Response to the final scope of the NICE Health Technology Appraisal review of CSII



April 2007

Diabetes UK is one of Europe's largest patient organisations. Our mission is to improve the lives of people with diabetes and to work towards a future without diabetes through care, research and campaigning. With a membership of over 175,000, including over 6,000 health care professionals, Diabetes UK is an active and representative voice of people living with diabetes in the UK.

Facts about diabetes

- Prevalence of diabetes is 2.2 million in the UK. It is predicted that diabetes prevalence will double world-wide, accounting for 3.07 million people in the UK.¹
- Diabetes affects the young and old, and has particularly poor outcomes in those of lower socioeconomic status and in those from black and minority ethnic groups.^{2,3}
- Evidence is available supporting the need for improved education of people with diabetes and their carers if better control and improved outcomes are to be achieved. 4,5,6
- Diabetes, if undetected or not well managed, can lead to many complications and have a devastating impact on quality of life.

Declaration

We have received sponsorship from pharmaceutical companies that also produce insulin pumps as part of their broad remit, no funds were received in relation to insulin pump therapy. Our relationship with pharmaceutical companies is governed by very strict ethical guidelines. Diabetes UK will not accept more than five per cent of total income per annum from one corporate partner with a vested interest in diabetes, nor more than 20 per cent of total income per annum from commercial organisations with a vested interest in diabetes, so as to not compromise our integrity. Please find attached a link to our ethics of working relationships statement: http://www.diabetes.org.uk/About_us/Privacy_policy/Sponsorship/

Executive Summary

- Diabetes UK recommends that the criteria for those considered suitable for CSII is expanded to reflect the biomedical and quality of life benefits that CSII can bring as a treatment option to people with diabetes. Availability should be based on clinical need, personal choice, and suitability.
- People with diabetes need to be motivated in order to self manage on a pump. It is vital that specialists, competent in delivering education in relation to self management and CSII, deliver this education to people with diabetes to support them to self manage on the pump.
- Recent figures suggest CSII is under used in the UK in comparison to Europe and the USA.
- Quality of life benefits have been demonstrated in CSII use in adults, children and young people including; reports of reduced anxiety, greater flexibility, freedom and autonomy, general health and well being, reduced health related problems, improved sleep, with similar findings for carers in relation to their own quality of life.
- Continuous Blood Glucose Monitoring is found to be beneficial by some people with diabetes as it empowers them to feel in greater control of their diabetes and can assist in detecting unrecognised hypoglycaemia and improving glycaemic control.

- CSII is associated with; improvements in blood glucose control and Hba1c, a reduction in hypoglycaemia including severe hypoglycaemia and night time "hypos", a reduction in glucose excursions, and improved efficiency of absorption of insulin including use in people with Type 2 diabetes on large amounts of insulin.
- CSII can represent good value for money as less insulin is required, and as it is associated
 with less primary care contacts, less hospital admissions and hospital out patients
 appointments, and through improved glycaemic control, less diabetes related
 complications.
- When calculating the costs of CSII the provision of specialists and the delivery of education must be included in the calculations.
- A postcode lottery has been identified with regards to the local implementation of the current NICE Technology Appraisal for CSII.
- Greater clarity is required from NICE regarding how services are accessed and how
 guidelines are implemented in order to support the development of high quality, accessible
 pump services for people with diabetes and eliminate the implementation post code lottery
 identified.
- The recommendations of the Diabetes UK and National Diabetes Support Team Insulin Pumps working group should be incorporated into NICE implementation guidance and recommendations.

Detailed Response

Background

Diabetes UK recommends the criteria for those considered suitable for CSII therapy should be expanded and that separate guidance is produced for adults and children and young people to reflect in more detail the differences in needs and issues. CSII therapy has many benefits that can enhance both the physical and emotional well being of a person with diabetes and their quality of life ⁷and can be considered good value for money⁸. Although it may not be suitable for all people with diabetes using insulin, we believe the outcomes demonstrated in terms of quality of life and bio-medically related benefits, support broadening the availability of CSII to other groups of people with diabetes regardless of age or type of diabetes. Availability should be based on clinical need, personal choice and suitability.

