NICE: the way forward with insulin pumps

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ARTICLE POINTS

1 NICE guidelines specify that insulin pump therapy should be available to patients with type 1 diabetes, provided that they meet specific defined criteria.

2 Diabetes teams should be able to initiate patients meeting these criteria onto pump therapy.

3 However, difficulties exist in terms of non-concordance with funding guidelines, a prejudice against pump therapy and a lack of trained staff in the field.

4 Some diabetes centres rely on pump manufacturers to supply training to new patients, but NICE guidance states that a trained diabetes team should initiate treatment.

5 Organisations such as INPUT are raising awareness of pump treatment and providing support for patients using it.

KEY WORDS

- **Insulin pump therapy**
- **Training**
- **Funding**
- **NICE guidance**

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Introduction

Insulin pump therapy is a treatment option for people with type 1 diabetes who fulfil the National Institute for Clinical Excellence (NICE) guidelines of frequent and unpredictable hypoglycaemia. NICE recently stated (2002) that insulin pump therapy treatment should be available for those who meet the criteria and cannot control their diabetes by other methods. Currently, around 20% of the population with type 1 diabetes would benefit from pump therapy treatment, with NICE guidelines (2003) initially suggesting 1–2% meeting the criteria for funding. Despite NICE guidelines, there is still debate at local level regarding the way forward. This article outlines each stage of obtaining pump therapy for patients with type 1 diabetes whilst highlighting the necessity of training health professionals in this treatment option.

Insulin pump therapy is recommended by NICE (2002) as an option for people with type 1 diabetes provided that:

- Multiple dose insulin therapy (including insulin glargine) has failed. NICE considers multiple dose insulin therapy to have failed when careful management of diabetes has not kept blood glucose levels within the recommended limits (4–7 mmol/l), resulting in disabling hypoglycaemia (repeated unpredictable hypoglycaemic episodes that require help from others and affect quality of life).
- Those receiving treatment are willing and able to use pump therapy effectively.

The guidelines also specify the following points:

- Pump therapy should be initiated by a trained specialist team (comprising a physician who specialises in pump therapy, a diabetes nurse and a dietitian).
- Individuals beginning pump therapy should be provided with training in its use and ongoing support should be available to them.
- The recommendations are also valid for children, adolescents, pregnant women, and women intending to become pregnant (under the care of a specialist team).
- Established pump users should have their insulin management reviewed as they may be suitable for a trial of insulin glargine.

Implications for practice

Diabetes teams should be able to initiate patients who meet these criteria onto pump therapy without any funding problems given recent NICE guidance. However, non-concordance with NICE guidelines for primary care trusts (PCTs) to fund pump therapy exacerbates the situation of postcode prescribing by the NHS in different areas of the country. There is also still much prejudice against pump therapy in the UK where health professionals believe it will mean more work for them in terms of training and the provision of a 24-hour help-line at each diabetes centre in the event of pump problems.

In light of the National Service Framework (NSF) for Diabetes standards (DoH, 2002), the empowered nature of patients using pump therapy means these individuals manage their own diabetes and work in an alliance with the health professional. Health professionals can learn much from existing pump therapy users in this way and could achieve the knowledge and experience to attain pump centre status in terms of their diabetes centre. The lack of trained staff in the field of pump therapy has also meant that patients may

have to travel to one of the 25 diabetes teams trained in pump therapy across the country for intensive education, initiation of the treatment, and ongoing support (many pump users from Kent have to travel to London centres, for instance).There is therefore a need for at least 28 dedicated pump centres across the country to reflect each strategic health authority, with the ideal scenario being the availability of pump expertise in most diabetes centres.

Trained staff may also face difficulties when patients using insulin pumps made by different manufacturers present at their clinics. There are now three leading manufacturers of insulin pumps in the UK, meaning discrepancies in training, or, worse, that patients are dissuaded from using the insulin pump of their choice because diabetes centres are unfamiliar with the technology or do not like some manufacturers or types of pump. This situation means that a certain pump manufacturer may be cited by the hospital as the sole provider and patients are not given the option of choice. This does not reflect patient empowerment outlined in standard 3 of the NSF for Diabetes priorities (DoH, 2002)

Funding issues

While the NICE guidelines have addressed the major funding issues for pump therapy, the resources have yet to be allocated. The final directions from NICE require PCTs to provide funding 'to ensure that a health care intervention that is recommended by NICE in a Technology Appraisal is normally available a) to be prescribed for any patient on a prescription form for the purpose of his NHS treatment; or, b) to be supplied or administered to any patient for the purpose of NHS treatment' (DoH, 2003). Funding to meet NICE recommendations has been included in the allocations made to the PCTs for the period 2003/4–2005/6. The Secretary of State for Health expects patients treated under the criteria in NICE guidance to have their pump therapy funded by the PCT/trusts (DoH, 2004).

This means that if patients meet the NICE criteria of repeated unpredictable hypoglycaemia, they will be funded by their PCT or NHS trust. INPUT (the Insulin Pump Therapy Group) has found that one of the reasons for lack of funding is the absence of guidance for diabetes consultants regarding suggested procedures for applying for pump funding. A lack of pump funding may be due to the simple fact that the diabetes consultant has not asked for it. Therefore, local agreements and arrangements need to be put into place regarding a definitive policy for funding pump therapy so that diabetes consultants who are responsible for applying for the patient's pump funding are clear about the content and format of the application.

Provision of funding

Funding of pump therapy is often arranged by the patient's

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1 Some diabetes centres do not conduct their own pump training for new patients, relying on pump manufacturers to fulfil this need.

