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DIABETIC Medicine

SYSTEMATIC REVIEW

Health-related quality of life assessment in health economic analyses involving type 2 diabetes

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Abstract

Aim: Incorporating health-related quality of life (HRQoL) measures into health economic analyses can help to provide evidence to inform decisions about how to improve patient outcomes in the most cost-effective manner. The aim of this narrative review was to assess which HRQoL instruments have been used in economic evaluations of type 2 diabetes management including in Indigenous communities.

Method: MEDLINE (Ovid), Embase (Ovid) and Cochrane were searched from inception to June 2022. Studies included patients with type 2 diabetes; economic evaluations, derived scores from direct questioning of individuals; and were in English. Records were assessed for bias using the JBI critical appraisal tools.

Results: A total of 3737 records were identified, with 22 publications meeting the criteria for inclusion. Across those 22 articles, nine HRQoL instruments had been utilised. Generic tools were most frequently used to measure HRQoL, including EQ-5D (−3 L and −5 L) ($n = 10$, 38%); SF-12 ($n = 5$, 19%); and SF-36 ($n = 4$, 15%). Two tools addressing the specific stressors faced by people with type 2 diabetes were utilised: Problem Areas In Diabetes tool ($n = 1$, 4%) and Diabetes Distress Scale ($n = 1$, 4%). Two publications reported whether the study population included Indigenous peoples.

Conclusion: A wide range of HRQoL instruments are used in economic evaluations of type 2 diabetes management, with the most frequent being varying forms of the EQ-5D. Few economic evaluations noted whether Indigenous peoples were featured in the study population. More research into HRQoL in people living with type 2 diabetes is urgently needed to improve evidence on effectiveness and cost-effectiveness of interventions.

KEYWORDS
health economics, health-related quality of life, indigenous, type 2 diabetes

1 | INTRODUCTION

In 2021, an estimated 537 million people were living with type 2 diabetes worldwide,[1] a disease which is particularly prevalent in Indigenous communities.[2] Globally, type 2 diabetes is the ninth leading cause of mortality and accounts for 12% of global healthcare expenditure.[3,4] This burden is predicted to increase substantially in the future, with approximately 643 million people expected to be diagnosed with type 2 diabetes by 2030.[5] Related healthcare costs are predicted to rise by 53% over this time,[5] primarily due to the costs associated with premature morbidity, therapies used to manage glucose levels and hospital admissions relating to diabetes complications.[6]

Type 2 diabetes is associated with both costs to the healthcare system and impacts on patients' health-related quality of life (HRQoL). The latter includes the stressors of living with a relentless chronic illness, and worry, fear, sadness and anger regarding the emergence of diabetes complications and unpredictable blood glucose levels.[7,8] This is in addition to physical health, general psychological well-being, economic status and social interaction.[9] Measurement of HRQoL, an individual's ability to participate in activities of daily living and their own interpretation of their physical, mental and social well-being,[10] is a crucial element in economic evaluations of various healthcare interventions from clinical trials for diabetes, which weigh up costs of treatment with improvements in health. Measuring HRQoL allows both the impact of the disease on patients and the extent to which treatment improves patient-reported HRQoL, to be reflected in evaluations of the effectiveness and cost-effectiveness of treatments from clinical trials. This information is increasingly required as evidence from clinical trials to support coverage and reimbursement decisions.

Multiple HRQoL tools have been developed that measure self-reported HRQoL, and each includes an array of questions and answers that address elements of the physical, mental and social domains of health (see Table 1).[11]

Key points

- A wide range of health-related quality of life (HRQoL) instruments are being used in the economic evaluation of type 2 diabetes management, with the most frequent being varying forms of EQ-5D, followed by SF-12. There were two diabetes specific tools, 'Problem Areas in Diabetes' (PAID) and 'Diabetes Distress Scale' (DDS), however, these are non-preference weighted tools, limiting their ability to be used in an economic analysis.
- Few economic evaluations noted whether Indigenous peoples were featured in the study population; of the two that did, the Assessment of Quality-of-Life-4D or the SF-12 tools were used to measure HRQoL, and both were conducted in Queensland, Australia.
- More research into HRQoL in people living with type 2 diabetes is urgently needed in order to meaningfully assess and compare studies and interventions aimed at improving the lives of this population and reducing the burden on the healthcare systems.

HRQoL tools can be non-preference or preference-weighted, depending on the way questions and answers are scored. *Non-preference-weighted* tools assume equal importance between health domains or questions, with equal scoring intervals between responses provided.[12] Scores can be placed on a scale and used to detect fluctuations in HRQoL, but do not reflect the relative importance of the health problem being reported.[13] *Preference-weighted* tools assign different values to answers, based on scoring algorithms developed using stated preference studies (typically undertaken in general populations).[13] As the physical, mental and social elements of health assessed by these tools will not all have the same impact on

TABLE 1 Examples of HRQoL tools and included elements.

