

Assessing cultural appropriateness of patient-reported outcome measures for Aboriginal people with diabetes: study protocol

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Key points

- Patient-reported outcome measures (PROMs) are increasingly being used in the public health sector to assess patient health outcomes and experiences
- Anecdotal evidence indicates that PROMs do not capture accurate information about the healthcare of Aboriginal people with type 2 diabetes
- This paper shares important lessons about implementation of culturally appropriate research by a cross-cultural team, with a focus on the ethical, methodological and consultative considerations in Aboriginal health research

Abstract

Background: Patient-reported outcome measures (PROMs) provide patients with a platform to report on healthcare services and interventions, including the management of diabetes and other chronic diseases. Given the major disparity in incidence and prevalence of diabetes between Aboriginal and non-Aboriginal people, it is crucial that PROMs meet the cultural, spiritual and medical needs of this high-risk population. Anecdotal evidence indicates that PROMs do not capture accurate information about the healthcare of Aboriginal people with Type 2 diabetes. Therefore, the aim of this study is to explore the perceptions of Aboriginal people in regional New South Wales (NSW), Australia, about the cultural appropriateness of a set of PROMs relating to diabetes management.

Methods/design: Up to 50 Aboriginal people aged 18 years or older with type 1 or type 2 diabetes living in the Shoalhaven region in NSW, will be recruited. Eligible, consenting participants will attend a focus group or individual interview where they will review the PROM tools (PROMIS 29 and PAID scale) currently used for diabetes management. Semi-structured questions will be used to gather information about PROMs and discussions will be recorded for analysis. Research team members will yarn about the data with Aboriginal co-researchers and community stakeholders to apply an Indigenous lens to coding and thematic analysis.

Conclusion: This study will explore the cultural appropriateness of government-initiated evaluation of health outcomes, and make recommendations about how these evaluations can be better suited to Aboriginal people. The lessons from this study will be of interest to those conducting research or quality assessment activities related to PROMs, and those involved with Aboriginal-focused research and project implementation.

Background

Diabetes is a major chronic health condition globally, and it places a high burden on healthcare systems and individuals.¹ Type 2 diabetes is the most prevalent form of diabetes; it is four times more prevalent for Aboriginal and Torres Strait Islander Australians than in the non-Aboriginal population.² Diabetes is the second-highest cause of death among Aboriginal people, accounting for 7.6% of deaths – six times higher than that among non-Aboriginal Australians.³ Aboriginal people who live in a remote area are twice as likely to have diabetes compared with Aboriginal people living in non-remote areas (20.8% versus 9.4%).² Early detection and intervention are necessary to address these high rates of diabetes in Aboriginal populations. As well as causing high morbidity and mortality, diabetes is detrimental to quality of life (QOL). People with type 2 diabetes are reported to express feelings of unworthiness and despair which in turn negatively affect their own management of their diabetes.⁴ Stress-related conditions are twice as likely to occur for people living with diabetes, due to the chronic nature of the disease.⁴ The use of QOL tools and disease-state blood and urine markers for complication screening are intended to improve the holistic management of diabetes and reduce the overall burden.

The concept of QOL differs between cultures⁵, so measuring QOL across cultural groups is complex. The methodologies used to develop common QOL assessment tools are usually shaped by western cultural perspectives.⁵ In Australia, the wording and format of QOL tools may be adapted to cater for Aboriginal people, but this does not account for their specific 'cultures, value systems and ways of knowing and being'.⁵ The connection and relationships Aboriginal people have with 'themselves, their communities, their environment and the natural and spiritual worlds are complex'.⁵ Assessing QOL with tools that do not address the specific needs of the Aboriginal population may result in misinformation about the QOL status of Aboriginal people, and perpetuate poor health outcomes, less adherence to advice and low attendance to westernised healthcare facilities.

