input
INsulin PUmp Therapy
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Dear Christopher,

REVIEW OF HTA 57 – Insulin Pump Therapy

We have the following issues we would ask the Appraisal Committee to consider further:

1.1. Clarify age group. Would it not be better to say children up the age of 12?
How will "commitment" be measured?
How will "competence" be assessed?
Benchmarks should be put in place to ensure consistent interpretation around the country, from clinic to clinic.

1.2. Obviously this would need to be changed to "older than 12."
We question the phrase "adequate control." We would suggest, "failed to achieve control."
Again, how do we define and measure these?

1.3. We have real issues with the new HbA1c guidance level of 8.5%. What was the basis for this decision? There is no approved medical guideline that says an A1c level of >7.5% constitutes control.
In the NICE Clinical Guidance for Type 1 diabetes (CG015) NICE state that 7.5% should be the target value for Type 1 diabetes (R44) and that those who seek to achieve an HbA1c of 7.5% should be given all appropriate support to achieve this. If one reads this new guidance in combination with CG015, NICE is giving conflicting messages.

Also, the IDDM European Study Group states that <7.5% is adequate control. This is also the level that the DCCT found was associated with a curilinear increase in the progression and incidence of secondary complications associated with diabetes. The results of the DCCT Study prompted the American Diabetes Association (ADA) to recommend that an HbA1c level of less than 7.0% should be the goal for most patients.

In 2002 the American Association of Clinical Endocrinologists (AACE) recommended that all patients with diabetes should strive for an A1C of 6.5%.

Under the guidance that we are revising, a patient with an HbA1c of 8.0% would be eligible for a pump in an area where pump uptake was less than 1-2%, but with the new suggested guidance they will not fit the guidance for a pump. In this sense the proposed guidance has become stricter!

1.4. Team should be pump-trained, not a consultant with 'a special interest in pump therapy', as this limits the number of consultants prepared and available to take pump patients even more than it is already. Also 'specialist team's' indicates that specialist staff training is necessary. This will alienate diabetes teams who do not have many pump patients. ALL diabetes teams should be aware of pump therapy as a treatment option and should be able to offer advice on diet and lifestyle as they are still dealing with patients on insulin!

1.5. As written, we will oppose this with every means at our disposal! Do any other chronic conditions have targets set? Do any other conditions have treatments withdrawn if targets are not met? If not, then this is clearly discriminatory! This section should be removed.

In its place we suggest implementing the Department of Health's Report, "Care Planning in Diabetes." This report is a key component of Standard 3 of the Diabetes National Service Framework (NSF) and incorporates all that is required.

"Care planning, combined with structured education, can empower people with diabetes to make choices about how they manage their condition on a day-to-day basis.

Care planning can be defined as a process which offers people active involvement in deciding, agreeing and owning how their diabetes will be managed. It aims to help people with diabetes achieve optimum health through a partnership approach with health professionals in order to learn about diabetes, manage it and related conditions better and to cope with it in their daily lives.

Care planning is underpinned by the principles of patient-centredness and partnership working. It is an ongoing process of two-way communication, negotiation and joint decision-making in which both the person with diabetes and the healthcare professional make an equal contribution to the consultation. It differs from the 'paternalistic' or 'healthcare professional-centred' model of consulting, traditionally applied in acute settings." (Dept of Health 2006)

1.6. The blanket exclusion of patients diagnosed with type 2 diabetes from consideration for a pump is unfair to patients who may have been misdiagnosed initially, or whose diabetes is poorly controlled because of it has progressed to a point where they are totally insulin dependent. The US Medicare system allows coverage for insulin pump therapy for all patients who meet the low C-Peptide test result criteria set out in the document linked at: http://cms.hhs.gov/transmittals/downloads/R143CIM.pdf . This change was implemented in 2002, reversing the previous criteria that excluded patients with type 2 diabetes from receiving pump funding. If type 2s are excluded from receiving pump therapy until at least the next review of HTA57, the UK will be fully 10 years behind the US in its attitudes to diabetes care. Is it the intention of NICE to portray the UK as a backwards-thinking nation that disregards international standards for diabetes care?

