

Patient-reported outcomes in the Swedish National Quality Registers

■ E. Nilsson^{1,2}, L. Orwelius³ & M. Kristenson²

From the ¹The Research & Development Unit of Local Health Care, Department of Medical and Health Sciences, Linköping University, Motala; ²Department of Medical and Health Sciences, Linköping University, Linköping; and ³Department of Intensive Care, Clinical and Experimental Medicine, Linköping University, Linköping, Sweden

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Patient-reported outcomes (PROs) are important in the healthcare system to gain understanding of patients' views on the effects of a treatment. There is an abundance of available patient-reported outcome measures (PROMs), both disease specific and generic. In the Swedish healthcare system, the national quality registers are obliged to incorporate PROs for certification at a high level. A review of the latest annual applications for funding ($n = 108$) shows that at present, 93 national quality registers include some form of PROM or patient-reported experience measure (PREM). Half of the registers include some type of generic measure, more than half include disease/symptom-specific measures, and around 40% include PREMs. Several different measures and combinations of measures are used, the most common of which are the EQ-5D, followed

by the SF-36/RAND-36. About one-fifth of the registers report examples of how patient-reported data are used for local quality improvement. These examples include enhancing shared decision-making in clinical encounters (most common), as a basis for care plans, clinical decision aids and treatment guidelines, to improve the precision of indications for surgery (patient and healthcare professional assessments may differ), to monitor complications after the patient has left hospital and to improve patient information. In addition, funding applications reveal that most registers plan to extend their array of PROMs and PREMs in future, and to increase their use of patient-reported data as a basis for quality improvement.

Keywords: health-related quality of life, PREM, PROM, quality improvement, quality register.

Abbreviations: NQR, national quality register; PREM, patient-reported experience measure; PRO, patient-reported outcome; PROM, patient-reported outcome measure.

Background

Patient-reported outcomes and outcome measures

Patient-reported outcomes (PROs) are important within the healthcare system to gain information about patients' views on the outcome of a treatment. The aim of health services is to increase health gain for patients in terms of both healthcare professional assessments of the presence, and severity, of a disease, and patient self-assessments of health. It is well known that these two assessments are not always consistent [1–3]. Therefore, outcomes within health services need to include both these dimensions; that is, clinical observations, laboratory measures and other examinations need to be combined with patients' own assessments of their perceived physical, mental and social well-being and functional ability.

This is important in most clinical settings. For planned interventions aiming to restore functional ability, for example hip replacement surgery, the outcome cannot be assessed only from X-ray images. Self-assessments by patients of whether or not they can move freely and without pain are also needed. PROs are also, or maybe particularly, important to help optimize the interventions within health services for patients with chronic diseases. In these cases, the objective of a health service is to limit the adverse effects of the disease (and treatment) as much as possible and to help patients to live with their disease with a good quality of life.

Even if healthcare professionals regularly ask patients about their progress, PROs are still not documented as thoroughly as traditional medical

outcomes. To systematically record patients' views on the effects of a treatment, patient-reported outcome measures (PROMs), which allow patients to describe the status of different health aspects before and after treatment, can be used. Commonly, a PROM consists of a self-administered questionnaire about one of the following areas [4]: (i) disease symptoms (both occurrence and severity); (ii) functional ability; and (iii) health status/health-related quality of life.

The main parts of existing PROMs were initially not designed as outcome measures; that is, they were designed to measure prevalent health, but not to capture health changes. Hence, their responsiveness may not always be optimal. Furthermore, PROMs may be difficult to categorize into one of the above three areas, as they often include items from more than one area. PROMs are often divided into two main types, disease-specific and generic; the latter are relevant for all types of diseases and health states. In general, a combination of complementary generic and disease-specific measures is recommended (Table 1), to detect all important changes in health-related quality of life and to avoid missing unanticipated effects [5], and because the disease in question may have substantial generic impact beyond the disease-specific impact [6]. In addition, a generic measure may be needed to describe the relative burden of the

specific disease in a general population [7]. Furthermore, it has been argued that disease-specific measures should only be interpreted in the context of generic measures and vice versa [8, 9].

