Insulin pump special eligibility criteria in New Zealand: a survey of prescriber opinion and practice

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ABSTRACT

AIM: Funding for insulin pump therapy (CSII) in New Zealand for people with type 1 diabetes is determined by meeting PHARMAC special authority (SA) criteria. We aimed to survey the opinion and practice of CSII prescribers with respect to the current SA criteria and contextualise the results with respect to contemporary literature and best practice.

METHOD: Quantitative and semi-qualitative survey of CSII prescribers in New Zealand. Mixed qualitative and quantitative analyses were used.

RESULTS: Of the 94 survey respondents, 88% stated the criteria needed updating. However, 75% maintained CSII funding by PHARMAC should remain under updated SA criteria. Most (60%) of respondents thought the current criteria did not promote health equity for Māori and Pasifika. Only 33% of respondents strictly adhered to the criteria. Thematic analyses of free text responses indicated that the criteria did not reflect quality of life benefits offered by CSII, changes in life course, clinician or patient autonomy, and beneficence of CSII not otherwise stated in the current criteria.

CONCLUSION: The majority of CSII prescribers in New Zealand disagreed with the SA criteria, resulting in most not strictly adhering to them. Updated criteria are required to improve health equity, and reflect best evidence.

Type 1 diabetes (T1D) is a lifelong condition that requires considerable effort and changes in lifestyle to effectively manage glucose levels. There are approximately 20,000 people with T1D in New Zealand. More intensive insulin therapy regimens have been proven to achieve glycaemic control (HbA1c ≤ 53 mmol/mol) and decrease long term complications from T1D.

One way of delivering insulin therapy is via a continuous subcutaneous infusion of insulin using a pump (CSII). CSII delivers a continuous infusion of rapid-acting insulin. It is cost-effective compared to multiple daily insulin injections and its use worldwide has been increasing steadily since its introduction. Currently in New Zealand, public funding for CSII is provided through the New Zealand Pharmaceutical Management Agency (PHARMAC). Approximately 11% of New Zealanders living with T1D use CSII, which is much lower compared to other high-income countries. Māori and Pasifika peoples with T1D are even less likely to use a publicly funded CSII. Since September 2012, PHARMAC requires applicants to meet specific special authority (SA) criteria in order to be eligible for CSII. There are three main categories for initial applications: severe unexplained hypoglycaemia; HbA1c criteria; and previous pump use before 1 September 2012. For each of these categories there are multiple sub-criteria that need to be met. Renewal criteria also exist for continuation of CSII which comes up bi-annually for insulin pump consumables and every four years for the insulin pump.

The PHARMAC SA criteria have not been significantly updated since their implementation 10 years ago. Since then, there has been a growing evidence base for use of CSII, and many health authorities internationally have adapted their own access pathways. Global position statements also support CSII, and cite the literature in support of them. New Zealand is unique in that there is no private health insurance pathway to CSII. Hence, people with T1D are reliant on PHARMAC criteria, or need to personally pay for the insulin pump (~$10,000) and the annual running cost of the consumables (~$2500/year). Publicly funded CSII is lowest among people experiencing the most socio-economic deprivation (8%, most deprived vs 15%, least deprived), suggesting the current criteria may be disadvantaging those with most financial need.

Anecdotally, it is known that prescribers in New Zealand face a dilemma with respect to adhering to PHARMAC SA criteria for CSII. Applicants
often do not meet funding criteria despite the fact they may show significant benefit, or due to health reasons outside of their control (ie adolescence). This is despite the growing evidence that CSII improves the lives of young people with T1D and is associated with diabetes treatment satisfaction in adults. To further understand this, we designed a survey to gauge prescriber practice and prescriber opinion about the current public funding criteria. We also examined contemporary literature and health funding reimbursement policies from comparable countries to contextualise the responses to the survey. In doing so, our intent is to highlight the need for the current CSII criteria to be reviewed and updated urgently to ensure better (and equitable) long-term health outcomes for people with type 1 diabetes in Aotearoa New Zealand.

Methods

Study design
We created a web-based quantitative and semi-qualitative survey using Qualtrics software (Version [Aug, 2021] of Qualtrics, Qualtrics, Provo, UT, USA). There were 43 questions, which took approximately 10 minutes to complete. Five of these questions were qualitative, with a free text comment box. (See Supplemental Document 1 for the full set of questions contained in the survey.) Before circulation, the survey was peer reviewed by three senior clinicians. The survey opened on 10/8/2021 and closed on 28/8/2021. Eligible participants were all CSII prescribers in New Zealand. An email via the New Zealand Society for Study of Diabetes (NZSSD) and the New Zealand Clinical Network for Children and Young People with Diabetes email databases was circulated, with an anonymous link to the survey and instructions to complete the survey only if they are an active CSII prescriber. Two email reminders were sent throughout the time period. There was no incentive to complete the survey. A returned survey from respondents indicated consent. It is not possible to reliably estimate how many people invited through the email databases are active CSII prescribers in New Zealand (eg allied health), and there is overlap in both databases. This study was approved by the University of Otago Ethics Committee (D21/264).

