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Original Article

A disease-specific questionnaire for measuring patient-reported outcomes and experiences in the Swedish National Diabetes Register: Development and evaluation of content validity, face validity, and test-retest reliability

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ABSTRACT

Objective: To describe the development and evaluation of the content and face validity and test-retest reliability of a disease-specific questionnaire that measures patient-reported outcomes and experiences for the Swedish National Diabetes Register for adult patients who have type 1 or type 2 diabetes.
Methods: In this methodological study, a questionnaire was developed over four phases using an iterative process. Expert reviews and cognitive interviews were conducted to evaluate content and face validity, and a postal survey was administered to evaluate test-retest reliability.
Results: The expert reviews and cognitive interviews found the disease-specific questionnaire to be understandable, with relevant content and value for diabetes care. An item-level content validity index ranged from 0.6–1.0 and a scale content validity/average ranged from 0.7–1.0. The fourth version, with 33 items, two main parts and seven dimensions, was answered by 972 adults with type 1 and type 2 diabetes (response rate 61%). Weighted Kappa values ranged from 0.31–0.78 for type 1 diabetes and 0.27–0.74 for type 2 diabetes.
Conclusions: This study describes the initial development of a disease-specific questionnaire in conjunction with the NDR. Content and face validity were confirmed and test-retest reliability was satisfactory.
Practice implications: With the development of this questionnaire, the NDR becomes a clinical tool that contributes to further understanding the perspectives of adult individuals with diabetes.

1. Introduction

Increased emphasis has been given to person-centred care and the patient's perspective in care outcome [1–3]. The International Alliance of Patients' Organizations (IAPO), the global voice of patients, recommends that the healthcare system should be designed and delivered to address the healthcare needs and preferences of patients, so that care is appropriate and cost-effective [4]. In addition, the roles and responsibilities of health-care professionals have shifted from 'telling' to 'listening', a change that highlights person-centred care compared with a conventional hierarchic approach [5].

The Swedish National Diabetes Register (NDR) has become a natural and necessary part of quality assurance and improvement in diabetes care. The register offers an opportunity to monitor the quality of care in terms of risk factors and diabetes complications, as well as the evolution of treatment methods. Furthermore, the register is an important research database in the field of diabetes.

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The Swedish NDR covering approximately 95% of all adults with diabetes in Sweden [6–8]. Children of 0–17 years are reported to a separate diabetes register (SWEDIABKIDS) and then to the NDR when they turn 18. The collection of information on patient assessments of daily life and experiences of care [9] is an important step way forward for the NDR to further improve diabetes care. Patient-reported outcome measures (PROMs) are defined as ' . . . any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else' [10]. Patient-reported experience measures (PREMs) focus on patients' experiences of the care (e.g., access to services) and/or the process (e.g., medical encounters and information issues). In addition, PREMs can involve outcomes and capture a patient's evaluation of the result [11].

For diabetes, aspects of patient-reported outcomes such as health-related quality of life, fear of hypoglycaemia, functional status, late complications, and treatment satisfaction are addressed in several questionnaires [12–20]. When we evaluated these questionnaires for use as a clinical and longitudinal assessment tool for the NDR, none was found satisfactory comprehensive and feasible. A combination of several questionnaires would result in too many items not evaluated or used as a clinical tool. We therefore decided to develop and evaluate a new disease-specific questionnaire, which can be used directly in the

Table 1
Summary of process in each development phase. Number of items and dimensions and draft version of questionnaire after the process.

Development phase	Process	Number of items and dimensions after process	Draft version of questionnaire after process
Phase 1 Item development	Item development from 29 semi-structured qualitative interviews [21]: "What is important for you?". T1D (n = 15) age range 22–64 years, diabetes duration 6–50 years. T2D (n = 14) age range 44–81 years, diabetes duration 5–23 years. Results presented in detail in [21]. Generation of items was discussed in the research group. Duplicates and items not suitable for the aim of the questionnaire were removed.	52 items and 11 dimensions	Version 1
Phase 2 Expert review and evaluation of content validity	Expert review by representative from the patients' association (the Swedish Diabetes Association). Rewordings, deletions and additions of some items were suggested. For example, rewordings were suggested in order to avoid negative overtones and to clarify response levels. A shorter time frame was suggested (i.e. four weeks instead of three months) and some changes to the order of the items. An item covering number of severe hypoglycaemic events was considered problematic in relation to the risk of losing one's driving licence when reporting such events to a physician. Suggested items to be added covered acceptance, contact offered with dieticians and psychologists, and information provided about patient organizations. One item about technical aids was suggested to be split into two: one for insulin and one for testing of blood-glucose level. Expert review by the Department of Measurement Technique at Statistics Sweden. Recommendation to reword the items to questions. Revisions were made on wording of the questions and the layout, as well as some rewording of instructions, items and response alternatives.	51 items and 9 dimensions	Version 2
	External expert panel review to inform decisions about which items to add, delete, retain or revise, and to review design and structure according to measurement technique aspects. A panel of 11 experts: individuals with T1D (n = 1) and T2D (n = 2), physicians (n = 2), registered nurses (n = 2), researchers (n = 4). Content validity was rated on a four-point ordinal scale, from not at all relevant to highly relevant. An item-level content validity index (I-CVI) was calculated. Overall, the number of items was reduced by collapsing detailed items into more comprehensive items. For example, detailed questions about how to handle hypo- or hyperglycaemia, the capability to take care of diabetes at work, in an education environment, when going to a party, or having the flu were replaced with items asking for capability to care for diabetes in everyday life or when everyday routines need to be set aside. Also, detailed process-oriented items about which information or services the diabetes clinic had provided (e.g. dietician, psychologist, and group-based education) were deemed to be covered by other parts of the register, and therefore deleted. Expert review by representatives from a local patient association suggested some minor revisions: for example, to reduce the number of items covering detailed aspects of blood-glucose level. They suggested a few changes in the grouping and the order the items were presented, and commented on wording, e.g. items that were too long or possible to misinterpret.	33 items and 7 dimensions	Version 3
	Second external expert panel review to formally assess the content validity of the items and dimensions. In total 11 experts in the panel: individuals with T1D (n = 1) and T2D (n = 2), physicians (n = 2), registered nurses (n = 1), researchers (n = 3) and representatives from patient associations (n = 2). Rewording of group headings and instructions; re-ordering of items.	33 items and 7 dimensions; 2 main parts (PROM and PREM)	Version 4
Phase 3 Cognitive interview and evaluation of face validity	Six audio-recorded semi-structured face-to-face cognitive interviews lasting 38–65 min were conducted with individuals with T1D (n = 3) and T2D (n = 3) to evaluate face validity and comprehension.		
Phase 4 Postal survey and evaluation of reliability	Regional postal survey (n = 1599). Total response rate after one reminder 61% (n = 972). T1D (n = 800) response rate after one reminder 60% (n = 477), T2D (n = 799) 62% (n = 495). Reliability was evaluated in a test-retest (n = 340) where a new questionnaire was sent 14 days after first response. Total test-retest response rate: 72% (n = 243). T1D response rate 69% (n = 117), T2D response rate 74% (n = 126).	33 items and 7 dimensions	Version 5, ready for national survey

T1D: type 1 diabetes, T2D: type 2 diabetes, PROM: Patient reported outcome measures, PREM: Patient reported experience measures.

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