SUBMISSION TO THE PBS ON THE DRAFT REPORT FOR STAGE TWO OF THE DIABETES REVIEW ON INSULIN PUMPS

4 AUGUST 2014

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MTAA and IVDA Joint Submission: Post-market Review of Products Used for Diabetes Management – Stage Two of the Diabetes Review on Insulin Pumps

Thank you for the opportunity to comment on the *draft report for Stage Two of the Diabetes Review on Insulin Pumps*.

MTAA and IVDA wish to express their concern with the nature and level of consultation in conducting the review. The review process lacks clarity and transparency.

The review process has failed to meet the stated objective "*to systematically evaluate the body of clinical evidence*" of insulin pump therapy to ensure the most appropriate management of diabetes in clinical practice. The review process is not consistent with other reviews (i.e. PBS or MBS reviews).

Overall, the draft report seems supportive of insulin pump use for diabetes management, however made no recommendations. The draft report contains several limitations: the findings do not accurately represent insulin pump use in Australia (i.e. sensor augmented insulin pumps use, which is high in Australia, was not included in this review), and evidence included is incomplete and dated.

The draft report is inappropriate to inform decisions for the use and funding of insulin pumps. It fails to include the recent best practice evidence, as well as cost effectiveness considerations. Barriers to patient access of future technology to improve management of diabetes also need to be considered.

MTAA and IVDA members have expressed their wish that the criteria for patient access to insulin pumps be reviewed and that it aligns to Australian and international best practice guidelines for diabetes management (NHMRC, Diabetes Australia and the RACGP). Due to the current accessibility criteria, patients who would clinically benefit most from insulin pump use are denied access.

MTAA and IVDA request the purpose and intent of the review on insulin pumps be clearly defined and communicated. We would like the opportunity to consult further with the Department for the consideration of including current evidence prior to finalising the report.

Please contact Alessandra Doolan on E: adoolan@mtaa.org.au or P: (02) 9900 0650 if you have any questions or require further information.

Yours sincerely,

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MTAA and IVDA Submission

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Overall comments and input on the draft Insulin Pumps Report

General comments to the draft Insulin Pump Report include:

- Fails to meet the stated objective of the review "…*to systematically evaluate the body of clinical evidence*":
    - Inconsistent literature search periods between the systematic reviews/RCTs (2000 – July 2012) and search of observational studies (January 2008 – May 2013)
    - Evidence included or excluded in the review is unclear
    - Effectiveness of the newest insulin pumps that provide sensor augmented pump therapy was not assessed in the review. Therefore, the review did not compare the health benefits provided by current technology with advancement in technology for the treatment of type 1 diabetes[1,2,3]
    - Evidence is dated and incomplete: key clinical and cost-effectiveness evidence that are important for evidence-based decisions were not included (Annex A).

- Lacks transparency:
    - No decision analytic protocol was provided; therefore there was no opportunity for public consultation on the scope of the evidence review
    - Search strategies for the literature search have not been made publicly available and only made available on request (Annex B)
    - Intent and outcome of the review and draft report are unclear.

- The review process and methodology was not performed in alignment with other Australian HTA processes (i.e. MSAC, PBAC, MBS Reviews).

The draft report should be revised to include 'missing' evidence in order to meet the stated and intended objective of a 'systematic' review. The scope and intent of the draft report are unclear – with no recommendations made. The draft report is inadequate to make evidence-based decisions on the use and funding of insulin pumps in Australia.

Question 1

Should the Programme prioritise any age groups in providing subsidised access to insulin pumps, and why?

The primary goal of any diabetes therapy is to achieve good glycaemic control in order to prevent diabetes associated short and long-term complications. Access to insulin pump therapy (IPT) should be informed by evidence and clinical guidelines (Australian and overseas) rather than restrict subsidised access to insulin pump therapy on the basis of age (i.e. **determination of IPT access is independent of age**).

The current eligibility criteria of the Insulin Pump Programme ("Programme") requires a patient to be 18 years or younger to be considered. This age restriction is not based on clinical evidence. It presents an ethical issue interrupting the continuum of care of young patients with type 1 diabetes on IPT under the Programme who cannot afford private health insurance to cover the cost of a new pump once they are over 18 years of age.

Recommendation:

The Programme should target those who would clinically benefit most from IPT including: those under the age of 18 or over the age of 18 (who have been on IPT when they were younger), women who are pregnant or trying to conceive, individuals with poor glycaemic control, individuals with high initial HbA1c and individuals with severe and/or unpredictable hypoglycaemia.

The Programme also should be expanded to include adolescents and adults with type 1 diabetes in accordance with clinical guidelines to avoid/prevent adverse diabetes-related health outcomes.

