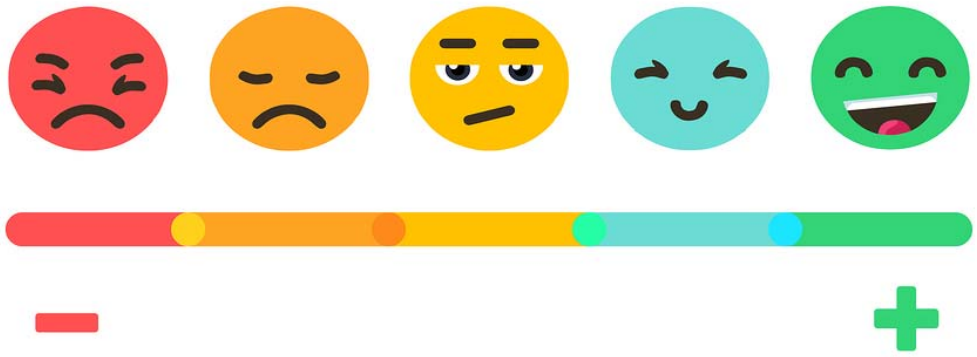
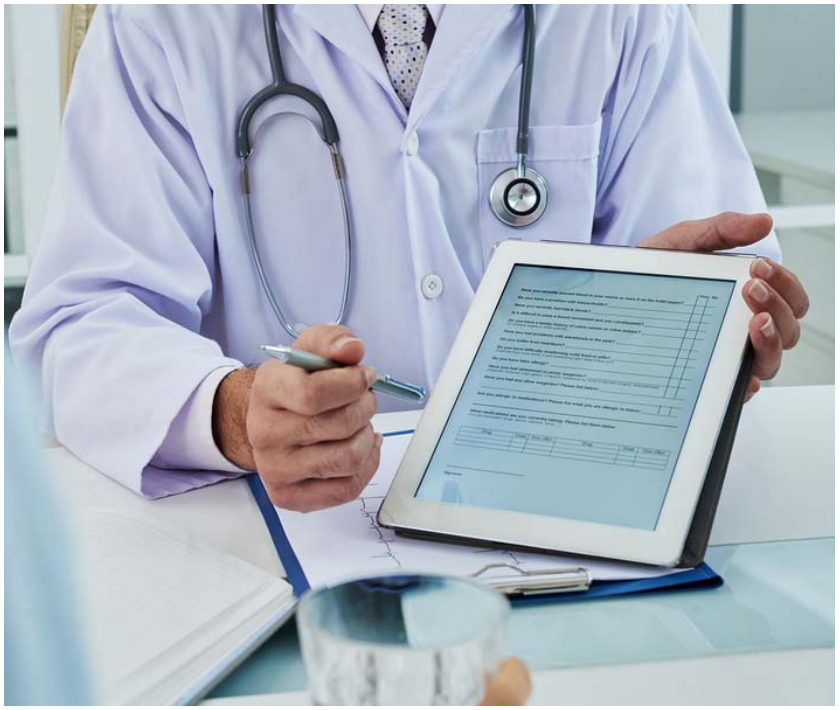
KCE REPORT 303

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

# USE OF PATIENT-REPORTED OUTCOME AND EXPERIENCE MEASURES IN PATIENT CARE AND POLICY





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Federaal Kenniscentrum voor de Gezondheidszorg
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ANJA DESOMER, KOEN VAN DEN HEEDE, MATTANJA TRIEMSTRA, JOHN PAGET, DOLF DE BOER, LAURENCE KOHN, IRINA CLEEMPUT

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# LIST OF ABBREVIATIONS

| ABBREVIATION | DEFINITION |
|---|---|
| ACTIVLIM | Measure of activity limitations for patients with upper and/or lower limb impairments |
| AMI | Acute Myocardial Infarction |
| AMSTAR | Assessing the Methodological Quality of Systematic Reviews |
| ASPE | Attentes et Satistfaction des Patients et de leur Entourage |
| BePPa | Belgian Paediatric Pain Association |
| BSM | Be service minded |
| CABG | Coronary Artery Bypass Grafting |
| CAT | Computerized Adaptive Tests |
| CATT-CAIT | Commissie voor advies in geval van tijdelijke tegemoetkoming voor gebruik van een geneesmiddel – Commission d'avis en cas d'intervention temporaire dans l'usage d'un médicament |
| CEA | Cost-effectiveness analysis |
| CKZ | Centrum Klantervaring Zorg |
| CNIL | Commission Nationale de l'Information et des Libertés |
| COPD | Chronic Obstructive Pulmonary Disease |
| CQI | Consumer Quality Index |
| EMA | European Medicines Agency |
| EORTC | European Organisation for Research and Treatment of Cancer |
| EORTC QLQ-C30 | European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaire |
| EQ-5D | EuroQol 5D |
| FDA | United States' Food and Drug Administration |
| GP | General Practitioner |
| HAS | Haute Autorité de Santé |

| | |
|---|---|
| HCAHPS | Hospital Consumer Assessment of Healthcare providers and Systems |
| HIS | Health Interview Survey |
| HRQoL | Health-related Quality of Life |
| HTA | Health Technology Assessment |
| ICHOM | International Consortium for Health Outcome Measurement |
| IKDC | International Knee Documentation Committee |
| IMA – AIM | InterMutualistisch Agentschap – Agence InterMutualiste |
| IRT | Item Response Theory |
| ISO | International Organization of Standardization |
| KOOS | Knee Injury and Osteoarthritis Outcome Score |
| MOC | Multidisciplinary Oncological Consult |
| NIH | American National Institute of Health |
| NIVEL | Netherlands Institute for Health Services Research |
| OECD | Organisation for Economic Co-operation and Development |
| PAM | Patient Activation Measure |
| PAQS | Platforme pour l'Amélioration continue de la Qualité des soins et de la Sécurité des patients |
| PaRIS | Patient Reported Indicators Surveys |
| PCI | Percutaneous coronary intervention |
| PCOM | Patient-centred Outcome Measure |
| POKIS | Pijnobservatieschaal foor Jonge Kinderen |
| PREM | Patient Reported Experience Measure |
| PROM | Patient Reported Outcome Measure |
| PROMIS | Patient-Reported Outcomes Measurement Information System |

| | |
|---|---|
| PROQOLID | Patient-Reported Outcome and Quality of Life Instruments Database |
| QALY | Quality of Life Adjusted Life Year |
| QoL | Quality of Life |
| RCT | Randomized Clinical Trial |
| REPOS | Rotterdam Elderly Pain Observation Scale |
| RIZIV – INAMI | Rijksinstituut voor Ziekte-en Invaliditeitsverzekering – Institut national d'assurance maladie-invalidité |
| ROM | Routine Outcome Monitoring |
| SF-36 | Short Form (36) Health Survey |
| VIP² | Vlaams Indicatorenproject voor Patiënten en Professionals |
| VPP | Vlaams Patiëntenplatform |
| WHOQoL(-brief) | World Health Organisation Quality of Life |
| WIV – ISP | Wetenschappelijk Instituut Volksgezondheid – Institut Scientifique de Santé Publique |

# SCIENTIFIC REPORT

# 1 BACKGROUND AND SCOPE

## 1.1 Introduction and scope

**PROMs and PREMS are increasingly used to capture what really matters to patients**

Mortality is still one of the principal clinical outcome measures used for assessing the quality of healthcare: e.g. survival after treatment is used to assess the effectiveness of treatment, standardised in-hospital mortality is used for assessing the quality of care in hospitals. Mortality measures were pioneered in the 1860' by Florence Nightingale[1] but were already criticised at that time as being incomplete measures of quality. In absence of alternative outcome measures, processes were monitored to assess to what extent evidence-based clinical guidelines were followed. This has some merits but is insufficient since it can hamper innovations or might divert the attention away from the ultimate goals of healthcare which are, mostly, improving patients' health, minimising disability and improving quality of life.[2, 3] The development and use of patient reported outcome measures (PROM) and patient reported experience measures (PREM) is growing to obtain this information (see 1.2 for a detailed description of these concepts). PROMs and PREMs co-exist next to other outcome measures (e.g. progression-free survival, cholesterol level, blood pressure) and are meant for the measurement of outcomes for which it is likely that patients are the best judges. Although the use of PROMs was initially restricted to clinical research there is an increasing interest in using PROMs in day-to-day clinical practice for improving individual patient care. In addition, also the use of PROMs and PREMs in quality monitoring (e.g. benchmarking individual providers, teams, organisations), performance measurement (e.g. comparing healthcare systems) and policy (e.g. pay-for-performance, reimbursement decisions) is increasingly applied and advocated to capture what really matters to patients.[4]

**Scope - lessons learned based on international initiatives**

In this report we explain what PROMs and PREMs are, why they can be relevant to patients, clinicians and policy makers and what the barriers and prerequisites are in case of implementation.

The study was requested by the federal public service for health, food safety and environment. The rationale for the study was to examine whether PROMs and PREMs could be valuable in Belgium, for which purposes and under which conditions, and to increase awareness amongst decision makers at different levels about the potential value, if any, of PROMs and PREMs for their decision making processes.

The research questions were:

- What are PROMs and PREMs?
- For which purposes could PROMs and PREMs be used in principle?
- What are barriers and facilitators for implementing PROMs or PREMs?
- What are prerequisites for implementing PROMs and/or PREMs in Belgium at provider-, institutional-, regional-, and federal level?

We focus on the use of PROMs and PREMs in daily clinical practice, quality assurance and policy (e.g. reimbursement decisions, payment models, etc.). The use of PROMs in trials is considered out of scope since this domain is already well advanced (e.g. United States' Food and Drug Administration (FDA)[5] recommended the inclusion of patient reported outcomes in US clinical trials[6]; also European Medicines Agency (EMA) discusses the use of PROMS in trials[7]), international guidelines for their use exist[8] and can nowadays be considered as commonplace. A detailed calculation of the costs associated with implementing PROMs or PREMs is also out of scope. Although it is recognized that such an implementation process and the actual use of PROMs and PREMs in daily practice is associated with a cost, the exploration of the potential value and the awareness creation have to be done first, before a principal decision on the implementation can be taken. Once a decision is taken, the required investments and operational costs need to be calculated to establish the implementation.

During the last decades numerous instruments were developed by clinicians and researchers to enable the consistent, reliable measurement of patient-reported outcomes and experiences. The quality of these instruments, in terms of their reliability and validity, varies considerably[a]. It is beyond the scope of this report to give an overview of these instruments or give a ranking of the preferred instruments. This study relevant to patients, clinicians and policy makers. Based on an analysis of international initiatives (see section 3), a review of the peer-reviewed literature (see section 2: a review of systematic reviews) and a critical analysis of current Belgian initiatives (see section 4) we discuss the benefits of using PROMs and PREMS, as aims at pointing out the important aspects that need to be considered when implementing a systematic measurement of patient reported outcomes and experiences, as well as which processes need to be followed during the implementation, depending on the aims of the PROMs and PREMs purpose.

## 1.2 A description of key concepts

In this section we describe the main concepts with a focus on PROMs and PREMs. Yet, many of the lessons learned for PROMs and PREMs might also apply for other types of measures, such as Patient Activation Measures (PAMs)[b]{Hibbard, 2004 #54}.

[a] An overview of generic and some disease-specific PROMs and PREMs for low back pain and Rheumatoid Arthritis was made by The Health Scientist (Wilco Jacobs) in preparation of the current report. This evaluation is available on request (at KCE).

[b] PAMs are measures, especially used in the population with chronic diseases, to assess the patient knowledge, skill, and confidence for self-management

### 1.2.1 Patient reported outcomes measures

**A patient reported outcome (PRO)** is any report of the status of a patient's health condition (e.g. quality of life, symptoms, treatment effects, functioning) elicited directly from the patient, without interpretation of the patient's response by a clinician or anyone else.[5, 11] As such they are not the same as self-reported outcomes which may be amended based on other information that may not have been provided by the patient themselves.[12]

The tools used (mostly questionnaires and survey's) to capture information about PRO's are called **patient reported outcome measures or PROMs**.[11] There are different types of PROMs used to capture information from patients. An important distinction can be made between generic and condition (or disease, or intervention or body part) specific PROMS:

#### Generic PROMs

Generic PROMs are not specific to any particular disease or condition and are intended to make comparisons between and within interventions as well as across different diseases and sectors of care. These instruments often focus on the impact of a person's health state on his 'health-related quality of life (HRQoL)' or 'Quality of Life (QoL)' in general, although some focus on specific dimensions of HRQoL, such as physical functioning.[4] Generic quality of life measures encompass many dimensions of life, such as physical and social functioning, pain, and depression or anxiety. This makes them particularly suitable for comparisons between conditions. Yet, their generic character is at the cost of less detail and sensitivity to clinically significant changes.[11] Disease-specific PROMs and population-specific PROMs (e.g. the Child Health Questionnaire) have the benefit of being more sensitive, but do not easily allow comparisons with outcomes in other disease areas or other populations.

There is no single 'gold standard' instrument but widely used examples of generic, multidimensional instruments are the EQ-5D, SF-36, PROMIS (Patient-Reported Outcomes Measurement Information System) and the WHOQOL-brief. These instruments differ on many aspects, such as scoring, aggregation of scores and initial purpose for which they were developed.

In terms of the results of generic PROMs, a distinction can be made between profile measures and single index measures. Profile measures generate a collection of scores, one for each item or dimension included in the instrument, whereas index measures aggregate separate item or dimension scores into one single score[c]. The choice between one or the other often depends on the purpose of the PRO measurement (cfr 1.3).

#### Condition-specific PROMs

Condition-specific PROMs measure patient-reported outcomes in a way that is specific to a particular disease (e.g. diabetes), set of conditions (e.g. cancer), a domain (e.g. pain), an intervention (e.g. knee arthroplasty) or part of the body (e.g. eyes). They are often referred to, for reasons of simplicity, as condition-specific or disease-specific measures. The questions in these instruments measure the severity of a particular condition or some specific aspect of health (e.g. functional limitations, symptoms), as viewed by the patient but some of these instruments also include generic elements (e.g. overall health-related quality of life, mobility, activities of daily living). They are more sensitive to detect changes over time or between groups for people who have the same condition, but are less suitable for comparisons across patient populations with different diseases. The level of specificity of the condition specific PROMS can differ, which can be illustrated by means of the following example:

The 'European Organisation for Research and Treatment of Cancer Quality-of-Life Questionnaire (EORTC QLQ-C30)' is a tool designed to assess symptoms, limitations etc., associated with cancer. It contains, for instance, questions about the degree of pain, nausea and vomiting and fatigue that are specific and relevant to cancer patients. The EORTC QLQ-C30 is

[c] The simplest way to get a single score is to sum up the item scores. More sophisticated approaches for generating a single index score incorporate (patient or public) preferences for the separate items or dimensions in the calculation. These approaches are most often used to generate utility values (cfr 1.3).

condition-specific but still quite general. In addition to this generic instrument for cancer patients, the EORTC also developed specific modules for tumour sites (e.g. lung, brain), treatment modalities (e.g. breast reconstruction), or QOL dimensions (e.g. cancer related fatigue) to be administered in addition to the core questionnaire.[13]

**Generic and condition specific PROMs are complementary**

It is clear that both generic and condition-specific PROMs have merits and limitations. The condition-specific PROMs outperform the generic PROMs in terms of clinical detail and face validity which makes them more suitable for clinical applications. They can also be used to make sure generic PROMS do not miss anything that is important from the patient's perspective (assuming that the condition-specific PROM is developed with input from patients about what matters most to them). Nevertheless this increased level of clinical detail can come with a higher assessment burden.[11] Furthermore many policy applications require comparison of PROMs across conditions. This can be considered as the main limitation of condition-specific PROMs and the main asset of generic PROMs. Indeed generic measures allow the comparison of outcomes across different patient groups and health services which makes them more suitable for policy (e.g. performance measurement, value for money). Condition- and generic PROMs can thus considered as being complementary.

### *1.2.2 Patient reported experiences measures*

It is important to distinguish PROMs from patient reported experience measures (PREM) which are a measurement of patients' perceptions of their experience of the process (rather than outcome) of care. This includes satisfaction (e.g. satisfaction with information given by nurses and doctors), subjective experiences (e.g. pain was controlled), objective experiences (e.g. the extent to which a predefined process occurred during a care episode such as 'waited more than 15 minutes past appointment time') and observations of healthcare providers' behaviour (e.g. whether or not a patient was given discharge information by a nurse).[4, 14]. The main limitation of PREMs is that they are influenced by expectations which are in turn depending on preferences, personality and previous experiences with healthcare and treatments. This is especially so when satisfaction measures are used.[15] Patient satisfaction measures should hence be considered as a subgroup of PREMs, i.e. encompassing only one aspect of patient experiences.

Both generic and service-specific PREMs exist and are in widespread use. Generic PREMs (e.g. during the hospital stay, how often did doctors listen carefully to you?) are not aimed for a specific condition but focus on a specific care setting (e.g. maternity care; psychiatric care; nursing homes; hospital).

Although PREMs seem to be an important tool to capture information about under-evaluated topics such as coordination of care for patients with (multiple) chronic conditions, development and use of such PREMs (and thus the knowledge about it) is still limited.[11]

### 1.2.3 *Patient-centeredness, patient involvement and patient empowerment*

PROMs and PREMs are usually applied in the context of a larger endeavour to improve patient participation, patient-centeredness and patient empowerment, alongside other instruments such as patient panels, qualitative interviews with patients, patient education and patient diaries. Patient empowerment is a broader concept than patient participation and patient-centeredness.[16] The relationship between these concepts was nicely summarized by Castro et al. as follows: ”by focusing on patient participation as a strategy, a patient-centred approach is facilitated, which leads to patient empowerment”.[16] Patient empowerment fits within the evolving thoughts about the role of patients in healthcare. Briefly, patients are increasingly regarded as the primary decision maker regarding their health and an equal partner in their healthcare choices. This viewpoint is linked to a modern vision of the individual’s freedom and ability to choose and the consequences of societal criticisms like the criticism of the biopower by M. Foucault[17, 18] and the criticism of the health system power by I. Illich[19]. It is generally agreed that patients should be supported to understand their therapeutic options. Concepts such as ‘empowerment’, ‘participation’, ‘capabilities’ are used, understood and interpreted in different ways. Information for but also from (about) patients, like PROMs and PREMs, can help to improve patients’ autonomy. However, it is important to remain cautious in order to avoid an increase in social and health inequalities. For example, there is evidence that health literacy is characterized by a socioeconomic gradient and also the capacity to express emotions, opinions and facts are not equally distributed. We remain also cautious with the possible use of patient empowerment to increase patients’ responsibility, especially financial responsibility. It is important to be aware of these ethical consequences and the methodological challenges associated with measuring patient-reported outcomes and experiences (i.e. trying to objectify subjectivity in a systematic manner) in all population subgroups. Examination of the ethical challenges associated with the use of measures to improve patient empowerment could not be elaborated in the current study. It should be kept in mind, however, that on the one hand the use of PROMs and PREMs does not automatically lead to patient empowerment and that on the other hand, patient empowerment is not necessarily obtained with the implementation of PROMs or PREMs. .

## 1.3 Why measuring patient-reported outcomes and experiences?

The common idea to measure patient reported outcomes and experiences is that there are some aspects only a patient can report. What’s more, the views about the outcomes of care might differ between patients (e.g. impact on their daily role and functioning) and clinicians (e.g. focus on pathophysiology).[20] PROMs and PREMs are complementary with traditional outcome measures and enable a more comprehensive understanding of outcomes and effectiveness. PROMs are essential to understand whether healthcare services and procedures make a difference to patients’ health status and quality of life. A text book example which can illustrate this is that *‘A surgeon might report improved blood flow after a coronary bypass[clinical outcome] but this is not much if the patient reports that they still get out of breath and experience pain when they exercise[PROM]’.*[21]

In this section we describe more in detail the different purposes of measuring PROMs and PREMs and at which levels (individual patient care, institutional level and policy level) they have potential value to the health system.[22]

**Shared decision making, patient-centred care and improved quality of the individual-level interaction between patients and providers**

There is a shift toward making health-care more patient centred with patients as active partners in the medical decision making process.[20] PROMs data can be used to support shared decision making and patient-centred care. Both individual patient-level data as well as aggregated data can serve this purpose.

At the individual patient-level, PROM data can be used as part of routine patient assessment and management. Data obtained from standardised PROMs might be particularly useful to[4, 20, 23]:

- Screen for common health problems and symptoms that are often overlooked (e.g. reduce incidence of undiagnosed but treatable depression in primary care);
- Increase diagnostic accuracy (e.g. knee osteoarthritis is confirmed when reports of pain of sufficient intensity and frequency are supported by imaging findings reflecting structural changes) and increase the diagnosis of comorbidities and the correct assessment of the severity of the disease;
- Monitor disease progression or regression as well as the effects of treatment can be done when PROMs are measured at regular time intervals;
- Support treatment decisions. PROMs can be, for instance, used by a clinician to decide to refer a patient, to start rehabilitation, to change the treatment plan or to provide self-care information;
- Facilitate communication between patients and providers. Individual-level PROMs might trigger the patient to talk about issues that he otherwise might not have thought to raise with his clinician or for formulating patient's goals. Indeed, PROMs can help in the understanding what matters to patients, which is especially important for patients with multiple chronic conditions;
- Facilitate communication within a multidisciplinary team discussing the patient's care.

Standardised PROMs can be complemented with individualised questions. Individualised questions could focus on the particular issues raised by patients during previous contacts. The data obtained from individualised non-standardised questions are not suitable for aggregation.

Besides the use of individual-level data also aggregated data from standardised instruments can be used in the clinician-patient interaction. At the level of a specific patient group PROMs can be used to inform patients, for instance, about the potential consequences of their condition or treatment on their functioning and quality of life.[21] These aggregated data can assist the patient to judge the likely benefits of treatment in his or her own case. The aggregated use of data will require that patients are informed about changes in PROMs based on the treatment but also to what extent several risk-factors (e.g. age, sex, pre-existing conditions, severity of condition) influence the impact of the treatment.[4]

The clinical use requires that PROM data are collected timely (an ideal health information system would routinely collect PROM data at the clinical level) and fed back timely to clinicians to enable its use. Their acceptance by clinicians will depend on the (face) validity, reliability and feasibility. The frequency of measurement (e.g. each consultation or at regular intervals) might have to be higher compared to higher level applications but can also take other forms (e.g. patient diaries). A general rule of thumb is that the points of measurement should reflect anticipated changes in health (e.g. elective surgery: pre- and post-operative measures; diabetes: ongoing measurement).[22] The usefulness of PROMs in clinical practice might increase when there are clear links between PROMs data and guidelines for practice and clinical pathways.[4] The use of individual PROMs is especially important for, but definitely not limited to, patients with longer-term conditions.

PREMs are less used on individual patient level, but more on service or institutional level to identify quality improvement initiatives.

**Information to drive improvement in quality of care**

Patient-centeredness is one of the dimensions of quality of care.[24] It has been claimed that the use of PROMs and PREMs in quality measurement and reporting has the potential to contribute to the transformation of healthcare into a more patient-centred model.[2, 4, 11] Although PREMs and PROMs are predominantly associated with the 'patient centeredness' dimension of quality of care, it is not limited to it. PREMs and PROMs can also be used to measure other dimensions such as timeliness, effectiveness, equity. As such, the use of PREMs, and patient satisfaction measures in particular, for the assessment and improvement of quality, became common in many industrialised countries.[25] But there is a disproportional focus on the 'patient information' dimension of patient centred care while the other dimensions (i.e. respecting patient values and

preferences; coordinated and integrated care; ensure physical comfort; provide emotional support) are less represented.[26] Nevertheless, better patient experiences seem to be related to higher levels of guideline adherence and better clinical outcomes.[14, 27] When measurement conditions (e.g. validated tools, adequate sample size) are respected, PREMs have their merits in measuring and improving the quality of care.[14] The use of PROMs for these purposes is relatively new.[23]

In the context of quality improvement, aggregated PROM and PREM data are used to assess and compare the performance of providers and to inform the general public to enable informed patient choice. Indeed, there are several mechanisms by which these comparisons are thought to improve healthcare:

- PROMs and PREMs are used to allow informed choices of care providers by citizens, patients and referring physicians and to introduce competition.[28] The patient's choice for a particular hospital, for instance, is often a trade-off between several criteria such as waiting times, travel distance, reputation, quality of care and GP recommendation. Yet, when the information about quality of care and outcomes (e.g. quality of life measures) is available this might play a dominant role in the patients' actual decision-making processes.[4, 29]
- Monitoring patient-reported adverse events such as pain, nausea and fatigue can be used on an aggregated level to understand which quality issues remain un- or insufficiently addressed under current practice.
- Benchmarking of PROMs data between providers ('How are providers performing relative to others doing the same kind of work') and monitoring key aspects of the quality of care they deliver ('Are providers meeting minimum standards of performance?') is the type of information that should help providers to identify the reasons for their performance, and then to identify what they need to do in order to improve.[4] 'Audit and feedback' about PROMs and PREMs are believed to reveal flaws in care processes and competencies of healthcare professionals. These performance data are not necessarily released to the public.[30] PROMs and PREMs cannot be used in isolation since 'audit and feedback' only seems to work when it identifies specific individuals or groups of providers responsible for poor performance target specific behaviours, is based on recent performance and a clear action plan with targets for improvements is provided.[30, 31]

In addition to the above applications, PROMs and PREMs could also be used in the context of accreditation programs or quality inspections. Of course is the measurement, feedback and reporting of PROMs and PREMs only one element in a chain of actions that should be undertaken to achieve quality improvement besides, for instance, a culture of quality improvement, increased patient engagement and leadership support.

Several challenges need to be addressed when PROMs and PREMs are used in the context of quality reporting. Variation in these measures is influenced by many patient-level variables (e.g. age; healthier or sicker population; health behaviours such as compliance; life events; new healthcare episodes) mostly beyond the control of the provider. The longer the time between the care episode and the outcome assessment, the higher the impact of these factors. These factors are unlikely to be randomly distributed across providers. Although very challenging, risk-adjustment is a prerequisite when PROMs and PREMs are compared between providers.[30] Further empirical research will be required to identify which provider characteristics (e.g. workload, volume of patients, hospital type) influence variations in PROMs.