Data analysis
Quantitative data was examined using simple descriptive statistics. Qualitative data analysis was undertaken on responses to free text survey questions. The qualitative data was manually coded by MG and MdB. All free text responses were exported into an Excel document, then read and re-read by MG and MdB. The qualitative data then underwent independent content analysis by MG and MdB where data was grouped around central, recurrent themes. The preliminary coding schema was discussed with a third researcher (SS) and revised before all data within each theme was re-examined. Direct quotes have been used to illustrate important findings.

Results

Quantitative
A total of 94 participants completed the survey. 41% of participants prescribed exclusively for paediatrics, 53% for adults and 6% for both. CSII prescribers from every DHB were represented. The vast majority of respondents agreed that the current criteria need updating (88%). When asked if the current SA criteria promoted health equity for Māori and Pasifika, 60% of respondents disagreed. The majority agreed that CSII should remain under a SA process (75%). Only 33% responded that they always strictly adhered to the PHARMAC criteria when prescribing, while 48% adhered to the criteria 75–100% of the time and 14% adhered 50–75% of the time. Similar proportions of adults and paediatric prescribers agreed that the criteria needed to be changed (88% vs 92%), and a similar number of adult and paediatric prescribers adhered 100% of the time (29% vs 32%).

The current specific requirements for each of the main categories of initial CSII application SA criteria were not agreeable with the majority of respondents. With respect to the severe hypoglycaemia criteria, 80% disagreed with the current sub-criteria. For example, 49% felt that placing a time frame on the occurrence of severe hypoglycaemia should be removed, and 89% of those who disagreed with the current sub-criteria expressed that there should be less than the currently required four episodes. With respect to the current HbA1c category, 85% of respondents disagreed with the current sub-criteria. For example, 49% felt that placing a time frame on the occurrence of severe hypoglycaemia should be removed, and 89% of those who disagreed with the current sub-criteria expressed that there should be less than the currently required four episodes. With respect to the currently required four episodes. With respect to the current HbA1c category, 85% of respondents disagreed with the current sub-criteria. Both the upper limit of ≤90mmol/mol (62% felt no upper limit is appropriate), and the lower limit of ≥65mmol/mol (63% felt no lower limit is appropriate) were disagreeable. Further, the majority of responders (65%) disagreed with sub-criteria requiring HbA1c improvements of at least
10mmol/mol using CSII. Of these, 52% selected that no amount of change should be included in the criteria. Sub-criteria specific to CSII use prior to 2012 which states “HbA1c has not deteriorated more than 5mmol/mol from baseline” was not agreeable with 73% of respondents. Of those who disagreed, 78% believed applicants should be allowed a 10mmol/mol increase from baseline. Other responses were mixed, with suggestions ranging from no increase to 9mmol/mol.

The majority disagreed with the current SA requirements for CSII renewal. For example, 76% disagreed with sub-criteria of: “HbA1c has not increased by more than 5mmol/mol from baseline”. Of those who disagreed, 71% thought a deterioration of up to 10mmol/mol should be allowed. The rest of the participants largely felt that no increase from baseline should be the standard. One of the renewal criteria for HbA1c requires the applicant to achieve and maintain “a reduction in HbA1c from baseline of 10mmol/mol”. Most (69%) of participants disagreed with these criteria. All those who disagreed thought the reduction should be less than 10mmol/mol, with 78% stating that no increase from baseline was appropriate. For renewal criteria for previous use before 2012, 77% of participants disagreed with the criteria “HbA1c has not deteriorated more than 5mmol/mol” since commencing pump therapy. Most (60%) felt that the increase from baseline should be 10mmol/mol, while 36% felt that there should be no increase from baseline since starting treatment.

Qualitative

Most participants (60/94) provided at least one free text response to a question. Of those 60 respondents, there were 101 free text comments. Themes identified were equity, beneficence that the current criteria did not reflect, quality of life, autonomy, life course and future proofing. A sub-theme for beneficence was identified (punitive), and for autonomy (clinician autonomy, or person with diabetes autonomy).