	Physical	Mental	Social	Pain	GHP	Emotional	Vitality	Treatment
EQ-5D	Y	Y	–	Y	Y	–	–	–
SF-12	Y	Y	Y	Y	Y	Y	Y	–
SF-36	Y	Y	Y	Y	Y	Y	Y	–
HUI-2/3	Y	Y	–	Y	–	Y	–	–
SF-6D	Y	Y	Y	Y	–	–	Y	–
DHP	Y	Y	Y	Y	Y	–	–	–
DDS	–	Y	Y	–	–	Y	Y	Y
PAID	–	Y	Y	–	–	Y	Y	Y
AQoL-4D	Y	Y	Y	–	Y	–	–	–

Abbreviations: AQoL-4D, Assessment of Quality-of-Life 4D; DDS, Diabetes Distress Scale; DHP, Duke Health Profile; GHP, General health perception; HRQoL, Health-related quality of life; HUI-2/3, Health Utility Index Mark 2 and Mark 3; PAID, Problem Areas In Diabetes; SF-12, 12-item short-form health survey; SF-36, 36-item short-form health survey; SF-6D, Short-form six-dimension; Y, Yes.

HRQoL, the use of algorithms allows for values to be assigned to answers that reflect what the population deems to be important for HRQoL and calculation of health state utilities.

Health state utilities represent the strength of individuals' preferences for different health states and are determined using an algorithm that represents the average stated preferences of a given population (usually the adult general public). Because the direct methods to measure health utilities such as Standard Gamble and Time Trade-Off are time-consuming and can be challenging for people with cognitive impairment,[14] preference-weighted HRQoL instruments in the form of multi-attribute scoring systems are widely used in health economic evaluation.[15] Health state utilities are reported on a scale anchored at 1 (representing perfect health) and 0 (representing dead), as required for the estimation of quality-adjusted life years (QALYs).

HRQoL can also be calculated in combination with healthcare economic analyses, to help clinicians decide how best to improve patient outcomes in the most cost-effective way. There are several ways to do this (see Appendix S1) including cost-utility analyses, which compare different health interventions with different health outcomes across various disease states.[16,17] This analysis requires a common outcome measure, which is QALYs.[18] QALYs are a measure of health that combines quality of life (QoL), as reflected by health state utilities, and quantity of life, as the number of years lived, into a single metric.[19] As QALYs are calculated by multiplying health state utilities with years of life, an individual with full health who lives for a short duration can have equivalent QALYs to an individual with poorer health and a longer lifespan.[20]

Whilst such health economic evaluations can help to ensure that maximal health gains are obtained for the money invested,[21] it is essential that these analyses accurately reflect the target population and the HRQoL issues pertinent to that group. When considering type 2 diabetes, it is unclear which HRQoL tools have been used in economic evaluation of therapies or whether they capture the challenges to HRQoL specific to the disease. Without this knowledge, the possibility of accurately comparing future health economic evaluations that consider HRQoL in this population is limited. This is especially imperative for Indigenous peoples with type 2 diabetes, as appropriate HRQoL measures are essential for addressing the disproportionate burden of disease within Indigenous communities.[22]

To address these gaps, this review aimed to identify which HRQoL tools have been used in economic evaluations of type 2 diabetes management, including in Indigenous communities.

2 | METHODS

A narrative review was conducted using rigorous processes and protocols adapted from the established systematic review methods outlined out by the Centre for Reviews and Dissemination, University of York.[23] Standards appropriate to a narrative review were applied.[24,25]

2.1 | Literature search

MEDLINE (Ovid), Embase (Ovid) and the Cochrane Library were searched by the first author (HS) from inception until June 2022 to identify relevant articles. The search strategy included the MeSH headings 'Diabetes Mellitus, Type 2'; 'Quality of life'; 'Health status'; 'Health care costs'; and 'Economics' and free-text search terms which were translated into Emtree headings for Embase

and is summarised in Appendix S2. Reference lists of all eligible studies were hand-searched.

Inclusion criteria:

- Studies including patients with type 2 diabetes only.
- Economic evaluation, including studies of the healthcare costs of interventions for type 2 diabetes.
- Both preference- and non-preference-weighted HRQoL tools that derive scores from direct questioning of individuals, rather than being extrapolated from a clinical value (e.g., HbA1c) or predicted through simulation modelling.
- English language studies only, due to lack of resources for translation.

2.2 | Data extraction and synthesis

All records were downloaded to Covidence™ and screened for eligibility by first author (HS) through reading titles and abstracts. Full texts were retrieved and reviewed by the first author (HS) to ensure they met the inclusion criteria. During a full-text read, the following data were extracted: HRQoL tools used, economic evaluations, if Indigenous participants were noted, duration of study, population, study aim and limitations. Data were extracted to a purpose-designed spreadsheet in Microsoft Office Word™ based on relevant elements (see Appendix S3). Based on the extracted results textual summaries, tables and figures were developed.