Today, there is an abundance of available disease-specific measures, as well as several generic measures. In both cases, they range from single-item measures to advanced item banks using modern technology, such as item response theory/Rasch analysis and computer adaptive testing, to create more individualized questionnaires and optimize the precision of the measurements. In addition, PROMs have been developed so that children can respond for themselves. For individuals who are not able to respond for themselves, a proxy measure that enables someone else to answer in their place is a means to ensure that their situation is also considered. Most of the questionnaires used as PROMs are multi-item measures that incorporate specific algorithms to create an index (the questionnaire is then often termed a scale) and, if multidomain, can be subdivided to form subscales. Globally, two of the most common generic measures of health-related quality of life in use today are the EQ-5D and the 36-item short-form (SF)-36/RAND-36.

Common generic measures

The EQ-5D comprises five items regarding mobility, self-care, daily activities, pain/discomfort and anxiety/depression, with responses on either three (no, moderate or severe problems) or five levels (no, slight, moderate, severe or extreme problems). The responses can be combined to produce an index value that was originally intended to be used in health economic evaluations. Items were chosen to reflect common health problems experienced by patients and therefore relevant treatment goals for healthcare providers [10, 11]. Additionally, the measure can be used by analysing the individual items/domains [12]. The EQ-5D was created in a joint venture between five European countries, one of which was Sweden.

The 36 items of the SF-36/RAND-36 scale are combined to form eight subscales (physical function, physical role function, bodily pain, general health, vitality, social function, mental health and emotional role function). This measure was developed to reflect the part of the well-known definition of health by the World Health Organization related to self-reports of physical, mental and social well-being and functional ability [13–15]. Additionally,

Table 1 Complementary information gained from generic and disease-specific measures

Generic measures	Disease-specific measures
Information about:	Information about:
<ul style="list-style-type: none"> • general aspects of self-rated health and health-related quality of life • unrecognized/unanticipated health problems • psychosocial needs • effects of comorbidities • adverse treatment effects 	<ul style="list-style-type: none"> • specific self-rated symptoms and signs for a certain disease, illness or functional impairment
Data from generic measures may also facilitate comparisons across patient groups and populations	

it is possible to calculate an index value analogous to the EQ-5D index from the SF-36 (termed the SF-6D) [16].

The RAND-36 was first used in the Medical Outcome Study, conducted by the RAND Corporation in the 1980s. Today, the instrument is distributed globally through two different sources in the USA: by QualityMetric as SF-36 (a licence fee is charged; includes designed questionnaires and software) and by the RAND Corporation as RAND-36 (freely available by downloading a prototype from the Website). In American English, the SF-36 and the RAND-36 are identical except that the algorithms for two of the subscales (bodily pain and general health) differ. QualityMetric has continued to develop even shorter forms, such as the SF-12 and SF-8, and nowadays also offers the SF-36 in many other languages. In Swedish, the SF-36 has been available since the beginning of the 1990s, whereas the newly translated and psychometrically tested RAND-36 (with slightly modernized wording compared with the SF-36, though still equivalent) has only recently been made accessible (the RAND Corporation gives general permission on its Website for all translations). Unlike the SF-36, the Swedish version of RAND-36 can be obtained free of charge from the PROMcenter (<http://www.promcenter.se/>) in Sweden (and no licence is required), which facilitates large-scale nationwide use.

How to choose the optimal PROM

Several guides to assist the choice of measure are available [17–20]. First, it is most important to consider the purpose of the measurement and identify health domains relevant for the patient group of interest, taking into account the patient characteristics (e.g. sex, age and disease). A measurement strategy can then be developed, building on the relationships between these health domains, which may reveal a need to include more than one PROM to cover all domains targeted as outcomes. In the next step, it is important to choose instruments for which validity, reliability and responsiveness of the questionnaire are acceptable for the purposes identified. Content validity is a key feature: Will the items of a proposed instrument be able to yield the relevant information needed for the intended patient group? Reliability and responsiveness are important to ensure the precision of the measurements as well as the ability to distinguish all important changes

after treatment [21]. In general, disease-specific measures may be more responsive to a given treatment than generic measures, because items cover the aspects that the medical intervention aims to improve. However, as mentioned above, generic measures may identify unanticipated needs for interventions, such as psychosocial needs or pain, or may be necessary to evaluate such interventions [22, 23]. Disease-specific measures may also contain some generic items. Furthermore, it is important that the results of the measurement are perceived as easy to interpret and (clinically) meaningful for those who will be using them, including patients. Although a change in the measurement score after treatment may be statistically significant, it must also be perceived as noticeable and important to both patients and clinicians. The minimum change in the scale score that can be recognized as an improvement for the patient group under study, in reality as well as statistically, is sometimes established as a means to facilitate interpretability [24].

