Mapping care provision for type 1 diabetes throughout Australia: a protocol for a mixed-method study

Ann Carrigan, Rebecca Lake, Sophia Zoingas, Jennifer Couper, Elizabeth Davis, Timothy Jones, David Bloom, Jeffrey Braithwaite, Yvonne Zurynski

ABSTRACT

Introduction Type 1 diabetes (T1D) is a chronic and incurable autoimmune disease, diagnosed in early childhood and managed initially in paediatric healthcare services. In many countries, including Australia, national audit data suggest that management and care of T1D, and consequently glycaemic control, are consistently poor. This can lead to adverse outcomes such as cardiovascular disease and nephropathy. T1D treatment is complex, multidisciplinary, multifaceted and life-long and should involve patient-centred, developmentally appropriate care. Although an emerging body of literature describes T1D models of care, their components, implementation determinants and associated outcomes are poorly understood.

Objectives To provide a study protocol to describe methods to map existing models of care for children and young adults with T1D. It will identify the gaps and needs in care delivery as viewed by healthcare providers and by children, young people and their families accessing care in metropolitan and rural or remote regions throughout Australia.

Methods and analysis A mixed-method study that includes provider and consumer-specific surveys and interviews about current T1D care provisions. Data will be analysed thematically (qualitative) and statistically (quantitative) and synthesised to describe the key characteristics of effective and sustainable models of care for T1D and to identify gaps.

Ethics and dissemination Ethics approval was granted by the Macquarie University Human Research Ethics Committee in July 2022 (#520221154439676). Results will be disseminated via publication in peer-reviewed journals and at relevant conferences.

BACKGROUND AND RATIONALE

Type 1 diabetes (T1D) is a chronic and incurable autoimmune disease that presents in early childhood and affects more than one million young people worldwide. In many countries, including Australia, national audit data suggest that management and care of T1D are consistently poor, possibly leading to adverse impacts such as diabetic ketoacidosis and long-term effects including cardiovascular disease and nephropathy. Critically, no change in mortality has been reported in recent years, and cardiovascular disease risk is strongly correlated with duration of T1D and therefore problematic for those diagnosed at a young age. Children and adolescents with T1D have a reduced life expectancy of approximately 12–16 years. An important modifiable factor to reduce these risks is maintaining optimal glycaemic control.

Although individuals understand the importance of good glycaemic control, registries show that around 85% fail to achieve recommended glycaemic targets. Additionally, the transition from paediatric to adult care is difficult to navigate, and treatment adherence rates reduce significantly due to competing life stressors such as higher education, career and social demands.

Globally, despite standardised international guidelines, T1D management and outcomes among individuals, clinics, jurisdictions and countries vary significantly. This highlights the complexity of the condition, where clinical outcomes for people with T1D have failed to improve as much as expected with major advances in insulin delivery and technology.
Some observers suggest that failures in the translation of successful interventions into practice and in the implementation of comprehensive and sustainable models of care may contribute to these findings.15 14

Managing T1D is complex because its management on individual and population levels has multiple interactions and consequences. Individuals living with diabetes do so within families, the immediate community, and wider society. Models of care do not always adopt this broad view. Successful solutions need to consider the complexity of the socioecological system in which the individual lives, in addition to their medical condition.15

Our group have undertaken a scoping review of the literature to examine the evidence for T1D models of care. Some studies reported healthcare and psychosocial benefits for models that involved structured education programmes,16 17 multidisciplinary teams18 19 and capacity building for self-care.20 21 We identified a significant gap in the literature: few studies addressed the implementation drivers or applied a guiding theoretical framework at the provider or health system level.

This study is part of an international collaboration to advance T1D care. In 2021, the Rio Tinto Children’s Diabetes Centre; a JDRF Centre of Global Excellence, commenced with the following three objectives: (1) to formulate a framework to develop, implement and evaluate models of care that lead to improved health outcomes and reduced burden for young people living with T1D, (2) to promote effective transfer of research outcomes into health policy and/or practice and (3) to develop novel advanced economic frameworks that include the broad true costs of T1D to enhance access to novel therapies and shape policies.

This protocol describes the project that will address objective (1). It will scope and map the provision of paediatric and transitional T1D care and investigate model scope, components and resourcing of services in Australia. We will review clinics and currently implemented T1D models of care using a mixed-method approach to comprehensively describe the key model components and to identify gaps, strengths and context-informed barriers and enablers to implementation. Findings will inform the future improvement of healthcare in T1D.

