INSULIN PUMP THERAPY PATHWAY:
DTN recommendations

Authors:
Prof Pratik Choudhary, Alistair Lumb, Emma Wilmot, Geraldine Gallen, Sara Hartnell, Iain Cranston, Jackie Elliott on behalf of the DTN committee.

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

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

OR

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

Following initiation in adults and children 12 years and older, CSII therapy should only be continued if it results in a sustained improvement in glycaemic control, evidenced by a fall in HbA1c levels, or a sustained decrease in the rate 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.

NICE TA151 does not specify high level of care, but does clarify that trained specialist team should provide structured education programs and advice on diet, lifestyle and exercise for people using CSII.

The DTN has been made aware that in many places across the UK, this has been interpreted as the need to complete a face to face structured education course. While all of us at DTN strive towards widespread access and availability of high-quality structured education in flexible insulin therapy, we are aware of a number of challenges to this that prevent people with type 1 Diabetes (PwT1D) from accessing insulin pump therapy.

Current challenges in access to CSII:

1. Lack of clarity in defining “high quality of care”.
2. Lack of access to accredited quality assured structured education such as DAFNE.
3. Where courses are available, there is limited capacity. Analysis done by the London T1. Network found that even if all courses were completely filled, the capacity for DAFNE just about covers the numbers of people who will be newly diagnosed with Type 1 diabetes, leaving long waiting lists for others. The National Diabetes Audit report showed that 33.9% of services did not deliver approved structured education, and almost a fifth of people with diabetes who are referred wait longer than 6 months. [NDA, 2018]
4. Some PwT1D are unable to access the education that is available due to limited timings, work or childcare commitments, financial or social circumstances.
5. Some teams only offer/prioritise education for those on a “pump pathway” without leaving adequate time to assess the effectiveness of self-management skills.
6. Some PwT1D who have acquired skills in flexible insulin management – either self-taught or through follow-up visits over time are forced to wait to do structured education courses for a long time when they may not need to.
7. Some centres do not leave adequate time between completing the course and starting insulin pump therapy to assess the impact of the course.
8. Some centres only offer a limited choice of insulin pumps.

These challenges may be the reason why insulin pump uptake in the UK remains low compared to other western European counties.
DTN response to these challenges.

DTN has developed the following guidance on defining high quality of care.

- **The person with type 1 diabetes should be seen in specialist diabetes service. We recommend that this be defined as a service that has:**
  1. a defined type 1 diabetes lead
  2. a multidisciplinary core comprising medical, specialist nursing and dietetic team members who are trained in and understand principles of flexible insulin therapy (i.e. carbohydrate counting, how to adjust insulin:carbohydrate ratios and how to adjust insulin sensitivity factors and basal insulin in response to glucose data)
  3. experience and training in the use diabetes technology (e.g. completed ACADEMY training program)
  4. a regular multi-disciplinary team (MDT) meeting to review complex individual cases and review decisions around diabetes technology.
  5. All specialist diabetes services offering pump therapy should submit data to the National Diabetes Audit – so that on a national scale we can assess the effectiveness of pump therapy compared to MDI
  6. People with diabetes who have raised HbA1c (> 8.5% (68 mmol/mol) or disabling hypoglycaemia are reviewed frequently (4-6 times / year) (Choudhary, 2020)

- **The person with diabetes should be using principles of flexible insulin therapy and receiving a “high level of care”**
  1. For many PwT1D, this will mean that they will have completed an accredited structured education course such as DAFNE.
  2. The PwT1D should have been reviewed by the MDT over the last 6-12 months (at least 3 times) with attempts made to optimise their therapy.
  3. If face-to-face structured education is not possible, on-line education resources that support principles of flexible insulin therapy should be utilised - e.g.:
    - Remote DAFNE: https://www.DAFNE.nhs.uk
    - https://www.bertieonline.org.uk
    - https://mytype1diabetes.nhs.uk
  4. We do not believe that the “tick-box” of a structured education is in the “spirit” of the NICE guidance. Rather, the multi-disciplinary team should be supporting the person with diabetes to utilise skills of flexible insulin therapy.