2.3 | Quality appraisal

Relevant records were reviewed using the Joanna Briggs Institute (JBI) critical appraisal tool relevant to that study; quality appraisal outcomes can be viewed in Appendix S4 and Data S1. A sample of the included papers were double extracted by research team members, with consistency found in data extraction.

3 | RESULTS

3.1 | Search outcomes

A total of 3737 records were identified, downloaded to Covidence™ and screened by reading titles and abstracts. Of these, 1280 records were excluded as duplicates and a further 2332 were excluded for not meeting the inclusion criteria. The remaining full-text records ($n = 125$) were re-assessed for eligibility and 103 did not meet the inclusion criteria, leaving 22 relevant records. See Figure 1.

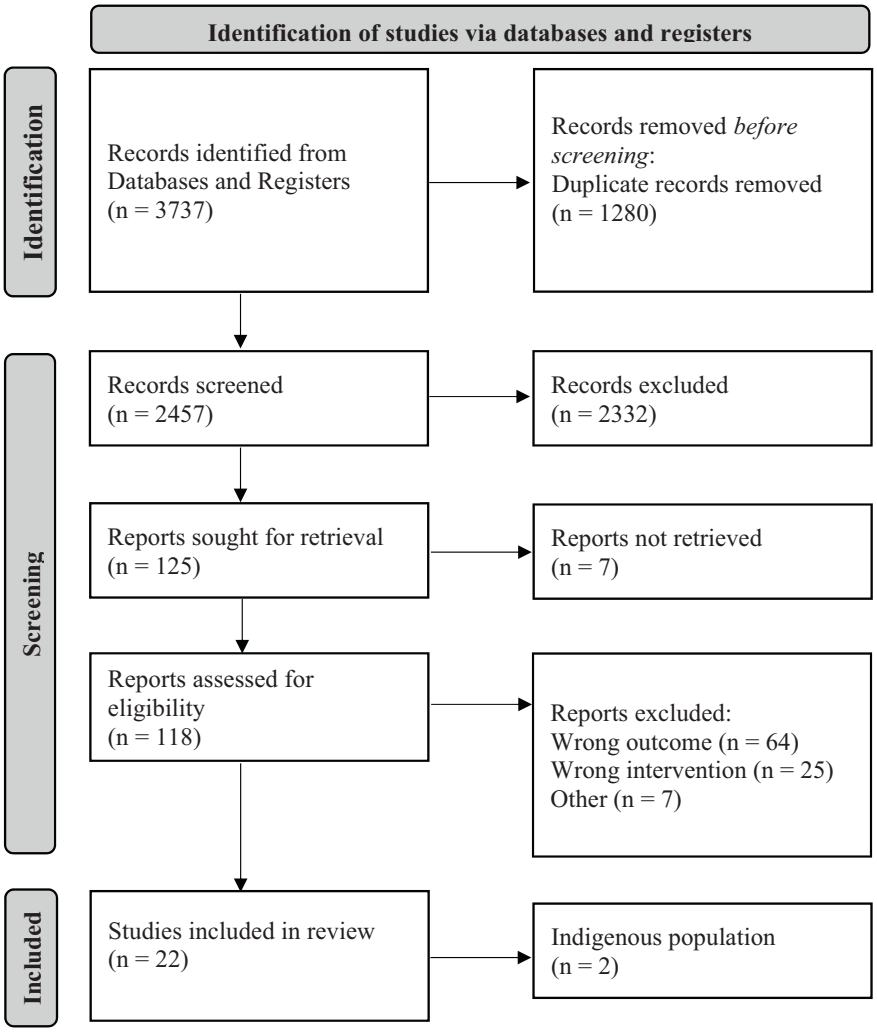
3.2 | HRQoL tools

Across the 22 included studies, nine different HRQoL tools were utilised (see Table 2). A brief description of these tools is found in Table 3. The most utilised HRQoL tool was the EQ-5D (38%)[26]; eight studies used EQ-5D-3L,[27–34] and two utilised EQ-5D-5L[35,36] (see Figure 2). The EQ-5D (−3 L and −5 L versions) was used in studies conducted across 14 countries and was presented to participants in the primary language spoken including English, Spanish, Bengali, Dutch, French, German, Czech and Italian. The second most utilised tool was the 12-item short-form health survey (SF-12).[37] It featured in five (19%) studies[34,38–41] which were conducted in predominately English-speaking countries (the United States of America, Canada and Australia). One of these studies[39] provided a Spanish translator to help participants completing the SF-12; for the other studies, an ability to read and understand English was an inclusion criteria.

