Response by Roche Diagnostics Australia Pty Limited to the Review by DoHA of insulin pumps

Prepared by:

Dr George Koumantakis
Manager, Scientific & Regulatory Affairs
Roche Diagnostics Australia Pty Limited

Introductory and Summary Remarks

Roche Diagnostics Australia Pty Limited (RDA) is pleased to provide comment to the Review by the DoHA on clinical benefits of insulin pump therapy for people with type 1 Diabetes. This document addresses each of the three Terms of References as requested starting with some remarks that attempt to capture the spirit of the overall submission

Patients have reported that insulin pump therapy offers a chance to live as normal a life as possible (Barnard et al, Practical Diabetes International. 24, 3, 143-148, *2007).* For some, this involves the freedom to take on activities previously restricted and for others the removal of something unpleasant, such as fear.

Insulin pump secretion mimics best physiological insulin secretion: Insulin delivery as facilitated by modern insulin pumps allows excellent matching of the individual's insulin needs to address their daily requirements. Insulin pumps therapy closer mimics physiologic insulin secretion than multiple daily injections (MDI) therapy, making it most suitable to meet individual insulin needs. It is the only current technology available to address Dawn Phenomenon in type 1 diabetes mellitus.

Insulin pump therapy facilitates easier therapy implementation and adherence: Our insulin pumps have features helping users to integrate intensive insulin therapy in daily life. Greater flexibility than with MDI and discreet use contribute to a higher quality of life. Insulin pump therapy therefore supports therapy adherence, a major factor for achieving good long-term glycaemic control, in a better way than MDI therapy.

Insulin pump therapy is the most effective way of insulin delivery providing important clinical benefits over MDI: Such benefits are especially so in those with poor glycaemic control on MDI. Insulin pump therapy improves glycaemic control more effectively and reduces the rate of severe hypoglycaemic episodes. Furthermore, insulin pump therapy improves aspects of quality of life. The value of insulin pump therapy in the treatment of type 1 diabetes has been pointed out in recent reviews and expert consensus statements

Insulin pump therapy allows semi-automated management of insulin therapy: Automated bolus advice and data management systems, computer-assisted basal rate programming and automatic suspension of insulin delivery are just some of the beneficial characteristics of insulin pump therapy. Our systems support users and their healthcare professionals to further optimise therapy.

Patient selection for pump therapy in Australia is at the discretion of the Endocrinologist in accordance with the wishes of the person with diabetes. The decision to wear a medical device is not taken lightly by the person with diabetes or the healthcare professional team. The majority of clinics in Australia have waiting periods, lengthy educational components and criteria around patient's motivation and abilities towards managing their diabetes. NDSS records show less than 1% registered with an Insulin Pump ceases therapy. **Local Australian evidence must be strongly preferred over international studies.** Clinical studies without strict criteria for pump selection are not reflective of the Australian healthcare setting.

A fully funded Type 1 Diabetes Insulin Pump Program must be re-established with the options for families who do not have access to alternative means of reimbursement. The Pump is medically proven to reduce HbA1c resulting in a reduction of complications. This is directly related to a high level of cost effectiveness with significant savings based on life year gained. Adjustment of the age eligibility, the indexed salary scale, combined with the full subsidy for the lowest income families, will ensure that the Program's ultimate aim is achieved. The changes will ensure that the Insulin Pump Program is truly accessible to lower income families, while providing the government with a high level of cost saving based on long term projections.

Term of Reference No 8:

Determine the clinical outcomes (e.g. HbA1C, health-related quality of life, and other potential benefits and harms) for people with type 1 diabetes) of insulin pump therapy. In this, consideration should be given to different age groups, with a particular reference to those under 18 who may be eligible for the Insulin Pump Program which is funded by the Australian Government;

Unlike many other medical interventions, Insulin Pump therapy can be prescribed to treat a variety of diabetes mellitus complications such as; failure to achieve glycemic targets, extensive glycemic variation, hyper or hypoglycemia, Dawn Phenomenon, occupational reasons such as shift work, gastroparesis, pregnancy and other lifestyle factors. This makes reporting of a singular outcome variable such as HbA1C difficult as you must isolate only those prescribed the technology for that specific reason.

There have been a number of publications and reviews published in relation to pump therapy and the above Term of Reference. It is suggested the most appropriate and relevant to this review is the "**National Evidence based Clinical Care Guidelines: for Type 1 diabetes in children, adolescents and adults".** These were developed on behalf of the Australian Government Department of Health and Ageing, by an Expert Advisory Group (EAG) representing specialist societies and organizations, with the active participation of consumer groups and community.

The Guidelines discussed a number of areas but for the purpose of this response we only report on the use of Insulin Pumps versus multiple daily injections (MDI). Specifically the Guidelines provide evidence that all studied adults and children with type 1 diabetes demonstrated a statistically significant reduction in HbA1c with the pump compared to MDI. It is worth noting clinical studies were not powered sufficiently to evaluate hypoglycaemic events however a study by Bock et al (wich included subjects with regular hypoglycaemic episodes) showed great improvement the incidence of hypoglycaemia.

