



Aalborg Universitet

AALBORG UNIVERSITY
DENMARK

Assessing the impact of diabetes on quality of life

what have the past 25 years taught us?

Speight, J; Holmes-Truscott, E; Hendrieckx, C; Skovlund, S; Cooke, D

Published in:
Diabetic Medicine

DOI (link to publication from Publisher):
[10.1111/dme.14196](https://doi.org/10.1111/dme.14196)

Publication date:
2020

Document Version
Accepted author manuscript, peer reviewed version

[Link to publication from Aalborg University](#)

Citation for published version (APA):

Speight, J., Holmes-Truscott, E., Hendrieckx, C., Skovlund, S., & Cooke, D. (2020). Assessing the impact of diabetes on quality of life: what have the past 25 years taught us? *Diabetic Medicine*, 37(3, Special Issue), 483-492. Advance online publication. <https://doi.org/10.1111/dme.14196>

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal -

Take down policy

If you believe that this document breaches copyright please contact us at vbn@aub.aau.dk providing details, and we will remove access to the work immediately and investigate your claim.

PROFESSOR JANE SPEIGHT (Orcid ID : 0000-0002-1204-6896)
DR ELIZABETH HOLMES-TRUSCOTT (Orcid ID : 0000-0001-9139-4663)
DR CHRISTEL HENDRIECKX (Orcid ID : 0000-0002-0075-828X)
DR DEBBIE COOKE (Orcid ID : 0000-0003-1944-7905)

Article type : PSAD Special Issue Paper

Title: Diabetic Medicine
Created by: Maria Davie
Email proofs to: jspeight@acbrd.org.au
Article no.: DME-2019-00673
Accepted Date: 27 November 2019
Short title/Authors running head: Impact of diabetes on quality of life
• *J. Speight et al.*

Assessing the impact of diabetes on quality of life: what have the past 25 years taught us?

J. Speight^{1,2}, E. Holmes-Truscott^{1,2}, C. Hendrieckx^{1,2}, S. Skovlund³ and D. Cooke⁴

¹School of Psychology, Deakin University, Geelong and ²Australian Centre for Behavioural Research in Diabetes, Diabetes Victoria, Melbourne, Victoria, Australia, ³Steno Diabetes Centre Northern Denmark, Aalborg University Hospital, Department of Clinical Medicine, Aalborg University, Aalborg, Denmark and ⁴University of Surrey, Guildford, UK

Correspondence to: Jane Speight. E-mail: jspeight@acbrd.org.au

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/DME.14196

This article is protected by copyright. All rights reserved.

What's new?

- Quality of life (QoL) is a multidimensional, subjective and dynamic construct that is recognized as an important outcome in its own right.
- It remains a challenge to assess the impact of diabetes on QoL with a standardized tool, balancing comprehensiveness, subjectivity and brevity.
- Monitoring well-being and providing psychological care is recommended in diabetes guidelines, but there is no recommendation to assess QoL or guidance on how to assess this.
- This review highlights several gaps in research and clinical practice, which need to be addressed if we are to improve the QoL of people with diabetes.

Abstract

Over the past 25 years, there has been significant acknowledgement of the importance of assessing the impact of diabetes on quality of life. Yet, despite the development of several diabetes-specific quality-of-life measures, the challenges we faced in 1995 remain. There is little consensus on the definition of quality of life because of the complexity and subjectivity of the concept. General quality of life comprises several domains of life, and these are highly individualized. Assessing the impact of diabetes on these life domains adds to the complexity. While comprehensive diabetes-specific quality-of-life measures typically increase respondent burden, brief questionnaires may not capture all relevant/important domains. Today, the lack of resolution of these challenges may explain why the impact of diabetes on quality of life is not systematically assessed in research or clinical care. Few researchers report detailed rationales for assessment, there is often a mismatch between the concept of interest and the measure selected, and data are misinterpreted as assessing the impact of diabetes on quality of life when, in reality, related but distinct constructs have been assessed, such as diabetes distress, treatment satisfaction or health status. While significant efforts are being made to increase routine monitoring of psychological well-being and understand the lived experience, no guidelines currently recommend routine clinical assessment of diabetes-specific quality of life, and there is no

consensus on which questionnaire(s) to use. The gaps identified in this review need urgent attention, starting with recognition that assessment of diabetes-specific quality of life is as important as biomedical markers, if we are to improve the lives of people with diabetes.

Introduction

*The shoe that fits one person pinches another;
there is no recipe for living that suits all cases*

(Carl Jung)

Living with diabetes requires life-long self-care, demanding a high commitment from the individual if both long-term health and quality of life (QoL) are to be protected. In this context, QoL is the ultimate goal. However, the demands of diabetes self-management do not sit easily with the unpredictable and high-paced nature of modern life. Indeed, there is often a conflict between what is required for optimal daily diabetes self-management and optimal daily QoL. While health professionals focus on the long-term benefits of maintaining optimal glucose levels, most people with diabetes are 'more concerned about the immediate demands of intensive treatment and tend to lose sight of possible future benefits' [1]. So, protecting QoL is not only the ultimate goal but also a daily goal, and one that can conflict directly with biomedical goals. In a society increasingly focused on instant gratification, we continually ask people with diabetes to subscribe to delayed gratification, sacrificing today's QoL for the promise of tomorrow's. However, it is *not* a promise and it is *not* tomorrow. It is a *hope* that managing diabetes carefully over many, many years will ultimately result in nothing—no complications—just life as other people without diabetes might reasonably expect. Therefore, to ensure that interventions are tailored to suit the individual and protect what matters to them, we need to value and assess the impact of diabetes and its treatment on QoL. Most people have some sense that QoL is important and, intuitively, have some understanding of what it means to them. Therein lies both the opportunity and the challenge.

