POST MARKET REVIEW OF PRODUCTS USED IN THE MANAGEMENT OF DIABETES

Stage 2 - Insulin Pumps: the clinical benefits of insulin pump therapy for type 1 diabetes across age groups.

Australian Diabetes Council

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Acronyms and Abbreviations

ADEA	Australian Diabetes Educators Associations
AIHW	Australian Institute of Health and Welfare
CGM	Continuous glucose monitoring system
CSII	Continuous Subcutaneous Insulin Infusion
DSM	Diabetes self-management
DSME	Diabetes self-management education
HbA_1c	Glycosolated haemoglobin on glycated haemoglobin
IDF	International Diabetes federation
IP	Insulin pump
IPC	Insulin pump consumables
IPP	Insulin Pump Program
IPT	Insulin Pump Therapy
ISPAD	International Society for Pediatric and Adolescent Diabetes
MDI	Multiple Daily Injections
NDSS	National Diabetes Services Scheme
NHMRC	National Medical Research Council
QoL	Quality of life
SMBG	Self-monitoring blood glucose
Type 1	Type 1 diabetes
Youth	Adolescents and young people up and including 18 years of age

Executive Summary

Australian Diabetes Council is Australia's first, oldest and largest diabetes consumer organisation and welcomes the opportunity to participate in the review of use of insulin pumps in Australia. We support the Government's efforts to ensure that clinical evidence underpins all aspects of diabetes management and care.

Australian Diabetes Council promotes evidence based, effective and sustainable health care delivery. As the peak Australian consumer body for people with and at risk of diabetes, Australian Diabetes Council advocates on behalf of our members as well as the wider community with and at risk of diabetes, and their families to ensure their voices are heard and their views well represented.

Australian Diabetes Council recommends that the Expert Advisory Group considers:

- Recognises the potential for insulin pump therapy contributing to the reduction of people with type 1 diabetes and their carers, and its potential for assisting in reducing long-term indirect and direct health care expenditure associated with type 1 diabetes.
- Adopts a holistic approach to the evaluation of outcomes from use of insulin pump therapy that not only focuses on the glycaemic control and prevention of chronic diabetes complications, but also includes the impact on quality of life and wellbeing of insulin pump users and their together with consideration of their lived experiences.
- Examines strategies to support research into the quality of life and other psycho-social benefits of insulin pump therapy, whilst awaiting the opportunity to assess the long-term clinical outcomes such as prevention of chronic diabetes complications from using the recently technologically advanced insulin pumps.
- Implements support systems to ensure equitable access to insulin pump therapy for all Australian with type 1 regardless of where they live or their socio-economic status.
- Explores strategies to ensure Australians with type 1 diabetes have comparable and affordable access to advances in insulin pump and glucose monitoring technology.
- Reviews and seeks to ensure all Australians with type 1 diabetes have equitable access to affordable best-practice recommendations of diabetes-self management education and support from a multidisciplinary specialist diabetes team for initiation and follow-up of insulin pump therapy use in both the private and public health system.

- Considers implementing a system for government subsidy for the purchase of insulin pumps for adults with type 1 that is comparable to the Insulin Pump Program for children and youth under the age of 18 years.
- Amends the eligibility criteria of the current Insulin Pump Program to allow additional support for families with multiple insulin pump users and increases the current full subsidy from 80% to 100% of the insulin pump's purchase price.
- Recognises the rights of the individual with type 1 diabetes and their carers to make decisions about the treatment options that best suit their circumstances in consultation with their treating doctor and multidisciplinary specialist diabetes team.

Introduction

Australian Diabetes Council

Formed in 1938 ADC is Australia's oldest and largest not-for-profit organisation focused on providing support and services nationally and internationally to people living with and at risk of diabetes, their families, carers, friends and allied health professionals.

As the peak consumer body for diabetes and the first diabetes organisation in Australia, as well as being the third oldest diabetes association in the world, we have a long history of successfully working with our members to create a powerful shared voice for diabetes, now and in the future. We also play a vital role in informing the whole community about diabetes and its complications.

ADC makes a positive difference to the everyday lives of those living with and at risk of diabetes and their carers. We do this by ensuring decisions in areas of policy, research, delivery of services and programs are made in the best interest of those living with and at risk of diabetes.

ADC raises funds and awareness to promote diabetes prevention and management, education and research through community events, corporate and individual membership, fundraising events and activities. We also co-ordinate, run and manage community and health-professional education programs, lifestyle programs, fundraising activities and events, corporate and individual membership as well as sponsorship.

Membership with Australian Diabetes Council provides members and the community with the strength of a shared voice. We consult with and act on behalf of our members to ensure that decisions on policy, research, and program and service delivery make a positive difference to the everyday lives of people living with or at risk of diabetes.

About Type 1 Diabetes

Prevalence and incidence

According to the National Diabetes Services Scheme (NDSS), 1,057,731 Australians were registered as having been diagnosed with diabetes by 31 October 2012, and 11.3% of all registrants have type 1 diabetes (type 1)[1]. The incidence of type 1 diabetes (type 1) in children aged 0-14 has been predicted to increase by 10% from 2008 to 2013[2]. The increasing prevalence of the type 1 is attributable to improved treatment and management leading to better end-point outcomes and longer life expectancy.

Although the peak incidence of type 1 occurs in childhood and puberty with half of all people diagnosed before the age of 18 years, it can occur at any age. Type 1 imposes a significant burden on the individual child and their families, but has a similar crushing impact on youth, older adults, families, carers and workplaces.

Whilst most people develop type 1 early in life, the prevalence increases with advancing age because of the chronic nature of the disease. Of the 119,325 of people registered with the NDSS as having type 1, 13,030 are 20 years and younger[3]. However, 59,826 people with type 1 are aged 20 to 59 years and, and importantly 46,371 people with type 1 are aged over 60 years[6].

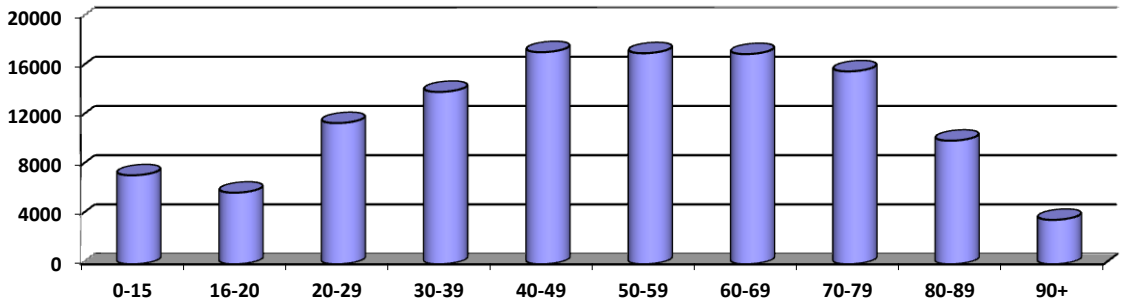

Figure 1; Age Distribution of People with Type 1 Diabetes[5]

[1] National Diabetes Services Scheme (NDSS) 2012, *NDSS Database*. NDSS, October 31 2012, Canberra.
[2] AIHW 2011, *Prevalence of Type 1 diabetes in Australian children*, Diabetes series no.15, Cat. no, CVD 54. Canberra.
[3] National Diabetes Services Scheme (NDSS) 2012, *NDSS Database*. NDSS, October 31 2012, Canberra.