People with diabetes need to be motivated in order to use CSII as it requires a person to take significant responsibility for day to day management including regular testing and confidence to act on the results ^{9,10}. The person must be supported by trained specialists who can provide structured education to ensure a person has the knowledge about diabetes, food, exercise and insulin and how they interact to affect blood glucose levels. Specialists should be competent in delivering information about dietary needs, carbohydrate counting, administering insulin via a pump and in the provision of ongoing support¹¹. This is crucial to ensure that people with diabetes using CSII do not develop Diabetic Keto Acedosis (DKA) as a result of lack of knowledge about how to self manage using CSII. Those specialising in pump education will also need to be sure that "all other staff who may come into contact with a pump user have sufficient knowledge of CSII." ¹¹All provision of care and education should be quality assured. ¹¹

Key to diabetes care is self management and choice in treatment that supports, motivates and empowers people to self care by enabling them to take more control of their diabetes. The current

policy agenda of choice¹² emphasises the need to listen to and engage with service users regarding service delivery to make services more responsive to patient needs. Information from our Children and Young Peoples' Members Survey 2006¹³ indicates that one of the top priorities for children and young people was increasing access to insulin pumps. At present we are concerned that the uptake percentage cited in the current NICE Technology Appraisal 57 is being used to arbitrarily limit the number of pumps made available to people within a Primary Care Trust (PCT) (to between 1-2% of the relevant population) creating a postcode lottery regarding implementation. This postcode lottery has also been identified via qualitative information we have received identifying barriers to access from people with diabetes ¹⁴. These include problems of identifying funding from the PCT, and the reluctance of health care professionals to explore CSII as a treatment option. It is estimated that close to 1% of people with Type 1 diabetes in the UK, of which perhaps only 0.1% are children with Type 1 diabetes, are using CSII therapy in contrast to an average of 10% in Europe and 20% in the USA suggesting under utilisation in the UK¹¹. As CSII is no longer a new therapy some of the previous safety concerns associated with insulin pumps have been addressed.

Quality of Life and Participation in Society

Several studies have outlined the health related quality of life benefits of CSII therapy 7,15,16,17,18,19,20,21 and some have demonstrated that those transferring from MDI to CSII are unlikely to wish to go back to MDI 7,15,20. People with diabetes should be able to enjoy and participate in life as fully as possible and treatment options like CSII should be available more widely to facilitate this. One study identified increases in quality of life when using CSII in all of the following parameters; social relations, time flexibility, physical complaints, worries about the future, diet restrictions, daily hassles, fear of hypoglycaemia, burdens of hypoglycaemic events, blood glucose fluctuations, self-efficacy and treatment satisfaction²¹. It is evident that a condition like diabetes can significantly affect many aspects of an individual's life. These parameters demonstrate how important the quality of life factor is in determining whether or not CSII should be more widely available to people with diabetes. The White Paper Our Health, Our care, Our Say¹², emphasises the importance of person centred care and quality of life. The policy emphasis on choice for people with long term conditions suggests that choice should feature more widely than it currently does in relation to treatment options such as CSII, emphasising the need for people with diabetes to have access to treatments that fit their lifestyle and that in turn will result in reducing short and long term complications. People with diabetes should not be denied treatment that can enhance their diabetes management and quality of life up until the point where they are experiencing sub-optimal glucose levels or disabling hypoglycaemia. As one carer puts it "surely prevention is better than cure". Another person with diabetes has commented; "if... end up in hospital I would probably stand more of a chance of getting a pump." Another report from a person with diabetes we received stated that their complications and health worsened as they had to go through the process of switching and trialling other regimes before being considered as suitable for CSII, despite identifying at an earlier stage their interest in being considered for pump therapy.

Improvements in health related quality of life can be attributed to CSII. People with diabetes are more likely to have Generalised Anxiety Disorder (GAD) than people without diabetes, with 14 per cent of people with diabetes as opposed to three – four per cent of the general population²². The causes of anxiety include the fear of hypoglycaemia. By making CSII more widely available

this can eliminate or reduce the level of stress and anxiety experienced by people with diabetes from these causes. Studies have shown a reduction in incidences of hypoglycaemia as a result of using CSII ^{7,15,16,21,23} and in one study in particular a resultant reduction in fear of "hypos". It is not just the "hypo" itself but the fear of it that can impact on the person's quality of life and the choices they make. As a child it can affect how they are treated by their peers, their school, and their sense of whether they can take part in activities that will affect their blood glucose levels, which has knock on effects on their social development and potentially their physical health. As an adult it can inform and/or restrict choices regarding driving, working and aspects of socialising and physical activity. Although some studies have reported anxiety in people using CSII regarding pump failure or malfunction ^{17,18} particularly in the early period of using the pump, studies have demonstrated that those who have converted to using CSII as opposed MDI report an improvement in their perception of their mental health ^{7,19}.