In this review, we present a brief history of how the impact of diabetes on QoL has been conceptualized and operationalized, identifying ongoing challenges in its measurement in research and clinical practice. We describe and critique a selection of generic and diabetes-specific measures, which were either designed with the intention of assessing the impact of diabetes on QoL or have been interpreted as doing so in landmark studies and, therefore, represent key developments over the past 25 years.

What we knew in 1995

Many measures have been developed to assess quality of life.

The strategies underlying these measures vary considerably

(The DCCT Research Group [2])

Theoretical exploration of the concept of QoL began in the mid-20th century and reflects a number of intersecting phenomena: the rise of the biopsychosocial model [3]; the rise of the 'patient' as an active 'consumer' of healthcare; and the changing face of global health. The demise of acute conditions and the growth of an aging population with long-term conditions required a focus not so much on 'cure', but on living well [4]. In this climate, interest in QoL assessment expanded rapidly 'as a valid indicator of whether or not a medical treatment is beneficial' [5], but universally accepted definitions remained elusive. It may seem obvious that QoL is a personal evaluation of how good or bad one's life is [6], but attempts to agree a more operational definition have had limited success. For some, QoL is the degree to which human needs (e.g. health, mobility, food, shelter) are met [7]. For others, it is clear that having one's basic needs met does not equate to a quality life: a 'life worth living'. Alternatively, Calman's 'expectations model' (known as 'Calman's Gap') suggests that QoL is the difference between an individual's hopes and/or expectations and their current experience [8]. This definition has inherent appeal, as it is concerned with an individual's own assessment of what he/she wants from life rather than what they need in their life.

A tale of two studies: the impact of diabetes treatment intensification on quality of life

Developed in the late 1980s for inclusion in the landmark Diabetes Control and Complications Trial (DCCT), the Diabetes Quality of Life (DQOL) questionnaire [2] was the first measure to assess diabetes-specific QoL. The DCCT Research Group noted that 'because intensive treatment would carry additional demands... it was anticipated that this might affect the quality of life of patients' [9]. Designed 'to address patient-perceived personal burden of the trial' [2], the DQOL includes four scales (Satisfaction, Impact, Diabetes Worry, Social/Vocational Worry). The DCCT terminated early, with overwhelming evidence favouring the benefits of intensive insulin therapy for the prevention of complications in people with type 1 diabetes. The DQOL showed that intensive insulin therapy did not impair QoL compared with standard treatment [10]; however, it was also reported that intensified treatment was associated with a significant, threefold increase in severe hypoglycaemia. With everything that was known about the burden of intensive insulin therapy and severe hypoglycaemia, the responsiveness of the DQOL and the validity of the conclusions drawn were called into question [11].

Meanwhile, in the UK, another large-scale landmark trial was also about to conclude. When the UK Prospective Diabetes Study (UKPDS) began in the late 1970s, there were no diabetes-specific measures of QoL available. So, researchers included a newly developed generic scale: the EQ-5D [12]. The EQ-5D has five questions about mobility, self-care, usual activities, pain/discomfort and anxiety/depression, and a 'thermometer' scale for rating 'my health today'. The EQ-5D detected significant differences between people with and without macrovascular complications (although not microvascular complications), but not between people randomized to different treatment regimens (intensive vs conventional). Thus, UKPDS researchers concluded that the 'therapies can be given according to clinical requirements without undue concern about adverse effects on QoL' [12]. However, the EQ-5D was designed to assess general health status not general QoL. In reality, the UKPDS had found no detectable differences in perceived *health*, and the impact on QoL was not measured [11].

Those early and prominent attempts to assess the impact of novel diabetes treatment regimens on QoL were visionary and commendable. However, they were also met with considerable and well-founded critique regarding the operationalization of the concept of QoL, which misled the research and clinical communities into thinking that intensive and conventional approaches to diabetes management were equivalent in their impact on QoL. With hindsight, it is clear that the EQ-5D, a measure of generic health not QoL [12], should not be expected to differentiate two forms of diabetes treatment (injections vs tablets). Subsequently, it had been demonstrated that the aspects of life commonly considered to be important for QoL include family, friends and work/school, and only a minority suggested health as important for QoL, even when they had a significant health condition, such as diabetes [6]. While the DCCT researchers designed a questionnaire that focused on the impact of diabetes, they took a functional approach. They included a mix of items, whereby some items (e.g. worry about ‘getting complications’) might be expected to raise concerns among those allocated to standard treatment, while others (e.g. worry about ‘losing consciousness’) might be expected to raise concerns among those allocated to intensified treatment. Consequently, examining total scores, rather than individual item scores, is likely to have masked the impact of the therapies on QoL [11]. Furthermore, the DQOL included many generic items (e.g. ‘how satisfied are you with your sex life?’), where an attribution to the impact of diabetes (or its treatment) was not invited [2].

What has the past 25 years of research shown?

*Quality of life research in diabetes will realise its full potential
when [we can] design, implement, and evaluate interventions
which influence factors that may affect quality of life.*

(Rubin and Peyrot [13])

Confusion about the concept of quality of life

While QoL has become a buzzword in healthcare research, there is considerable confusion in the literature and little consensus about how to assess generic QoL or diabetes-specific QoL. For

example, the Australian Centre for Quality of Life's directory of instruments includes no fewer than 1200 measures, each purporting to measure QoL in some form, and each containing a unique mixture of dependent variables [14]. Few papers report a detailed rationale for assessment, and then often match the wrong measure to the concept of interest, misinterpreting their data as measuring the impact of diabetes on QoL when, in reality, they have assessed treatment satisfaction, health status or diabetes distress. While these errors were noted in a 2009 review [15], there is little evidence that this situation has improved. Further, as Polonsky noted two decades ago [16], researchers and clinicians appear to apply one or more of three criteria when attempting to assess the impact of diabetes on QoL. They: 1) use whatever has been used in other studies; 2) consider QoL to be an 'umbrella' construct for psychological health (e.g. depression, well-being) and then use any instrument that appears to have reasonable psychometric properties; and 3) use any questionnaire that includes 'QoL' in the title or has been referred to as 'QoL' in a previous paper.