An additional challenge is that rapid feedback for PROMs is not always possible as PROMs are often measured 6 months or later after treatment (e.g. full effect of knee surgery is believed to be reached after 6 months only). Moreover, the longer the time window, the more difficult it becomes to attribute outcomes to the healthcare practice (e.g. Is pain 6 months after hip prosthesis due to pre-operative assessment, surgeon competency, rehabilitation protocols, access to post-acute care?). The timing issue is also important for PREMs. To attribute PREM results to the correct providers it is important to ask questions about specific care episodes (e.g. a questionnaire about all care received during the last 12 months may generate an accurate portray of the overall quality of healthcare but does not reflect the care delivered by the providers most responsible for the measured outcomes).[14]

It is also important to identify conditions where outcome variation between providers exists and for which intensive quality improvement initiatives can make a difference. Standardized high-volume procedures with little to no variation in outcomes may, for instance, not be the best choice to start with.

Also the level of detail that is required needs to be addressed. Since most PROMs and PREMs are developed for research purposes, for quality improvement a selection of questions may serve the purpose.[23] Easy to complete questionnaires that result in useful information for patients will also contribute to better response rates. This is essential since response rates of 70-80% are aimed at to avoid bias. Besides paper surveys and checklists, newer technologies are a valid option (e.g. tablet at the point of care, PC or smartphone) when the impact on response bias (e.g. patient subgroups not having access to digital technologies) is assessed.[23] In addition, if patients are asked to complete PROMs at different time intervals (e.g. to monitor the evolution of pain scores) they are more likely to do so if they get some form of direct feedback.[23]

In a next step these data can also be linked to cost data to assess efficiency. It is, for instance, possible that outcomes are good, but produced at high cost or that costs are low, but outcomes poor.[4]

**Population health monitoring and macro-level performance measurement**

The incorporation of patient-reported outcome measures into population health monitoring programs is believed to give a more comprehensive picture of population health status than is currently available from traditional health outcome measures such as mortality and morbidity. The addition of PROMs to population health surveys helps to generate information at the population level that is supportive in performing public health activities such as disease prevention, health promotion, measurement of health disparities, and evaluation of interventions.[32] An ideal indicator captures meaningful change in health status in response to a major policy initiative or health promotion program or helps to identify conditions with the greatest burden (e.g. to prioritise research funding for conditions where the greatest improvements can be achieved by technological advancements).[30] In recent years, patient-reported outcome measures (more specifically, generic HRQoL) already proved their usefulness in measuring the burden of conditions, and they consistently reflect population-level socioeconomic status, such as educational attainment and income. What's more, HRQoL seems to correlate negatively with behavioural and lifestyle risk factors and to predict morbidity, mortality, and healthcare utilization, often better than objective measures of health.[32] HRQoL can support prediction of future disease burden, resource allocation, and identification of public health problems. This large-scale data collection of patient reported outcomes is time-consuming and expensive and generally only done via national health surveys. This might change in the future with the emergence of new digital technologies allowing to store existing PROMs in clinical information systems. The value of these measures at the population level will increase when these data are linked to other surveillance data, such as clinical registries, billing and hospital discharge data.[32]

**Relative effectiveness assessment and cost-effectiveness for reimbursement decisions**

In the context of tightening government budgets, population ageing, an increasing prevalence of people with chronic diseases and technological evolutions and innovations, there is growing pressure to demonstrate the cost-effectiveness of treatments and services.[33] The use of PROMs in Health Technology Assessment (HTA) can help payers to make decisions about reimbursement. HTA aims at informing decision makers about the relative effectiveness, cost-effectiveness, patient and organisational issues of health interventions, to support reimbursement decision making processes. PROMs can help to identify which treatment to offer to specific patient groups, which patient groups to prioritise and which treatments to reimburse to optimize health gains on a population level and use scarce health resources efficiently.

More specifically, PROMs can be used to estimate the relative effectiveness and cost-effectiveness of health interventions. Relative effectiveness, which compares the clinical effectiveness of two treatment strategies for the same disease, can be assessed by means of condition-specific and generic PROMs. For example, the assessment of the relative effectiveness of

radiotherapy for the treatment of breast cancer would imply a comparison of the outcomes of radiotherapy versus chemotherapy in this patient population. The outcomes measure could encompass, besides the classical clinical outcomes such as survival, PROMs.

Cost-effectiveness analyses typically require the use of a PROMs that can be translated into utility values. If the intention of the evaluation is to support general resource allocation decisions across conditions, i.e. going beyond the resources allocated for the condition under consideration, a generic PROM with utilities from the general public is required. The EQ-5D, for instance, is a generic HRQoL measure that assigns public utility values to each health state that can be described with the EQ-5D descriptive system. This allows comparability between conditions (because of the generic nature of the measure) and avoids bias due to e.g. coping with a serious disease (because of the public utility values, meaning that the same health state description always gets the same utility value). If reimbursement decisions are limited to resource allocation to treatments within a particular condition, also disease-specific PROMs leading to patient utility values can be used. The choice between these approaches depends on the healthcare system. Some countries will prefer generic PROMs for economic evaluations (e.g. the UK), others prefer disease-specific PROMs (e.g. Sweden).

Eventually, the utilities are used for the calculation of quality adjusted life years (QALYs) gained from an intervention, where the utilities serve as the weights of the life-years gained. QALYs are the most frequently used effectiveness measure in cost-effectiveness analyses (CEA). CEA calculate the incremental cost of an intervention compared to the standard intervention for the condition, and balances this with the intervention's incremental effectiveness, often expressed in terms of QALYs gained, compared to the standard intervention. The outcome of a CEA is an incremental cost-effectiveness ratio (ICER), reflecting the incremental cost of the intervention per extra QALY gained, as compared to the best alternative intervention for the same condition.[4]

Both the relative effectiveness assessment, the economic evaluation and the assessment of patient issues in HTA, require the availability of these data. Routine collection of PROMs associated with utility values in clinical trials is therefore crucial for HTA.

Besides their use in classic HTAs, PROMs can also help to assess the real-world impact of new technologies. After all, many technologies are still introduced without a sound evidence base.[30]

### Contracting of services and payment models

PROMs and PREMs are relevant in the context of contracting healthcare services. It is required to measure outcomes in some form to know what the result from contracting a given set of services is. In other words, PROMs are important to know if the contract results in value for money. The contracting party or payer can use PROMs and PREMs in many ways such as[4]:

- Specifying minimum performance levels for PROMs or PREMs via their contracts with providers or only contract high-performing providers;
- Monitoring the performance of the providers that hold a contract;
- Incentivising providers to improve quality (or attain a certain level) by linking payment to performance on PROMs (e.g. value-based purchasing program that awards improvement, achievement and consistency of patient experience levels: see see text box 3 on HCAHPS).

Both generic PROMs and PREMs can be used in the context of contracting and payment models. But also condition-specific PROMs have their place, especially in contracting decisions. The use in contracting is nowadays mostly limited to a limited number of particular treatments or conditions. It is expected that this will increase when for more conditions/treatment-standardized specific PROMs data are collected. As is the case in quality improvement initiatives (see above) risk-adjustment (both for hospital as patient factors) is of utmost importance in case PROMs and PREMs are used in payment models. This is not only so to avoid that providers with a large proportion of patients of, for instance, lower socio-economic categories are disadvantaged[34] but also to avoid undesired behaviour (e.g. patient selection, upcoding, etc).

**Table 1 – Purpose and characteristics of PROM and PREM data collection**

| Level | Purpose | Data collection method | Sample | Type of measure | Frequency | Use | Remarks |
|---|---|---|---|---|---|---|---|
| **Micro-level** | Shared decision making and care in partnership with patients | Individual or aggregated patient data (e.g. checklist, web-portal, integration in medical records …) | All patients from the target group | Condition-specific PROMs | Longitudinal (chronic care)<br>Pre-post (elective surgery) | Screening; Diagnosis;<br>Monitor disease progression;<br>Support treatment decisions;<br>Facilitate communication (patient-provider; provider-provider) | Aggregated data will require that impact of risk-factors (e.g. age, co-morbidities) is taken into account |
| **Meso-level** | Information to drive quality improvement[d] | Mostly patient or electronic surveys that are aggregated at the level of the provider or organisation (Benchmarking, public reporting) or patient group (adverse events monitoring) | All patients receiving a particular service (in case providers are compared) or a sample | Generic and/or service-specific PREMs<br>More recently also, in general, condition specific PROMs | Cross-sectional | Public reporting to allow informed provider choice;<br>Monitoring patient-reported adverse events<br>Comparing providers and organisations to minimal quality thresholds or benchmarking them to identify poor performers and learn from good performers<br>Use of PROMs and PREMs in accreditation programs | Risk-adjustment required |
| **Macro-level** | Population health monitoring | National health surveys (mostly telephonic or face-to-face household interviews) | Representative population sample | PREMs and mostly generic PROMs (e.g. HRQOL) | Recurrent cross-sectional measurements | Supportive information for public health activities;<br>Monitor effect of major policy initiative; Identify patient groups (e.g. certain socio-economic groups), conditions, etc. with a lot of room for improvement | Value of these data increase when they can be linked to other data sources (e.g. clinical registries) |

[d] When cross-country initiatives mature (e.g. PaRIS initiative), they can drive quality improvement at the macro-level as well.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Re-imbursement decisions | As part of a HTA (data are study based) or real world evaluation of health interventions (clinical registries) | Patients getting standard intervention as well as patients getting new intervention | Generic and/or condition-specific PROMs, depending on type of reimbursement decisions (within indications only or across indications) | Longitudinal | Assess relative effectiveness and cost-effectiveness of treatments and services<br>Assess patient issues and organisational issues associated with condition and treatment | Reference data needed from the general population to make appropriate relative effectiveness and cost-effectiveness assessments |
| | Contracting services and payment models | Patient surveys (PREMs);<br>Clinical registries (condition-specific PROMs) | All patients from the target group or a representative sample | Generic PREMs (P4P) or (condition specific-) PROMS (meeting minimum thresholds) | Cross-sectional (PREMs);<br>Pre-post (elective surgery PROMs);<br>Longitudinal (chronic care PROMs) | Pay-for-performance;<br>Contracting decisions | Risk-adjustment to avoid unintended effects (e.g. patient selection) |

**Key points**

- **Measurement in healthcare is still predominantly focused on clinical outcome and process measures. Nevertheless, PROMs and PREMS are increasingly used to complement these traditional outcome and process measures in an attempt to better capture what really matters to patients and to enable a more comprehensive understanding of outcomes and effectiveness.**
- **Patient reported outcome measures (PROMS) capture any report of the status of a patient's health condition elicited directly from the patient, without interpretation of the patient's response by a clinician or anyone else. A distinction can be made between generic (i.e. not specific to any particular disease or condition which enables comparisons between and within interventions as well as across different diseases and sectors of care) and condition-specific PROMS (i.e. specific to a particular disease, set of conditions, a domain, an intervention or part of the body).**
- **Condition- and generic PROMs are complementary. The condition-specific PROMs outperform the generic PROMs in terms of clinical detail and face validity which makes them more suitable for clinical applications. Nevertheless this increased level of clinical detail can come with a higher assessment burden. Moreover, a comparison across conditions is not possible with condition-specific PROMs. The main asset of generic PROMs is that they allow the comparison of outcomes across different patient groups and health services which makes them more suitable for policy applications.**
- **Patient reported experiences measures (PREMs) are a measurement of patients' perceptions of their experience of the process (rather than outcome) of care.**

- **PROMs and PREMs have different applications at the micro-, meso- and macro-level:**
  - **At the micro-level PROMs are used in the context of shared-decision making and patient-centred care by using individual patient-level data to: screen for common health problems and symptoms that are often overlooked; increase diagnostic accuracy; monitor disease pro/re-gression; support treatment decisions; facilitate communication between patients and providers as within the multidisciplinary team. Aggregated patient data can be used in the clinician-patient interaction to inform patients (e.g. consequences of their condition) or to drive quality improvement (e.g. monitot PROMs to understand which quality issues remain un- or insufficiently addressed under the current practice.**
  - **At the meso-level PROMs but still to a larger extent PREMs are used for quality improvement purposes. Aggregated data are used to assess and compare the performance of providers (benchmarking and feedback) and to inform the general public to enable informed patient choice (public reporting). PROMs and PREMs feedback, benchmarking and reporting are to be considered as only one element in a chain of actions that should be undertaken to achieve quality improvement. To make PROMS and PREMs successful in the context of quality improvement it is important that the measurement is not unnecessary burdening (e.g. limit level of detail of questionnaires) care providers and that rapid actionable feedback is provided. When providers are compared risk-adjustment is a pre-requisite.**
  - **At the macro-level PROMs and PREMs can be used for population health monitoring and macro-level performance measurement . Therefore many countries start to add PROMs and PREMs to population health surveys to generate information at the population level that is supportive in performing public health activities such as disease prevention, health promotion, measurement of health disparities, and evaluation of interventions. The value of these measures at the population level will increase when these data are linked to other surveillance data, such as clinical registries, billing and hospital discharge data.**
  - **In addition, PROMS and PREMs can also be used in the context of relative effectiveness assessment and cost-effectiveness to support payers to make reimbursement decisions. PROMs can help to identify which treatment to offer to specific patient groups, which patient groups to prioritise and which treatments to reimburse to optimize health gains on a population level and use scarce health resources efficiently. PROMs can be used to estimate the relative effectiveness and cost-effectiveness of health interventions, PREMs to assess patient and organisational issues.**
  - **PROMs and PREMs are also relevant in the context of contracting healthcare services where the contracting party can use PROMs and PREMs to: specify minimal performance levels; to monitor the performance of providers holding the contract and to incentivise providers to improve quality or attain a certain level of quality by linking payment to PROMs and PREMs performance..**

# 2 EVIDENCE ABOUT IMPACT: A REVIEW OF REVIEWS

## 2.1 Introduction

Several reviews prior to 2010 have already analysed and described the available evidence on the impact of the use of PROMs and PREMs with a broad perspective including all type of conditions, settings and measures.[35-37] Based on the available evidence there seems to be an impact upon the processes of care (e.g. increase in the rate of diagnoses and advice and education provided by the healthcare professionals). However, the impact of the use of PROMs and PREMs on outcomes of care remains inconclusive for the vast majority of the systematic reviews. In addition, these systematic reviews have consistently observed methodological limitations with regards to design (e.g. lack of training on how to interpret the information collected by the PROMs) and analysis. In this narrative review of reviews we update the available evidence with systematic reviews published from 2010 onwards.

## 2.2 Objective

The objective of this chapter was to analyse the evidence about the impact of PROMs and PREMs on process – and outcome measures based on a narrative review of systematic reviews. In addition, also the potential facilitators and barriers encountered during the implementation of PROMs and PREMs initiatives will be listed.

## 2.3 Method

Reviews were identified through a systematic literature search in two databases (Medline, and Cochrane library reviews). The databases were searched in November 2017 with the following restrictions: date limits (from 2010-current). Inclusion criteria are depicted in Table 2.

Inclusion criteria were tested on a set of 100 references by one reviewer, after which some small modifications were made. Next all titles/abstracts of references were distributed among two reviewers each screening half of the articles. Full-text of possible relevant references were obtained and again screened on inclusion criteria by one researcher; in case of doubt a second reviewer was asked to check the study on inclusion criteria. Reference lists were screened for additional references.

Included systematic reviews were methodologically assessed with AMSTAR (http://amstar.ca/Amstar_Checklist.php) and conformable to the KCE process notes (http://processbook.kce.fgov.be/node/359) by two reviewers each assessing half of the included publications.

Search date, searched databases, type and number of included studies and country setting were recorded for each systematic review. Next to this, from each systematic review, a description of the target population and interventions was extracted together with the reported outcomes for the respective interventions. Also the **conclusions** from each review as stated by the authors were extracted.

Data from the systematic reviews were extracted and categorized along different axes:

1. Target population included in the systematic review (age groups and pathologies/conditions);
2. Type of intervention (e.g. routine use of PROMs in clinical practice; benchmarking PROMs/PREMs for quality; Pay-for-performance based on PROMs/PREMs);
3. Type of designs of the included studies (systematic review; RCT; controlled trial; observational study);
4. Country;
5. Type of outcome.

Data analysis and synthesis was descriptive, along the above axes. The results about the impact of PROMs and PREMs on processes and outcomes are analysed and presented separately from the facilitators and barriers.

**Table 2 – Inclusion and exclusion criteria**

| | Inclusion | Exclusion |
|---|---|---|
| **P** | All type of patients for which PROMs or PREMs are measured | Studies conducted in low and middle income countries; |
| **I** | Interventions concerning PROMs or PREMs that are listed in Table 1. This entails a wide variety of interventions such as:<br>• Routine use in clinical practice for screening, diagnosis;<br>• Quality improvement via benchmarking;<br>• Reimbursement decisions;<br>• Performance monitoring. | Use of PROMs/PREMs in clinical studies |
| **C** | Usual care | N/A |
| **O** | • Outcomes (e.g. PROM/PREM);<br>• Processes (e.g. changing referral practices; discussing issues with patients)<br>• Secondary: adverse events/patient safety; mortality/survival; costs.<br>• Barriers and facilitators for implementation | |
| **T** | Review articles without a restriction of the type of primary studies that were included. Furthermore, the search strategy has to be reported and at least two databases were searched. | • Primary studies;<br>• Reviews focusing on literature about one particular country. |

## 2.4 Results

### *2.4.1 Search and inclusion*

A detailed search strategy can be found in Appendix 1.1. Table 3 shows the number of hits obtained in the two databases. All 1181 references were checked on title/abstract by one researcher to see if they fulfilled the inclusion criteria. As mentioned before, we sought for systematic reviews published since 2010. Thirty-six reviews were possibly relevant (and one additional reference was found).

**Table 3 – Number of hits per database**

| Database | N hits |
|---|---|
| **OVID_MEDLINE** | 908 |
| **Cochrane_reviews** | 273 |
| **TOTAL** | 1181 |
| **After deduplication** | 1181 |

The 37 obtained full-text systematic reviews were then screened on inclusion criteria and 15 references were retained. There are 11 systematic reviews about the impact of PROMs and PREMS (of which 3 also include information about barriers and facilitators) and 4 systematic reviews about facilitators and barriers.

### *2.4.2 Methodological assessment*

In annex to Chapter 2 it is shown with a colour which criteria of the AMSTAR instrument were met (Yes=green/No=red/Partly=orange). The included reviews can be considered as moderately performed systematic reviews. The quality of the reviews was taken into account in the analysis of the results, however no reviews were excluded based on the methodological assessment.

### 2.4.3 Impact on processes and outcomes

**Type of interventions studied**

Although PROMs and PREMs can be used for multiple purposes (see Table 1) the vast majority of the included reviews focus on the use of PROMs (i.e. 15 systematic reviews) in clinical care as a tool to support the improvement of quality of care.

**Type of target populations included in systematic reviews**

The majority of the included systematic reviews (i.e. 6 reviews)(Chen et al. 2013[38]; Groen et al 2015[39]; Howell et al. 2015[40]; Kotronulas et al. 2014[41]; Nama et al 2013[42]; Yang et al. 2018[43]) are within the domain of oncology. Other domains are: a mixed population (Boyce and Browne, 2013[44], Berger 2013[45]); palliative care (Etkind et al 2015[46]); non-malignant pain (Holmes et al. 2016[47]) and mental health (Kendrick et al. 2016[48]).

**Impact of PROMs used in the patient-clinician relationship**

There are 10 reviews including information about the impact of the routine use of PROMs in clinical care.

- The review of Boyce and Browne (2013)[44] included 16 RCT's (mixed population) about the impact of PROM-feedback on patient reported outcomes and found either no effect or an effect. In fact, only one study, where PROMs were used as a management tool to identify and prioritise issues in clinical care, found an overall statistically significant difference between the intervention and control groups. An additional six studies (of which five used PROMs as a management tool and 1 as a screening tool for otherwise unsuspected conditions) found positive results favouring the intervention group for certain domains or subgroups. In 9 studies there was no effect. As such, it seems that the use of PROMs as a management tool in clinical care (primarily based in an outpatient setting on a specialised patient population) demonstrated the greatest impact of feedback.
- The review of Chen et al. (2013)[38] included 27 studies (16 RCT's) evaluating the impact of PROM-use in clinical practice on processes and patient outcomes within the domain of adult cancer care.
    - The evidence about the impact on processes is convincing for patient-provider communication; monitoring treatment response and identifying unrecognised problems while it is reasonably strong for patient management:
        - Patient-provider communication improved in 21 of the 23 included studies. The two remaining studies concern one with a ceiling efect (high start at baseline, leaving little room for improvement and one study with low cancer severity (hence a patient group with a reduced need for communication for the treatment);
        - Monitoring of treatment response improved in all 11 studies that evaluated this.
        - Identifying unrecognised problems in a large variety of settings was found in 15 of the 16 included studies. One RCT did not find a significant effect.
        - Positive changes to patient management were reported in 13 studies while in 4 studies no effect was found. It appears that the routine feedback of PROMs only work when other measures are taken such as education, referral services and a detailed patient management plan following the PROM result. There is also a need to develop better measures of change to patient management as it is often complex and difficult to quantify.

- The evidence about the impact of the use of PROMs in clinical care on outcomes is convincing for patient satisfaction while it is unclear for health outcomes and not measured for patient health behaviour:
  - A strong effect on patient satisfaction was found. Thirteen studies reported a very strong to moderate positive effectof the use of PROMs on improved patient satisfaction. For the three studies that did not find such a positive effect, one study reported a possible ceiling effect meaning that both the intervention group and control group had a very high baseline patient satisfaction level potentially impeding any demonstration of a significant difference between two arms during the follow-up period.
  - Although there were positive effects of the use of PROMs on some health outcomes (especially symptoms, side effects and toxicity) reported in 13 studies (compared to only 2 studies with no effect) these findings needs to be confirmed by better designed studies covering a large set of well developed outcome measures.

- The review of Chen et al. (2013) also illustrated that it is important to provide feedback: with sufficient intensity (multiple times over a sustained period of time), targeting multiple stakeholders (doctors, nurses, allied health workers, as well as patients); with simple, clear, graphical and longitudinal meaningful interpretation of the results, and providing sufficient training for both health professionals and patients. There is also some supporting evidence that complex issues (e.g. routine screening and feedback of depression) may need to be integrated with other strategies (e.g. decision-making aids, education, clear management plans and clinical pathways) to have an impact. Finally, PROMs seems to have a larger impact in subgroups witth more severe problems at baseline.
- The review of Etkind et al. (2015)[46] included 16 studies (10 RCT's) evaluating the impact of PROM use in clinical care on processes and outcomes in the palliative care setting. The authors found strong evidence that collecting and feedback of PROMs in clinical care can increase the recognition and reporting of symptoms and the number of actions taken. The impact on outcomes is less clear. While some positive effects were found for psychological and emotional HRQOL, no significant effect was found for overall HRQOL or on symptom burden.
- The review of Groen et al. (2015)[39] included 26 studies (no RCTs) exploring the contribution of electronic PRO services to promote patient empowerment in cancer survivors. The authors found indications that IT services may contribute to empowerment by providing knowledge. Illustrating findings of these positive contributions are: the opportunity to identify personally relevant issues and health goals, providing knowledge of personal symptoms and physical and psychosocial functioning by graphi presentations, when ePROs are fed back to patients with coaching statements, it may improve the effectiveness of the encounters with health professionals.
- The review of Holmes et al. (2016)[47] included 13 studies (2RCTs) in the domain of non-malignant pain. The evidence on both processes and patient outcomes was not convincing. Although PROMs are regarded as useful to assess and quantify the patients' pain, as well as a way to view pain within the context of a patients' life the outcomes related to this construct are inconclusive. Yet, this evaluation relies on perceptions rather than on comparative study designs. Also the impact on clinical decision making and the therapeuthic relationship can only be, in absence of comparative study designs, evaluated via qualitative research. Based on the available research it seems that clinicians have the impression that PROMs contribute to the decision making process especially for choosing a treatment and to develop an individualised treatment plan and set goals. The same holds for its impact on the therapeutic relationship with improved patient-physician interaction and patient involvement. The results on the impact of PROMs on the evaluation and consecutive changes to treatment plans are less clear. Both the opinions and quantitative study results are conflicting with studies reporting an effect on, for instance, referral patterns and medication prescriptions, while other studies don't report an effect. Also the evidence on outcomes is inconclusive. One RCT reported a significant impact on pain levels while another (although some effect

was shown on pain related to strenuous activity) did not. Studies evaluating the impact on patient satisfaction and health status did not find a significant effect.

- The review of Howell et al. (2015)[40] included 30 studies (16 RCTs and 4 systematic reviews) in the domain of cancer care. The authors found convincing evidence for an impact of PROMs on processes such as patient-clinician communication (positive effect with more discussion of symptoms, emotional well-being etc.), early detection and symptom monitoring (positive effect on monitoring and detecting otherwise unreported symptoms), clinical decision making (indications for changes in referral patterns to psychologist in case of emotional distress and medication prescriptions such as analgesia). The use of PROMs appear to have no impact on the length of consultations. Also the impact on symptom management appears to be positive with indications for increased self-management and improved clinician's attention to symptom severity. The impact on patient outcomes is less clear. A positive effect on patient satisfaction was found in a systematic review (systematic review of Chen et al. 2103), but this effect was not always significant (ceiling effect). For both 'well-being' and 'perceived quality of care' there were studies favoring the interventions while other studies diid not show a significant effect.
- The review of Kendrick et al. (2015)[48] included 13 RCT's and 4 cluster RCT's in the domain of community mental health care. The results were inconclusive for both processes and outcomes. There was no significant effect reported on: symptom scores (13 studies); Health- related quality of Life (2 studies); suicide risk (1 study) and social functioning (1 study). Three studies evaluated changes in the management of care for patients witth mental health problems. Two of the studies did not found a significant change in drug therapy and one study while one study found a significant increase in referrals towards mental healthcare in the intervention group.
- The review of Kotronulas et al. (2014)[41] included 24 studies (20 RCT's) in the domain of cancer care.
  - Processes: four studies showed that patient outcomes such as emotional problems, social and sexual functioning are discussed more often. Also the symptom awareness, inter-professional communication, streamlining of the consultations and general patient clinician communication were reported to improve. The impact on medical decision making is less clear. Two studies found that the use of PROMs resulted in earlier referrals. Yet the intial effect on referrals to psychosocial care could not be confirmed during follow up. In addition, no statistically significant changes were reported for clinical actions sucha s analgesia prescriptions in case of pain. The acceptability of the intervention was moderate to high among patients and healthcarte professionals.
  - Patient outcomes: the 7 studies that evaluated the impact of PROM-use on symptom prevalence and reduction found mostly clinical important reductions, however these clinical important differences could not always be proven by statistically significant differences. The impact on quality of life was mixed with 9 RCT's without a statistically significant effect and 3 other studies with conflicting evidence. No statistical significant changes were reported on psychological symptoms.
- The Cochrane review of Nama et al. (2013)[42] aimed to evaluate the effectiveness of PROMs as an alternative to routine follow-up in women after treatment for gynaecological cancers. However, none of the identified studies met the inclusion criteria. Therefore, the authors' conclusion is limited to a research recommendation on the need for RCTs on this topic.

