

Clinical and cost-effectiveness of continuous subcutaneous infusion for diabetes: updating review

Feedback from Stakeholders of Juvenile Diabetes Research Foundation (JDRF)

Summary

- In summary, the NICE report appears to give a detailed, realistic and balanced view of where we are and the criteria for proceeding on an expanded program of pump use. It should be highlighted that we are lagging far behind other countries in our use of pump technology available today. Furthermore, with valuable research ongoing into closed loop systems and as technology advances towards a true artificial pancreas we must ensure that T1DM sufferers in this country are at least up to speed with current available apparatus, and that means biting the budget bullet and making the technology - and support - available on a wider and more equitable scale.
- The technological learning curve can only increase - for users, carers and healthcare professionals - and generations will be unable to take advantage of the advances yet to come.
- Results (pg. 14, 15, 16) – 1% as a statistically insignificant reduction is scientifically mistaken. This means 1% point reduction in HbA1c. In reality, the reduction should be 13%. 13% is NOT insignificant. Makes same mistake on insulin input – should say 13%.
- Overall, the document appears biased against pumps.

Chapter 1

1.2 Complications of diabetes

- When NICE is looking to cost the effects of reduced HbA1Cs it must consider the life-long reduction in costs to the NHS via reduced complications across the board.

1.8 Quality of life

- Quality of life is of high importance to sufferers and primary carers, and we are pleased that the report takes this into account.
- Our personal experience bears this out. Phoebe has used the Medtronic Paradigm pump for eighteen months. After an initial 'settling in' period - surprisingly short - she became, at aged eleven, both comfortable and proficient with its use and routine.
- The freedom of lifestyle choices - being able to attend functions with previously unmanageable/unsuitable eating arrangements such as parties or school outings - has been as important to Phoebe as reducing her HbA1C.
- The fine control delivered by skilled pump use enables users to enjoy flexibility in eating and exercise schedules, increasing the opportunities to keep fit. Phoebe dances competitively, training

on average three nights and one day a week, with regional and national competitions every three or four weeks.

- Using a pump has helped create a level field for competition, reducing the likelihood of hypo's and again allowing her more flexibility to train and compete, sometimes over a day-long program. These benefits are less easy to measure than blood sugar levels; but they are just as important in the short and long term.
- Also, the pump, by allowing a more normal lifestyle should reduce the burn out associated with people with type 1 diabetes when after years of jabbing themselves in the finger and in the stomach, a child will suddenly hit a wall and say: 'I don't want to have diabetes anymore. I am on strike. I will not test my blood; give myself those extra three shots a day.' Dangerously this is often when children reach adolescence which is a particularly difficult period to control because of increased hormone-related insulin resistance. If even some of this burn out can be prevented, the pump is an improvement.
- The pump has literally saved my daughter, who has a terrible fear of injections, from a tortured life while maintaining an hba1c of between 5.5 and 6.9.
- **Reducing episodes of hypoglycemia and hyperglycemia** is another measurable target when considering pumps and MDIs. Since Phoebe started using the pump we have noted a marked reduction in both extremes, something that has allowed Phoebe more flexibility in her lifestyle choices and improved her quality of life.
- First and foremost the reduced fear of hypos mean that parents and patients alike live with a lower level of anxiety. We still awaken every night to test her blood at 2 am. But we would be doing this even more were she not 'on the pump'.
- Additionally, the indirect costs of lost productivity currently not incorporated adequately in your model will be realised. The costs to which I refer are the lost productivity of carers of young type 1's who have to give up work in order to keep their child alive. Initially I did not return to work when my child was diagnosed two years ago as I needed to go to her school to test blood at lunch, make adjustments to insulin boluses, etc. However, now because she is on the pump, she is much more independent at age 8 than her peers who are on a multiple injection regime as she can program the pump handily with little supervision. I have begun working part-time and expect to rejoin the work force full-time within the next year. In my experience this will not be the case for equivalent aged children using multiple injections. The time spent on my daughter by members of her school staff is less than that spent on the child using injections. This obviously has an opportunity cost associated with it that has flow through impact on the economy as a whole.

Why Insulin Pumps DO improve the quality of life. Comments from a 16-year-old pump user who has type 1:

- Avoids the insulin rush that comes from large injection. The basal dose delivered throughout the day enables even and near normal delivery of insulin. This also avoids the ravenous feeling resulting from large injections.
- No need for the snack before bedtime required on the injection regime, which made it harder to fall asleep.

- Enables much better blood glucose control.
- Less painful to insert infusion set once every three days than enduring 4-5 injections each day – ie 1:12-15.
- Gives more freedom and control to the individual.
- Can discreetly give bolus when eating out.
- Do not need to worry about what food is eaten as can painlessly take several boluses as meals progress. This enable better control than can be obtained from single injection which can lead to under or overshooting insulin required.