Second generation measures of diabetes-specific quality of life

In the mid-late 1990s, recognizing that the DQOL was low on sensitivity and responsiveness, two European research groups developed a second generation of diabetes-specific QoL measures: the DSQOLS (Diabetes-Specific Quality Of Life Scale) [17] and the ADDQoL (Audit of Diabetes-Dependent Quality of Life) [18].

Like the DCCT researchers before them, when designing the DSQOLS [17], Bott *et al.* took a functional approach to explaining specific aspects of diabetes that might impact upon aspects of QoL. Designed specifically for people with type 1 diabetes, the DSQOLS included 44 items measuring the impact of diabetes on 'social relations', 'leisure time flexibility', 'diet restrictions', 'physical complaints', 'daily hassles', 'worries about the future' and a further 20 items measuring treatment satisfaction. Like the DQOL, there was a mix of generic and diabetes-specific items (e.g. 'I feel physically ill', 'Because of my diabetes my family life is affected'). There was no opportunity for respondents to indicate that an aspect of life was 'not applicable' or that one aspect of life was of greater personal importance than another. The DSQOLS has been validated in English [19], and has

demonstrated the immediate and sustained (up to 1 year) effects of a structured diabetes education programme, administered in routine care [20].

In their design of the ADDQoL [18], Bradley *et al.* attempted to remain true to the theory underpinning generic QoL research by exploring the impact of diabetes on domains of life important to the individual. To generate questionnaire items, they used the Schedule for the Evaluation of Individual Quality of Life (SEIQoL) method. This involved undertaking person-centred interviews with 12 adults with diabetes to determine the aspects of life important for their QoL and impaired by having diabetes. They identified 13 domains: ‘working life’, ‘social life’, ‘family life’, ‘friendships’, ‘sex life’, ‘holidays and leisure activities’, ‘travel’, ‘worries about own future’, ‘worries about future of others’, ‘motivation to achieve things’, ‘physical activities’, ‘others fussing’ and ‘enjoyment of food’. The ADDQoL was framed such that respondents were first asked to respond to a statement such as: ‘If I did not have diabetes, my [insert domain] would be’ (from ‘very much better’ to ‘very much worse’ on a seven-point scale, with ‘not applicable’ (N/A) options available for 10 of the 13 items). Next, they rated how important each domain was to their overall QoL (from ‘very important’ to ‘not at all important’, on a four-point scale). The widespread use of the N/A options (e.g. 44% for employment) confirmed the need to offer people the option to indicate when an aspect of life is not relevant to them. The wide variation in the importance ratings provided evidence of the need to weight QoL domains [18]. Overall, the aspect of life most negatively impacted by diabetes was ‘enjoyment of food’, and this was more marked for people with insulin-treated than non-insulin-treated diabetes [18]. The validity of this finding was supported elsewhere in the literature [21, 22].

Despite having a strong conceptual foundation and psychometric properties, the ADDQoL has also met with criticism. A key concern is the hypothetical nature of the item wording ('if I did not have diabetes...') [15]. In addition, some argue that weighting items is impractical and uninterpretable, as the responses from each individual do not "represent the same 'true' level of QoL" [23].

Recently, the impact of diabetes on key life domains was assessed in the second global Diabetes Attitudes Wishes and Needs (DAWN-2) study. The DAWN-2 Impact of Diabetes Questionnaire (DIDP) questionnaire was designed through a multinational, multidisciplinary process, which aimed

to produce a brief, comprehensive, and universally relevant measure (i.e. for adults with type 1 or type 2 diabetes, across cultures), capable of capturing positive or negative impact. In contrast to the >40-item ADDQoL and DSQOLS, the DIDP measures the perceived impact of diabetes with six items: physical health; emotional health; financial situation; leisure; work; and family/social life [24]. Known-groups validity has been demonstrated for diabetes type, treatment type, and absence/presence of complications and severe hypoglycaemia [25,26], while responsiveness (sensitivity to change) is yet to be determined. The DIDP has been used to quantify and benchmark the impact of diabetes on people's lives across different life stages, types of diabetes and cultures, in 17 countries [27].

The development of the DIDP domains was informed by extensive previous research on the key life domains considered to be important for QoL for people with diabetes, and aligns with several of the most discriminatory items included in the ADDQoL [18]. Like the ADDQoL, the DIDP is an attributional measure, which means ratings do not reflect the actual level of the life domain but are based on the individual's attribution of the 'perceived impact' of diabetes on the life domain. High completion rates support that people with diabetes are able to make meaningful assertions of how diabetes impacts on the key life domains using the brief global DIDP items [26]. However, the prioritization of brevity may be at the cost of comprehensiveness and specificity. For example, the DIDP does not assess life domains shown to be compromised among adults with diabetes, and responsive to intervention, such as dietary freedom or independence [26].

Importance of theoretical underpinnings and rigorous design

In the past 15 years, the US Food and Drug Administration has provided guidance about the documentation required if questionnaires are to be used to support labelling claims for medicinal products [28]. If you wish to claim that a certain diabetes treatment improves QoL, then the development of the questionnaire will be heavily scrutinized to ensure that it does, indeed, assess what is claimed for the particular target population. It is insufficient to demonstrate satisfactory psychometric properties alone; a questionnaire needs to also have satisfactory face and content validity. For both the DQOL and the DSQOLS, there is almost no information in the development papers about how the questionnaires were designed [2,17]. We do not necessarily suggest that they

were not designed carefully (to the standard of their day) but, rather, that there is an absence of published evidence. Today, researchers need to answer the following questions, among others: What is the conceptual framework for the questionnaire? How were items generated and in which populations? To what extent do the items represent the concerns of people with diabetes (rather than the perceptions of their clinicians)? To what extent were the items debriefed with people with diabetes to determine ease of understanding, ease of completion, comprehensiveness, redundancy and omissions?