Finally, it may also be essential to consider the feasibility of the measurement in the intended context. For example, is the choice of delivery mode (paper and pencil versus electronic) acceptable for all proposed respondents? An important, and common, question is whether the administrative and respondent burden is acceptable. Indeed, for some patient groups, a more precise but lengthy questionnaire may have to be substituted for a shorter one in order to ensure a high response rate [21]. Furthermore, respondent burden needs to be considered in the context of respondent motivation. Results have suggested that patients may prefer a (slightly) longer questionnaire if the content is more meaningful, and the ability to cover all aspect perceived as important [25]. The issue of administrative burden will, with the transition to Web-based questionnaires, diminish in future. Although patient involvement and participation are advocated at present, the involvement of patients in the choice of PROM is paradoxically not common practice [26].

There is no universal consensus regarding the exact content of different health domains, and hence, questionnaires that claim to measure the same concept may in fact vary substantially. In selecting a PROM, it is therefore necessary to examine and evaluate all items (questions and response alternatives) in the questionnaires individually [27]. Additionally, it is important that the

information obtained from the PROMs should complement the clinician-reported outcomes included [4].

Patient-reported experience measures

Whereas PROMs focus on health outcomes, patient-reported experience measures (PREMs) focus on patients' experiences. PREMs can be divided into satisfaction and experiences, relating to patients' satisfaction with or experiences of the structure (e.g., access to services and convenience of localities) and/or the process (e.g., medical encounters and information issues). In addition, PREMs can comprise outcomes; however, whereas PROMs measure outcomes as patients' descriptions of their present health status (treatment outcome from the patient's perspective), PREMs capture patients' evaluation of the result (satisfaction with treatment outcome) [28, 29] (Fig. 1).

Although PREMs are important measures, they are not without limitations. Patient satisfaction is influenced by expectations, which in turn depends on preferences, personality and previous experiences of health care and treatments [29]. To reduce this influence, it has been suggested that patients should be asked about specific experiences rather than only satisfaction [30]. For example, patients should be asked more specifically whether the information they received regarding certain aspects of their medication had been sufficient, rather than whether they were satisfied with the information about their medication in general. Additionally, asking specific questions may yield more useful suggestions for improvements, as it is well known that measuring satisfaction in general terms often results in high satisfaction rates because subjects

tend to overlook occasional unpleasant experiences when making global assessments [31].

As for PROMs, there are many available PREMs. However, whilst a PROM is most often chosen from existing questionnaires with acceptable psychometric properties, thereby providing possibilities for international comparisons, it is not uncommon for individual research projects or individual clinics to develop their own PREM. Like PROMs, PREMs vary from single items of global assessment to multi-item questionnaires. Single-item transition PREM questions (asking patients whether or not they have improved/worsened since the treatment; by some considered a PROM) are sometimes used to establish criterion validity of different PROMs [32]. Also, there are questionnaires that include both PREM and PROM items, making categorization more difficult.

There is a known positive relationship between patient satisfaction and health, but the exact nature and direction of the relationship remains to be elucidated (healthier patients become more satisfied, but it also seems that satisfied patients may become more healthy) [33–37]. It is not possible to generalize from the results of studies so far, but the strongest relationship seems to be between emotional/social aspects of health-related quality of life and satisfaction with clinical encounters and/or with the communication with health-care professionals [38].