Question 2

Should the Programme be expanded to provide access to women with type 1 diabetes who are pregnant or planning a pregnancy and meet the financial eligibility requirements?

Evidence on the effectiveness (glycaemic control) and safety of insulin pump use during pregnancy was not included in the review.

The review did not consider the health benefits of IPT use in pregnant women. However, there is evidence to support this:

- Women with type 1 diabetes using insulin pumps during pregnancy had lower HbA1c without increased risk of severe hypoglycaemia or diabetic ketoacidosis[4]
- IPT should be continued for pregnant women with diabetes if IPT has been initiated before pregnancy[5]
- IPT is recommended for pregnant women if multiple daily injections (MDI) have proven unsuccessful.[6]

Recommendation:

The Programme should be expanded to cover women with type 1 diabetes who are pregnant or planning a pregnancy, as there is evidence to show that IPT use provides clinical benefits.

Question 3

Do you consider it a greater priority to provide expanded access to the Programme in terms of age ranges covered and pregnant women, or more affordable access for the currently eligible population, i.e. children and adolescents aged 18 years and under?

The clinical benefits of IPT are not determined by age, but rather the clinical needs of patients with type 1 diabetes.

"The important clinical question is not whether CSII[*] is more efficacious than MDI in general adult type 1 diabetes mellitus, but whether CSII further improves glycaemic control when this control continues to be poor with MDI, and evidence exists that in most cases it does" [7]

Access should be targeted to those who fail on MDI and have good clinical prospects (minimising short and long term complications) due to insulin pump use (an individual's diabetes is 'well-managed' in terms of HbA1c levels, glycaemic variability, risk of hypoglycaemia and/or quality of life compared to MDI).

Recommendation:

Access to the Programme should be based on meeting the clinical needs of those who require and benefit from IPT - as determined by the clinician/endocrinologist that IPT is the most appropriate insulin treatment option for a particular patient. Access should be irrespective of age or pregnancy status. It is also important that the Programme is adequately funded to meet this clinical need.

Question 4

In your experience in dealing with service providers, is the delivery of type 1 diabetes products particularly insulin pumps and consumables, satisfactory? Do you have any suggested improvements?

Note: The Juvenile Diabetes Research Foundation (JDRF) administers the Insulin Pump Programme and Diabetes Australia administers the National Diabetes Services Scheme, (NDSS) which provides subsidised insulin pump consumables.

Recommendations:

Recommendations are based on MTAA and IVDA members' experiences gained through working with patients, healthcare professionals and JDRF:

- **Eligibility for and accessibility of IPT for individuals with type 1 diabetes should be based on significant unmet clinical need, including children and transitioning patients from adolescence to adulthood already using insulin therapy (i.e. once individuals turn 18 years they are no longer eligible for the JDRF Programme even if the individual falls within the "low socio-economic" criteria). This means that the improved health outcomes experienced through the use of insulin pump would be negated.**
- **JDRF should continue to manage the Insulin Pump Programme. Since its establishment, JDRF has "*proven its capability of managing"* the Programme in Australia.**
- **Pump 'consumables costs' should only be drawn from the NDSS budget and should NOT be drawn from the funds allocated for the Insulin Pump Programme.**

[*] Insulin pump therapy is also known as continuous subcutaneous insulin infusion therapy (CSII).

This ensures sufficient pumps are supplied to lower income families, who meet the Programme's criteria and cannot afford insulin pumps. There are *"inconsistencies between different states regarding accessing NDSS service*s".

- **Government should ensure that pumps are fully subsidised for the lowest income family bracket by increasing the maximum subsidy from 80% of total pump cost to 100% of total pump cost. Increasing the lowest indexed income salary level used for Programme eligibility assessment better reflects today's average rates.**

Question 5

Are the clinical eligibility criteria for the Insulin Pump Programme appropriate? If not, what should the criteria be?

A reasonable minimum target for individuals with type 1 diabetes who should be offered IPT is around 15–20% - a proportion of children or adults on MDI who have markedly elevated HBA1c and wide variability in blood glucose concentration, often have unpredictable, moderate (non-severe) hypoglycaemia. However, insulin pump use in Australia is only around 10%[8], which is less compared to the US and other countries such as the UK.[9] There are currently 117,939 Australians registered with type 1 diabetes[10] therefore, less than 12,000 individuals with type 1 diabetes currently have access to IPT. The majority of insulin pump users (86%) obtained their pumps with financial assistance from private health insurance.

Recommendation:

The Programme's eligibility criteria should not be age restricted but should be evidence-based and in alignment with Australian and international guidelines on insulin pump use. The criteria needs to be revised to ensure that eligibility under the JDRF Programme is based on clinical need (i.e. poor glycaemic control and quality of life) and continues to provide IPT to patient who turns 18 years of age. Access to IPT for pregnant women and those attempting to conceive should also be included in the criteria.