Realising the potential of quality-of-life research

In the late 1990s, a team of UK clinicians had observed that the German Diabetes Teaching and Treatment Programme (DTTP) had achieved impressive biomedical outcomes (reducing both HbA1c and severe hypoglycaemia, unlike the DCCT) that were sustained over several years [29]. They wanted to undertake a UK trial to determine whether similar effects could be achieved. The DTTP enabled a *flexible* intensive insulin regimen, but this had not been emphasized in the German descriptions, and its impact on QoL had not been assessed [30]. Meanwhile, emerging UK research showed that 'dietary freedom' and 'enjoyment of food' were the domains of life most negatively impaired by type 1 diabetes [17,31]. This suggested that the DTTP may produce QoL benefits, and this was counter-intuitive because of the intensive injections and finger-prick monitoring required [30]. Thus, the ADDQoL was included in the evaluation with the impact of diabetes on QoL noted as a co-primary endpoint. In other words, the trial would not be considered successful unless the intervention achieved a reduction in HbA1c *and* in the negative impact of diabetes on QoL. In the UK, the DTTP was renamed 'Dose Adjustment for Normal Eating' (DAFNE). The trial demonstrated that DAFNE reduced both HbA1c and the negative impact of diabetes on QoL, and also that 'general QoL' improved [32]. Such findings had never been observed in a diabetes trial. Referring to the DAFNE findings, Wolpert and Anderson wrote: 'the tools of intensive diabetes management should be presented to the patient as a means of increasing the freedom in their lives rather than simply as a means of intensifying glycaemic control' [1]. In the words of Rubin and Peyrot [13], QoL research had begun 'to realise its full potential'.

Where are the current gaps?

Researchers are striving to address a number of methodological issues in their efforts to study quality of life in people with diabetes

(Rubin & Peyrot [13])

Which measure of the impact of diabetes on quality of life should we use?

The extensive research on the impact of diabetes on QoL during the past 25 years has increased our understanding of the complexity of the impacts of diabetes on QoL, and an arsenal of related patient-reported outcome measures has been developed. It is beyond the remit of this review to provide specific recommendations about the best measure to select and, indeed, it is unlikely that any single measure will be appropriate in all circumstances. Table 1 distinguishes generic and diabetes-specific QoL with increasing specificity, i.e. at the global level, broad domains and specific domains. Table 2 provides an overview of considerations when selecting a generic or diabetes-specific measure, based on conceptual, psychometric and practical considerations.

Decisions about which measures to use for a particular purpose need to be taken in collaboration with people with diabetes and other key stakeholders based on the specific purpose for and context of making the assessment. A recent study has examined both the acceptability to people with diabetes and the psychometric properties of contemporary diabetes-specific QoL measures. It suggests the DIDP is the strongest measure across predetermined criteria, but properties such as responsiveness and predictive validity were not assessed in this cross-sectional study [33,34]. A full report will be published in due course and these findings need to be corroborated.

Ongoing measurement challenges

In the assessment of diabetes-specific QoL, we continue to justify the prioritization of some measurement attributes at the cost of others. For instance, the comprehensive ADDQoL and DSQOLS include a vast number of items, sacrificing brevity and potentially leading to user (participant and clinician) burden. Furthermore, while many of the DSQOLS' functional items are responsive to

changes in treatment [20], they more accurately assess the related, but distinct, concepts of diabetes distress and treatment satisfaction. In contrast, efforts have been made recently to reduce both the length and complexity of scales, including only those global dimensions shared by all and foregoing importance ratings (e.g. DIDP). However, brief scales potentially ignore important life domains identified in both qualitative and quantitative research [18,31]. The question of how many, and which, aspects of life needs to be considered in the assessment of quality of life remains unanswered.

Assessing the impact of diabetes on QoL using standardized measures acts to constrain both the assessed and expected ‘impact’. People with diabetes report difficulty in isolating the impact of diabetes, from other life factors, on QoL [34]. For example, while an individual may be able to reflect easily and quickly on how satisfied they are with their finances (a generic QoL dimension), it may be more difficult to reflect on the impact of their diabetes on their finances (e.g. DIDP), or consider if their financial situation would be better if they did not have diabetes (e.g. ADDQoL). With regard to response options, both the DIDP and ADDQoL include bi-directional response options, allowing either positive or negative responses. However, existing questionnaires do not allow for the possibility of a combination of both positive and negative impacts within a single domain. For example, diabetes may be perceived to negatively impact on health, but self-care activities since (such as dietary changes) may be perceived as having a positive impact on health. Thus, the respondent is required to average out the direction of the perceived impact in their response.

Populations with little evidence

Views about QoL and what it means vary naturally across the lifespan and across cultures. For this reason, it is vital that QoL measures are developmentally and culturally appropriate. The DAWN-2 study is one of the few that has compared the impact of diabetes across countries and cultures, with large variations identified [27]. This suggests that further work is needed to explain these findings and determine ways to minimize the variation.

In comparison with adults, we know less about the impact of diabetes on the QoL of children, adolescents, younger adults and older adults. It is clear that what matters for a child’s or adolescent’s quality of life (as well as how diabetes affects it) would be different from that of an adult, and that this

will change with age [35–37]. A systematic review of 17 studies examining QoL in children and adolescents with type 1 diabetes showed that generic QoL was no different from that of peers without diabetes, but that diabetes-specific impacts, e.g. on daily functioning and emotional well-being, were present [38]. In addition, young adults (with type 1 or type 2 diabetes) are specific sub-populations that may require modification of existing tools or development of new ones, as neither the paediatric nor adult measures may serve them well enough. Few studies are focused on older populations who have the highest prevalence of diabetes and are the fastest-growing section of the population [39].