Usefulness of PROMs in health care

Although PROMs are used increasingly in routine health care to measure treatment outcomes and to monitor changes over time, the same question-

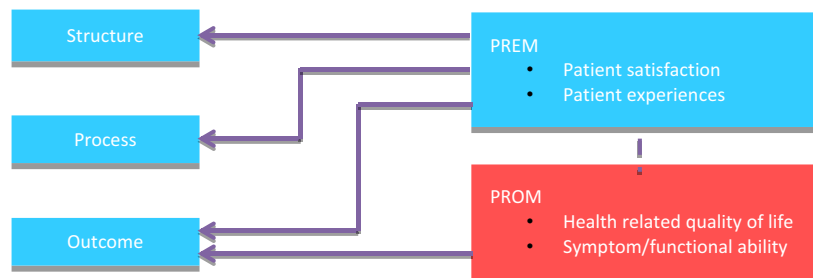


Fig. 1 Illustration of patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) in relation to Donabedian's three quality measures (structure, process and outcome). PROMs allow patients to describe their symptoms and present health status as a result of the given healthcare/treatment, whereas PREMs capture patients' evaluation of their satisfaction with, or experience of, the structure and process as well as of the results of healthcare.

naires may also be used for other purposes. Therefore, in some cases, to use the term 'PROMs' is somewhat misleading (though today common practice), as many of these other purposes refer to use in the clinical setting not directly related to a particular intervention (i.e. not proper outcomes). Other uses include identifying and determining the priority of problems important to the individual patient, facilitating communication and shared clinical decision-making, screening for hidden problems and identifying risk groups or groups in need of further interventions and support. Using patient-reported data during consultations can help healthcare professionals to identify the need to make changes to the treatment plan or medication, refer patients to other professionals, order further tests or take actions to improve patients' self-efficacy to handle their disease [39–43]. It has been shown that if doctors have the results of the measurement available during the patient encounter, it allows the most important current health issues for the patient to be directly addressed [44–54]. Patients are also reported to feel more empowered, maybe because the use of this type of measurement encourages them to reflect upon their situation, thereby increasing self-awareness, and also because it indicates that the healthcare professionals will be interested in listening to their problems [55].

There is increasing evidence for these effects of the use of patient-reported data, whereas the evidence for health improvements as a result of the use of such data is still weak. In a recent review in the oncology setting (in which most studies in this area have been conducted to date), Chen *et al.* [40] found evidence that routinely collected patient-reported data with feedback to clinicians resulted in positive effects on patient–provider communication and patient satisfaction. It has been suggested that feedback may have a significant positive impact on healthcare professionals with respect to earlier adjustment of treatment plans, especially in the short term. Feedback theories, such as the feedback intervention theory (FIT), might help to explain these positive results. According to the FIT, healthcare professionals will become more focused on the task when given formerly unknown information about the patient [56]. Chen *et al.* further showed evidence, albeit less strong, that increased PROM use has positive effects in terms of the monitoring of treatment outcomes (including adverse effects) and the detection of unrecognized problems. The weakest, but still positive, evidence

was found to support an effect on changes in patient management over time. Regarding health effects, the authors found some evidence that symptoms and adverse effects were improved (due to earlier detection and management), in contrast to overall health-related quality of life or social well-being. They could not find any studies of the impact on changes in patient health behaviour or on health service organizations or population health [40].

Although aggregated data at organizational, regional or national level may be used for evaluations and benchmarking, the evidence as well as the theory base for the usefulness of patient-reported data to evaluate healthcare performance is still weak [39, 57]. The world-leading political decision of the National Health Service in England to investigate mandatory use of PROs (including the EQ-5D) as a marker of provider performance and as a means of public decision-making about choice of provider is based on ideology. The outcome of this important decision will be of great interest to all researchers, clinicians and decision-makers in this field [58]. Moral implications have also been considered; a healthcare service for patients must measure and show consideration for the health-related quality of life of these patients [59]. Therefore, the decision to use PROs in a healthcare system comprises democracy as well as scientific issues. The optimal approach is not only to use these data as a measure of result, but to use them also for learning and as the basis for improvements of health services in the clinical setting.

It has been suggested that some studies failed to show the hypothesized positive effects of using PROs because (i) patient-reported data were not directed to persons with a mandate to make appropriate changes in care plans and medications, (ii) no alternative or better treatment was available, (iii) the PROM used was inadequate for the particular patient group, or (iv) the patient-reported data were considered difficult to interpret and were therefore disregarded by healthcare professionals [60]. However, few well-designed studies have been conducted in this field, and more research is clearly needed.