Of the 22 studies included, four[29,30,34,42] used multiple tools to judge HRQoL and results between the tools were not always congruent. For example, the 36-item short-form survey (SF-36)[43] and EQ-5D (−3L and −5L versions) were used to estimate HRQoL in individuals with type 2 diabetes versus normal glucose tolerance, with individuals with type 2 diabetes reporting a significantly lower HRQoL.[29] However, the SF-36 recorded lower mean values (0.81 normal glucose tolerance vs. 0.77 individuals with type 2 diabetes) than the EQ-5D-3L (0.92 normal glucose tolerance vs. 0.86 individuals with type 2 diabetes). Another study[42] also reported discrepancies in HRQoL measured using two different tools, when assessing the cost-effectiveness of an intensive lifestyle intervention versus usual care in overweight individuals with type 2 diabetes. When using the short-form six-dimension (SF-6D) tool,[44] there was a 0.02 difference in values between people receiving the intervention versus standard care ($p < 0.01$). However, when using the Health Utility Index Mark 2 (HUI-2)[45] and Health Utility Index Mark 3 (HUI-3),[46] the difference in mean HRQoL between groups was not significant (−0.003 for HUI-2 [$p = 0.28$]; 0.00 for HUI-3 [$p = 0.99$]).

Two HRQoL tools were tailored to the unique stressors faced by people with type 2 diabetes: the Problem Areas In Diabetes (PAID) scale[47] and the Diabetes Distress Scale (DDS).[48] The PAID scale features twenty questions relating to diabetes distress and was used in a study assessing the cost-effectiveness of a web-based, self-monitoring programme versus usual care for type 2 diabetes.[30] No significant difference in HRQoL was found between groups when assessed using the PAID scale or the EQ-5D-3L. The DDS includes seventeen questions across four areas: emotional burden, regimen distress, distress caused by physicians and interpersonal distress. It was used in a study comparing a

FIGURE 1 Prisma flow chart.[28]



Mediterranean lifestyle programme with usual care for people with type 2 diabetes.[49] An improvement in the HRQoL of participants assigned to the intervention was found using the DDS, but was not significant (*no p value stated*).

3.3 | HRQoL measurement in economic evaluation

Nine (35%) studies used preference-weighted HRQoL tools to calculate of QALYs as part of their economic analyses. QALYs were calculated based on health state utilities obtained from the EQ-5D (−3 L or −5 L versions), SF-12, SF-36, HUI-2/3 and SF-6D.[27,28,30,35,39,42,50]

The algorithms used to calculate health state utilities in these studies were determined using various population studies. Most studies calculated health state utilities using algorithms derived from the stated preferences of populations in the United Kingdom (UK); however, only two of these studies were actually conducted in the UK.[30,32] Other studies conducted in Australia,[27] Bangladesh[28] and the United States of America[42] also used stated preferences from population studies in the UK to calculate health state utilities and QALYs.

Some studies conducted a cost-utility analysis whereby the incremental cost per QALY gained was used to determine the cost-effectiveness of the intervention compared to standard care.[27,28,30,35,42,50] For example, Li et al.[30] examined the cost-effectiveness of a web-based self-management programme for people with type 2 diabetes compared with usual care, with HRQoL determined using the EQ-5D-3L and the PAID scale. As the EQ-5D-3L is a preference-weighted tool, outcomes could be presented as QALYs. By comparison, the PAID scale is a non-preference-weighted tool with outcomes presented as a unit of change. An incremental cost-effectiveness ratio using the EQ-5D-3L data and UK value set[51] was calculated to be £5550 per QALY gained and £58 per unit of improvement using the PAID scale. Notably, neither instrument showed a statistically significant difference.

Multiple studies reported healthcare costs alongside HRQoL but did not use utility analysis methods.[29,31–34,36,38,40,41,49,52–56] For example, Markle-Reid et al.[40] compared a community-based intervention with usual care for people with type 2 diabetes and measured outcomes

TABLE 2 HRQoL tool used in each article.

Purpose	Tool
Adibe et al. 2013[45]	HUI-2/3
Balkrishnan et al. 2003[39]	SF-12
García-Pérez et al. 2022[38]	EQ-5D-5L
Hay et al. 2018[40]	SF-12
Hua et al. 2022[29]	EQ-5D-3L
Islam et al. 2020[30]	EQ-5D-3L
Janssen et al. 2020[31]	EQ-5D-3L and SF-36
Li et al. 2018[32]	EQ-5D-3L and PAID
Markle- Reid et al. 2018[41]	SF-12
Pawaskar et al. 2018[47]	SF-36
Pawaskar et al. 2018[48]	SF-36
Reed et al. 2018[33]	EQ-5D-3L
Rodriguez et al. 2019[34]	EQ-5D-5L
Segal et al. 2016[49]	AQoL-4D
Simon et al. 2008[35]	EQ-5D-3L
Tin et al. 2015[36]	EQ-5D-3L
Toobert et al. 2007[44]	DDS
Varroud-Vial et al. 2004[50]	DHP
Warren et al. 2018[42]	SF-12
Williams et al. 2012[37]	EQ-5D-3L and SF-12
Wu et al. 2018[51]	SF-36
Zhang et al. 2018[43]	HUI-2/3 and SF-6D