Disease process, treatment and impact

Type 1 is an auto immune mediated illness leading to the destruction of the insulin producing beta cells in the pancreas. It is a serious chronic disease that cannot be prevented or cured, triggered by unknown environmental factors. Type 1 is marked by an almost complete inability to produce the hormone insulin resulting in a life-long need for insulin replacement for survival.

Type 1 is associated with high health care costs for the individual as well as high Australian health care expenditure. The disease causes significant morbidity and is associated with reduced quality of life (QoL) and life expectancy. Long-term, or chronic, diabetes complications include macrovascular disease such as coronary heart disease, stroke and peripheral vascular disease. Chronic diabetes complications also include microvascular disease such as renal disease, retinopathy and neuropathy which in Australia are the most common causes of dialysis, blindness in people aged less than 60 years of and non-traumatic amputation respectively[4]. The burden and costs of the disease increases with the presence of chronic diabetes complications[7]. Short-term, or acute, diabetes complications arise from excessive insulin or insufficient insulin dosage resulting in hypoglycaemia and diabetic ketoacidosis (DKA) respectively, which have the potential to cause serious injuries, illness and even death.

The daily attention to self-care, or diabetes self-management (DSM), cautious adherence to treatment regimens and risks of acute and chronic diabetes complications impose a significant burden on the individual person with type 1 and their family and carers. Either having type 1 diabetes or caring for someone with type 1 is associated with poor mental health and wellbeing[5].

Type 1 is treated with insulin in the form of either subcutaneous injections or infusion. The approach to treatment has changed greatly in the last two (2) decades. A highly individualised approach to intensive insulin treatment improves outcomes by reducing or delaying chronic diabetes complications[6,7,8] To achieve this, a careful balance of food, meal times and exercise together with monitoring of stringent glycaemic control is needed.

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[4] Colagiuri S, Brnabic A, Gomez M, Fitzgerald B, Buckley A, Colagiuri R 2009, *DiabCo$t Australia Type 1: Assessing the burden of Type 1 Diabetes in Australia*, Diabetes Australia, Canberra.
[5] AIHW 2011, *Diabetes and poor mental health and wellbeing: an exploratory analysis*, Diabetes series no. 16,Cat. no. CVD 55, Canberra.
[6] The Diabetes Control and Complications Trial Research Group (DCCT) 1993, The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus, *New England Journal of Medicine,* vol. 329, no 14, pp. 977-86.
[7] DCCT/Epidemiology of Diabetes Interventions and Complications (EDIC) Research Group 2000, Retinopathy and nephropathy in patients with type 1 diabetes four years after a trial of intensive therapy, *New England Journal of Medicine*, vol. 342, no 6, pp. 81-9.
[8]DCCT/EDIC Research Group, 2005, Intensive diabetes treatment and cardiovascular disease in patients with type 1 diabetes, *New England Journal of* Medicine, vol. 353, no.25, pp.2643-53.

Intensive treatment is often administered as multiple daily injections (MDI) of insulin where between four (4) or more subcutaneous injections are needed every day. However, advances in technology now make it possible to use subcutaneous insulin infusions (CSIIs), or insulin pump therapy (IPT), where insulin is delivered via an insulin pump (IP). An IP is a small programmable computerised device attached via an infusion tube to a subcutaneous cannula that only has to be replaced through one (1) injection every three (3) days. The IP is programmed to deliver insulin that closely mimics a normal physiological insulin response. Using IPT has been associated with both improved glycaemic control and less episodes of hypoglycaemia, but more importantly with improved QoL and satisfaction with treatment for people with type 1[9].

Insulin pump users in Australia

There are many factors that have contributed to the increasing number of pump users. The improvement of technology has reduced the risk of adverse events from IP malfunction. Improving technology has also made IPs easier to program and use. Guidelines for the content and delivery of diabetes self-management education (DSME) for insulin pump initiation and follow up may have also contributed to reduced adverse events through increased user knowledge.

Increased affordability has contributed to the increasing number of pump users. Private health insurance reimbursement, the Government's Insulin Pump Program (IPP) and subsidised insulin pump consumables (IPC) through the NDSS have all made IPT more affordable and contributed to its increased use over the past 10 years.

The Australian Institute for Health and Welfare (AIHW) reports that 10,510 (10%) people with type 1 used IPT at the end of June 2010 and that the number of new IPT users increased from 107 per month in 2003 to 140 per month in 2010[10]. Insulin pump therapy was also more common among people living in high socio-economic status areas (14%) than among those living in lower socio-economic areas (6%)[10].

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[9] Misso ML, Egberts KJ, Page M, O'Connor D, Shaw J 2010, Continuous subcutaneous insulin infusion (CSII) versus multiple insulin injections for type 1 diabetes mellitus. *Cochrane Database of Systematic Reviews*, issue 1, art. no. CD005103.

[10] AIHW 2012, *Insulin pump use in Australia*, Diabetes series no.18, cat. no. CVD 58, Canberra.

In preparation for this submission, Australian Diabetes Council surveyed its type 1 members during the first week in February 2013 to gain an understanding of their perspective and experience with IPT, and to ensure their views informed this submission. 5,000 members with type 1 were surveyed. The survey closed after six (6) days. The response rate for parents of children type 1 was 21%. Similarly, the response rate of adults with type 1 was 17%[11].

The AIHW reported that almost half of all IP users were aged under than 25 years old and that 18% started using the pump therapy within two (2) years of being diagnosed with type 1[12]. According to communications from the National Operations Manager of the NDSS as of 1 May 2012, 2,014 (36%) of the 5,633 IP users under the age of 25 live in New South Wales[13]. Interestingly, of the 12,023 NDSS registered IP user nationally at this time, 6,390 (53%) were aged over 25 years[14]. Information from the NDSS confirms that the number of IPT users is continuing to increase. Currently, New South Wales has 4,400 NDSS registered IP users with 520 new IP users in 2010, 649 in 2011 and 705 in 2012 with the trend of adult users continuing to increase[14].