People with diabetes report experiences of greater flexibility, convenience and autonomy regarding their diabetes management when using CSII within several studies ^{7,15,17,18,19,21}. This again enhances their sense of well being. The burnout due to demanding self care routines has been reported in the evidence and impacts significantly on quality of life and emotional well being ²⁴. Poor emotional wellbeing is also associated with poorer adherence to self care routines which in turn can lead to poor diabetes control, resulting later in an increased risk of developing complications ²⁴ and increased costs to the NHS. The restrictive sense of tight routine which often accompanies diabetes self management can be eased through the use of CSII. People have reported greater flexibility in what they eat and when they eat and in participating in different activities ^{7,15,17,18,19,21}. Although increased testing is required, the greater flexibility is liberating, enabling people with diabetes to have greater freedom in their daily living and socialising without the restrictions of planning mealtimes and ensuring the availability of food. Anecdotal reports we have received identify people feel their glucose control and health have improved as a result of switching to CSII, as well as it having a positive impact on their lifestyle.

Improvements in quality of life could also be felt as a result of the biomedical improvements experienced. A reduction in the frequency of hypos, episodes of DKA and resultant hospital admissions can improve the emotional well being outcomes for a person who experiences these as a result of their diabetes. Studies have shown that people with diabetes on CSII report a general sense of well being or increased well being and treatment satisfaction ^{7,16,17,18,21} as a result of using CSII. Improved glycaemic control reduces the risks of developing long term complications and knowledge of this can improve the sense of well being.

Improvements in sleeping patterns have also been reported through studies examining quality of life in relation to CSII ^{7,17,19}. Disrupted sleep obviously has a knock on effect with regards to a person's physical and emotional well being and their ability to participate fully in aspects of their life such as education, work and socialising.

Although a systematic review (poster abstract) questions the quality and validity of many of the studies investigating the impact of using CSII on quality of life there is no strong evidence that there is no benefit. The fact that there is limited research evidence is a weakness of the research and does not prove that there is no positive impact on quality of life²⁵. Reports we have received about CSII have also been overwhelmingly positive and cite improvements associated with quality of life as one of the benefits of CSII.

Empowerment, control and self management

Standard 3 of the diabetes National Service Framework (NSF)²⁶ outlines the importance of empowering people with diabetes to manage their condition:

"All children, young people and adults with diabetes will receive a service which encourages partnership in decision making, supports them in managing their diabetes and helps them to adopt and maintain a healthy lifestyle. This will be reflected in an agreed and shared care plan in an appropriate format and language. Where appropriate, parents and carers should be fully engaged in this process." ²⁶

Studies have outlined the increased sense of empowerment and control felt by people with diabetes over their diabetes as a result of converting to CSII, particularly in encouraging children and young people to gain autonomy in managing their diabetes ^{15,19}.

Blood glucose monitoring is vital in enabling people with diabetes to adjust their food/insulin intake accordingly to prevent both hypoglycaemia and hyperglycaemia that could contribute to the development of complications in the long term²⁷. New technologies for the delivering and monitoring of blood glucose are developing at a very fast pace. Continuous Blood Glucose Monitoring (CBGM) and CSII are being accessed by an increasing number of people with diabetes. CBGM enables people to monitor their glucose levels closely and one RCT of the realtime CBGM has found it beneficial in improving glycaemic control in people with type 1 diabetes who are poorly controlled²⁸. Another study, whilst identifying that CBGM was no better than standard capillary glucose measurements for improving glycaemic control did find CBGM useful for detecting unrecognised hypoglycaemia in both people with Type 1 and Type 2 diabetes ²⁹. Some people with diabetes find it empowering to be frequently aware of their levels as it enhances their control over their diabetes by providing information to support self management decisions. This method of linking blood glucose monitoring and insulin delivery more directly is that which mimics how the pancreas works. People with diabetes using the two together have reported that it provides a greater level of control and management of blood glucose levels. It enables them to know exactly what their blood glucose level is and exactly what level of insulin to give to keep within target range of 4-6 mmol. Many People with diabetes report that monitoring and judging what insulin to give, what activities can be undertaken, what food is eaten and the impact on their blood glucose levels as frustrating, difficult, time consuming and can, if not careful, either take over their whole life or cause burn out at times. As stated by a person with diabetes themselves when using a pump and continuous blood glucose monitor "the important thing about living with diabetes is that I control my diabetes and that it does not control me. Use of the pump and continuous blood glucose meter is enabling me to completely control my diabetes and therefore leaving me free to live my life."