- The review of Yang et al. (2018)[43] included 43 studies (16 RCT's) in the domain of cancer care.
    - Processes: In 37 of 43 studies an increase in communication was found following the implementation of PROMs (discussion of symptoms in general, discussion of patient care, treatment plans, emotional function, discussion of health-related quality of life issues). The results of the nine studies evaluating the impact on patient management are less clear. Changes in management actions, such as making changes to medications (2 studies), referring patients to other professionals (5 studies), offering advice (1 study), or acting on quality of life issues in some way (2 studie) were reported. Other studies, found little impact on medication management (4 studies), test ordering (3 studies), and referrals (2 studies), perhaps due to a lack of clear guidelines regarding how to act upon the PROM data.
    - Patient outcomes: The results about patient outcomes are inconclusive. In three studies, a decrease in symptom severity was noted following PROM-use while in another study no difference was found. Specifically, psychological outcomes such as depression and anxiety appeared to be unchanged. Patient quality of life (5 studies) and satisfaction with care (4 studies) both appear to be unaffected by PROM-use.

**Benchmarking and public reporting of PROM data**

The review of Boyce and Browne (2013)[44] investigated the impact of providing PROMs feedback (benchmarks) to healthcare professionals on patient-reported outcomes. The one study which provided PROMs feedback at a group-level did not find an effect and, in fact, found that health deteriorated for all participants. This study focused on the functional status of an elderly population over the course of the 4 years so the likelihood of finding an effect may have been outweighed by the level of health decline.

The review of Berger (2013)[45] included 25 studies (in a mixed population and in a mix of care settings), but only one reported the effect of public reporting of PREMs. The single study reported mixed effects on patient level, other effects analysed in the reviews such as effects on patient choice or on disparities were not reported.

**Population health monitoring and macro-level performance measurement**

The systematic reviews included in this study do not provide information about this.

**Relative effectiveness assessment and cost-effectiveness for reimbursement decisions**

The systematic reviews included in this study do not provide information about this.

**Contracting of services and payment models**

The systematic reviews included in this study do not provide information about this.

**Table 4 – Summary of included systematic review evaluating the impact on processes and outcomes**

| Author | Search until | Studies | Setting | Interventions | Impact on processes | Impact on outcomes | Author conclusions |
|---|---|---|---|---|---|---|---|
| **Boyce and Browne 2013** | February 2012 | 16 RCT's | Mixed: outpatient, primary care; inpatient | Feedback from PROMs to healthcare professionals at Patient-level (management and screening tool) | | **=/+** | *In conclusion, the use of PROMs as a quality improvement tool is a highly versatile and complex intervention. The effectiveness of PROMs feedback seems to be related to the function of the PROM. However, the evidence regarding the impact of PROMs feedback on patient outcomes is weak, and methodological issues with studies are frequent. The use of PROMs as a performance measure is not well investigated.* |
| | | 1 RCT | Elderly in primary care | Feedback from PROMs to healthcare professionals at group-level (Benchmarking) | | = | |
| **Chen et al. 2013** | October 2011 | 27 studies (including 16 RCT's) | Adult cancer patients in the in- and outpatient setting | Composite PROMs that are routinely collected and used in clinical practice | Patient-provider communication (+); Monitoring treatment response (+); Detecting unrecognised problems (+); Patient management (+/=); | No studies on patient health behaviour; Patient satisfaction (+); Health outcomes(+/=); | *There is growing evidence supporting the routine collection of PRO to enable better and patient-centred care, especially in cancer settings. Despite the strong evidence in supporting the notion that the well-implemented routine collection of PROs enhances patient-provider communication and improves patient satisfaction, and growing evidence supporting ideas that it also improves the monitoring of treatment response and the detection of the unrecognised problems, the evidence-base was weak for its impact on changes to patient management and improved health outcomes and non-existent for changes to patient health behaviour, strong and effective quality improvement, increased transparency, accountability, public reporting and better healthcare system performance.* |
| | | 0 studies | | System performance and quality improvement | | | |
| **Etkind et al. 2015** | | 16 studies (including 10 RCT's) | Palliative care setting | Routine use of PCOMs (patient-centered outcomes): capture and feedback | Increased reporting/recognition of symptoms (+); greater congruence between patient and professional HRQOL scores (+); larger number of actions taken based on HRQOL data (+); | improved psychological and emotional HRQOL for patients (+/=) and carers (+/=) but found no improvement in symptom burden (+/=), and no change in overall HRQOL (=) | *We have presented evidence that implementation of PCOMs (Patient centered outcome measures) in palliative care improves processes of care and psychological and emotional HRQOL. To date, the evidence for impact on psychological outcomes is only moderate, but it does indicate that PCOMs data capture and feedback can positively impact patients' health status. However, there is evidence that PCOMs feedback does not appear to improve* |

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| | | | | | | | *overall HRQOL in palliative care. The evidence for these conclusions predominantly stems from oncology settings. To aid implementation projects, future work should investigate other disease areas and particularly other settings of care relevant to palliative care patients* |
| **Holmes et al. 2016** | January 2015 | 13 studies (2 RCT's, also 2 qualitative studies) | Patients with non-malignant pain | Routine use in clinical practice: Assessment; Decision making; Therapeutic relationship; | Assessment (=);<br>Decision making (+/Q);<br>Therapeutic relationship (+/Q);<br>Evaluating and changing R/ (=/+): | Potential implications for outcomes: pain (=/+); health status (=); patient satisfaction (=) | *Due to the poor quality, lack of generalisability and heterogeneity of these studies, it is not possible to provide a comprehensive understanding of how PROMs may impact clinical treatment of non-malignant pain. The literature suggests that PROMs enable pain assessment, decision-making, the therapeutic relationship, evaluation of treatment and may influence outcomes. Further research is needed to provide better evidence as to whether PROMs do indeed have any effects on these domains.* |
| **Howell et al. 2015** | September 2013 | 30 studies (16 RCT's, also 9 qualitative studies) | Cancer patients or cancer survivors | Routine use of PROMs in clinical practice | • Patient-clinician communication (+);<br>• Early detection and symptom monitoring (+);<br>• Clinical decision making (+)T;<br>• Symptom management (+);<br>• No impact (=) on length of consultation. | Patient satisfaction (=);<br>Perceived QoC (=/+);<br>Well-being (= or +); | *PROMs use in routine cancer clinical practice is growing with improvements on essential care processes shown but a number of implementation barriers must still be addressed. The lack of standardization in PROMs used in cancer organizations may make it difficult to use these data for quality monitoring in the future.* |
| **Kendrick et al. 2016** | May 2015 | 17 studies (13 RCT + 4 cRCT) | People with common mental health disorders | Feedback of PROM scores to clinician, or both clinician and patient | Changes in the management of common mental health disorders (CMHDs) (+/=) | Mean improvement in symptom scores (=);<br>Health- related quality of Life (=)<br>Adverse events (=)<br>Social functioning (=) | *We found insufficient evidence to support the use of routine outcome monitoring using PROMs in the treatment of common mental health disorders (CMHDs), in terms of improving patient outcomes or in improving management. The findings are subject to considerable uncertainty however, due to the high risk of bias in the large majority of trials meeting the inclusion criteria, which means further research is very likely to have an important impact on the estimate of effect and is likely to change the estimate. More research of better quality is therefore required particularly in primary care where most CMHDs are treated. Future research should address issues of blinding of assessors and attrition, and measure a range of relevant symptom outcomes, as well as possible harmful effects of* |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | | *monitoring, health-related quality of life, social functioning, and costs. Studies should include people treated with drugs as well as psychological therapies, and should follow them up for longer than six months.* |
| **Kotronulas et al. 2014** | May 2012 | 24 studies (20 RCT's) | Adult patients with active anticancer treatment | Routine use of PROMs in cancer care | Medical decisions made/ advice given/ changes in treatment/ referrals made (+/=);<br>Patient outcomes discussed during consultation (+);<br>Timing of referrals (+); | Physical symptoms (+/=);<br>Quality of life (±);<br>Psychological symptoms (=);<br>Supportive care needs (±);<br>Patient satisfaction with intervention (+)<br>Awareness of patient outcomes HP (+/=)<br>Health services outcomes and utilisation (=) | *The use of PROMs in clinical practice seems to be most effective in increasing patient satisfaction with communication about emotional concerns. Discussion of POs during consultations may increase and, in some studies, is associated with improved symptom control, increased supportive care measures, and patient satisfaction. Additional patient-related outcomes could be usefully addressed in future trials, including perceived self-care self-efficacy, social activity, work limitations, or survival. Patients and healthcare professionals are willing to engage in the routine use of PROMs during anticancer treatment. However, it is paramount that PROM intervention implementation is effective and incorporates strategies that increase patient adherence to the actual use of PROMs and HP engagement in the active incorporation of PROM feedback during encounters with patients.* |
| **Yang et al. 2018** | 43 studies (16 RCT's) | | Adult oncology population | Routine use of PROs | Patient-clinician communication (+): symptom awareness (+); streamlines consultation (+); inter-professional communication (+)<br>Patient management (+/=) | Symptoms such as anxiety, (+/=);<br>Patient satisfaction (=)<br>Quality of life (+/=) | *Our review suggests that PROs facilitate patient-clinician communication through various mechanisms that could perhaps contribute to improvements in symptom management and survival. The impact of PROs on clinical outcomes, however, remains poorly studied.* |

### 2.4.4 Facilitators and barriers

The evidence search revealed 7 reviews on potential facilitators and barriers related to the dissemination and use of PROMs/PREMs in clinical practice (Antunes 2014[49], Boyce 2014[50], Gleeson 2016[25], Yang 2018[43], Chen 2013[38], Etkind, 2015[46], Howell 2015[40]). Within the included reviews, only one publication (Gleeson 2016, analysis of 5 primary studies) was found on PREMs and its facilitators and barriers across a mix of healthcare settings.

**Facilitators and barriers related to PREMs**

The single retrieved review evaluating the facilitators and barriers of PREMs (Gleeson 2016[25]) identified, based on the few primary studies found, facilitators and barriers both in the process of data collection as in organisational aspects. Main barriers mentioned related to data collection were lack of understanding of using PREMs for quality improvement and expertise of the staff in data analysis and quality improvement, poor specificity of the results (with findings not applicable to, or relevant for, their own organisation or setting) and timing of the feedback (frequency too low or not on time to making and sustaining successful improvements). Therefore staff needs more training in data analysis and statistics to facilitate full understanding and use of the PREM results. On organisational level, following facilitators/barriers were reported: (1) working in a culture supportive of quality improvement, change and patient views (in contrast to an organisational culture or staff resistance to quality improvement initiatives); (2) management support and encouragement allowing dedicated time to staff to discuss results and plan improvement (in contrast to lack of time or resources to collect, analyse or act on data and lack of engagement or support for change from management); (3) ward-specific survey to facilitate sense of ownership over improvement actions and the use of national publicly reported survey as an incentive to use PREM results; and (4) evidence-based co-design for patient involvement (i.e. patient narratives of their experiences, shared with staff at collaborative meetings with patients). Overall could be stated that no single best way was found to use PREM data in clinical practice but that the main facilitators and barriers should be taken into account for a successful shift towards a more patient-centred approach.

**Facilitators and barriers related to PROMs**

Three of the 6 reviews on facilitators/barriers related to the use of PROM data, were focused on (adult) oncology patients (Yang 2018[43], Chen 2013[38], Howell 2015[40]). Two other reviews on palliative care settings (Antunes 2014[49], Etkind 2015[46]) and one review included studies across a mix of care settings (Boyce 2014[50]).

In the three papers on **oncology** patients following common barriers were reported: (1) technical issues related to the collection of PROM data (e.g. technical problems with completion of the (electronic) questionnaire, lack of reminders to complete the questionnaire, difficulty quantifying care experience with PROs, liability issues (e.g. PROMs reported by patients electronically between visits); (2) patients and clinicians' perceptions on the utility of PROs (e.g. finding PRO use inconvenient and too time-consuming, PROs not directly assessing relevant health issues from a patient's perspective, patients not believing PROs to be personally useful); (3) lack of financial resources (e.g. limited reimbursement and incentives for clinicians).

A solution, suggested in Yang 2018, to overcome the technical issues in the context of (routine) clinical practice consisted of using less than 20 questions, 10 min in length, incorporated in an electronic device, and administered in clinic (rather than home), private and comfortable space to complete questionnaires. The perception of both clinician and patient could be altered by using questionnaires tailored to them and to cancer type, stage and phase of cancer journey, also using presentation issues (such as summaries, visual representations of PRO data), with explicit identification of symptom thresholds and the provision of concrete management guidelines. Above all, an increased education of the clinician and the patient, taking into account the patient preferences, will facilitate the implementation of PRO data in clinical management of oncology patients.

In the review of Antunes 2014, the focus was more on the perception of the clinician on the implementation process of PRO data in **palliative care** settings, reporting a fear of change, feeling of assessment, work open to criticism and fear of added work as main barriers. Potential facilitators were leadership (to motivate individuals and reassure them that the use of

PROMs is beneficial and aims to improve the quality of care provided to patients), ownership of the measures, the provision of (timely) feedback, a preparation phase of reassurance and coordination, educations and a selection of measures. In the review of Etkind 2015 the (limited) evidence on acceptability and feasibility of completing and feeding back PROMs, showed that patients found the intervention helpful in discussing important issues or telling professionals how they were feeling and that patients would use PROMs feedback as part of standard care. The evidence reported in 6 studies revealed more mixed results on the acceptability to professionals: health-related QoL summaries facilitated communication and provided a useful overall impression of patients' experience in contrary to the interference of the intervention with their daily practice and difficulty completing the intervention protocol.

The single study on facilitators and barriers in a **mix of care settings** (Boyce 2014) found similar issues, as already mentioned in oncology and/or palliative patients. For example the workload associated with collecting and analysing data, the need for statistical support for the analysis and interpretation of the data, professionals' attitude (e.g. professionals not open to receiving feedback or changing their clinical practice, potential to damage patient-clinician relationship).

Overall could be stated across the retrieved reviews and across the different healthcare settings, that formal training of the staff (on data collection and analysis) is needed for the implementation of patient-reported data in clinical practice (including a shift in the patient and clinicians' perception). Also support from management, including sufficient time and resources dedicated to change clinical management, was mentioned as an important facilitator. More technical aspects related to the collection of PRO data, such as the choice of the questionnaire, the user-friendliness of the questionnaire, clear guidelines on the data collection process (e.g. timing, frequency, and location of administration) or statistical support for the analysis and interpretation of the data were also repeatedly reported.

## 2.5 Discussion

Based on this review of reviews several observations can be made. A first observation is that the evidence about the use of PROMs and PREMs that is published in systematic reviews is limited to the use of PROMs in routine clinical care. Only one review (Boyce and Browne, 2013[44]) report evidence (from one study) about the impact of benchmarking PROM data. The use of PREMs and PROMs for other purposes was not included in the systematic reviews. The impact of the use of PREMs was not evaluated in one of the included systematic reviews.

A second observation is that most research is conducted in the domain of oncology and that PROMs-use in other domains is much less evaluated.

A third observation is that there seems to be an impact of PROMs-use on the care process. More in particular, the evidence about the impact of PROM-use on the patient-clinician relationship is the most convincing. It seems that the use of PROMs helps to discuss symptoms and outcomes that are otherwise not discussed. One potential underlying mechanism is that PROMs feedback can act as a reminder to clinicians to address particular areas. This ''reminder effect'' is particularly evident in symptom alerts, which notify clinicians if a patient's symptom either crosses a threshold of severity or worsens significantly.[46] Another potential mechanism is the 'actionability of the feedback'. The effect is, after all, most pronounced in specific patient populations with a large number of problems (e.g. chronic conditions) and when there is much room for improvement (e.g. severely ill and bad PROMs at baseline).[44] It also enhances the inter-professional communications.[43] While clinicians mostly believe that the use of PROMs contributes in some way to the assessment of the patient (e.g. pain level), the evidence about the use of PROMs as a screening tool is not straightforward which is especially so for more complicated problems (e.g. depression).[47] Clinicians also believe that the use of PROMs affect the consultation process through goal setting with the patient and shared decision-making (e.g. treatment decisions).[44, 47] Nevertheless, the impact of PROMs on clinical decisions is not straightforward. While favourable effects were shown on referrals, medication prescriptions and other treatment decisions, this was not always the case. These finding suggest that more

attention needs to be paid to these processes of care and to better training of clinicians in the use of PROMs data (i.e. interpretation of changes in PROM scores and intervention selection). In addition, more attention needs to be paid to the role of patient symptom self-management or the training of patients in the use of PROMs data in the context of self-management strategies.[47]

A fourth observation is that the impact on outcomes is less clear. While favouring results were reported concerning patient satisfaction and symptom control, this was not always the case. Moreover, for several other outcomes (quality of life, symptom burden, pain etc) no statistically significant changes were reported in most of the included reviews. This does not preclude that more recent studies could show a positive impact, however. There is recent evidence from a primary pragmatic trial in metastatic cancer patients that measuring PROs has a statistically significant positive impact on overall survival.[51]

A fifth observation is that facilitators and barriers play an important role during the implementation process. Across the different retrieved studies, common barriers and facilitators could be identified. Barriers could be related to the technical aspects of the PROM questionnaire, for example technical problems to complete the electronic questionnaire, but also to the lack of implementation in routine clinical practice, e.g. lack of reminders to complete the questionnaire, no disease-specific questionnaires whereby the perception by the patient and the caregiver arises that the PROMs are not measuring relevant health issues. A third common barrier to the use of PROMs in clinical practice, is the lack of support, from management level towards the clinicians to dedicate sufficient time and effort to implement the PROMs in clinical management to sufficient financial resources and incentives to facilitate its implementation. Logically, these barriers could also be interpreted as potential facilitators when they are reversed. Ideally, the implementation of PROMs in clinical practice is supported by organisational facilities, such as support from management (including financial incentives), and technical opportunities, such as a questionnaire adapted to the target population, which is also user-friendly for data collection and analysis, embedded in an environment of quality improvement in which the clinicians are trained to implement the PROMs in their routine clinical practice and in which the patient perceives a better monitoring of his symptoms and can increases his self-empowerment.

A sixth observation is that PROMs might work. In most systematic reviews all results for all of the evaluated processes indicate in general that there is either a significant improvement or no improvement. A statistically significant negative results is rarely reported. Although publication bias might be a reason for this observation, an additional explanation might be that the way in which the PROMs are implemented are an important factor to make them work. Howell et al. (2015)[40] report a number of implementation issues to consider when PROMs data are used by clinicians: (i) limiting data collection so as to minimize patient burden and completion time to within ~30 min, (ii) collecting PROM data at baseline and selected follow-up times while minimizing the number of assessments, (iii) considering whether measurement equivalence has been established when using different modes of patient-reported data collection (e.g. web, telephone, tablet, or paper), (iv) collecting data via electronic technologies whenever possible, and (v) employing methods to minimize missing data including educating site personnel, patients and clinicians, and real-time monitoring of adherence.

As already mentioned above, only some evidence could be retrieved on the impact of PROMs on clinical outcomes. No conclusion can be drawn on the potential effect on macro level, such as the implementation of PROMs in payment models, due to lack of primary studies specifically on the effect of PROMs. In the review of Gillam 2012 the pay-for-performance model in the United Kingdom is reviewed on the quality of primary medical care. Yet, the individual effect of PROMs could not be identified based on the data that were published in this review. The authors concluded that that observed improvement in quality of care were modest and the impact on costs, professional behaviour and patient experience remained uncertain.

**Key-points**

- **A systematic review of systematic reviews (published from 2010 onwards) resulted in 11 studies about the impact of PROMs and PREMs on processes and outcomes of which 3 also included results about facilitators and barriers during implementation.**
- **The majority of the reviews (n=6) about the impact of PROMs and PREMs were conducted in the domain of oncology. Other studied domains were: a mixed population, palliative care, non-malignant pain and mental health. It is clear that domains such as primary care and chronic conditions are largely understudied. They all focused on the impact of PROMs within the patient clinician relationship. Only two reviews (with one primary study each) included information about the impact of PROMs and PREMs when used for benchmarking or public reporting purposes. The impact of other purposes such as population health monitoring, cost-effectiveness evaluation for reimbursement decisions and contracting services or payment models were not covered by the included reviews.**
- **The evidence suggests the use of PROMs in clinical practice has an impact on the care process.**
  - **PROMs help to discuss symptoms and outcomes that are otherwise not discussed. In addition to a "reminder effect", it seems that the impact depends on the "actionability of the feedback" given that the impact is greatest when patients have a number of problems and when there is much room for improvement (bad PROMs at baseline).**
  - **PROMs also enhance the inter-professional communication within the multidisciplinary team.**
  - **While favourable effects were shown on changes in clinical decision making (e.g. referrals, medication prescriptions) and negative findings were not reported a favourable result was not always the case. Authors of systematic reviews suggest that the impact can be improved when clinicians are trained in how to use PROMs and when strategies are used to increase patients' self-management.**
- **The impact of the use of PROMs on patient outcomes is less clear. While the studies included in the reviews rarely or never include negative findings, often include studies with favourable results (e.g. improved physical symptoms or patient satisfaction), in general, the evidence about an impact on outcomes is not yet convincing.**
- **Facilitators and barriers play an important role during the implementation process.**
- **Common barriers are:**
  - **Related to technical e.g. technical problems to complete the electronic questionnaire, lack of implementation in routine clinical practice ) and conceptual (e.g. PROMS that are measured are not relevant for patients and clinicians) aspects of the PROM questionnaire.**
  - **The lack of support, from management level towards the clinicians to dedicate sufficient time and effort to implement the PROMs in clinical management to sufficient financial resources and incentives to facilitate its implementation.**
- **Implementation success can be improved by:**
  - **limiting data collection so as to minimize patient burden and completion time,**
  - **collecting PROM data at baseline and selected follow-up times while minimizing the number of assessments,**
  - **considering whether measurement equivalence has been established when using different modes of patient-reported data collection (e.g. web, telephone, tablet, or paper),**

- **collecting data via electronic technologies whenever possible**
- **employing methods to minimize missing data including educating site personnel, patients and clinicians, and real-time monitoring of adherence.**

# 3 INTERNATIONAL EXAMPLES AND LESSONS LEARNED

## 3.1 Cross-country initiatives

There is a plethora of PROM- and PREM initiatives which result in fragmentation of efforts and hampers comparisons between countries, between providers, between treatments and in time. Some countries (see section 3.2 for details about France, England and The Netherlands) supported the development and implementation of PROMs or PREMs as part of a national policy initiative. There is, however a growing awareness that cross-country collaboration could enhance this domain. We briefly discuss in this section the five most commonly cited cross-country initiatives within the domain of PROMs and PREMs which are not limited to a specific domain or disease: ICHOM[e], OECD – PaRIS[f], The Commonwealth Fund[g], PROMIS[h] and PROQOLID[i]. The discussion of international collaborations around specific domains such as pathology specific disease registries (e.g. renal registry[52], arthroplasty registry[53]), are beyond the scope of the current report.

e www.ichom.org

f www.oecd.org/health/paris.htm

g www.commonwealthfund.org

h http://www.healthmeasures.net/explore-measurement-systems/promis

i https://eprovide.mapi-trust.org/about/about-proqolid

### 3.1.1 *ICHOM - International Consortium for Health Outcomes Measurement*[j]

**The initiative and its objective**

ICHOM aims to develop standardised sets of condition-specific patient reported outcome measures to support cross-country comparisons and knowledge gathering. After all the use of PROMs in clinical practice is still modest and when they are measured benchmarking possibilities are limited due to a lack of standardization (e.g. the definitions used often vary between institutions, countries, etc.).[54] ICHOM develops 'Standard Sets of PROMs' for different conditions and sub-populations with as main objective to be used in clinical practice and clinical studies. The relevance to the health systems (e.g. in terms of public health burden: chronic diseases) plays a role in which 'Standard sets' are prioritized by ICHOM. ICHOM is a non-profit organization with as founders 'Harvard Business School', 'Karolinska Institute' and 'the Boston Consulting Group'. It is now forming networks of organisations (hospitals, government agencies, professional organisation, industry, etc.) around the world. These organisations also act as sponsors and they work together to start to measure, benchmark and use PROMs (and clinical) data.[54] The sponsors receive, depending on their membership type ('bronze'; 'silver'; 'gold'), feedback reports (with international benchmarks) and a voice in which 'standard sets' should receive priority. The end product (set of outcome measures) are published on the ICHOM-website and publicly available.