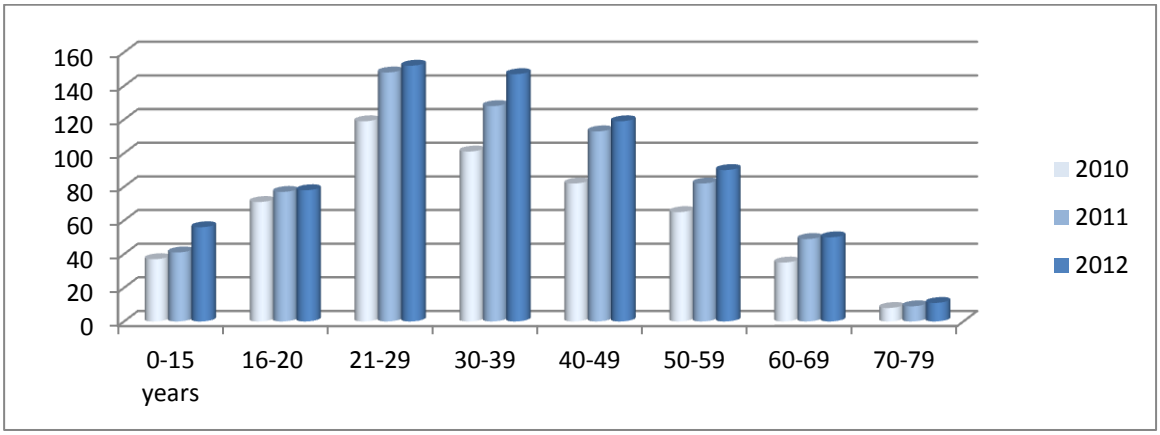

Figure 2; Age Distribution of NSW NDSS Registrants Starting Insulin Pump Therapy 2010 to 2012

[11] Australian Diabetes Council 2013, *Type 1 Diabetes Member Insulin Pump Survey*, February 2013, Sydney
[12] AIHW 2012, *Insulin pump use in Australia*, Diabetes series no.18, cat. no. CVD 58, Canberra.
[13] NDSS 2012, *NDSS Database*. NDSS, May 1 2012, Canberra.
[14] NDSS 2013, *NDSS Database*. NDSS, 12 February 2013, Canberra.

Results from Australian Diabetes Council survey found that the majority (69.9%) of IP users had been diagnosed with type 1 for 10 years and more, and 30.4% for more than 25 years, before starting to use IPT[11].

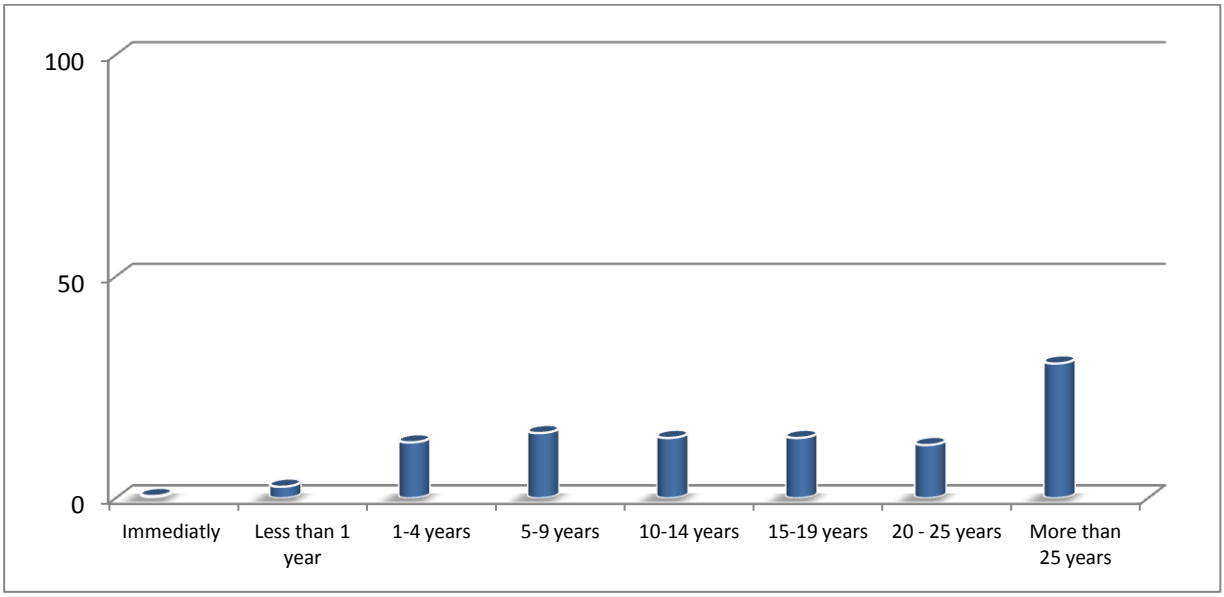

Figure 3; Years with Type 1 Diabetes at Insulin Pump Initiation

Clinical Outcomes of Insulin Pump Therapy

Australian Diabetes Council promotes timely access to evidence based best-practice diabetes management and care for all Australians living with diabetes. The evidence suggest that IPT may improve outcomes for people with type 1 through providing better glycaemic control than using MDII[15]. However, IPT offers many other benefits for people with type 1 of all ages and for their carers and families, and their life experiences and treatment preferences should also be at the centre of both individual treatment and health policy decision.

Glycaemic control and chronic diabetes complications

Although genetics and other factors may influence the risk, there is a strong relationship between glycaemic control as measured by glycosolated haemoglobin (HbA1c) and the development of chronic diabetes complications in type 1. Evidence from extensive research confirms that prolonged, or chronic, hyperglycaemia from less than optimal glycaemic control is associated with the development of the chronic complications in type 1[16, 17]. The duration of the disease is also associated with an increased risk of developing chronic complications warranting intensive treatment and optimal glucose control from early diagnosis[18]. Importantly, intensive treatment and optimal glucose control as measured by HbA1c in older adults, with longer duration of diabetes have also been shown to reduce the progression of existing chronic complications such as retinopathy in type 1[19].

Supporting the evidence that use of IPT offers better control than MDI[20], consideration for use of IPT has become best-practice recommendations in the management of type 1. Australian *National evidence-based clinical care guidelines for type 1 diabetes in children, adolescents and adults* (National Guidelines) recommend that IPT should be considered as

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[15] Misso ML, Egberts KJ, Page M, O'Connor D, Shaw J 2010, Continuous subcutaneous insulin infusion (CSII) versus multiple insulin injections for type 1 diabetes mellitus. *Cochrane Database of Systematic Reviews*, issue 1, art. no. CD005103.
[16] DCCT/Epidemiology of Diabetes Interventions and Complications (EDIC) Research Group 2000, Retinopathy and nephropathy in patients with type 1 diabetes four years after a trial of intensive therapy, *New England Journal of Medicine*, vol. 342, no 6, pp. 81-9.
[17] DCCT/EDIC Research Group, 2005, Intensive diabetes treatment and cardiovascular disease in patients with type 1 diabetes, *New England Journal of* Medicine, vol. 353, no.25, pp.2643-53.
[18] International Diabetes Federation (IDF) 2011, *Global IDF and International Society for Pediatric and Adolescent Diabetes (ISPAD) Guideline for Diabetes in Childhood and Adolescence*, Brussels, Belgium, pp 1 -132.
[19] DCCT/Epidemiology of Diabetes Interventions and Complications (EDIC) Research Group 2000, Retinopathy and nephropathy in patients with type 1 diabetes four years after a trial of intensive therapy, *New England Journal of Medicine*, vol. 342, no 6, pp. 81-9.
[20] Misso ML, Egberts KJ, Page M, O'Connor D, Shaw J 2010, Continuous subcutaneous insulin infusion (CSII) versus multiple insulin injections for type 1 diabetes mellitus. *Cochrane Database of Systematic Reviews*, issue 1, art. no. CD005103.

