

Insulin Pump Services



Report of the Insulin Pumps
Working Group

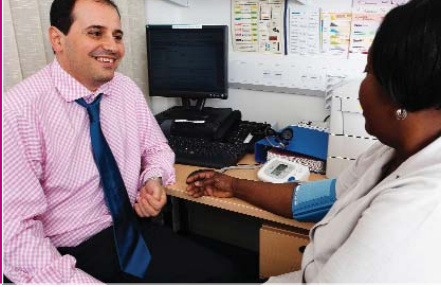
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Contact details	Laura Ladd Diabetes Policy Team Room 408 Wellington House 133-155 Waterloo Road London SE1 8UG
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Foreword

In England, there are an estimated 2.35m people with diabetes and this is predicted to grow to more than 2.5m by 2010. Diabetes is one of the great health threats of the 21st century and it is essential that we work

together to create services that meet the needs of the diabetes community. Insulin pumps are one method of treating the condition, and it is on insulin pump services that this report focuses.

NICE published guidance on the use of insulin pumps in March 2003. There is still unacceptable variation in access to this therapy across the country, however, suggesting that the guidance is not being implemented consistently.

The Insulin Pumps Working Group was set up in November 2005 to address this problem, and this report outlines the group's findings. Specifically, work initiated by the group has led to the development of:

- An extension of the PBS prevalence model to include specific information on insulin pumps
- A generic specification for insulin pump care – best practice model
- A national framework contract for supply of pumps and consumables
- A home delivery service for consumables
- Recommendations for future research
- Identification of issues for NICE to consider when it revisits its guidance on pump therapy in 2007.

The report also outlines examples of what others have done around the country to improve their provision of insulin pump therapy.

In keeping with the NICE guidance, the group concluded that pump therapy should be offered as one option within an overall approach to insulin therapy for adults, adolescents and children. Although not suitable for everyone, pumps can make a huge





difference for some people, and should be built into comprehensive and coherent diabetes services. Some additional costs are involved in providing pumps and consumables, but pump therapy can produce cost savings elsewhere in diabetes services.

This document sets out the findings of the Insulin Pumps Working Group. We hope that it helps in clarifying the NICE guidance and bringing some uniformity to the provision of insulin pumps across the NHS in England.

A handwritten signature in black ink, appearing to read 'Sue Roberts'.

Sue Roberts
National Clinical Director for Diabetes

A handwritten signature in black ink, appearing to read 'Douglas Smallwood'.

Douglas Smallwood
Chief Executive
Diabetes UK



Background

Diabetes mellitus (diabetes) is a chronic metabolic disorder characterised by elevated blood glucose levels (hyperglycaemia) resulting from a lack of the hormone insulin or resistance to its action. If not controlled effectively, diabetes can lead to complications including kidney failure, blindness, limb amputation, coronary heart disease, stroke and damage to the nervous system, peripheral vasculature and skin.

There are two major types of diabetes. Type 1 diabetes is due to an absolute loss of insulin production and therefore administration of insulin is necessary for survival. Type 2 diabetes results from reduced insulin production and reduced tissue sensitivity to insulin (known as insulin resistance). In Type 2 diabetes, blood glucose levels may be managed with diet and lifestyle modifications alone following diagnosis. As the condition progresses, the addition of oral glucose-lowering drugs to diet and lifestyle modifications are usually required. Over time, many people with Type 2 diabetes also need insulin to control their blood glucose levels adequately.

Continuous Subcutaneous Insulin Infusion (CSII) or 'pump therapy' provides significant improvement in glycaemic control and quality of life for some people with Type 1 diabetes. It is a method of administering insulin over twenty four hours via a small needle inserted under the skin. A small amount of insulin is delivered all the time and the individual must give booster amounts (bolus) to match food or reduce raised blood glucose levels. Safe and effective use requires the individual to monitor their blood glucose on a regular basis so that they can make sound decisions. Pumps can make it easier to achieve healthy blood glucose levels with less danger of severe and incapacitating hypoglycaemia. Patient education and regular support from a competent team, so critical for all those using insulin to manage their diabetes, is particularly important for pump users.

The current guidance is outlined in Health Technology Appraisal Guidance – No.57 – Guidance on the use of continuous subcutaneous insulin infusion (CSII) for diabetes¹. Issued by NICE in February 2003 (ref: TA057), this guidance recommends pump therapy as an option for adults and children with Type 1 diabetes provided that:

¹ Available on the NICE website at <http://www.nice.org.uk/58194>



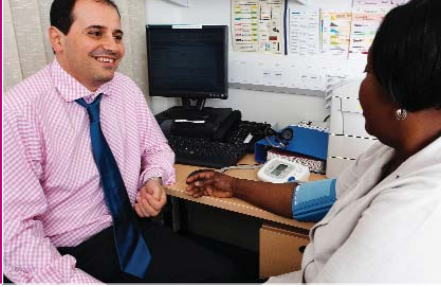
- Multiple dose insulin (MDI) therapy (including, where appropriate the use of insulin glargine) has failed; and
- Those receiving the treatment have the commitment and competence to use the therapy effectively.

The guidance also mentioned the importance of patient education and staff training and the benefits for certain subgroups of patients.

These broad recommendations have been interpreted differently across the NHS in England – as a result access is variable. Funding of CSII can depend upon:

- Primary Care Trust (PCT) policy
- The capacity of enthusiasts to generate funding from other sources
- The organisation of the supply chain for pumps and consumables
- The geographical proximity to teams who can support individuals on pumps

It is often not recognised that the guidance also applies to children, and, generally, not all patients who come within the guidance are benefiting.



The Insulin Pumps Working Group

The Insulin Pumps Working Group brought together a wide range of people with an interest in insulin pumps, including clinicians and pump users from across the country. They considered how the current variability in pump provision could be reduced, and problems resolved.

The terms of reference of the group were:

- To agree what needs to be done to enable local services to deliver the NICE HTA on insulin pumps for adults, children and young people.
- To consider other issues relating to insulin pump therapy and feed into the development of further NICE guidance.

As a result of the work of the Insulin Pumps Working Group and its sub-groups, a number of tools have been developed that can help in the development of a pump service. In addition, the group has made a number of suggestions for further work to assist in the equitable delivery of pump services across the country.

Finally, the group has identified a number of issues that have been referred to NICE for consideration during their review of CSII, due to take place in 2007.

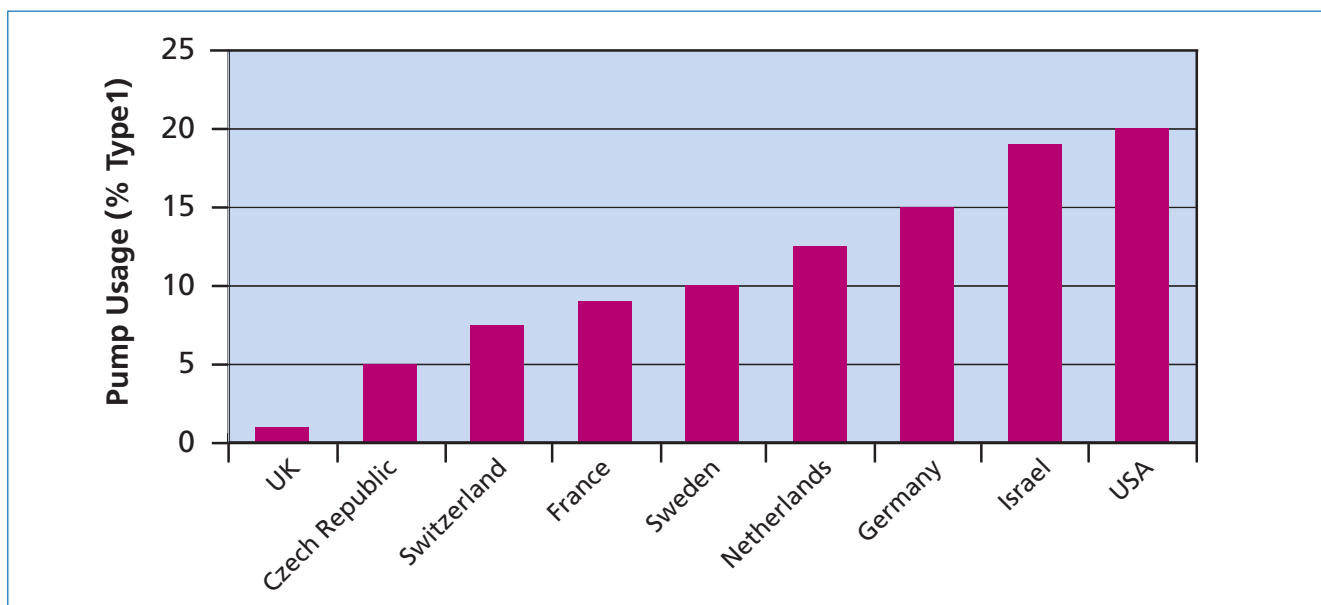


Context and Prevalence

Evidence made available by the International Diabetes Federation (IDF) suggests that the incidence of Type 1 Diabetes Mellitus is increasing worldwide by about 3% per year and this pattern is shared across high and low incidence countries.

The number of people with Type 1 diabetes treated by CSII can be estimated from a variety of sources, including national registers, manufacturer's records, and published reports of pump practice in various countries.²³⁴ Collating this information, there is consensus that several countries are now treating about 15-20% of people with Type 1 diabetes by CSII (USA, Israel, Germany), and in most of the UK's European neighbours a substantial proportion (~10%) of people with Type 1 diabetes use insulin pumps for routine management (France, Sweden and the Netherlands). In contrast, overall UK pumps usage is probably no more than 1% of people with Type 1 diabetes and in some areas of the country, and in children, it is much less (perhaps 0.1% of children with diabetes). Thus, the present take up of CSII in the UK is dramatically lower than in most other countries of comparable economic standing and level of healthcare provision.

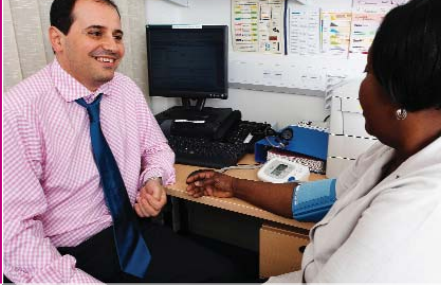
Estimated insulin pump usage in different countries (J Pickup).