Patient-Reported Outcome Measures (PROMs) are used to assess health-related QOL in some health settings. PROM surveys are completed by patients attending a health service⁶ to provide information about how health services affect a patient's QOL and health conditions. The data is used to inform a holistic approach to patient-centred care⁷ and in most cases a disease-specific measure is combined with a QOL survey. The Patient-Reported Outcomes Measurement Information System-29 (PROMIS 29)⁸ and the Problem Areas In Diabetes (PAID) scale⁹ are two PROMs used in diabetes management in the public health sector in New South Wales (NSW), Australia. PROMIS 29 is a survey to assess a broad range of health-related QOL-impacted domains such as sleep, fatigue, anxiety and depression, physical functioning, pain and social impacts.¹⁰ The PAID scale is

designed to measure a patient's perspective of diabetes-related stress. The PROMIS-29 has been shown to be useful in patients with chronic musculoskeletal pain¹¹ and chronic knee pain.¹² The PAID scale has been translated and adapted to the Greek¹³ and Chinese¹⁴ languages and the validity has demonstrated emotional differences for those with type 1 compared with type 2 diabetes.¹⁵ Despite the surveys being useful and adapted for specific populations, they have not been examined with Aboriginal communities.

The Agency for Clinical Innovation is a government agency that drives innovation in clinical care in NSW. The agency has established the Patient-Reported Measures (PRM) Aboriginal Health Working Group to assess the cultural validity of the current PROMs. However, there are no validated Australian Aboriginal population-specific PROMs reported in the literature. Culturally appropriate, valid and reliable QOL measures are needed to help address the major disparity in incidence and prevalence of diabetes between Aboriginal and non-Aboriginal people.

The primary aim of this two-phase, qualitative study is to investigate the accuracy and cultural appropriateness of the PROMIS-29 and PAID PROMs for health outcomes assessment in Aboriginal people with diabetes in the Shoalhaven region of NSW, Australia.

The secondary aim of the study will be to codesign a diabetes-specific PROM with Aboriginal people in a regional area, if the tools are not accurate or culturally appropriate. The aim of this protocol is to provide guidance for other cross-cultural research teams regarding ethical and consultative considerations in Aboriginal health research, particularly in relation to the cultural appropriateness of using PRMs to assess health-related outcomes of Aboriginal people.

Methods and design

Study design, methodology and setting

This two-phase, qualitative study will use critical Indigenous methodology to explore the perceptions of the cultural appropriateness of a diabetes PROM set for Aboriginal people in five regional Aboriginal communities in the Shoalhaven region of NSW, and potentially inform the codesign of an Aboriginal PROM. Indigenous methodology, based on Aboriginal 'ways of knowing, doing and being'¹⁶ and relationality¹⁷ will be applied to the research planning, implementation and analysis. The main data collection method will be 'yarning'-style focus groups and individual interviews.¹⁸ 'Yarning' is a culturally respected story form of communication that involves a person-centred framework allowing health professionals to reorient their communication to Aboriginal people. Yarning is used as a method of engagement and a way to connect, exchange information and share knowledge and lived experiences.¹⁸

The study will involve Aboriginal people living in the southern Shoalhaven region from the following communities: Nowra, Jerrinja, Wreck Bay, Sanctuary Point and Ulladulla. The Shoalhaven region is located approximately 160 km south of Sydney on the east coast of Australia and incorporates communities extending a further 70 km north along the coastline of NSW and the Australian Capital Territory (ACT). It is understood that similarities and differences may exist between these peoples but this study will investigate the findings relative to non-Aboriginal people.

Community consultative group

An established Aboriginal community consultation group will guide each stage. This will ensure the Indigenous culture is respected and reflected to build strong foundations for project design and delivery throughout the research, including the engagement process. The group includes Aboriginal Elders, Aboriginal healthcare professionals and Aboriginal community members to ensure the needs and aspirations of Aboriginal people are represented. Once analysis is complete, the content will be reviewed in a community meeting with the consultative group. This will ensure the integrity of the study and will provide direction to the principal and associate researchers. At the end of the project, through custodianship, the audio recordings and written information will be given to the community consultative group.

Selection criteria

The study participants will be Aboriginal people aged 18 years or older with type 1 or type 2 diabetes living in Nowra, Jerrinja, Wreck Bay, Sanctuary Point or Ulladulla.

Recruitment

Participants from each of the Aboriginal communities will be invited to participate in a focus group or individual interview, depending on their personal preference and availability. The research team conducted extensive community consultation as part of the project development and ethics processes. Local Aboriginal Land and Community Councils and Aboriginal Controlled Community Health Services have tabled the proposed study at their regular meetings and agreed for the distribution of recruitment packs at consenting community-based recruitment sites. Recruitment packs consist of print and electronic posters and flyers with recruitment contact details, participant sign-up sheets and participant information sheets. The recruitment sites will display the posters and flyers, record details of potential participants and provide the participant information sheet.