part of intensive management in youth and children, including infants[21]. The International Diabetes Federation (IDF) and International Society for Pediatric and Adolescent Diabetes (ISPAD) *Global Guidelines Diabetes in Childhood and Adolescence* (Global Guidelines) recommend that IPT should be considered in the management of children and youth with type 1[22]. Moreover, the National Guidelines recommends use of IPT for adults attempting to improve their glycaemic control, leading up to and during pregnancy and for those who already have microvascular diabetes complications[20].

When parents were asked to list the benefits of insulin pump therapy, 77.5% responded that it had improved their child's glycaemic control and 48.5% cited the possibility of preventing the development of chronic diabetes complications.

When adults were asked to list the benefits of insulin pump therapy, 83% responded that their glycaemic control had improved and 58% cited the possibility of preventing the development of chronic diabetes complications.

(Australian Diabetes Council Insulin Pump Survey February 2013)

Diabetes self-management

Diabetes self-management in type 1 is complex and time consuming.

Type 1 is a 'do-it-yourself' disease where the majority of DSM decisions are made by the person with the disease or their carer. People with type 1 or their carer need confident applications of acquired diabetes-specific knowledge and skills, daily attention to balancing food intake, insulin and physical activity and ongoing SMBG to prevent hyperglycaemia and hypoglycaemia.

The introduction of short- and long-acting insulin analogues with more predictable onset, peak and duration (profile) did make it somewhat easier to manage type 1 with MDI, but the risks of developing acute diabetes complications, particularly hypoglycaemia, are still a major concern. This is compounded by the attempt to achieve optimal glycaemic control increasing the risk of hypoglycaemia particularly with an intensive insulin treatment administered through a regimen with endogenous insulin which has a different profile to the body's own (exogenous) insulin.

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[21] Craig ME, Twigg SM, Donaghue KC, Cheung NW, Cameron FJ, Conn J, Jenkins AJ, Silink M, for the Australian Type 1 Diabetes Guidelines Expert Advisory Group 2011. *National evidence-based clinical care guidelines for type 1 diabetes in children, adolescents and adults*, Australian Government Department of Health and Ageing, Canberra.

[22] IDF 2011, *Global IDF and ISPAD Guideline for Diabetes in Childhood and Adolescence*, Brussels, Belgium, pp 1 -132.

Insulin pump therapy offer users an insulin administration method that can more closely mimic normal background (basal) as well as post-meal (bolus) insulin release. The IP can be programmed to deliver basal insulin adjusted to the varying insulin requirements during the different times of the night and day, and from day-to-day. Similarly, bolus dosages can be calculated according to the type of food as well as to the expected varying absorption rate of that food. Newer IPs have inbuilt technology to assist with calculation of insulin according to current blood glucose levels and planned activity. In addition, advancing technology has seen wireless transmission of SMBG results to the IP reducing the complexity of assisted bolus dosage calculations, and this makes IPT an even more attractive treatment option for people with type 1 and their carers. Moreover, the predictable profile and very short duration of the type of insulins used in IPs allows for safe and effective dosage for correction of elevated blood glucose levels.

Although access to specifically targeted DSME programs is important for safe and effective initiation and ongoing use[23], IPT have offered people with type 1 a treatment method that more closely resembles the normal physiological insulin release patterns. People with type 1 and their carers commonly experience that managing the disease is easier when using IPT.

82% of parents found it easier to manage their child's diabetes when using insulin pump therapy.

79% of adults also found it easier to manage their diabetes when using insulin pump therapy.

(Australian Diabetes Council Insulin Pump Survey February 2013)

Day-to-day blood glucose management

Glycosolated haemoglobin measurements are important for the monitoring of ongoing long-term glycaemic control. However, it does not provide any information about the everyday blood glucose excursions, for example overnight hypoglycaemia, post-prandial, or after meal, hyperglycaemia. Self-monitoring blood glucose is the optimal method to ascertain the daily variation of blood glucose levels, establishing the cause and effect relationships of management strategies and mapping common patterns. Best-practice recommendations identify SMBG frequency and timing, interpretation and application of SMBG results as core components of the DSME program for initiation of IPT[24].

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[23] Australian Diabetes Educators Association (ADEA) 2007, *The effectiveness and appropriateness of educational components and strategies associated with insulin pump therapy (IPT): a comprehensive systematic review*, Canberra.

[24] ADEA 2007, *The effectiveness and appropriateness of educational components and strategies associated with insulin pump therapy (IPT): a comprehensive systematic review*, Canberra.

Self-monitoring blood glucose assists the person to achieve more stable blood glucose levels within the desired target range without the fluctuations between hyperglycaemia and hypoglycaemia commonly experienced when attempting to achieve optimal glycaemic control. Interestingly, of people under 30 with type 1, IPT users have a higher purchase rate of blood glucose test strip from the NDSS than non-user. IP users are the only people with type 1 who buy enough blood glucose test strip to SMBG at recommended levels[25].

Acute diabetes complications

Preventing and managing acute diabetes complications such as mild hypoglycaemia and hyperglycaemia or more s acute complications such as severe hypoglycaemic episodes with fitting and/or unconsciousness and diabetic ketoacidosis (DKA) remains a constant and serious concern for people with type 1 and their carers.

Hypoglycaemia

Hypoglycaemia is a serious side-effect of insulin therapy. Whilst inconvenient, interruptive, uncomfortable and a source of anxiety and concern, mild hypoglycaemic episodes are usually effectively recognised and treated by youth and adults with type 1. However, severe hypoglycaemia is associated with increased risk of injuries, morbidity and in extreme cases even death. There is limited evidence that IPT users have less frequent episodes of mild hypoglycaemia than those using MDI, but there is conclusive evidence that IPT users have fewer episodes of severe hypoglycaemia.[26]. This is significant for parents and carers of children. It is also significant for the frail and elderly, people living alone and those who have developed hypoglycaemic unawareness, the ability to recognise signs and symptoms of hypoglycaemia, as a complication of diabetes. This is a source of great anxiety for people with type 1 and their carers and often results in the need for constant observation, care and monitoring as well frequent SMBG throughout the day and overnight.

