Utilisation, access, and recommendations regarding technologies for people living with type 1 diabetes

A consensus statement of the Australian Diabetes Society (ADS),
the Australian Diabetes Educators Society (ADEA),
the Australasian Paediatric Endocrine Group (APEG),
and the Australasian Diabetes in Pregnancy Society (ADIPS) Working Group.

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Contents

Foreword

It is the overarching opinion of the Working Group that all people living with type 1 diabetes should have equitable access to the most effective diabetes management systems, including technology where clinically appropriate, regardless of age or concessional status.

As diabetes management technologies continue to evolve, so too must management strategies and health care systems. The Working Group was therefore assembled to develop a consensus statement on diabetes management technologies that reflects a national approach to best practice across the lifespan. Members of the Working Group comprise key stakeholders including people with type 1 diabetes and representatives of multiple national bodies involved in the management of diabetes.

For the purpose of the consensus statement, diabetes management technologies refer to devices for insulin delivery, glucose monitoring, and insulin dose advice. The integration of insulin pumps and continuous glucose monitors by control algorithms to provide varying levels of automation for insulin delivery was also considered.

It is expected that the consensus statement will be read in conjunction with the Australian Living Evidence Guidelines in Diabetes for a detailed review of diabetes management technologies.[1] Diabetes Australia also has complementary position statements on insulin pump therapy (2014) and 'do it yourself' technology (2018) among people with type 1 diabetes as well as glucose self-monitoring among adults with type 1 or type 2 diabetes (2017) in Australia.[2-4] It is also acknowledged that technology forms one part of holistic care for people with type 1 diabetes, and that optimal implementation of technology requires extensive education for people with diabetes, families, and carers that goes beyond the devices themselves.

Suggested citation

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Summary

All people living with type 1 diabetes should have equitable access to the most effective diabetes management systems, including technology where clinically appropriate, regardless of age or concessional status. The consensus recommendations should be read in conjunction with the Australian Living Evidence Guidelines in Diabetes.[1]

Implementation framework

The Working Group has developed a strategic implementation framework for diabetes management technologies that comprises:

- Developing the scope of practice for health care professionals (HCPs) as well as accreditation and credentialling processes across primary care, private practice, and tertiary centres.
- Reviewing equity of access for diabetes management technologies in the context of current funding systems and advocating for change.
- Developing eligibility criteria for technologies that may be individualised by experienced HCPs across multiple glycaemic and psychosocial parameters.
- Expanding current approaches to benchmarking and appraisal of implementation strategies to ensure effective and sustainable health care.
- Reviewing systems for the approval of new technologies and adverse event reporting to ensure the most efficacious technologies are made promptly available in Australia with an increased focus on safety.
- Developing standards regarding the role of industry in education for people living with type 1 diabetes to ensure transparent and collaborative communication.
- Proposing Medicare Benefits Schedule (MBS) item numbers for the optimal implementation of technologies that generate complex and lengthy reports.

Choosing diabetes management technologies

Willingness of the person with type 1 diabetes and their engagement with technology should be key in deciding to start or continue all devices.

Consider using technologies especially if:

- The person with type 1 diabetes (or their caregivers if appropriate) have realistic expectations.
- Individualised diabetes management goals are not achieved despite intensive therapy.
- The burden of other approaches to intensive self-management is having a significant detrimental impact on quality of life.

Consider avoiding technologies if:

- The person living with type 1 diabetes considers that real or perceived disadvantages of technology outweigh benefits after discussions with HCPs.
- Safe or appropriate use of technology cannot be ensured following concerted efforts with additional education by a multidisciplinary team of experienced HCPs.

Conclusion

The members and organisations that formed the Working Group will continue to advocate for people with type 1 diabetes to have greater access to diabetes management technologies irrespective of age, concessional status, or level of health insurance. Furthermore, this consensus statement will form the basis for future collaborations between professional bodies in the Working Group to develop key elements of the proposed implementation framework.

Objectives

The consensus statement aims to:

1. Provide an overview of existing diabetes management technologies for insulin delivery, glucose monitoring, and insulin dose advice in Australia;
2. Highlight inequity of access to technology for people with type 1 diabetes;
3. Highlight barriers in the Australian health care system for;
    a) The provision of access to technology and
    b) Health professionals to provide appropriate support for people with type 1 diabetes using diabetes management technologies;
4. Outline consensus recommendations to optimise health care for people living with type 1 diabetes using diabetes management technology in Australia.

Introduction

Type 1 diabetes presents significant challenges for optimal management. Despite ongoing developments in diabetes care, people with type 1 diabetes still experience the debilitating impact of glycaemic fluctuations as well as a disproportionately high risk of vascular and pregnancy related complications.[5-10] The ongoing advancement of technologies that deliver insulin, measure glucose, and provide advice for insulin doses therefore has a major role in reducing the impact and the economic cost of diabetes for people with type 1 diabetes and the national health system.