**Working Process and Content**

ICHOM brings together working groups, organised around a particular medical condition. The working group members come from different countries and include patients, health professionals, researchers, outcome measurement experts and policy makers.[54] Working groups follow a structured series of teleconferences, facilitated by ICHOM, with each teleconference covering a set of topics:

- Prioritizing outcome domains according to the ICHOM-framework which stipulates an outcome hierarchy: 1) survival and recovery; 2) recovery process (time to recovery and disutility of the care or treatment process in terms of discomfort, retreatment, short-term complications, errors and their consequences); 3) the sustainability of health (recurrences of the original disease or longer-term complications; new health problems).[28] For each standard set a varierty of outcome domains are chosen (e.g. symptom burden, functional status, QOL).
- Selecting outcome measures based on criteria such as: extent of domain coverage (extent to which the instrument or item covers the a priori defined domains); psychometric properties (e.g. validity, sensitivity, reliability); feasibility to implement (e.g. length of questionnaires, translation availability including existence of cross-cultural validation, absence of licence fees); ability to interpret scores in a clinically meaningful way; actionability. To date most of the ICHOM Standard Sets still include so-called 'legacy' instruments. These are instruments which are internationally recognised, validated, and widely translated. However these instruments can have sub-par psychometric properties compared to more modern outcome measurement techniques and tools and they are also not developed within a comprehensive framework with consistent measurement properties across different domains.[55]
- Prioritizing case-mix domains; and
- Selecting case-mix definitions (based on patient and demographic characteristics).

j www.ichom.org

A structured consensus-driven (e.g. modified Delphi-technique), underpinned by an initial literature review, is used and the end result is a globally agreed set of PROMs (amongst other outcomes) for the particular condition.[54, 55] Although the ICHOM approach follows a general pattern, the operationalisation may differ between working groups (e.g. selecting members, thresholds used during the modified Delphi-approach). The translation procedure for instruments includes: forward-backward translation, review new instrument with original developers to make sure that intended purpose and construct are preserved; test new versions with patients in the target region; patient interviews to check if question's meaning was understood as such by the patients; review of the instrument by a panel and finalisation. Nowadays, patients are systematically involved in the development of ICHOM standard sets which was not the case during these initial Standard Set development processes. For the recent developed standard sets patient representatives are included in the working groups. In addition, patient advisory groups comprising 6 to 10 patients support the working groups (e.g. identifying outcome domains of interest). Also, to check if the final recommendations correspond with patients' values patient surveys are used.[11] ICHOM standard sets are condition-specific (see Table 5 for an example) but ICHOM is developing a core set of outcomes measures that would cut across conditions and form the basis of all adult health Standard Sets. This harmonization of outcomes measures will support the scaling of implementation and data analysis across multiple Standard Sets and condition areas. ICHOM has now produced 21 standard sets of outcomes, while 10 Standard sets are under development.[56] A growing number of conditions in a variety of domains are covered:

- Cardiovascular: 3 developed (heart failure, coronary artery disease – see Table 5; stroke), 2 in progress (atrial fibrilation and hypertension);
- Congenital anomalies; 2 developed (cleft lip & palate; craniofacial microsomia), 2 in progress (facial palsy, congenital upper limb anomalies);
- Digestive: 1 developed (inflammatory bowel disease);
- Malignant neoplasms: 5 developed (colorectal cancer, breast cancer, localised and advanced prostate cancer, lung cancer);
- Maternal and neonatal : 1 developed (pregnancy and childbirth);
- Mental and behavioral disorders: 1 developed (depression and anxiety);
- Musculoskeletal: 2 developed (low back pain, hip & knee osteoarthritis); 1 in progress (inflammatory arthritis);
- Neurological: 2 developed (dementia and parkinson disease);
- Primary/preventative care: 1 developed (older person), 3 in progress (oral health, adult overall health, pediatric overall health);
- Sense organ: 2 developed (macular degeneration, cataract);
- Urogenital: 1 developed (overactive bladder);
- Diabetes, blood and endocrine organs: 2 in progress (chronic kidney disease, diabetes).[56]

**Table 5 – Summary of Standard Set of Outcomes for Patients With Coronary Artery Disease**

| Category | Measure | Details | Timing | Data source |
|---|---|---|---|---|
| **Longitudinal outcomes (All)** | All-cause mortality | Date of death | Tracked for 5 years after index event – reported at 1 and 5 years | Administrative |
| | Admissions (for AMI, haemorrhagic stroke, ischemic stroke or heart failure) | Date of each admission and discharge | | |
| | Procedural interventions | Date of PCI and/or CABG | | |
| | Acute renal Failure | New requirement for dialysis | | |
| **Patient – reported health status (All)** | Angina, dyspnoea, depression, functional status, health-related quality of life | SAQ-7, PHQ-2, Rose Dyspnoea | 30 days + then annually to 5 years after index event | Patient reported |
| **Acute complications of treatment (PCI and CABG)** | Mortality post procedure | Date of death | Within index hospitalization + within 30 days of procedure | Clinical or administrative |
| | Place of death | Options: home, acute care hospital or rehab, nursing home or hospice | | |
| | Stroke and stroke type | Ischemic, haemorrhagic, other | | |
| | Acute renal failure | New requirement for dialysis | | |
| | Total length of stay | Date at arrival and discharge | Within index hospitalization | |
| | Post-procedure length-of stay | Date of intervention and discharge | | |
| **Major surgery complications (CABG only)** | Prolonged ventilation | Mechanical ventilation >24h post-surgery | Within index hospitalization | Clinical |
| | Deep sternal wound infection | Requires operative intervention, positive culture and antibiotics | Within index hospitalization + within 30 days of procedure | |
| | Reoperation required | Return to operating theatre (for other than wound) | | |
| **Interventional cardiology complications (PCI only)** | Significant dissection | Type C to F dissections | Within index hospitalization | Clinical |
| | Perforation | Angiographic or clinical evidence for perforation | | |
| | Emergent CABG for failed PCI | Emergency cardiothoracic surgery | Within index hospitalization + within 30 days of procedure | |
| | Vascular complications requiring intervention | At percutaneous entry site | | |
| | Bleeding event within 72 h | Within 72 h of PCI | Within index hospitalization + within 72 h | |

*Source: McNamara et al. 2015[57] ; see McNamara et al. 2015[57] for the standard set with risk factors for case-mix adjustment (e.g. age, sex, height, weight, diabetes, baseline creatinine)*

### 3.1.2 OECD initiatives

**Monitoring national progress in measuring (PROMs and) PREMs**

The OECD monitors the progress of PROMs and PREMs initiatives among its Member States to have input for their cross-national initiatives (e.g. 'Health at a Glance', PaRIS[k]) but also to draw lessons about what works and what not (see Text box 1 for 'principles for establishing national systems of PREMs'). In a recent report[11] the progress in measuring patient experiences (between 2006 and 2016), as well as the lessons learned were discussed.

To enable a stable and long-term PREM initiative *a governance structure* needs to be put in place. The OECD observed that several of its member states (e. g. Norway, Denmark and the Netherlands) established a new organisation to build up expertise in de the measurement and reporting of PREMs while other countries charge an existing institution (e.g. a Ministry of Health or a Central Bureau of Statistics) with this task. The OECD states that the creation of a new institute more often resulted in robust results. In some countries the responsibility is divided over different organisations which is a challenge (or threat) for the development of robust strategies in measuring and reporting PREMs. Despite the governance structure a clear political commitment and stable budget is required to make the collection and reporting of PREMs part of routine activities of a health system. Nevertheless, it seems that willingness to pay in some countries, even in those with a long-standing tradition in PREMs (e.g. The Netherlands and England), is diminishing because of general budget cuts in healthcare. As such, the financial sustainability of PREMs seems to be more vulnerable than that of administrative data such as billing data.

About half of the surveyed OECD countries *involve patients* in the development of PREM-surveys. Focus group discussions or interviews of representative patients groups as the most frequently used methods.

PREMs *are used to* compare and monitor health systems, compare performance of different providers and inform the public. Some countries (e.g. France, Denmark) use PREMs also in the process of inspection, regulation and accreditation or for funding allocation and pay-for-performance. In England, for example, in the 'Commissioning for Quality and Innovation payment framework (CQUIN) a composite score is calculated based on 5 PREM-questions (e.g. Where you give enough privacy when discussing your condition or treatment?). This composite score is used in the allocation of pay-for-performance budgets which amount approximately 1-2% of the providers total income. The use of PREMS in planning (e.g. health workforce or quality improvement programs) or selective contracting (e.g. in The Netherlands) exist but is less widespread. More and more countries include PREMs in their national population survey. Nevertheless, to generate actionable feedback for specific priority domains additional data collection efforts are undertaken for specific provider settings (e.g. emergency care) and patient populations (e.g. diabetes, stroke). Another evolution is the focus of surveys on policy priorities such as patient safety and integrated care.

Although most countries are conducting *cognitive tests and analysis of psychometric analysis* it is often not done systematically for all surveys. The methods for data collection (i.e. target population, sampling, data collection mode, phrasing of survey questions and response categories) and analysis on the other hand are in general standardised for each PREM-survey. Another observation is that provider-level PREMs are increasingly used and most of the countries that use them are making them available online. An area that requires attention is the reporting of PREMs data in an informative and understandable format. Although some countries (e.g. England, Norway, the Netherlands) evaluate the *reporting mechanisms,* more efforts are required to improve reporting and adapt it to the changing needs of the audiences and the different goals of use. This is crucial to enable stakeholders to make better use of the data.

k www.oecd.org/health/paris.htm

**Text box 1 – Principles for establishing national systems of patients experience measurement as proposed by OECD, HCQI Project**

- Patient measurement should be patient based (e.g. input from patients via focus groups or interviews to make sure that the questions concern topics that are important to patients).
- The goals of patient measurement should be clear (e.g. external [e.g. accountability to general public] versus internal [e.g. quality improvement by providers]). Although some measures can serve several goals, determining the goal before measurement is essential. When the goal is quality improvement the instrument should deal with actionable elements of the care process. When the goal is to facilitate choice, the measures should be able to show meaningful differences between providers.
- Patient measurement tools should undergo cognitive testing and the psychometric properties should be known. It is also important that changes to questionnaires are documented and when necessary re-tested.
- The actual measurement and analyses of the patient experiences should be standardised. Countries can, for instance, introduce accreditation procedures for the various agencies/vendors who conduct surveys.
- The reporting method of findings of patient experiences measurement should be chosen with care.
- International comparability of measurement of patient experiences should be enhanced.
- National systems for the measurement of patient experiences should be sustainable which requires long-term health system commitment and resourcing. Also the sustainability of the organizational and research and development infrastructure is an important condition for success.

*Source: OECD 2017*[11]

**PREMs in ambulatory care in 19 OECD countries**

Nineteen OECD countries participate in the 'Health at a Glance' indicator on the patient experience with ambulatory care which includes information on: doctor spending enough time with patients during a consultation; doctor providing easy-to-understand explanations; doctor providing the opportunity to ask questions and express concerns; and doctor involving patients in decision making affecting their care and treatment.

Since the introduction in 'Health at the Glance' 2013, more and more countries report data for this indicator. Currently, the OECD database includes data as from 2005 with for most countries data from 2010.

**PaRIS or 'Patient-Reported Indicators Survey'**

An assessment of the use of PROMS and PREMs in OECD countries resulted in, among other information, the following observations and recommendations:

- There exist several PREMs but coverage and comparability remain limited. Therefore, the OECD should undertake the following steps subsequently: build on its collaboration with the Commonwealth Fund (see section 3.1.3) to benchmark PREMs in ambulatory care; work with countries to extend PREMs to clinical areas that have received little attention to date: mental healthcare, long-term care, palliative care, emergency care, informal care and preventive care; develop PREM surveys of patient experience that assess neglected aspects of care: co-ordination for individuals with chronic; conditions, and patient safety.
- The challenges for PROMs are larger since implementation is still at a very early stage and the the existence of multiple concurrent initiative hinder international comparability. What's more, PROMs are particular developed for hospital-based procedures and virtually absent for conditions for which the need will be the highest in the near future (e.g. chronic conditions, mental health). The OECD should therfeore undertake the following steps subsequently: standardise and harmonise PROMs benchmarking for patients who have undergone hip and knee surgery (application of PROMs in OECD countries which is

most widespread); extend its PROMs work to longitudinal studies of chronic disease patients (with a particular focus on care co-ordination) starting with cancer care since PROMs are available within this domain and other complementary material (e.g. survival rates) exist at the level of the OECD; develop PROMs in areas where little to no PROMs exists such as for patients with multiple chronic conditions for which generic and specific PROMS should be complementary developed.[11, 58]

OECD Health Ministers acknowledged this pressing need to develop internationally comparable PROMs and PREMs and called upon the OECD to take the lead. This resulted in the PaRIS-initiative ('Patient-Reported Indicators Survey'). It is an initiative of the OECD, with two main objectives:

- To accelerate and standardise international monitoring, in population groups where patient-reported indicators are already used (stroke, heart attack, cancer, hip and knee surgery and mental illness). It was decided to start with cancer care (i.e. breast cancer: because of complementary data on screening, survival and mortality is available) and hip and knee problems. There will be no new instruments developed but panels of experts will convene to agree on which existing instruments are most appropriate to be used in the PaRis-initiative. Piloting the data collection is foreseen in a selection of countries from May 2018 onwards.[58] This work stream was launched in December 2017 and it is expected that early in 2019 a pilot data collection can start. Mental health has been pointed out as the next domain for which indicators will be developed.[59]
- To develop new patient-reported indicators in critical areas of healthcare, where none currently exist (complex, long-term conditions), and to publish international benchmarks of health system performance for these healthcare areas. While the OECD has already experience in collecting patient experience data in ambulatory care (e.g. feedback reports included in Health at a Glance reports since 2013), the OECD recently anounced that a module will be developed for population based survey's that also includes experiences for patients with intensive use of care (chronic care module which respondents are asked to fill in if they score positive on some pre-screening questions) and generic PROMs. In addition, a new survey on patients with chronic diseases (e.g. diabetes, COPD, cardiovascular diseases, neurological diseases) will be developed.[59] The goals are:
    - *"to report internationally comparable health outcomes and experiences of patients with chronic conditions by using risk-adjusted indicators that can be repeatedly measured over time;*
    - *to support the analysis of variation in the outcomes and experiences of patients between providers and healthcare systems and the explanation of this variation by the characteristics and behaviours of patients, providers and healthcare systems."[59]*

This stage of the PaRIS-initiative is still in its early stages and decisions at every level of the process still need to be taken: 1) identifying the target population (adults: 18 years or older, presence of one or more chronic conditions and visiting the physician within a defined period); 2) developing the sampling strategy (via primary healthcare services); 3) designing the survey questions (in collaboration with other international initiatives such as ICHOM, Commonwealth, etc. and with a focus on functional health outcomes and health-related quality of life); 4) developing the data collection strategy.[58]

Collaborations are sought with other international partners, such as ICHOM and the Commonwealth Fund.

### 3.1.3 The Commonwealth Fund

**The initiative and its objective**

The Commonwealth Fund is an American private foundation that supports independent research on healthcare issues in order to improve healthcare practice and policy. An international program in health policy is designed to stimulate innovative policies and practices in the United States and other industrialized countries.[60] As part of this international program the Commonwealth Fund conducts surveys to explore the experiences of doctors and patients and population health, to highlight opportunities for cross-national learning and health system improvement. The surveys target different populations on a 3-year cycle: the general population (age 18 and older); older or sicker adults; primary care physicians. Eleven countries participate in the survey: Australia, Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland, the United Kingdom and the United States.[11, 60] Important themes covered by the survey are: accessibility (e.g. access and use of emergency departments, waiting times to see physicians; cost of care as barrier), continuity of care (e.g. gaps in care co-ordination), patient experience, perceptions of the health system, and health promotion and disease prevention.[11, 60]

**Working Process and content**

The surveys include both general population surveys as surveys that focuses on specific sub-populations. The focus may differ per year. The Commonwealth Fund supports sub-contractors in each country to conduct computer-assisted telephone interviews of random samples of adults (probability-based overlapping landline and mobile phone sampling design with standard within-household selection procedures), using a common questionnaire translated and adjusted for country-specific wording as needed. The survey development, translation and pilot-testing is usually done in collaboration with researchers in each of the eleven countries. The 2016 survey, for instance, focused on the health and healthcare experiences of the general adult population. The overall response rates varied from 11 percent (Norway) to 47 percent (Switzerland) which is rather low and might introduce reporting bias. The sample sizes varied between 1 000 and 7 124.[61] Data were weighted (e.g. systematic nonresponse across known population parameters including region, sex, age, education, and other demographic characteristics) to ensure that the final outcome was representative of the adult population in each country. One of the main limitations, however, remains: it is highly likely that difficult to reach population (e.g. undocumented immigrants and adults with relatively low incomes, people who lack proficiency in the relevant language) are insufficiently represented.[61]

### 3.1.4 PROMIS® - Patient-Reported Outcomes Measurement Information System

**The initiative and its objective**

PROMIS is a cooperative research program initiative funded by the American National Institutes of Health (NIH) with as aim to develop, evaluate, and standardize item banks that could be used to assess common symptoms and function in adults and children.[33, 62] The PROMIS tools are copyright-protected but publicly available, readily accessible (for non-commercial use), and easy to use. Although started as a US-based initiatives, with 'PROMIS International' a volunteer consortium of scientists and clinicians was launched to expand the activities of PROMIS to other countries including the assessment of cultural relevance and the assistance with coordination of translation and cross-cultural validation activities. The hope is that governments, academic institutions, industry, and other partners and stakeholders in the United States and beyond will see the value of this initiative and will financially support the ongoing development, coordination of resources, and maintenance on a long-term basis.

### Working Process and content

PROMIS supports PRO-science by building a collaboration of scientists across academic institutions, government, health organizations, and industry.[55] Primary research sites are supported by three centres: a statistical centre, a technical centre, and a network centre. The PROMIS initiative offers a powerful example of how collaborative partnerships can advance PRO development nationally. Ongoing work in the Netherlands, Germany, Spain, Canada, and other countries demonstrates how international collaborators and partners can work together and join forces within this domain.[63]

PROMIS uses a uniform qualitative process with detailed systematic review, focus groups, cognitive interviews, and translatability for each item bank. PROMIS makes use of 'Item Response Theory' (IRT) and 'Computerized Adaptive Tests' (CAT) to construct the item banks. IRT allows the development of item banks to measure 'underlying concepts' in a variety of ways. IRT models estimate the underlying scale score from the items. Via IRT a large number of items from different questionnaires are calibrated to a common metric to estimate the underlying scale score. It can be compared to the assessment of biomedical markers, where for example, measurement of an HbA1c level is independent from the manufacture of the laboratory device.[55] CAT is an approach (the choice of an item depends on the score on the preceding item) to administering the subset of items in an item bank that are most informative for measuring the health construct. CAT, for which a computer is required, helps, to reduce the number of items that needs to be administered.[64] For example, when administering a functional impairment questionnaire using CATs, the computer would be unlikely administer an item that represents a very high level of functional impairment (e.g. I have problems getting dressed) once it had decided (following previous item responses) that the respondent probably had very little impairment (for example, if they responded positively to a statement about exhausting exercise).[65] The PROMIS initiative, which began in 2004, has resulted in more than 60 state-of-the-science measures for adults and 50 measures for children.[33]

### Key points

- **There are a plethora of PROM- and PREM initiatives which result in fragmentation of efforts and hamper comparisons between countries, between providers, between treatments and in time. Yet, several cross-country initiatives emerge to join forces.**
- **ICHOM (International Consortium for Health Outcomes Measurement) aims to develop standardised sets of condition-specific patient reported outcome measures to support cross-country comparisons and knowledge gathering. The main objective of ICHOm is to develop PROMs for use in clinical practice and studies. ICHOM brings together working groups (patients, health professionals, researchers, outcome measurement experts and policy makers), organised around a particular medical condition. They use a structured consensus approach underpinned by an initial literature review. The following topics are covered: 1) prioritizing domains; 2) selecting outcome measures based on criteria such as psychometric properties, feasibility, ability to interpret scores and actionability; prioritizing case-mix domains; selecting case-mix definitions.**
- **The Commonwealth Fund conducts surveys to explore the experiences of doctors and patients and population health, to highlight opportunities for cross-national learning and health system improvement. The surveys target different populations on a 3-year cycle: The general population (age 18 and older); older or sicker adults; primary care physicians. Eleven countries participate in the survey.**
- **PROMIS (Patient-Reported Outcomes Measurement Information System) is a cooperative research program initiative funded by the American National Institutes of Health (NIH) with as aim to develop, evaluate, and standardize item banks that could be**

used to assess common symptoms and function in adults and children.

- The OECD monitors PREMS in ambulatory care in 19 countries. PREMs are also part of the Health at a Glance report. This report is published yearly by the OECD and includes key performance measures with benchmarks for OECD member states. Besides these initiatives the OECD recently launched the PaRIS-initiative with two main objectives:
  - To accelerate and standardise international monitoring, in population groups where patient-reported indicators are already used starting with breast cancer and hip and knee problems. There will be no new instruments developed but panels of experts will convene to agree on which existing instruments are most appropriate to be used in the PaRis-initiative. Piloting the data collection is foreseen in a selection of countries from May 2018 onwards.
  - To develop new patient-reported indicators in critical areas of healthcare, where none currently exist (complex, long-term conditions), and to publish international benchmarks of health system performance for these healthcare areas. This stage of the PaRis-initiative is still in its early stages.

    Collaborations are sought with other international partners, such as ICHOM and the Commonwealth Fund.
- The OECD established some general principles for PREMs:
  - Patient measurement should be patient based (e.g. patient involvement in developing process of questionnaires)
  - The goals of patient measurement should be clear.
  - Patient measurement tools should undergo cognitive testing and the psychometric properties should be known. Changes to instruments should be documented and when necessary re-tested.
  - The actual measurement and analyses of the patient experiences should be standardised. Countries can, for instance, introduce accreditation procedures for the various agencies/vendors who conduct surveys.
  - The reporting method of findings of patient experiences measurement should be chosen with care.
  - International comparability of measurement of patient experiences should be enhanced.
  - National systems for the measurement of patient experiences should be sustainable which requires long-term health system commitment and resourcing. Also the sustainability of the organizational and research and development infrastructure is an important condition for success. Countries which installed a clear governance structure for PREM initiatives (a new institution or one single existing institution responsible) were more successful than countries were responsibilities were scatted across several organisations.

## 3.2 In-depth country studies: research questions and methodology

### *3.2.1 Research question*

This section with in-depth country studies aims to analyse and synthesize the lessons learned from the implementation and use of PROMs and PREMs in three countries: France, the Netherlands and the United Kingdom. The UK was selected as they have world-famous programmes for PROMs and PREMs and lots of experience. The Netherlands was chosen because it is a country with substantial experience in the implementation of PROMs and PREMs. In addition, the researchers who performed the in-depth country studies were based in the Netherlands which facilitated access to knowledge, literature and experts through their personal network. France was included because much of the grey literature is in the national language, which made it more feasible to include this country than another language country.

The research question is formulated as follows:

How are PROMs and PREMs implemented and used for improvement of patient care and for policy purposes in the three selected countries (the UK, the Netherlands and France), and what are the lessons learned?

### *3.2.2 Methods*

#### *3.2.2.1 Search and pre-selection of grey literature*

The search of grey literature focused on the implementation and use of PROMs/PREMs on clinical practice and health policy in France, the Netherlands and the United Kingdom. For each country, the following three complementary search strategies were performed to minimize the risk of omitting relevant sources.[66]

- Google searches
- Targeted websites
- Consultation with experts

**Google searches**

A series of Google search strings were constructed to identify potentially relevant documents within each selected country. The first 200 results of each Google search per country were assessed for relevance based on the title and short description, and potentially relevant documents were retrieved for full-text evaluation. See Appendix 2 for the search strings used for each country.

**Targeted websites**

Various targeted websites were searched such as websites of government organizations and health agencies, patient organizations, professional organizations, special interest groups, research institutes and universities. See Appendix 3 for an overview of these targeted websites per country.

We also reviewed European or international websites for relevant information concerning the three countries, e.g. European Observatory on Health Systems and Policies, the International Consortium for Health Outcome Measurements (ICHOM), OECD, and the World Health Organization (WHO).

All publications were scanned and evaluated for their relevance, and the pre-selected publications were listed in a document (per country).

**Expert consultation**

We contacted 3-5 national experts per country via e-mail (see Appendix 4 for list of experts that responded). The mail outlined the objectives of the study and the document with (pre-) selected literature was enclosed. The selection of national experts and literature was based on the previous Google searches.

The national experts were asked to review whether important publications, information sources or national websites had been missed, and to respond within two weeks. They were also asked whether they would be willing to participate in a telephone or Skype interview (20-30 minutes). This interview

was organised for two experts (Prof. Nick Black for the UK, and Prof. Etienne Minvielle for France), both carried out by two senior researchers from NIVEL and lasting roughly 45 minutes. The interviews were recorded (following consent) and a summary transcript was made. In addition, we received written comments from an expert at the Haute Autorité de Santé (HAS) in France (Dr Arnaud Fouchard) who kindly agreed to review the KCE text prepared for France.

All new documents that were collected via the national experts were added to the lists of grey literature and it was agreed with some of the national experts that they would review the texts produced for the report.

The analysis of the situations in the three selected countries was finalized in 2017, without completing this analysis with more recent data (up until publication of this report in June 2018).

#### *3.2.2.2 Full-text evaluation and selection of documents*

**Inclusion criteria**

Based on the full-text evaluation, documents were included in the review if they focused on general healthcare for adults and met the following criteria:

- A substantial part of the document (a chapter for example) is focused on policy goals for the use of PROMs or PREMs, such as quality improvement, reimbursement, accountability, informing patient choice, disease management, etc.;
- The document reports on the implementation, use and (possible) effects of PROMs/PREMs on policy and practice.

The documents included could be scientific or research reports, policy documents or white papers, presentations, meeting reports, university/Master's theses, guidelines, or handbooks etc. In fact, everything except peer-reviewed books and journals accepted by Medline could be included.

**Exclusion criteria**

Documents were excluded from analyses if they mainly or solely focus on:

1. Care for children, elderly or mental health or specific conditions since these were out of scope;
6. The use of PROMs/PREMs in clinical research or in clinical trials;
7. Local initiatives or reports on one or few care providers or organizations (e.g. quality reports);
8. The development and testing of measurement instruments;
9. Pilot studies on a small scale, with few organizations (<3) and a small patient group (<100);
10. Anecdotic information (unless document is recommended by experts);
11. Newsletters, conference programmes, announcements of events, abstract books etc. (i.e. containing no full texts and in which PROMs/PREMs are only rarely mentioned);
12. PROMs or PREMs with another meaning (e.g. used as a name or as an abbreviation with another meaning);
13. Other sectors, not about human beings (e.g. veterinary medicine).

#### *3.2.2.3 Data extraction*

Data was extracted from the grey literature by first reading the document and then completing a record in the data extraction file for each report/text. This was done by three senior researchers at NIVEL (one per country). Consensus meetings were held to discuss and harmonize the extraction procedures and results for each country.

**Data extraction template**

A data extraction template for the grey literature was developed in line with the aims of the project and partly based on the data extraction template for the general overview on PROMs and PREMs.

The following data were extracted (see Appendix 5 for the template):

1. *General information* about the publication, including title, authors, year and country of publication, type and subject of document, etc.;
2. *Description of PROMs/PREMs* included in the publication: names, generic or disease-specific, patient populations, etc.;
3. *Implementation of PROMs/PREMs*: setting, aims, level or scale, time period, stakeholders involved, target groups, time period, participation and response, public reporting, etc.;
4. *Impact of PROMs/PREMs* on healthcare and policy: demonstrated effects on communication, disease management, overall quality, patient choice, transparency, reimbursement, competition, etc.;
5. *Enhancing or impeding factors*: facilitators and barriers for the implementation/use of PROMs/PREMs;
6. Recommendations and conclusions as described in the document;
7. *Background or contextual information*: health system or policy context, mandatory/voluntary participation, legislation, costs etc.).
8. To harmonize reporting across the three countries, pull-down menus (i.e. standardized picklists) were developed where relevant and possible.