Question 6

What are the most important features of an insulin pump that assist in achieving optimal health outcomes or impact greatly on quality of life?

It is important that insulin pump systems have a range of settings and features that are able to meet individual patient needs. These features include the ability to:

- program variable basal rates over the 24 hours mimicking physiologic insulin secretion
- rapidly react to changing insulin requirements by temporarily adjusting the basal rate
- directly deliver a bolus recommended by bolus advice integrated in the pump system without the need for manual transfer of a recommended bolus to the pump
- remote control dosing by caregivers and decreasing interruption of a child's activity.[11]

It is important to note that even the best technical characteristics of an insulin pump system will not translate into optimal therapy outcomes, if (a) the patient does not use the system to its full extent or (b) the healthcare professional cannot configure the system to its full extent.

Different categories of insulin pumps based on major differences are recognised by the Prostheses List. These categories include:

- insulin pumps that deliver insulin only
- sensor augmented pumps that combine insulin delivery and continuous glucose monitoring (CGM) capability
- sensor augmented pumps with automated insulin suspension that stop insulin delivery when glucose levels go too low in reaching a pre-set low glucose threshold.

Effectiveness evidence on sensor augmented pump therapy was excluded from the review. The reasons are unclear and not explained in the draft report/review. While the comparison table in Appendix A of the draft report identified pumps with CGM capability, it did not differentiate between sensor augmented pumps that do and do not have automated insulin suspension. Numerous RCTs[1,2] and non-randomised studies[12,13,14,15,16] have shown the associated clinical benefits in using automated insulin suspension. These include significantly reduced hypoglycaemia exposure and events including total prevention of seizure, coma and hypoglycaemia.

Recommendation:

Patient groups should have access to a range of insulin pumps. This is to ensure various features are available to assist in providing optimal health outcomes and quality of life to meet individual patient's needs. Access to new (advanced) and emerging technologies should also be considered in the review.

References

[1] Yeh HC et al. Comparative effectiveness and safety of methods of insulin delivery and glucose monitoring for diabetes mellitus: a systematic review and meta-analysis. *Ann Intern Med*. 2012; 157(5):336-47.

[2] Ly T et al. Effect of sensor-augmented insulin pump therapy and automated insulin suspension vs standard insulin pump therapy on hypoglycaemia in patients with type 1 diabetes: a randomised clinical trial. *JAMA* 2013; 310(12):1240-7.

[3] Bergenstal RM et al.: ASPIRE In-Home Study Group. Threshold-based insulin-pump interruption for reduction of hypoglycemia. *N Engl J Med*. 2013; 369(3):224-32.

[4] Kallas-Koeman MM et al. Insulin pump use in pregnancy is associated with lower HbA(1c) without increasing the rate of severe hypoglycaemia or diabetic ketoacidosis in women with type 1 diabetes. *Diabetologia* 2014; 57(4): 681-9.

[5] Endocrine Society Clinical Practice Guideline. Available: http://www.hormone.org/patient-guides/2014/diabetes-and-pregnancy.

[6] Blumer IE et al. Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinology & Metabolism* 2013; 98(11): 4227-49.

[7] Pickup JC. Insulin-pump therapy for type 1 diabetes mellitus*. N Engl J Med 2012*; 366(17): 1616-24

[8] Australian Institute of Health and Welfare. 2012. Insulin pump use in Australia. Diabetes series no. 18. Cat. No CVD 58. Canberra: AIHW.

[9] Pickup JC. Are insulin pumps underutilized in type 1 diabetes? Yes. *Diabetes Care* 2006; 29(6): 1449-52

[10] NDSS. http://www.ndss.com.au/Global/Data%20Snapshots/June%202014/NDSS-NartionalSnapshots-30June2014-TYPE1.pdf

[11] Blackman SM et al. Insulin pump use in young children in the T1D Exchange clinic registry is associated with lower hemoglobin A1c levels than injection therapy. *Pediatr Diabetes*. 2014; doi: 10.1111/pedi.12121 [Epub ahead of print]

[12] Choudhary P et al. Insulin pump therapy with automated insulin suspension in response to hypoglycemia: reduction in nocturnal hypoglycemia in those at greatest risk. *Diabetes Care* 2011; 34(9):2023-5.

[13] Ly T et al. Analysis of glucose responses to automated insulin suspension with sensor-augmented pump therapy. *Diabetes Care* 2012;35:1462–65

[14] Danne T et al. Prevention of hypoglycemia by using low glucose suspend function in sensor-augmented pump therapy. *Diabetes Technology and Therapeutics* 2011; 13(11):1129-34.