The high acquisition cost of diabetes management technologies remains a key barrier to equitable access for people living with type 1 diabetes.[2,11,12] In addition, government funding strategies for insulin pumps, continuous glucose monitoring (CGM), or flash glucose monitoring are not available for all people with type 1 diabetes. Therefore, despite important government initiatives that improve access for some groups, diabetes management technologies appear to be underutilised overall. It was estimated in 2020 that approximately 21% of people with type 1 diabetes used insulin pumps across the lifespan nationally [correspondence]. The Australian Government's means tested Insulin Pump Program has subsidised approximately 1,500 insulin pumps for people under 18 years of age since the program's inception in 2008. However, it has been reported that 80% of pump users in Australia obtained their device via private health insurance and approximately twice as many pump users were living in areas of high compared to low socioeconomic status.[13,14] It has also been reported that smaller proportions of people with type 1 diabetes used insulin pump therapy with increasing geographic remoteness among the paediatric population, although remoteness had less impact on use among adults when adjusted for age.[13] Analysis of the Australian National Diabetes Audit (ANDA–2019) reported that 44% of young people at participating centres used insulin pumps and 62% used CGM, whereas 27% of adults used insulin pumps and 23% used CGM.[15]

In this context, the Australian Government began funding for CGM in April 2017 for people with type 1 diabetes under 21 years of age meeting eligibility criteria through the National Diabetes Services Scheme (NDSS).[16] The CGM Initiative was then extended in March 2019 to include some adults with type 1 diabetes, concessional status, and 'high clinical need', as well as women who were planning pregnancy, were pregnant, or immediately post-pregnancy (up to three months).[16] A further extension from March 2020 included funding for CGM and flash glucose monitoring, and expanded access to adults with type 1 diabetes and concessional status or those of Aboriginal or Torres Strait Islander origin without the requirement of 'high clinical need'.[17] While these funding strategies assist some groups, they do not facilitate equitable access to interstitial glucose sensors as the majority of adults do not have concessional status. Furthermore, these eligibility criteria will negatively impact youth who do not retain concessional status once they reach 21 years of age and lose access to a vital component of their self-management plan. With relevance to any future extensions for adults with type 1 diabetes, the Government's initial approach that focussed on 'high clinical need' was too restrictive, focussed only on severe hypoglycaemia, and did not consider quality of life or individualised management goals. Furthermore, access

to insulin pump therapy remains almost entirely restricted to those with Gold or Silver tiers of private health insurance with hospital cover.

In addition to ongoing advocacy for greater access to devices for people with type 1 diabetes, it is important to highlight the increasing workload that diabetes management technologies have on the health care system. Current generation insulin pump reports and CGM / flash glucose monitoring profiles for example, provide large volumes of complex data but do not currently have specific MBS item numbers to remunerate HCPs for the significant amount of additional time required to interpret them or alter management. It is unclear at this stage how increasing utilisation of complex hybrid closed loop systems or future technologies will impact workload, but this also requires planning for appropriate and safe implementation strategies. In addition, the degree of expertise required of HCPs to manage these technologies warrants further consideration of their scope of practice and credentialling as well as accreditation for service providers.

This consensus statement includes an overview of available diabetes management technologies, highlights the inequity of access and barriers to optimal utilisation of technology, and provides consensus recommendations to improve health care for people living with type 1 diabetes in Australia.

Methods

Members of the consensus statement Working Group comprised key stakeholders including people with type 1 diabetes as well as representatives of multiple national bodies involved in the management of diabetes (see Acknowledgements). A number of meetings over 2019–2021 and collaborative drafting processes led to consensus recommendations based on expert opinion and therefore have very low certainty of evidence according to the GRADE framework. It is expected that the consensus statement will complement and be read in conjunction with the Australian Living Evidence Guidelines in Diabetes[1] for continually updated evidence-based recommendations regarding the comparative efficacy of technologies.

1. Outline of diabetes management technologies

For the purpose of the consensus statement, diabetes management technologies refer to devices for insulin delivery, glucose monitoring, and insulin dose advice. There are also technologies that integrate insulin pumps and glucose monitors to provide varying levels of automation for insulin delivery. Introductory concepts regarding definitions and components of these technologies have been described in the 'National Diabetes Care Course' by the National Association of Diabetes Centres (NADC).[18]

Insulin delivery

Management of type 1 diabetes requires basal insulin delivery as well as intermittent rapid-acting insulin boluses for meals and correction of hyperglycaemia. Continuous subcutaneous insulin infusion (CSII) therapy comprises a portable, battery operated device that pumps insulin to the subcutaneous tissue via an infusion set (or tubeless system for patch pumps).[19] Available devices may vary in some features such as colour, style and size, water resistance, insulin type recommended, whether devices can be software upgraded, or the capacity to integrate with CGM systems. Modern pumps are able to be programmed to deliver basal rates that alter as often as every half to one hour by doses as small as a fraction of 1 unit of insulin.[19] Multiple pre-determined basal rates or temporary basal rates may be programmed for use in different settings such as exercise, shift-work, and illness. Insulin bolus doses are usually calculated with in-built bolus calculators based on glucose level and user input of carbohydrate content for meals, and are adjusted for any insulin remaining in the body from previous boluses.[19] Insulin bolus doses may be provided immediately, over hours, or a combination of both for a proportion of the bolus.[19] Insulin and glucose results can also be uploaded and processed by software that may be reviewed by the person with type 1 diabetes and their HCPs. Comprehensive discussions regarding CSII therapy and the different available pumps are also important since these devices require additional education, accurate carbohydrate counting, and the capacity to manage reasonably complex trouble-shooting for the device and data-uploading processes.[20,21] Individuals and carers with low vision or reduced dexterity as well as those with limited literacy or numeracy abilities should not be excluded, although they may require additional consideration to ensure safe utilisation. Potential disadvantages of CSII include continuously being attached to a device, financial cost, difficulties related to adhesive patches, risk of diabetic ketoacidosis (DKA) with interruption of insulin delivery, and most pumps not being adequately rated for use when swimming.[19-22]