### 3.2.3 Outline of this chapter

This chapter presents country reports on the findings from the grey literature, presented for France, the Netherlands and the United Kingdom. A brief description of the country and the healthcare system is first provided, followed by a description of the amount and types of documents found, and a short history on PROMs and PREMs in each country. Then the results of data extraction are chronologically presented according to the subsequent elements required for implementing PROMs or PREMs:

- Aims and stakeholders;
- Selection or development of PROMs and PREMs;
- Types of PROMs and PREMs implemented;
- Measurement procedures, methods and response;
- Analyses and presentation of results;
- Actual use of the information;
- Other lessons (i.e. lessons that cannot be attributed to one of the steps above).

These subjects are aligned with documents describing the process of implementing PROMs and PREMs.[67, 68] Actually, many of these elements seem to be required in practice and appear to demand the order depicted above. For example: a PROM or a PREM has to be available (i.e. selected or developed) before it can be used in measurements.

Furthermore, paragraph 3.6 presents the transversal analysis, considering the findings in the three countries. Background or detailed information on the search strategies, data-extraction and findings are included in the Appendices.

## 3.3 Report on France

### 3.3.1 French population and healthcare system

France has a population of 67 million inhabitants and the average life expectancy at birth is over 80 years (82.4 years, compared with the EU average of 80.6).[69] The French population has a good level of health, with the second highest life expectancy in the world for women (85.6 years). It has a high level of choice of providers, and a high level of satisfaction with the health system.[69]

The French healthcare system is a social insurance system, it has historically had a stronger role for the state than other Bismarckian social insurance systems. Just over three-quarters of total healthcare expenditure is publicly funded (77% versus 76% for the EU), with out-of-pocket spending among the lowest in Europe.[69] Public insurance is compulsory and covers the resident population; it is financed by employee and employer

contributions, as well as increasingly through taxation. Complementary insurance plays a significant role in ensuring equity to access. Provision is mixed; providers of outpatient care are largely private, and hospital beds are predominantly public or private non-profit-making.[69]

### 3.3.2 Search results

A total of 20 documents were selected and examined for the grey literature data extraction. This included 3 reports[70-72] (1 was a thesis[72]), 6 handbooks or guides (procedural documents)[73-78], 4 press releases / news items / website texts[79-82], 3 presentations[83-85], 2 conference reports[72, 86] and 2 (legal) ordinances[87, 88].

The documents mainly focussed on the measurement of patient experiences (PREMs) and were often produced by the French National Health Authority (Haute Autorité de Santé, HAS). The handbooks present procedures on how PREM data should be collected.[70, 73, 76] We also found a number of documents highlighting the legal framework for collecting data on patient experiences in France.[73, 74, 77, 79]

The HAS was the main author of relevant grey literature on measuring patient experiences and outcomes in France (12 out of 18 documents), illustrating their important role in co-ordinating and collecting PREMs (and, in the future, PROMs) in France.

### 3.3.3 Expert consultation

We received three responses from national experts in France. This led to the inclusion of four new references (including the thesis text) in the grey literature[72, 73, 77, 87] and a very valuable interview with Professor Minvielle at the Ecole des Hautes Etudes en Santé Publique (EHESP) in Paris, France.[89] An expert from the HAS (Dr Arnaud Fouchard) kindly agreed to review the KCE text prepared for France.[90]

### 3.3.4 History of PROMs and PREMs in France

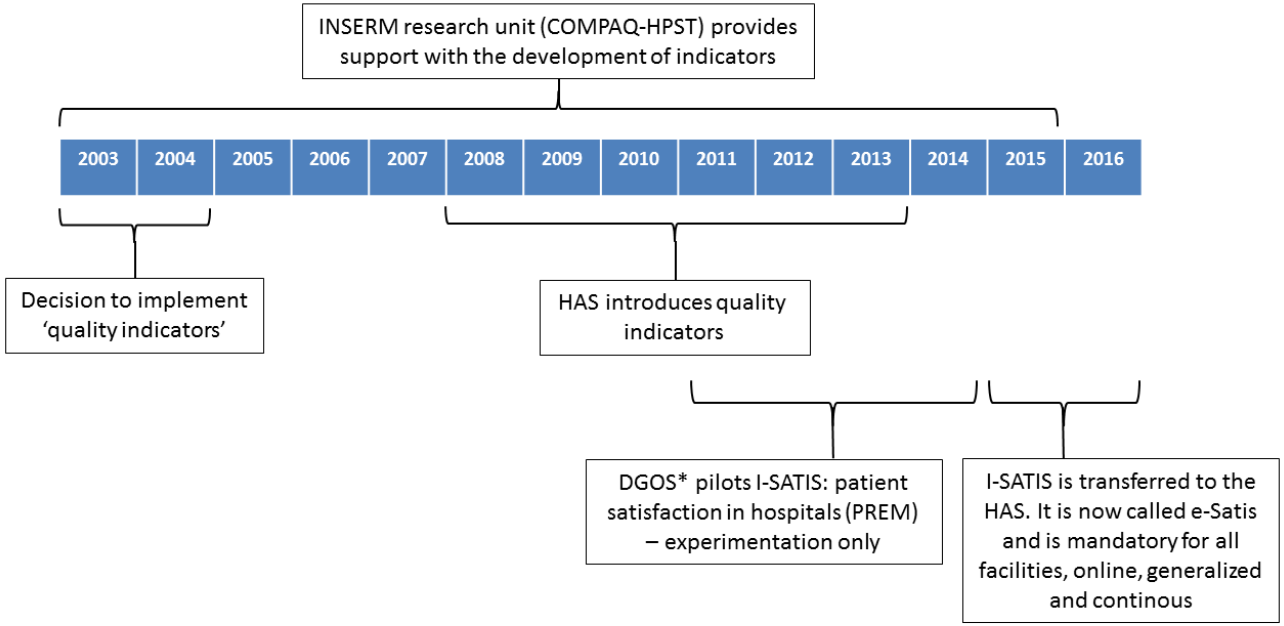
The introduction and use of PROMs and PREMs is a recent development in France. This country did not have any 'quality indicators' until 2003, but a number of scandals related to hospitals, especially associated with nosocomial infections, led to the collection of this type of information, including data on patient satisfaction (PREM).[77] This process was carried out in a context where the national press had already developed and was publishing hospital rankings.[89]

Following long debates in 2003 and 2004 regarding the definition of the first set of indicators, it was decided that the quality indicators should mainly be process measures, as they are easier to develop and closer to the work of healthcare professionals.[89, 77] The first indicators were developed to assess the means and organization regarding hospital-acquired infections. Then, following these recommendations, process indicators were implemented in hospitals and incorporated in patients' records ('patient-traceur').[74] This also allowed France to benchmark their hospitals.

To help develop and test the indicators, the French Ministry of Health and the HAS funded a research project based at INSERM called COMPAQ-HPST (COordination de la Mesure de la Performance et Amélioration de la Qualité:Hôpital-Patient-Sécurité-Territoire; see: http://compaqhpst.fr/en/). This project lasted for 13 years and aimed to produce different validated 'quality indicators' for French hospitals in collaboration with the HAS.[89] In 2008 the HAS instituted a system to improve the quality and safety of care based on quantified indicators, generalized and mandatory for public and private health institutions (secondary care).[77]

Since 2015, HAS started to focus on the development of patient-reported indicators (mainly PREMs) in order to observe quality from the patient's perspective.[90] Patient satisfaction indicators were introduced only recently, with measurements initially collected by phone surveys under the supervision of the Ministry of Health and lastly under the supervision of the HAS, by an online survey with national results publicly reported in December 2016.[90]

**Figure 1 – Brief overview of the history of PROMs and PREMs in France**




* Direction Générale de l'Offre des Soins

### *3.3.5 Aims and stakeholders*

The grey literature for France indicates that the main stakeholders involved in the implementation of PROMs/PREMs in France are healthcare providers (mainly hospitals), the HAS, and the French Ministry of Health (see Box 1).

The aims of the activities concerning the quality and safety indicators (four types: structure, process, PREMs and outcomes measured on national databases)[90] are threefold:

1. To collect quality indicators so that hospitals can improve their services;
2. To provide information to patients and the public so that there is more transparency and patients can make informed decisions;
3. To collect information that can be used for national and regional regulations.

**Box 1 – Organizations and project mentioned in the text**

***Ministry of Health:*** The Ministry of Health has the overall strategic co-ordination of activities on quality and safety in healthcare with the HAS, and funds research projects.

***Haute Autorité de Santé****:* Develops and implements quality indicators (including PREMs and PROMs) in France, in collaboration with partners like DGOS.

***DGOS****:* Direction Générale de l'Office des Soins. Was originally responsible for collecting PREMs data in France during the experimentation phase.

***COMPAQ-HST****:* Research project linked to French policy of health indicators until 2015 (Ministry of Health and Haute Autorité de Santé)

### *3.3.6 Selection or development of PROMs and PREMs*

We were not able to find much information in the grey literature regarding this point. We did find documents which present the survey methodology (e.g. handbooks)[73, 74] or evaluation reports for data collection in a sample of pilot hospitals[71], but none of the selected documents had a specific focus on how the PREMs were selected or developed.

### *3.3.7 Types of PROMs and PREMs implemented*

We did not find specific information on the types of PROMs or PREMs that were implemented but we were able to find the actual questionnaire that is used for I-Satis (30 questions), as this was defined in an ordinance in 2012.[87]

### *3.3.8 Measurement procedures, methods and response*

The majority of the documents either report on the implementation of PREMs on a national level or provide frameworks or perspectives anticipating their implementation on a national scale.[71]

There is a legal basis for data collection that dates back to 1996 (ordinance 96-346 of 24 April 1996) which concerns the certification of healthcare establishments in France (an independent assessment of the quality and security of the delivery of their services). The healthcare establishments covered by the ordinance are all establishments with a medical activity, surgery or obstetrics. Hospitals must collect and present annual 'quality indicators', including patient satisfaction data (see the e-Satis initiative in Box 2). The statistics are assessed by an independent organisation (HAS) and put in the public domain.[75]

**Box 2 – The e-Satis Initiative (OECD 2017)[11]**

The e-Satis initiative measures patient satisfaction and experience in hospitals. Importantly, the survey also includes questions about care co-ordination, including questions about hospital discharge and how well care is co-ordinated between hospitals and GPs.

The information is fed back to hospitals to help them improve quality. It also provides information and choice to the public. The data are also used for the purpose of pay for performance, in that hospitals receive bonuses for good results. There are regional-level data and national level data.

The e-Satis data was published for the first time in 2016. If hospitals do not get satisfactory results then a note is made on their accreditation record, which is public. Accreditation is compulsory for all public and private hospitals in France.

We were not able to obtain many details about the implementation of the e-Satis initiative in the grey literature (e.g. response rates) but were able to obtain a copy of the questionnaire and a number of important details from the expert at the HAS[90] (see below).

Since moving to the HAS in 2015, the survey has changed in a number of ways: it has changed name (from I-Satis to e-Satis), it is now a web-based survey (it was a telephone survey) and it is continuous (meaning a patient can provide multiple responses over time[l]).

**e-Satis procedures[90]**

Currently, e-Satis only concerns facilities whose care lasts for more than 48 hours, but the HAS is working on expanding it to ambulatory surgery. Facilities have to collect emails from patients, export a list of them in a defined format and drop it, on a regular basis (every 2 weeks or at least once a month), continuously, on a secured platform maintained by the HAS.

The platform (called e-Satis) sends an email to every patient, with a link directing them to the questionnaire. The name of the facility is also mentioned as it is available when the facility drops its list. The patient receives the email two weeks after discharge, with a unique secured link allowing the person to answer the questionnaire on the platform. The link can be used for up to 10 weeks and a reminder is sent one month after sending the first message. The HAS analyses the data collected on this platform.

Data are collected using a data collection template[78] and data are dropped on the platform according to a .csv format and must contain mandatory information. If these rules are not fulfilled, the data file is rejected and the facility receives a report mentioning the rejection.

Data are presented by hospital on the platform (for them) as a dashboard, with real time details on emails dropped on the platform and the number of patient answers. Real time results of satisfaction are currently not available. The annual results are available for every hospital on the national reporting platform 'Scope Santé' (http://www.scopesante.fr/#/) and on the HAS website.

A grading system is used to grade the hospitals, with a grade from 1 to 5 for each item depending on its rating of satisfaction. An overall satisfaction score is calculated for every patient answering the questionnaire. The mean of the patients satisfaction score gives a global satisfaction score for the hospital.

An adjusted version of this score is used for public reporting, allowing comparisons between hospitals. Four grades have been defined (based on a 4-months of data) and these appear on the 'Scope Santé' website:

- Dark green for an adjusted global satisfaction score of 77.3 out of 100 and above
- Light green ranging from 74 to 77.3
- Yellow ranging from 70.7 to 74
- Orange ranging for adjusted global satisfaction score under 70.7

Note: There is a threshold of 30 fulfilled questionnaires required for hospitals to be included in the comparison. Under this threshold they appear as "not-enough data" (to allow comparison) on the 'Scope Santé' website.

### *3.3.9 Analyses and presentation of results*

After data collection and data validation, an analysis and presentation of the results should be performed. We found that this was done in a number of ways in France:

- The HAS is responsible for the collection of measures of patient satisfaction and experience, via the e-Satis initiative (see 3.3.8 and Box 2).
- Data are collected continuously and a national measure is done every year,

l http://www.has-sante.fr/portail/jcms/c_2027566/fr/interview-de-brigitte-le-cossec-sur-les-evolutions-de-l-indicateur-i-satis

- As part of an accreditation procedure, all health establishments in France must collect and report on a number of quality indicators, including PREMs (see e-Satis initiative).
- Data analysis (of the quality indicators) and the presentation of findings is done by the HAS. A detailed report is prepared and made available for each hospital.
- Global results of e-Satis are put in the public domain.[77] See next section (3.3.10).

### 3.3.10 Actual use of the information

As mentioned above, the aims of collecting patient experience data in France are threefold (see 1.1.1). Regarding the first aim (to provide information to patients and the public), a recent development has been the introduction of a 'Welcome Handbook' for all new patients at French hospitals (defined in an ordinance of 15 April 2008).[77]

The 'Welcome Handbook' outlines important information about the hospital (e.g. how the hospital is managed, how patients can file complaints, the certification report, etc.) and includes a report about the satisfaction of patients. The latter has been introduced so that '*patients have information that favours a free choice of hospital*'.[77]

### 3.3.11 Other lessons

Various lessons were highlighted in the grey literature. A first one is that there is a strong legal structure in France, implemented by the French government (Ministry of Health and HAS), regarding the measurement of patient experiences. It has been mandatory (by law) for healthcare establishments (hospitals) to collect this data since 2006. There is even a penalty (fine) if the data is not collected and the data provided are checked (to have reliable data).

Patient privacy has also been an important issue in France.[89] This is overseen by the CNIL (Commission Nationale de l'Informatique et des Libertés) and the I-Satis initiative was confronted with a number of important issues related to patient privacy (as sensitive information is being collected via the survey by external polling companies). Many of these issues were addressed by moving the data collection to the HAS and making it an online survey answered by patients (for a phone survey, one needed to ask the patient for his/her consent because it involved personal data; with an online survey, the patient chooses to answer questions and consent is obtained in this way).[90]

An interesting point made by Professor Minvielle is that process measures (rather than PROMs) are better indicators for hospital organizations (e.g. did the patient receive a discharge letter?).[89] Having process measures creates an incentive for administrative persons in the organization (secretaries, nurses, physicians) to work together and find solutions.

Financial incentives can also help with the implementation of PROMs and PREMs.[89] It was found that hospitals that were rewarded in the pilot studies were very proud of their results (even though this financial incentive was not high). The results were an acknowledgement of their work and many hospitals wanted to present the positive findings.

There are a number of statistical challenges associated with PROMs and PREMs which can be an important barrier for their implementation.[89] How are the indicators calculated and what is the ideal adjustment (e.g. the mortality ratio for an outcome measure)? Having a research institute to support the implementation of the indicators can help with this process (e.g. the COMPAQ-HPST until 2015 in France).

**Quality indicators:**

Professor Minvielle noted that it is important to find persons in the hospitals who can translate the bureaucratic jargon of the quality indicators into concrete procedures for healthcare professionals.[89] This helps make the quality indicators less bureaucratic.

Funding the collection of quality indicators was also seen to be a challenge in France.[89] Data collection is made by the hospital and the data analysis is carried out by HAS. The hospitals have a schedule to collect and complete

the data collection, but due to the important financial pressures at hospitals, it can be difficult to find funding for the quality indicators.

### 3.3.12 Summary of findings

- Compared to the UK and the Netherlands, France has a recent history regarding the implementation of PREMs.
- There has been a focus on the implementation of PREMs in inpatient (hospital) care (and soon ambulatory surgery).
- There is a strong legal framework that defines the collection of quality indicators (including PREMs) by healthcare providers (hospitals).
- PREMs are collected at a national level for all hospitals in France (the e-Satis initiative).
- The HAS performs a key role in implementing PREMs, including data collection and the analysis of data.
- When implementing the process and other quality indicators, France established a research unit at INSERM to support and advise the HAS.
- Privacy aspects of data collection have been important in France.
- France is planning to implement PROMs in the coming years.

## 3.4 Report on the Netherlands

### 3.4.1 Dutch population and healthcare system

The Netherlands is densely populated with a healthy population and a healthcare system that has been transformed in 2006 to a system of managed competition.[91] This country is the most densely populated country in the European Union after Malta. Life expectancy is good (81.8 years in comparison to 80.9 for the EU), though not one of the highest in Europe. Before 2006 the Dutch health system was a hybrid system based on social insurance, combined with a long-standing role for private insurance covering the better-off. The 2006 reforms shifted the focus to the demand side, introducing three managed markets for a defined universal health insurance package, plus healthcare purchasing and provision. The government stepped back from direct control of volumes and prices to a more distant role as supervisor of these markets. The government provides a web site to help patients choose healthcare providers; other independent web sites are also available. Nevertheless, opportunities to make choices during the care process are limited, as is the extent to which patients exercise their notional choice.

### 3.4.2 Overview of the types of documents

A total of 27 documents were examined for data extraction. Six of those documents were not a result of the google search, but recommended in the expert consultation.[92-97] A substantial amount of the documents focussed on PROMs and / or PREMs in general or even quality indicators in general[68, 93, 95, 96, 98-105], while others addressed one or more specific examples of the use of (data from) PROMs or PREMs[94, 106-109]. Some of these documents were more concerned with what implementation of PROMs and PREMs should look like and how results may be used (visions for the future)[67, 68, 96, 97, 99, 104, 105, 110], rather than evaluating how implementation has proceeded (lessons from the past).[95, 98, 100, 101, 107] In addition, several documents provide frameworks for selection and implementation of PROMs and PREMs.[67, 68, 96]

The organizations that drafted the documents and / or performed the underlying projects varied in type and nature. Many of the documents were drafted by research institutes[67,68,94-97,105,107,108,110-113] or health insurance companies[93,99,102-104,114,115]. In addition, several documents came from governmental organizations.[98,109] Finally, some were drafted by organizations of healthcare providers or professionals[92,94,106] or consultancy companies[100,101].

### 3.4.3 History of PROMs and PREMs in the Netherlands

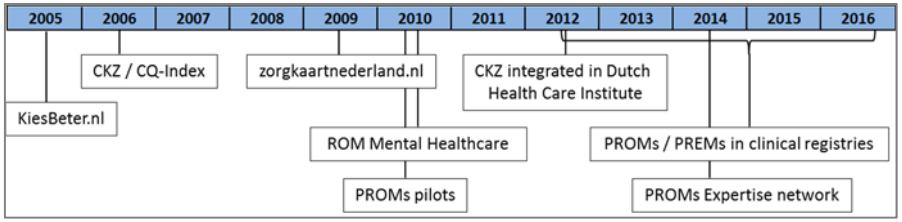
Figure 2 provides a timeline with several important developments regarding PROMs and PREMs over the past decade.[95] The timeline starts in 2005, the year in which the website kiesBeter.nl was developed to inform citizens and patients about healthcare, various diseases and for the publication of provider scores on quality indicators. Subsequently, in 2006, a fundamental reform of the Dutch healthcare system towards managed competition was introduced. The same year, the centre for consumer experiences in healthcare (Centrum Klantervaring Zorg; CKZ) was established to stimulate the availability of information on quality of care (see Figure 2). This centre was funded by the government and guided the development and implementation of the Consumer Quality Index (CQI; CQ-Index); a family of patient experience surveys (PREMs) together with a scientifically based methodology for survey development, data collection and analyses.[107]

In 2009 the patient federation (Patiëntenfederatie Nederland) launched a website (ZorgkaartNederland) where patients could provide ratings and reviews on healthcare providers and doctors.[95]

In 2010, two substantial initiatives were launched for PROMs.[95] The first is Routine Outcome Monitoring (ROM) in mental healthcare which still exists in 2017. The aim of ROM was to provide data for clinical practice, quality improvement and accountability including benchmarking. The second initiative for PROMs is a series of small PROMs pilots funded by health insurance companies to explore the potential of PROMs as a source of information on quality of care.

In 2012 the CKZ was integrated in the Dutch Health Care Institute and abandoned its role in developing and implementing the CQ-Index.[95] At the same time, initiatives to embed PROMs and PREMS in clinical registries emerged increasingly. This process appears to be ongoing.[98, 106] Finally, a PROMs Expertise network was formed in 2014, consisting of experts who share knowledge on PROMs.[67]

**Figure 2 – Brief overview of history of PROMs and PREMs in the Netherlands from 2006 onwards**




### 3.4.4 Aims and stakeholders

The stakeholders involved and the aims they pursue with measurements of PROMs and PREMs are important for the way in which these PROMS and PREMs may best be implemented. From the grey literature it becomes apparent that many initiatives pursue multiple aims for the implementation of PROMs and PREMs, such as clinical practice, quality improvement, benchmarking, reimbursement, public reporting etc. Few documents specify a single aim for measurements with PROMs and PREMs and if so, they generally do not rule out other aims but simply focus on one.[92, 93, 102, 110]

Some of the documents specifically mention that combining multiple aims for measurements with PROMs or PREMs (or quality indicators in general) is difficult because those aims often require slightly different information, or different kinds of analyses and presentation[67]. On the other hand it is mentioned that substantial costs are associated with measurements and that there is a risk of patients receiving multiple questionnaires.[100, 114] Separate measures for different aims would aggravate these issues.

The amount and type of stakeholders involved (for actual implementation) or targeted (for future implementation) varies markedly across documents. In the Netherlands, the major stakeholder groups are patient organizations, healthcare providers and health insurance companies.[68] At least one of these stakeholder groups is associated with efforts described in each document and often there are more involved. Governmental organizations are occasionally involved such as the Healthcare Inspectorate (for monitoring and enforcing quality and safety)[108] or the Dutch Health Care

Institute (for enhancing public reporting or assessing effectivity of medical interventions)[68, 109]. See Box 3 for some major parties involved in implementing PROMs/PREMs in the Netherlands.

**Box 3 – Organizations and institutes involved (stakeholders) and mentioned in the text**

**Private parties**

*Miletus Foundation*. A consortium of health insurance companies aimed at providing data from PROMs and PREMs to insurers.

*Dutch Institute for Clinical Auditing* (DICA). An organization that hosts many clinical registries for medical specialists for various diseases.

*Dutch Association of Health Insurers*. The umbrella organization of nine health insurers in The Netherlands.

**Public parties**

*Dutch Health Care Institute*. This institute enhances quality of care through health technology assessment, promoting the quality of guidelines and stimulating the development and public availability of quality indicators.

*Healthcare Inspectorate* (IGZ). This national inspectorate promotes public health through effective enforcement of the quality of health services, prevention measures and medical products.

### *3.4.5 Selection or development of PROMs and PREMs*

Several documents in the grey literature from the Netherlands specifically focus on how PROMs may be selected.[67, 68, 105] These documents stress that the outcomes of interest (PROs) should be selected first, such as physical ability or fatigue, and *then* the instruments (PROMs) that best measure these PROs. In addition, the importance of involving patients in this process is deemed essential, for example to hear from them which outcomes are the most relevant and to test whether they interpret the items in a PROM as intended (usability). If no suitable existing PROM is available to measure the PROs of interest, a new one may be developed.[67, 68, 105]

Importantly, one of the documents focusses specifically on using PROs and PROMs for public reporting to meet legislative requirements (see Box 4). The document does this by aligning the selection process of PROs and PROMs with the requirements of the Dutch Health Care Institute. If stakeholders follow this process and jointly endorse the instrument for the Dutch Health Care Institute, public reporting becomes mandatory for all the relevant providers.[68]

**Box 4 – Some notes on legislative aspects**

***The Care Institutions Quality Act*** (1996-2016) entailed, among other things, that healthcare institutions make available information on quality of care (article 5). This Act did not specify how this information should look like and whether this information should include comparisons between healthcare providers.

***The Health Insurance Act*** (2006-present) entails, among other things, the existence of the Dutch Health Care Institute from 2014 onwards. This institute was given the task to foster a register for quality standards (guidelines) and measurement instruments for quality of care (which includes quality indicators based on PROMs or PREMs). Patient organizations, healthcare providers and health insurance companies are expected to submit quality standards and measurement instruments to the register. Upon acceptance of a measurement instrument for the register, the instrument can be scheduled for public reporting and then becomes mandatory for all providers that deliver the care on which the instrument focuses. If stakeholders struggle to agree on the submission of quality standards or measurement instruments for the register, the Dutch Health Care Institute has the authority and the means (funding) to push the development and submission of standards or measurement instruments.

Expert knowledge is considered essential for selecting PROs and PROMs. Therefore, various documents have integrated this expert knowledge and recommend that stakeholders consult experts in the field of clinometrics and survey methodology.[67, 68]

Regarding PREMs, there is more focus on developing new questionnaires than on selecting existing ones. A large initiative in the Netherlands is the Consumer Quality Index (CQ-Index; CQI), a family of PREMs that was implemented from 2006 onwards. An evaluation in 2011 revealed that 20 CQ-Index surveys were newly developed and a large number of surveys was still under development.[107] In addition, a patient satisfaction questionnaire was developed for implementation in various hospitals rather than selected from existing surveys (core questionnaire for the assessment of patient satisfaction in academic hospitals; COPS[108]). As with PROMs, patient involvement regarding the content and usability of the surveys is highly recommended.[107]

### 3.4.6 Types of PROMs and PREMs implemented

The generic PROM used frequently is the EQ-5D[92, 94, 109]. In addition, the use of Visual Analog Scales was mentioned for hip or knee surgery.[92] The condition specific PROMs observed in the literature are the HOOS-PS and KOOS-PS for elective hip or knee surgery[92], the Skindex for skin disease[113, 116], the Dermatology Life Quality Index[116], the Oxford Hip Score and the Oxford Knee score[112]. In addition, a group of collaborating hospitals reported to use the EORTC QLQ-C30 & LC1 for lung cancer and the EORTC-QLQ-PR25, SHIM, ICIQ, IPSS and EPIC for prostate cancer.[94]

As indicated, the CQ-Index is by far the biggest initiative for measuring PREMs. The CQ-Index generally entailed rather specific surveys that were quite elaborate; more recently, the idea is to move to a smaller set of more generic and shorter PREMs surveys.[103, 115] In addition to the already mentioned satisfaction survey (COPS), a large and well known website for reviews and ratings was also identified in the grey literature (www.zorgkaartnederland.nl[95, 112]). The Net Promotor Score (NPS), a single item on recommendation of the care provider with a 10-point rating scale, was studied as a possible summary score.[112] Although the NPS is often considered the 'ultimate question' in the business and marketing literature, the study concluded that the NPS is not a particularly good summary score for patient experiences.