OBJECTIVES

The overall goals of this research are to map the current models of care for T1D and to formulate a framework to develop, implement and evaluate optimal models of care that lead to improved health outcomes and reduced burden of care for children and young people living with T1D and their families. To achieve this aim, the domains underpinning the provision of T1D care will be assessed on three levels: healthcare providers, children and their families, and young people who are transitioning from paediatric to adult services, using two methods of data collection (figure 1).

Understanding what models of care have been implemented for T1D nationally will support a series of consultations with clinicians, managers, policy-makers, families and young people living with T1D. Ultimately, we will identify adaptable models and trial these in different contexts in a future project. The core aim is to codesign novel, personalised and integrated models of care that are fit for purpose and can be tested in the future.

METHODS AND ANALYSIS

Study design

This mixed-method, cross-sectional research consists of surveys and interviews with healthcare providers, children living with T1D and their families, and emerging adults. The design comprises collections of providers’ and individuals’ data gathered via surveys, including demographic information and specific questions about the provision of T1D care. Each survey was designed in collaboration with healthcare providers (endocrinologists), parents caring for a child with T1D, and emerging adults living with T1D. Qualitative interviews will be conducted to enable in-depth exploration of the information available through surveys, providing a more nuanced and comprehensive understanding of current models, needs, gaps, barriers and enablers experienced at the provider, consumer and system levels. Together, these methods of data collection will facilitate a thorough exploration of various domains to map current service provision for T1D in diverse contexts in Australia (figure 1).

Quantitative methodology

Three online deidentified surveys will be widely distributed to three groups of participants throughout Australia using the REDCap platform,22 which is hosted by Macquarie University: (1) healthcare providers who offer services for T1D, (2) children and families living with T1D and (3) emerging adults living with T1D who are transitioning or have recently transitioned from paediatric to adult care (transition group). Participants will have the option to indicate if they would like to take part in qualitative interviews.
Qualitative methodology
We will invite participants who indicate an interest during the survey to participate in interviews where they will be asked a series of open-ended questions that will be designed based on the survey results. The purpose of these interviews is to expand on areas of interest and verify the findings from the questionnaire data. Interviews will be audio recorded and are expected to last approximately 45–60 min. The interview script commences with ‘Can you please elaborate on what you think is meant by …’ and is deliberately open ended to allow participants to freely express their views.

Study setting
The preference is to conduct interviews in person; however, we will also offer to conduct them electronically via Zoom meeting software due to participants’ locations and other commitments and the COVID-19 pandemic. We will follow all local health guidelines in terms of social distancing when conducting interviews in person. When interviews are conducted electronically, the researcher conducting the interviews will adhere to the following measures to always ensure security, as outlined by Macquarie University:

1. Enable waiting room (for all interview guests).
2. Enable meeting passwords.
3. Not share the Zoom link or code on social media or any public website.
4. Set screen sharing to ‘host’ only.
5. Turn off the annotation feature if not needed.
6. Restrict other features as needed in host controls.

Length of study
We anticipate 12–24 months of data collection, followed by six months to prepare publications and disseminate findings.

Study participants and recruitment
For providers, all TID services across Australia will be approached. These services will be identified through the Australian Paediatric Endocrinology Group (APEG) and through the network of clinical chief investigators on the JDRF grant. It is anticipated that approximately 5–4 services will respond in the larger states and 1–2 services to respond from the smaller states and territories, for a total sample of 16–24 services.

Children, families and young people will be recruited through the clinical services as well as the National Diabetes Services Scheme (NDSS), which registered 4090 people with TID over a 12-month period before September 2022. In addition, we will recruit through Diabetes Australia and JDRF Australia including their newsletter subscribers and social media networks; and snowball effect social media, newsletters and flyers. We will turn comments and tagging off the Facebook posts. Emails will be distributed via the existing networks of JDRF, Diabetes Australia and the Australasian Diabetic Data Network.

A sample of approximately 400 children/families and another sample of 400 young people (16–25 years) is expected to ensure geographical representation across the 8 states and territories of Australia. This number is considered adequate based on previous research in a similar context and takes into consideration participant loss to follow-up.