STANDALONE INSULIN PUMP THERAPY: Key messages

- Willingness and engagement should be key in deciding to start or continue CSII.
- Consider CSII therapy **especially** if:
  - There are realistic expectations regarding benefits of CSII therapy.
  - Individualised diabetes management goals (especially HbA1c) are not achieved despite intensive management with other interventions.
  - Planning pregnancy and individualised diabetes management goals (especially HbA1c) are not achieved.
- **Consider** avoiding CSII therapy if:
  - The person with type 1 diabetes considers that real or perceived disadvantages of CSII outweigh benefits after discussions with HCPs.
  - Safe use of CSII cannot be ensured following concerted efforts with additional education by a multidisciplinary team of experienced HCPs.

Glucose monitoring

In addition to insulin delivery, people living with type 1 diabetes must regularly monitor glucose levels to make self-management decisions. Self-monitoring of capillary blood glucose (SMBG) requires multiple finger prick checks at discrete time-points before and after meals and activity.[11] Interstitial glucose monitoring technologies continue to evolve, with different sensors currently able to provide one to two weeks of real-time or intermittently scanned (i.e. flash glucose monitoring) continuous glucose measurements before requiring replacement.[23] In addition, while interstitial glucose levels lag slightly behind blood glucose levels, some modern interstitial glucose sensors have been approved to direct insulin doses without confirmatory finger prick checking[24] or other calibration.[23,25,26]

Current CGM systems measure interstitial glucose approximately every 5 minutes and relay this information with an indicator of the predicted glucose trend to the user in real-time as well as being recorded to generate reports for HCPs and users.[23] Modern systems also include the functionality for remote monitoring by up to five support people as well as alarms when glucose levels reach predetermined high or low thresholds.[23]Alarms when glucose levels are predicted to reach high and/or low thresholds are also available with some CGM systems.[23] Remote monitoring and alarms may be of particular utility overnight and among those with impaired awareness or reduced ability to recognise and communicate symptoms of hypoglycaemia.[27-29] Despite the benefits of alarms, frustration with frequent or intrusive alerts as well as alarm fatigue may be problematic for some people living with type 1 diabetes.[12,23]

Flash glucose monitors also provide interstitial glucose readings, although data can only currently be accessed if a 'reader' or smart-phone based application is manually placed in close proximity to the sensor. Glucose readings are stored for up to eight hours in the sensor and therefore a minimum of three, eight-hourly scans by the 'reader' or smart-phone are required per day to collect 24 hours of uninterrupted glycaemic data.[26] However, individuals with type 1 diabetes may scan glucose levels as frequently as they choose to monitor trends throughout the day. Currently available first generation flash glucose monitors do not provide alarms or real-time third-party remote monitoring and therefore may not be favoured over CGM systems for those with impaired awareness or reduced ability to recognise and communicate symptoms of hypoglycaemia.[30] However, from March 30th 2021 the FreeStyle Libre 2 Flash Glucose Monitoring System with the addition of optional real-time alarms was also approved by the Therapeutic Goods Administration (TGA) for use in Australia.[31] Recommended flash glucose monitor attachment sites are limited to the upper arm and may present challenges of reduced sensor adhesion for some people with type 1 diabetes and in some environments. The lower acquisition cost of individual flash glucose sensors may also favour this technology over CGM when used intermittently and when cost is a key

determining factor. For people without access to government subsidy, manufacturer subscriptions and other promotions may lower the annual cost of some CGM systems and are comparable but typically more expensive than 12 months of continuous flash glucose monitoring.

Current evidence suggests that the proportion of time using interstitial glucose monitoring correlates with the degree of glycaemic benefit.[11,32-34] Furthermore, the interpretation of reports from interstitial glucose monitoring requires detailed discussions between HCPs and people living with type 1 diabetes to correlate multiple potential contributing factors with observed glucose levels and subsequently tailor advice regarding insulin, diet, and other lifestyle measures. People with type 1 diabetes therefore require a high degree of engagement with the technology and their HCPs to derive optimal glycaemic outcomes.

