and young people 14 -17y, will be considered for pump therapy jointly by the adult and children's diabetes teams.

¹ <http://www.nice.org.uk/ta151>

² 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.

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2. Assessment Process

Understanding pump therapy

Children/families interested in CSII will be shown an insulin pump, and the principles of pump therapy will be explained. 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 well motivated and willing to take control of their diabetes.
- Have a good knowledge and understanding of diabetes including knowledge of “sick-day rules” and management of illness, (including use of blood ketone measurement to guide management), insulin-adjustment, exercise management and problem-solving skills.
- Have a sound understanding of how exercise, insulin and food intake affect blood glucose levels.
- Understand the principles of Basal-bolus therapy and carbohydrate counting
- Be doing sufficient blood glucose tests (minimum 4 tests daily)

Where appropriate, additional teaching and support will be provided.

The diabetes team will explain:

- The limitations of CSII
- The process of selecting an appropriate insulin pump
- Training that would be provided
- Circumstances where CSII would be discontinued

Commitment to CSII

Families wishing to proceed with pump therapy, and who have shown the necessary skills and commitment will be considered for CSII by the multi-disciplinary team. If considered suitable, and taking into account other factors such as the team’s capacity to provide appropriate support, the family will be asked to complete a written agreement (see Appendix 1), committing themselves to necessary standards of care and support of their child with diabetes, including the support of their child in school and outside the family home.

See Table 1 for summary of process of pump initiation and ongoing support.

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Table 1. Summary of initiation and ongoing support for CSII

Summary of Process		
Pre-pump Assessment		<ul style="list-style-type: none"> • Confirm Suitability • Arrange initial pump training • Sign written agreement • Arrange initial pump training
Initial Pump Training & Pump Start [See Appendix 2: Record of Pump Start]	Day 1	<ul style="list-style-type: none"> • Pump handling • Use of pump 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 selection and insertion
	Day 2	<ul style="list-style-type: none"> • Trouble-shooting • Use of pump workbook • Exercise management • Fasting tests • Sick-day rules • Pump failure • Reversion to MDI
Initial Support	First 2 weeks	<ul style="list-style-type: none"> • Daily telephone contact to “fine tune” pump settings • Managing hypo- and hyperglycaemia • Pre- and post-meal glucose testing • Fasting routine as instructed in patient workbook in order to adjust basal rates
	4 weeks	<ul style="list-style-type: none"> • Review of glycaemic control and pump settings • Infusion sites • Dietary review • Problem-solving • HbA1c
Ongoing support		<ul style="list-style-type: none"> • Regular outpatient attendance • Adherence to safe pump care (adequate blood glucose testing, canula changes, responding to hyperglycaemia, fasting routines, etc) • Attendance at pump education sessions (at least annually) • Fasting routine as instructed in patient workbook in order to adjust basal rates
Transition	Age 16+	<ul style="list-style-type: none"> • Refresh knowledge & skills • Adherence to safe pump care • Independent Living education • Transfer to adult physician by mutual agreement
In Emergency	Ongoing	<ul style="list-style-type: none"> • 24 hour company helpline for Technical support and advice only. • PDSN/ consultant office hours. • Emergency access to Children’s Assessment Unit

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3. Initiation of CSII

Choice of insulin pump

The diabetes team will give advice regarding the choice of insulin pump, taking into account patient/family preferences. 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

Patients/families will attend pump training provided by a representative of the appropriate insulin pump company and a diabetes specialist nurse. A record of the pump start will be kept (see appendix 2). Subsequently, daily contact is maintained for the first 2 weeks to help refine pump settings, with an outpatient appointment after 4 weeks.

4. Ongoing care

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

Patients/families are expected to undertake adequate blood glucose tests, and will maintain a log-book of carbohydrate intake and insulin administration. They will undertake fasting blood glucose profiles, as directed by the diabetes team for determination of basal rates of insulin. They 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 (CGMS) profile will be offered to patients where clinically necessary/appropriate.

Families will ensure they can administer subcutaneous insulin with an insulin pen or syringe, in the event of pump failure.

Emergency Care

- 24-hour 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

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Support for CSII in schools

It is unrealistic and unfeasible for schools to take on management of insulin pump therapy. Accordingly, parents must be prepared to make appropriate arrangements to support their child in school, including if necessary, attending school to undertake blood tests and deliver insulin. A similar commitment is required for the support of children whilst they are at nursery, with relatives or other carers or otherwise away from home.

