

# Stakeholder Forum Summary

## Stage 2: Insulin Pumps (Type 1 Diabetes)

### Post-Market Review of Products used in the Management of Diabetes Department of Health, 12 September 2013

*This document is intended to provide a broad summary of the views expressed by stakeholders and only information provided at the Forum has been included. No attempt was made to reach consensus and the views and opinions should not be considered as medical advice. This Summary, along with all other comments contributed by attendees, will be provided to the Diabetes Review Reference Group for consideration.*

#### PURPOSE AND CONTEXT

The Stakeholder Forum provided an opportunity for the Department to seek the views of a broad range of stakeholders to help inform the insulin pump component of the Post-Market Review of Products used in the Management of Diabetes. The Forum forms a part of several public consultation processes undertaken for this Review.

The Forum sought the advice of stakeholders in relation to their experiences and knowledge of the benefits of insulin pumps, while considering the limitations of the evidence available on clinical benefits. Themes and questions that arose out of the written public submissions and literature reviews undertaken by the Department were presented for discussion.

As a part of the public consultation processes, written public submissions were invited to address the Review's Terms of Reference 8–10. The submissions are published on the [PBS website](#).

The findings of the insulin pumps component of the Review will be compiled into a report that will be provided to the Pharmaceutical Benefits Advisory Committee (PBAC) for noting in the context of the broader Review, and then to Government for consideration, noting that insulin pumps are not subject to PBAC evaluation processes.

Four focus questions were posed at the Forum to prompt discussion:

1. *The evidence from the literature does not demonstrate that insulin pump therapy is more effective than multiple daily injections at controlling blood glucose levels or reducing the number of hypoglycaemic events. There is also a lack of strong evidence for improved quality of life in under 18's. Considering this, what do children, carers, and clinicians see as the advantages and disadvantages of insulin pump therapy?*
2. *There is limited evidence regarding the differences between available insulin pumps in terms of how insulin pumps affect clinical outcomes. What aspects of an insulin pump brand or type might be important to clinical outcomes and desirable to a patient (i.e. software, dose increments, customer support, etc.)? What factors influence health professionals' decisions when recommending a particular insulin pump?*
3. *Are there advantages in having multiple insulin pumps available under the Insulin Pump Programme in terms of requirements needed for optimal clinical outcomes? That is, are different insulin pump types better or more suitable for different patients, and why?*
4. *In relation to the eligibility requirements for the Programme:*
  - a) *What type of patients should be prioritised to receive a subsidised insulin pump, considering, but not limited to, the following characteristics:*
    - age;

- *income and means-testing;*
- *blood glucose control (HbA<sub>1c</sub> levels and hypoglycaemic events);*
- *previously having received an insulin pump and stopped therapy; and*
- *diabetes complications.*

## **SUMMARY OF KEY DISCUSSION POINTS RAISED BY STAKEHOLDERS**

- Insulin pumps can benefit clinical outcomes, including glycaemic control, reducing the frequency and severity of hypoglycaemic events, and reducing the frequency of sick days.
- Insulin pumps can greatly improve quality of life, specifically, reducing patients' and their families' anxieties, and allowing greater flexibility, independence, and insight into managing their type 1 diabetes.
- Success with insulin pump therapy depends on the type of patient (e.g. risk level), the motivation of the patient and their family, and the quality of education and support for patients, families, and health professionals.
- The clinical data to date seem to compare datasets that are not comparable. By pooling data (i.e. in a systematic literature search), the context and nuance is generally lost. In the literature, there is limited evidence for the benefits of insulin pumps due to this cancellation effect, which is also apparent in the National Health and Medical Research Council (NHMRC) *National Evidence-Based Clinical Care Guidelines for Type 1 Diabetes for Children, Adolescents and Adults*. However, there is some tension between this literature review and on-the-ground experience. It is difficult to assess this type of therapy using randomised controlled trials. Observational and cohort studies may provide stronger and more beneficial evidence on the use, benefits, and effectiveness of insulin pump therapy.
- The Department stated that there were funding restraints for the Insulin Pump Programme. Stakeholders noted that there are high costs associated with insulin pump therapy, such as specialised training and ongoing support. Insulin pumps may have some positive cost-benefit outcomes associated with reduced hypoglycaemic events and hospital admissions.
- It is necessary to support the rapidly changing technology including avenues for government subsidy. Education and support needs to adapt to these rapid changes as well.
- All sub-groups of patients should be considered for eligibility for the Insulin Pump Programme.
- It was acknowledged that there are numerous issues regarding access to insulin pumps through private health insurance, including denial of access through providers. *The Department stated that this issue is outside the scope of the Review and would be referred to the appropriate area of the Department.*
- Although some patients may miss out on an insulin pump, they can be adequately managed on insulin injections.
- Specific insulin pump features are important, such as small dose increments for children or those requiring low amounts of insulin, waterproofing, tubing or tubeless design, and the potential for a closed loop system.
- It is important to ensure a baseline quality control and to have a wide variety of insulin pumps available to allow adequate patient choice, and guaranteed supply and replacement of insulin pumps. Education for patients, families, and health professionals in the use of a variety of insulin pumps is critical.