The community nurse or Aboriginal health worker in each community will be responsible for the participant sign-up sheet, and may also approach members of

the community who are eligible to participate. Potential participants may also approach Aboriginal health workers or the principal or associate researchers about participating. Aboriginal health workers will share the contact details of potential participants (who have agreed to be contacted) with the principal researcher. We aim to recruit enough participants during the 3-month recruitment period to conduct 3–4 focus groups of 5–10 participants and 5–10 individual interviews. Preliminary community consultation about this study started in September 2019, so potential participants may already be aware of the study.

The principal or associate researchers will contact the potential participants listed on the participant sign-up sheets inviting them to join the study. Additionally, a snowballing technique may be used by the consultative committee if not enough participants are recruited to the focus groups and interviews.

To accommodate all literacy levels, verbal delivery of both the participant information sheet and the consent form will be available. Consenting participants will sign or provide a recorded verbal consent at the beginning of each focus group or individual interview.

Data collection and outcome measures

Consistent with Indigenous methodology, focus groups or individual interviews will be conducted in the community by the principal and associate researchers. Written versions of the PROMIS-29 and PAID PROMs will be circulated at each focus group or interview, and it will also be read out.

A semi-structured focus group (approximately seven questions, Appendix 1: available from www.phrp.com.au/wp-content/uploads/2021/03/Appendix-1.-Focus-Group-Questions.pdf) or interview guide (approximately 13 questions, Appendix 2: available from www.phrp.com.au/wp-content/uploads/2021/03/Appendix-2.-Interview-Questions.pdf) will be used to inform the discussion. Appendices 3 and 4 contain the guiding questions that will address the following: positives about the surveys, improvements for the surveys, omissions, mode of delivery, and important factors that influence diabetes management. Participants will be offered the option of reading or hearing the transcript read out prior to analysis. Any corrections or clarifications of the data will be noted on the transcripts.

If any participants are visibly distressed during the interview, appropriate measures will be taken by secondary facilitators (JH, CK) to minimise any immediate risks. Following the focus group or interview, the participant will be offered appropriate counselling services. An Aboriginal liaison officer will also be available to support participants if required. The principal or associate researcher will follow up any participants who indicate distress within 48 hours of the focus group or interview.

The focus groups and interviews will be audio recorded and transcribed by the principal researcher, associate researcher (JH) or by a professional transcription company which will sign a confidentiality agreement.

Data analysis

Data will be coded and analysed using thematic analysis as outlined by Braun and Clarke¹⁹ with an Indigenous lens. Associate researcher (CK) will provide an Aboriginal cultural perspective throughout the analysis process. First-level analysis will consist of preliminary coding of transcripts by one Aboriginal (CK) and two non-Aboriginal researchers (AB, JH). Discussion and consensus on codes will be created in first-level analysis and then discussed with the broader research team. First-level analysis will be presented to the community consultation group to gain feedback to inform thematic analysis. A descriptive summary of each resulting theme, with supporting quotes will be collated and presented to the community consultative group. After final analysis, the data will be presented to the community consultation group.

Reflexivity

The critical Indigenous methodology that informs and will guide the conduct of this study assumes the current PROMs are not suitable for the Shoalhaven Aboriginal communities. The premise of the study is to retain the spirit and integrity of the views of Aboriginal people in responding to government-initiated evaluation of health outcomes. Studying and reporting on the cultural appropriateness of the PROMs is intended to value the spirit and integrity of Aboriginal people by making these evaluations more suitable to Aboriginal people.

Two clinician researchers involved in this study are employed within the High Risk Foot Service in the Local Health District where this research is located. As a Leading Better Value Care initiative²⁰, the service was required to implement the use of PROMs. The clinician researchers noted that Aboriginal patients attending the service had trouble completing the survey or commented to clinicians on the number of questions. This experience with the use of PROMs informed the critical Indigenous methodology chosen to inform the study methods. The methodology is therefore grounded in the assumption that there is a power imbalance and that Aboriginal perspectives have not been considered in the PROM development, and that it is therefore somewhat colonised.

Principal researcher AB is a non-Aboriginal woman who has been working as a podiatrist with the study communities for the past 9 years, providing education, foot assessments and organising podiatry referrals.

Associate researcher JH is a non-Aboriginal woman, dietitian and diabetes educator who specialises in diabetes and who has been working in health for

11 years, and more recently been involved with the Aboriginal study communities with AB and CK.