Abbreviations: AQoL-4D, Assessment of Quality-of-Life 4D; DDS, Diabetes Distress Scale; DHP, Duke Health Profile; HRQoL, Health-related quality of life; HUI-2/3, Health Utility Index Mark 2 and Mark 3; PAID, Problem Areas In Diabetes; SF-12, 12-item short-form health survey; SF-36, 36-item short-form health survey; SF-6D, Short-form six-dimension.

including the costs related to the intervention, overall healthcare and different resources.[40] The SF-12 was used to assess HRQoL, and a significant difference was found between the intervention and usual care groups at 6 months for individual general health ($p=0.02$), vitality ($p=0.06$) and mental health ($p=0.03$).[40] However, the SF-12 outcomes were not converted to health state utilities using the SF-6D, thus could not be applied to a utility analysis.

3.4 | Indigenous populations

Only two studies detailed the proportion of Indigenous participants in their study population; both were undertaken in Australia. Warren et al.[41] studied the effect of a telehealth intervention on the control of type 2 diabetes and reported the percentage of participants identifying as being Indigenous Australians in the intervention (13%) and control (14%) groups. This study was conducted in the city of Townsville in Queensland, where the traditional owners and custodians of the land are the Wulgurukaba people of Gurrumbilibarra country and the Bindal people of Thul Garrie Waja country. This study used the SF-12 tool, but failed to reach their recruitment target and had poor follow-up. In the other study,[54] all the participants identified as being Indigenous Australians. This study was conducted in twelve rural and remote Indigenous communities in the Cape York region of northern Queensland. It was an economic evaluation of an intensive management programme involving Indigenous health workers assisting Indigenous adults with poorly controlled type 2 diabetes and used the Assessment of Quality-of-Life 4D (AQoL-4D) tool. No significant difference was found between the intervention and control groups ($p=0.62$), but in both groups, an overall decline in HRQoL was reported. Notably, a study by Tin et al.[33] was conducted in the Solomon Islands and Nauru, but did not mention the percentage of participants who were Indigenous.

4 | DISCUSSION

4.1 | Major findings

This study aimed to determine which HRQoL instruments have been used in economic evaluations of type 2 diabetes management, including in Indigenous communities. Nine different tools assessing HRQoL in different ways were identified across 22 records. Indigenous populations with type 2 diabetes were poorly represented in these studies, with only two papers detailing the percentage of participants who were Indigenous. In all the studies, reduced HRQoL was found to be a major problem for individuals with type 2 diabetes when compared to those without the disease, but no single tool had been used to ascertain HRQoL.

The EQ-5D (−3L or −5L versions) was most frequently used to measure HRQoL (38%), followed by the SF-12 (19%) and SF-36 (15%). With the use of health state utilities, these tools can be used to estimate QALYs and used in economic analyses. Notably, for the SF-12 and SF-36 which are non-preference-weighted, this process requires the SF-6D.[57] PAID and DDS were the only tools used that were specific for type 2 diabetes and were both non-preference-weighted tools. Although they could not be used in utility analysis, they could still be converted into an incremental cost-effectiveness ratio.

4.2 | Implications of study findings

The use of multiple HRQoL tools makes it difficult to compare studies and interventions aimed at impacting

TABLE 3 Overview of HRQoL tools.

Tool	Questions (responses)	What is assessed	Outcomes
AQoL-4D	12 (4)	Independent living, relationships, mental health, senses	• Preference-weighted • Raw scores: range 12–48, higher score = reduced QoL • Utility[a]: range −0.04 – 1
DDS	17 (6)	Emotional distress, interpersonal distress, regimen-related distress, physician-related distress	• Non-preference-weighted • Range:1–6, higher score = reduced perception of QoL, 2–2.9 = moderate distress, ≥3 = high distress
DHP	17 (3)	Physical, mental, social, general, perceived health, self-esteem, anxiety, depression, pain, disability	• Non-preference-weighted • Range 0 – 100, higher score = greater QoL
EQ-5D	5 + VAS (3/5)	Mobility, self-care, usual activities, pain, discomfort, anxiety, depression, perception of personal health with VAS	• Preference-weighted • Utility[a]: range −0.654 – 1 • VAS: range 0 – 100, higher score = greater QoL
HUI-2[b]	15/40 (3–5)	Sensation, mobility, emotion, cognition, self-care, pain, fertility	• Preference-weighted • Utility[a]: range −0.36 – 1
HUI-3[b]	15/40 (3–6)	Vision, hearing, speech, ambulation, dexterity, emotion, cognition, pain	• Preference-weighted • Utility[a]: range −0.03 – 1
PAID	20 (5)	Social situations, food, friends, family, diabetes treatment, relationships with healthcare professionals, social support	• Non-preference-weighted • Range 0 – 100, higher score = greater diabetes distress, scores≥40 = severe diabetes distress
SF-12[c]	12 (3–5)	Limits in physical, social and usual role activities due to physical or emotional problems, bodily pain, mental health, vitality, general health perception	• Non-preference-weighted • SF-6D to calculate utility scores • Range 0 – 100, higher scores = better physical and mental health
SF-36[c]	36 (2–6)	Limits in physical, social and usual role activities due to physical or emotional problems, bodily pain, mental health, vitality, general health perception	• Non-preference-weighted • SF-6D to calculate utility scores • Range 0 – 100, higher scores = better physical and mental health
SF-6D[c]	11 (3–5)	Physical function, social function, role limitations, pain, mental health, vitality	• Preference-weighted • Range 0.296 – 1, 0 = heath equal to death, 1 = perfect health