² Selam JL. *Insulin pumps in Europe*. Infusystems 2005; 4:19

³ Jankovec Z, Krcma M, Lacigova S, Zourek M, Rusavy Z. *National registry of patients treated with continuous subcutaneous insulin infusion (CSII) in the Czech Republic: long-term results*. Infusystems 2005; 4:21-24

⁴ Adamson U, Lins P-E. *Insulin pump therapy in Sweden*. Infusystems 2002; 1:10-13



There is some evidence from manufacturers' estimates that new pump starts in high-use countries are slowing, so that a plateau at around 20-25% of people with Type 1 diabetes may be reached. This is consistent with recent estimates of people with Type 1 diabetes who would benefit from CSII on clinical grounds (as opposed to those who might simply prefer this therapy as their form of routine management).⁵ However, it is clear that further work needs to be done to better understand current use of CSII, and its potential future use.

⁵ Pickup JC. *Are insulin pumps underutilised in type 1 diabetes? Yes.* Diabetes Care 2006; 29: 1449-52



The Aim of this Report

The Department of Health has produced comprehensive guidance in order to support high quality commissioning. *Health Reform in England: Update and Commissioning Framework*⁶ sets out the essential steps that PCTs should follow when commissioning health and care services. This will be supplemented by the forthcoming publication of a commissioning framework for health and well-being. A *Diabetes Commissioning Toolkit* was published in November 2006⁷, providing tools that can be used across diabetes as a whole.

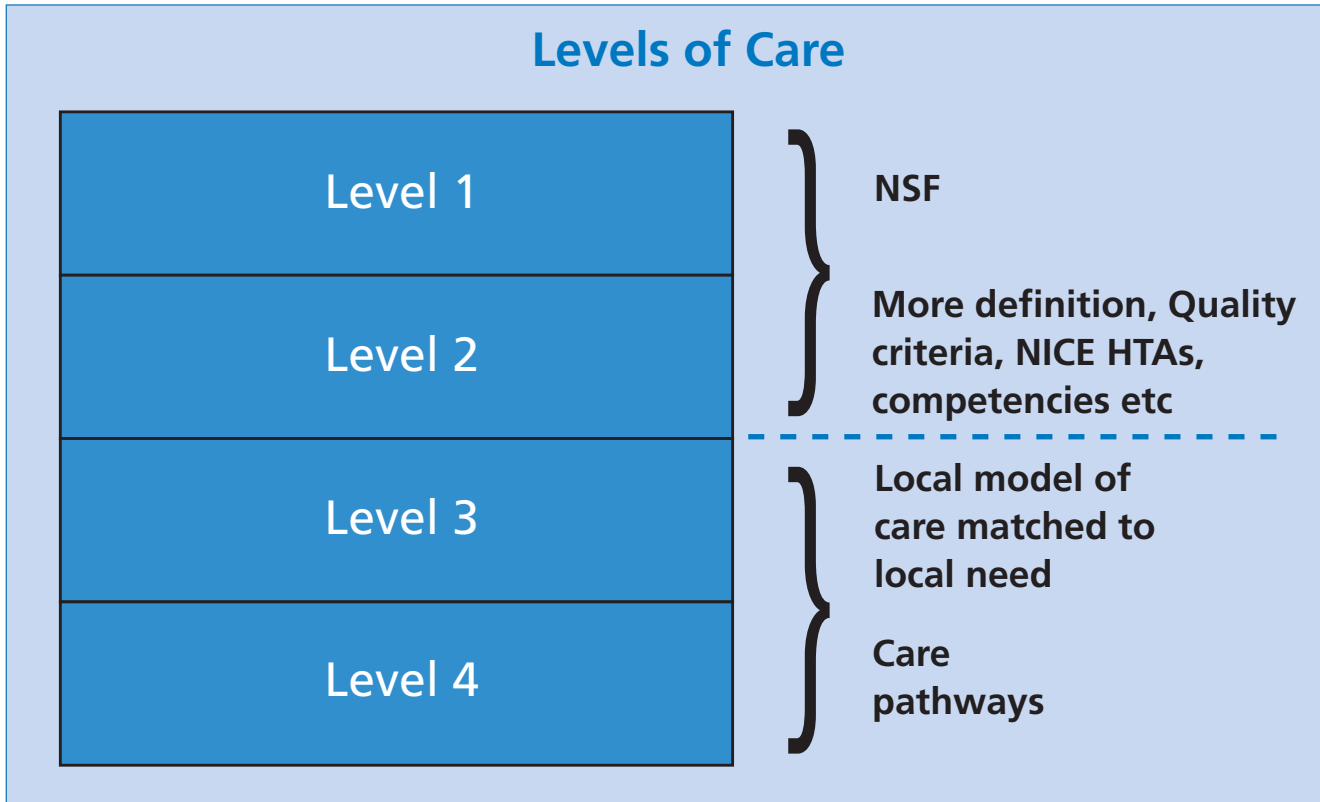
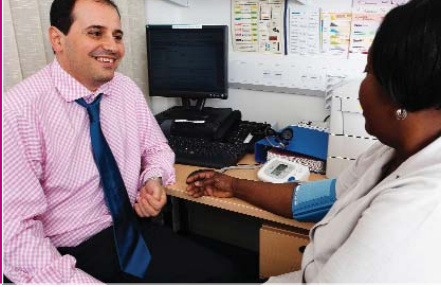
The Insulin Pumps Working Group has tried to develop tools that will fit into this overall framework. Some of the information in this report will be of use to commissioners of services, and some will be of use to those providing a service. Commissioners of diabetes services will need to ensure that service providers are adhering to the NICE guidelines on pump therapy, and considering the findings of the Insulin Pumps Working Group outlined in this document.

When looking at planning services, this report uses the terminology of 'levels of care'. This concept is now widely used in diabetes, and is described in *Levels of Care; a new language for service redesign and planning*.⁸

⁶ Available on the Department of Health web site at http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4137226&chk=D2YSig

⁷ Available on the DH website at http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4140284&chk=cVa0iw

⁸ Available on the NDST web site at http://www.diabetes.nhs.uk/downloads/levels_of_care1d.pdf



Level 1 and Level 2 provide an account of the core elements of care for a particular condition, without stipulating where, by whom or in what order services should be delivered as this can vary significantly from one locality to another. For diabetes, the National Service Framework provides the level 1 evidence.

Level 2 looks at each detailed part of the “map” identified in Level 1 and outlines the core principles of each part and the relevant quality markers and best practice. The NICE guidance on insulin pumps is an example of a level 2 resource.

This report and the tools outlined in it also aim to be a level 2 resource to enable the redesign of insulin pump services at Levels 3 and 4.



Planning Pump Services

This section outlines the key considerations for planning any pump service. The Insulin Pumps Working Group identified a number of factors that should be considered when planning an insulin pumps service. These include:

- User involvement
- Needs assessment
- Service planning
- Paying for pump services
- Service specification and a best practice model
- The role of diabetes networks
- Audit

User involvement

User involvement should be a critical part in designing patient centred services that match the specific needs of the local population, and the views of people with diabetes should be sought throughout the assessment, planning, specification and monitoring processes of commissioning. Patient groups such as Diabetes UK and INPUT can help local diabetes services to access the views of users. Diabetes networks often have well developed user involvement programmes.

Needs assessment

Commissioners will wish to consider the predicted need for an insulin pump service in their area. NICE estimated that the percentage of people requiring pump therapy would be around 1-2%, and it is known that many areas of the UK still have less than 1% uptake. This is very different from other areas of the world such as the USA, Israel and Germany, where usage is reported to be 15-20% of people with Type 1 diabetes. It seems likely that pump use in the UK will eventually be far greater than the NICE estimate. Most patients commenced on an insulin pump will remain on a pump for the



rest of their lives. Recent research indicates that more than 80% of paediatric patients maintained pump therapy at around 4 years⁹, and it is inevitable that this cumulative effect will increase the overall proportion of pump users over time.

The Yorkshire and Humber Public Health Observatory (YHPHO) is the lead Public Health Observatory for diabetes and has already produced the PBS Diabetes Population Prevalence Model to model the prevalence of diabetes over 10 years. In order to assist commissioners in carrying out a needs assessment for insulin pump provision, YHPHO will be developing a specific tool, which will appear on their web site alongside the PBS Diabetes Prevalence Model. This will include a simplified model for establishing a Type 1 diabetes population estimate by age group, and an estimate of potential insulin pump usage. It will also be in a format that will allow commissioners to map trends of insulin pumps usage in their population over time. It will be presented through a web based tool and tables.¹⁰

Service planning

Commissioners will need to ensure that there is a comprehensive service for all their patients with Type 1 diabetes – adults, young people and children – that adheres to the relevant NICE Guidelines. Access to pump therapy is an essential component of good Type 1 diabetes care. While the needs of children and young people will need to be considered separately from adults, it is important that pump therapy is available to all ages.

While access to pump services should be an integral part of the local model of care, the way that this is delivered will vary greatly across localities. This will depend on a variety of local factors, such as the number of children with diabetes, the geography of the area and the availability of, or potential for development of, local expertise.