Patient-reported data in the Swedish National Quality Registers

To date, the main use of PROMs has been in clinical trials or research. However, their use in routine clinical settings is increasing. The

transition from research to routine care outcome measures is evident in the approximately 100 Swedish National Quality Registers (NQRs). An NQR is an optional register that contains individual-based information on medical problems, interventions and outcomes (Sweden has many compulsory national health registers, although none containing outcomes). It is envisioned that NQRs should be used actively and integrated for continuous learning, quality improvement, research and knowledge management, to create state-of-the-art health services with the best possible health gain for patients. Quality register data offer the possibility to conduct nested randomized trials and can be complemented with other data sources, such as hospital records or information from the mandatory national health registers [61].

National registers make it possible to follow the health outcomes for all Swedish patients within the specific field of the register and to make comparisons between counties, hospitals and clinics. All registers send annual reports with new applications for funding to an executive committee and are then given feedback on their performance. This is an important part of the quality assurance of the

NQRs. In November 2014, there were 81 certified NQRs (seven at the highest of three levels, i.e. level 1) with financial support from the Swedish government, and 24 so-called candidate registers seeking certification. Since the year 2010, the inclusion of PROs has been a requirement for certification at level 2, and from 2014, the NQRs have been required to specify in their annual funding applications how PROM and PREM data from the register are used for healthcare quality improvement.

A review of the latest funding applications ($n = 108$) shows that 93 NQRs include some form of PROM or PREM; the distribution of these measures is shown in Fig. 2. This is a small increase since the latest published overview [62], and this increase is probably ongoing based on the fact that many registers report plans for extended use. There is huge variation in the application of PROMs and PREMs amongst the registers; for example, from pilot studies in a few hospitals to well-established nationwide use, paper and pencil or online questionnaires (and preparation for item banks), from one point of measurement to longitudinal measurements over several years, use of a single PROM

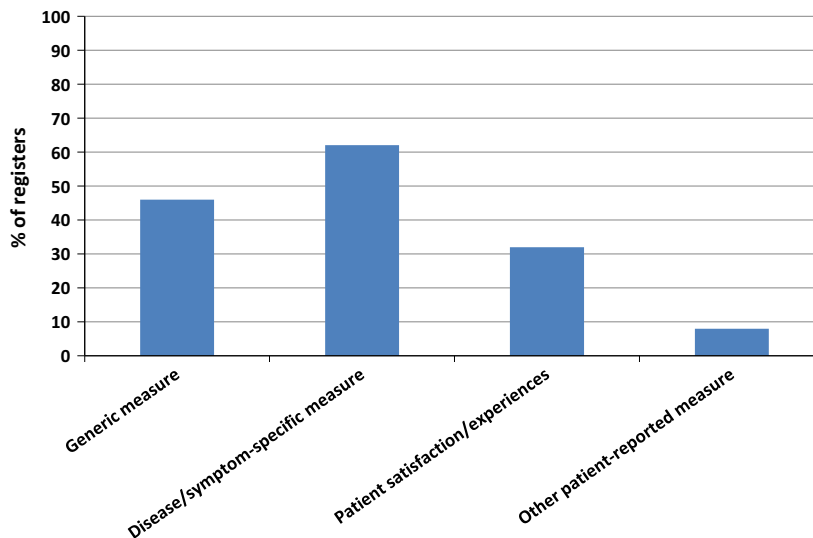


Fig. 2 The current self-reported inclusion of patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) in the Swedish National Quality Registers. The most common generic PROMs were the EQ-5D (around 35 registers) and the short-form (SF)-36/RAND-36 (around 10 registers). Of the approximately 10% of registers reporting not including any PROMs or PREMs, most reported planning for inclusion within the near future. Furthermore, several of the registers already including these measures reported planning extended use. 'Other patient-reported measures' included measures of work situation, lifestyle factors and burden of care from the perspectives of the relatives of the patient (from the 108 annual applications for funding for 2015).

or PREM or well-reasoned combinations, and from collecting patient-reported data but only presenting them descriptively in the annual reports to incorporating the data into computer-based decision aids, using them in face-to-face dialogue with the patient at the clinic visit (shared decision-making) or for extensive analysis at the group level to gain more information about the patient group.

