



Les GlucoMaîtres

(Masters of Glucose)

Groupe de support des familles qui vivent avec le diabète de Type 1
Support group for families living with Type 1 Diabetes

<http://www.glucomaitre.com>

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Objet: Response to AETMIS report : Comparison of the insulin pump and multiple daily insulin injections in intensive therapy for Type 1 diabetes

Comparaison entre la pompe à insuline et les multi-injections quotidiennes d'insuline pour le traitement intensif du diabète de Type 1.

Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS). Comparaison entre la pompe à insuline et les multi-injections quotidiennes d'insuline pour le traitement intensif du diabète de type 1. Rapport préparé par Brigitte Côté et Carole St-Hilaire. (AETMIS 04-07). Montréal : AETMIS, 2004, xiv-90 p.

Dear Dr. Deschenes:

Our support group of families living with Type 1 diabetes, *Les Gluco-Maitres*, would like to thank you for the review of the literature, the synthesis of the responses to a questionnaire and comments on the economic aspects of insulin pump therapy also known as continuous subcutaneous insulin infusion. We have anticipated this document for quite some time and we appreciate the opportunity to read your report.

Unfortunately, the final conservative recommendations and general dilution of the benefits of insulin pump therapy suggest that the committee did not fully understand the benefits/value of insulin pump therapy, or that it was not able to express very well its position.

With these comments in mind, please read the following that address the AETMIS report:

Select Group:

- While pump therapy technology has been available for more than 20 years, it has been available to children at the Hospital Centre of Université Laval (CHUL hospital) in Quebec City for only three and half years, when parents of a four-year-old child insisted on expanding the therapy technology with the assistance of one nurse from Ontario who shared her expertise. Since then, families of young children throughout Quebec who have chosen pump therapy have studied to learn how to manage this therapy and have searched out resources in order to successfully make this part of their child's life. The selection of the first children to receive access to the pump start team was based on the medical need of the child. These were tough cases. Since this time several families of children have opted for this therapy to improve glycemic control and their quality of life. Yes, they were a select group, but not an elite group. Unlike families of children who have unconditional access to pacemakers, other cardiology devices or other medical devices such as Kangaroo pumps (for G-tube feeds) as recommended by medical specialists, these families must individually campaign to gain access to this therapy and then they must work hard and sacrifice to continue to pay for this medical treatment. Of course they are a select and motivated group. The wording of the report suggested that these families were an elite group and therefore do not merit government assistances attention. To continue to limit access to medically approved treatment to only those with sufficient personal financial resources would be unethical.
- Doctors have told us that they are unable to prescribe insulin pump therapy to everyone that could medically benefit from it because of the costs involved for the patient and/or their family. On many

occasions, doctors hesitate to suggest the therapy for this reason. With a situation like this, it is certain the therapy is limited to a select and motivated group.

Quality of Life:

We were astounded to read the conclusion that there is no difference in the quality of life between those patients on multiple injections as compared to those on insulin pump therapy. (*Some specific comments are here and as well in the section 'Voice of the Pump User'*)

- We fail to understand why you rejected the article Kamoi *et al.* 2004 on page 11 which not only examined the differences in the quality of life between these two groups but also the differences in the quantity of insulin taken between these two groups.
- With insulin pump therapy, the patients and their families can take control. The patients manage their diabetes with insulin, rather than adapting their lives to the use of insulin injections. In addition, no consideration has been given to caregivers of Type 1 diabetic children or other family members faced with meal adaptations three times a day, every day, plus denial of full participation in any of the various possible holiday occasions. Families in our group could share many stories about the stress particularly among siblings that arise, and how this has changed with insulin pump therapy.
- There was no mention of the psychological depression that is common among Type 1 diabetics, many factors which potentially could be eliminated by insulin pump therapy.
- Nowhere did you explore the problem with Type 1 diabetic males and females entering puberty and how insulin pump therapy modifies/ helps these situations.
- In today's climate of suspicion towards the use of syringes among young people, it is possible for adolescents to fail to give themselves necessary insulin injections when in the presence of their peers. This results in emergency situations that further exclude them from the group. Surely there is a psychological cost to Type 1 diabetics, particularly adolescents who have to pull out needles rather than discretely using a remote control to give insulin doses when in the presence of their peers.

Perhaps you could attend one of our support group meetings to learn more from the pumper families about the differences in quality of life. More study at the grassroots level will tell you a different story than what was written in the AETMIS report.

Glargine

- Surprisingly the report made frequent reference to the long lasting insulin Glargine (Lantus). Glargine was approved for use in Canada in April 2002, but was made available in Canada only recently (Medical Post, Jan 2005). Until then, this insulin was not used in clinical practice in Canada but was available for scientific study only. Insulin pump therapy on the other hand has been a part of approved clinical practice across Canada for several years. We thought that this report was meant to compare current insulin pump therapy practices with current multiple injection practices.
- While the AETMIS report fully supports the statistical results of Glargine from the scientific studies, it fails to point out clearly that it alone does not respond to variations in daily physiological needs, something which the pump does with only one fast acting insulin.
- It is worthy to note that currently glargine is prescribed only for those over 17 yrs of age in Canada. Quoting the use of this drug in the paediatric population when it is neither proven nor approved for use in this country is negligent.