GLUCOSE MONITORING: Key Messages

- Willingness and engagement should be key in deciding to start or continue CGM/flash glucose monitoring.
- Consider CGM/flash glucose monitoring therapy **especially** if:
  - There are realistic expectations regarding benefits of CGM/Flash glucose monitoring.
  - Individualised diabetes management goals are not achieved despite intensive management with other interventions (especially frequent hypoglycaemia).
  - There is frequent and/or severe hypoglycaemia or impaired awareness of hypoglycaemia (CGM **may** be preferred).
  - Remote monitoring of real-time glucose levels is required (CGM **may** be preferred).
  - Planning pregnancy.
- **Consider** avoiding CGM/flash glucose monitoring if:
  - The person with type 1 diabetes considers that real or perceived disadvantages of CGM/flash glucose monitoring outweigh benefits after discussions with HCPs.
  - Appropriate use of CGM/flash glucose monitoring cannot be ensured following concerted efforts with additional education by a multidisciplinary team of experienced HCPs. The definition of appropriate use of CGM/flash glucose monitoring may be individualised but reflects frequency of use, changes to insulin therapy based on the available data, upload of data for review by HCPs, and use of devices in accordance with manufacturer recommendations.

Technology for insulin dose advice

Optimal education for people with type 1 diabetes is comprehensive and needs to be tailored to the individual's age and learning level involving carers as required. Individualised education should include carbohydrate counting as well as training for insulin dose adjustment according to current glucose levels, previous insulin doses, diet, and physical activity.[35] Additional elements of education should comprise insulin to carbohydrate ratios, insulin sensitivity factors, insulin on board (related to active insulin time), as well as glycaemic index and glycaemic load of meals.[35] Various education systems have been developed for people with type 1 diabetes, and the technologies designed to assist with insulin dosing incorporate varying levels of complexity. A complete review of education and the available technologies for insulin dose advice is beyond the scope of this document. The most commonly used technologies for insulin dose advice include insulin pumps with built-in calculators, free-standing insulin dose advisors, and applications for smart-devices. Many glucose meter manufacturers produce devices with bolus calculator functions, and most of these devices may be accessed without cost by those registered with the NDSS.[36] Insulin dose advisors may serve as an important tool when moving beyond

fixed doses of insulin because of the inherent lability of blood glucose levels in people with type 1 diabetes and the complex interaction of multiple factors on glycaemia. All insulin pumps available in Australia for people with type 1 diabetes have an in-built insulin dose advisor, and their use should be encouraged in conjunction with education around carbohydrate counting and other insulin dose advisor settings. In addition, applications for smart-devices offer a portable solution within a device that does not carry the perceived stigma that may exist for some medical devices. However, not all applications have been assessed or approved by professional or regulatory bodies and therefore require more cautious consideration.[37]

INSULIN DOSE ADVISORS: Key Messages

- All people living with type 1 diabetes that titrate insulin therapy may benefit from insulin dose advisors.
- **Consider** avoiding insulin dose advisors if:
  - The person with type 1 diabetes considers that real or perceived disadvantages of insulin dose advisors outweigh benefits after discussions with HCPs.
  - Appropriate use of insulin dose advisors cannot be ensured following concerted efforts with additional education by a multidisciplinary team of experienced HCPs. The definition of appropriate use of insulin dose advisors may be individualised but reflects ability to quantify carbohydrate content, changes to insulin therapy based on the available data, upload/provision of data for review by HCPs, and the use of approved insulin dose advisors.

Integrated insulin pumps and continuous glucose monitor systems

Insulin pumps may be integrated with CGM systems that facilitate varying levels of automation for insulin delivery. The first integration of systems with automation of insulin delivery allowed basal insulin to suspend when the predetermined low glucose threshold was reached.[38,39] As CGM sensor technology improved in accuracy, basal insulin delivery could also suspend when algorithms predicted that the low glucose threshold might be reached in the near future to reduce the frequency, severity, and duration of hypoglycaemia.[38,39]

Hybrid closed loop systems have been developed more recently and are able to automatically increase or decrease basal insulin delivery based on sensor glucose levels. These systems appear to provide the best glycaemic outcomes due to the dual capabilities of increasing basal insulin delivery to mitigate hyperglycaemia and decreasing basal insulin delivery to reduce the burden of hypoglycaemia.[40-44]

Limitations of integrated insulin pumps and CGM include financial cost, sensor failures, capillary calibration checks, being attached to multiple devices, the need for manual boluses, and potential alarm fatigue.[45,46] In addition, commercially available hybrid closed loop systems are not recommended for use in pregnancy or young children, and may have difficulties in accounting for missed boluses, marked hyperglycaemia, and strenuous exercise.[45-50] For some people with type 1 diabetes, there may also be perceived loss of autonomy over glycaemic targets or other factors imposed by the various approved algorithms in hybrid closed loop systems. At the time of writing, the only available hybrid closed-loop systems in Australia were the MiniMed™ 670G or 770G (Medtronic™), although other companies are expected to release additional hybrid closed loop systems with different algorithms in the near future. Supporting their use, hybrid closed loop systems have recently been reported as relatively cost-effective compared to multiple daily injections with capillary glucose testing among adults in the Australian context.[51]

INTEGRATED CSII AND CGM SYSTEMS: Key Messages

- Willingness and engagement should be key in deciding to start or continue integrated systems.
- Consider integrated systems (usually hybrid closed-loop systems) **especially** if:
  - There are realistic expectations regarding benefits.
  - Individualised diabetes management goals are not achieved (especially HbA1c, time-in-range, or hypoglycaemia) despite intensive management with other methods.
  - The burden of other approaches to intensive self-management has a significant detrimental impact on quality of life.
- **Consider** avoiding integrated systems if:
  - The person with type 1 diabetes considers that real or perceived disadvantages of integrated systems outweigh benefits after discussions with HCPs.
  - Safe use of integrated systems cannot be ensured following concerted efforts with additional education by a multidisciplinary team of experienced HCPs.