## SUMMARY OF STAKEHOLDER RESPONSES TO FOCUS QUESTIONS

*Q1: The evidence from the literature does not demonstrate that insulin pump therapy is more effective than multiple daily injections at controlling blood glucose levels or reducing the number of hypoglycaemic events. There is also a lack of strong evidence for improved quality of life in under 18's. Considering this, what do children, carers, and clinicians see as the advantages and disadvantages of insulin pump therapy?*

- Although published literature shows limited evidence in support of insulin pump use, anecdotal evidence is to the contrary. It is important to note that pooling data from trials and sub-populations can result in a cancellation effect that makes it difficult to draw a conclusion. Data collection needs to be patient centred.
- Randomised controlled trials are not designed to demonstrate the benefits of insulin pump therapy. Observational studies offer clearer evidence of these benefits.
- Success with insulin pump therapy is dependent on patient characteristics, the level of support available and the education provided on how to best manage an insulin pump.
- Insulin pumps offer greater flexibility and independence in lifestyle and self-management of diabetes. For both the patient and their family, they provide psychological benefits, alleviate fear of hypoglycaemic events, increase the capacity to prevent hospitalisation and handle sick days, and reduce stigma and anxiety. Patient and family motivation is a critical component in ensuring the best outcomes are achieved from an insulin pump.
- While insulin pumps provide quality of life advantages for patients, there is a high cost associated with specialised training of health professionals to support their use. These ongoing training and support costs may be higher than standard therapies. However, there may be a positive cost-benefit outcome in decreased hospital admissions linked to hypoglycaemic events for people using insulin pumps. The Department noted that there are funding restraints for providing insulin pump subsidies.

*Q2: There is limited evidence regarding the differences between available insulin pumps in terms of how insulin pumps affect clinical outcomes. What aspects of an insulin pump brand or type might be important to clinical outcomes and desirable to a patient (i.e. software, dose increments, customer support, etc.)? What factors influence health professionals' decisions when recommending a particular insulin pump?*

- The desirable features of an insulin pump will depend on the individual patient and their lifestyle.
- Health professionals need to have access to information available on insulin pumps so that they can tailor treatments to their patients.
- Currently, insulin pump provision is directly linked to clinical knowledge. Provision of an insulin pump must be accompanied by appropriate education to ensure that the chosen pump best suits the needs of the individual. It is important for patients to be fully informed when deciding on an insulin pump.
- Different features of insulin pumps include ability to control dose management, water proofing, continuous glucose monitoring connectivity, and design features such as reduction in blockages and improved loaders for cannula insertion.
- Insulin pumps have now been in use for over ten years and are quickly evolving. Newer pumps have few discriminating features between them. They have the ability to be integrated into a closed loop system, are waterproof and essentially have the same

mechanics. It is the software that is the main point of difference, although there are occasionally other issues.

- Insulin pumps give a patient greater insight into managing their diabetes.
- In the USA, 70% of people are using a tubeless patch pump. These pumps are not yet subsidised in Australia.