Any overall model for the delivery of diabetes care for all people with diabetes will need to consider how people will access services, and how those services will be managed, taking all relevant NICE guidance into account. This will include the NICE

⁹ Wood J R et al, *Durability of Insulin Pump Use in Paediatric Patients with Type 1 Diabetes*, *Diabetes Care* 29:2355-2360, 2006

¹⁰ More information available at <http://www.yhpho.org.uk/diabetes.aspx>



insulin pumps guidance¹¹, NICE Type 1 diabetes guidance¹², and NICE guidance on patient education models in diabetes¹³. Having clear operational protocols for each element that are regularly audited and monitored will help to ensure this. These could be developed through local diabetes networks, involving people with diabetes (or user representatives), and could include:

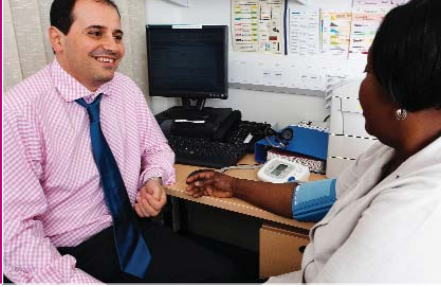
- Where people with Type 1 diabetes will routinely be managed, and where care planning will take place, including how this will link with specialists in insulin management
- Arrangements for transfer of patient care between sites and between services, including transfer between paediatric and adult services
- Type 1 diabetes education programmes for people of all ages, therapies and learning abilities and styles
- Arrangements for the pump service, for example local, hub and spoke etc, with details of how the various components will be delivered
- Administration of supplies
- Ongoing local support for pump users
- Clearly defined follow-up arrangements with monitoring of patient experience and satisfaction

There needs to be a clear understanding of where pumps fit into the overall care of people with Type 1 diabetes, taking into account issues around safety and governance. Is it right to develop a pump service within a Type 1 service that has inadequate specialist nursing support, no experience of providing quality assured patient education, little access to dietetic advice, and is unable to support 24 hour advice? The key issue is not the insulin pump, but the development of a single cohesive service whether the patients are on pumps or not.

¹¹ Available on the NICE web site at <http://www.nice.org.uk/guidance/TA57>

¹² Available on the NICE web site at <http://www.nice.org.uk/guidance/CG15>

¹³ Available on the NICE web site at <http://www.nice.org.uk/guidance/TA60>



The over-riding principle should be to provide insulin pump services as locally as possible whilst still maintaining an appropriate level of expertise. The models to choose from are:

- Do not provide a local pump service – clear referral arrangements need to be agreed with another pump service
- Developing pump service – strong network links required with an established pump service
- Established pump service – should be developing and maintaining expertise and providing ongoing support to services with a smaller number of patients

Patients initiated on insulin pumps should have the option to be transferred back to local services for their ongoing care wherever possible (ie where the local service is competent to provide that care), and the long-term aim should be to provide assessment and initiation as a component of care in all locally based Type 1 services.



What others have tried

The West Yorkshire Paediatric Diabetes Special Interest Group is a multi-disciplinary group that was established in October 2000. It was set up originally to encourage peer support and share good practice in the management of paediatric/teenage diabetes care. Over the years it has encouraged good communication between the 16 centres who care for the children with diabetes in the Yorkshire region. The group meet annually in Leeds, which has the specialist paediatric pump service, for a full day meeting looking at advances in the management of children with diabetes.

Insulin pump therapy is now offered on a shared care basis between each of these centres and Leeds. Patients have the pump initiated in Leeds with full care offered to the families for 6 months. The referring hospital diabetes staff are encouraged to attend the pump initiation sessions with their patients, or go to Leeds separately for advice on managing a patient on a pump. The families contact the Leeds paediatric diabetes team with any questions about their ongoing diabetes management. The families are aware that any emergency care will take place at the hospital nearest home. The staff at the local hospital can contact Leeds to get advice on diabetes related problems.

When the referring hospital feels ready to look after all aspects of pump therapy with their patient, then discussions take place between the local service and the Leeds service and the patient is formally handed back. However, arrangements can be made to review patients intermittently on a shared care basis.

For further information contact Fiona.Campbell@leedsth.nhs.uk

There is no minimum number of patients who should be cared for within a pump service, particularly during the period of development of pump expertise. The aim should be to encourage the development of insulin pump expertise as locally as possible. Pump services with only a small number of patients initiated and being given on-going care should have strong network links with a bigger service. This would also apply to paediatric services. There are substantial benefits of networking between established services, and there is a key role for larger services in developing and



maintaining expertise in smaller services. The initiating service has a responsibility to ensure that those services who they refer patients back to, are competent to provide ongoing care. If the local service is not competent (or confident) then the person with diabetes should not be referred back if that is agreed by all parties, including the person with diabetes.

Service specification and a best practice model

The Diabetes Commissioning Toolkit contains a generic specification for diabetes care that describes a best practice model. Appendix C sets out a similar specification, specifically tailored to insulin pumps. The contents of the specification are based on advice given by members of the Insulin Pumps Working Group. Commissioners may wish to adapt this framework to meet local requirements, taking a view on which elements it would be appropriate to include for their own services, and making appropriate amendments should NICE recommendations change.

Paying for pump services

Currently, insulin pumps and consumables are specialised service exclusions under Payment by Results. This is because the number of pumps used is low and unpredictable, the relevant Healthcare Resource Group (HRG) includes more routine treatment, and the distribution of different activity within the HRG is not even across providers. The associated out-patient attendances and any admissions will normally be covered within the tariff, although from 2006/07 onwards, multi professional outpatient attendances are included in local flexibilities. This means that they can be paid for outside the tariff subject to advance agreement by both provider and commissioners. *Payment by Results in 2007-08*¹⁴ makes it clear that commissioners and providers should agree local prices for insulin pumps and consumables, and put in place local arrangements for monitoring activity. These local prices should be paid as an additional payment to the relevant HRG, outpatient tariff, or locally agreed payment under flexibility.

¹⁴ Available on the DH website at http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4141101&chk=dhIxsM



What others have tried

PCTs in Leeds are currently providing insulin pump funding for any Type 1 patient who fulfils the NICE guidance criteria. In the absence of a nationally agreed pump tariff, attendances are currently paid for within the Payment by Results tariff. The future diabetes model in Leeds has less emphasis on where care is delivered and more on it being competency based, thus taking into account practice based commissioning. An agreed service specification and local tariff will be used for patients commencing on pump therapy, recognising that this work may take place in any appropriate setting.

For further information contact Paula.Dearing@leedspect.nhs.uk

The role of Diabetes Networks

Local diabetes networks can provide valuable assistance by identifying options for how the components of a pumps service can be provided. Commissioners will wish to ensure that these networks are the focus for developing an overall strategy to deliver the Diabetes NSF within a locality, and that a model for pump services provision is included as part of overall diabetes care.

Networks are a key resource for strategic delivery of the diabetes National Service Framework, and should be the best source of clinical advice to commissioners on all aspects of diabetes care. As a consequence networks will need to take a view on the relative priority of pump service development. They should monitor the availability and uptake of insulin pumps on their patch, benchmark against other networks, and work with their clinical staff to develop clinical protocols and guidelines where appropriate.

It is hoped that the use of the tools provided in this report will lead to greater national consistency in the interpretation of the NICE guidance. This should give commissioners more confidence to approve funding of CSII when the managing clinician has made a decision to treat that is consistent with the guidance. It should also help to ensure that patients moving between PCTs will continue to receive funding. Networks can help with this at a local level by developing consistent arrangements within the network,



and between neighbouring networks. Arrangements need to include continued provision of support and consumables. Provision must also be made for EU individuals who have come to stay in the UK who are already established pump users in their parent country.

Audit

As the number of people using pump therapy increases and this treatment option becomes more mainstream, service needs for these individuals will require ongoing review. Local audit should be carried out to support improvement & service development, and should be supplemented by national benchmarking.

In order to address these issues, networks may wish to consider setting up a Pump Services Advisory Group. This group would consist of pump users, multi-disciplinary health care professionals with a special interest in CSII who have significant experience working with pump therapy, and patient group representatives (eg Diabetes UK, INPUT). The remit of such a group would be to advise those providing diabetes services on how a pump service should develop over time, and to share best practice.

There is currently no national register of pump users. Commissioners may choose to stipulate that a local register is established as a way of managing the contract with chosen providers.

Audit involves improving care by repeatedly matching practice against agreed standards and implementing change accordingly.

The audits might include:

- Ensuring that NICE guidelines are followed
- Checking that CSII is considered for all eligible patients
- Determining that the glycaemic and clinical outcomes of CSII at a centre meet the locally agreed quality indicators
- Checking that the side effects of pump therapy are routinely recorded and monitored
- Monitoring the rate of pump discontinuation to ensure it is not too high



- Ensuring that patient experience and satisfaction with the treatment and the service remains high

The detail of audit will vary between centres but could gather information about the pump clinic or service (structure), the average and individual patient characteristics and how they are managed (process), and the outcome and side effects of treatment. This would require consistent collection of an agreed dataset. The dataset in Appendix A has been suggested, although further work is required to validate and agree this for national use. Further consideration also needs to be given to developing a system for national collection of any agreed dataset.

What others have tried

An insulin pump clinical database has been established at Leeds University. Data from Leeds, Bournemouth, Harrogate, Warwick and Middlesbrough is currently collected, with other services in the process of recruitment. The aim of this database is to allow research into

- the long term impact of pump therapy on glycaemic control
- complications of diabetes (which would not be possible in a randomised clinical trial due to its shorter duration)
- an economic evaluation of the impact of pump therapy on overall healthcare costs

It is hoped that, if successful, this could form the basis for a national register for pump patients.

For more information contact R.G.Feltbower@leeds.ac.uk



Providing a Pump Service

This section outlines the view of the group on what is best practice in the provision of a pumps service. It includes and builds upon the current NICE guidance on pump therapy.

Who should have access to a pump service?

As a reflection of NICE guidance on pumps and management of Type 1 diabetes, CSII should be considered in adults after a trial of multiple dose insulin therapy (MDI), including use of long-acting analogues, and a course of structured education. It is of particular benefit for:

- Those able to achieve target HbA1c (<7.5% without complications, <6.5% with complications) but only at the expense of frequent hypoglycaemia which has an adverse effect on quality of life
- Those who have made significant efforts to optimize control but have a high HbA1c due to marked fluctuation in blood glucose levels and for whom further reduction in levels will result in unacceptable hypoglycaemia

However, it is important to consider all of the critical elements of care, not just failure of MDI which was the “gold standard” of intensive diabetes care in 2003, but has now been updated by more recent guidance¹⁵. Insulin management is difficult, as individuals need to manage their diabetes in the context of lifestyle, danger of hypoglycaemic events, and so on. To provide the individual with maximum support, all individuals should have the opportunity to take part in structured education on an ongoing basis¹⁶. This education should meet national guidelines, and be provided at times appropriate to the patient’s needs. Ongoing insulin management should normally be reviewed as part of the care planning process¹⁷. Particular attention also needs to be given to glycaemic control for those who are pregnant, or planning a pregnancy, and those with accelerated complications.