'Do it yourself' technology and regulatory issues

The Working Group does not endorse the use of any technology unless approved by the TGA and used according to manufacturer instructions. However, clinicians should be aware of these devices/systems and be able to discuss the functionality and potential risks of using them. It is also important to understand that the development of these systems reflects significant frustration with costs of technology, perceived loss of autonomy regarding the lack of customisation options for glycaemic targets and other factors imposed by the various internationally approved algorithms, and the typically slow rate of regulatory approval for commercial systems.

- **CGM / flash glucose monitors:** There are third-party devices currently available that can be worn next to sensors for flash glucose monitoring to generate real-time glucose readings and have the capability to share data. There are also online interest groups that discuss methods to prolong the functional life of interstitial glucose sensors beyond manufacturer recommendations. The Working Group does not endorse these practices or technologies.
- **CSII / Integrated technologies:** Currently unapproved ('open source') algorithms may be accessed online that function with some insulin pumps, CGM systems, and often another home-made device to create 'do it yourself' closed loop systems. The Working Group does not endorse the use of these systems.

Future systems

The scope of the consensus statement relates to commercially available technologies in Australia. However, a brief overview of the rapidly evolving landscape of diabetes management technology is provided to highlight the importance of the implementation framework outlined in this document.

Implantable glucose sensors, sensors for additional analytes, more rapid acting insulins, longer-lasting glucose sensors and insulin delivery infusion sets as well as alternative technologies for glucose sensing continue to be investigated. The automated review of uploaded insulin and glucose data is another focus, with machine learning hoped to provide advice for manual pump settings and to inform control algorithms. Closed loop systems involving insulin and glucagon are also being studied. In addition, control algorithms for closed loop systems continue to develop with the ultimate aim of devising a fully automated system that does not require manual boluses or other input from the user.

Transplantation

Pancreas and islet cell transplantation is offered by few tertiary centres in Australia and represents an important intervention for a select group of eligible people with type 1 diabetes and co-existing end stage kidney disease (simultaneous pancreas-kidney transplantation) or severe / debilitating hypoglycaemia (islet cell transplantation). CSII with or without CGM is often used prior to progressing to transplantation, however the role of evolving technology among people with type 1 diabetes who are eligible for transplantation warrants further investigation.

2. Inequity of access to diabetes management technologies

Insulin pumps

The Australian Government's Insulin Pump Program was established in 2008, is administered by the Juvenile Diabetes Research Foundation (JDRF), and provides a means-tested subsidy for the cost of an insulin pump.[2,14] The Insulin Pump Program has limited funding and is restricted to a proportion of people with type 1 diabetes under the age of 18 years (~220 per year following the 2018-19 budget) who meet eligibility criteria comprising health care team approval, no access through private health insurance, and a family's combined annual income below a means tested threshold (currently ≤$109,610 AUD).[14] While the Insulin Pump Program has subsidised insulin pumps for approximately 1,500 young people since its inception, the majority of the paediatric population with type 1 diabetes still require parents to pay for private health insurance to cover the cost of insulin pumps. Young people up to 21 years of age may be covered by their parents' private health insurance, and sometimes up to 25 years of age if in full-time study or else with various additional loading.[52] The NDSS was initiated in 1987 and subsidises the price of insulin pump consumables for people with type 1 diabetes of all ages.[2] The level of subsidy provided for insulin pump consumables is approximately 90% based on the difference between available retail prices and the cost on NDSS order forms for those without concessional status.

Among the adult population with type 1 diabetes, insulin pumps usually require supplementary private health insurance or else people with type 1 diabetes may completely self-fund ($6,994–$8,574 AUD per device as of March 2021).[53] According to the Private Health Insurance Act of 2007, private health insurers may cover the cost of insulin pumps under hospital or general treatment policies.[54,55] The commencement of an insulin pump usually does not require hospitalisation, and some private health insurers will cover the cost of insulin pumps in the ambulatory setting as well.[55] Australian private health insurance has undergone recent reform with the creation of a tier based structure.[56] The highest tier hospital cover policies (Gold) will cover insulin pumps on an unrestricted basis, however some funds also offer to provide insulin pumps with lower tiers of cover.[56] Basic level insurance lists insulin pumps under the category of 'restricted cover permitted', indicating that insurers may choose to offer insulin pumps as additional clinical categories on a restricted or unrestricted basis.[56] However, apart from Gold tier policies the Working Group is only aware of a limited number of lower tier policies that offer insulin pumps as additional clinical categories. In the absence of a comprehensive list of all private insurers and the cost of policies that provide insulin pumps, it is not possible to accurately quantify the range of costs for appropriate coverage. From the Working Group's limited searches (in March 2020), the least expensive fund cost ~$1,370 (AUD) per year for an individual living in a major metropolitan city, earning less than $90,000 (AUD) per year, with an excess of $750, in an anonymous Silver policy. This cost was ~$530 (AUD) more per year than the least expensive hospital cover offered by the same fund at the time of writing. Quotes for private health insurance may significantly increase with older age as well as longer periods without insurance due to Lifetime Health Cover loading.[57] Insulin pump consumables are an additional cost not covered by private health insurance. At the time of writing, the additional costs to people with type 1 diabetes for consumables as part of insulin pump therapy in Australia was ~$340 (AUD) per year above the subsidy provided by the NDSS assuming one reservoir and infusion set is used every three days.[58]