Impact on carers

Carer quality of life is important and will impact on the person with diabetes and other family members. Improvements felt by one party are likely to result in improvements for the others. CSII has a beneficial impact not only on the quality of life of the person with diabetes but also their carers¹⁹. A U.S based qualitative study identified the impact of switching from MDI to CSII. One parent described CSII as the "zen in diabetes management" in contrast to the description of MDI

as "background music", indicating the strength of feeling regarding the perceived benefits of CSII for their child¹⁹. The increased sense of freedom and flexibility in meal times and diabetes management in general expressed by people with diabetes on CSII is also expressed by parents¹⁹. Parents expressed feeling like the "food and time police" and worrying about their child's glucose control when children were out of the "parent radar", when their children were on MDI¹⁹. Although increased stress was identified by carers as they adjusted to the transition of using CSII and learnt to use the pump, the positives were in parent's being able to "unclog" their minds and in not having to be concerned regarding scheduling meals and snacks¹⁹. Worry was also relieved, with parent's reporting less stress over all including worries over; hypoglycaemia, mealtimes, and how their children are when they are not with them, particularly as parent's can check the pump via a history log of how much of a bolus of insulin has been given¹⁹.

Management of metabolic control and Type 1 Diabetes

The benefits associated with CSII even in comparison to insulin glargine include; improved glycaemic control and a reduction in Hba1c, a reduction in the severity and frequency of hypoglycaemia, a reduced amount of total daily insulin and a reduction in consultant consultations, hospital admissions, and in some instances, episodes of hyperglycaemia 30,31,32,33,34,35

NSF standard 4 states that adults with diabetes should receive high quality care to support optimal blood glucose and blood pressure levels and control for other risk factors that could lead to the complications of diabetes²⁶. Whereas intensive insulin therapy usually decreases HbA1c but with an increased incidence of hypoglycaemia, evidence has already demonstrated the benefits of CSII in improving Hba1c levels and decreasing hypoglycaemic events, and particularly night time "hypos", and recent evidence also demonstrates the benefits of CSII in reducing glycaemic excursions ^{7,15,16,18,21,23,30-36}.

The 5 nations trial showed a reduction in glucose excursions using CSII and the "greatest immediate benefit" to people with diabetes from this was the significant reduction, of at least 50 per cent, in severe hypoglycaemia ⁷. This finding confirms, in an RCT, the benefit of CSII in reducing the risk of severe hypoglycaemia, as suggested by previous uncontrolled studies⁷. In addition one small study also indicates that CSII could be beneficial in reducing hypoglycaemia and glycaemic control in older people³⁷.

Whilst concerns regarding DKA have been raised in some studies, the 5 nations trial stated that "ketoacedosis occurred very rarely and all episodes were during the first CSII treatment phase" for those participating in the study. It is important that people with diabetes are provided with high quality education to support them in the use of their pump, thereby helping to reduce the risk of developing DKA through poor self management on the pump ^{7,17,20,21}.

CSII should be available to people with diabetes to enable them to achieve optimal blood glucose levels. It is well known that good blood glucose control contributes to reducing the risk of developing diabetes related complications. These complications are associated with greater morbidity and mortality rates for people with diabetes and increased costs to the NHS in treating the complications of diabetes. The diabetes NSF suggests that the presence of complications "increases NHS costs more than five fold" and increases the likelihood of hospital admission.

Not only do people with diabetes have a human right to be as healthy and well as possible and to participate in society, but the economy also suffers if people with diabetes are unable to work and contribute to society owing to sickness and progressive complications.