Abbreviations: AQoL-4D, Assessment of Quality-of-Life 4D; DDS, Diabetes Distress Scale; DHP, Duke Health Profile; HUI-2, Health Utility Index Mark 2; HUI-3, Health Utility Index Mark 3; PAID, Problem Areas In Diabetes; QoL, Quality of life; SF-12, 12-item short-form health survey; SF-36, 36-item short-form health survey; SF-6D, Short-form six-dimension; VAS, visual analogue scale.

[a]Utility-weighted scores: 0 = heath equal to death, 1 = perfect health and <0 = health worse than death.

[b]HUI-2 and HUI-3 are used together but are separate tools.

[c]SF-12 and SF-6D are shortened variations of the SF-36.

HRQoL in this population, for several reasons. Firstly, the various tools used to measure HRQoL may not necessarily measure the same HRQoL constructs and dimensions and may differ in their specificity, sensitivity and relevance to type 2 diabetes. This is highlighted in Zhang et al.,[42] where a statistically significant difference in HRQoL was found using SF-6D instrument but in the same population no difference was found using the HUI-2/3 instruments, and raises the question as to which result most accurately reflects HRQoL within this population. These differences can be attributed to the difference in questions asked as HUI-2/3 is more sensitive to changes in physical functioning and sensation, whereas SF-6D captures role limitations that are not addressed in HUI-2/3.[58] Secondly, the instruments may differ in terms of the characteristics and properties of the utilities used to preference weight the health state descriptions.

The EQ-5D (−3L and −5L versions), SF-12, SF-36, SF-6D and HUI-2/3 have many strengths and provide a generic measure of HRQoL. Although these tools are

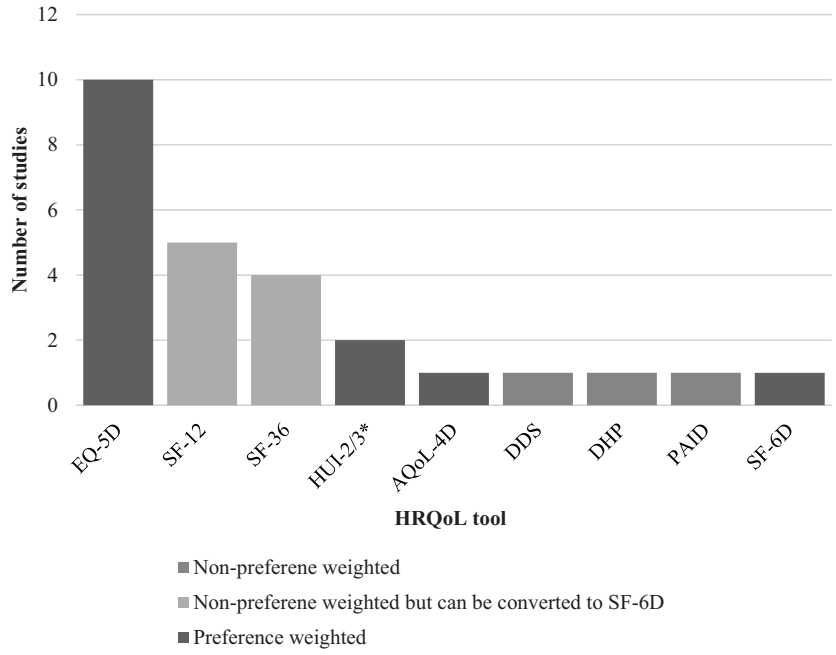


FIGURE 2 HRQoL tools featured in economic analyses involving type 2 diabetes.