Older children may be able to manage their pump unaided, but still require the back-up of their parents in the event of problems arising at school or away from home. All children with diabetes will be provided with a care plan for school which is agreed between Parents, the school and the healthcare team.

Some schools may be willing to become involved in aspects of pump management. This is discretionary, and subject to the agreement of the school authorities. Appropriate training will be provided to schools who agree to participate in pump care.

For families facing difficulties with pump management of their child in school, then the diabetes team will endeavour to provide practical assistance to circumvent the problems, with the goal of providing *adequate* care.

Transition to adult care

In order to ensure that young people who will be transferring to adult care have adequate skills and knowledge, all young people who wish to remain on an insulin pump must attend a pump refresher course (**Independent Living Education**) in the 2 years prior to transfer. Young people who are unwilling to attend this refresher education will not be able to continue on CSII.

Independent Living Education is tailored to meet the needs of this group of young people using CSII, and covers safe pump management and life skills teaching. The Curriculum will include aspects of their lives which are relevant i.e. independent living, leaving home, safety and lifestyle.

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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 or skin trauma
- Psychological distress, despite appropriate support and advice
- Family/personal difficulties in providing safe pump management, or inability to ensure safe pump management (eg at school)
- Inadequate self-care
 - inadequate blood glucose tests
 - 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 (eg episode of diabetic Ketoacidosis, insulin overdose, intentional non-administration of insulin)
- Failure to improve glycaemic control 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, 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 addressing these areas. 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, within a reasonable period of time (3-6 months), then the patient/family will be advised of a recommendation to discontinue insulin pump therapy. If the patient/family still wish to continue with pump therapy, then a further attempt to address areas of concern will be made. If this is unsuccessful within a further 3 month period, then the recommendation to discontinue pump therapy will be put into effect.

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6. Emergency Management of Hyperglycaemia

Management of hyperglycaemia/illness

Children on CSII are at increased risk of diabetic ketoacidosis (DKA). Moreover, DKA may occur without markedly elevated glucose levels (“euglycaemic DKA”). Accordingly, when significant hyperglycaemia occurs, particularly if unexplained by carbohydrate intake or other factors, prompt remedial action is necessary.

It is vital to check blood ketones to determine appropriate steps.

Reasons for hyperglycaemia

- Canula occlusion - the commonest reason for unexpected hyperglycaemia is occlusion of the canula. Canulas should be changed every 48-72 hours. The longer a canula is left in situ, the greater the risk of site infection and occlusion.
- Occlusion or disconnection of insulin tubing or reservoir
- Pump failure
- Inadequate insulin dosing (eg missed meal bolus)
- Stress or intensive (anaerobic) exercise (hyperglycaemia is usually short-lived, and normalizes spontaneously)
- Illness
- Insulin not working – this may follow incorrect storage (insulin is denatured if frozen, and should not be stored below 4°C), or excessive environmental temperatures (eg very hot climate (>25°C)).

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I. Advice for *Initial* Management of Hyperglycaemia/illness

Child with Blood Glucose >14mmol/L, vomiting or otherwise unwell

- Check blood ketones
 - Children who do not appear obviously unwell, can remain at home.
 - Children who appear significantly unwell should attend CAU without delay, regardless of blood glucose and ketones, particularly if vomiting
- If ketones normal (<1.0mmol/L) administer correction bolus **via insulin pump** and recheck glucose and ketones in 2-4 hours
- If ketones elevated (>1.0mmol/L), or correction bolus given by pump has not corrected hyperglycaemia, administer rapid-acting insulin by **subcutaneous insulin injection** immediately **and** Perform pump check (see below)
- Continue to monitor blood glucose and ketones 2-4 hourly.
 - Children who are improving, should continue to monitor blood glucose and ketones until normalization of blood tests and resolution of symptoms.
 - If blood glucose remains high, see **Advice for Ongoing Management of hyperglycaemia/illness** (below)