Comments from people with diabetes regarding the positive impact pumps have had on their lives include:

- "I love my pump... I would never wish to give it back"
- " since having my pump my Hbalc has dropped and I feel much better"
- " a major step forward in diabetes control and lifestyle (parent)"
- "the pump has completely changed my life"
- "it has been a major positive change with far fewer hypos"
- "feel strongly that all type 1 diabetics...given the chance to consider whether it's (pump) right for them"

Children and Young People

CSII is being successfully used by children and adolescents, improving their glycaemic control ^{16,36,38,39,40}. "In young children with Type 1 diabetes, variable appetite, fluctuating activity levels and limited verbal communication skills complicate care and add to the risk of hypoglycaemia."³⁶ Incidences of hypoglycaemia are associated with negative cognitive development in young children, therefore CSII can be beneficial as it supports tight glucose control whilst reducing the risk of hypoglycaemia. Insulin pumps provide a more physiologic delivery of insulin affording people with diabetes greater flexibility in their eating regimen which can support improved diabetes management and reduce the risk of hypoglycaemia. Since the late 1990s when CSII has become more common in use in young people, early clinical outcome studies have demonstrated a significant decrease of HbA1c in the follow up of patients started on CSII, and a decrease of severe hypoglycaemia. In addition the use of a single injection site for a period of two-three days with CSII has been shown to reduce the variability of absorption of subcutaneous insulin to about 3 per cent which is significantly less than reported for injected boluses. ¹⁶

The main aim of diabetes management is to maintain blood glucose levels as near normal as possible. As such a greater proportion of people with diabetes are using MDI and intensive therapy to mimic the actions of the pancreas it is becoming increasingly common for paediatric diabetes teams to recommend intensive insulin therapy to manage day to day blood glucose levels, and prevent development of complications for many children with diabetes. Recent research has demonstrated that glycaemic levels even in the first 5 years following diagnosis can be a predictor for the development of complications like retinopathy and nephropathy later on therefore it is important that children are supported to achieve good glycaemic control ⁴¹.

NSF standard 5 states that children and young people should be "supported to optimise the control of their blood glucose and their physical, psychological, intellectual, educational and social development". Studies have identified the increased sense of independence felt by young people using CSII in managing their diabetes; ^{15,19} encouraging their involvement with their care. Children and young people are able to use the pump as long as they are provided with the education and support to use it.

The quality of life issues identified previously apply to children and young people, particularly in affording them greater freedom and flexibility, reducing the burden of the self care routine and going some way to addressing some of the problems children encounter at school when having to do an injection. The issues at school are causing problems for many children and their parents when the child is at school if the child is unable, unwilling or is not trusted to inject themselves. Teachers do not generally accept the responsibility for ensuring that an injection is done and Diabetes UK is receiving an increasing number of reports that parents of children with diabetes are having to attend school to give their child their lunchtime injection when the child is using MDI. This can affect the child at school and also disrupt parents' routines, at the potential cost of their employment and therefore income, affecting the whole family. CSII could help remove some of the barriers children experience at school regarding school trips and participating in certain activities and the issue of sharps disposal whilst at school, and teachers may be more willing to push a button on a pump than inject a child. Although this may not be the responsibility or remit of the NICE technology appraisal for CSII, the practical reality of using CSII includes these unintended benefits.

Anecdotal reports identify that if a baby develops Type 1 diabetes, the amount of insulin required can be very small. Although little research has been undertaken in this area, reports do exist of the benefit of using a pump on very small babies as a means of gauging the smallest amount of insulin required and therefore avoiding hypoglycaemia ^{42,43}. A number of paediatric consultants have reported that the most effective way of managing the metabolic control of a small baby with Type 1 diabetes, although not many cases are reported, is to use CSII.

Pregnancy and Pre pregnancy

The effect of poor maternal blood glucose levels on the developing foetus have been identified in the evidence⁴⁴. Beyond the medical benefits of CSII in terms of glycaemic control⁴⁵, quality of life benefits can be identified in terms of reduced anxiety in relation to hypoglycaemia and anxiety regarding morbidity and mortality outcomes for the baby. Concerns regarding these could prevent women with diabetes from considering pregnancy and could exacerbate anxiety levels during pregnancy. Increased anxiety can affect a person's self care routine²⁴ impacting on the health of the woman and her foetus. One woman has reported to us she found it beneficial to have a pump during pregnancy.