Some documents mention actual use and implementation of PROMs or PREMs without specifying the instruments. For example the yearly report of DICA mentions registering PROMs or PREMs for seven conditions without specifying the exact instruments.[106]

### 3.4.7 Measurement procedures, methods and response

The majority of the documents that report on implementation of PREMs or PROMs describe a nationwide scale. Others provide frameworks or perspectives anticipating nationwide implementation.[67, 68, 105] Documents in which implementation is not on a national scale often focus on quality improvement or clinical practice.[94, 110, 113, 116] This was to be expected since such applications are less dependent on comparisons of provider scores and accordingly, do not require large scale measurements for many providers.

For data collection, three strategies emerge from the literature. First, data collection in bulk using postal or online questionnaires occurs, usually among a sample of patients (rather than all patients).[98, 107-109, 112, 116] Second, PROMs and PREMs are increasingly integrated in clinical registries, often with the intent to administer surveys at specific moments during treatment (rather than bulk measurements where patients are invited to participate at various phases of treatments).[92, 106] Importantly, PROMs measurement generally requires monitoring outcomes on multiple occasions. One of the documents discusses an approach using repeated measures as well as an approach using a single data collection including items on both the present and the past.[68]

Finally, a large website with online ratings and reviews is mentioned in some of the documents (Zorgkaart Nederland). On this website patients provide ratings at their own initiative and accordingly, there is no sampling frame that would allow an assessment of representativeness.[95, 112] Reponse rates are not sufficiently mentioned in the examined literature to observe a general trend, let alone distinguish between various strategies for data collection.

Importantly, data collection should be performed in a standardized and consistent manner to enable comparison between healthcare providers. Therefore, consistency of measurement procedures across providers requires clear guidelines and instructions for sampling, data collection and data entry. A special accreditation existed for measurement organisations that wanted to collect data using the CQ-Index for healthcare providers for benchmarking.[107]

A recurring issue with survey research in general and PROMs and PREMs in particular, is that some patient groups are consistently underrepresented in the data. This applies for example to groups such as immigrants and patients with low (health) literacy.[107]

### 3.4.8 Analyses and presentation of results

The aim and application of results of PROMs and PREMs is of great importance for analyses and presentation. For example, if PROMs and PREMs are used for benchmarking, public reporting and reimbursement, validity, reliability and case-mix or risk adjustment are deemed essential.[68,98] For quality improvement and clinical practice, the importance of these issues is substantially less pronounced. Instead, clarity, comprehensibility and usability of data are emphasized.[111]

The logistics of data analyses can be detrimental to timely reporting. In one of the documents, it was mentioned that analyses for benchmarking, public reporting and reimbursement were often completed many months after data collection for a national but decentralized data collection followed by central analyses for benchmarking and case-mix adjustment.[107] As a consequence, stakeholders considered the results outdated when they became available.

Another issue with benchmarking is that differences between healthcare providers are generally very small so that the scores of (nearly) all providers are similar.[95, 107] This makes results difficult to use for patient choice or pay for performance as it hardly narrows down which providers to choose (patients), or which providers to contract / reward (health insurers). Accordingly, small differences may be one of the reasons why actual use of results lags behind initial expectations (see next section).

### 3.4.9 Actual use of the information

The actual use of information obtained from PROMs and PREMs varies or remains to be determined and documented. In general, information is often not available, or the use of information lags behind initial expectations. In addition, evidence on the actual use of PROMs and PREMs is often not available in the documents studied, for example in documents on future implementation of PROMs and PREMs, or documents on ongoing implementation that has not yet yielded useful results. In other cases, the actual use of the information is simply not discussed.

When actual use *is* discussed, it generally lags behind initial expectations.[95, 98, 107] In addition, some of the documents are dedicated to explore the use of results of PROMs/PREMs and illustrate that fruitful use of results is far from self-evident. For example, expectations of use of PROMs in clinical practice are rather high, but in 2016 a completely exploratory study was performed using dummy data to investigate possibilities and preferences of doctors and patients regarding the use of PROMs during consultations. The study yielded many practical considerations for using PROMs during consultations, such as that aggregated data was more appreciated than individual data, that PROMs data are most useful shortly after the diagnosis, etc. Nevertheless, the study remained somewhat cautious regarding the definitive value of using PROMs during consultations and recommended further research in different settings for different diseases.[110] Similarly, a recent study looking at presentation of PREMs for quality improvement in a hospital that had used PREMs for a number of years, still found many conventional strategies for presenting results to be suboptimal.[111] These findings indicate that moving from the availability of data from PROMs and PREMs to fruitful use of such data is a substantial effort in itself.

Regarding the use of PROMs data for quality improvement and in clinical practice, extra guidance and education for professionals was frequently recommended.[97, 110, 116] This may be due to the fact professionals will often benefit from additional knowledge on the surveys used, the scores derived from those surveys and elements of presentation of results such as confidence intervals for example.

### 3.4.10 Other lessons

Various lessons from the grey literature cannot be attributed directly to one of the logical steps of implementing PROMs or PREMs. For example, regarding the CQ-Index, it was observed that many surveys were developed at the initiative of various stakeholders and institutes, while a central governance and prioritization of survey development and measurement was lacking.[107]

Other issues that emerge from the grey literature are the costs and administrative burden of registration and data collection. In this context, several facilitators, barriers and recommendations are mentioned by various stakeholders and experts including:

- The importance of a good data-infrastructure to facilitate data collection and analyses so that these activities hardly require additional efforts beyond those already required in clinical practice. This includes aligning indicators, measurement procedures and data-infrastructures.[95, 101]
- Limiting the number of indicators that providers are required to make available to other stakeholders. This includes limiting the total number of indicators and avoiding situations where different stakeholders request similar but slightly different indicators.[101] For PROMs and PREMs for example, a risk of overlapping surveys was observed by the Miletus Foundation.[114]

In the Netherlands, solving these and other issues are largely left to stakeholders, with the government providing modest support, but little enforcement. Initially, the government pushed the availability very forceful following the introduction of managed competition in 2006. However, achieving public reporting of valid and reliable data on quality of care appeared much more complex than anticipated. In addition, government efforts yielded substantial resistance among providers. The government then changed its approach by reducing its involvement to a role of support and monitoring the development of publicly available data on quality of care.[68, 95] This means that stakeholders should work together to develop information on quality of care, to reduce administrative burden, to achieve data infrastructures that support data collection and analysis, and to limit the number of indicators.

The final point to be made is that joint responsibility of stakeholders for developing and implementing measures of quality of care requires a lot of trust between stakeholders, as well as transparent and predictable processes of indicator development, decision making, and sufficient time for stakeholders to prepare actual use of the data. In this context, building trust has been recognized and recommended as an important facilitator or challenge in several documents. In addition, a model of gradual transparency has emerged where providers first collect data themselves and improve their registrations (year 1), followed by data collection and sharing information on the completeness and accuracy of the data with other stakeholders (year 2), and finally sharing the actual results with all stakeholders (year 3). This allows providers with lower initial scores to learn from the results and improve their quality of care before they have to share their results with others.[102, 106]

### 3.4.11 Summary of findings

- From 2006 onwards, various substantial endeavors have been undertaken to develop and implement PROMs and PREMs in the Netherlands.
- Initially, efforts fully focused on PREMs (i.e. the CQ-Index), but PROMs gradually received more attention. In addition, CQ-Index surveys were rather elaborate and disease specific. It appears as if developments regarding PREMs move to a smaller set of more generic and shorter surveys.
- In most cases more than one stakeholder is involved in developing information on quality of care based on PROMs and PREMs. Consequently, such information will be used for various goals.
- It is stated that combining different goals is difficult. However, it is also recognized that providing data on quality of care is associated with substantial costs and administrative burden, and combining goals may be one way to limit costs and burden.

- Selection and / or development of PROMs and PREMs requires expert knowledge and patient involvement. Several documents show how stakeholders may guide this process.
- Various strategies for data collection have been pursued. Integrating PROMs and PREMs in so-called clinical registries appears the most supported option at present. Importantly, comparing the performance of providers requires that data collection is standardized across providers. Accreditation of measurement organizations has been used as one means, together with standardized frameworks and specific guidance or tools for data-collection, analyses and reporting..
- It is recognized that different stakeholders use the data for different goals and may therefore require different types of analyses and presentation for the same data.
- Logistics of local data collection and central data analyses may delay the availability of results, so that results are perceived as out-dated.
- The actual use of the results appears to lag behind initial expectations. This may be partly due to little differences between providers. In addition, the way information is presented, and the usability of this information for quality purposes could be improved. After all, producing good data alone is not enough to achieve fruitful use of such data.
- Both the availability of good data-infrastructures and implementation of data collection as part of the clinical workflow appear to be preferred strategies for moving PROMs and PREMs forward in the Netherlands.
- Trust between stakeholders, which may be achieved through a gradual process of sharing data, is considered essential for further development and use of data from PROMs and PREMs.

## 3.5 Report on the United Kingdom

### *3.5.1 Population and healthcare system*

To characterize the population and healthcare system of the United Kingdom (UK), we utilized information of the European Observatory on Health Systems and Policies (see Box 5).[117] In short, the United Kingdom has a generally healthy population, though showing considerable geographical variations and health disparities. The healthcare system is provided by a national health service (NHS) that offers a comprehensive package of public services, free at the point of use, predominantly financed from taxation. Although the health systems of England, Scotland, Wales and Northern Ireland have diverged since 1997, with ideological differences in approaches to care organization and delivery that have led to different payment systems, their health systems still have much in common.

**Box 5 – Characteristics of the population and health system of the United Kingdom**

The United Kingdom (UK) comprises Great Britain (England, Scotland and Wales) and Northern Ireland. It has a population of around 64 million, 80% of whom live in England. For the UK as a whole, life expectancy increased between 1980 and 2013 from 73.7 to 81 years (slightly above the EU average of 79.9 years). However, these averages also mask considerable variation within the UK, both geographically (Scotland has poorer health) and between socio-economic groups.

The UK's healthcare system was established in 1948 as a national system available to all residents, funded through taxation, provided by publicly owned hospitals and free at the point of use. The UK government allocates money for healthcare in England directly, and allocates block grants to Scotland, Wales and Northern Ireland that decide on their own healthcare policy. Health services are predominantly financed from general taxation: 83.5% of total health expenditure in the UK came from public sources in 2013.

Despite the description as a “national” health service (NHS), in practice the health system never was the same across the four nations. This variation has increased with the transfer of powers for healthcare and public health to Northern Ireland, Scotland and Wales from 1997 onwards, in a process called “devolution”. Although all nations have maintained national health services which provide a comprehensive package of services, the coverage and the purchasing of specific services varies across the UK. In England the payment systems intend to create incentives for quality and efficiency. In particular with the Payment by Results system for most hospital care (based on national average costs for certain diagnosis-related groups) and Pay for Performance (P4P) linking a small proportion of provider income to certain goals.

*Source: WHO / European Observatory on Health Systems and Policies, 2015.[117]*

### 3.5.2 Overview of the types of documents

A total of 39 eligible documents were selected for data extraction. These publications were mainly selected from the grey literature search (26 from targeted websites, 4 via snowballing, 1 via Google), and eight were suggested by the consulted experts. Most documents focussed on measuring patient experiences in general, on both PROMs and PREMs; only 13 publications specifically addressed certain PROMs or PREMs (either generic or disease-specific).

All selected documents focussed on the implementation of PROMs or PREMs and 25 documents presented how the measurement process is, will or should be designed. Including seven policy documents (white papers or strategies)[11, 118-123], six handbooks or guides[124-129], four documents presenting a framework or indicators[118, 130-132], five documents reflecting opinions or policy commentaries (columns, blogs and responses to consultations)[94, 133-137], one consultation document[138] and one quality statement of the NHS concerning their patient survey programme[139]. In addition, 15 research reports and one NICE guidance[126] provided evidence on patient experience measurements and specific issues of the implementation process.

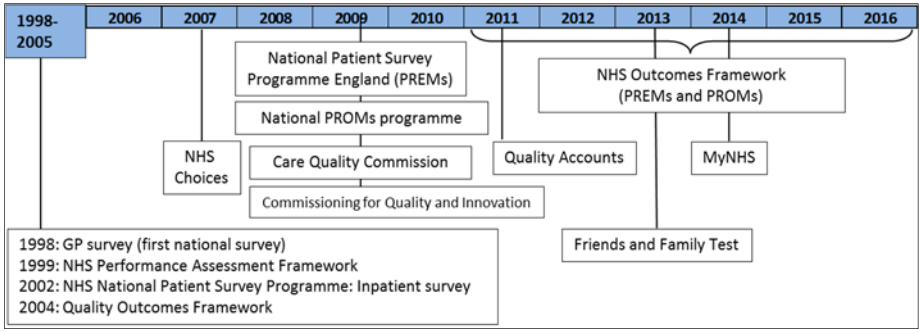
Six documents (3 policy papers or strategies, and 3 research documents) had an international scope concerning the comparison of countries, including the UK, on health system performance or payment systems.[11, 120, 123, 140-142]

Most documents were published by research institutes and/or universities (for example Picker Institute, The King’s Fund, University of Oxford and the London School of Hygiene and Tropical Medicine), followed by governmental or regulating organizations (Department of Health, Care Quality Commission, NICE and NCGC) and international organisations (WHO, Health Services and Policy, RAND). Some documents were drafted by organizations of healthcare providers or professionals (NHS, BOA), a charity organization (Macmillan Cancer Support) or a consultancy company (PWC).

### 3.5.3 History of PROMs and PREMs in the United Kingdom

Almost two decades ago, the United Kingdom started with the systematic measurement of patient experience and ever since this systematic approach has been expanded over the years and became a prominent part of the NHS performance management and service improvement in the last decade. Figure 3 provides a timeline for the UK, illustrating several important developments (surveys, websites, frameworks, and regulating initiatives) regarding the measurement of patient experiences.

**Figure 3 – Brief overview of the history of PROMs and PREMs in the UK, from 1998 onwards**




This history started in 1998 with a first national *GP survey* (on general practitioner services). Followed in 1999 by the *NHS Performance Assessment Framework*; the first framework that explicitly embedded patient experiences in the English NHS as one of six domains designed to deliver high-quality, cost-effective care. Then an *Inpatients survey* was one of the first nationwide hospital surveys in the world and a pioneer in the launch of the NHS patient survey programme in 2002.

In 2009 the *National Patient Survey Programme* of England marked the start of a systematic approach to measuring the experience of patients (PREMs) for various NHS services.[143] This programme includes surveys of several categories of users: inpatient, outpatient, accident and emergency (A&E), community mental health, cancer, maternity and general practitioner (GP) services.[118] Development and co-ordination of the programme is funded and managed by the *Care Quality Commission* (CQC), established in 2009. The national patient survey programme is continuously being refined and improved, ensuring that the programme obtains the best results possible about the topics most important and relevant to patients' experience of healthcare (see: http://nhssurveys.org/publications).[139]

In 2009 another initiative was launched for PROMs: the *National PROMs Programme*.[4, 11, 124] This marked the introduction of a mandatory routine collection of patient reported outcome measures (PROMs) for NHS patients in England. Several condition-specific PROMs, together with the generic EQ-5D had to be completed by patients both before and after four elective surgical procedures.

Along with the survey programmes, pay-for-performance schemes were introduced in order to secure improvements in the quality of services and better outcomes for patients. This started with the *Quality and Outcomes Framework* in 2004, focused on general practitioners.[140, 142] Together with the PROMs programme, a new payment framework was introduced in 2009: *Commissioning for Quality and Innovation* (CQUIN).[144] This framework makes a proportion of healthcare providers' income conditional on demonstrating improvements in quality and innovation in specified areas of patient care. Thus, a proportion of the income of hospitals depends on achieving quality improvement and innovation goals, agreed between the Trust and its commissioners.

In 2010, the national PROMs programme was integrated in the *NHS Outcomes Framework*, together with many quality indicators and surveys from the national patient survey programme (PREMs). This framework came into force in 2011, has been further developed and refined, and is still ongoing in 2016/17. It started with three domains (quality, safety and patient experiences), and currently has five domains with overarching indicators and improvement areas. Including domain 4 on 'Ensuring that people have a positive experience of care – Patient experience'.[138] The outcomes framework intended to sharpen the accountabilities in the system for delivering better and more equitable outcomes.

The *PROMs programme* survived the change of government in 2010, and continued for about two years as part of the *Outcomes Framework*. Data have continued to be collected in elective surgery and published by the Health and Social Care Information Centre till 2012. Then the *PROMs programme* has effectively stalled, due to a shift in responsibility from the Department of Health to NHS England, the restructuring of the NHS and financial restraints.[136]

Furthermore, the websites *NHS Choices* (2007) and *MyNHS* (2014; see Box 6) were launched for making health and social care data transparent, including public reporting on the collected quality information.

**Box 6 – Characteristics of the public website My NHS[119]**

This website is part of NHS Choices and was released in 2014. Developed to support transparency, opening data to public scrutiny and driving improved performance. It draws on existing data for a range of services – currently hospitals, local authority social care and public health, mental health hospitals, GP practices and a range of surgical specialties – and presents it in an accessible and comparable format. Thus making health and social care data transparent, openly available and easy to use. Anyone can use the service to see how their local hospital measures against a range of key quality indicators, how the local authority performs on the delivery of adult social services, and how public health services as a whole are doing within a local area. Data is presented in the form of simple, intuitive dashboards and available in raw format. Ultimately, by making an increasing amount of data transparent, the introduction of this website is expected to drive up the quality of services in the UK.

#### *3.5.3.1 Policy documents*

Over the last decade, several vision documents, white papers, legislation and NHS constitutions have been launched as key drivers for developing plans to improve patient experiences in the UK. Box 7 presents a list of such documents.

**Box 7 – Key documents and legislation driving the improvement of patient experiences in the UK**

- 2008: High Quality Care for all: NHS Next Stage Review Final Report
- 2009: Health Act
- 2010: NHS Constitution: the NHS belongs to us all
- 2010: 'Equity and excellence: liberating the NHS' (white paper)
- 2012: Generic NICE Guidance 'Patient Experience in Adult NHS Services'
- 2012: NHS Constitution for England
- 2013: Francis Inquiry – Final report
- 2014: NHS Five Year Forward View
- 2015: Care Act
- 2015: NHS England's Insight Strategy

In June 2008, the report 'High Quality Care for all: NHS Next Stage Review' provided evidence for NHS reform, and a vision for making the service fit for the 21st century.[145] A vision that wanted to make the NHS more accountable to patients and to free staff from excessive bureaucracy and top-down control. In 2009 the Health Act came into force and ever since, service providers and commissioners of NHS care have a legal obligation to take the NHS Constitution into account in all their decisions and actions.[125] In 2010, the 'NHS Constitution: the NHS belongs to us all' established the key principles and values of the NHS in England and set out the rights and responsibilities of patients, the public and staff to ensure that the NHS operates fairly and effectively. That same year the new government published a white paper 'Equity and excellence: liberating the NHS', signalling that more emphasis needs to be placed on improving patients' experiences of NHS care.[122]

A new NHS Constitution for England was launched in 2012, stating that high quality care is safe, effective and focused on patient experience. (see: https://www.gov.uk/government/publications/the-nhs-constitution-for-england) Subsequently, a NICE-guidance provided extensive evidence, methods and recommendations on 'Patient Experience in Adult NHS Services'.[126] In 2013 a report on the Francis Inquiry (about an investigation into the Stafford Hospital and unusually high death rates) once again stressed the importance of accurate and timely analysis of performance data for the delivery of safe and effective care.

In October 2014, a 'Five Year Forward View' presented a vision of health and care leaders in England, setting out a new direction for the health and care system. Then the Care Act came into effect from 1st April 2015, representing the most significant reform of care and support for England in more than 60 years. With section 91 (Part 2 Care Standards) requiring the Care Quality Commission to conduct periodic reviews, assess performance and publish assessment reports in respect of regulated activities and registered service providers (to allow for meaningful comparison of services).

Finally, the NHS England launched an 'Insight Strategy' (2015) with new proposals for making better use of multiple data sources, both patient outcome and experience data, including public surveys, Patient Reported Outcome Measures (PROMs) and related measures, social media analysis, online ratings and feedback. Ever since, the government and the NHS have continued to stimulate equal, safe, effective and person-centred care and to create a culture of transparency. Simultaneously looking for better ways to measure, monitor, analyse, report and utilize the information on patients' experiences with NHS services. For example by collecting online data with the Friends and Family Test, enhancing the use of digital technology for the electronic administration of e-PROMs, stimulating patient choice with the website MyNHS, investigating ways to assess the quality of integrated care or patient pathways[146], developing various guides and tools for implementing patient surveys[124, 139], and enhancing information governance and data security requirements (e.g. Information Governance Toolkit[119]).

### 3.5.4 Aims and stakeholders

Stakeholder involvement is one of the key elements of implementing PROMs and PREMs, starting with considering and discussing the aims with all relevant stakeholders.

#### 3.5.4.1 Aims of using PROMs and PREMs

The initiatives regarding PROMs and PREMs in the UK pursue multiple aims, such as quality improvement or performance measurement and benchmarking for transparency, accountability and governance. Few documents specify a single aim for the patient experience measurements, but if so 'quality improvement' is the ultimate purpose.

The main aims reported for measuring patient reported experiences (PREMs) are: to evaluate care and clinical pathways from the patients' perspective for quality improvement, monitoring, benchmarking, commissioning and regulation or inspection (e.g. for a risk-based surveillance system).

For measuring patient reported outcomes (PROMs) the various goals as defined in the documents are: to assess the appropriateness, responsiveness, (cost-) effectiveness and efficiency of care, to assess the impact of health interventions or health technology assessment (HTA), for benchmarking, to enable the comparison of providers and commissioners, to identify best practices and practice variation, to ensure equity in access to care services, to support decision-making in clinical practice and clinical management (by providing feedback to patients and professionals), to support patient empowerment, transparency and choice, and for commissioning or contracting. Furthermore, PROMs are recommended to be used – in addition to PREMs – for the comparison of health system performance between countries.[11]

In a study supporting the use of PROMs in the National Clinical Audit (NCA) programme the purposes were defined as to be able to: 1) compare performance between providers and commissioners in the National Health Service (NHS), 2) compare the cost-effectiveness of alternative providers in delivering the specific services (i.e. linking outcomes and resource use), and 3) assess the cost-effectiveness of alternative interventions and other changes in the NHS.[147]

One document illustrated the initial aims of PROMs, by reporting that the Bupa hospitals already started in 1998 with collecting PROMs data, using PROMs to promote and market the health-related quality of life benefits of the provided interventions and for creating a learning culture. Starting from the desire to spot clinical 'bad apples', it soon became clear that PROMs offered the potential for continuous quality improvement and to provide feedback to professionals and patients. Thus PROMs were likely to become a key part of how all healthcare is funded, provided and managed.[4]

To summarize, the objectives of PROMs and PREMs are multiple and somewhat varying. There appears to be a general difference, with a tendency that PROMs are more often used for assessing the effectiveness or efficiency of healthcare interventions, for accountability and commissioning or contracting, and PREMs are (likely to be) increasingly used for the comparison of healthcare providers or systems.

#### *3.5.4.2 Stakeholders*

There are various stakeholders and persons involved in the efforts as described in the documents. These include policy makers, commissioners, purchasers, managers, professionals, researchers, patients and the general public. The main stakeholders of performance measurement in the UK are the Department of Health (DH) and its arm's length bodies such as the NHS, the Care Quality Commission (CQC), and the National Institute for Healthcare Excellence (NICE). As well as the NHS service providers, their managers and healthcare professionals, and the patients or general public themselves. The major stakeholders and organizations involved in conducting patient surveys the UK, as far as mentioned in the documents and apart from the researchers, are displayed in Box 8.

**Box 8 –Stakeholders and organizations involved in patient surveys in the UK**

***Department of Health*** (ministerial department)

***NHS England***: public body, responsible for NHS services to deliver the best possible care for patients, funding Clinical Commissioning Groups to commission services for their communities.

***NHS Commissioning Board***: a health authority hold to account on delivering improvements in choice and patient involvement, and in maintaining financial control.

***Clinical Commissioning Groups*** (CCG): commissioners are contracting providers.

***Care Quality Commission*** (CQC): the independent regulator of health and adult social care providers in England, responsible for monitoring and inspection of registered services.

***Monitor***: sector regulator of all providers of NHS-funded services, responsible for promoting value for money whilst maintaining or improving quality.

***The public / Health Watch*** (national consumer organization)

Patients, families and carers / Patients Like Me (patient network)

***National Institute for Health and Care Excellence*** (NICE): a public body that advises on the efficacy and cost-effectiveness of care interventions, serving both the English and the Welsh NHS.

***NHS Information Centre for Health and Social Care*** (NHS IC): played a central role in delivering the PROMs programme, responsible for linking identifiable, record-level (PROMs) data to existing routinely collected administrative data including Hospital Episode Statistics (HES).