Because of the current interest in promoting the use of NQR data to improve health services, an in-depth study was performed to (i) identify scientific publications showing the benefits of using NQR patient-reported data and (ii) interview representatives of some of the NQRs to present examples of the use of patient-reported data for healthcare quality improvement.

Scientific publications

Examples of publications that highlight the benefits of using PRO data from the Swedish NQRs are shown in Table 2. In addition, information about their use of PRO data may be retrieved from the annual reports of the registers (some in English). Some registers report a growing interest in international comparisons and cooperation, for example through the International Consortium for Health Outcome Measurement (<https://www.ichom.org/>) which promotes international measuring and reporting of PRO data in a standardized manner. International collaboration and well-designed prospective registries have been promoted as prerequisites for a learning healthcare system, especially with regard to rare conditions [63].

Quality improvement work

In their annual funding applications, 20 NQRs presented more or less extensive examples of varying formats of how PROM and PREM data from their register are used for healthcare quality improvement. These examples included using patient-reported data for shared decision-making in clinical encounters (most common), as a basis for care plans, in clinical decision aids and patient overviews, to make changes to treatment guidelines, as indications for surgery (patient and healthcare professional assessments may differ), to monitor complications after a patient has left hospital and to improve patient information. Reasons given for not presenting any examples included current lack of inclusion of any PROMs or PREMs in the register, had recently started to

include patient-reported data and therefore no results to present, and a lack of knowledge amongst the register steering group (responsible for writing the applications) about how patient-reported data from the register are used locally in the clinics attached to the register.

Examples from different types of registers (elective surgery, chronic disease, acute disease, certain age groups) are described in more detail in the following paragraphs.

The Swedish Hip Arthroplasty Register. The Swedish Hip Arthroplasty Register (<http://www.shpr.se/en/default.aspx>) was initiated in 1979; this was the second NQR in Sweden. All patients undergoing total hip replacement in Sweden are followed longitudinally through the register. PROs are captured before and after surgery (1, 6 and 10 years) in a short questionnaire, including the EQ-5D. Data collection is managed by the individual hospitals and reported via a Web application. The response rate at the 1-year follow-up is 90% [64]. All outcomes are disclosed publicly in annual reports at hospital level. Results are used for local quality improvement, for example to improve guidelines, care processes and patient information. Outcome analyses of aggregated data have identified patient-related and surgical factors associated with both favourable and poor outcomes [65, 66]. In an ongoing registry project, this information is used to develop a shared decision-making tool to better inform patients and clinicians about expected outcomes following total hip replacement.

The Swedish National Cataract Register. The National Cataract Register (NCR) (<http://www.eye.netsweden.se/page/25/the-swedish-national-cataract-register.aspx>) was initiated in 1992. Since 1995, the register has used its own disease-specific instrument, Catquest-9SF (revised in 2007), to determine patient-perceived usefulness of surgery. So far, the NCR has identified categories of patients who experience no benefit from cataract surgery, hence indications for surgery have become more precise. Furthermore, the NCR has shown that patients with coexisting diseases of the eye have a higher risk of deterioration after surgery, and these patients will now be operated on by the most experienced surgeons [67, 68]. Novel understanding has been gained in situations in which patient-reported and clinical outcome data are not in agreement. For example, in the case of a poor

Table 2 Publications in the years 2000–2014 showing the benefits of using patient-reported outcome (PRO) data from the Swedish National Quality Registers