Scientific Literature Review

- The report's focus on randomized studies and the downplaying of the work accomplished in non-randomized trials makes little sense. Statistical comparisons of patients before and after pump starts are equally important if not more important than comparisons of randomly selected patients for a therapy treatment. Many of the non-randomized studies are based on selected, motivated patients that make randomization impossible. They require patient motivation because of the learning and manipulations involved. People are not plants who fit well into randomized experimental designs. This is probably why the medical evidence in the clinics with optimum pump therapy practices in Québec are better than those found in the literature that was consulted. The motivation and the selection of the patients are key to the success of this treatment. A clearer response would have been found if several clinics in Quebec, particularly CHUL, were consulted and would have supported the non-randomized studies.

- Other studies have been published since the publication of the AETMIS report in support of insulin pump therapy. Refer to several examples listed at the end of this letter.^{1,2,3,4,5}

Variation in the insulin pump therapy methodology among medical practitioners

- In the report, we read no acknowledgement of the variation among insulin pump therapy methodologies in the scientific articles. As such, we agree with the recommendation that there should be a consensus on the guidelines for the use of insulin pump therapy. Different members of our group would argue that doctors who have taken the time and the interest to learn the therapy well, have the most successful patients and patients with self-confidence that leads to success in other areas. A common policy among medical practitioners would be most welcomed, such that poor practices would be weeded out.

Lack of Recognition of the Advantages of Insulin Pump Therapy Compared to Multiple Daily Injections

There are many advantages of insulin pump therapy which were not brought forth in this study.

- The report measured the efficacy of each therapy based only on two indicators: HbA1c and average blood glucose values. Limiting the evaluation to only two factors biases the study and does not recognize other benefits that insulin pump therapy provides.
- Nowhere in the report did we see a focus on the advantages of micro-dosing, where the pump can administer at least ten times smaller doses than syringes. This is of particular importance in paediatrics.
- There was no exploration of the medical benefits of a reduction in the quantities of insulin taken, a reduction phenomena that happens when a patient switches from multiple injections to pump therapy.
- As well, there was no examination at the changes in the mood swings of a child at school because of reduced sugar swings, even though the topic was alluded to on page 14, noting that there are fewer variations with the pump.
- There was no mention of the fact that caregivers and the patient can confirm their given doses, in occasions where there is doubt.

Economic Considerations

- The economic analyses were overwhelmingly biased against insulin pump therapy. On page 33, the report clearly stated that cost analyses were limited to only a cost analysis. It was not a cost/benefit analysis. Only the direct costs incurred by four components of insulin pump therapy were included (acquisition of the pump, cost of accessories (reservoirs etc), user training and other necessary supplies (antiseptic wipes etc.)). Benefits were not estimated because according to the report, it was 'difficult to determine the most effective method'. Rather than examine the potential short term and long term returns on an investment, it was easier to not include these aspects in this report.
- There was no examination of the reduction of health care and social costs arising from the reduction of the number of visits to the emergency room by patients who have adopted pump therapy.
- There was no examination of the costs saved because of the reduced length of hospital stay for certain surgeries (example: Type 1 diabetic with tonsils or adenoids removed).
- There are numerous other benefits that have been ignored.

Voice of the Pump User

- The report did not acknowledge the reason why there were only 11 families of young children who responded to the voluntary questionnaire. In case you were unaware, Dr. Brigitte Côté gave our support group only two weeks at Christmas holiday time to respond to the AETMIS survey. The questionnaire was sent out on December 19, 2003 and responses were required for January 6, 2004 and no later because of the urgency from your agency to produce a report. Despite this, it took over a year for the AETMIS organization to report that respondents living with Type 1 diabetes gave their unanimous support in favour of pump therapy. Shortly a petition of over 16,000 signatures will be deposited at the Legislative Assemble in support of government financing of pump therapy when medically prescribed. Support for changes in quality of life and other aspects of insulin pump therapy could easily be found among the signatures of patients and family members of these patients, and their medical practitioners.
- Final recommendations by AETMIS include that the Ministry of Health create a multidisciplinary group, including Diabetes Quebec, clinical centres and researchers to develop guidelines, establish common tools, survey the use of insulin pump therapy and to re-evaluate the use of pump therapy. We strongly recommend that there is a voice for the pump user and/or caregivers of Type 1s on this committee and that there are sufficient resources available so that these persons can fully participate in any meetings.

- Pump users were not contacted to comment on the quality or the content of a preliminary version of the report.
- There was no mention of the dossier concerning children wearing insulin pumps in schools.

Voice of Endocrinologists and Montreal Children's Hospital

- We noted that only 2 of over 130 endocrinologists in Québec were acknowledged for their comments on the report. Why was the opinion of only two endocrinologists sought? Is this representative?
- As well, we noted that there was no participation from the Montreal Children's Hospital, a major paediatric centre, which is extensively involved in insulin pump therapy in Quebec.