*Q3: Are there advantages in having multiple insulin pumps available under the Insulin Pump Programme in terms of requirements needed for optimal clinical outcomes? That is, are different insulin pump types better or more suitable for different patients, and why?*

- Availability of multiple insulin pumps can allow tailoring to the individual and offers considerable quality of life advantages. Although this is difficult to quantify, it does offer patient centred choice. It is important to determine if the pump is delivering insulin only or serving as a monitoring device as well.
- Supply issues must be considered in the context of the needs of rural and remote patients.
- It is important to manage the risks and standards associated with education of health professionals on the range of insulin pumps available. Patients and families must have a strong relationship with their health professional to achieve quality health outcomes from insulin pump use.
- There are challenges associated with keeping abreast of new technologies for health professionals and patients.
- There will need to be a mechanism for new technologies to be reimbursed by the Australian Government.
- It may be valuable to consider what has been learnt from the use of insulin pumps in oncology in terms of quality of life.

*Q4: In relation to the eligibility requirements for the Programme:*

*a) What type of patients should be prioritised to receive a subsidised insulin pump, considering, but not limited to, the following characteristics:*

- *age;*
  - *income and means-testing;*
  - *blood glucose control (HbA<sub>1c</sub> levels and hypoglycaemic events);*
  - *previously having received an insulin pump and stopped therapy; and*
  - *diabetes complications.*
- All sub-groups of patients should be considered for eligibility for the Insulin Pump Programme.
  - Criteria used in clinical practice that may guide eligibility criteria, include:
    - ascertain the motivation and goals of the parents/carer and child;
    - ensure that the patient is prepared to do at least four blood glucose tests per day;
    - ensure that there is a basic level of numeracy in the child and/or carer ; and
    - ensure that the families have a pragmatic approach to areas they need to address.

- Diabetes is an individual condition. Age should not be a determinant in accessing insulin pumps under the Insulin Pump Programme. These devices have a positive impact on quality of life and flexibility for patients with type 1 diabetes.
- Insulin pumps may be useful during pregnancy.

## **ADDITIONAL PERSPECTIVES RAISED BY STAKEHOLDERS**

### *Clinicians, Health Professionals, and Health Professional Peak Bodies*

- Education and support should cover implementation of any changes and also how insulin pumps are accessed and funded. Education also needs to account for the needs of people in rural and remote areas, people from Aboriginal and Torres Strait Islander backgrounds, and people from culturally and linguistically diverse backgrounds.
- Formal training is required for health professionals to understand the different types of insulin pumps available, so that they can provide appropriate advice on the range of pumps and what each can offer to the patient.

### *Industry and Industry Peak Bodies*

- There will need to be a mechanism for new technologies to be reimbursed by the Australian Government. In the USA, 70% of people using an insulin pump are now using a tubeless patch pump, which is not yet subsidised in Australia.
- There needs to be a diversity of insulin pumps available to address diverse patient needs.
- In higher risk patients (such as those with hypoglycaemia unawareness), the benefits of using insulin pumps may outweigh the risk.
- It was not accepted that insulin pumps are not more effective than multiple daily injections.
- The issue of barriers to accessing new technologies was raised.

### *Consumers and Consumer Peak Bodies*

- The focus should be on evidence associated with quality of life benefits for the patient and their family, as well as on HbA<sub>1c</sub> levels.
- Diabetes is an individual condition. Age or other discriminating factors should not be a determinant in accessing insulin pumps under the Insulin Pump Programme. These devices have a positive impact on quality of life and flexibility for patients with type 1 diabetes.
- Access and Private Health Insurance issues including demand and replacement. Insulin pump warranties expire after four years; however, some private health insurance providers will not replace the pump until after five years. This discrepancy needs to be addressed. *The Department stated that this issue is outside the scope of the Review and would be referred to the appropriate area of the Department.*
- Consideration needs to be given to ways to improve the operation of the Insulin Pump Programme, in particular how it is funded, rather than just focussing on eligibility criteria.
- It may be traumatic for some patients to return to multiple daily injections after being on an insulin pump. All people should have the opportunity to access insulin pump therapy.