Regarding recruitment for interviews the aim is to recruit 12–24 participants from each of the three participant groups (providers, children and families, and young adults). Purposive sampling will be used to ensure broad representation across geography, socioeconomic status (based on the Australian Bureau of Statistics, Index of Relative Indexes for Areas; ABS IRSAD), ethnicity and age. Based on experience of the authors and according to Braun and Clark (2021), data saturation is likely to be reached; however, if new themes continue to emerge, additional participants will be recruited and interviewed.

The nature of the Australian population ensures that people from Aboriginal and/or Torres Strait Islander and culturally and linguistically diverse (CALD) backgrounds will be recruited if their English language skills are sufficient to complete the survey. We recently conducted a population-based study where the survey was offered in English, with >5000 respondents; 11% identified as Aboriginal and/or Torres Strait Islander and 25% were from CALD backgrounds, suggesting that appropriate representation is possible.

For those accessing the research invitations electronically (via email or Facebook ads), the invitations will include a link to each of the surveys hosted on the RedCap platform at Macquarie University in Australia. The surveys are attached as online supplemental files 1–3 and the interview script can be found as online supplemental file 4. Participants will have the opportunity to contact the study investigators via email or phone for more information about the study. Participants will be informed that their experiences are very valuable, but they are not obliged to disclose personal details if they do not wish to.

Inclusion criteria
Providers must provide TID services in Australia. This will include, but is not limited to, paediatric and adult endocrinologists, nurse practitioners, clinical nurse consultants, diabetes educators, nutritionists, social workers and psychologists. Families must have a parent or carer of a child with TID. A second adult family member or carer is also welcome to participate. The transitional group participants must have started or completed a transition to adult TID care. They may include a family member if they desire.

Reimbursement
Participants in the family and transitional groups will be offered payment in line with the New South Wales recommended remuneration for health consumers for participating in interviews as part of the project. Providers will
receive no financial reimbursement for survey completion or interviews.

Data collection
Data in this project will include demographic information and experiences with T1D and qualitative interview data. Demographic data and experiences with T1D will be captured using REDCap. Qualitative data from interviews with consenting participants will be audio recorded and transcribed and last approximately 45–60 min. Adults in the family groups will be interviewed individually before children and young people (8–16 years) and then a family interview will be conducted with all consenting family members together. To ensure the questions for the children’s interview schedule are sensitive, informed and insightful, children’s interviews will take place after interviews with parents to seek guidance on how to conduct the children’s interviews to facilitate their understanding and help judge how to conduct the interview.

Member checking or providing participants with an opportunity to review or edit their responses is not a common practice in qualitative research and will not be considered as part of this research study. Such practice is more common for studies where a misunderstanding of the study topic/interview is likely; however, we do not envisage this occurring in this study.

Data analyses
The quantitative data that includes demographic and health-related data from the surveys will be analysed using SPSS V.22.0.27 This analysis will include the frequency distribution of different components of services across Australia. For example, health professionals who contribute to a multidisciplinary team. Two members of the research team using an open coding process by NVivo28 will independently analyse the qualitative data thematically. Themes will be extracted that characterise the provisions of T1D care for providers and consumers.

Synthesis and integration of results
The literature review findings will highlight the barriers and enablers of existing global models of care. These findings will be compared with the outcomes from the surveys and interviews about models of care throughout Australia. Additionally, these results will be compared with barriers and enablers of existing global models of care, and a national or international clinical practice guidelines and recommendations regarding delivery of T1D care. For example, guidelines published by the APEG or the International Society for Pediatric and Adolescent Diabetes. Together these findings will be synthesised and integrated to describe the characteristics of an effective and sustainable T1D model of care.

Patient and public involvement
Patients or participants will be directly involved in the current study.

DISCUSSION
This research seeks to map the provision of care for T1D healthcare providers and young individuals living with T1D. We will undertake a survey and review of clinics and models of care for T1D using a mixed-method approach. This will involve considering various domains and the complexity of the socioecological system in which the individual lives. Given that morbidity has remained unchanged in young people and cardiovascular disease risk is strongly correlated with the duration of diabetes age at onset of TID,6 evaluating the current status of delivery of diabetes care in Australia is crucial for identifying gaps and addressing barriers. This can be achieved by utilising a conceptual framework such as the Consolidated Framework for Implementation Research.29 The Consolidated Framework for Implementation Research provides a theoretical lens to understand the process of introducing and managing new models of care within a complex healthcare system.29 We will gain a deeper understanding of the factors that help or hinder implementation in different settings,29 allowing for personalised, integrated models of care that are fit for purpose.