The Guidelines show increased quality of life for both patients and their families and that, on average, there are advantages for the pump therapy over MDI. Studies confirm the pump group has better treatment satisfaction than the MDI group. Studies revealed that the pump was favoured over MDI due to the perception of better mental health, perception of better general health, and better quality , respectively (NHMRC Guidelines, 2011).

When considering clinical studies outside of Australia; patient selection criteria and training and support from the clinical team must reflect the Australian Healthcare setting.

Term of Reference No 9:

Investigate the cost-effective use of different insulin pumps available under the Insulin Pump Program;

As reported in: **National Evidence based Clinical Care Guidelines: for Type 1 diabetes in children, adolescents and adults** (discussed with Term of Reference 8)

An important analysis reported within these Guidelines confirmed an improvement in the long term costs and outcomes of the pump versus MDI. The results of the analysis indicated that the upfront cost of the pump therapy is more expensive than MDI, as it requires a greater utilization of equipment and training at initiation along with additional consumable supply needs throughout the treatment . However, the lifetime use of pump therapy was shown to improve cost effectiveness ratio when the long term health and quality of life improvements associated with the pump therapy were included.
The improvements in HbA1c, as a direct result of the pump, contribute to reduced incidence of diabetes-related complications and increased life expectancy. Improved glycaemic control associated with pump therapy reduced long term complication rates and costs and again these were offset by the increased cost over a lifetime of insulin pump therapy compared with MDI therapy. Comparing insulin pump therapy with MDI severe vision loss was reduced by 21% in adults and 12% in adolescents, end stage renal disease reduced by 22% in adults and 16% in adolescents, and peripheral vascular disease reduced by 24% in adults and 16% in adolescents. Myocardial infarction was reduced by 11% in adults and 4% adolescents. The study demonstrated that the pump therapy was associated with an improvement in life expectancy of 0.393 years for adults compared with MDI and 0.537 years for adolescents.

In a study performed by the JDRF (Nov 2011, Type 1 Diabetes Insulin Pump Program Review) and submitted to DoHA it is concluded:

The subgroups of studied individuals with type 1 diabetes had a calculated incremental cost effectiveness ratio, when using the pump, of $A74 147 per quality adjusted life years for adults and $A74 661 for adolescents, which is considered a good value for money in Australia.

In our opinion the data included in the above JDRF study is the most relevant and up-to-date account of pump therapy in Australia. Any other overseas-based studies suffer from differences in the reimbursement and differences in mode of health care delivery and should be interpreted with caution by the Reviewers.

Term of Reference No 10:

Consider the clinical criteria and eligibility under the Insulin Pump Program, to ensure those who would most benefit from insulin pump therapy receive support to assist in their care.

The Insulin Pump Program (managed by the JDRF) provided government-funded subsidies on a means tested basis to purchase insulin pumps for children under 18, with clinical approval from a health care professional. The Program run over nearly four years from 1 November 2008 to June 2012.

In 2011 the JDRF conducted a survey which confirmed that the size of co-payment required by the family to access a pump was still the largest barrier to uptake and in Oct 2011 the Department deemed it appropriate to seek co-payment agreements from the third parties including insulin pump manufactures (Roche Diagnostics Australia) in order to eliminate this barrier. We have been able to work with JDRF and have subsidised the co-payment requirement for the individuals in the lowest income bracket, who qualify for 80% subsidy. Due to significant economic and market access pressures faced by the medical industry in Australia it is unlikely that any such subsidies will be able to be maintained by the industry with any future insulin pump programmes.

However, it is essential that this review recognises the significant contribution such a programme has made to its members as managed by the JDRF:

Quality of Life- Patient feedback (JDRF Report Nov 2011):