II. Advice for *Ongoing* Management of Hyperglycaemia/illness

- If the child is not obviously unwell, but blood glucose remains >14mmol/L, despite appropriate corrective actions, **and**
 - The Pump Check confirms pump is working satisfactorily, **and**
 - Ketones stable or reducing,
 - Increase pump basal rate to 140% of normal. If the child/family is unsure how to do this, ask them to consult the company “pump hotline” for advice
- Continue to check blood glucose and ketones 2-4 hourly.
- If the child is not obviously unwell, but blood glucose remains above 14.0mmol/L and/or blood ketones remain above 1.0mmol/L, continue to increase basal rate by increments of 20% every 2-4 hours, until glucose and ketones are normalized. Exceptionally, basal rates of 200% or more may be required.
- As glucose and ketones improve, reduce basal rate in 20-40% increments, to prevent development of hypoglycaemia.
- Children who are significantly unwell, or who have hyperglycaemia (glucose >14mmol/L), with increasing ketones, (>3.0mmol/L), despite additional insulin administered by subcutaneous injection, should attend CAU for assessment and exclusion of DKA, **without delay**.

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Pump Check

A pump check should be performed in the event of significant hyperglycaemia, which has not responded to administration of extra insulin via the pump, or when elevated ketones are present:

- Inspect the infusion line*. If the line appears kinked, blocked or has become disconnected, replace the line.
- Inspect the pump.

If it appears to be functioning normally, disconnect the pump and infusion line and infuse insulin via the line to verify that the pump is working and the line is not occluded.

If insulin does not pass through the tubing, replace the line and insulin reservoir.

If the line is not blocked, and insulin does not pass through the line, then it is likely that the pump has failed. If the pump is not working, the family must contact the pump company immediately and revert to insulin injections.

- If the pump is functioning, replace the canula.
- If hyperglycaemia persists despite replacing the canula, replace the insulin in the pump and line, preferably from a “fresh” batch of insulin.

*Note the Omnipod insulin pump is an “all-in-one” device, and does not have a separate infusion line and canula – if necessary, the whole unit should be replaced.

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Appendix 1: Patient Agreement Form for CSII

Norfolk and Norwich University Hospitals NHS Foundation Trust

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Patient Agreement for Continuous Subcutaneous Insulin Therapy (Pump Therapy)

After deciding on Insulin Pump Therapy, the family are asked to sign this written agreement committing themselves to necessary standards of care and support of their child with diabetes, including the support of their child in school and outside the family home.

After determining eligibility for Insulin Pump Therapy, the family will be asked to sign a written agreement committing themselves to necessary standards of care and support of their child with diabetes, including the support of their child in school and outside the family home.

I Understand that the insulin pump I am being given to manage my child's diabetes remains the property of the NHS. Funding for the equipment that is required for the insulin pump is provided by the NHS.

Providing that the Children's Diabetes team and I feel that insulin pump therapy has been successful then the pump therapy can continue. I agree to attend education sessions and clinics as advised by the Children's Diabetes team as part of my continuing care on insulin pump therapy.

I understand that insulin pump care at school remains the family's responsibility. The Children's diabetes team and School Health will provide school with advice and support.

I understand that failing to attend appointments and follow clinical advice about my child's pump therapy could result in funding being withdrawn. In these circumstances I will return the insulin pump.

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.....

D.O.B.....

Signed (parent).....

Date.....

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Appendix 2: Record of Pump-Start

Date	Name Hospital No.	
Dr/DSN/Rep attending Pump Start:	Date of Birth	
	Address	
	<i>Use label</i>	
Contact Details	Home Telephone:	
	Mobile No:	
Current MDI regimen (average per day)	Quick-acting	Total Daily Dose (TDD)
	Long-acting	
Starting Dose for CSII	TDD x 75% =	
Insulin: carbohydrate ratios	Breakfast	
	Lunch	
	Dinner	
	Overnight	
Insulin Sensitivity Factor (ISF) or correction factor	1 unit of insulin drops BG by mmol	
Insulin on Board I.O.B (duration of action of my quick acting insulin)	Use Default setting of 3 hours	
Target blood glucose		
Last dose of Long-acting insulin to be given	Dose	Time
	Advise infusion set/canula must be changed every 2-3 days (maximum) or sooner if the infusion site is causing discomfort (eg is red, sore, irritated or painful)	
Last 2 HbA1c results	Date/result	Date/result
Pump Trainer(s)		
Technical Support No.		
Contact No. for supplies		

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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.
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