Private health insurers also have various restrictions that limit how often people with type 1 diabetes can change their insulin pump with funding from their policy. Anecdotally from the Working Group's experience,

some funds will only allow an insulin pump 'renewal' a number of years after the four year warranty period has expired, and some funds only allow an upgrade if there is a device malfunction after expiration of the pump's warranty. In the absence of a comprehensive list comparing private health insurers and their various restrictions, people with type 1 diabetes and HCPs must navigate already challenging management decisions and rapidly evolving technologies with further complexity added by individual funder restrictions. Pump manufacturers, a few hospitals throughout Australia, and some charitable foundations have taken steps to provide temporary access through 'loan pumps' as well as compassionate access to insulin pumps in a limited number of cases. These compassionate access pathways highlight the limitations of current funding systems, are not always publicly advertised, and may further disadvantage those in rural and remote areas without access to tertiary centres or HCPs familiar with these access pathways.

Glucose monitoring

CGM is broadly subsidised for young people under 21 years of age, and is fully subsidised for children 10 years of age and under.[59] However, not all interstitial glucose sensors are indicated for use in all age groups or conditions. Eligibility criteria for young people between 11 and 21 years of age comprise the documentation of: more than one episode per year of significant hypoglycaemia requiring third party assistance; impaired awareness of hypoglycaemia; inability to recognise or communicate about symptoms of hypoglycaemia; or significant fear of hypoglycaemia for the young person or carer which seriously affects the health and wellbeing of the young person or contributes to hyperglycaemia as a reaction to this fear.[59] The CGM Initiative that provides coverage for young people with type 1 diabetes commenced in April 2017.[16]

The CGM Initiative was extended from March 2019 to include people with type 1 diabetes of all ages who were considered to have the highest clinical need. Extended eligibility criteria comprised:[16]

- Children and young people with conditions very similar to type 1 diabetes, such as cystic fibrosis related diabetes and neonatal diabetes, who require insulin;
- Women with type 1 diabetes who are actively planning pregnancy (up to 12 months), pregnant, or immediately post-pregnancy (up to three months); and
- People with type 1 diabetes aged 21 years or older with concessional status, or of Aboriginal or Torres Strait Islander origin, and have a high clinical need to access CGM products. Valid concessional status requires a 'Health Care Card', 'Pension Card', or a Department of Veterans' Affairs (DVA) Gold or White Card.

The CGM Initiative was further extended from March 2020 to cover flash glucose monitoring as well as CGM.[17] Eligibility criteria were also expanded for adults over 21 years of age with concessional status or of Aboriginal or Torres Strait Islander origin by removing the requirement of 'high clinical need'.[16,17] While the CGM Initiative greatly assists some groups, it does not facilitate equitable access to interstitial glucose sensors for the majority of adults who do not have concessional status. Furthermore, the CGM initiative will negatively impact young people who do not retain concessional status as they reach 21 years of age and lose access to a vital self-management tool. Limited non-for-profit organisation support for temporary access to CGM is also available on a case-by-case basis and further highlights the limitation of current funding systems.

Apart from CGM and flash glucose monitors, the existing funding for SMBG results in out-of-pocket costs of approximately $15 (AUD) per box of 100 strips above the NDSS subsidy. This applies to all people with type 1 diabetes without concessional status who are registered with the NDSS.[60]

Technology for insulin dose advice

People with type 1 diabetes who are registered with the NDSS may acquire glucose meters with insulin dose advisor functionality without cost through clinicians or other manufacturer specific pathways.[36]

Integrated insulin pumps and continuous glucose monitor systems

There is currently no unified source of funding for both the insulin pump and CGM components of integrated systems. HCPs and people living with type 1 diabetes must therefore consider funding options for CSII and CGM separately, as outlined above.

3. Health care systems and barriers

The 2011 national evidence-based clinical care guidelines for type 1 diabetes in children, adolescents and adults provide extensive insights into holistic care for people with type 1 diabetes.[35] However, the continually evolving landscape of diabetes management technologies requires further attention. Therefore, the Australian Living Evidence Guidelines in Diabetes critically underpins the consensus statement and will ensure national recommendations remain updated with the most contemporary evidence.

Comprehensive guidelines are also needed regarding the scope of practice for HCPs as well as which HCPs and services should be involved in commencing and monitoring diabetes management technologies across primary care, private practice, and tertiary care settings. The extensive framework provided by the Australian National Adult Insulin Pump Therapy Working Group in 2013 remains relevant,[61] and the consensus statement Working Group intends to integrate updated technologies with this work as well as broaden the scope across the lifespan of people with type 1 diabetes and across the range of health care services. The approach to scope of practice and scale of expertise for rural and regional areas also requires particular attention.