¹⁵ Available on the NICE web site at <http://www.nice.org.uk/guidance/CG15/quickrefguide/pdf/English>

¹⁶ Available on the NICE web site at <http://www.nice.org.uk/guidance/TA60>

¹⁷ For more information see http://www.diabetes.nhs.uk/downloads/care_planning_in_diabetes_report.pdf

Providing a Pump Service



It is essential that all professionals providing routine management for diabetes, understand the role and importance of pump assessment.

In general therefore, CSII should be considered for those patients who have been unable to achieve their agreed care plan goals following impeccable Type 1 care. Impeccable Type 1 care is outlined in NICE Clinical Guideline 15 *Type 1 diabetes: diagnosis and management of Type 1 diabetes in adults*¹⁵. The key components are:

- Patient centred care, including the development of an individualised care plan
- A multi-disciplinary team approach
- Patient education
- Blood glucose control
- Arterial risk-factor control
- Surveillance and management of late complications

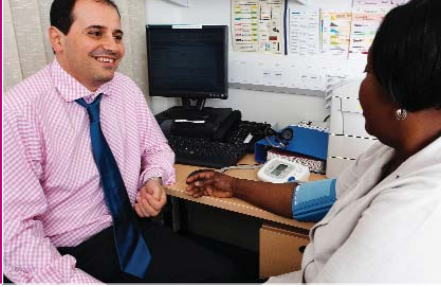
Local services may use this guidance as the foundation for their local model of care for Type 1 diabetes, within which CSII will be a part.

Due to the diversity of presentation, spectrum of age and complexity of management of diabetes in children, CSII should be considered for all children and may have to be initiated early in the management of the child's diabetes, even as early as the point of diagnosis. If there is no local service for children, this should be commissioned from an established children's CSII service.

Who should pump therapy be initiated and delivered by?

CSII therapy should be initiated by a trained specialist team, which will normally comprise:

- Physician
- Diabetes specialist nurse
- Dietitian



However, it is important that the team has all of the competencies required to provide a robust service, and that these competencies are available from more than one member of staff. It is particularly important that more than one nurse is trained and that the whole department is familiar with the support of CSII. They should also ideally have knowledge of the use of pumps from more than one manufacturer.

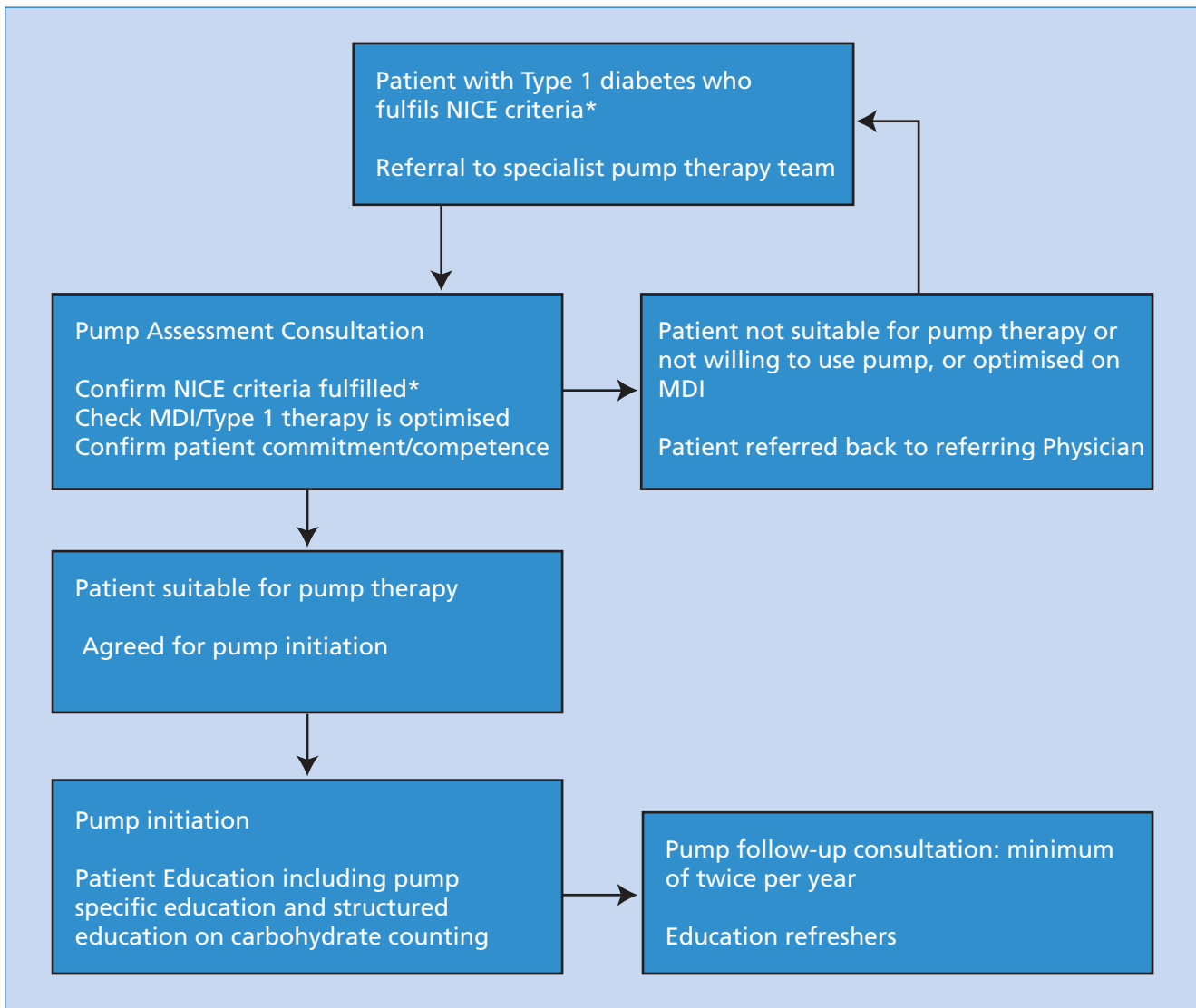
The range of activities carried out by the insulin pump team include:

- Confirmation that previous management has been impeccable and adhered to best practice in all respects. There may be room for further adjustment
- Assessment of suitability for insulin pump therapy
- Initiation of pump therapy for suitable patients
- Education & support for pump users
- Follow-up
- Support and training for other healthcare professionals involved

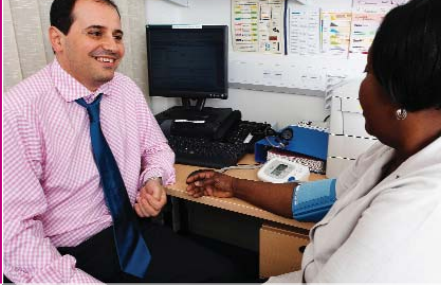


An insulin pump pathway

A typical pathway is shown below



*The current NICE criteria may be amended as a result of the ongoing review of HTA no. 57



In this chapter, the following areas are considered:

- Referral
- Assessment
- Patient Education
- Workforce
- Suppliers
- Supporting patients
- Follow-up

Referral

Differing insulin regimes may be needed at different stages of an individual's life (eg developmental in adolescence, moving away, pregnancy etc) and it is important that therapeutic options are discussed routinely.

Current experience suggests that education programmes may provide the skills that patients need to manage insulin and improve quality of life without requiring a pump. Unless there are clinical reasons not to, all adults should have been offered a quality assured structured education programme prior to being assessed for pump therapy. This will enable the development of skills to provide optimal use of basal bolus insulin therapy, including carbohydrate counting, exercise and alcohol advice, and sick day rules. Should an accredited education programme become available for children and their parents, this criterion should apply to paediatric referrals also. Lack of a local structured education programme is not a reason to decline a referral for an assessment for pump therapy. If a patient is referred who hasn't already been on a structured education programme, they should be offered a programme at that stage, or the assessing clinician would need to assure themselves as part of the assessment that there are no educational deficits (skills, knowledge, attitudes and capacity).

Where problems are identified there should be clear local protocols for maximising the best use of any current regimen including further education, psychological support, transfer to MDI, and use of analogues. Referral to the insulin pump service should not



be an automatic assumption when problems occur. However, barriers should not be put up for those who may benefit and meet the criteria. Pump therapy should be considered for and by all people with Type 1 diabetes, including children, and referral made to a pump service for those who could benefit.

A referral for pump assessment should normally be from a Consultant Physician providing Type 1 diabetes care. However, local models of care may give permission for other staff to refer. A referral from a GP with a Special Interest in Diabetes, for example, may be appropriate.

Assessment

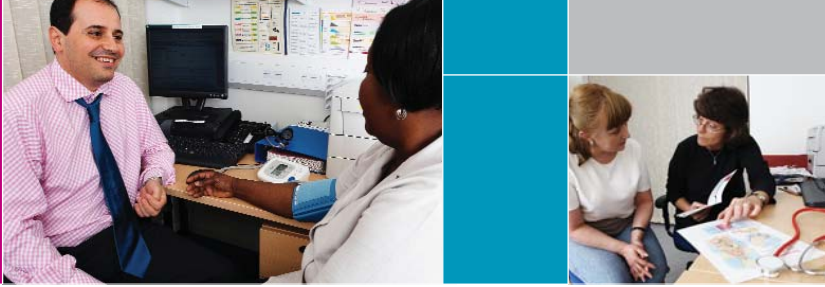
In adults, the criteria for initiating CSII (insulin pump) are that the patient should:

- Be motivated to succeed
- Have realistic expectations
- Be willing to monitor blood glucose values at least four times a day
- Be willing to work with multi-disciplinary team
- Demonstrate self-management skills
- Have tried a basal bolus regimen with long acting insulin analogue eg Glargine

The patient should also fulfil at least one of the following criteria:

- Repeated episodes of hypoglycaemia
- Unawareness of hypoglycaemia
- High HbA1c with hypoglycaemia despite high level of self-management

Adults will be expected to monitor blood glucose levels at least four times per day and to be competent at dosage adjustment and carbohydrate counting for meals, physical activity and other lifestyle issues. They should be able to self-manage hypo and hyperglycaemia, ketone testing, and understand that they should revert to subcutaneous injections when appropriate.