Many responses commented on the issue of equity, typically commenting that Māori, Pasifika and people with lower socio-economic status were discriminated against in the current criteria. When asked to provide general comments, 16 participants (27.7%) specifically raised this as an issue. An illustrative example is:

\[ I \text{ also think these criteria discriminate against the groups who do poorest} \]

in NZ, Māori, Pasifika and those of lower socioeconomic status. They are less likely to reach the criteria or continue to meet them over time, yet have the most to benefit.

Beneficence for the person with diabetes outside of the current criteria was commonly expressed by respondents, without specifically mentioning quality of life. Twenty-three respondents (48.9%) mentioned this. For example:

\[ \text{CSII has many benefits other than just } \]
\[ \text{HbA1c eg making life easier, promoting education, and not more adverse effects than injections. It should be seen as part of modern diabetes treatment options.} \]

Eighteen participants (81%) felt that all or part of initial application criteria requiring unpredictable and significant variability in blood glucose, including significant hypoglycaemia affecting the ability to reduce HbA1c, was not relevant as it restricted applicants benefitting from CSII therapy. Similarly, under the previous use criteria requiring the patient to have no increase in severe unexplained hypoglycaemic episodes from baseline, seven participants (41.2%) disagreed on the basis of beneficence:

\[ I \text{ think if there is an increase [in hypoglycaemia], then it needs to be addressed, but it does not mean that the pump is an inappropriate method of administering insulin.} \]

Seven participants (14.9%) responded that the criteria could be punitive, for example circumstances where applicants were being punished by removal of CSII:

\[ I \text{ think that the criteria that mandate there must be continued reduction in hypoglycaemia or continued excellent control, would lead to many children having pumps removed, despite them being the most effective treatment for their diabetes.} \]

Similarly, quality of life was mentioned frequently by responders as being an area that the current funding criteria did not take into account. In the final comments, 11 participants (23.4%) mentioned this specifically.
Two autonomy subthemes identified were 1) the person with diabetes’ autonomy and 2) clinician autonomy, with most participants referring to clinician autonomy:

All patients with Type 1 should be allowed pumps if their specialist thinks they would benefit from one. (example of clinician autonomy)

The criteria take away the option for individuals who work hard to maintain their control but do not meet criteria because their HbA1c is too good. Because of the requirements for reduction in HbA1c this causes inequity, particularly as socioeconomic impacts causing HbA1c to climb can result in losing funding despite there still being benefit from pump over MDI. (example of patient autonomy)

Life stage/course affecting glycaemic control also presented as a prominent theme. This was mentioned by 12 of the respondents (25.5%). Pregnancy, where tighter control than previous is required for better obstetric and neonatal outcomes, and adolescence were two particular areas that were specifically mentioned:

HbA1c limits make no sense in the developing child and adolescent, with changing social and developmental challenges.

We recommend an additional criteria for pre-conception and pregnancy care given these women often have low HbA1cs that don’t meet current criteria.

Finally, seven respondents (14.9%) made note of a need to change the SA criteria in order to allow future proofing of diabetes technology. Mention of continuous glucose monitoring in particular came up, as did closed loop systems and automation.

With the closed loop systems, there is significant improvement in QOL and mental burden with pump use, which should also be considered in setting of criteria.

Discussion

In this study, we gauged prescriber opinion and practice with respect to the PHARMAC CSII SA criteria in New Zealand. With 94 respondents, who work across all DHBs, the sample is representative of the majority of CSII prescribers in New Zealand. CSII technology is rapidly advancing, presenting a challenge to keep publicly funded access criteria contemporary. Whilst the majority of prescribers felt that SA criteria are still needed in order to access CSII, the overwhelming majority (88%) felt that the criteria need updating. The results show that many criteria are largely disagreeable with prescribers. This has led to a significant portion of prescribers not strictly adhering to the criteria when making an application and prescribing CSII. This has the potential to cause a moral, ethical, and professional conflict both in workplaces, due to different prescribing practices, and when taking the needs of people with T1D into account.