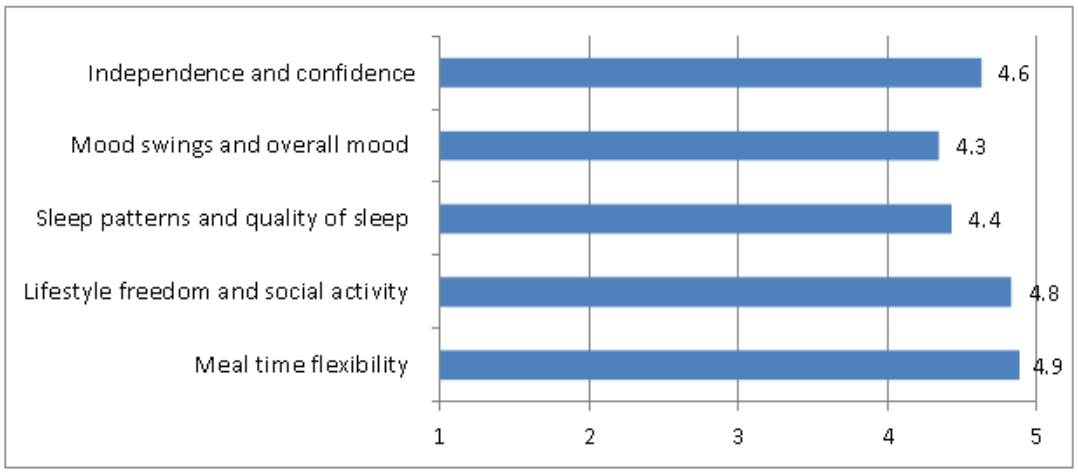

Figure 10. – Average responses recorded in survey for changes in quality of life since pump usage (1=much worse, 2=slightly worse, 3=no change, 4=some improvement, 5=large improvement)

HbA1c- Clinical Feedback data (JDRF Report Nov 2011):

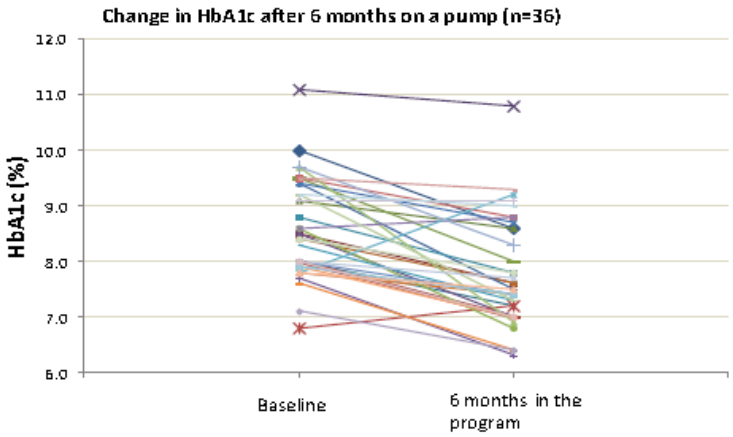

Figure 11. – Show Base HbA1c levels taken as part of the Program application process and compares to HbA1c levels taken in clinic aprox 6 months after pump initiation.

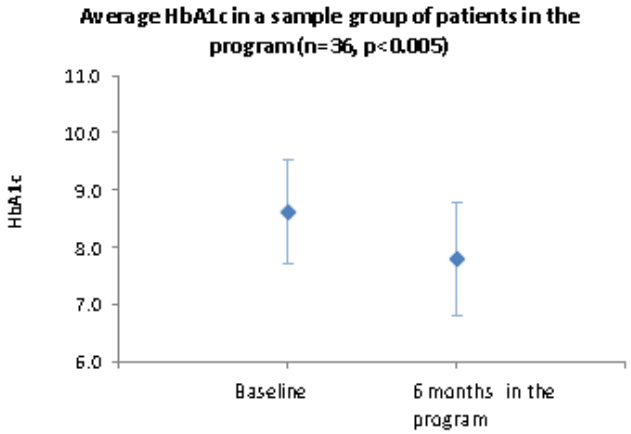

Figure 12. –Shows the average drop in HbA1c levels as reported in the JDRF clinical survey

In the sample studied, the average HbA1c level at Program commencement was 8.6% ± 0.9 (mean ± SD) and the average HbA1c level taken at approximately 6 months post pump initiation was 7.8% ± 1.0 (mean ± SD) which show a significant reduction of 0.9% in HbA1c (n=36, p<0.005) (Figure above). The reduction observed in this sample of children from low income families is greater than reported in the literature (Guidelines, 2011) which showed an average reduction of 0.25% in general population of children.

Further recommendations for an Insulin Pump Program in Australia.

Our recommendations below are based on valuable experiences gained through working with the patients, health care professionals and the JDRF.

- Make insulin pump therapy available and accessible to people with type 1 diabetes who are under 22 years of age. The increase in eligibility is based on the significant unmet clinical need of transitioning patients from children to adolescence in terms of insulin therapy

- Renew and expand this program under the management of JDRF. This organization has proven its capability of managing such a critical programme in Australia and is uniquely positioned as a patient group and medical research foundation specifically focused on type 1 diabetes.

- Government must ensure that pumps are fully subsidized for the lowest income family bracket by agreeing to increase the maximum subsidy rate from 80% of total pump cost to 100% of total pump cost

- Pump "consumables costs" should only be drawn from the NDSS budget, and should not reduce the necessary funding needed to supply pumps to lower income families. Forward estimates budget for the type 1 Diabetes Insulin Pump Program should fund insulin pumps alone and therefore better match the needs of the community..

- Increase the lowest indexed income salary level used for Program eligibility assessment to better reflect today's average rates

- Fund the introduction of a more systematic and comprehensive data collection process to ensure that profiling of patients is carried out more effectively and efficiently.