Acute hyperglycaemia and diabetic ketoacidosis

Insulin pump therapy has been associated with an increased risk of acute hyperglycaemia and DKA caused by interruption of insulin delivery from malfunctioning IP, accidental dislodging of the cannula or kinking of the delivery tube. Whilst the risk has not been eliminated, efforts in the last two (2) decades to improve IP technology and insulin pump consumables (IPCs) together with targeting prevention as part of DSME for IPT has

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[25] AIHW 2012, *Diabetes among young Australians*, Diabetes Series no. 18, cat. no. CVD 59, Canberra.
[26] Misso ML, Egberts KJ, Page M, O'Connor D, Shaw J 2010, Continuous subcutaneous insulin infusion (CSII) versus multiple insulin injections for type 1 diabetes mellitus. *Cochrane Database of Systematic Reviews*, issue 1, art. no. CD005103.

reduced the risk of DKA. Emerging evidence now suggests significantly reduced rates of DKA in IPT use compared to MDI, particularly in children[27, 28].

> *'…..The pump literally saved my life. After several severe hypo incidents where the final one nearly killed me, I went onto pump therapy. I have not been admitted to hospital for a hypo or hyper in the 9 years I have been on the pump….'*
>
> *(Quote from Australian Diabetes Council Insulin Pump Survey Respondent February 2013)*

Sick-day management

There is limited evidence that managing sick days in IPT increases the ability to prevent development of DKA. However, IPT provides the means to improve the prevention of DKA. Allowing the opportunity to adjust IPs insulin delivery to a temporary basal rate for hyperglycaemia caused by any acute illness e.g. infection, and to administer correction bolus dosages with confidence and minimal fear of overdosing as the insulin used is very-short acting.

Pregnancy in diabetes

Any pregnancy in pre-existing diabetes is a high-risk pregnancy[29]. Elevated maternal blood glucose levels have detrimental consequences for the developing foetus. Maternal hyperglycaemia is also associated with a significant risk of miscarriage, severe congenital birth defects, premature labour, still birth and birth of large or small babies. For the woman planning or being pregnant, poor glycaemic control is associated with infertility, preeclampsia, premature labour, and a high risk of experiencing birth trauma through instrumental or surgical delivery. Poor glycaemic control in pregnancy also increases the risk and/or accelerates the damage of pre-existing diabetic retinopathy and nephropathy.

However, risks to the foetus and the mother can be significantly reduced through maintaining blood glucose levels closer to that of people without diabetes. [30].Managing blood glucose levels in pregnancy is often extremely difficult due to morning sickness in early pregnancy, significantly increasing insulin requirements from late in the second

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[27] Jakisch BI et al for the German/Austrian DPV Initiative and Working Group for Paediatric Pump Therapy 2008, Comparison of continuous subcutaneous insulin infusion (CSII) and multiple daily injections (MDI) in paediatric Type 1 diabetes: a multicentre matched-pair cohort analysis over 3 years, *Diabetic Medicine*, vol. 25, no. 1.
[28] American Association of Clinical Endocrinologists (ACCE) Consensus Panel on Insulin Pump Management 2010, AACE Consensus Statement on Insulin Pump Therapy, *Endocrinology Practice*, vol. 16, no 15.
[29] Australian Diabetes in Pregnancy Society (ADIPS) 2005, *Position statement; Consensus Guidelines for the Management of Patients with Type 1 and Type 2 Diabetes in Relation to Pregnancy*.

semester. This makes blood glucose levels difficult to manage and increasing the risks of severe hypoglycaemia, hyperglycaemia and DKA. Use of IPT from preconception and throughout pregnancy is best-practice recommendations for the management of women with type 1 during this stage.[31].

> *'…..The pump has definitely changed my life for the better. I now have two beautiful healthy babies and manage my weight well for the first time in my life…..'*
>
> *(Quote from Australian Diabetes Council Insulin Pump Survey Respondent February 2013)*

Wellbeing and life balance

Bettering the end-point outcome of type 1 thorough improved glycaemic control is important. The positive effect from using IPT on people with the disease throughout their diabetes journey and the impact on the carers of people with type 1 of all ages is equally important.

Treatment satisfaction and engagement

Research confirms that people with type 1, and particularly youths and their parents, have higher treatment satisfaction rates using IPT [32, 33]. The person with type 1 and their carers' satisfaction with the treatment regimen may well mirror their perception of how much of an intrusion or how difficult it is to manage the disease. Achieving optimal blood glucose levels still requires active engagement with the disease and increased treatment satisfaction may increase diabetes self-determination and self-care confidence thus leading to improved DSM practices.

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[30] ADIPS 2005, Position statement; *Consensus Guidelines for the Management of Patients with Type 1 and Type 2 Diabetes in Relation to Pregnancy*.
[31] Craig ME, Twigg SM, Donaghue KC, Cheung NW, Cameron FJ, Conn J, Jenkins AJ, Silink M, for the Australian Type 1 Diabetes Guidelines Expert Advisory Group 2011. *National evidence-based clinical care guidelines for type 1 diabetes in children, adolescents and adults*, Australian Government Department of Health and Ageing, Canberra.
[32] Battelino T 2006, Risk and benefits of continuous subcutaneous insulin infusion (CSII) treatment in school children and adolescents, *Pediatric Diabetes*, vol. 7, suppl. 4, pp. 20-4.
[33] Low KG, Massa L, Lehman D, Olshan JS 2005, Insulin pump use in young adolescents with type 1 diabetes: a descriptive study, *Pediatric Diabetes*, 2005, vol. 6, pp. 22-31.

Mental health and quality of life

Having type 1 is associated reduced QoL and with increased levels of anxiety and depression[34, 35, 36]. The risk of developing chronic complications is a constant source of

> *'…..Insulin pumps are life changing for children with diabetes! When my son went on a pump for the first time since his diagnosis I felt like he had a normal life! Our life was no longer controlled by diabetes. …… Every child with diabetes should have access to insulin pump therapy!!!…..'*
>
> *(Quote from Australian Diabetes Council Insulin Pump Survey Respondent February 2013)*

anxiety for people with type 1 and their carers. Australian research has shown that 28% of adults with type 1 report severe diabetes related stress. Worrying about the future and the possibility of developing serious complications were the most frequently reported concerns[37]. Similarly, parents and carers also report reduced QoL and higher levels of anxiety, stress and depression[38, 39]. Research has confirmed that adults using IPT report higher QoL[40], suggesting similar findings of improved QoL among children and youth with type 1 and their carers[41].