2.5. This section misrepresents the aetiology, disease processes, and long-term prognoses of both type 1 and type 2 diabetes. Proposed revision: "Type 1 diabetes mellitus requires life-long treatment with insulin. Type 2 diabetes mellitus is initially managed by diet and weight loss. As the disease inevitably progresses, oral glucose-lowering drugs are introduced. Over time, most type 2 diabetes patients will need insulin to control their blood sugar levels. Causes of beta-cell dysfunction in patients with type 2 are under investigation as the United Kingdom Prospective Diabetes Study (UKPDS) showed that seven years after diabetes diagnosis many patients produce only half as much insulin as non-diabetic individuals. Various types of exogenous (injected) insulin distinguished are by their speed of onset and duration of action. Insulin requirements change depending on food intake, hormonal changes, stress levels, exercise or illness. Insulins with varying times to onset and durations of action are usually combined in treatment regimens, which are then delivered by multiple injections timed to coincide with requirements. Many type 2 diabetes patients can achieve control of their diabetes using a basal insulin and oral medications but all type 1 diabetes patients and many type 2 diabetes patients require both bolus and basal insulin. The Diabetes Control and Complications Trial (DCCT) showed conclusively that in type 1 diabetes, achieving good control of blood glucose through an intensive regimen, including frequent self-monitoring of blood glucose (SMBG) reduces the risk of complications. The UKPDS showed similar findings in type 2 diabetes. Intensive insulin regimens attempt to mimic the normal secretion of insulin by the pancreas. However, exogenously administered insulin does not activate the feedback mechanism that the liver and pancreas use to regulate insulin and glucose secretion, whereby insulin production decreases and increases as blood glucose levels change. Therefore, people taking insulin need to check their blood glucose levels regularly, a minimum of 4 times per day, by using a monitor (glucometer). Frequent daily glucose measurements enable short-term control of blood glucose levels by allowing the patient or caregiver to adjust insulin doses. Long-term monitoring of control is achieved by measuring glycosylated haemoglobin (HbA1c) levels, which reflect average blood glucose levels over the preceding 6 to 9 weeks. According to the DCCT and the UKPDS, an A1C of less than 7.5% is associated with greatly reduced risk for long-term diabetes complications. (The normal A1C range for people who do not have diabetes is 4.5–5.5% according to most available assays' reference ranges)."

3.2. The term "repositioned" with reference to cannula changes implies that the same cannula may be removed and reinserted in a different site. Let's keep it clear that the pump relies on disposable supplies to deliver insulin into the body. Also, it is important that the purposes of basal and bolus delivery (respectively) be explained. Many healthcare professionals in the UK whom we have encountered believe that patients wearing an insulin pump must also inject long-acting basal insulin (that is, they believe that the main advantage of a pump is not having to inject at mealtimes only, a belief that significantly misinterprets the technology). Proposed revision: "The pump is programmed to deliver basal rates of insulin throughout a 24-hour period, with boluses (doses) programmed separately at meal times and to correct glycaemic excursions. The main advantage of modern insulin pumps is that they can deliver different basal rates of insulin at different times of the day and night. It is recommended that the disposable cannula is removed and replaced every 72 hours (3 days)."

3.4. The reference to the requirement of “insulin, lancets, test strips and glucometers for monitoring” as originally worded implies that only insulin pump users need these things. ALL people with diabetes who take insulin require insulin, lancets, test strips, and glucometers. This need is not different between the MDI and pump using populations. The original wording implies that pumping is made more expensive or burdensome by these accoutrements when in fact these supplies are required no matter what form of insulin therapy patients’ use.

4.1.7. It may be worthwhile to expand the statement regarding puberty as a time when diabetes is difficult to control. This difficulty is very often not any fault of the patient or his/her family. Rather, we propose that the statement be expanded to say: “The time of puberty was also identified as a difficult time to control diabetes because of fluctuations in sex and growth hormones, which dramatically affect insulin sensitivity throughout adolescence.”

4.2.4. Surely the figure of £413 for a hospital stay resulting from hypoglycaemia is an underestimate as it does not factor in the lost productivity of a patient who is off work for a day or two following the incident?

4.3.1. The committee is described as “mindful of the need to take account of the effective use of NHS resources.” We would like to see a broad survey of the way that NHS resources are used to deal with the long-term complications of poorly controlled diabetes, including retinopathy, neuropathy, nephropathy, etc. These conditions lead to significant costs across the NHS.

4.3.3. In addition to pump users experiencing more gradual onset of hypoglycaemia, we propose that the following statement be added to the paragraph: “Additionally, reduced frequency of hypoglycaemic events may help restore and maintain patients’ symptomatic responses to hypoglycaemia, reducing the risk that they will suffer from hypoglycaemia unawareness.”