**Key skills included in this should include:**

- Measuring glucose pre-meal, at least 4 times a day: with either SMBG or Flash/CGM
- Carbohydrate counting (reviewed by a trained educator as part of the MDT)
- Bolusing before eating carbohydrate and using calculations that include carbohydrate counting, insulin:carbohydrate ratios and correction factors.
- Understanding the impact of exercise, illness and alcohol and the principles of adjusting therapy in response to these
- Understanding the principles of how to adjust basal and/or bolus insulin in response to glucose patterns

**Exceptional circumstances:** We recognise that for a proportion of PwT1D who meet the criteria of HbA1c > 8.5% (68 mmol/mol) and/or disabling hypoglycaemia, factors such as mental health or cognitive function among others may mean that despite efforts of the MDT, they are unable to acquire these skills. In these individuals, provided they have a high level of support from a skilled MDT, a “trial” of insulin pump therapy may be indicated where the MDT feel appropriate, with clearly defined with outcomes: These should be specified and agreed with the person with diabetes at the start, if the following “safety” criteria are met:
  1. Minimum of 2 glucose measurements / day over last 3 months.
  2. Has had training on sick day rules and ketone management
  3. Review against outcomes in 3 and 6 months.
**Recommended DTN - Pump pathway**

1. All people with diabetes who meet NICE criteria of HbA1c > 8.5% and/or disabling hypoglycaemia should be considered for insulin pump therapy.

2. They should be offered high quality care as defined above.
   - The MDT should assess the skills described above – and if there are gaps in those skills these should be addressed on an individual basis.
   - For many, this will mean referral to a structured education course.
   - For some this may include 1:1 support for key skills such as dose adjustment or carbohydrate counting.

3. For some, on-line training or refresher courses may be adequate / appropriate.

4. When referred to interventions such as structured education, this should be completed within the referral-to-treatment target of 18 weeks.

5. Once the intervention / education has been completed, unless there is clinical urgency (e.g. due to ongoing recurrent severe hypos), the team should review the individuals frequently (at least 2-3 times over the next 6 months) to assess the impact of the intervention before being re-assessed by the MDT.

6. If the MDT is satisfied that the person with diabetes has adequate skills, and despite review over 6 months and appropriate changes to therapy continues to meet funding criteria for CSII – they should be referred for CSII.

7. This referral should be measured against standard NHS 18-week referral to treatment.

8. This should include time taken to offer the person with diabetes adequate choice of insulin pump. The DTN virtual showroom can support this.

9. Teams may find it appropriate to work in groups or hubs to enable appropriate choice of insulin pump and allow timely pump starts.
Recommended DTN - Pump pathway

HbA1c > 8.5% (69.5 or 70 mmol/mol) and/or disabling hypoglycaemia

MDT to assess skills

Skills assessment
1. Measuring glucose pre-meal 4 or more /day
2. Carbohydrate counting (reviewed by a trained educator as part of the MDT)
3. Bolusing before eating carbohydrate and using calculations that include carbohydrate counting, insulin: carbohydrate ratios and correction factors.
4. Understands the impact of exercise, illness and alcohol and the principles of adjusting therapy in response to these
5. Understands the principles of how to adjust basal and/or bolus insulin in response to glucose patterns
6. Sick day rules / ketone testing

Skills gap

Individualised plan to address skills gap
1. Structured education (eg DAFNE)
2. Virtual education
   - DAFNE online
   - Mytype1diabetes
   - Bertieonline
   - DTN education videos
3. 1:1 support and education
4. Support group education
   - Exercise groups
   - Carb counting groups
   - Dose adjustment groups
   - Peer support groups
   - Psychological support
   - Motivational support

18 weeks [RTT]

Re-assess at 3–6 months depending on the skills gap

Using skills adequately Adequate support from team

Decision to start pump

Start pump

18 weeks [RTT]
Flow chart for commencing CSII remotely

Person with diabetes meets criteria for CSII/ person with diabetes due pump upgrade

Decision made at T1DM MDT to proceed with CSII

DEVICE CHOICE

Device choice and mode of training agreed with person with diabetes

Device ordered from company and sent directly to person with diabetes

Face to face training

Time agreed with DSN/ Industry representative

Person with diabetes attends diabetes centre for training

Physical/virtual attendance by industry rep.

Joint training session with DSN and industry rep.

Clinical checklist completed by DSN

Technical checklist completed company rep.

Decision to proceed

Follow up day 3,5,7 with HCP

Virtual training (Group of 2)

Consent completed by person with diabetes and returned to diabetes centre

Written confirmation of settings sent by industry rep. to HCP

HCP sends pre-determined pump settings and person with diabetes contact details to industry rep.

Date arranged for virtual training

Technical training session delivered (2 hours 30mins)

DSN training session delivered (30mins)

Checklists completed by company rep/ DSN/ person with diabetes

Manufacturers:
- MEDTRONIC
- OMNIPD
- SOOIL
- TANDEM
- ACCU-CHEK
- YPSOMED

1. Access
2. Availability
3. Agreeable
4. Technical literacy