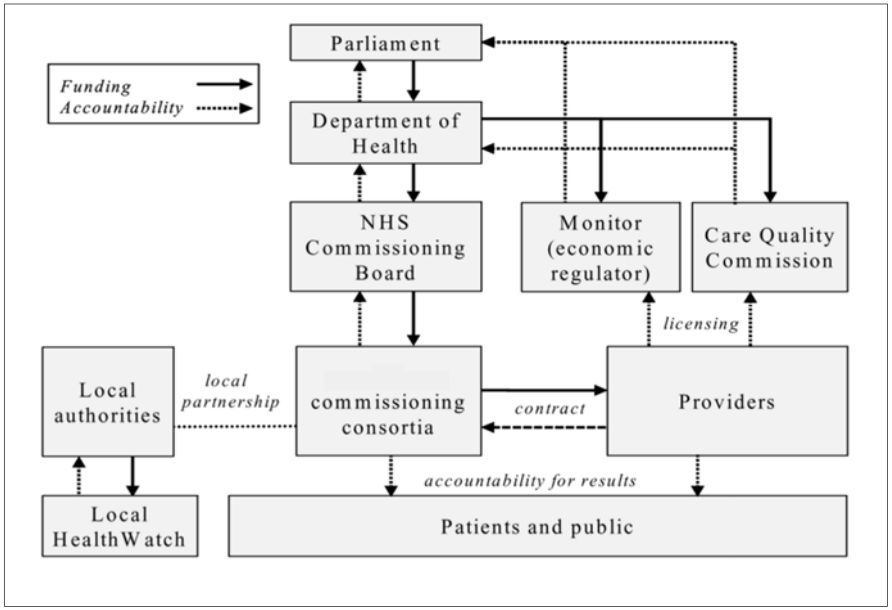
***Health and Social Care Information Center*** (HSCIC, now ***NHS Digital***): the national provider of information, data and IT systems for commissioners, analysts and clinicians in health/social care.

***National Information Board*** (NIB): develops with various organizations the strategic priorities for data and technology, to help ensure that health and care in the UK is improving and sustainable.

***Contractors****:* responsible for the collection of questionnaire data, data aggregation and analysis, and the conversion of data into an electronic record for transmission to the NHS IC / NHS Digital.

In addition, Figure 4 illustrates the relationships and roles of the various stakeholders and regulators involved in the NHS. Commissioners or Clinical commissioning groups (CCGs) use the data of patient surveys to establish the quality of services which they are contracting. The Care Quality Commission (CQC) acts as a quality inspectorate across health and social care for both publicly and privately funded care. In addition, Monitor acts as an economic regulator since 2012. All NHS providers are overseen by both Monitor (which will be part of NHS Improvement from 1 April) and CQC to maintain levels of safety and quality, and to ensure continuity of services.[122]

**Figure 4 –Stakeholders involved in the NHS**




*Source: Department of Health / NHS, 2010 Equity and Excellence.[122]*

### 3.5.5 Selection or development of PROMs and PREMs

Several documents specifically focus on the selection and evaluation of PROMs or PREMs in the design or further development of surveys. Some of these documents particularly stress that measures should focus on aspects that are important to patients or that items should be selected that matter most to patients.[125, 128, 135, 137, 139, 146] Patient involvement is not only required to develop and evaluate existing instruments, but also for usability research in order to test the clarity and appropriateness of PROMs/PREMs data and to see how patients actually interpret results.[139] In general, patient involvement and stakeholder engagement in designing, testing and

evaluating patient surveys regarding their content and usability is highly recommended.[125, 127, 128, 142, 143]

The instruments selected for the national PROMs programme (see below and Appendix 6) were chosen by the Department of Health after careful consideration and testing in pilot studies.[148] In the UK and internationally, the EuroQol (EQ-5D) is the most commonly used generic PROM.[11]

Trends in the UK are the development of shorter but also more integrated and broader instruments, and the use of overall scores and open questions to collect comments (qualitative data). For example, PROMs and PREMs being combined in the Cancer patient experience survey[121], the development of short (about 20-items) PREM-questionnaires covering the domains of patient-centred values[134, 146], and the development of an integrated Adult inpatient survey for acute trusts (including outpatients and the A&E survey) broadened to cover a wide range of urgent and emergency care services.[118]

### 3.5.6 Types of PROMs and PREMs implemented

The UK has largely implemented PROMs and PREMs, including various patient experience surveys such as the Inpatient survey or the GP patient survey, and the EQ-5D as the preferred generic PROM along with various condition-specific PROMs.[11, 124, 129, 138] All national PROMs questionnaires include a section called the EuroQol 5 dimension (EQ-5D-3L™). Patients' answers to the EQ-5D-3L™ questions can be translated into a numeric measure of quality of life. Responses to the EQ-5D element of the PROMs questionnaires can be used to compare outcomes across conditions. Whereas the condition-specific questionnaires contain more detailed questions which allow for more in-depth analysis of patient outcomes.[124]

Appendix 6 provides an overview of major survey programmes and the associated instruments (PROMs/PREMs) developed and used in the UK. Currently, the GP Patient Survey is sent to about 850 000 people every year; the NHS inpatient survey to 190 000; the cancer patient experience survey to more than 110 000; and the Friends and Family Test (FFT) is gathering responses from more than a million people every month.[133]

It should be noted that the FFT is not always considered as a PREM and receives little support from clinicians, who feel that the FFT is not really useful because of the very low response and the 5-point ratings show a ceiling effect. But this overall rating can be seen as a PREM and the comments made by patients, their family or friends are particularly considered as being useful for quality improvement.

### 3.5.7 Measurement procedures, methods and response

A majority of documents report about the implementation of PREMs or PROMs on a nationwide scale. Only two publications report on pilot studies conducted in a selected number of sites.[133, 146]

Importantly, data collection should be performed in a standardized and consistent manner to enable comparison between healthcare providers and health systems. The national patient surveys are run by eligible NHS organisations, or more commonly by the approved contractors working on their behalf.[139] Approved contractors and in-house trusts are provided with guidance on how to sample and how to ensure its accuracy. In addition, a central co-ordination and several standards, handbooks or tools ensure the consistency of measurements across providers.

It emerged from the literature that conventional 'pencil and paper' questionnaires and postal surveys are most often used in the UK. A postal survey was even described as "by far the easiest and most reliable method to implement in a short period of time, particularly because it provided the easiest way of adding capacity (or 'scaling up' collections) without significant investment or burden".[146] A few documents report on other modes of data collection, such as using tablets or personal computers for online surveys.[119, 133, 147] Sometimes, questionnaires were completed on site, for example in a waiting room, supported by volunteers.[133]

Patient surveys typically aim to achieve 500 responses per organization, but the sample size for PROMs measurements is recommended to be 150 in order to make meaningful comparisons between centres/ hospitals.[146, 148]

PROMs surveys are typically administered at specific moments before and after elective surgery. The collected data are linked to clinical registries (HES), case-mix adjusted and published on the website of the Health and

Social Care Information Centre (HSCIC) or currently NHS Digital (see http://content.digital.nhs.uk/proms). Though the mandatory participation of providers and the voluntary participation of patients generally showed overall high post-operative response rates (80-90%), the response in terms of complete pre- and post-treatment data was often much lower (4-38%).[148] The recommended response rate is 80% for both recruitment and post-operative response, to minimise the risk of data being unrepresentative.[129, 148] Later surveys indeed showed very good response rates (77% pre-operative and 73% post-operative).[149] But national sample or population surveys, conducted with postal questionnaires including PROMs, often yielded much lower responses (63% or 68% in cancer surveys and 38% in general practice).[149]

The response to cross-sectional patient experience surveys (PREMs) is generally around 30-40%[146], whereas previously (in 2005-2013) the average response rate used to be more than 50%.[126, 143] This suggests that there is a trend towards a descending response over time, perhaps because of increased 'questionnaire burden', although no firm conclusions can be drawn from these findings.

Nonetheless, data are increasingly collected online and it is suggested that an electronic collection of data, for example with e-PROMs, may result in better response rates.[147, 149] E-PROMs are electronic ways of administration, for use inside or outside clinical setting; for example: via the internet, using mobile devices or kiosks in clinics.[147] Another possible advantage of using digital technologies is saving costs. Whereas the estimated central costs (without local costs due to staff time) of paper questionnaires are about £5 per patient successfully recruited, almost 60% of these costs is for data entry, a factor that may be reduced using digital technology. According to Picker Institute Europe, collecting feedback online, in near real-time, can be cost effective; once established and in use the ongoing and marginal costs are very limited.[134]

### 3.5.8 *Analyses and presentation of results*

The logistics of measurements, such as an inclusion period or the time lag between data-collection and reporting, can be detrimental to timely reporting.[139, 149] This particularly holds for the data collected with PROMs because of the time lag between pre- and post-surgery measurements (often at least 3 months) and it may take 18 months before the results of surgical procedures become available.[149] As a consequence, stakeholders considered the results more or less outdated by the time they became available and there is a need for more real-time feedback.[134]

A recurring issue with survey research in general, and PROMs and PREMs in particular, is that some patient groups are consistently underrepresented in the data. In the UK, this problem particularly applies to community mental healthcare, and also for specific vulnerable or marginalised groups such as disabled, less healthy or elderly patients and those who have less access to healthcare.[11, 146, 148] Therefore, risk-adjustment is needed to account for this response bias and differences in case-mix between providers, thus ensuring the comparability of data across service providers.[139]

Another issue regarding benchmarking and monitoring outcomes is that differences between healthcare providers and between measurements over time tend be rather small.[140] This might be partly due to skewed data and a 'ceiling' effect (i.e. lack of differentiation between trusts), which can be demotivating and makes it hard to measure changes or to assess priorities for quality improvements. Also other statistical and technical data issues may have an influence, such as regression to the mean, random variation, small changes, sample size limitations, case-mix adjustment. Several documents provide guidance on these issues, but few documents present recommendations, guidelines or standards for the presentation and interpretation of results.[118, 147, 148]

#### 3.5.8.1 Websites and quality accounts

Results of patient surveys (PROMs and PREMs) are either presented on the public website My NHS (see http://www.nhs.uk/pages/home.aspx and Box 6), or on Healthcare Quality Improvement Partnership (HQIP, see http://www.hqip.org.uk/) for clinical audit data. All NHS providers also need to produce and have signed off by boards, an annual Quality Account to be published on the NHS Choices website.

Patients also provide ratings on NHS services by completing the Friends and Family Test at their own initiative, but this response is rather low and as there is no sampling frame the results are not likely to be representative.[134] More information about the Friends and Family Test and detailed data for each care setting can be found at https://www.england.nhs.uk/ourwork/pe/fft/friends-and-family-test-data/.

### 3.5.9 Actual use of the information

There is some evidence found in the grey literature on the actual effects of using information obtained with PROMs or PREMs on quality improvement,[134, 140, 143, 144, 150] though these effects are generally modest. For example, longitudinal analyses of inpatient surveys in NHS acute trusts in England showed a small improvement in the 'overall rating' given by patients over the years 2005–13,[143] with most trusts showing little overall improvement. Specialist trusts appeared to show better patient ratings than general acute trusts, however. There was also a 'ceiling effect': trusts that were performing comparatively well generally show smaller improvements over time than trusts with lower baseline scores. On the other hand, where there have been system-wide pressures beyond the hospital, a deterioration in patient experience was often seen – for example, in lengths of wait for a bed after admission to hospital and timely discharge from hospital.[143]

Even after one year “High Quality for All”, the Department of Health reported on the progress made in 2008-2009, stating that “there are already excellent examples of quality improvement initiatives across the country, often local initiatives with enthusiastic clinicians and staff measuring that they do and working on quality”.[144] Setting targets and offering extra funding for realizing these targets seems to help.[144] There is also good evidence that better use of data and technology improves patient outcomes and the value of services.[119]

On the other hand, whereas the data do not change much year on year, practice variation and health disparities seem to persist. There are still distinct findings with respect to certain patient groups or between geographical regions. For example, trusts outside London, especially the north east, generally performed better over the period 2005–13.[143] This shows there is still potential for quality improvement and instigates additional research on practice variation and equity of care in the United Kingdom.

Furthermore, as this issue of actual quality improvement was not always the focus of the selected documents, more longitudinal research and monitoring on this subject can be done or may already be published in the peer-reviewed literature. It might, for example, be interesting to know whether the use depends on the pre-defined aims and user-groups (e.g. regulators, commissioners, trusts, managers, clinicians and patients) and to assess the specific facilitators and barriers associated with the usability in order to develop specific guidance on the actual use of PROMs/PREMs for different goals.

Some standards, handbooks or tools already provide such guidance. For example, NHS England and Monitor have developed data standards to support costing, pricing and payment systems to incentivise new models of care to deliver best outcomes and value for patients.[119] Thus supporting the use of PROMs in the reimbursement for services, and giving patients a role in determining how much a provider is paid based, in part, on their view of the outcome.

#### 3.5.9.1 Transparency and patient choice

A critical element in encouraging consumer-driven quality improvement is transparency: the availability of comprehensive and comparable information.[119] Therefore, the data and metrics, for example as published on My NHS, need to be understandable for citizens as well as professionals.[4] It was expected that the publication of hospital performance data in terms of PROMs is likely to generate a provider response independent of any effect on patient choice, because of providers’ own goals

in terms of quality and reputation, clinicians' pursuit of clinical improvement, and changes in behaviour where PROMs are linked to various incentives offered by commissioners and regulators.[4] However, specific evidence on whether patient choice and transparency contribute to quality improvement was not found in the grey literature. A reason for the limited effects of public reporting and information systems on quality of care might be that these effects are difficult to isolate as they are frequently part of broader improvement initiatives.[142]

### 3.5.10 Other lessons and expected future developments

Various lessons from the grey literature cannot be attributed directly to one of the previously described stages of implementing PROMs/PREMs. For example, the culture change, evidence and time needed to implement PROMs/PREMs[125, 146], or the need to build a comprehensive measurement and quality system for performance assessment including the feedback of patients[11, 123], the general problems regarding the funding and costs of data collection[146], and the advantages of a central co-ordination and standards for data collection.[118, 139] Or the generally perceived challenges regarding the governance, financing and prioritization of surveys, the overall administrative burden of data collection and registrations[119] and guaranteeing the confidentiality of patient information or procedures to obtain a patient's consent.[119, 139]

Several specific facilitators, barriers and challenges in this respect are:

- **The rationale**: Before implementing PROMs/PREMs, there is the need to address the fundamental questions: 'What problem are we trying to solve?' and 'When we have the data, what will we do with it?'[137]
- **Costs, resources and new technology**: Information technology plays an essential and rapidly expanding role in the UK, partly due to the increased focus on access to performance data, for making the quality of care more transparent.[119] At the same time, there is an increase of financial pressures and lacking resources, and funding and financing performance measurement is a major barrier. So the need to make use of the best available, cost-effective technologies has become increasingly urgent. Resulting in progressive improvements in the timeliness accuracy and completeness with which data is entered into electronic records and made accessible to carers and patients.[119] There is also a great challenge in developing cost-effective modes of data collection by using new information technologies and improving the implementation of PROMs and PREMs in clinical practice. For example by using digital services for data collection and further integration of PROMs/PREMs in clinical registrations and digital care or patient records. In this respect, the NIB formulated a milestone ahead: having all care records digital real-time and interoperable in 2020.[119]
- **Data standards**: Together with increasing new technologies, there is a growing need for standardization of information, data management systems, registrations and record keeping. Consequently, new data quality standards for all NHS care providers were developed (by HSCIC/ NHS Digital, CQC, Monitor and NHS Trust Development Authority, NHS TDA) and are nowadays part of the regulatory regime of the CQC.
- **Barriers regarding new technologies and digital services**: A lack of universal Wi-Fi access, a failure to provide computers or tablets to ward or community-based staff, and outmoded security procedures frustrate healthcare professionals and encourage inappropriate 'workarounds'. Also, the technical solutions delivered may not have taken sufficient account of the way clinicians work in practice.[119] Nonetheless, developments such as the increased uptake of smartphones and extensive online access, may overcome these barriers.

  **Confidentiality of information**: An important aspect of data collection and a digital development is the confidentiality of patient information. As it is essential that patients, and citizens in general, have confidence in all users of their data and are able to make a decision about whether to share it. In progressively moving towards real-time digital record-keeping, with the objective to collect all the information required to support clinical care, a *framework for action* was introduced in 2014. This framework recommends a step-by-step approach and a prioritization of the safe development of linked administrative data for

all NHS-funded care, offering detailed proposals on setting a standard of NHS vigilance.[119]

### 3.5.11 Summary of findings

- The UK has a long history of implementing PROMs and PREMs, starting almost two decades ago.
- Many PREMs have been developed as part of the NHS National Patient Survey Programme, from 2002 onwards, for many sectors and patient groups.
- The routine collection of PROMs was introduced in 2009 with the National PROMs programme for four elective surgery procedures, using both generic and condition-specific PROMs, but after this programme was integrated in the Outcomes Framework it has practically been stalled in 2012.
- Many policy documents and stakeholders have had a key role in driving the implementation of PROMs/PREMs in the United Kingdom. Most important stakeholders being the Department of Health, the NHS, the Care Quality Commission (CQC) and the commissioners or Clinical commissioning groups (CCGs) who use the data of patient surveys to establish the quality of services which they are contracting.
- Along with the survey programmes, several pay-for-performance schemes were introduced in order to secure improvements in the quality of services and better outcomes for patients; e.g. the *Quality and Outcomes Framework* for general practitioners in 2004, and the *Commissioning for Quality and Innovation* (CQUIN) framework in 2009.
- Although conventional 'pencil and paper' questionnaires and postal surveys are most often used in the UK, there are trends towards shorter or more integrated instruments, and the use of overall scores and open questions to collect comments (qualitative data). Also, data are increasingly collected online or electronically, for example with e-PROMs, which is likely to result in better response rates and to be more cost-effective than paper questionnaires.
- Several documents provide guidance for collecting, analyzing and interpreting the data.
- Data are publicly reported via websites (e.g. MyNHS) and annual quality accounts.
- There is some evidence for the actual effects of using PROMs or PREMs on quality improvement, but these effects appear to be rather small and practice variation and health disparities seem to persist.
- There is no evidence reported on the expected (side-)effect of transparency / public reporting on quality improvement.
- Much is currently expected from and invested in new technologies and the move towards real-time digital record-keeping.
- Although the UK used to rely heavily on national top-down targets to improve performance in the health and care system, these targets seem to become less relevant while it is expected that clinicians will increasingly take personal responsibility in providing personalized care.

## 3.6 Transversal analysis: lessons learned from three countries

A transversal analysis of findings regarding the implementation of PROMs/PREMs in France, the Netherlands and the United Kingdom (UK) shows many similarities but also differences between the three countries. The experiences and evidence regarding PROMs/PREMs in these countries can be used to draw general lessons.

### *3.6.1 Different health systems and stages of implementation*

Table 6 presents background information regarding the health systems and implementation of PROMs/PREMs in the three countries that we reviewed. Both the health systems and the implementation trajectories for PROMs and PREMs differ between the countries, with the UK as first adopter, and France being in the earliest stage of performance measurement. All countries have a legal basis for measuring patient experiences, and all started with PREMs and subsequently implemented PROMs.

**Table 6 – Background information regarding PROMs and PREMS in France, the Netherlands and the UK**

| | France | The Netherlands | United Kingdom |
|---|---|---|---|
| **Type of healthcare system** | Bismarck* | Bismarck* roots and regulated competition since 2006, with less central planning and governance. | Beveridge Model** with a National Health Service (NHS). |
| **PROMs first introduced nationally** | Planned | 2010 PROM mental healthcare and PROMs pilots by health insurers. | 2009 (National PROMs Programme) |
| **PREMs first introduced nationally** | 2011 (i-Satis) | 2006 (CQ-Index for public reporting and accountability) | 1998: GP services (GP survey)<br>2002: Hospitals (Inpatient survey)<br>2009: many other sectors (National patient survey programme) |
| **Sectors in which PROMs/ PREMs are used** | Hospital care (PREMs) | Various (Hospital care, primary care, mental healthcare, long-term care)<br>See for PREMs (CQI-questionnaires): https://www.zorginzicht.nl/bibliotheek/cqi-overzicht/Paginas/Home.aspx | Various (GP services, Hospital care, Accident & Emergency care, Mental healthcare, Maternity care, Social care, Cancer care) |
| **Major stakeholders** | • Ministry of Health<br>• Haute Autorité de Santé<br>• Hospitals and healthcare establishments (with a medical activity, surgery or obstetrics) | • Ministry of Health<br>• Healthcare providers<br>• Healthcare inspectorate (IGZ)<br>• Health insurance companies<br>• Patient organizations | • Department of Health<br>• National Health Service<br>• Healthcare providers<br>• Care Quality Commission<br>• Clinical Commissioning Groups<br>• Patient organizations |

| | France | The Netherlands | United Kingdom |
|---|---|---|---|
| **Aims** (alphabetical order) | • Public reporting / Transparency<br>• Quality improvement<br>• Pay for performance (P4P) | • Accountability / Governance<br>• Benchmarking / Monitoring<br>• Clinical practice<br>• Patient choice / Empowerment<br>• Pay for performance (P4P)<br>• Public reporting / Transparency<br>• Quality improvement | • Accountability / Governance<br>• Benchmarking / Monitoring<br>• Clinical practice<br>• Patient choice / Empowerment<br>• Commissioning, Contracting, P4P<br>• Public reporting / Transparency<br>• Quality improvement |
| **Financing** | • Ministry of Health | • Ministry of Health<br>• Health insurance companies<br>• Funds and foundations<br>• Providers | • Department of Health<br>• National Health Service Trusts<br>• Care Quality Commission<br>• Clinical Commissioning Groups<br>• Providers<br>• Innovation funds / Prizes |
| **Legal basis** | • Ordinance 96-346, 24 April 1996 | • Health Insurance Act (Zorgverzekeringswet), 2006<br>• The Care Institutions Quality Act (Kwaliteitswet zorginstellingen), 1996 | • Health Act, 2009<br>• NHS Constitution Care Act, 2014 |
| **Data protection authority**<br>- **Legislation** | Commission Nationale de l'Informatique et des Libertés (CNIL) | • Autoriteit Persoonsgegevens<br>• Wet bescherming persoonsgegevens (Wbp)<br>• Wet medisch-wetenschappelijk onderzoek (WMO)<br>• Wet op de geneeskundige behandelingsovereenkomst (Wgbo) | • National Data Guardian<br>• A legal provision: 'section 251' (http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/what-is-section-251/) |

** A social health insurance system – with insurers called "sickness funds" that is usually financed jointly by employers and employees through payroll deduction.*
***In this system, healthcare is provided and financed by the government through tax payments.*

The UK was by far the earliest adopter of national PROMs and PREMs surveys; starting with a GP questionnaire in 1998 and a nationwide inpatient survey (both PREMs) in 2002. Subsequently a national PROMs programme for elective surgery was installed in 2009 and many other sectors have used both PROMs and PREMs ever since. The Netherlands has implemented national surveys since 2006. They started with many pilot studies on newly developed PREMs (Consumer Quality Index questionnaires, CQIs) and started to implement PROMs as a quality indicator from 2010 onwards (first in mental healthcare; Routine Outcome Measurement, ROM-GGZ). France is a late adopter, having installed PREMs (I-Satis and later e-Satis) on a national scale from 2011 onwards and planning to implement PROMs in the coming years.

### *3.6.2 Comparable aims*

Although the health systems differ, the three countries have comparable stakeholders and aims for implementing and PROMs and PREMs. They all have adopted PROMs/PREMs in order to monitor, improve and assure the quality of healthcare. Broadly, PROMs/PREMs are being used for:

a. Policy reasons such as governance, regulation, commissioning/ reimbursement and transparency – aimed to monitor performance across professionals, specialties or divisions, organizations, regions or whole health systems; and

b. Clinical practice: for screening/diagnosis, health needs assessment, patient monitoring, shared decision-making etc. – aimed to improve the clinical management and individual patient care.

Depending on the aims, stakeholders and end-users, the information is collected, analysed and presented at the health system level (for monitoring, governance, regulation and commissioning/contracting), at the organizational level (for quality management, benchmarking and clinical auditing), or it is directly linked to clinical practice.[128] Table 7 provides an overview of the levels of data aggregation and the intended purpose of PROMs and PREMs for the three countries. The table underlines that for PROMs, all possible goals have been included in one or more implementation efforts in the Netherlands and the UK. For France, implementation of PROMs is not yet realized and we did not have information on specific goals for PROMs in France. For PREMs, it appears that none of the countries have attempted to include PREMs in clinical practice for applications such as screening and diagnosis, health needs assessment and monitoring, patient choice, or shared decision-making. In addition, PREMs appear not to be implicated in determining value for money at the system level.

The extent to which the intended goals are achieved is of interest. Unfortunately, there is no easy answer to this question. On the one hand, there appear to be promising examples for each of the intended goals, while on the other hand many initiatives failed to reach the intended goals, are restructured, aborted, or followed up by other types of initiatives. Moreover, even promising initiatives that appear to reach goals, or are expected to reach goals, are often terminated or restructured. The most pronounced example is the world-leading the PROMs programme in the UK; this programme effectively stalled in 2012 due to a lack of funding.[136] Thus, given the observations made in this report it can only be stated reliably that many aims are pursued for both PROMs and PREMs and that initiatives to pursue these aims are often modified, restructured or replaced. This illustrates that achieving the aims as intended appears difficult and often does not meet the pre-existing expectations. At the same time however, there appears to be a persistent faith in the potential of PROMs and PREMs that drives continuing efforts for implementation and optimization. It should be acknowledged that these overall findings derive more from the Netherlands and the UK than from France as for the latter, experiences with PROMs/PREMs are more recent.

**Table 7 – Country comparison of the level of data aggregation and intended targets of PROMs and PREMS**

| Level of aggregation | Intended purpose | PREMs | PROMs |
|---|---|---|---|
| Health System | System-wide performance assessment | FR, NL, UK | NL, UK |
| | Determining value for money | - | NL, UK |
| Commissioners / health insurance companies | Contracting/ Pay-for-performance | FR, NL, UK | NL, UK |
| | Monitoring quality | FR, NL, UK | NL, UK |
| Providers/ organizations | Clinical audit | FR, NL, UK | NL, UK |
| | Quality improvement | FR, NL, UK | NL, UK |
| Clinical practice (professionals and patients) | Screening and diagnosis | - | NL, UK |
| | Health needs assessment and monitoring | - | NL, UK |
| | Patient choice | - | NL, UK |
| | Shared decision-making | - | NL, UK |

### *3.6.3 Different implementation strategies*

There are different approaches for implementing PROMs/PREMs that lie on a continuum between two extremes. One extreme is where the government or management of a healthcare institution drives the implementation process, defines the rules, performs the assessments and takes action based on the results. This could be considered as a strict top-down approach. Another extreme is where the entire initiative is driven from the field, with healthcare providers setting up a data collection system, assessing and using the data in their daily practice or for defining quality improvement strategies. In-between these two extremes, intermediate approaches exist. Also the emphasis on either of these approaches may shift over time as was observed for the Netherlands and the UK.

Although many initiatives state that they have multiple aims, it might be argued that top-down approaches tend to focus somewhat more on external accountability and control, while bottom-up approaches tend to focus more on quality improvement and clinical management.