[15] Agrawal P et al. Usage and effectiveness of the low glucose suspend feature of the Medtronic Paradigm Veo insulin pump. *Journal of Diabetes Science and Technology* 2011;5(5):1137-41

[16] Garg S et al. Reduction in duration of hypoglycemia by automatic suspension of insulin delivery: the in-clinic ASPIRE study. *Diabetes Technology and Therapeutics* 2012; 14(3):1-5.

Annex A – Additional evidence to be considered

Systematic Reviews

- Churchill JN, Ruppe RL, Smaldone A. Use of continuous insulin infusion pumps in young children with type 1 diabetes: a systematic review. *J Pediatr Health Care* 2009; 23(3):173-9.

- Pickup JC, Sutton AJ. Severe hypoglycaemia and glycaemic control in Type 1 diabetes: meta-analysis of multiple daily insulin injections compared with continuous subcutaneous insulin infusion. *Diabetic Medicine* 2008; 25(7):765-74.

Cost-effectiveness studies of insulin pump therapy vs MDI

- Castell C et al*.* Assessing the efficiency of using continuous subcutaneous insulin infusion (CSII) versus multiple daily injections (MDI) in Spanish diabetes mellitus type - 1 (DM1) patients. *Value in Health* 2005;8:A161.

- Clegg J et al*.* Health Economic Analysis of Continuous Subcutaneous Insulin Infusion Compared to Multiple Daily Injections for the Treatment of Type 1 Diabetes in Poland. *Value in Health* 2008; 11(6):A336.

- Cohen N et al. Continuous Subcutaneous Insulin Infusion versus Multiple Daily Injections of Insulin: Economic Comparison in Adult and Adolescent Type 1 Diabetes Mellitus in Australia. *Pharmaeconomics* 2007; 25(10):881–97.

- Cummins E et al. Clinical effectiveness and cost-effectiveness of continuous subcutaneous insulin infusion for diabetes: systematic review and economic evaluation. *Health Technology Assessment* 2010; 14(11).

- Giardina S et al. A cost-effectiveness analysis of continuous subcutaneous insulin injection vs. multiple daily injections in type-1 diabetes patients in Italy. *Value in Health*. 2009; 12(7):A407.

- Goodall G et al. Continuous subcutaneous insulin infusion versus multiple daily injection of insulin in patients with type 1 diabetes: A long-term health economic analysis in the Norwegian and Swedish settings. *Value in Health* 2006; 9(6):A227.

- National Institute for Health and Clinical Excellence. Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. TA151. London: NICE; 2008 Available at: http://guidance.nice.org.uk/TA151/ReviewDecision.

- Nicklasson L et al. Continuous subcutaneous insulin infusion versus multiple daily injections for type 1 diabetes: a cost effectiveness analysis for Sweden. *Diabetologia* 2006; 49:541.

- Ning G, Lynch P. Cost-effectiveness of CSII in China. *Value in Health*. 2010; 13(7):A527.

- Quiroz M et al. Insulin pump cost-utility analysis compared to multiple daily injections in type 1 diabetic patients in the Mexican social security institute, 21st century hospital. *Value in Health*. 2012.

- Roze S et al. Cost-effectiveness of continuous subcutaneous insulin infusion versus multiple daily injections for intensive control of Type 1 diabetes: a French analysis. *Diabetologia* 2002; 45:A302.

- Roze S et al. Health-economic comparison of continuous subcutaneous insulin infusion with multiple daily injection for the treatment of Type 1 diabetes in the UK. *Diabetes Medicine* 2005; 22:1239–45.

- Scuffham P, Carr L. The cost-effectiveness of continuous subcutaneous insulin infusion compared with multiple daily injections for the management of diabetes. *Diabetes Medicine* 2003; 20: 586–93.

- St Charles ME et al. Health Economic Comparison Between Continuous Subcutaneous Insulin Infusion and Multiple Daily Injections of Insulin for the Treatment of Adult Type 1 Diabetes in Canada. *Clinical Therapeutics* 2009; 31(3):657–7.

- St Charles ME et al. A Cost-Effectiveness Analysis of Continuous Subcutaneous Insulin Injection versus Multiple Daily Injections in Type 1 Diabetes Patients : A Third-Party US Payer Perspective. *Value in Health* 2009; 12(5):674–86.

- Zakrzewska K et al. Continuous subcutaneous insulin infusion reduces incidence of diabetes-related complications when compred with multiple daily injections for type 1 diabetes treatment: A health economic analysis in Switzerland. *Diabetes* 2005; 54:A610.

- Zakrzewska K et al. Health economic comparison of continuous subcutaneous insulin infusion with multiple daily injection for the treatment of type 1 diabetes in the UK. *Value in Health* 2004;7:649–50.

Annex B - Search strategy for RCTs literature review (provided by the Diabetes Review Secretariat when requested by MTAA)

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