National Quality Register	Conclusions
Swedish Hip Arthroplasty Register [64, 65, 70, 71]	Socio-economic differences in PRO (HRQoL, pain, satisfaction) should be taken into account, for example through better adaptation of pre- and postoperative information to patients with lower education levels. The register's nationwide PROM programme provides valuable information; for example, that younger patients show less improvement of HRQoL after surgery, highlighting the importance of offering complementary nonsurgical interventions.
Swedish Spine Register [72]	Most of the outcome variables in the register are PROs, but they do not always produce consistent results, and thus may not capture the same information, indicating that using complementary measures may be important. The register advocates the establishment of internationally validated core sets (combinations of measures).
Swedish Hernia Register [73]	Register data showed divergence between clinician-reported complications and patient-reported adverse events from a postsurgery questionnaire. The questionnaire captured previously unknown dissatisfaction and complaints. It was therefore concluded that postoperative care and subsequent information needed improvement, to give patients a better understanding of what to expect after surgery.
Swedish National Cataract Register [67, 68, 74]	Patient-reported data revealed less benefit of cataract surgery for patients with eye comorbidities; hence, such patients need special attention. Furthermore, analyses of patient-reported data have led to new protocols, with a shortened interval between surgeries for the two eyes, thereby avoiding long periods of bothersome anisometropia.
Swedish National Register for Gynecological Surgery [75]	Patient-reported data generally showed high treatment satisfaction and few symptoms and adverse events after vaginal hysterectomy. However, some women developed urinary stress incontinence, and therefore, efforts should be made to treat latent incontinence preoperatively.
Swedish Stroke Register [76–79]	Patient-reported data identified problems with fatigue amongst stroke patients, and intervention studies are now necessary to determine the best way to address this concern. Furthermore, sex differences regarding general health, depression and satisfaction with information and communication have been found (worse outcome for women). It was concluded that the medical management for women may need to be adapted.
Swedish National Registry for Systemic Treatment of Psoriasis [80]	Patient-reported data have been used to evaluate the benefits of changing from older systemic treatments to newer, but more expensive, biological agents. HRQoL improved somewhat with the new treatments, especially for those with initially more severe psoriasis.
Swedish National Knee Ligament Registry [81–83]	Both generic and disease-specific measures of HRQoL have shown sex differences in outcome (worse in women), which need to be better addressed. Patient-reported data have also been used to evaluate long-term effects of surgery, trying to determine the optimal time for surgery (is earlier surgery preferable?).
National Tonsil Surgery Register (part of the National Ear, Nose, and Throat Register) [84]	Patient-reported postoperative symptoms and adverse events are collected systematically, allowing for comparisons between different surgical techniques from the patient's perspective (e.g. less postoperative pain is reported after tonsillotomy than after tonsillectomy).

HRQoL, health-related quality of life; PROM, patient-reported outcome measure.

PRO combined with a good clinical outcome, the need for accurate follow-up and improved patient information about the proper use of spectacles after surgery has become evident [68]. In summary, collecting data on PRO has added a new dimension for evaluating the outcomes of surgery for the NCR.

The Swedish Stroke Register (Riksstroke). Riksstroke (<http://www.riksstroke.org/eng/>) was initiated in 1994, and since 1998, all hospitals in Sweden caring for stroke patients in the acute phase contribute data to this register. From an initial focus on quality assessment of acute in-hospital stroke services, the scope of the register has been gradually widened to more fully cover the quality of services and the late outcomes after stroke, through follow-up at 3 months and at 1 year after the event. At both follow-up times, there is an emphasis on PROs, such as activities of daily living (ADL) function, self-perceived health, health-related quality of life, mood, pain, satisfaction with different aspects of stroke services, rehabilitation and community support. Questions about the need of support from the next of kin are also included. Patient representatives from national stroke support organizations have played an important role in the development of the Riksstroke PRO strategy and choice of PROMs. Overall, more than half of the outcome measures are PROMs (other outcomes include survival, complications, compliance to stroke preventive therapies including smoking cessation and access to services). With regard to process measures and medical outcomes, PROMs have been included and carefully considered in the quality improvement work to improve stroke services at hospitals, as well as in primary and municipal care.

The Swedish Intensive Care Register. The Swedish Intensive Care Register (SIR) (<http://www.icuregswe.org>) is a quality register for all intensive care units (general, thoracic, neurosurgery, paediatric and burns units) in Sweden. SIR was initiated in 2001, and since 2005, the register has included patient-reported data [health-related quality of life, ADL, body mass index (BMI) and current employment] at three time points (2, 6 and 12 months) after discharge from the intensive care unit. The register uses PRO data to identify risk groups as well as for decision-making in clinical encounters to examine whether changes in the medical treatment and care are indicated, before (ADL, BMI and employment; retrospectively), during and/or after the intensive care period [69]. In addition, the

register uses PRO data at an individual level during the follow-up visit for shared decision-making with the patient and next of kin. This strategy can empower the patient and help in the next stage of the physical and psychological rehabilitation process. For example, patients can be offered further contact with a counsellor, psychologist or physiotherapist, or an outreach clinic.