Easy-to-use formats and enlarged fonts are critical when asking older adults to complete questionnaires [40]. The ADDQoL Senior [41] was developed taking into account formatting and age-specific changes to the domains of life assessed. This has shown that the greatest impact of diabetes is on ‘independence’ and ‘freedom to eat as I wish’.

Finally, there is a need to design and harmonize measurement frameworks to ensure that the diabetes-specific QoL for research and clinical purposes, through systematic collaboration with people with diabetes, carers and multi-stakeholder expert groups.

Translation/implementation

*QoL is such a subjective evaluation and so specific to the individual...
that there is no substitute for asking patients what is important to them, how
good these things are in their life and
how the elements of their life affect each other and their overall QoL*

(Walker and Bradley [37])

Quality of life is recognized as an important outcome in its own right but it is rarely assessed (well) in diabetes research and clinical practice. However, when the only outcomes measured by health professionals, systems and policy makers are biomedical (e.g. HbA_{1c}, lipids), interventions to support the person with diabetes will only be valued if they result in improved biomedical outcomes [42].

In clinical trials, the impact of new diabetes treatments/technologies on QoL has been reasonably well evaluated, but this could be more consistent and there are many instances where inappropriate tools have been used or their data misinterpreted as QoL [15]. There is a need for harmonization of measurement of the impact of new treatments/technologies on QoL in clinical trials; however, there remains no consensus or standards for which tools to use. An important recent development is the consensus on core patient-reported outcomes relevant for particular purposes in diabetes. The global International Consortium for Health Outcomes Measurement (ICHOM) diabetes standard set [43] includes: the WHO-5 (general emotional well-being), the Problem Areas in Diabetes (PAID; diabetes distress), and the Patient Health Questionnaire (PHQ-9; depressive symptoms). The recommendations to measure the outcomes of diabetes using these three measures were based on: 1) a consensus that the measures assess core outcomes established as important to people with diabetes, so-called 'patient-important' measures; and 2) pragmatic criteria of their broad scientific validation, multiple language versions, and being freely available. However, these strengths do not negate that the measures do not provide a theoretically grounded or comprehensive assessment of the impact of diabetes on a person's QoL.

In terms of the assessment of QoL in clinical diabetes care, progress has been made to integrate assessment of psychological well-being as an indicator of QoL, but more work is needed. In October 1989, the St Vincent Declaration set out several general goals for people with diabetes, including: 'sustained improvement in health experience and a life approaching normal expectation in quality and quantity' [44]. Thus, there was a goal of achieving QoL but, at that time, limited options for measuring it. The WHO's response included the DiabCare Quality of Care Monitoring Programme, which recommended assessments of general well-being and satisfaction with diabetes treatment [45]. Over the past two decades, increasing numbers of (inter)national guidelines have recommended routine monitoring of mental health and/or psychosocial aspects of diabetes, with the aim of improving integration of these factors in the individual's clinical care planning [46]. Studies have shown that using validated psychological measures and discussing the outcomes is feasible, acceptable and highly valued by people with diabetes [47]; however, there are no specific

recommendations to assess diabetes-specific QoL in clinical practice. As noted earlier, QoL is a multidimensional, subjective and dynamic construct, which may be difficult to capture comprehensively in a standardized tool in the clinical setting. Clinicians are asking psychologists for a short QoL measure that is easy to use in their diabetes clinics, but are we in a position to recommend a QoL measure for use in clinical practice? Although such a questionnaire may provide a standardized approach to monitoring and enable assessment of change over time, asking open-ended questions is an important alternative approach for routine practice. It provides the person with diabetes the opportunity to raise any aspect of their life that they consider highly important and to discuss how diabetes and/or its treatment is affecting it.

The Path Forward

This review has identified a significant unmet need for adopting a systematic and methodological approach to the assessment of the impact of diabetes on QoL in research and clinical care. In many ways, the opportunities and challenges we faced in 1995 in assessing the impact of diabetes on QoL remain, and they are both conceptual and practical. How do we assess comprehensively the full and individualized impact of diabetes on QoL while balancing this against respondent burden and generalizability? How can respondents reliably isolate the impact of their diabetes from that of other health issues or life in general? How can we assess both negative and positive impacts of diabetes, potentially even within the same life area (e.g. health)? These questions have led to the development of a range of measures. But are we any closer to a measure that answers all these questions? Or do we need to prioritize certain strengths/limitations of our approach based on the setting or population? There is a need for the field to revisit the core concept of QoL and ensure it is operationalized appropriately, using the ‘best practice’ principles for developing new questionnaire measures. Furthermore, QoL research has shown that understanding and exploring QoL can reveal motivating factors that are relevant in everyday clinical care. For example, if dietary freedom is important, the person may be motivated to consider multiple daily injections or an insulin pump; if maintaining

independence is important, then the person may be motivated to prioritize their eye health and to undertake the behaviours needed to achieve this. Eilander *et al.* [48] implemented a QoL monitoring intervention in 11 Dutch paediatric diabetes clinics: surveys after implementation showed 67% of healthcare professionals believed that discussing QoL contributed to adolescents' health and 92% felt the tool had additional value to routine care; 85% of adolescents felt they were 'heard', but clinics struggled with logistics, such as time, staffing and workflow design. This highlights that clinical guidelines are a necessary step forward but that it is equally important to allocate resources to resolving how to implement the guidelines and provide psychological care following the assessment [49], improving models of care by learning from best practice [50].

Conclusion

Despite the importance of QoL ('a life worth living'), we appear to be somewhat paralysed by the complexity of the rigorous assessment of diabetes-specific QoL (both conceptually and methodologically). The reality remains that the impact of diabetes on QoL is not systematically assessed in research or, for the vast majority of people with diabetes, in clinical care, although international initiatives such as ICHOM highlight the importance of this field and enable progress to be made. There are huge benefits of including its assessment in our approach to diabetes care. As Wolpert and Anderson [1] stated, 'focusing on the immediate lifestyle benefits can be critical to overcoming patients' ambivalence about change and promoting engagement in self-care'. Recent studies show that people with diabetes value these assessments, and we know more about the key barriers to the routine assessment, and the importance of the maturation of IT health systems and resources for person-centred care, which ensures adequate follow-up can be made in response to QoL findings. However, it remains that clinicians, and the health systems that reimburse them, need to prioritize QoL as being at least as important as biomedical markers of health if QoL research is to achieve its full potential in improving the lives of people with diabetes.