The need for national consensus regarding a diabetes management technology implementation framework with HCP oversight is further highlighted by existing funding criteria. Current funding systems usually require only a clinician letter and/or order form to apply for an insulin pump through a private health insurer or Insulin Pump Program. The application for government funded CGM/flash glucose monitoring also requires a HCP order form and the first delivery of CGM is sent to the individual's HCP. However, it is concerning that devices may be purchased directly from manufacturers without HCP input or education for people with type 1 diabetes who are required to self-fund CGM or flash glucose monitors. Furthermore, representatives from diabetes management technology manufacturers often provide information and education about devices directly to people with type 1 diabetes. However, the content and rigour of this education is not standardised. The ideal would be to ensure experienced and ongoing HCP oversight for all people with type 1 diabetes using diabetes management technology.

There are already considerable efforts to optimise service delivery for diabetes management technologies. The National Association of Diabetes Centres has recently released the NADC Diabetes Technology Standards and an optional accreditation program which were developed in part with funding from Diabetes Australia and the NDSS.[62] These standards aim to assist HCPs to review their own performance and are intended to support applications for accreditation for diabetes centres across the health sector and facilitate high quality service when providing care to people using diabetes management technologies.[62] Further efforts are also warranted to ensure appropriate funding for service provision by HCPs to manage the increasing volume and complexity of data that must be interpreted for optimal and safe outcomes for people living with type 1 diabetes.

4. Consensus statement recommendations

Concurrent with this consensus statement, the Living Evidence for Diabetes Consortium was established to provide continually updated evidence-based guidelines for diabetes management technologies. Consensus statement recommendations should therefore be read in conjunction with the Australian Living Evidence Guidelines in Diabetes.

Commencing diabetes management technologies

The Working Group believes that all people with type 1 diabetes should have equitable access to all technologies that assist in the optimal management of their condition, improve quality of life, and reduce the burden of self-management.

The Working Group recommends establishing suitability criteria to determine which individuals with type 1 diabetes would derive particular benefit from diabetes management technologies. Rather than focussing on strict glycaemic thresholds to guide clinical or funding decisions, the Working Group emphasised that optimal glycaemic improvements are derived when people with type 1 diabetes actively engage with the device and HCPs.

Therefore, essential criteria for commencing technology comprise:

- Willingness to use technology with realistic expectations of benefits and limitations.
- Willingness to have regular contact with appropriate HCPs / health care services.
- Development of individualised diabetes management goals with an appropriate diabetes specialist who outlines the role of technology in reaching these goals.
- Ability to count carbohydrate content for insulin delivery technologies.

Criteria indicating that intensified therapy with technology may be of particular benefit:

- History of severe hypoglycaemia.
- Reduced ability to recognise or communicate symptoms of hypoglycaemia.
- Fear of hypoglycaemia.
- Poor quality of life relating to the impact of diabetes.
- Glycaemic variability.
- Frequent hospital presentations for dysglycaemia including hypoglycaemia or DKA.
- Pregnancy or planning pregnancy.
- Occupations incompatible with frequent finger prick checking (HCPs working in operating theatres, long distance and commercial drivers, professional and non-professional athletes, defence force, airline/air-force personnel, police force, those working in hazardous environments where finger prick checking is not practicable, among others).
- Suitable for islet or simultaneous pancreas/kidney transplantation, or previous islet transplantation but still requiring insulin.
- Requirement for remote monitoring of glucose levels.
- Needle phobia.
- Insulin allergy.

Continuing diabetes management technologies

Due to limited resources, the Working Group proposed that there should also be criteria for continued use of diabetes management technologies. This has particular applicability in instances where the government is subsidising management devices or the related consumables, and provides an implementation framework for subsidisation of other technologies in the future.

Essential criteria for continuing technology comprise:

- Demonstration of the ability / willingness to continue using technology.
- Demonstration of the ability / willingness to continue regular contact with HCPs / services.
- Demonstration of technology assisting the person with type 1 diabetes to reach individualised diabetes management goals.
- Demonstration of an appropriate specialist commencing, reviewing progress, and signing off on continued use of diabetes management technology.

The Working Group proposed that the focus of these criteria be on supporting all people living with type 1 diabetes while also recognising that diabetes management technology may not be necessary or appropriate for everybody. When there is concern about the ability or willingness of an individual living with type 1 diabetes to continue using technology, a thorough assessment should consider contributing factors. Multidisciplinary efforts should also be made to support and assist people with type 1 diabetes to engage with diabetes management technology and to individualise care to address issues such as burnout, self-image, expectations, and other factors. In addition, the inclusion of individualised diabetes management goals is a recognition of the full spectrum of benefits potentially offered by technology rather than the focus being limited to the achievement of strict glycaemic targets. Individualised goals may relate to quality of life, fear of hypoglycaemia, participation in healthful behaviours, and improved glycaemia among others. These individualised goals may also change following commencement of technologies.