Children and adolescents will be expected to self-monitor according to need and ability, and to have had structured education once suitable programmes have been validated for this age group and their parents. Specific support should also be provided to parents.

The specialist team should be competent to assess psychological as well as biological and pharmacological factors.

The goals of pump therapy and the anticipated benefits for the individual should be clearly defined in advance of initiation. These benefits should be outlined as part of a comprehensive care plan, which should be fully discussed and fully agreed with the patient. The care plan should be ongoing and evaluated at regular intervals. Ceasing of pump therapy should only be considered if the goals within the care plan are not being met, and a full assessment of the reason for failure has been carried out.

The following objectives of CSII therapy are outlined in the NICE guidance:

- Improved glycaemic control (a lower mean blood glucose level and/or less variation in blood glucose levels and fewer episodes of hypoglycaemia)
- A greater degree of flexibility in lifestyle (for example, less rigid mealtimes, ability to do shift work and ability to take part in social activities)
- Patient able to take greater control over their condition
- Lower patient anxiety about episodes of hypoglycaemia

If the patient and clinician agree that other criteria for success should be used, the reasons for this should be clearly documented for example maintenance of a current level of HbA1c may be the aim for some children.

Patient Education

All individuals beginning CSII therapy should be provided with specific training in its use. Ongoing support from a specialist team should be available, particularly in the period immediately following initiation of CSII. It is recommended that specialist teams agree a common core of advice for CSII users and that further work is undertaken to develop a national model of best practice.

Providing a Pump Service



Patient education should be delivered by the specialist team through an agreed programme, meeting national quality criteria, to demonstrate user competence in key areas. A record should be kept of this training and of user competence. The programme should be quality assured using the National Diabetes Support Team/Diabetes UK self assessment tool¹⁸.

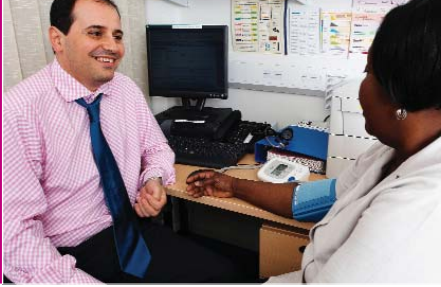
The curriculum for insulin pump training needs to incorporate insulin pump specific issues including:

- The mechanics for the insulin pump
- Insulin stacking and unexplained hypoglycaemia
- Unexplained hyperglycaemia eg insulin crystallisation in the tubing
- Different bolus options depending upon the meal and glycaemic index
- Variable basal rate infusions
- Impact of insulin resistance eg menstrual cycle, weather and “hormones”
- Enabling contact with other users

Education refreshers to be offered on an annual basis and attendance at these sessions could be used as one of the criteria for success

Insulin pump training in children incorporates the particular development of problem solving skills for both the child and parents. Individualised training is the norm, however, groups could be considered if deemed appropriate on account of similar age, gender and learning needs.

¹⁸ Available on the Diabetes UK web site at http://www.diabetes.nhs.uk/downloads/Patient_Education_Tools_Project/Patient_Education_Tools_Project_2006.pdf



What others have tried

Warwick Hospital's diabetes service has improved the involvement and understanding of their patients through using a variety of approaches:

- Joint meetings with presentations by pump users and healthcare teams for patients considering pump therapy, allowing patients to make informed decisions about their suitability for therapy
- Development of an Expert Patient Group which is also able to support others in getting the most out of pump technology
- Peer support provided for pump users, facilitating learning both for patients and for the healthcare staff caring for them
- Expert patient involvement in lectures for healthcare staff, raising awareness on the role of insulin pump therapy
- Pump users providing feedback on the current service and how it can be improved and changed

A typical patient comment was "The meetings are a perfect way to keep up to date on the latest research, technology etc but also a great opportunity to chat over coffee with other users of all ages."

For further information contact Shirineb@aol.com

Workforce

Care for pump users will often need to be delivered by staff working within pump service networks that include a number of local diabetes services. This type of networking is particularly important while new services are developing. Patients may need to be initiated in an insulin pump service, and subsequently transferred back to the local diabetes service for follow up care. As more local diabetes services begin to initiate patients onto pumps, they will require support from more specialist services in building up their expertise and educator skills. In the longer term, large specialist services should take a key role in educating and supporting staff throughout the network.

Providing a Pump Service



Specialist members of insulin pump teams must attend a recognised course in CSII. These specialist team members then need to assure themselves that all other staff coming into contact with patients on insulin pumps have sufficient knowledge of CSII. This includes staff throughout the hospital and in primary care, who may come into contact with pump users while they are being treated for other conditions. This general knowledge of insulin pumps is an integral element of the overall support of people with diabetes being treated in all areas of the NHS.

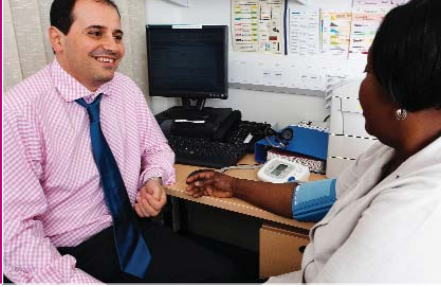
Staff will need to be trained to do their job according to the competencies required. A number of competencies have been developed that are specific to CSII¹⁹. These include:

- Diab2 IPT 01: Assess the suitability of insulin pump therapy for an individual with Type 1 diabetes
- Diab2 IPT 02: Provide preliminary education about insulin pump therapy for an individual with Type 1 diabetes
- Diab2 IPT 03: Provide dietary education for an individual with Type 1 diabetes who is contemplating insulin pump therapy
- Diab2 IPT 04: Enable an individual with Type 1 diabetes to administer insulin by pump
- Diab2 IPT 05: Provide ongoing support to an individual administering insulin by pump
- Diab2 IPT 06: Provide ongoing dietary education for an individual with Type 1 diabetes administering insulin by pump

Staff working within a pump service will wish to continually develop their skills, and the service will want to develop a team with a spectrum of experience.

There is currently no national curriculum for training staff in CSII. A small number of centres are currently offering courses that have been independently validated. These courses are generally oversubscribed, indicating that there is significant demand for this type of training. A suggested core content for a curriculum is attached as

¹⁹ Diabetes Competency Framework is available on the Skills for Health website at http://www.skillsforhealth.org.uk/view_framework.php?id=110



Appendix B, although further work is required to validate this and agree a curriculum for national use.

Consideration should be given to establishing a sustainable workforce and pool of expertise. Pump networks might consider developing a team with varying skill mix from “novice” to “expert”²⁰.

Pump Suppliers

A helpful principle that should guide the supply of insulin pumps is to offer as much choice of pumps as possible without compromising patient safety, and without restricting the choice of pump in order to achieve cost savings. An effective pump service would try to achieve a balance between offering choice, and standardising the supply of pumps so staff can maintain appropriate levels of expertise. The views of local staff and patients may also be helpful in choosing pumps. This could be achieved by:

- Working with local patient groups to agree a pump “menu”
- Seeking the views of clinical staff, including the time involved to achieve and maintain competence on a variety of pumps, and any good or bad experiences with particular pumps
- Considering the views of individuals being initiated on pumps

Suppliers should provide comprehensive education to staff in the use of their pumps. The nature of this education should be included in the specification provided to the supplier. The supplier can also be required to provide a helpline for patients to deal with technical issues (see following section on supporting patients).

Ownership of all pumps should be clearly documented, and a list should be kept of patients on pumps. If a patient ceases to use a pump, then the pump should be returned to the owner (usually the PCT or Trust) so that it can be assigned to a different patient.

²⁰ for more information see Benner P (1984) *From Novice to Expert: excellence and power in clinical nursing practice* London; Addison Wesley

Providing a Pump Service



If a patient moves to another area of the country, the pump should go with the patient, regardless of ownership. The pump centre taking over the care of the patient should continue to support the patient on that pump, even if it is not one that the new centre is familiar with. It should be the responsibility of the centre to seek additional training to familiarise themselves with new pump technologies. The cost of consumables for that pump should also be automatically picked up in the area that the patient has moved into. Any change of pump should only be by negotiation with the patient.

As pump technology improves, some patients may benefit from transferring onto a newer pump when this can provide a clear clinical benefit. However, patients should be made aware that in most cases, an upgraded pump will only be provided when the life of the current pump has expired and not whenever a new model becomes available.

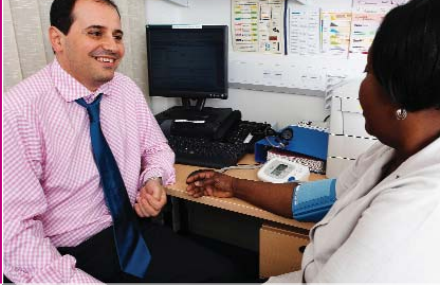
What others have tried

Originally, consumables were ordered in bulk and delivered to the diabetes centre at Harrogate District Hospital. Pump users had to attend the centre to collect their supplies. This was not only inconvenient for the pump users but caused increasing storage problems, particularly with each pump company having at least one user in the locality.

Harrogate therefore moved to their current system in which the pump user orders supplies as needed directly from the company. The invoice for these supplies is sent to the diabetes centre so that they can monitor each individual's usage of consumables, and the invoice is then passed to the Trust's Finance Dept to obtain reimbursement from the PCT.

This arrangement is much preferred by pump users, still gives the opportunity to control usage and the identification of a specific patient does not incur a charge for vat.