2 There is no generic procedure that hospital consultants should follow to gain access to funds. Each PCT should have its own mechanism in place to ensure that funding is available.

3 The final decision regarding whether or not the patient should be treated in line with NICE recommendations rests with the consultant.

4 NICE guidance (2003) states that a trained diabetes team should initiate pump therapy, and therefore the manufacturer should not be involved in patient education.

5 Health professionals currently being trained are still reluctant to take the next step and initiate patients onto the treatment themselves.

diabetes consultant (Wilson, 2004). Some diabetes centres still do not conduct their own pump training with new patients, relying on the pump manufacturer to fulfil this need. As this continues, health professionals are not familiarising themselves with this treatment option. This means they are not gaining expertise in this area and patients cannot go to their diabetes centre with questions if they need help and support. Many of the telephone calls to INPUT relate to information needs such as this which could be addressed by the individual's diabetes centre with the correct training. This would also help to build an alliance with the pump patient and their diabetes team.

There is no generic procedure that hospital consultants should follow to gain access to funds. Each PCT should have its own mechanism in place to ensure that funding is available for patients treated in accordance with NICE guidance. It is usual for PCT prescribing advisors to be involved and guidance on insulin pumps was sent to all GP prescribing advisors and purchase advisors in England and Wales at the time of its publication (DoH, 2004)

INPUT suggests that hospital consultants should request a lump sum for funding future patients for the following year. This should be an allocation amount for 25% of the type 1 patients attending the diabetes centre. This means that funding does not have to be applied for on an individual basis and ensures that it is already in place when insulin pump therapy treatment is decided upon. This means care is in place when a patient with a clinical need presents.

It is for each PCT to decide how regularly it assesses its insulin pump patients. However, the DoH has stated that funding is available to PCTs if patients meet specific NICE criteria, and that if individuals are not getting the financial support they require, this is a case for the Secretary of State for Health. This funding includes the money to employ appropriately trained staff and precludes the need for 'capping'. Therefore, the final decision regarding whether or not the patient should be treated in line with NICE recommendations rests with the consultant. Once this decision has been made, the PCT should release the necessary funds (DoH, 2004).

Pump companies – what should patients expect?

If the pump manufacturer does not play a part in educating the patient, what role do they play after supplying the pump? The pump manufacturer provides technical backup in the event of a pump malfunction. NICE guidance (2003) states that a trained diabetes team should initiate pump therapy, and therefore, in INPUT's opinion, the manufacturer should not be involved in patient education, but should be concerned only with training diabetes teams in the technical operation of pump equipment. Also, the only way forward for developing training and education for diabetes centres is for them to gain the experience themselves by initiating pump therapy and not relying on the manufacturers to do so.

The way forward

If diabetes teams embrace the training of their own patients in the use of pump therapy, they will increase their confidence with this treatment option. In order for diabetes teams to carry their training forward, they need either existing patients to attend their diabetes clinics or new patients who can be initiated onto this course of treatment. Existing pump therapy patients are also an expert source of knowledge, having experienced the practicalities of living with pump therapy and its demands.

Health professionals currently being trained are still reluctant to take the next step and initiate patients onto the treatment themselves. Hammond (2000) reported a survey by Everett of 300 diabetes centres in the UK regarding their interest in insulin pump therapy. She found that, although health professionals were interested in pump training courses and stated that they would like to attend, barriers such as a lack of knowledge, skills and confidence were cited as reasons for diabetes centres not going ahead with the initiation of pump therapy in patients.

Conclusion

The use of pump therapy is rising in the UK

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1 The current shortage of trained health professionals means that diabetes teams are missing out on the experience and knowledge of pump treatment.

2 The need for a 24 hour helpline to be available for patients when they experience difficulties is also highlighted by the lack of health professionals trained in pump therapy.

3 A paradigm shift must take place in order for NICE guidance to be part of diabetes service delivery.

as individuals become aware of this treatment option via the internet and through organisations such as INPUT. The current shortage in available trained health professionals means that diabetes teams are missing out on the experience and knowledge of this treatment option.

The need for a 24 hour helpline to be available for patients when they experience difficulties is also highlighted by the lack of health professionals trained in pump therapy. Currently this need is fulfilled by INPUT, which is a national voluntary organisation. NICE guidance is clear about the way forward with pump therapy. This must not remain just a paper exercise – a paradigm shift must take place in order for NICE guidance to be part of diabetes service delivery. ■

Department of Health (2002) *National Service Framework for Diabetes: Standards*. DoH, London.

Department of Health (2003) *Directions to Primary Care Trusts and NHS Trusts in England Concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Clinical Excellence (NICE)*. DoH, London

Department of Health (2004) *Allocation of Funding to Primary Care Trusts*. http://www.dh.gov.uk/assetRoot/04/01/22/96/04012296.pdf

Hammond P (2000) New insulin pump forum launched in the UK. *Practical Diabetes International* **17**: 278–79

National Institute for Clinical Excellence (2002) *Technical Appraisal Guidance No. 57: Subcutaneous Insulin Infusion (Insulin Pump Therapy) for Diabetes*. NICE, London

National Institute for Clinical Excellence (2003) *Technical Appraisal Guidance No. 57: Guidance on the use of Continuous Subcutaneous Insulin Infusion for diabetes*. NICE, London

Wilson VL (2004) Insulin pump therapy: a postcode lottery? *Diabetes and Primary Care* **6**(1): 49–52