Health equity is a priority in New Zealand. The majority of prescribers felt that the current SA criteria did not meet this obligation. The qualitative responses elaborated on this further, with prescribers describing that CSII has widened the health gap due to inequitable access despite Māori and Pasifika having much to gain from easier access to this technology. Māori and Pasifika patients are known to have low CSII use compared to NZ Europeans, and are two to three times more likely to cease CSII technology once obtained. This is likely due to Māori and Pasifika people with T1D having higher HbA1c values. It is universally agreed that intensive insulin regimens are vital in decreasing microvascular complications of diabetes, and contemporary evidence has shown that CSII has the largest improvement in HbA1c in people with the poorest glycaemic control. Therefore, improving CSII access and uptake for Māori and Pasifika could improve health outcomes. Recently, with the introduction of SGLT2 inhibitors to the Pharmaceutical Schedule, health equity was addressed by having all people of Māori and Pasifika ethnicity eligible to benefit from this drug class in the management of type 2 diabetes. Therefore, there is precedent within the PHARMAC framework to address health inequity by removing barriers created due to eligibility criteria.

CSII is known to improve quality of life for both people with T1D and their caregivers.\textsuperscript{15,19,21–23}
The lack of this consideration in the current SA criteria was highlighted by survey respondents. Other countries which publicly fund CSII, such as the UK, have specifically considered quality of life when forming their criteria. The current requirement of specific HbA1c values with the criteria was disagreeable to most prescribers, and also divergent from best evidence on many levels. The lower value of ≥65mmol/mol is above the recommended international guidelines, effectively excluding a proportion of the population where there is evidence that CSII could help reach glycaemic targets. An unintended consequence of not including quality of life benefits is that people with good glycaemic control are known to deliberately worsen their glycaemic control in order to access funded CSII, which is clinically and ethically inappropriate. Pregnancy, where very tight glycaemic control is required, is a particular population where the current criteria are too restrictive to allow access. At the other end of the glycaemic spectrum, the upper HbA1c cut-off of ≤90mmol/mol is in contrast to evidence which states people with the poorest glycaemic control have the largest improvements in HbA1c when placed on CSII therapy. CSII is also much more cost-effective the greater the HbA1c improvement. Renewal criteria based on HbA1c were also disagreeable and often seen as punitive. Such limits do not take into account the change in glycaemic control over the course of a person’s life. Physiological and developmental reasons make glycaemic control more challenging in adolescence compared to early and middle childhood, regardless of compliance. However, evidence shows that adolescents who use CSII tend to hold their HbA1c steady during this period, compared to those on MDI regimens who show a trend of increasing HbA1c during puberty.

The criteria based on severe hypoglycaemia were also disagreeable to most respondents. Episodes of severe hypoglycaemia can have significant consequences in all age groups, including short term cognitive impairment, seizures, cardiovascular events and death. Within this evidence base there is no reference to a time frame or frequency of events, despite this being written into the SA criteria. There is also no reflection on the risk of such an event—for example, even one severe hypoglycaemic event in a truck driver poses significant risk. Further, meeting the current criteria requires an individual to raise their HbA1c. However, evidence now shows that people most at risk of severe hypoglycaemia have very high HbA1c, which is in direct contradiction to this requirement. The current definition of severe hypoglycaemia by PHARMAC states an episode “requiring the assistance of another person”. This disadvantages adult applicants, who are much less likely than children to have a second party present to assist them with a hypoglycaemic event. Overall, the current criteria access on the grounds of severe hypoglycaemia are discrepant with the current evidence base, and do not allow for important clinical scenarios including safety. Based on the evidence presented above, the current PHARMAC CSII SA criteria are misaligned with the evidence base and comparable health systems.

There were several limitations in our study. The results may be biased if those most interested in the topic were also those who were most likely to respond. The computer survey design of the free text questions meant that our qualitative responses were limited, and we were unable to clarify or expand on comments further. This led to some answers lacking enough detail to be included into themes. Indeed, given so many respondents stated that they did not strictly adhere to the criteria, it would have been interesting to explore prescribing practice when the patient doesn’t meet them, yet the process is still completed. We also could not calculate the percentage of insulin pump prescribers who responded to the survey, as we do not have a complete list of all insulin pump prescribers in New Zealand. The assumption was that anyone who responded was a prescriber, however it is possible that not all prescribers were on the email lists that the survey was sent out on. However, these are balanced by the following strengths of our study: a peer reviewed survey design that provided a lens on how the current criteria may contribute to health inequity, the high number of CSII prescribers who participated, and representation of prescribers from every DHB. This means that our results are more likely to be representative of the true opinion from the majority of the cohort who work within the PHARMAC criteria.

Conclusion

The current SA criteria for both initial application and renewal for CSII are disagreeable with the majority of prescribers who frequently do not strictly adhere to them. This is likely a result of the existing SA criteria being out of date with the contemporary evidence base. Of primary concern is that the SA criteria do not promote health equity. Therefore, renewed criteria, with consultation from healthcare professionals involved in diabetes management, is urgently required.
COMPETING INTERESTS:
Nil.

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