Funding sources

J.S., E.H.T. and C.H. are supported by core funding to the Australian Centre for Behavioural Research in Diabetes, provided by collaboration between Diabetes Victoria and Deakin University.

Competing interests

J.S. developed and owns the copyright of the *QoL-Q Diabetes*. S.S. developed the *DAWN Impact of Diabetes Profile*. All other authors declare no competing interests.

References

1. Wolpert HA, Anderson BJ. Management of diabetes: are doctors framing the benefits from the wrong perspective? *BMJ* 2001; **323**:994–996.
2. The DCCT Research Group. Reliability and validity of a diabetes quality-of-life measure for the diabetes control and complications trial (DCCT). The DCCT Research Group. *Diabetes Care* 1988; **11**:725–732.
3. Engel GL. The need for a new medical model: a challenge for biomedicine. *Science* 1977; **196**:129–136.
4. Kowitz SD, Nan H, Speight J. In: Fisher EB, LD Cameron, AJ Christensen, U Ehlert, B Oldenburg, FJ Snoek, et al., eds. *Principles and Concepts of Behavioral Medicine: A Global Handbook*. New York, NY: Springer, 2018.
5. Spilker B, Revicki DA. Taxonomy of quality of life. In: Spilker B, DA Revicki, eds. *Quality of Life and Pharmacoeconomics Trials*. 2nd edn. Philadelphia: Lippincott-Raven Publisher, 1996.
6. McGee HM, O'Boyle CA, Hickey A, O'Malley K, Joyce CR. Assessing the quality of life of the individual: the SEIQoL with a healthy and a gastroenterology unit population. *Psychol Med* 1991; **21**:749–759.
7. Hornquist JO. The concept of quality of life. *Scand J Soc Med* 1982; **10**:57–61.
8. Calman KC. Quality of life in cancer patients—an hypothesis. *J Med Ethics* 1984; **10**:124–127.

9. Jacobson AM, DCCT Research Group. The Diabetes Quality of Life Measure. In: Bradley C, ed. *Handbook of Psychology and Diabetes: A Guide to Psychological Measurement in Diabetes Research and Practice* Chur, Switzerland: Harwood Academic Publishers, 1994.
10. The DCCT Research Group. Influence of intensive diabetes treatment on quality-of-life outcomes in the diabetes control and complications trial. *Diabetes Care* 1996; **19**:195–203.
11. Bradley C. Importance of differentiating health status from quality of life. *Lancet* 2001; **357**:7–8.
12. UK Prospective Diabetes Study Group. Quality of life in type 2 diabetic patients is affected by complications but not by intensive policies to improve blood glucose or blood pressure control (UKPDS 37). U.K. Prospective Diabetes Study Group. *Diabetes Care* 1999; **22**:1125–1136.
13. Rubin RR, Peyrot M. Quality of life and diabetes. *Diabetes Metab Res Rev* 1999; **15**:205–218.
14. Australian Centre on Quality of Life. Directory of Instruments.
<http://www.acqol.com.au/instruments#measures> 2019.
15. Speight J, Reaney MD, Barnard KD. Not all roads lead to Rome—a review of quality of life measurement in adults with diabetes. *Diabet Med* 2009; **26**:315–327.
16. Polonsky WH. Understanding and assessing diabetes-specific quality of life. *Diabetes Spectrum* 2000; **13**:36.
17. Bott U, Muhlhauser I, Overmann H, Berger M. Validation of a diabetes-specific quality-of-life scale for patients with type 1 diabetes. *Diabetes Care* 1998; **21**:757–769.
18. Bradley C, Todd C, Gorton T, Symonds E, Martin A, Plowright R. The development of an individualized questionnaire measure of perceived impact of diabetes on quality of life: the ADDQoL. *Qual Life Res* 1999; **8**:79–91.
19. Cooke D, O'Hara MC, Beinart N, Heller S, La Marca R, Byrne M et al. Linguistic and psychometric validation of the Diabetes-Specific Quality-of-Life Scale in U.K. English for adults with type 1 diabetes. *Diabetes Care* 2013; **36**:1117–1125.
20. Cooke D, Bond R, Lawton J, Rankin D, Heller S, Clark M et al. Modeling predictors of changes in glycemic control and diabetes-specific quality of life amongst adults with type 1 diabetes 1 year after structured education in flexible, intensive insulin therapy. *J Behav Med* 2015; **38**:817–829.

- Accepted Article
21. Peyrot M, Rubin RR. Living with diabetes: the patient-centred perspective. *Diabetes Spectrum* 1994; **7**:204–205.
 22. Schlundt DG, Pichert JW, Gregory B, Davis D. Eating and diabetes: a patient-centred approach. In: Rubin RR, ed. *Practical Psychology for Diabetes Clinicians: How to deal with the key behavioural issues faced by patients and health care teams* Alexandria: American Diabetes Association, 1996.
 23. Trauer T, Mackinnon A. Why are we weighting? The role of importance ratings in quality of life measurement. *Qual Life Res* 2001; **10**:579–585.
 24. Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. *Diabet Med* 2005; **22**:1379–1385.
 25. Nicolucci A, Kovacs Burns K, Holt RI, Lucisano G, Skovlund SE, Kokoszka A *et al.* Correlates of psychological outcomes in people with diabetes: results from the second Diabetes Attitudes, Wishes and Needs (DAWN2) study. *Diabet Med* 2016; **33**:1194–1203.
 26. Holmes-Truscott E, Skovlund SE, Hendrieckx C, Pouwer F, Peyrot M, Speight J. Assessing the perceived impact of diabetes on quality of life: Psychometric validation of the DAWN2 Impact of Diabetes Profile in the second Diabetes MILES - Australia (MILES-2) survey. *Diabetes Res Clin Pract* 2019; **150**:253–263.
 27. Nicolucci A, Kovacs Burns K, Holt RIG, Comaschi M, Hermanns N, Ishii H, *et al.* Diabetes Attitudes, Wishes and Needs second study (DAWN2): Cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. *Diabet Med* 2013; **30**:767–777.
 28. US Department of Health and Human Services FDA Center for Drug Evaluation and Research, US Department of Health and Human Services FDA Center for Biologics Evaluation and Research, US Department of Health and Human Services FDA Center for Devices and Radiological Health. Guidance for Industry: Patient-Reported Outcome Measures: Use in medical product development to support labeling claims. Available at <http://wwwfdagov/downloads/Drugs/GuidanceComplianceRegulatoryIn> 2009.