For more details contact peter.hammond@hdfnhs.uk



Current options for procuring pumps and consumables include:

- Buying both pumps and consumables outright
- Operating lease for pumps and buying consumables
- Linked deal, for example where the pump is provided free of charge but dependent upon the purchase of an agreed volume of consumables

NHS Supply Chain has agreed to develop a national framework contract for insulin pumps and pump consumables. Tendering will be carried out in March 2007, with contracts awarded in October 2007. This will provide an opportunity for all existing pumps and consumables to be made available at nationally agreed prices. It will not restrict access to the equipment of choice, but will ensure best value for money to all purchasers.²¹

NHS Home Delivery has agreed to extend its service to provide a delivery service direct into the patient's home for consumables, and potentially for emergency replacement of pumps. The service has already been piloted successfully for continence products in many areas of the country. It allows direct prescribing of products by clinicians and/or PCTs, with delivery made to the patient's home according to an agreed schedule. The web based ordering system would have the added advantage of providing a "pump register" as a by-product of using the service. It could also potentially be expanded to provide a recording mechanism for serious events, for example cannula problems or pump failures.²²

Supporting Patients

Much of the support required by patients should be provided to them already as part of a good Type 1 diabetes service. This includes the development of an agreed care plan, structured education, and a 24 hour helpline for clinical advice.

Pump users must be able to access the same standard package of support available to all people with Type 1 diabetes, for example an agreed care plan and a named contact.

²¹ For further information contact Darren.Henderson@supplychain.nhs.uk

²² For further information contact Steve.Davies@supplychain.nhs.uk

Providing a Pump Service



All pump centres should provide a 24 hour helpline for patients to obtain technical support for their pump. This can be provided by the pump suppliers. In addition, a helpline should be provided by every insulin pump service to deal with clinical issues – it should not be provided by a third party organization such as the pump supplier.

The provision of a clinical helpline is part of standard Type 1 diabetes care, and there is no reason why the same helpline cannot be used by pump users so long as staff are familiar with the clinical care of patients using CSII.

Peer support and expert patient advice should be available to all pump users if wanted or required.

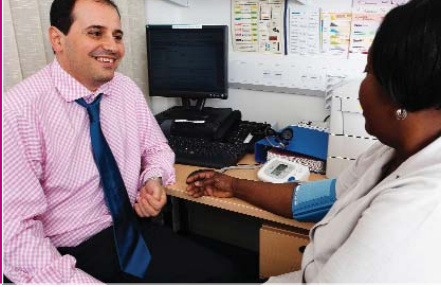
What others have tried

INPUT organise and support regional “pump clubs” throughout the UK and the Republic of Ireland. These are both social and educational groups who meet periodically to discuss how best to further the awareness of pump therapy in their area. Each area has a “Pump Pal” who talks to prospective pump patients. The “Pump Pal” also introduces new pump users to the benefits of pump therapy. This follows on from the initial hospital training they received when starting the pump.

INPUTs Parent Support Network provides help and assistance to the parents of children on pumps. There are many different problems experienced by children with diabetes, whether on a pump or not. The experience of others who have had the same problems with their child often helps other parents.

While INPUT cannot advise patients on whether insulin pump therapy is appropriate for their individual needs, nor will it give medical advice, it can offer a programme of activities to provide the latest information about pump therapy.

For more details contact John.Davis@input.me.uk



Follow Up

Patients on pumps should have a minimum of two follow up clinic appointments per year. CSII follow up and general diabetes follow up could be carried out in two different centres depending upon the availability of local pump services, the local model of care and the agreement of the person with diabetes. Ongoing care can also transfer from a specialist pump service to a local specialist service over time, according to the levels of competence of this service.

Annual patient update education/refresher courses should be provided.

Once initiated on an insulin pump, patients should be able to continue on CSII so long as they are happy to do so and the diabetes care objectives that they have set within their care plan are being met. It is not good practice, for example, to remove a pump from a patient following pregnancy. However, criteria should be agreed with the patient whereby if the patient is not doing well on the pump, CSII can be ceased. This should be part of the care plan, and should be reviewed at follow up appointments.



Research

CSII is an area of new practice where its position in the overall management of Type 1 diabetes is still unclear.

Areas to consider for further research include:

- Trials comparing MDI/impeccable Type 1 care against CSII
- Details of pump use, quality of life, and outcomes for different groups of patients (eg age, gender, duration of diabetes, ethnicity, socioeconomic status) or with different technologies (eg different insulin, different pump types)
- Potential for use of CSII in other patient groups (eg in pregnancy, for severely insulin resistant Type 2 diabetes)

All such research would benefit from detailed economic analysis.

A great deal of information can be gained through evaluation of local services.

What others have tried

A team at Gloucestershire Royal Hospital collected observational data on the patients that they had initiated on insulin pumps. They used routinely collected data to assess whether patients on insulin pumps used more or less hospital services following initiation onto the pump.

They found that the number of hospital admissions dropped, and the number of consultant appointments was reduced. However, the number of consultations with specialist nurses remained the same. There was some evidence that there may also have been reduced contact with GP practices. They then used the tariff to quantify the savings being made in the overall care of these patients.

For further information contact Thomas.Ulahannan@glos.nhs.uk



Issues that have been highlighted

During the preparation of this report, a number of issues have been highlighted which are controversial, and where further national guidance would be helpful. NICE is currently undertaking a review of HTA no. 57, and consulted on the draft scope for the review in October 2006.

Issues that cause the most difficulty are:

- Use of the term “failure of multiple dose injection therapy” is unclear and has been interpreted differently. NICE should consider whether additional guidance can be provided that would help to reduce this variability.
- The indication in the current guidance that only 1-2% of Type 1 patients are likely to benefit from CSII is felt to be misleading.
- Indications within the current guidance are very limited. A range of other indications have been suggested. A number of these are of the type that will never be subject to large randomised clinical trials, and NICE will need to give consideration to how these will be dealt with during review of the guidance.
 - Quality of life issues for adults, including the number of injections daily being required to achieve control, frequent sick days, marked glycaemic swings or dawn phenomenon, impaired exercise capacity, and difficulties with shift work or travel across time zones.
 - Additional issues for children and their parents, including school performance, inability to fully integrate into school life, behavioural issues eg meal times, and impact on family dynamics.
 - Pregnancy including women contemplating pregnancy
 - Acute painful neuropathy or symptomatic autonomic neuropathy
 - Hypoglycaemic unawareness
 - Extreme insulin sensitivity
 - Needle phobia with adverse metabolic sequelae

Issues that have been highlighted



- Insulin allergy
- Use in Type 2 diabetes, particularly for severe insulin resistance
- Availability of pumps on the basis of patient preference.

CSII for children has particular challenges given the diversity of their presentation, spectrum of age, and the complexity of management of diabetes in children. CSII can potentially be very beneficial for this group, and some paediatricians recommend that all children and adolescents should be offered the choice of CSII or MDI as an initial method of intensifying insulin therapy. This is an area on which further NICE guidance would be particularly helpful.

- Understanding of Type 1 diabetes has increased greatly following publication of the NSF and the Type 1 NICE Guideline. Principles from these publications need to be incorporated into future pump guidance.

NICE will need to have a clear implementation plan for the revised guidance, with links made to this document to ensure consistent delivery of and access to pump services.



Recommendations

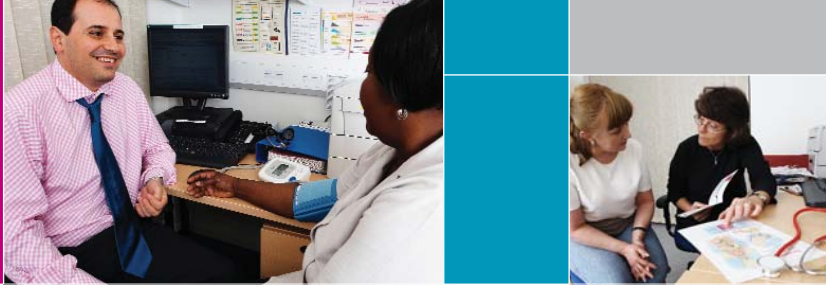
The Insulin Pumps Working Group set out to agree what needed to be done to enable local services to deliver the NICE HTA on insulin pumps for adults, children and young people. They also considered other issues relating to insulin pump therapy to feed into the development of further NICE guidance. The group has identified the following issues:

- Commissioners of diabetes services should ensure that CSII is included as part of a comprehensive Type 1 service as required by NICE HTA no. 57.
- Commissioners, in conjunction with clinicians and patient representatives, should carry out a needs assessment for insulin pumps. The development of a specific tool to supplement the PBS Diabetes Prevalence Model will assist them to do this. Further work should be done to understand the current use of CSII, and its potential future use.
- The Insulin Pumps Working Group recommends that clinical communities, working with their partners (eg professional organisations such as Diabetes UK) urgently develop and agree a national curriculum with appropriate links to accreditation bodies for staff training and patient education.
- There needs to be a robust and efficient supply chain from procurement through to home delivery, meeting the needs of patients and health professionals.
- Further work should be done to understand the costs of an insulin pump initiation pathway. Insulin pumps and pump consumables are specialised service exclusions within PbR. The development of a tariff for CSII could provide an opportunity to review the funding mechanism for insulin pumps. In the absence of a national tariff, commissioners may wish to develop a local tariff covering the cost of the pump and consumables.
- Health professionals, patient groups and interested partner organisations, should give consideration to setting up pump interest groups to collaborate on the following:
 - Agreeing the content of pump registers, and a minimum data set

Recommendations



- Developing audit criteria
- Establishing a process of collaborative peer review
- Reviewing ongoing Research and Development (R&D) needs, and sponsoring appropriate developments to ensure a continued active R&D agenda in CSII



Membership of the Insulin Pumps Working Group

Graham Archard, General Practitioner

Deborah Beskine, parent of a pump user, INPUT

Mary Bilous, Diabetes Specialist Nurse, James Cook University Hospital, Middlesbrough

Shirine Boardman, Consultant Physician, Warwick Hospital

Stuart Bootle, General Practitioner and pump user

Heather Bowler, parent of a pump user, INPUT

Sally Brooks, Writer, National Diabetes Support Team

Fiona Campbell, Consultant Paediatrician, St James's University Hospital, Leeds

John Davies, Consultant Physician, South Warwickshire Hospitals

John Davis, pump user, INPUT

Geoff Durrant, Vice-Chair, Solihull PCT

Joan Everett, Diabetes Specialist Nurse, Royal Bournemouth Hospital

Carole Gelder, Paediatric Diabetes Specialist Nurse, St James's University Hospital, Leeds

Wendy Griffin, Dietician, Newcastle

Peter Hammond, Consultant Physician, Harrogate District Hospital

Moira Harrison, pump user, INPUT

Madeleine Johnson, Assistant Director of Public Health, North East SHA

David Kerr, Consultant Physician, Royal Bournemouth Hospital

Dawn Kitchener, Insulin Pumps Nurse, Leicester

Bill Lamb, Consultant Paediatrician, Bishop Auckland Hospital

Ian Lawrence, Consultant Physician, Leicester

Membership of the Insulin Pumps Working Group



Gill Morrison, Diabetes Specialist Nurse, Royal Liverpool University Hospital

Martin Norris, Diabetes UK (co-chair) – until Summer 2006

John Pickup, Professor of Diabetes and Metabolism, Guy's Hospital, London

Sue Roberts, National Diabetes Clinical Director (co-chair)

Gary Tempest, Diabetes Policy Team, Department of Health

Bridget Turner, Diabetes UK (co-chair) – from Summer 2006

Sarah Walter, System Reform Programme Manager, National Diabetes Support Team

Philip Weston, Consultant Physician, Royal Liverpool University Hospital

Neil Wilson, Carer, INPUT

Pat Wilson, Diabetes Specialist Nurse, Isle of Wight

Valerie Wilson, pump user, INPUT

The Insulin Pumps Working Group would also like to thank the following people for their help in preparation of this report.