	EQ-5D	SF-12	SF-36	HUI-2/3	AQoL-4D	DDS	DHP	PAID	SF-6D
Percentage of total	38%	19%	15%	8%	4%	4%	4%	4%	4%

not specific to type 2 diabetes, they have been validated for use in this populations with type 2 diabetes in several studies[59–62] and have been used globally to assess HRQoL in a range of chronic health conditions including asthma[63] and heart disease.[64,65] However, these tools may not capture the unique complications and concerns faced by people with type 2 diabetes. For example, poor quality sleep is associated with reduced HRQoL[66] and individuals with type 2 diabetes are at greater risk of developing a sleep disorder[67]; however, sleep quality is not explicitly assessed in generic HRQoL instruments. Managing and living with type 2 diabetes can have an emotional toll that results in varying degrees of diabetes distress.[68] For example, individuals often feel unsupported and uncomfortable in social situations and healthcare appointments due to the negative stigma of type 2 diabetes,[69] and strict regulation of blood glucose can cause anxiety around mealtimes and fear of potential hypo- or hyper-glycaemic events.[70] Only two studies used disease-specific instruments DDS[49] and PAID scale,[30] to measure HRQoL with both tools focusing on issues specific to individuals with type 2 diabetes.[47,48] Questions address concerns about diet, hypoglycaemia, treatments, support, long-term co-morbidities, and the impacts of type 2 diabetes on day-to-day life. Both tools have been validated for use in health practice.[71,72] However, neither tool was specifically designed to assess overall HRQoL, and both the DDS and PAID scale are non-preference-weighted, therefore do not allow estimations of QALYs.

As populations differ in the significance that they place on different elements of HRQoL, the population whose stated preferences are used to determine utility should reflect the local setting in which the HRQoL instrument will be used. This is not always achievable; therefore, health state utilities might not adequately reflect the values of the population being assessed.[27,28,42] For example, a study[28] undertaken in Bangladesh using the EQ-5D-3L obtained preference-weighted data from Bangladeshi patients, but used stated preferences elicited from a primarily Anglo-Saxon population in the United Kingdom. Individuals with chronic health conditions, such as type 2 diabetes, could potentially place a different weight on specific health domains compared to the general population and yet there are limited stated preferences that are based on a population with a specific health condition. Consequently, there is ongoing debate as to whether patient preferences or general public preferences are the most appropriate basis for calculating QALYs, with suggestions that both should be calculated if feasible.[73] For health state utilities to be as accurate as possible, further research is needed to determine stated preferences scores not only for different

populations but also for varying populations with type 2 diabetes.

It is well established that Indigenous peoples are disproportionately impacted by type 2 diabetes and the associated co-morbidities,[74] thus should be a major focus of type 2 diabetes health economics research. The results of this review emphasise that unfortunately, this is not the case. Across the 22 articles, only 2 papers mentioned Indigenous populations and they were both Indigenous Australians based in Queensland. The lack of studies addressing HRQoL measures in Indigenous peoples could be contributing to worsening outcomes, because data upon which economic analysis and associated decisions are based may fail to reflect HRQoL considerations unique to Indigenous cultural perspectives. Indigenous populations are very diverse and come from a wide range of backgrounds that vary in cultural practices and values. It is therefore not appropriate to sample a small population who live in close proximity and then apply those findings to all Indigenous people within the same country or globally. Further research involving HRQoL in Indigenous peoples with type 2 diabetes and their stated preferences is urgently needed.

4.3 | Relevance to clinical practice

Whilst there are an array of interventions for type 2 diabetes that can improve physical outcomes, a key goal should be improving an individual's HRQoL. Interventions that improve a patient's HRQoL have greater adherence rates, thus are a better investment.[75] A systematic review[76] examining the influence of HRQoL on treatment adherence in patients with diabetes mellitus found a positive association between HRQoL and adherence with type 2 diabetes treatments. This suggests that interventions impacting HRQoL also influence adherence rates, which is an important consideration for healthcare providers. As HRQoL improvement is a strong predictor of adherence, this should be taken into consideration when allocating resources.[77]

4.4 | Comparison with other studies

A systematic review of instruments designed specifically to measure HRQoL in individuals with type 2 diabetes (e.g., PAID) found 17 papers, and each study used a different tool.[78] There was no discussion about whether these tools could be incorporated into economic analyses or QALY calculations and no reference to Indigenous peoples.[78] The review found variations in the content of each instrument and encouraged the use of diabetes specific HRQoL instruments in future studies to further the understand of these differences and their effect on different populations. The review discussed the need to examine the effects ethnicity has on diabetes specific HRQoL instruments and to determine the validity of these scales in developing countries.[78] Our review echoes the conclusion that more research is needed into existing diabetes specific HRQoL tools and their validity in specific populations with type 2 diabetes, especially Indigenous peoples. This could include the use of both generic and diabetes specific tools in parallel, to facilitate investigation of the extent to which generic HRQoL tools adequately capture aspects of HRQoL most important to diabetes patients.