- Accepted Article
29. Muhlhauser I, Jorgens V, Berger M, Graninger W, Gurtler W, Hornke L *et al.* Bicentric evaluation of a teaching and treatment programme for type 1 (insulin-dependent) diabetic patients: improvement of metabolic control and other measures of diabetes care for up to 22 months. *Diabetologia* 1983; **25**:470–476.
 30. Speight J, Bradley C. DAFNE: improved quality of life with intensified treatment is counter-intuitive to many clinicians. *BMJ* 2002:Rapid response. Available at: <https://www.bmjjournals.org/rapid-response/2011/2010/2029/dafne-improved-quality-life-intensified-treatment-counter-intuitive-many-c>.
 31. Bradley C, Speight J. Patient perceptions of diabetes and diabetes therapy: assessing quality of life. *Diabetes Metab Res Rev* 2002; **18** Suppl 3:S64–69.
 32. DAFNE Study Group. Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: dose adjustment for normal eating (DAFNE) randomised controlled trial. *BMJ* 2002; **325**:746.
 33. Speight J, Holmes-Truscott E, Hendrieckx C, Coates E, Heller SR, Cooke D. Comparison of the acceptability and psychometric properties of scales assessing the impact of type 1 diabetes on quality of life: results of the YourSAY:QoL study *Diabetes* 2019; **68**:809-P.
 34. Schipp J, Holmes-Truscott E, Hendrieckx C, Coates E, Heller SR, Cooke D *et al.* A qualitative investigation of the acceptability to adults with type 1 diabetes of five diabetes-specific quality of life measures. Findings of the YourSAY: Quality of Life study (193). *Australasian Diabetes Congress*. Sydney, 2019.
 35. Eiser C, Morse R. A review of measures of quality of life for children with chronic illness. *Arch Dis Child* 2001; **84**:205–211.
 36. McMillan CV, Honeyford RJ, Datta J, Madge NJ, Bradley C. The development of a new measure of quality of life for young people with diabetes mellitus: the ADDQoL-Teen. *Health Qual Life Outcomes* 2004; **2**:61.
 37. Walker J, Bradley C. Assessing the quality of life of adolescents with diabetes: Using the SEIQoL, DQOL, patient and diabetes specialist nurse ratings. *Practical Diabetes International* 2002; **19**:141–144.

- Accepted Article
38. Nieuwsteeg A, Pouwer F, van der Kamp R, van Bakel H, Aanstoot HJ, Hartman E. Quality of life of children with type 1 diabetes: a systematic review. *Curr Diabetes Rev* 2012; **8**:434–443.
 39. Kalyani RR, Golden SH, Cefalu WT. Diabetes and Aging: Unique Considerations and Goals of Care. *Diabetes Care* 2017; **40**:440–443.
 40. Sinclair A, Viljoen S. Quality of life in older people with diabetes. *Nursing in Practice* 2013;
 41. Speight J, Sinclair AJ, Browne JL, Woodcock A, Bradley C. Assessing the impact of diabetes on the quality of life of older adults living in a care home: validation of the ADDQoL Senior. *Diabet Med* 2013; **30**:74–80.
 42. Jones A, Vallis M, Pouwer F. If it does not significantly change HbA1c levels why should we waste time on it? A plea for the prioritization of psychological well-being in people with diabetes. *Diabet Med* 2015; **32**:155–163.
 43. International Consortium for Health Outcomes Measurement. Measuring Results that Matter: Type 1 and Type 2 Diabetes in Adults Data Collection Reference Guide. Version 1.0.0. Available at: <https://ichom.org/files/medical-conditions/diabetes-in-adults/dia-reference-guidepdf> 2019.
 44. WHO and IDF in Europe. The St Vincent Declaration on the Treatment of Diabetes. *Acta Ophthalmol Scand* 1997; **75**:63.
 45. Bradley C, Gamsu DS. Guidelines for encouraging psychological well-being: report of a Working Group of the World Health Organization Regional Office for Europe and International Diabetes Federation European Region St Vincent Declaration Action Programme for Diabetes. *Diabet Med* 1994; **11**:510–516.
 46. Speight J, Hendrieckx C, Pouwer F, Skinner TC, Snoek FJ. Back to the future: 25 years of ‘Guidelines for Encouraging Psychological Well-being’ among people affected by diabetes. *Diabet Med* doi: 10.1111/dme.14165. [Epub ahead of print].
 47. Snoek FJ, Kersch NY, Eldrup E, Harman-Boehm I, Hermanns N, Kokoszka A *et al.* Monitoring of Individual Needs in Diabetes (MIND)-2: follow-up data from the cross-national Diabetes Attitudes, Wishes, and Needs (DAWN) MIND study. *Diabetes Care* 2012; **35**:2128–2132.

