The Australian Centre for Behavioural Research in Diabetes

FAQ's

In addition to conducting and collaborating on research, the Centre supports other clinicians and researchers who are interested in developing a more person-centred practice. For example, many professionals have questions about which questionnaire(s) would be best to evaluate an education program or new treatment; or would like to monitor psychological well-being but do not know which is the best instrument to use. For more information on any of these issues please refer to our below list of frequently asked questions. If there are additional diabetes-related research questions you would like answered here, please contact us and we will do our best to answer your questions.

Why isn't it enough to measure change in HbA1c when evaluating an intervention?

The HbA1c is a valuable measure of average blood glucose levels in the past 6 to 8 weeks, and a reliable indicator of future health as it is strongly associated with risk of diabetes-related complications. However, it does not provide information about the individual's everyday hypos and hypers or their self-care activities, and it does not tell us anything about their knowledge of diabetes, their beliefs about diabetes, their self-management skills, their confidence, or how diabetes impacts on their emotional well-being or quality of life. Yet, all these variables are important outcomes to be considered when evaluating an intervention targeting diabetes self-care. The demands of diabetes self-care can be considerable. Therefore, one of the crucial determinants of a successful intervention and implementation is the behaviour itself. Furthermore optimal blood glucose levels do not necessarily equate to optimal quality of life or vice versa. For example, maintaining very tight blood glucose levels might result in an HbA1c within target range but the efforts to achieve that might impair the individual's emotional well-being or quality of life. It may be possible to find other ways to maintain an optimal HbA1c or it might even be appropriate to relax those efforts for a while.

How do I measure quality of life (QoL)?

Clinicians and researchers are often interested in measuring quality of life. Living with diabetes is known to impair both the quality and quantity of life, which by itself can affect motivation and self-confidence to continue the diabetes care.

Before selecting a measure it is necessary to define what you mean by quality of life. Many clinicians and researchers refer to measuring QoL but when we ask them about that in more detail, they are often referring to other aspects of the individual's experience, e.g. emotional well-being, treatment satisfaction, health status. For QoL, there is not a common definition, but there is a general consensus that it is:

- multidimensional (physical, psychological and social),
- subjective (QoL means different things to different people),
- dynamic (QoL will change over time and as a result of various factors) Because of these characteristics, measuring QoL is complex.

The best way of assessing it is to ask individuals about what is important for their QoL, and how they evaluate the quality. Not all aspects of QoL are equally important for each individual, or relevant in different circumstances. Although this qualitative method is preferred, for the purpose of clinical trials or clinical practice, quantitative (questionnaire) measures are needed. A variety of measures have been developed for the general population and more specifically for people with diabetes. However, many questionnaires have been used to assess QoL when they actually measure another concept entirely.

This has led to inappropriate use of questionnaires and misinterpretation of the results. Some studies have used questionnaire measuring one aspect of quality of life (e.g. health status) or assessing a different concept (e.g. depression, treatment satisfaction). The results may still be very relevant and interesting but are not informative with regards to QoL.

Jane Speight and colleagues have published a systematic literature review on this topic, which discusses the measures most frequently used to assess QoL in diabetes research .

Reference
Speight J, Reaney M, Barnard K. (2009). Not all roads lead to Rome—a review of quality of life measurement in adults with diabetes. Diabetic Medicine, 26(4), 315-327 .

How do I select the right questionnaire?

In selecting the best measure the following questions should be considered: (extract from

Speight J, Reaney M, Barnard K. (2009). Not all roads lead to Rome—a review of quality of life measurement in adults with diabetes. Diabetic Medicine, 26(4), 315-327)

What is your question?
Appropriate selection of measures follows from the objectives of the research study, knowledge of the patient population and the development of specific research questions. What type of outcome would be a useful measure for the given population, condition or intervention under evaluation?

Is the content relevant?
This can be assessed by examining the instrument and considering each item (and its response options) individually. This is particularly important when considering use of generic measures. For example, both the SF-36 and EQ-5D (EuroQoL 5-Dimension) include items about self-care, which may be irrelevant in a young population with few complications or when comparing two long-acting insulins. Despite the limitations in in some subgroups, the SF-36 and/or the EQ-5D may still be important to understand people's health status.