Representation by Diabetes Quebec

- Diabetes Quebec represents the total diabetes population of which 90% have Type 2 diabetes, often associated with poor life-style choices. The other 10% of the population have Type 1 diabetes, an auto-immune disease. We hope that this organisation will be capable of best representing the needs of type 1 diabetics and more specifically those using insulin pumps.

Independent Monitoring System

- Members of our support group, Les GlucoMaîtres, would like to see monitoring independent of charitable organizations. It should be a part of the Ministry of Health statistical department where personal medical information is not shared.

CONCLUSION

When a person is diagnosed with the auto-immune disease Type 1 diabetes, which is usually at a young age, their lives depend on their 24/7 combined balanced management of carbohydrates, level of physical activity and their intensive insulin regime, stress, infections etc. There is no vacation period for this disease. Failure to maintain daily vigilance over this disease can quickly cost a life or severe complications. For a type 1 diabetic, a lack of vigilance can quickly cost a life or severe complications.

While it is much anticipated, a cure for Type 1 diabetes is not in the foreseen future. Even the costly Edmonton Protocol for islet transplants, one of the most promising avenues of research for a cure, is not guaranteed, and has huge after-treatment costs of anti-rejection medications involved. The alternatives for management of Type 1 diabetes today are limited either to multiple injection therapy or to insulin pump therapy.

A recent study (Svensson et al 2004)⁶ demonstrates a considerable reduction in long term cardiovascular complications due to diabetes in patients who could, from a young age maintain glycemic control. This conclusion is even more convincing knowing that diabetic children carry the history of their diabetes control all their lives. This article clearly showed that inadequate glycemic control during the first five years of Type 1 diabetes in children accelerates time to the occurrence of detectable complications. This argues that the earlier that a Type 1 diabetic improves glycemic control, the lower the risk of complications. We need to offer Type 1 diabetics technology that is available today if we want to assure their health in the future.

We applaud the initial efforts of AETMIS, but we all must recognize that those with Type 1 diabetes, an auto-immune disease, must have financially equal access to medically appropriate treatment when prescribed.

When making budget decisions related to support for patients diagnosed with Type 1 diabetes, the Government of Quebec and its agencies must consider the long-term financial advantages as well as the personal health benefits of insulin pump therapy and the comments outlined in this letter.

Sincerely,

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On behalf of the Type 1 Support Group GlucoMaîtres www.glucomaitre.com
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cc. Philippe Couillard, Minister of Health and Social Services
Louise Harel, Member of Parliament, Hochelaga-Maisonneuve Porte-parole de l'opposition officielle en matière de santé et de condition des aînés
Diane Legault, Member of Parliament for Chambly, Parliamentary Adjoint to the Ministry of Health and Social Services
Michel Audet, Minister of Finance

p.j. Signatures supporting this letter

¹Hirsch, I.B., Bode, B.W. Garg, S. Lane, W.S., Sussman, A. Hu, P. Santiago, O.M., Kolaczynski, J.W. 2005. Continuous subcutaneous insulin infusion (CSII) of insulin aspart versus multiple daily injection of insulin aspart/insulin glargine in Type 1 diabetic patients previously treated with CSII. *Diabetes Care* 28(3):533-538

²McMahon, S.K., Airey, F.L., Marangou, D. A., McElwee, K.J. Carne, C.L., Clarey, A.J., Davis, E.A. and Jones, T.W. 2004. Insulin pump therapy in children and adolescents: improvements in key parameters of diabetes management including quality of life. *Diabetic Medicine* 22: 92-96

³Peyrot M, Rubin R. Validity and Reliability of an Instrument for Assessing Health-Related Quality of Life and Treatment Preferences: The Insulin Delivery System Rating Questionnaire. *Diabetes Care* 2005; 28:53-58.

⁴Retnakaran, R., Hochman, J., Hans DeVries, J, Hanaire-BROUTIN, H., Heine, R.J., Melki, V., Zinman, B..2005. Continuous subcutaneous insulin infusion versus multiple daily injections. *Diabetes Care* 27 (11): 2950-2596.

⁵Wilson DM, Buckingham BA, Kunselman EL, Sullivan MM, Paguntalan HU, Gitelman SE. A Two-Center Randomized Controlled Feasibility Trial of Insulin Pump Therapy in Young Children with Diabetes. *Diabetes Care* 2005;28:15-19.

⁶Svensson; M. Eriksson; J.W., Dahlquist, G. 2004, Early Glycemic Control, Age at Onset, and Development of Microvascular Complications in childhood-onset Type 1 Diabetes, *Diabetes Care*; Apr 2004; 27, 4; Health Module, p. 955

The group GlucoMaîtres is a support group of families living with Type 1 diabetes. Created in February 2002, the group has over 110 families who meet, exchange information and inform themselves during a monthly meeting or by the Internet. <http://www.glucomaitre.com>.