People with Type 2 Diabetes requiring insulin

CSII could help people with Type 2 diabetes using insulin but experiencing difficulties in controlling their diabetes to achieve optimal blood glucose levels. In people with Type 2 diabetes the control of hyperglycaemia can remain a problem despite maximum oral therapy and large doses of subcutaneous insulin⁴⁶. These people, especially those who are obese, may need significantly large amounts of insulin without achieving even "adequate" glycaemic control⁴⁶. "It is known that the absorption of insulin shows wider variations if either the concentration of insulin

or the volume of insulin in which it is delivered is high."⁴⁶ Debate in the literature suggests that large boluses of subcutaneous insulin may degrade in the subcutaneous tissue. CSII results in an efficient and predictable absorption of insulin from the infusion site⁴⁶. A small study of the use of CSII in people with Type 2 diabetes supports the assertion that CSII improves the bioavailability of insulin, with the study proposing that CSII may be suitable for adults (study participants) with Type 2 diabetes with severe insulin resistance or poor diabetes control, with CSII stabilising glucose levels and improving outcomes⁴⁶. Within the study of people with Type 2 diabetes the participants reported an increased sense of well being and improved energy and activity levels as a result of using CSII.

Health Economics and Cost Effectiveness

The key costs associated with CSII are the capital purchase of the pump and consumables. The estimated average yearly costs are around 1650 pounds per person⁴⁷. As CSII is associated with improved glycaemic control and a reduced incidence of complications the cost effectiveness ratio is estimated to be 25,648 pounds per QALY which is reported as representing good value for money⁸.

In addition evidence has shown that cost benefits can be felt in the local health service and in the long term, as in the long run CSII is associated with reduced consumption of insulin, less contacts in primary care, reductions in hospital admissions and hospital outpatients contacts. ¹¹

When calculating the entire costs needed for providing CSII including the costs of specialists competent in educating people in the use of CSII is imperative, as are the costs of providing structured education to people with diabetes to support them in the use of CSII for their diabetes self management. The Insulin Pumps Working Group report identifies components that could form part of a structured education programme for pump users¹¹. In order to support CSII to be an effective and sustainable treatment option these foundations must be commissioned as part of a pump service and remain in place thereafter.

Cost savings may result through PCTs signing up to the newly proposed procurement system. Also systems could be set up where PCTs buy a certain number and range of different types of pumps for loan to enable people to trial them before a final decision is made by them as to whether they wish to switch to pump use. The costs during the trial period would then be just the consumables, particularly after the initial set up costs of this system of "loan" pumps.

Implementation of NICE guidelines

Provision of CSII and pump services are not uniform across localities in the UK¹⁴. This results in an unfair post code lottery regarding access to assessment for CSII, CSII itself or to specialist clinical support for education . The current NICE guidance is open to interpretation and a lack of clarity has resulted in many people reporting various barriers to access or no access at all despite their potential suitability in some cases. One person stated explicitly "this whole process is very frustrating" with people feeling they have to jump through several hoops before gaining access to a pump even once deemed suitable. This can also result in expense to people with diabetes who choose to try and self fund a pump rather than go through a long process.

Difficulties with funding and PCT deficits have been cited as reasons for not giving people with diabetes access to CSII. People stated the following; "fobbed off...pumps are expensive", "..been

told I would benefit from ..a pump... but there is no funding available to me". Another common barrier cited is the lack of training and knowledge of local staff to support people to use a pump. This can be used as a reason by PCTs and Local Health Boards not to fund pumps.

The recommendations of the Diabetes UK and National Diabetes Support Team working group should be incorporated into NICE implementation guidance and recommendations, to cover; assessment, referral, follow-up, ongoing support, education, support during initiation, supply of consumables, discontinuation, staff training and competencies. This work involved all stakeholders in insulin pump delivery and is a consensus view of how insulin pump services should be provided as part of a cohesive service for all people with Type 1 diabetes. Guidance from NICE regarding how services are accessed and how guidelines are implemented need to be clearer to support the development of high quality, accessible pump services for people with diabetes and eliminate the implementation post code lottery identified.

Conclusion

- Pump therapy is a popular and alternative insulin delivery option and awareness should be raised amongst healthcare professionals and people with diabetes alike.
- Transparent, consistent and equitable protocols should be in place in all localities covering:
- Funding for pumps and consumables so they are accessible when criteria are met
- The development of local pump centres, with appropriate infrastructure, staff, education and training to be encouraged. Local arrangements need to be put in place to support this.
- Teams delivering pump therapy services should establish a database to support quality assurance and adverse events reporting and national audit.

Acknowledgements: Diabetes UK would like to thank members of our UK Advisory Council for their contributions to this consultation

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