Quality registers for children. Paediatric registers are linked via a liaison group (<https://childreg-carmona.se/>), and many include PRO data (e.g. The Swedish Pediatric Rheumatology Register and The Swedish Pediatric Kidney Register). Since 2008, the Swedish Paediatric Diabetes Registry (SWEDIABKIDS) has been part of the nationwide national diabetes registry (<http://demo.ndr.nu/>), which was created in 1996 as a tool to facilitate systematic quality assurance for patients with diabetes. SWEDIABKIDS has several functions: as a quality register, for daily care support, and as an educational tool for individual diabetes clinics. Current PRO-related research from SWEDIABKIDS includes studying the association between glycated haemoglobin (metabolic control) and health-related quality of life, investigating how children manage their diabetes and various subgroup analyses according to sex and age. The Swedish Pediatric Rheumatology Register and the Swedish Pediatric Kidney Register use PRO data for shared decision-making at the individual level. The results are discussed with the child and the next of kin/parents during the clinic visit and can empower and guide in a variety of decisions that need to be made.

Overall, from the funding applications, there were no clear correlations between how NQRs use their PRO data (i.e. the intensity and form of use, especially for quality improvement) and the type of register (interventions/elective surgery, chronic disease management, specific target populations, etc.), the level of certification or the age of the register.

Future challenges

We need patient information about health status for diagnosis and to choose the best intervention, as well as to evaluate whether interventions are appropriate for the patient's needs. This information is important for all stakeholders in health services: for patients and their relatives, for staff and for purchasers. Since the initial discussions

Table 3 Summary of key messages

Most national quality registers currently collect patient-reported data, and modern means of data collection, such as national and international item banks, are continuously evolving.

Analyses and presentation of patient-reported data are, however, still at a very basic level.

Data need to be analysed to explore variation, for example to discover why some but not all patients benefit from certain interventions.

The results of the analyses then need to be presented in such a way to provide inspiration for quality improvement and guide healthcare professionals in their daily work.

about whether there was actually any need for patient reports, much progress has been made but further discussion about whether and how to implement such reports is still ongoing. It has been argued that patient-reported data are too difficult, too expensive and too cumbersome to use. Nevertheless, valid measures are currently available and we now have (and soon will have even more) convenient procedures for data collection, such as national and international computer-based item banks (an ongoing evaluation of suitable item banks for future use in Sweden is being conducted by the six NQR support centres). These collected data now need to be used more extensively and effectively.

Outcome measures have long been used for economic evaluation of healthcare costs and to determine social and economic priorities. Whilst this is very important, there is a need to use the data to generate improvements. This means not only analysing the mean but also examining variations, to understand why some patients improve in terms of self-rated health, whilst others do not; why some subgroups have more self-reported complaints (e.g. pain) than others; and why some have better, or worse, self-rated outcome than indicated by clinical measures. We have shown here that this is now becoming a reality, for a broad range of patients and in many different settings, and has led to important changes in healthcare services. Further challenges include inspiring others to use their PRO data and to work towards gaining a better

understanding of such data for patients with multimorbidity. However, it may be some time before PROs are widely used as a means for guiding healthcare professionals in their daily work (Table 3).

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Conflict of interest statement

No conflicts of interest to declare.

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EN is a part-time employee of Quality Register Center Stockholm and a former employee of PROMcenter, LO is a part-time employee of PROMcenter and the Swedish Intensive Care Register, and MK is a part-time employee of PROMcenter and a member of the Executive Committee for the National Quality Registers, which monitors and approves financial support for all the national quality registers. The manuscript has been read and approved by all the authors.

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Correspondence: Evalill Nilsson, The Research & Development Unit of Local Health Care, Region Östergötland, S:t Larsgatan 9D, S-581 85 Linköping, Sweden.
(fax: +46 101038501; e-mail: evalill.nilsson@regionostergotland.se.)■