Flexibility and a sense of well being

People using IPT and their carers often report that they feel better. This can have many reasons from already reported improved QoL to less hypoglycaemia, more stable blood

> *'…..I have xxx children on insulin pumps, as well as myself. Pumps have made my life much easier, we can now be flexible with meal times and the type of food consumed. It is now possible to sleep through the night without waking and testing someone, therefore my physical and mental health has improved.'*
>
> *(Quote from Australian Diabetes Council Insulin Pump Survey Respondent February 2013)*

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[34] AIHW 2011, *Diabetes and poor mental health and wellbeing: an exploratory analysis*, Diabetes series no. 16,Cat. no. CVD 55, Canberra.
[35] AIHW 2012, *Diabetes among young Australians*, Diabetes Series no. 18, cat. no. CVD 59, Canberra.
[36] Speight J, Browne JL, Holmes-Truscott E, Hendrieckx C, Pouwer F, on behalf of the Diabetes MILES –Australia reference group 2011, *Diabetes MILES – Australia 2011 Survey Report.* Diabetes Australia, Canberra
[37] Speight J, Browne JL, Holmes-Truscott E, Hendrieckx C, Pouwer F, on behalf of the Diabetes MILES –Australia reference group 2011, *Diabetes MILES – Australia 2011 Survey Report.* Diabetes Australia, Canberra.
[38] Colagiuri S, Brnabic A, Gomez M, Fitzgerald B, Buckley A, Colagiuri R 2009, *DiabCo$t Australia Type 1: Assessing the burden of Type 1 Diabetes in Australia*, Diabetes Australia, Canberra.
[39] AIHW 2012, *Diabetes among young Australians*, Diabetes Series no. 18, cat. no. CVD 59, Canberra.
[40] AIHW 2012, *Insulin pump use in Australia*, Diabetes series no.18, cat. no. CVD 58, Canberra
[41]Battelino T 2006, Risk and benefits of continuous subcutaneous insulin infusion (CSII) treatment in school children and adolescents, *Pediatric Diabetes*, vol. 7, suppl. 4, pp. 20-4.

glucose levels and improved glycaemic control. However, the significance of only needing one (1) injection for cannula change every three (3) days instead of four (4) to six (6), or more, injections every day must also be considered, particularly for children.

More research into IPT use is necessary as the individual user's life experience and wellbeing is the foundation to holistic and person centred approach in diabetes management[42].

Increased lifestyle flexibility is one of the most commonly cited reasons for both starting and wishing to start IPT[43]. The benefits of increased lifestyle flexibility are extensive. Insulin pump users can take a flexible approach similar to that of people who do not have diabetes as IPT allows users to match the type and amount of food they have according to their appetite. Insulin pump users can also vary the carbohydrate content of their meals according to the available meal in instead of adhering to a fixed amount to achieve blood glucose level in target range and ultimately optimal glycaemic control. Most of all, IPT users do not have to adhere to strict meals times, allowing adults more freedom in their home, social and work life and children more freedom in their school activities. The flexibility that IPT use offers also extends to increased freedom to participate in unplanned physical activity and exercise as well as increased ability to play higher level, competitive sports[44].

90% of parents and 88.5% of adults stated that using insulin pump therapy had provided them with more flexibility with food and meal times. Similarly, and 61% of parents and 58% of adults felt that it provided more flexibility for exercise and playing sports.

(Australian Diabetes Council Insulin Pump Survey February 2013)

The importance of lifestyle flexibility to the life experience of people with type 1 and their carers should not be underestimated. Benefits range from improved clinical outcomes such as reduced insulin requirements finding it easier to obtain and maintain a healthy weight[45] to a sense of freedom, spontaneity and normality for the person with type 1 as well as their carers.

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[42] ADEA 2008, Position statement; Client Centred Care, *Australian Diabetes Educator,* vol. 11, no.1, pp.26-28.
[43]AIHW 2012, Insulin pump use in Australia, Diabetes series no.18, cat. no. CVD 58, Canberra
[44] AIHW 2012, Insulin pump use in Australia, Diabetes series no.18, cat. no. CVD 58, Canberra
[45]Misso ML, Egberts KJ, Page M, O'Connor D, Shaw J 2010, Continuous subcutaneous insulin infusion (CSII) versus multiple insulin injections for type 1 diabetes mellitus. *Cochrane Database of Systematic Reviews*, issue 1, art. no. CD005103.

Parents of children with type 1 report that IPT has improved their children's engagement in school and extra-curricular activities thus having a positive impact on their social development and ability to meet educational benchmarks. Adults with type 1 and carers of people with typ1 find that IPT has made it easier to balance employment commitments and demands with family life and diabetes management, and youth find that flexibility of IPT allows them to socially engage and interact with their peer group.

> *'…..My daughter loves it so much because of lots of reasons, but the best for her is that she can sleep in for the first time in her life…'*
>
> *(Quote from Australian Diabetes Council Insulin Pump Survey Respondent February 2013)*

Cost Effective Use of Different Insulin Pumps Available under the Insulin Pump Program

In light of the current and predicted future rise of diabetes and its estimated proportion of the Australian health care expenditure, Australian Diabetes Council recognises the need to ensure the most cost- effective use of all health care resources. However, Australian Diabetes Council recommends that the number and types of IPs available under the IPP not be limited on basis on their purchase price, cost-effectiveness of different pumps, or measurable cost-effectiveness of IPT. In recognition of the inherent difficulties measuring short- and long-term cost effectiveness as well as the intangible costs and the burden experienced by people affected by type 1, Australian Diabetes Council urges a balanced approach that also takes into consideration equitable access to safe and evidenced-based treatment practices, management support systems and use of self-management equipment and products such as IP and IPC.

Glycaemic control and chronic diabetes complications

Although research has confirmed that using an IPT has improved glycaemic control, there is little evidence suggesting how best to achieve cost effective improved glycaemic control through IPT. Development of technology has advanced significantly in the last decade with improved inbuilt features for safety and to assist users' adjustment of therapy to achieve optimal glycaemic control in efforts to prevent chronic diabetes complication. However, as risk of chronic diabetes complications also increases with the duration of diabetes, cost efficiencies from reduction in the rate of chronic diabetes complications in children and youth using newer IP attributable to financial support through the IPP may not be evident for many years.

Whilst any reduction in health care expenditure associated with type 1 and the financial burden experienced by those affected may not be clear for several years to come, there is extensive evidence that use of IPT to achieve improved glycaemic control[46] may delay progression of existing chronic diabetes complications[47] which is often already evident in some younger people with type 1[48]. Insulin pump use may therefore reduce direct health-expenditure from costs associated with renal failure and blindness..

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[46] Misso ML, Egberts KJ, Page M, O'Connor D, Shaw J 2010, Continuous subcutaneous insulin infusion (CSII) versus multiple insulin injections for type 1 diabetes mellitus. *Cochrane Database of Systematic Reviews*, issue 1, art. no. CD005103.
[47] The Diabetes Control and Complications Trial Research Group (DCCT) 1993, The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus, *New England Journal of Medicine,* vol. 329, no 14, pp. 977-86.
[48] AIHW 2012, *Diabetes among young Australians*, Diabetes Series no. 18, cat. no. CVD 59, Canberra

Any restriction to achieve cost efficiency in the IPP must be considered with extreme care, and monitoring and research into long-term impact encouraged.