Rather than applying punitive threshold criteria for the cessation of technology, individualised management goals should allow the consideration of observed benefits and disadvantages to direct the most appropriate management strategy. The individual living with type 1 diabetes should then be supported by their HCPs to address any barriers to effective implementation of technology, to choose a more appropriate technology, or to have a break from technology if appropriate. HCPs should also update people with type 1 diabetes who have chosen to have a break from technology of any subsequent systems or new technologies which are developed and which may overcome previous barriers to effective implementation.

Current focus for advocacy

1. **Equitable access to diabetes management technologies as well as appropriate education and health care service delivery.**

The members and organisations that formed the Working group will:

- Advocate for increased access to insulin pump therapy for all people living with type 1 diabetes, especially those without access to private health insurance for whom intensified therapy with technology may be of particular benefit.
- Advocate for further expansion of the CGM Initiative to provide access for all individuals with type 1 diabetes who meet essential criteria for commencing technology (defined above).
- Collaborate with relevant industry, political, and other key stakeholders to develop a standardised framework for education provided by the diabetes technology industry that also includes digitally secure and transparent clinical record documentation.

2. **Appropriate funding for health care delivery that involves diabetes management technologies.**

   - Members of the Working Group intend to prepare submissions to the Australian government that highlight the need to review existing MBS item numbers and develop new MBS item numbers for the evolving landscape of diabetes management technologies in order to appropriately support people with type 1 diabetes and ensure optimal use of devices to achieve the best possible outcomes.

3. **Expedited review of diabetes management technologies.**

   - In the context of rapidly evolving technologies, the Working Group highlighted the need for streamlined government review and implementation processes that include HCPs to avoid unnecessary delays in clinical access to diabetes management technologies. One approach to streamline TGA approvals for diabetes management technologies could represent their inclusion in existing fast track approval pathways used for medications.[63] The members and organisations that formed the Working Group will continue to advocate for these changes and collaborate with all levels of government to ensure the fastest possible access to diabetes management technologies.

Credentialling / accreditation for care providers and health care services

Working Group representatives from multidisciplinary and national diabetes management organisations have highlighted the need for a unified national approach to health care delivery for diabetes management technologies. Integration of existing work by the NADC on accreditation as well as 'the Australian National Adult Insulin Pump Therapy Working Group' on scope of practice will be foundational to more cohesive recommendations. The broad expertise from the Working Group will also facilitate the development of training and credentialling standards to ensure best practice for the implementation of diabetes management technologies throughout Australia.

Benchmarking and evaluation of the health care system

The unified approach to health care delivery for diabetes management technology requires ongoing evaluation of performance and changes over time. The Australian National Diabetes Audit (ANDA) and Australasian Diabetes Data Network (ADDN) are existing frameworks that provide valuable data for benchmarking across centres as well as investigating the national and regional impact of technologies and policy change on clinical outcomes. The expansion of current approaches will improve the generalisability of results and the inclusion of standardised outcomes for technologies across both initiatives with a component of longitudinal follow-up will provide greater insights.

Safety / adverse event reporting

The Working Group highlighted the lack of a standardised system for reporting the full spectrum of adverse events related to diabetes management technologies. Adverse event reporting forms an integral part of ensuring safety for people with type 1 diabetes and should be part of the evaluation and benchmarking of devices and health care systems. The Working Group will address adverse event reporting collaboratively with government, industry, and other key stakeholders.

Conclusion

The Working Group believes that all people with type 1 diabetes should have equitable access to the most effective management systems, including technology where clinically appropriate, regardless of age, concessional status, or level of private health insurance. This national consensus statement provides a unified implementation framework to ensure optimal utilisation of diabetes management technologies. In addition to ongoing advocacy for greater access, the proposed implementation framework highlights the need for accreditation, credentialling, and technology-specific MBS item numbers to support the management of people with type 1 diabetes using technologies that generate large volumes of complex data. The Working Group also outlines the need for ongoing appraisal of implementation strategies, safety reporting, and funding initiatives to ensure sustainable health care and optimal outcomes for all people living with type 1 diabetes throughout Australia.

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Contributing members

Contribution as part of the Writing Group that involved attendance at meetings, document drafting, and critical review of the consensus statement:
Anthony Pease, Sofianos Andrikopoulos, Mary Abraham, Maria Craig, Brett Fenton, Jane Overland, Sarah Price, David Simmons, and Glynis Ross.

Contribution as part of the Working Group that involved attendance at meetings and critical review of the consensus statement:
Esther Briganti, Roger Chen, Susan Davidson, Elizabeth Davis, Louise Ginnivan, Sarah Glastras, Jane Holmes-Walker, Sybil McAuley, Margaret McGill, David O'Neal, Simone Patterson, Sophie Poulter, Anthony Russell, Stephen Twigg, Helen Woodhead, and Sophia Zoungas.

Contribution as part of the Working Group that involved critical review of the consensus statement:
Elif I Ekinci, Mark Forbes, Barbora Paldus, Jonathan Shaw, Carmel Smart, Cheryl Steele, and Natalie Wischer.

Contribution as part of the Working Group that involved attendance at meetings:
Lucy Casson, Sridhar Chitturi, Grant Cracknell, Gabrielle Howard, and Christopher Nolan.

Disclosures

Conflict of interest statements are available on request.

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