The limitations of this study may include the following factors: the survey questions may not accurately capture findings of all participants and may not be generalisable to countries outside of Australia. A risk of selection bias towards those who are included in NDSS, subscribe to diabetes networks newsletters and social media also exists. Although we are making every effort to capture diversity across Australia, our research may not be inclusive of all areas and groups as surveys and interviews will be conducted in English.

Expected outcomes
This research will determine the key drivers and characteristics of an effective and sustainable model of care for young people. Adopting an evidence-based approach, we will map the current models of care for T1D within Australian and identify sustainable models of care that integrate and implement new knowledge and technologies to achieve person-centred care. Ultimately, the outcomes will advance the understanding of how to reduce the morbidity and mortality of T1D and its burden on children, their families, the health service and the community.

ETHICS AND DISSEMINATION
Consent
No known health or safety risks are associated with participation in any aspect of the described study. Ethics approval for conducting the study was obtained from Macquarie University Human Research Ethics (# 520221154439676). The results will be actively disseminated through peer-reviewed journals, conference presentations and reports to stakeholders.

Should a survey participant decide not to complete the survey, or decline to answer some questions, their...
submitted data may still be used in the analysis. Should a participant withdraw from an interview, or withdraw their consent after the interview, their data will not be used as part of the formal analysis. We do not anticipate participant withdrawal having any impact on the study; however, should it occur, some modification of results may occur.

Managing risk/distress

Children and/or young people will have an adult family member present in the same location during the individual interviews to ensure they feel safe and supported by a familiar adult. Interview techniques will be used appropriately, according to age, and data anonymity and confidentiality will be upheld throughout. Interview questions will be crafted and presented according to the age of the person being interviewed, their disease state and their cognitive status.

Participants will be informed as part of the survey by interview participant information and consent forms (PICF) that potential for distress exists as the questions relate to issues around healthcare. They will be informed that they do not have to answer any question that makes them feel uncomfortable and that they are able to stop at any time. If participants do become distressed, researchers will be able to arrange for free counselling or other support. The research team will refer distressed participants to appropriate mental health services.

The lead investigator will also ensure all participants are aware of the duty of care to appropriately manage any clinical concerns that may arise and will use her clinical judgement and prior research experience with families facing challenges because of complex parental illness to provide up-to-date information on accessing support opportunities. Clinicians involved as associate investigators on this study and senior academics from Macquarie University will be available to offer the researcher and families involved expert advice and guidance if required.

Survey respondents will need to read and electronically agree to consent before proceeding to the survey. Interview participants will be sent, or provided with, the PICF before the interview and asked to provide informed verbal consent before the interview begins. All participants over the age of 18 years will be able to provide verbal informed consent. Those under the age of 18 years will be required to give verbal consent, and their parent or carer must also provide consent. Participants will also be reminded that participation is voluntary, that they do not have to answer any question they do not wish to, and they can revoke their consent at any time during the study. The research team will also explain and clarify that participation or refusal to participate will remain unknown to others outside of the study and will not affect their employment or future healthcare treatment.

Confidentiality

The study protocol, materials and all data will be stored in password-protected electronic files. Once the potential participants have been contacted for the interviews, all data will be de-identified with a study code assigned. All participants will be advised that any information shared that by law must be disclosed to a relevant authority will not be kept confidential.

In this project, audio recordings of interviews will be made. This is so qualitative data can be accurately analysed. Once transcriptions of audio recordings have been made, audio recordings will be destroyed. All data relating to this research project will be destroyed after a 5-year storage period. This is in line with General Retention and Disposal Authority University Records (GDA 23) (2005) and the Australian Code for the Responsible Conduct of Research (2007) requirements. All identifying information in typed transcripts will be edited to protect participant anonymity. A reidentification key/code will be securely stored elsewhere, as will participant consent forms. All data presented in publications and reports that arise from this research will only include deidentified data. Only Macquarie University researchers involved in this project will have access to identifiable data, following relevant Macquarie University ethics clearances. All results will be distributed in a deidentified manner. This research will not disseminate findings that could foreseeably cause harm or embarrassment to participants.