Steve Davies, NHS Supply Chain

Paula Dearing, Leeds PCT

Darren Henderson, NHS Supply Chain

Dawn Jones, Diabetes Policy Team, Department of Health

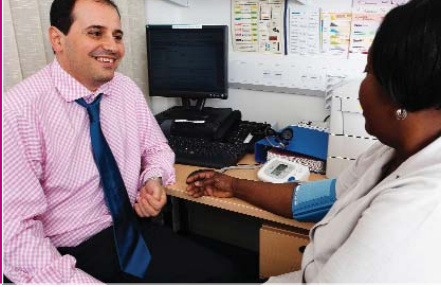
Andy Kingdom, Yorkshire & the Humber Public Health Observatory

Laura Ladd, Diabetes Policy Team, Department of Health

Lorraine Oldridge, Yorkshire & the Humber Public Health Observatory

Stuart Simms, North East Public Health Observatory

Thomas Ulahannan, Consultant Physician, Gloucester



Appendix A

Proposed Data Set

The CSII service or clinic

Number of patients being treated by CSII

Number of new patients treated by CSII each year

Place where clinic located

Staff of clinic

- Number of doctors (position)
- Number of nurses
- Number of dieticians
- Other staff involved in service

Patient details when first seen

Age

Sex

Ethnic group

Address, hospital number

Name of PCT

Name of GP

Type of diabetes

Duration of diabetes/date of diagnosis

Referring doctor/hospital

Details of structured education programme attended

Reason for referral

Details of intensive insulin injection regimen (Type/dosage)

Other conditions and illnesses

Diabetic tissue complications

Current drugs



Starting or declining CSII

Reason for starting CSII

(Reason for not offering CSII)

Aims of pump therapy for individuals

Source of funding (PCT/self-funding/other)

Pump model

Pump insulin

Date started CSII

Details at each visit (recommended for use also whilst patients undergoing optimization on MDI):

Date

Therapy (MDI/CSII)

Weight

BMI

HbA1c

Blood glucose profiles (mean daily blood glucose/SD/SD of fasting BG or other measure of day-to variability)

Basal insulin rates

Prandial insulin/insulin:CHO ratio

Treatment complications

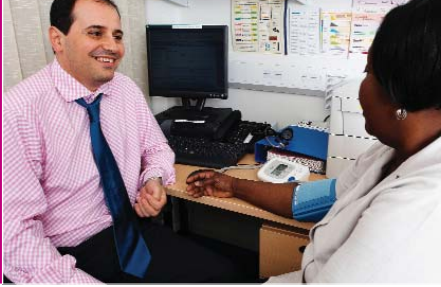
- Hypoglycaemia (severe/moderate/minor)/DKA
- Infusion site
- Pump and cannula functioning/problems
- Other

Quality of life measure eg Problem Areas in Diabetes (PAID)²³ or the Pediatric Quality of Life Inventory (PedsQL)²⁴

Clinical events/notes/actions

²³ For further information contact Joan.Everett@rbch.nhs.uk

²⁴ For more information see www.pedsql.org



Appendix B

Suggested Core Content for a Curriculum for Professional Education in CSII

Evidence base and physiology of CSII

This should include:

- Overview – the strengths and weakness of CSII
- Aims of treatment with CSII
- Analysis of research into CSII in relation to:-
 - Glycaemic control
 - Hypoglycaemia
 - Hyperglycaemia
 - Diabetic Ketoacidosis and other adverse events
 - Quality of life issues
 - Comparison of rapid acting analogues and soluble insulin in pump use

Basal rate initiation and on-going management

This should include:

- Appreciation of the normal physiology associated with basal insulin production, compare and contrast this with basal rate management using multi dose injections (MDI) and CSII
- Establishment of an initial starting basal rate dose for individuals transferring from MDI onto CSII
- Principles that must be considered when establishing a basal rate
- Methods that can be utilised to determine the effectiveness of a set basal rate
- Consequences of an incorrectly set basal rate
- Adjustment of basal rate according to glycaemic response



- Identification of situations where it would be appropriate to instigate a temporary change in basal rate
- Conversion back onto MDI
- Management of short breaks in pump therapy

Effective management of bolus doses of insulin

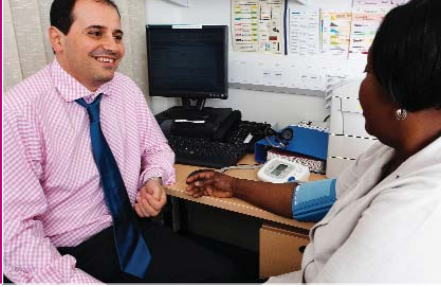
This should include:

- Physiological response to a glycaemic load and the appreciation of methods that can be utilised via an insulin pump to mimic this response
- Terminology used to describe the various types of bolus
- Factors that will influence the bolus method of choice and its impact
- Administration of correction doses
- Assessment of the effect of a bolus dose of insulin
- Adjustment of bolus dose according to glycaemic response
- Determination of insulin sensitivity for carbohydrate and correction
- Detrimental effects of an incorrectly administered bolus

Practical training in CSII

This should include:

- Identification of all insulin pumps available in the UK and appreciate their various features
- Pump operation skills
- Practicalities of wearing an insulin pump



Infusion site and infusion set management

This should include:

- Identification of the sites that can be used for cannula insertion
- Recognition of the different types of cannula and insertion devices available
- Cannula insertion techniques
- Insight into potential problems that are associated with the use of a cannula, infusion set and be able to troubleshoot
- Factors which may influence cannula / line safety and comfort

Dietary management of diabetes with pump therapy

This should include:

- CHO counting
- Energy requirements
- Alcohol
- Glycaemic index
- Flexibility and food eg eating out exercise

Management of glycaemic excursions

This should include:

- Setting glycaemic targets
- Identification of the potential causes of hyperglycaemia and hypoglycaemia in relation to CSII
- Management of hypoglycaemia, hyperglycaemia and diabetic ketoacidosis on an insulin pump
- Emergency equipment required by pump users



Illness

This should include:

- Sick day rules
- Hospitalisation, including management during investigations and surgical procedures

Children and young people

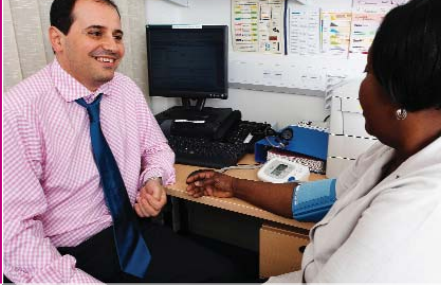
This should include:

- Appreciation of the special needs of children and young people
- Candidate selection
- Transfer from paediatric to adult services
- Service provision

Pregnancy

This should include:

- Evidence base for the use of CSII in pregnant women
- Special needs of pregnant women converting onto CSII
- Dietary considerations for pregnant women using pumps
- Site management
- Glycaemic targets



- Management of:
 - Basal rate
 - Insulin to carbohydrate ratio
 - Correction and carbohydrate bolus doses
 - Management of women using pumps during:
 - Periods of morning sickness
 - The antenatal period
 - Caesarean section
 - Breast-feeding
 - The postnatal period
- Service provision

User involvement

This should include:

- Contact with pump users describing their personal issues and experiences

Candidate assessment regarding suitability for CSII

This should include:

- Identification of patients who will / will not benefit from CSII
- Controversy associated with candidate assessment
- Appreciation of national guidance
- Assessment strategies

Exercise and activity

This should include:

- Effects of anaerobic and aerobic exercise on blood glucose levels
- Scenarios where exercise would not be advised



- Pump management strategies in relation to:
 - Anaerobic and aerobic exercise
 - Short term and prolonged activity
 - Unplanned and planned activity
 - Day to day activity
 - Site management
 - Wearing or removal of the insulin pump

Lifestyle and real life issues

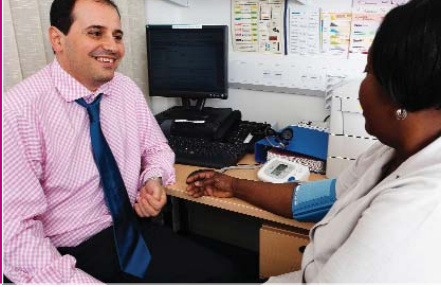
This should include:

- Impact of CSII on every day life
- Travel including time zones, potential effects of hot and cold climates
- Eating out including alcohol
- Intimacy
- Driving
- Situations where insulin pumps should be removed
- General maintenance of the insulin pump
- Exposure to water

Provision of structured patient education

This should include:

- Initial and on-going educational requirements for people using insulin pumps
- Psychological impact of insulin pump therapy on individuals and the need for ongoing support



Service provision incorporating national guidelines

This should include:

- Identification of key members of the multidisciplinary team required to initiate insulin pump therapy
- NICE guidance in relation to CSII
- Resource implications to set up and maintain a service for insulin pump users

Appendix C

Generic specification for insulin pump care – best practice model

The aim of the generic specification is to provide a Level 2 description of insulin pump care in order to facilitate the development of Level 3 models of care that are locally appropriate.