1.12 Use of CSII in the UK

- **Current pump usage statistics do not adequately enumerate benefits or costs:** Because the critical mass of pump usage has not been achieved in the UK (and the studies that were analysed and incorporated into the econometric models in your report rely on such small numbers) best practice methods for pump usage have not been incorporated into reduced hba1c, morbidity and mortality figures. Until there is a large group of professionals familiar with optimising the pump and a large group of people with type 1 diabetes using it, the optimal results will not be achieved. As a small example, if every child were able to use a pump from diagnosis, hba1c improvements on both a ‘metabolic memory’ and on an on going basis will have longer-term cumulative impact.
- **Support generally for the use of pumps in the UK is shockingly poor** - all the more deplorable when one considers a majority of pump research was conducted in this country. In our view children should be placed on a MDI or pump regime on diagnosis - or at least at the cessation of the co-called 'honeymoon' period - as a matter of course. It is no longer in question that these forms of treatment essentially - and again in *most* cases - reduce HbA1C levels. Whilst pumps do not suit everyone they are, where the opportunity to use them arises, overwhelmingly beneficial not only to sufferers of T1DM but also to their primary and key carers - parents, teachers and fellow students.

Chapter 2

2.3 CSII versus best MDI

- Failure to achieve good control for one year on MDI is not the best criteria for switching to CSII. A lot of time and effort is wasted.

The benefits of CSII:

- Less injections
- Less pain
- Better hypo awareness
- Fewer hypos
- Much improved HbA1c (and reduced risk of complications, reduced misery, costly admissions etc)

- Better flexibility
- Not having to feed hypos for sport, alcohol (so better weight management is possible)
- Better management of illness/ exercise and other changes with temp basals and patterns

2.4.1.1. Sample size

- Sample sizes are not significant - the studies that were analysed and incorporated into the econometric models in your report rely on such small numbers.

2.5.6 Insulin dose

- The use overall of **less insulin** in treatment/ management of T1DM to be an important factor.
- The pump avoids the insulin rush that comes from large injection. The basal dose delivered throughout the day enables even and near normal delivery of insulin. This also avoids the ravenous feeling resulting from large injections.

Chapter 4: Economics: CSII versus MDI

- **Total absolute cost of higher pump penetration is low:** If the UK achieved the 25% penetration achieved in the US amongst the target under 16 age group, the total cost would be but £7.5 million per annum. This comprises .15% of the total budget for diabetes in the UK in 2007 (*The Economist Intelligence Unit 2007: The Silent Epidemic: An Economist study of diabetes in developed and developing countries.*)
- In the cost analysis, no reference is made to use of public funds and benefits (i.e. Children With Disabilities, school statements) to support parents of children with type 1 diabetes. These costs would be lower for parents of pumps not needing to go to school to give injections, accompany school trips, or have statemented carers in their children's schools.
- Until a substantial sub group of the population has migrated to the pump, economies of scale and experience cannot be utilised. These will range from reductions in pump prices seen in all consumer electronics as well as consumables manufacture, increases in the size of training sessions, reducing the training costs per capita, etc.

Chapter 6

6.1 Education of patients

- In the UK one has to have 'failed' after things like DAFNE and MDI. That NICE also allows for pump withdrawal is disturbing and immoral IMO. If they tried to withdraw mine, I would consider every option including a legal challenge under the Human Rights Convention (knowingly

causing a deterioration in health must contravene this, surely?), MP's, MSP's and the press. NICE needs updating.

- Insulin Pumps should be the **FIRST** line of defence, **NOT** the last, so when a person is diagnosed with type one, **THEY** get the option of MDI or pump and sufficient training on diabetes management.
- I agree on the whole that access to pumps for children is limited only to pushy parent advocates. There seems to be no mandate to keep Paediatric Diabetic Consultants apprised of new treatments. **Training must begin from the top down, not from the parents up as seems to be the case currently.** Hence, the UK has a disproportionately small population of pump users relative to other countries.
- One area of concern raised in the report is the requirement for additional training for healthcare professionals. Obviously if pumps were made more readily available - and again, it is clear to those of us fortunate enough to be able to use pumps that everyone should have access to this form of treatment - then more NHS staff will need to be trained in the operation and management of pumps and set change operations.
- Speaking from our own experience, and acknowledging that a certain fundamental understanding of the operating and support platform is required by healthcare staff, it is the primary carer - or, in the case of teenagers/ young adults, the user - who requires the most intensive training.

General Comments

- It is important to acknowledge the vital role played by community support groups. In our case we receive excellent support from our diabetes team at the Alex (Children's hospital) and particularly from the community nurses, but the most valuable day-to-day help comes from fellow carers and users via the Children With Diabetes (CWD) network. When Phoebe first expressed an interest in using a pump, and we started the process of trials and application through our PCT, the doctor at the Alex was as much in the dark about the value - and operation - of pumps as we were. We've learned together, along with the nurses, about working with the pump. Even with this gradient of learning curve we have found the process relatively straight forward and the results have exceeded our initial hopes and expectations.
- It is important to us that the NICE report has considered and acknowledged that the T1DM community has an experienced support community in place to aid the widespread integration of better controls via pump technology.
- The criteria by which success - or otherwise - of pump use is measured is primarily the **lowering of HbA1C levels**. Our experience of switching, at first to MDIs and latterly to use of a pump, shows a quantitative reduction in HbA1C levels well in excess of the minimum levels required (1.0 mmols). This appears to be the case in most - but not all - cases so far trialed.