- Accepted Article
- 48. Eilander M, de Wit M, Rotteveel J, Maas-van Schaaijk N, Roeleveld-Versteegh A, Snoek F. Implementation of quality of life monitoring in Dutch routine care of adolescents with type 1 diabetes: appreciated but difficult. *Pediatr Diabetes* 2016; **17**:112–119.
 - 49. Halliday JA, Hendrieckx C, Beeney L, Speight J. Prioritization of psychological well-being in the care of diabetes: moving beyond excuses, bringing solutions. *Diabet Med* 2015; **32**:1393–1394.
 - 50. Wylie TAF, Shah C, Connor R, Farmer AJ, Ismail K, Millar B *et al.* Transforming mental well-being for people with diabetes: research recommendations from Diabetes UK's 2019 Diabetes and Mental Well-being Workshop. *Diabet Med* 2019; **36**:1532–1538.

Table 1 Differentiating generic and diabetes-specific quality of life with increasing specificity of domains

		Sample wording for item and response	
		Generic QoL (no attribution; may be influenced by other health problems or issues in life)	Diabetes-specific QoL (attribution to diabetes)
Global domain (single item)	QoL	e.g. 'How is your QoL?' 'extremely good – extremely bad'	e.g. 'How is your diabetes affecting your QoL?' 'extremely positive impact – extremely negative impact'
Broad domains (brief measure)	Physical, psychological, social aspects of life	e.g. 'How is your social life?' 'extremely good – extremely bad'	e.g. 'What is the impact of diabetes on your social life?' 'extremely positive impact – extremely negative impact'
Specific domains* (detailed measure)	e.g. work/studies, family/friends, social life, holidays, leisure, independence, finances, dietary freedom etc	e.g. 'How are your relationships with family/ friends?' 'extremely good – extremely bad'	e.g. 'How does diabetes impact on your relationship with family/friends?' 'extremely positive impact – extremely negative impact'

QoL, quality of life.

*Numerous domains that may be considered important for QoL at this level. It is important to note that such domains need to be relevant to the general population in order to be considered 'QoL' domains. For example, an item about the extent to which your diabetes treatment regimen is causing distress is appropriate for a diabetes distress scale but not for a diabetes-specific QoL scale.

Table 2 Questions to consider when selecting generic and diabetes-specific measures to assess the impact of diabetes on quality of life

	Generic measures	Diabetes-specific measures
What is your purpose in using the measure? Consider the target condition group, population, intervention, and setting.	May be useful when comparing the outcomes of people with diabetes with other populations and are important for the calculation of QALYs.	May be useful when comparing diabetes treatments/technologies or when specifically interested in the attribution of how diabetes is affecting a person's life.
Does the measure have good face validity? Face validity can be assessed by looking over the instrument and considering each item (and its response options) individually. Consider whether the content is relevant and if any relevant issues are missing.	Tend to include items about self-care or ability to walk, which may not be relevant to populations with fewer or less advanced diabetes-related complications (e.g. younger people or those with a shorter duration of diabetes). Conversely, these measures often exclude items, such as dietary freedom, demonstrated to be an important issue for QoL in people with diabetes. Such omissions may mean that the full impact of diabetes is not assessed and potentially significant treatment benefits may not be demonstrated. Consequently, generic measures may not be useful when comparing	Likely to appear to be more relevant due to the attribution to diabetes and the inclusion of issues relevant to living with diabetes. However, it remains important to check item content and ensure that items that may be important for the population's or individual's QoL and/or affected by the intervention are not missing.

	Generic measures	Diabetes-specific measures
	two long-acting insulins, two glucose monitoring devices or two structured education programmes.	
Does the instrument have good content validity? Has the instrument been developed for the purpose for which you will use it and with the population who will complete it? For example, is there evidence of qualitative research with the target population underpinning the design of the measure?	May have good content validity in the general population but may not be entirely suitable for people with diabetes, e.g. because they exclude issues of relevance or place too much emphasis on issues that are not relevant (see above for examples).	Take care to ensure that the measure has been designed for your specific population (e.g. adolescents versus older adults with type 1 diabetes, different diabetes types). Different or additional content may be required.
Will the measure be acceptable to respondents?	Generic instruments may lack face validity for people with diabetes if too many items seem irrelevant to their situation, to the impact of the intervention or simply because the questionnaire, as whole, does not refer to the impact of diabetes.	Some diabetes-specific measures may include sensitive issues (e.g. impact of diabetes on romantic relationships and intimacy) which may affect their acceptability. Questionnaire complexity and length also impact on acceptability, particularly if the

	Generic measures	Diabetes-specific measures
What is the burden on respondents? This is particularly relevant in clinical care and when other measures will need to be included in studies with a broad remit.	As above, generic instruments may lack face validity for people with diabetes and increase the perceived burden of completing the questionnaires.	population is 1) elderly or very young, and/or 2) has low literacy levels. Typically, people are more willing to complete questionnaires that they perceive to be relevant to their condition and personal situation, and easy to complete (i.e. not complex or confusing).
Will responses be influenced by other conditions/factors?	Generic measures are particularly susceptible to the impact of other conditions as there is no attribution to diabetes required or desired. For example, comorbid conditions are likely to affect responses to generic measures. Consequently, generic measures need careful and appropriate interpretation.	Diabetes-specific measures typically include an attribution to diabetes (although there are exceptions at an item level), minimizing the possibility of influence by other conditions/factors. Conversely, it can sometimes be difficult for people with diabetes to isolate the impact of diabetes (e.g. on their mood or their leisure time) from other factors, particularly if they have lived with the condition for most of their lives.

	Generic measures	Diabetes-specific measures
Has the measure been validated in the target population? Consider diabetes type/treatment, age group, country, and language?	In many cases, generic measures are likely to be available in multiple language versions. This is a pragmatic reason for selecting a generic over a diabetes-specific measure.	Several diabetes-specific QoL measures are available in multiple language versions.

QALY, quality-adjusted life year; QoL, quality of life.