Are any relevant issues missing?
This is particularly important when considering use of generic measures. For example, neither the SF-36 nor the EQ-5D include items regarding dietary freedom, demonstrated to be an important issues for QoL in people with diabetes. Omission of such issues may mean that the full impact of diabetes cannot be assessed and a lost opportunity to demonstrate significant treatment benefits.
Will responses be influenced by other conditions/factors?

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The use of generic measures can be useful but need appropriate interpretation. In an elderly population, co-morbid conditions are likely to affect scores derived from generic measures.

Will the measure be acceptable to respondents?
Some measures may include sensitive issues, or be more complex or lengthy than others, which may impact on their acceptability, particularly if the population is elderly or very young and/or has low literacy skills.

What is the burden on respondents?
The lack of a 'gold' standard instrument and/or the complexity of the intervention may necessitate administration of several instruments in one questionnaire booklet, e.g. diabetes-specific and generic, measuring various concepts such as QoL, health status, well-being, health beliefs, in order to achieve holistic evaluation. Researchers must be aware of the burden that this may place on respondents, though it is unlikely to be as burdensome as many biomedical procedures that they may be required to undergo.

Has the measure been validated in the given population and/or country/language previously?
Researchers need to be aware of the need to ensure that the measure(s) they select have been validated or be prepared to undertake the psychometric validation themselves.

How will I analyse and interpret the data?
Clinicians and researches need to consider whether or not they feel confident not only in the selection of appropriate measures but also in undertaking their analysis and interpretation. If not, they may be better placed to collaborate (in a multidisciplinary team) with a social scientist experienced in the development, use and interpretation of measures in diabetes.

When should I choose a generic or diabetes-specific questionnaire?

Generic questionnaires assess concepts that are relevant to everyone. The results enable comparison of outcomes between different samples (e.g. comparison with the general population or with people living with another chronic condition).

However some items may be irrelevant for people with diabetes, or may bias the results. For example many depression measures include items about energy levels, which for people with diabetes may be influenced by high blood glucose levels and not necessarily indicate a symptom of depression. On the other hand, relevant domains are not covered by these items, for example, the impact of diabetes on dietary freedom.

Overall, a diabetes-specific instrument is preferred. The items are more relevant for people with diabetes, which will make the measure more meaningful, acceptable and less burdensome to complete. These measures are more likely to be sensitive to change, which is important when evaluating the effect of an intervention. Therefore, the results of these diabetes-specific measures enhance the understanding of the impact of diabetes. That being said, the validity of the results will depend on the quality of the measure and its overall fit with the aims of your project.

Do I need to apply for ethics approval?

If you are planning to conduct a human research project, you have to seek ethics approval. Almost any research activity that involves human participation (including completion of questionnaires, interviews and focus groups, access to human tissue which is not on the public record etc.) is considered human research.

However, in cases where data are collected for the purpose other than research, you might not need to submit an ethics application. This might be the case if your project falls into one of the following categories of data collection or use:

Archival data, if it is from a public domain
Please note, you will have to apply for ethics approval if the information you intend to use is identified personal information (states or implies identity), not in a public domain or if you will collect data in addition to the archival research.

Administrative data collection

Collection of data from staff or other stakeholders for the purposes of informing or improving a process within your organisation is not considered research. Still, if you later decide to use this data for research purposes, you will need to apply for ethics approval. In addition, the use of identified data always requires ethics approval.

Teaching and learning

If you collect human data solely for teaching or learning purposes and do not expect to publish or present any data, no ethics application is necessary. However, if you think the project may be published, it is recommended that you apply for ethics approval before running the project, as this is easier than getting approval subsequently.

Quality assurance or clinical audit

Usually data collected for quality assurance purposes or an audit, does not require ethical review, if it is for your organisation's own information. However, if information is to be taken outside the organisation and used for a published paper, research project etc, this is considered research and requires ethical review.\

Negligible risk research involving collections of non-identifiable data

Your research involves negligible risk if you use existing non-identifiable data or records or if it does not involve any foreseeable risk of harm or discomfort, which means there must not be the possibility of anything more than inconvenience. Although in this case you are not required to apply for ethics approval, you will probably need to complete a form to confirm that the project is of negligible risk, and provide a letter (or similar evidence of approval) from the person in charge of the data.

Please consider that even if your project does not require ethical approval, this does not mean that it is free of ethical considerations. As a researcher you should act responsibly and always apply the highest standards of research integrity and ethical behaviour, no matter if a formal ethics approval process is involved or not.

For further information please refer to the National Statement on Ethical Conduct in Human Research.