The specification sets out information under the following categories:

1. Heading – the name of this part of the service
2. Descriptor – a more detailed description of what this part of the service aims to do/provide
3. Best practice quality markers – signposting of any relevant national quality markers that might apply, e.g. this might include relevant NICE guidelines or recommendations of best practice by the Insulin Pumps Working Group
4. Evidence for improvement – suggestions of indicators that could be used to assess whether the care that is being delivered is of a high quality or can be used in improvement/audit cycles
5. Suggested key outcomes – suggestions of outcomes that could be specified as part of the provider's contract. It is assumed that the suggested key outcomes can also be used as evidence for improvement.



The value of specifying services

Using this generic specification will provide assurance to providers, to commissioners, to people with diabetes and insulin pump users, carers, and staff, that key success factors for diabetes services have been taken into account.

There are a number of important features that should apply to most of the specific areas outlined in this generic specification. These will be crucial to ensure the quality of care, and failing to take these into account may considerably reduce the benefit and ultimate improved outcome for pump users.

These features would include:

- That they were designed in response to the local needs assessment, ensuring the service can meet the specific needs of the local population
- Had an inclusive design process that involved people with diabetes and insulin pump users, and all clinicians with both specialist and generalist experience
- Took note of the principles of delivery for all long term conditions, embodied in the chronic care model²⁵ (see the NHS Long Term Conditions Model)²⁶
- Took into account the overarching principles of the Diabetes NSF²⁷, including the centrality of self management as the key to good outcomes and the need for a proactive organisation

²⁵ Available on the IHI website at <http://www.improvingchroniccare.org/change/model/components.html>

²⁶ Available on the DH website at http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/LongTermConditions/LongTermConditionsArticle/fs/en?CONTENT_ID=4130652&chk=d8PRGO

²⁷ Available on the DH website at <http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Diabetes/fs/en>



- Made sure that there are a range of options available to pump users to support self management and individual preferences
- That, where possible and realistic, services are close to the user's home and based in the community
- Ensured and demonstrated that staff have the competencies needed to deliver the functions¹⁹
- Are covered by written protocols and guidance that are adhered to and monitored
- Have agreed local plans to deliver key outcomes such as access, continuity of care etc
- Contribute to national data collections or audits when available
- Have arrangements in place for local audit, benchmarking against national quality markers when available

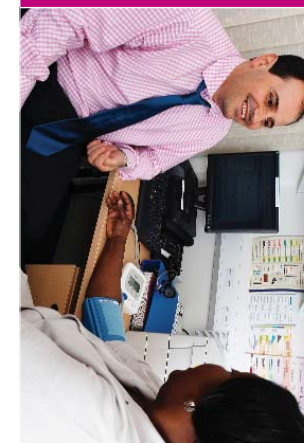


Heading	Descriptor	Best Practice Quality Markers	Evidence for improvement	Suggested Key Outcomes
Referral	Effective and timely referral of appropriate patients to a patient centred pump service	<p>Use of pump therapy considered for all eligible patients²⁸</p> <p>All adults offered an externally validated structured education programme prior to referral²⁹</p> <p>All patients referred according to agreed pathway</p> <p>CSII provided as part of a comprehensive Type 1 service through local provision or referral into a recognised pump service</p> <p>Pump services has network links to other services</p>	<p>Documented assessment</p> <p>Confirmation of education offered prior to referral</p> <p>Agreed referral pathway</p> <p>Clinicians aware of referral pathway</p> <p>Patients aware of referral pathway</p> <p>All components of care outlined in NICE guidance are present currently³⁰</p> <p>Evidence of strong network links to larger centre</p> <p>Outline of network support arrangements</p>	<p>% of Type 1 patients on pump therapy</p> <p>100% patients offered structured education programme prior to referral</p> <p>% patients receiving structured education programme prior to referral</p> <p>% patients being seen within agreed timescale from referral to first appointment</p> <p>% appropriate referrals to pump service</p> <p>Availability of each component within local diabetes service</p> <p>All patients being treated in services that provide the full range of components of care</p>

²⁸ See current NICE guidance on CSII at <http://www.nice.org.uk/58194>

²⁹ See NICE guidance on patient education models at <http://www.nice.org.uk/guidance/TA60>

³⁰ See current NICE guidance on CSII at <http://www.nice.org.uk/58194>



Heading	Descriptor	Best Practice Quality Markers	Evidence for improvement	Suggested Key Outcomes
Pump assessment and initiation	Proactive approach to identifying patients who can benefit from pump therapy	<p>Clear assessment criteria based on existing NICE guidance and taking into account suggested changes to NICE guidance³¹</p> <p>Effective assessment of patient's ability to self-monitor</p> <p>Agreement on criteria for success between patient and health professionals prior to initiation on pump³²</p>	<p>Documented assessment criteria</p> <p>Criteria for success agreed and documented prior to initiation</p>	<p><5% adults and <10% of children to cease using pump therapy following initiation</p> <p>% people using a recognised and recorded tool that supports joint decision making</p> <p>% of patients where completion of an explicit care plan at annual review included use of a joint decision making tool (Better Metrics 4.12)³³</p>
Patient Education	Appropriate education for patients using pump therapy	<p>All patients beginning CSII to be provided with specific training in its use</p> <p>Education refreshers to be offered on an annual basis</p>	<p>Details of training provided and quality assurance¹⁸</p> <p>Feedback collected from patients on education provided</p>	<p>100% patients provided with specific training on pump use</p> <p>Measurement of patient satisfaction in respect of ease of access, attention/interaction, respect for the individual, knowledge gained, empowerment and age/cultural appropriateness</p> <p>% patients offered an education update within 1 year</p> <p>% patients attended an education update within 1 year</p>

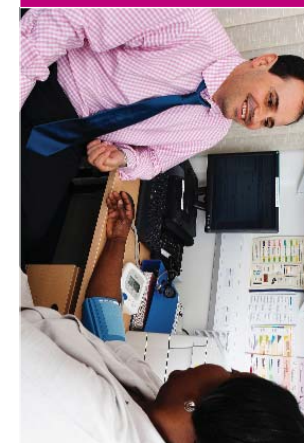
³¹ See current NICE guidance on CSII at <http://www.nice.org.uk/58194>

³² See Care Planning in Diabetes report at http://www.diabetes.nhs.uk/downloads/care_planning_in_diabetes_report.pdf

³³ See the Office of the Strategic Health Authorities website at <http://www.osha.nhs.uk>



Heading	Descriptor	Best Practice Quality Markers	Evidence for improvement	Suggested Key Outcomes
Workforce	Availability of an appropriately trained workforce to support patients using pump therapy	<p>Pump therapy to be initiated by a trained specialist team (competency based)</p> <p>Whole department in pump service to be familiar with the support of CSII</p> <p>Staff in pump service to ensure that all other staff coming into contact with pump users (including those in other organisations) have sufficient understanding and skills of CSII</p> <p>Smaller pump services, or developing pump services to have strong links with a larger specialist service</p>	<p>Minimum team comprising physician, diabetes specialist nurse and dietician</p> <p>Evidence of CPD/education undertaken by staff</p> <p>Evidence of educational activities and support provided to other staff</p> <p>Evidence of educational activities and support provided by larger specialist service</p>	
Suppliers	Selection and provision of appropriate equipment	<p>Clear policy on pumps available agreed between commissioners, health professionals and patients</p> <p>Agreed process for ordering and delivering consumables making use of best practice recommendations</p>	<p>Documented policies</p> <p>Provision of maximum patient choice without compromising patient safety</p> <p>Cost-effective provision of consumables while maintaining maximum convenience for patients</p>	Measurement of patient and carer satisfaction with the supply of pumps and consumables



Heading	Descriptor	Best Practice Quality Markers	Evidence for improvement	Suggested Key Outcomes
Supporting adults, children and parents	<p>Appropriate ongoing support for pump users</p> <p>Provision of a patient centred pump service</p>	<p>Full package of Type 1 diabetes support to be available³⁴</p> <p>Helpline(s) available for technical problems and clinical issues</p> <p>Peer support and expert patient advice available to pump users</p>	<p>Availability of all elements of Type 1 diabetes support outlined in NICE guidance (eg care plan)</p> <p>Details of available helpline(s)</p> <p>Details of support available</p> <p>Patient & carer feedback</p>	<p>Measurement of patient satisfaction in respect of ease of access, attention/interaction, respect for the individual, knowledge gained, empowerment and age/cultural appropriateness</p>
Treatment	Provision of a pump service that results in a good service	<p>Pump centre able to demonstrate improved glycaemic control amongst pump users</p> <p>Pump service able to demonstrate reduced need for emergency treatment amongst pump users</p> <p>Pump service able to demonstrate reduced diabetic complications and improved physical/psychological well-being amongst pump users</p>	<p>Information collected on agreed indicators including patient experience and satisfaction</p> <p>Information collected on agreed indicators</p>	<p>Improved HbA1c blood results</p> <p>Reduction in hypoglycaemia frequency</p> <p>Reduction in need for paramedic or other external assistance</p> <p>Reduction in hospital admissions</p> <p>Documented improvement in diabetic complications</p> <p>Number of people/parents able to return to work</p> <p>Reduction in number of phone calls and appointments needed to assist patients to manage their own diabetes</p>

³⁴ See NICE Type 1 diabetes guidance at <http://www.nice.org.uk/guidance/CG15>



Heading	Descriptor	Best Practice Quality Markers	Evidence for improvement	Suggested Key Outcomes
Follow Up	Appropriate follow-up of pump users and cost-effective use of CSII	<p>Pump user to have a follow-up clinic appointment at least twice per year</p> <p>Progress evaluated against goals in patient's care plan. Ceasing of pump therapy only to be considered if goals are not being met</p>	Local follow-up protocol	<p>% patients offered follow up appointment within 1 year</p> <p>% patients attended a follow up appointment within 1 year</p> <p>Documented evaluation showing that patient is continuing to benefit from pump therapy</p>





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