Besides type 2 diabetes, asthma is another chronic health condition that significantly impacts HRQoL and healthcare spending. A study comparing the EQ-5D-5L with an asthma-specific HRQoL questionnaire in individuals living with asthma concluded that the EQ-5D-5L was a reliable measure of HRQoL, but did not react to small changes in asthma control which were detected by the asthma-specific questionnaire.[79] Subsequently, it was suggested that supplementary measures to the EQ-5D-5L would provide a greater comprehensive evaluation of asthma interventions. Whilst the EQ-5D-5L is a good generic measure of HRQoL, for complex chronic diseases like asthma and type 2 diabetes tools that are tailored to disease-specific concerns provide a more accurate interpretation of HRQoL. One option could be to develop supplementary 'bolt-on' questions for the EQ-5D-5L, which would allow for additional items of HRQoL specific to type 2 diabetes to be considered. The use of 'bolt-ons' has been proposed as a way to improve the validity and responsiveness of HRQoL instruments in certain settings and health conditions.[80] This has been done in some other disease areas such as in psoriasis.[81] However, the rationale for doing this requires evidence on comparative psychometric performance that is beyond the scope of this review.

4.5 | Study limitations and strengths

The literature search was largely conducted by one individual, thus could be subject to researcher bias. However, random audits were undertaken (SJ) for which consensus was achieved. Another limitation was that a search of grey literature was not conducted nor were experts in the field contacted for unpublished data. Furthermore, the search was only conducted using three databases (MEDLINE (Ovid), Embase (Ovid) and Cochrane Library). Use of more databases may have highlighted additional records. However, the databases selected are premier life sciences and biomedical bibliographical datasets and the search conducted was systematic and thorough across the databases, using both indexed MeSH and free-text search terms which were translated into Emtree headings for Embase.

4.6 | Future directions

A standardised set of questionnaires to assess HRQoL in people living with type 2 diabetes is urgently needed, in order to meaningfully assess and compare studies and interventions aimed at improving the lives of this population and reducing the burden on the healthcare systems. Further evidence is required to understand how these instruments compare in terms of measuring HRQoL relating to type 2 diabetes. Use of generic instruments in parallel with type 2 diabetes specific instruments in future studies would assist in exploring the extent to which generic tools capture specific aspects of diabetes related problems which are important to patients.

Research is needed to determine which HRQoL metrics are of greatest importance to different populations with type 2 diabetes, including Indigenous peoples who were found to be underrepresented.

Investigations into whether preference-weighted instruments, such as EQ-5D, could be mapped accurately from disease-specific instruments, such as PAID, would be useful. Mapping techniques allow for EQ-5D results to be predicted from clinical symptoms, generic or condition-specific HRQoL instruments.[82] Such a mapping, if proved to have a high degree of accuracy, can be used to derive health utilities from studies that used only non-preference-weighted instruments for HRQoL measurements and allow for QALYs to be calculated.

5 | CONCLUSION

This narrative review revealed that a variety of standardised, generic tools are available to measure HRQoL for economic evaluations of treatments for type 2 diabetes. There was some evidence that these HRQoL tools may perform differently and yield different results. The HRQoL tools most commonly employed in the studies surveyed were the EQ-5D (−3L and −5L versions) and SF-12. Both are generic tools designed to measure HRQoL in a range of populations and have been validated for use specifically in individuals with type 2 diabetes. Both tools can be preference-weighted and converted to health state utilities used to calculate QALYs . By comparison, the DSS and PAID scale are specifically designed to measure the emotional and mental impacts of type 2 diabetes on participants, but do not consider an individuals' overall HRQoL and are non-preference-weighted.

This review found that Indigenous peoples with type 2 diabetes were poorly represented within the studies analysed and highlighted the need for greater research in Indigenous populations with type 2 diabetes, a population with high prevalence of diabetes and its complications. The use of generic instruments in parallel with type 2 diabetes specific instruments would assist in exploring what aspects of diabetes related problems are being captured or overlooked by generic instruments. These developments could potentially provide a holistic and relevant assessment of HRQoL in people with type 2 diabetes and provide data on the economic consequences of this disease for society. Urgent research is required as HRQoL and healthcare costs are important factors in making decisions on reimbursement or subsidisation of new treatment. With an expanding range of treatments available for type 2 diabetes, evidence is required to compare different treatment options in terms of improvements in HRQoL and incremental costs to determine their cost-effectiveness.

AUTHOR CONTRIBUTIONS

HS, SJ, EIE, ND and AT-D contributed to the study design, data acquisition, analysis and interpretation. All authors contributed to drafting and agreed upon the final manuscript.

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DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

STATEMENT

When conducting an economic analysis involving type 2 diabetes, there are a range of alternative instruments which can be used to measure patients' HRQoL, making it challenging to compare findings from clinical studies and trials. This manuscript explores which HRQoL instruments are currently being used in economic evaluations

of interventions relating to type 2 diabetes and found a wide range of tools that varied in terms of which aspects of HRQoL are assessed and their ability to be used in an economic analysis. These observations will stimulate further work into HRQoL tools in economic analyses involving type 2 diabetes, contributing to improved allocation of limited resources in type 2 diabetes care.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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