4.3.6. Understanding that the Committee has already drawn the conclusions reported in this paragraph, we propose a reconsideration of two aspects: 1) The A1C benchmark must be changed from 8.5% to 7.5%. 2) a proviso be added to the end of the paragraph: “for whom, despite a high level of care, it has been impossible to maintain a HbA1c level of less than 7.5%, or who experience disabling hypoglycaemia at an A1C below 7.5%” An A1C of 6.0% is no use to anyone if a patient who experiences persistent hypoglycaemia has a road accident because his or her A1C is “too good” to qualify for insulin pump therapy.

4.3.10. The description of insulin therapy in general in this paragraph makes it sound onerous and burdensome rather than lifesaving and life-enhancing. Further, this paragraph makes pump therapy sound positively impossible for anyone with merely normal hygiene standards and intelligence. This is a gross misrepresentation: yes, life with insulin-dependent diabetes is a great balancing act but the sheer fact that millions of people around the world do it every day should suggest that it’s not beyond the grasp of most mere mortals! We suggest the following revision to the statement that begins “Additionally, the use of effective insulin pump therapy…”: “Additionally, the use of effective insulin pump therapy would require replacing the cannula every at least every 72 hours and programming the pump (similar degree of difficulty to operating a mobile phone).”

4.3.11. Reiterating our objection to Sec. 1.5 with regard to the targets to be set and met, we also object stridently to the Committee’s conclusion that the “absence of such benefits within a reasonable time period should warrant a withdrawal of CSII therapy.” More to the point, the absence of such benefits should warrant a review of the patient’s diabetes care regimen, potentially including referral to a different diabetes care team, re-education, and increased support. If a patient is not succeeding on insulin pump therapy after having been prescribed the treatment because he or she was not doing well on injections, simply returning the patient to injection therapy hardly guarantees any better outcome! Surely patients who are sick deserve more and better care, not worse and less.

Finally we feel that it is appropriate to include the patients’ view of insulin pump therapy.

First introduced with somewhat crude technology in the late 1970s, the pump was designed by scientists and physicians in an effort to mimic the functions of a healthy pancreas. The first insulin pumps were actually adapted from similar pumps that were used to deliver constant medicine to treat cancer patients undergoing chemotherapy. Unfortunately, while the “theory” of pump therapy was sound, the initial practice of it was somewhat shaky. The technology to create a safe mechanical system was not yet in place; consequently, early pump users faced such challenges as not having adequate alarms to let them know when the pump was experiencing a technical malfunction.

From a lifestyle perspective, the pump required such unusual commitments as plugging it in every night and so not being able to move around while sleeping. Yet, many early pump users stuck with the system despite its flaws; they still achieved better blood sugar control on those pumps than they did with injection therapy. Two of our members have been using pumps for over 30 years and remember the early days.

Fortunately, times have changed and today's pumps are small, sleek, and safe and really do allow the user to "think like a pancreas" as the initial pump creators had envisioned. That is, just like a pancreas, an insulin pump releases small, continuous amounts of insulin into the body. In pump terminology, this is known as basal insulin and is pre-programmed into the pump to meet individual patient needs. And just as a pancreas produces insulin quickly to counteract carbohydrate intake, an insulin pump allows its wearer to dial in additional insulin to cover the amount of carbohydrates ingested. This insulin is known as bolus insulin. The combination of correct basal insulin rates with additional bolus insulin allows the person with diabetes to achieve the closest thing possible to a functioning pancreas. With over 35 years of technology behind them, insulin pumps are now pager-sized devices containing tiny computers, run on batteries. They are extremely safe, comfortable, and easy to wear.

Insulin is delivered through a thin tube that is connected both to the pump and the person wearing the pump, through a catheter, placed under the skin. The tube can easily detached for some activities, such as showering, that are easier to do without the pump on. Insulin pumps allow their users to continue any physical activity they're involved in – they don't inhibit sports, recreation, work, or sex. In fact because the pump user is able to lower the basal insulin rate during exercise or other activities that normally lower blood sugar, he or she will generally experience fewer hypoglycaemic episodes.

Certainly, any major change in diabetes treatment takes time to implement, and many people are involved in making that change occur; physicians, educators, manufacturers, and most important, the patients themselves. Anyone living with diabetes knows we must all act as our own advocates for getting the best health care possible, and it is very often the patient who must insist on making the switch to pump therapy.

We thank the Committee for giving us the patients, the opportunity to comment upon the draft recommendations of a treatment that changes lives. Our lives!

Yours faithfully

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