Associate researcher CK is an Aboriginal woman and descendant from the Yuin Nation. She has worked in the health sector for 13 years and is the project lead for an initiative to improve access to care and outcomes for Aboriginal people living with diabetic-related foot disease in the Illawarra Shoalhaven area. CK is currently the acting manager seconded to the Aboriginal Chronic Conditions Network at the Agency for Clinical Innovation.

Associate researcher KD is a non-Aboriginal woman who was born in Yuin Country on the far South Coast of NSW and works as a research education manager in the public health sector. She has 25 years' experience in Aboriginal health research and Aboriginal health researcher development.

Ethics approval

As this study is located in the Aboriginal Southern Shoalhaven area, ethics approvals were obtained from the Joint University of Wollongong and Illawarra Shoalhaven Local Health District Health and Medical Human Research Ethics Committee (HREC): 2019/ETH13468 (24/02/2020), Australian Capital Territory Health HREC: 2020.STE.00005, 2019/ETH13468 (09/06/2020) and the Aboriginal Health and Medical Research Council: AHMRC 1453523 (05/06/2020). Site specific approval: 2019/STE17503 (23/06/2020).

Discussion

Aboriginal adults in Australia have a high risk and prevalence of type 2 diabetes, and need culturally appropriate tools to self-report diabetes-related health outcomes and QOL. PROMs are becoming embedded in Australian healthcare but have not been tailored to be culturally appropriate for the Aboriginal population. This study will report on how Indigenous methodologies have been applied to qualitative research methods, by involving Aboriginal co-researchers, an Aboriginal consultative committee and the Aboriginal people with diabetes for whom PROM tools have been designed.

The study findings will contribute to improved understanding of the accuracy and cultural appropriateness of the PROMIS-29 and PAID scale PROMs for diabetes care and health outcomes in Aboriginal people with diabetes from Shoalhaven, Australia. Researchers and clinicians in all settings where PROMs are administered in different cultural groups will be interested in the study findings and the research methods used in this study to assess cultural appropriateness. If the study findings indicate that PROMs are not deemed appropriate by Aboriginal community members, the process that the cross-cultural research team undertake to codesign recommendations for QOL assessment will be described. To our knowledge, this will be the first time that the cultural appropriateness

and accuracy of PROMs have been evaluated and reported on for the purpose of improving diabetes care and health outcomes in Aboriginal people.

We expect that Aboriginal people with diabetes in this study will benefit from participating in discussions about the cultural appropriateness of PRM tools and contribute towards the development of a culturally validated tool. It is likely that these contributions will contribute to a sense of wellbeing that comes from contributing knowledge and perspectives, particularly as part of a group.

Potential limitations in this study include low community engagement, and associated low participation rates. These limitations could relate to a lack of trust toward research in the Aboriginal community, particularly if there no perceived community benefits. These potential limitations will be mitigated by ethical, responsible and informed research processes. Risk mitigation strategies include: the development of a community consultation group that will ensure the study maintains and prioritises the integrity of the Aboriginal community, including ownership of the data through custodianship. The researchers have participated in ongoing community consultation with local Land and Community Councils and established Aboriginal groups and services to ensure the communities are comfortable with the researchers involved in the study, and their intentions for this study. The researchers have discussed the study with a large number and a broad range of community members and are confident that there is adequate community support and engagement in the study.

We envisage that this study will lead to improved diabetes care and management for Aboriginal people in rural and remote communities in NSW and will also inform the process for improving cultural appropriateness of PROMs so they can be used to better manage the complex needs of Aboriginal people living with diabetes and other chronic health conditions. A culturally validated diabetes PRM has the potential to be used in conjunction with objective disease-state blood and urine markers that relate to other chronic diseases such as chronic kidney disease, and peripheral vascular disease.

The results of this study may also serve to provide a paradigm for a research approach to the wider, global Indigenous nations.

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Peer review and provenance

Externally peer reviewed, not commissioned.

Competing interests

None declared.

Author contributions

AB, JH, CK and KD were responsible for the design of study and this paper. AB, JH and CK were responsible for the consultation, planning and interaction with the Aboriginal Land and Community Councils, services and communities in the Shoalhaven. AB and JH were responsible for drafting the manuscript. All authors have read, commented on and approved the final version.

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