Acute diabetes complications

Acute diabetes complications such as mild hypoglycaemia and DKA often associated with sick-day management for minor illness e.g. an infection are frequent reasons for hospitalisation, particularly in children and youth with type 1[49]. Hospital admission for DKA has also been associated with non-adherence to treatment especially in youth 12 to 24 years of age[49]. However, as IPT have been shown to increase treatment satisfaction particularly in youth[50], it may also contribute to improved treatment adherence and therefore hospitalisations. Importantly, as using IPT has been shown to reduce the frequency of severe hypoglycaemia and DKA, the use of IPT may contribute to the direct health expenditure savings through reduce hospital admission rates in people with type 1.

40% of parents and 45% of adults reported that using IPT reduced the frequency of hypoglycaemic episodes.

41% of parents and 46% of adults stated that using IPT reduced the frequency of hyperglycaemic episodes. .

(Australian Diabetes Council Insulin Pump Survey February 2013)

Wellbeing and life balance

The intangible costs of poor wellbeing and life balance of people affected by type 1 should not be under-estimated. A balance should be sought between short-term cost efficiencies with the possibilities of achieving long-term cost efficiencies not only from a reduction of morbidity and mortality from type 1, but also from increased QoL and wellbeing of the people affected by type 1.

The benefits of IPT use for children and youth include not only increased lifestyle flexibility, but also treatment satisfaction and a feeling of wellbeing. This has the potential to increase the ability to meet educational benchmark and personal aspirations for achievement in extra-curricular activities, and to strengthen social development and engagement.

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[49] AIHW 2012, *Diabetes among young Australians*, Diabetes Series no. 18, cat. no. CVD 59, Canberra.
[50] Low KG, Massa L, Lehman D, Olshan JS 2005, Insulin pump use in young adolescents with type 1 diabetes: a descriptive study, *Pediatric Diabetes*, 2005, vol. 6, pp. 22-31.

Parents report that since starting insulin pump therapy, their children are happier (59%), feel better (50%), are coping better with diabetes (58%) and have achieved a better balance between school and home life (56%).

(Australian Diabetes Council Insulin Pump Survey February 2013)

Carers of children and youth report less anxiety and worrying about diabetes management when using IPT.

Eighty-three percent of parents found it easier to manage their child's diabetes when using an insulin pump.

(Australian Diabetes Council Insulin Pump Survey February 2013)

The increased lifestyle flexibility that IPT offers may also bring social benefits to the wider Australian community through increased social engagement and participation in community activities. The flexibility of IPT may assist carers of children as well as adults with type 1 making it easier to meet the challenges posed by achieving a balance between work commitments and the demand of diabetes; thus bringing long-term socio-economic benefits through workforce participation and increased economic productivity.

'……..Pumps have made my life much easier, we can now be flexible with meal times and the type of food consumed. It is now possible to sleep through the night without waking and testing someone, therefore my physical and mental health has improved...

…The pump is the best thing that happened to my daughter. Without it she had to be with me at all times. I wasn't able to work if more than 10 minutes away…'

(Quote from Australian Diabetes Council Insulin Pump Survey Respondent February 2013)

Equitable access

Financial barriers

Insulin pump use is more prevalent among people with a higher disposable income[51]. The government's IPP provides financial support in form of a subsidy to children and youth and the amount available is determined on a sliding scale depending on parental income. Access to 'full subsidy' is means tested and is dependent on eligibility to receive Centrelink support. However, even a 'full subsidy' will leave parents with a significant up-front cost of $800-$1800.

Although, the individual co-contribution may be minimised choosing the least expensive IP, this is not aligned with best-practice nor may it be cost-effective as the choice of IP should be based on individual's needs to maximize the benefit for IPT e.g. integrated blood glucose monitor and IP system for calculation of bolus dosage, ability to set different bolus dosage rates throughout the day to cater for school and sport activities suitable for the individual child or youth. The 'owner' contribution is cited as the most common reason why children and youth do not access the IPP for purchase of an IP.

> *84% of families received reimbursement from their private health insurers for their child's insulin pump. A total of 9.7% of respondents had an insulin pump on loan from the manufacturer or a diabetes centre. Only 6.5% of survey respondents indicated that they had received their child's insulin pump through the government Insulin Pump Program.*
>
> *33% respondents stated that their child did not use insulin pump therapy because they could not afford to buy the insulin pump.*
>
> *(Australian Diabetes Council Insulin Pump Survey February 2013)*

Access across the life-span

Adults with the financial means to purchase the appropriate private health insurance cover can currently access an IP fully reimbursed by their insurer. As there is no comparable scheme to the Government's IPP for adults, people with type 1 who are not in a financial position to purchase health insurance have no access to financial support, and neither are they likely to be able to afford $4000-9000 cost of an IP. Consequently, the most disadvantaged adults with type 1 may not be able to benefit from IPT, for example women who are pregnant or planning pregnancy, people who are unable to participate in the work-force because of existing chronic diabetes complications and who would benefit for IPT to slow the progression of those chronic diabetes complications. Extension of the IPP

[51] AIHW 2012, *Insulin pump use in Australia*, Diabetes series no.18, cat. no. CVD 58, Canberra.

to people with type1 aged over 18 years should be explored to support socio-economically disadvantaged adults accessing IPT.

91% of all adults with type 1 received reimbursement from their private health insurers. Only 4.2%. funded the purchase of the insulin pump themselves

(Australian Diabetes Council Insulin Pump Survey February 2013)

Access to improved technologies

'…..I cannot afford to buy a pump, even though my brittle diabetes and gastro-paresis sees me have daily hypoglycaemia and other problems. I would benefit so much with a pump....'

(Quote from Australian Diabetes Council Insulin Pump Survey Respondent February 2013)

Cost effectiveness of IP cannot be determined by purchase price alone. Efforts should be made to provide Australians with type 1 equitable access to new and improved IP technology.

Whilst all have inbuilt safety mechanisms and alarms, the different IP have various features e.g. remote bolus activation, bolus calculations, wireless integration with blood glucose monitors. Diabetes treatment options are intensified and determined by the individual's life-style and other needs. Similarly, the choice of IP should be determined by the individual's needs.

Ongoing and rapid advances in technology are resulting in IP improvement and restricting the access to IPs on the ground of cost may deny vulnerable people with type 1 access technology than can improve QoL and also be life-saving. Some systems now so advanced that IP can be used in conjunction with continuous glucose monitoring (CGM) systems which have the ability set alarms for blood glucose levels above target providing the opportunity to fine tune glycaemic control with real time insulin adjustments. This technology offer particular benefits to infants and others children who may not be able to recognise or treat hypoglycaemia.

'…..The continuous blood glucose sensor has made the biggest difference to managing my daughters' diabetes whilst on the pump, although in Australia it is very expensive to buy the sensor and consumables. It could save a diabetics life. Their life is hard enough with the daily grind of managing type 1, in a first world country like Australia we should be using the latest technology & it should be accessible to all diabetics...'

(Quote from Australian Diabetes Council Insulin Pump Survey Respondent February 2013)

Many children hesitate having to carry the pager size IP every day.

> *Almost one third (28%) of all adults and 21% of children found it difficult to carry the pump all the time. Having to carry the pump all the time was listed as one of the reasons for not considering insulin pump therapy in 61% of adults and 67% of children.*
>
> *(Australian Diabetes Council Insulin Pump Survey February 2013)*

'Patch pumps' are the most recent and most technological advanced pumps. These pumps are small and discrete, the size of a large band-aid and water proof. However, 'patch pumps' such as the Omnipod are not available through the IPP. Unfortunately, neither can it be accessed through private health insurance because IPs are classified as prosthetic devices, and the 'patch pump' is a disposable 'patch'.

> *'…..would like the Omnipod to be approved in Australia. The tubes on the current pumps available here are the reasons we have not yet considered a pump...'*
>
> *(Quote from Australian Diabetes Council Insulin Pump Survey Respondent February 2013)*

Access to diabetes self-management education and support

Diabetes self-management education is essential for people with type 1 and their carers to learn how to apply diabetes specific knowledge and skills with confidence during the day-to-day management of the disease. Diabetes-self management education and training has been found to be essential for successful initiation of IPT[52]. The most effective method for DSME in IPT has been found to be delivered by multidisciplinary teams comprised of doctors, nurses, dietitians, and diabetes specialist educators with experience and expertise in IPT[52]. Moreover, access to regular follow-up for review is also part of best-practice recommendations[52] and lack of follow-up has been identified as a barrier to IPT uptake[53].

Confident application of the new skills and knowledge needed for ongoing safe and optimal use of IPT. Medicare reimburses people for five (5) annual individual consultations of a minimum of 20 minutes with allied health professional for type 1 and other chronic diseases. However, as DSME for IPT requires consultation with both a dietitian and

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[52] ADEA 2007, *The effectiveness and appropriateness of educational components and strategies associated with insulin pump therapy (IPT): a comprehensive systematic review*, Canberra.
[53] AIHW 2012, *Insulin pump use in Australia*, Diabetes series no.18, cat. no. CVD 58, Canberra.

diabetes educator, this does not meet the assessment, education, training and follow-up needs for IPT. Moreover, private health insurance reimburses customers for purchase of an IP, but no reimbursement exists for consultations with a diabetes educator to learn how to program the pump and adjust insulin dosage according to requirements. Similarly, the IPP does not make provisions to assist access to DSME for IPT to ensure safe and cost effective use of the pump.

Access across the geographic divide

It has been well documented that people living in rural and remote Australia has less access to health services and poorer health outcomes. For children and youth with type 1 this is an especially difficult situation as accessing diabetes services for DSME in general and particularly for IPT initiation and follow-up services are both time consuming and costly in terms of travel to the nearest service providers. In view of maintaining cost effective, and safe, use of IP, some consideration should be given to making additional funding through the IPP available for children and youth who need to travel long-distances to access DSME for initiation of IPT and follow-up.

'…….We had to travel to xxx (1380 kilometres) to get pump at cost of $3500 to our family as we could not get a pump in the xxx..... We needed it as we live 50km from town and it was not possible for us to be present at school each day to give injections...'

'.....We have no support where we live at all in either a doctor, endocrinologist or educator..... We do everything ourselves and have phone access to the educator..... There is a very big gap in the number of medical personnel who have any idea about pumps. As a mum of a type 1 child I have to tell the doctors what to do.'

'.....many other people in the region that would like to try pump therapy but are reluctant as there aren't any educators in our area or doctors who deal with them.....'

(Quote from Australian Diabetes Council Insulin Pump Survey Respondent February 2013)

Clinical criteria and eligibility under the Insulin Pump Program

Australian Diabetes Council urges the Expert Advisory Group to approach the introduction of clinical criteria with extreme care. Whilst recognising the special circumstances, difficult life situations and vulnerability of children and youth with type 1, Australian Diabetes Council recommends that the review of potential eligibility criteria under the IPP explores strategies to ensuring equitable access to IPT for all Australian with type 1 across the life-span.

Clinical criteria

International and national practice recommendations provide some guidance on which type 1 population groups should be offered IPT. Global Guidelines recommends that IPT should be available as part of comprehensive best-practice diabetes care and management of children with type 1[54]. National Guidelines identify several type 1 population groups which may especially benefit from IPT. These are children and youths including infants and young children, women who are planning pregnancy, pregnant women, adults with hypoglycaemic unawareness and/or microvascular diabetes complications and people with desire or motivation to improve their glycaemic control[55]. The National Guidelines also recommends IPT should be offered to people with type 1 who exhibit specific desirable IPT treatment-related behavioural factors, for example the capacity to master certain technical skills[53]. Whilst these recommendations may provide a guide to clinical judgements about IPT use, Australian Diabetes Council urges a more holistic and client centred approach to the decision making process about the potential benefits from using IPT. The views and long-term health interests and treatment preference of people with type 1 and their families and carers and their lived experience through their own diabetes journey must be at the centre of the decision making process. Decisions about IPT should be taken by the person with type 1 and/or their carer in consultation with the treating doctor and the rest of the multidisciplinary diabetes team.

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[54] IDF 2011, *Global IDF and ISPAD Guideline for Diabetes in Childhood and Adolescence*, Brussels, Belgium, pp 1 -132.

[55] Craig ME, Twigg SM, Donaghue KC, Cheung NW, Cameron FJ, Conn J, Jenkins AJ, Silink M, for the Australian Type 1 Diabetes Guidelines Expert Advisory Group 2011. *National evidence-based clinical care guidelines for type 1 diabetes in children, adolescents and adults*, Australian Government Department of Health and Ageing, Canberra.

Eligibility criteria

In light of the current and predicted future rise of diabetes and its estimated proportion of the Australian health care expenditure, Australian Diabetes Council recognises the need to ensure the most cost-efficient, effective and safe treatment practices, management support systems and use of DSM equipment and products such as IPs and IPC. Australian Diabetes Council broadly supports the current means testing criteria for the IPP. However, in view of the socio-economic disparity evident in IPT uptake[56], extending the 'full subsidy' to 100% of the purchase price for an IP through the IPP should be considered. In the interest of equitable access to care across the life-span, providing a comparable scheme to the IPP or other means of support for adults with type 1 wishing to use IPT should also be considered.

'....Insulin pumps are an opportunity for long term diabetics like me to more easily manage their diabetes allowing the mental anguish to be reduced so we can live a more normal life. I respect all the work that is being done to find a cure or preventative measures. But for me the pump is my cure as being a long term diabetic. I feel that when the cure comes it will not be applicable to me but help those in the future, the pump is a cure for us old school diabetics who remember washing the blood off our glucose sticks, boiling needles to sterilise them etc. We need pumps....!!!!!!!!!!!!'

(Quote from Australian Diabetes Council Insulin Pump Survey Respondent February 2013)

[56] AIHW 2012, Insulin pump use in Australia, Diabetes series no.18, cat. no. CVD 58, Canberra