In France there has been more of a top-down approach, with the Ministry of Health of establishing a strong legal framework for PREMs (and other quality indicators) and the HAS coordinating data collection, analysis and presentation of the results. In the Netherlands the nationwide implementation of PREMs was instigated by a top-down approach, because of a reform of the health system in 2006 and the introduction of regulated market competition, but bottom-up initiatives of healthcare providers, patient organizations and health insurance companies quickly followed and the government reduced their own involvement from 2012 onwards. Similarly, in the UK, there was initially a strong top-down approach, reinforced by governmental and regulating bodies and supported by white papers, legislation and reimbursement schemes. The aim was to monitor accountability and reimbursement of healthcare performance, but slowly – and more recently – the approach is shifting towards bottom-up for use in clinical practice.

### 3.6.4 Various instruments and survey methods

Whereas France uses a single PREM questionnaire to evaluate hospital care, the UK and the Netherlands use a wide range of both generic and disease-specific PROMs and PREMs. Table 8 shows a comparison of the instruments and methods used.

Conventional 'paper and pen' surveys used to be the most common method for data-collection in the Netherlands and UK, but online/digital survey methods (e.g. web-based surveys or data collection on-site, in the hospital wards, with tablets, mobile phones or kiosks) are increasingly used in the three countries (including France). Electronic methods offer more flexibility to patients (e.g. multiple data entries for long stays at a hospital), the possibility of real-time feedback to clinicians and the challenge to link PROM/PREM data to clinical records and registration. By linking data, comprehensive analyses and comparisons of health services (benchmarking) and evaluating treatments (health technology assessments) becomes feasible.

In general, PREM data are collected retrospectively and PROMs are measured pre- and post-treatment. The response rates in the Netherlands and the UK generally ranged from 70-90% for PROMs and 30-50% for PREMs (no data in the grey literature for France). Response rates are generally lower in disabled, elderly patients, ethnic minorities. There also seems to be an overall decrease in response rates over time which may suggest survey / questionnaire 'fatigue'.

**Table 8 – Country comparison of data collection and public reporting**

| | France | The Netherlands | United Kingdom |
|---|---|---|---|
| **PROM questionnaires** | no available information | Generic: EQ-5D<br>Specific: varies by disease/ condition | Generic: EQ-5D<br>Specific: varies by disease/ condition |
| **PROM measurement methods** | no available information | • Postal surveys<br>• Online surveys<br>• Mixed mode data collection (invitation with login details followed by postal survey)<br>• Follow-up (pre- and post-surgery) or retrospective measurements | • Postal surveys.<br>• Electronic data collection (e-PROMs) via internet, mobile devices or kiosks in clinics.<br>• Pre- and post-surgery measurements. (The difference in health status scores is a measure of the outcome of the procedure.) |
| **PREM questionnaires** | 30 Questions defined in an ordinance[87] | Varies by condition, services, treatments. | National Patient Survey Programme, including many PREMs for several sectors and conditions.[139] |
| **PREM measurement methods** | i-Satis<br>Originally collected by telephone, now a web-based survey. | • Postal surveys<br>• Online surveys | • Usually paper questionnaires/ postal surveys. |

| | France | The Netherlands | United Kingdom |
|---|---|---|---|
| | | • Mixed mode data collection (invitation with login details followed by postal survey)<br>• Qualified data collectors (contractors) | • Online (web-based) surveys, telephone interviews (CATI) or qualitative surveys.<br>• Qualified/ approved contractors.<br>• Co-ordination by Picker Institute. |
| **Public reporting** | • Annual hospital reports<br>• Hospital 'Welcome handbook'<br>• Comparative statistics reported by HAS | • Kiesbeter.nl<br>• ZorgkaartNederland.nl<br>• Miletus foundation (on request)<br>• Many initiatives did not result in public reporting | • Quality Accounts (annually)<br>• MyNHS / NHS Choices |

### *3.6.5 Similar challenges concerning data analysis and presentation of results*

The presentation of PROMs and PREMs analyses must be standardized and easy to interpret in order to facilitate the use of information. Several guides, handbooks and quality standards have been published to this effect in all three countries. All three countries stimulate transparency and have public websites for reporting patient experiences. French hospitals also make their data publicly available via their 'Welcome Handbook'.

Table 9 and Table 10 provide a summary of facilitators and barriers regarding the analysis and presentation of PROMs/PREMs in the three countries.

### Table 9 – Country comparison of facilitators regarding the implementation of PROMs and PREMS

| Facilitators | France | The Netherlands | United Kingdom |
|---|---|---|---|
| **1. General conditions and contextual factors** | • Strong legal basis established by ordinances which are legally binding. | • Trust between stakeholders that results are used in an appropriate manner. | • Political and economic drivers.<br>• Leadership, vision, drive and persistence.<br>• Organizational culture and knowledge of staff: desired values and behaviours embedded in the organizations; general awareness and understanding of what matters most to patients.<br>• Trust and confidence from the public in the collection, storage and use of their personal data. |
| **2. Selection of PROMs/PREMs** | • Initial support from a research unit (based at INSERM) to define and establish the quality indicators (incl. PREMs). | | • National framework (definitions, measures, indicators, etc.).<br>• Extensive piloting / testing.<br>• Evidence base for (measuring) patient experiences/ outcomes. |
| **3. Data collection** | • Central co-ordination (HAS) which ensures harmonised data collection. | • Central co-ordination preventing multiple measurements in the same population.<br>• Good data infrastructures for data collection.<br>• Instructions to ensure standardized data collection across providers. | • Engaged and motivated patients and families, willing to cooperate<br>• Central co-ordination of data collection, coordinated actions.<br>• Data standards and information standards for processes, datasets, platforms and interfaces.<br>• Standards for data collection.<br>• Increased use of technologies and digital services (e.g. internet, smartphones).<br>• Involving lay volunteers for on-site data-collection. |
| **4. Analysis and presentation of data** | • Central co-ordination (HAS) which ensures comparative analyses. | • Good data infrastructures for data analysis and presentation.<br>• Easy to read documents transferring knowledge on PROMs and PREMs to stakeholders. | • Data standards and information standards for processes, datasets, platforms and interfaces.<br>• Standards for analyses and publication.<br>• Easier access to (raw) data and providing more interactive and 'automated tools' for analyses and presentation. |
| **5. Evidence for policy makers or managers and facilitators for establishing the intended effects of PROMs/PREMs** | | • Gradual progression towards public reporting (several years), allowing providers to first learn how to deal with the results before they are made public. | • A rigorous performance monitoring and evaluation system.<br>• Staff engagement, training and support, and local ownership of intelligence from measurements.<br>• Use of performance data for commissioning, clinical auditing and accreditation.<br>• Transparency: availability of comparable, reliable and understandable public information.<br>• Financial incentives (pay-for-performance schemes, rewards). |

**Table 10 – Country comparison of barriers regarding the implementation of PROMs and PREMS**

| Barriers | France | The Netherlands | United Kingdom |
|---|---|---|---|
| **1. General conditions and contextual factors** | • Patient privacy affects data collection<br>• Funding for data collection | • Privacy legislation<br>• Operational complexity of measurements and governance.<br>• Funding and administrative burden. | • Pressure on financial and operational resources.<br>• Costs associated with initial investments: incremental costs of the resources needed for measurements (e.g. developing or adapting computer systems or administration processes).<br>• Reorganisation of the NHS (2012) led to a loss of focus on PROMs.<br>• Gaps in the infrastructure of systems and processes constrain interoperability, causing difficulties in transferring data and posing barriers to service improvement.<br>• Conflicting or competing national priorities and organizational agendas.<br>• Limited trust-wide focus and co-ordination of actions. |
| **2. Selection of PROMs/PREMs** | | | • Confusion in the definition of patient outcomes, experiences and satisfaction.<br>• Tension between generic or 'broad' measurements and the need for analysis by particular subgroups or specific conditions.<br>• Difficulties in measuring experiences with integrated care.<br>• Limited flexibility around addressing local priorities in surveys. |
| **3. Data collection** | Data on patient satisfaction is collected by every hospital in France and is submitted to the HAS for data analysis. | • Nonresponse, particularly in specific subgroups. | • Different methods and formats of data collection hamper comparisons between services.<br>• Technical problems or lack of electronic devices (tablets, hand-held computers or kiosks) hamper the on-site data collection.<br>• Survey fatigue and adverse effects on response rates.<br>• Opt-in/opt-out mechanisms reduce response rates and increase bias.<br>• Lower response rates among certain populations (e.g. disabled and vulnerable people) introducing response bias.<br>• Small samples and low response rates yield less robust data. |
| **4. Analysis and presentation of data** | • The annual results are available on the national reporting platform 'Scope Santé' (http://www.scopesante.fr/#/) and on the HAS website.<br>• A grading system is used to grade the hospitals, with a grade from 1 to 5 for each | • Data logistics can be time-consuming to the extent that results are outdated by the time they become available. | • Limited availability of standardised data hamper comparisons between services.<br>• Statistical and technical data issues (e.g. risk-adjustment, skewed data, ceiling-effects).<br>• Concerns about accuracy of data (biases, confounding factors and chance).<br>• Struggles with case-mix adjustment (if data to be used for public reporting). |

| Barriers | France | The Netherlands | United Kingdom |
|---|---|---|---|
| | item depending on its rating of satisfaction.<br>• The mean of the patients satisfaction score gives a global satisfaction score for each hospital. | | |
| **5. Evidence for policy makers/ managers and barriers in establishing intended effects** | | • Small differences between providers do not help patient choice or pay for performance. | • Difficulties in demonstrating the impact of PREM/PROM-measurements on quality of care.<br>• A risk of perverse incentives created by inaccurate or unreliable indicators or performance data.<br>• Not sharing information within organizations limits quality improvement.<br>• Aggregated data hamper the possibility to break down data at site, trust or national level.<br>• Delay in publication of results causes loss of relevance.<br>• A 'blame culture' hampers learning from and acting on patient survey data.<br>• Making sense of the data. For example: the ongoing nature of care being delivered by a range of providers, multiplies the difficulty in interpreting results. Also, response shift makes is harder to interpret PROM data.<br>• Lack of an understanding of effective improvement interventions and of variations between trusts/services.<br>• Difficulty to implement changes.<br>• Lack of time between surveys (between receiving the results and starting the next survey) to implement improvement work. |

### *3.6.6 Scarce evidence on the use and effects of PROMs/PREMs*

Despite ample reporting on the use of PROMs/PREMs in France, the Netherlands and the UK, the grey literature showed very little evidence on actual quality improvements. For example in the UK, where PROMs were introduced to improve the equity and appropriateness of care, recent studies still show significant health disparities, practice variation and regional differences (such as the persisting 'London effect', showing lower quality scores in the region of London as compared to the rest of England). Few longitudinal studies show a modest overall improvement in patient experiences in the UK, mostly following a national focus or target, supported by extra funding or commissioning (e.g. improved access to primary care or cleanliness in hospitals).

The scarcity of evidence in the grey literature seems to be caused by various impeding factors, including a lack of published longitudinal studies, difficulties in the interpretation of results and implementing changes, technical and statistical problems with data such as incomparable or

inaccurate data, confounders and difficulties with appropriate risk-adjustment or case-mix correction (see the 'Barriers' mentioned in Table 10).

### *3.6.7 Lessons learned in the three countries*

The facilitators and barriers regarding the implementation of PROMs/PREMs, as extracted from the grey literature, are presented in Table 9 and Table 10 respectively. Especially for the UK, a lot of lessons can be drawn because of the long-term and ample experiences with national surveys and frameworks, whereas fewer lessons can be drawn for the Netherlands and France because of the more recent introduction of PROMs and PREMs and fewer (monitoring) studies found for these countries.

Facilitators and barriers can be broadly divided into the following categories and concern the following aspects:

1. General conditions and contextual factors (including aims):
    - Strong political and economic drivers – including policy statements, legislation and a strong legal framework, central funding and co-ordination of measurements – reinforce the implementation and use of PROMs/ PREMs.
    - Central government initiatives, though, may yield resistance by providers and might – in the long-run – have to be replaced by stakeholder initiatives.
    - Subsequently, changes in commissioning and healthcare professionals' behavior are needed to create positive incentives and to establish sustainable improvements in care based on patient feedback.
    - Prioritizing patient experiences and outcome measures requires a culture shift in healthcare policy and management. In addition, a climate of trust, openness and transparency is needed.
    - A combination of a 'top-down' and 'bottom-up' approach might be effective in realizing sustainable improvements in healthcare performance.
    - It takes time to implement PROMs/PREMs in the quality assurance of a health system, often requiring several years of development and testing.
    - Refocus on key aspects of care that patients identify as being important.
2. Selection of PROMs/PREMs:
    - For both PROMs and PREMs, many surveys exist in the Netherland and the UK.
    - For PROMs, it appears that surveys are often selected from existing surveys using methodological frameworks. Often, the EQ-5D is selected as a generic survey and complemented by a disease-specific survey.
    - For PREMs, it appears as if survey are more often newly developed rather than selected.
    - First priority for implementation in the three countries was PREMs, followed by PROMs.
    - Addressing multiple goals with PROMs / PREMs appears difficult.
    - A combination of a 'top-down' and 'bottom-up' approach might be effective in realizing sustainable improvements in healthcare performance.
3. Data collection:
    - Leadership, a central research unit and standards are needed to co-ordinate and support data collection.
    - Alignment of surveys is needed to assure efficient data collection and to reduce survey burden.
    - A research unit is needed to support central data collection, analyses and monitoring.
    - Specialized personnel is needed to co-ordinate data collection.



- There is need for innovative, electronical and mixed methodologies that can be embedded in the clinical care process, that are cost-effective, flexible and less burdensome for patients, and that provide faster (´real-time´) feedback and turnaround of results from patient surveys. An annual survey is 'old school' and electronic systems have minimal cost implication once developed. Real-time surveys provide more quickly and up-to-date data and contribute to the relevance and use in clinical practice.
- Diminish time pressure on staff and patients by allowing sufficient time for questionnaire administration.
- There is still need to develop administration methods and questionnaires that ensure high consent and response rates.

4. Analyses and presentation of data:
   - Benchmarking and public reporting require high standards for validity, reliability and comparability (case-mix adjustment) of the data.
   - Linking PROMs/PREMs data to clinical databases/ registrations and clinician/ professional-based quality indicators, may help to establish the effectiveness, appropriateness and value of healthcare interventions/treatment.
   - Combining quantitative measurements and qualitative feedback (such as comments) provides complementary insights into the quality of services.
   - Qualitative data helps in the interpretation of PREMs results.
5. Evidence for policymakers or managers (barriers and facilitators for establishing the intended effects of PROMs/PREMs):
   - Achieving fruitful use of results appears to be much more difficult than anticipated.
   - Specialized personnel is needed to act upon the results (i.e. designing and implementing quality improvement strategies).
   - Constant evaluation and optimization of measurement instruments and methods is needed to optimize and assure the quality and usability of data.
   - The shift from acute/hospital care to community and social care demands the development of instruments for evaluating the performance of integrated and long-term care.
   - More monitoring and evaluative studies are needed to collect evidence for implementing PROMs/PREMs and to establish the effects on health system performance and improvements in clinical practice or other effects such as increased patient choice, patient empowerment, transparency and healthcare market competition.

### *3.6.8 Key messages for Belgium*

When implementing PROMs or PREMs, we advise to take the following issues into consideration:

- Use both a 'top-down' (policy driven) and a 'bottom-up' (clinically driven) approach to improve healthcare performance and clinical practice.
- Establish a legal basis for PROMs/PREMs (i.e. legislation and legal framework).
- Take time to implement PROMs/PREMs in the health system, for example to extensively test the newly developed patient feedback systems.
- Realize a 'culture shift' by putting patients' experiences and outcomes as a priority in healthcare policy and management, and by acknowledging patient-centeredness and value-based healthcare as the key principles and major motivators for using PROM/PREM-data.
- Create a culture of trust, openness and transparency, for example by allowing professionals to learn from PROM/PREM-data for several years before results are shared with other stakeholders and / or the general public.

- Introduce positive incentives for implementation of PROMs/PREMs, for example by rewarding participation of providers, or rewarding providers that achieve high response rates.
- Set up a national infrastructure and standards for data collection, analysis and presentation of results.
- Work with an independent research institute to help support, implement and advise (including research) on PROMs/PREMs.
- Establish a central research unit/organization to support central data collection, analyses, presentation and monitoring of survey results.
- Hire specialized personnel or educate available staff to co-ordinate and support data collection and to design and implement improvement strategies within care organizations.
- Monitor requirements for standardization and comparability across providers and act upon it by (re-)assessing and disseminating standards.
- Consider that although specific surveys appear more precise, implementing a large number of specific surveys appears more difficult than implementing a smaller number of more generic surveys.
- Select samples of patients (for policy purposes) or approach each patient for participation (e.g. PROMs for clinical purposes).
- Use innovative, electronical and mixed methodologies that can easily be embedded in the clinical care process, methods that are cost-effective, flexible and the least burdensome for patients and providers, and methods that provide (near) ´real-time´ feedback (up-to-date data).
- Diminish time pressure on staff and patients, for example by allowing sufficient time for questionnaire administration and quality improvements.
- Link PROMs/PREMs data to clinical databases/ registrations, in addition to clinician/ professional-based quality indicators, in order to broadly establish the effectiveness, appropriateness and value of healthcare interventions/treatment.
- Combine quantitative measurements and qualitative feedback (such as comments) to gain complementary insights into the quality of services.
- Constantly evaluate and optimize measurement instruments and methods in order to get the most out of patient surveys (e.g. response, accuracy, robustness and usability of data and quality reports).
- Use standard PROMs/PREMs for policy and practice purposes to enable international comparisons
- Use PROMs/PREMs to stimulate and evaluate person-centered and value-based healthcare, and use PROMs to evaluate the (cost-)effectiveness of treatments.
- Take into account that despite an abundance of PROMs and PREMs initiatives, hard evidence of positive and sustainable effects have not yet clearly emerged. Therefore, more research and close monitoring of nationwide initiatives is urgently needed.

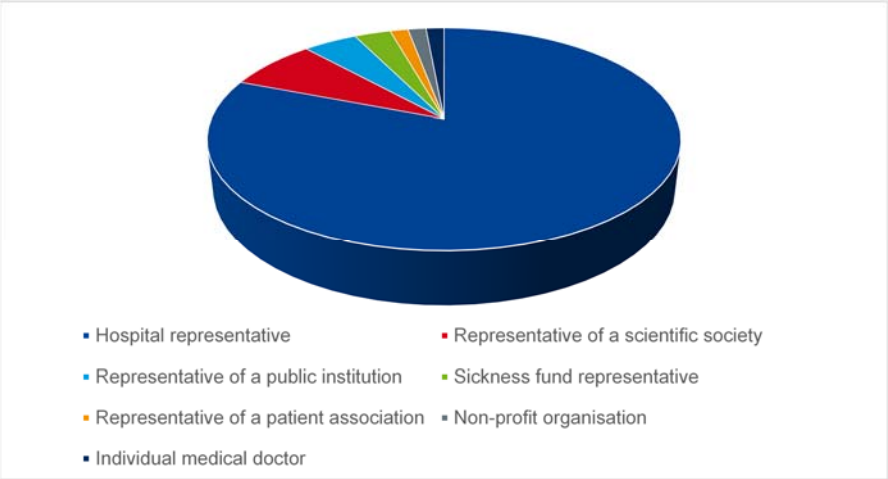
# 4 THE BELGIAN CONTEXT

## 4.1 Online survey about Belgian initiatives

An online survey was carried out to get an idea of the current use of PROMs and PREMs in Belgium. The objective was not to be exhaustive, but rather to get a rough idea whether hospitals or other organisations are using PROMs and/or PREMs and if so, for what purpose. All Belgian (general and psychiatric) hospitals, 35 scientific societies (general and specialised, excepted paediatrics and mental health), and about 10 experts and stakeholders involved in the project (such as the former WIV – ISP, currently Sciensano, public institutions, patient association platforms) were invited to participate. The general directors of the hospitals were asked to forward the link to the survey to those people in their institution that took responsibility for a PROM and/or PREM initiative in their institution or were informed about these initiatives. This could be several different people for one institution. From the responses, a number of cases are selected for further analysis of the specific issues for the implementation of PROMs and PREMs in the Belgian context (next section).

We received 56 fully completed questionnaires and 12 incomplete questionnaires but nevertheless with useful information. Among 68 useful questionnaires, 55 were completed by a representative of a hospital or hospital network (from 41 different hospitals), 1 by a patient representative, 5 by representatives of a scientific association, 3 by representatives of a public institution (such as RIZIV/INAMI, Federal Public Service Public Health), 1 by a non-profit organisation, 1 by an individual medical doctor, and 2 by representatives of a sickness fund (Figure 5).

**Figure 5 – Respondent categories**




**PREMs are measured more often than PROMs**

Thirty-eight percent of the hospital representatives reported the use of at least one PROM within their hospital, whereas 76% reported using at least one PREM. Within the PREMs, the “Vlaamse Patiënten Peiling” is the most frequently used instrument in Flemish hospitals. Eighteen out of 41 responding hospitals reported having implemented this questionnaire. Besides this questionnaire, about 60 other PREMs are being used, sometimes validated existing measures such as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), but most of the time self-developed questionnaires or questionnaires of unknown origin.

In the French-speaking region, two initiatives stand out: the project ASPE (17 hospitals), coordinated by BSM (Be Service Minded) and a pilot project driven by PAQS[m] and LUSS[n] in collaboration with five hospitals. The

[m] Plateforme pour l'Amélioration continue de la Qualité des soins et de la Sécurité des patient.

[n] Ligue des Usagers des Services de Santé.

questionnaire of the Picker Institute (PPE-15), entirely dedicated to PREMs, was analysed and adapted by patients' associations. The specificity of the latter project is the involvement of patients in the design of the project and in the future continuous improvement measures which are going to follow the data collection and analysis.

Also in the context of the Health Information Survey (HIS) in the general population, organised and coordinated by Sciensano, PREMs are measured. Items included in the HIS relate to patient experiences with GP consultations, specialist consultations (at the outpatient department of a hospital, at an ambulatory practice or by telephone) and with healthcare in general. Questions relate to the speed of getting an appointment for a consultation, the waiting time in the waiting room at the day of consultation, time spent by the doctor, explanations given by the doctor, opportunity to ask questions or raise concerns about the recommended treatment, involvement in the decisions about care and treatment, and delays in getting healthcare due to distance or transport problems.

A more detailed description of the VPP and project ASPE is provided in Text box 2.

### Text box 2 –Largest PREMs initiatives in hospitals in the Flemish and French-speaking communities in Belgium

**Project ASPE (French-speaking community)**

The project ASPE (Attentes et Satisfaction des Patients et de leur Entourage) is a project set up by the independent private consultancy company BSM for the French-speaking part of Belgium. It originated from a PhD project of the director of BSM, followed by a project supported by the Walloon Ministry of Health until 2004, which was then moved to BSM from 2005 onwards to guarantee continuity.

The project ASPE aims to

- provide methodological support to the quality-improvement initiatives of participating hospitals, both scientifically (content based on literature) and statistically
- standardise measurements of patient-reported experiences and satisfaction in order to allow benchmarking between participating hospitals,
- provide comparative analytical data of key variables about patient satisfaction and experiences,
- identify 'best practices' and priority areas for action to improve patients' and their family's satisfaction and experiences,
- exchange experiences of successful cases and organise site visits, including concrete advice from colleagues

Participation by hospitals is voluntary. Although the project is coordinated by BSM and all scientific analytic work is performed by collaborators of BSM, the project is governed by a steering group of 9 representatives of the participating hospitals. Currently, 17 hospitals participate in the project, representing 40 sites. Besides the governing body (*comité de pilotage*), responsible for the strategic decisions and priorities, a coordinating committee (*comité des coordinateurs*) exists with members of all participating hospitals. The coordinating committee has a very important role. It is responsible for the administration, communication and follow-up of concrete initiatives in collaboration with the quality coordinators of the participating hospitals.

The project governing committee decides on the activities performed during the project. Several domains are worked on. The participants are free to choose to which activity they participate and to which activity they do not participate. However, once engaging in an activity, the participating hospital is committed to adhere to the terms of the chosen framework (duration, instrument, mode of distribution, …) in order to ensure valid and comparable data.

Both generic and domain-specific PREMs are used. The generic PREM relates to the classic hospitalisation as well as to the one-day clinic. Domain-specific activities currently included encompass maternity care, paediatrics, day hospitalisation and surgery, emergency department, medical imaging, revalidation, hotel function, social service,

consultations, geriatric care, intensive care (visitors' experiences), nuclear medicine, high-risk pregnancy, dialyse, medically assisted pregnancy, chronic psychiatry, acute psychiatry, treating physician, retirement home, satisfaction of staff. For some of these domains, an annual benchmarking is performed, for others every two or three years and some upon request. Each year, 7 to 8 benchmarks are performed. Data of about 50.000 questionnaires are analysed each year for these purposes. For each benchmarking exercise, a detailed presentation as well as an executive summary is provided. The results are sent to the general directors and quality coordinators of the participating hospitals.

The questionnaires are developed with the partners in consultation with patients and healthcare professionals. They are based on literature, the methodology for analysing the data on patient experiences and the multi-attribute model applied to analyse the service quality dimensions from the patient's point of view. The questionnaires are systematically pre-tested in other patient populations, in different contexts and hospitals.

The hospitals are free to use their own results of the benchmarking studies for marketing purposes, however, always without making reference to any of the other hospitals participating in the project by name.

Hospitals who wish to participate in a benchmarking exercise for one or more of the domains are required to follow the instructions regarding the timing and the protocol of the study. The questionnaires include questions about the patients' profile, reason for choosing the hospital, quality indicators based on patients' experiences, PREMs, global performance indicators (quality, satisfaction, trust, empowerment, recommendation, etc) and an open question regarding suggestions. For example, for the classic hospitalisation the questionnaire for 2018 encompasses 30 questions on the patient profile, 12 PREMs, 70 quality indicators covering 9 generic themes, and 6 general satisfaction questions and one open question.

Besides benchmarking, other services are provided: scientific and practical support to partners, exchange of experiences between partners, an online closed "patient-friendly hospital"-platform on which partners can discuss experiences and scientific evidence is posted, board tables, and updates regarding e.g. e-health and scientific advances in the field of patient satisfaction and experiences.

**The *Vlaamse Patiënten Peiling* (Flemish community)**

The Flemish Indicator Initiative 'VIP²' aims to improve the quality of patient care by means of clinical process and outcome indicators. The initiative was initiated by the two hospital umbrella organisations, the Flemish government and the association of chief physicians. All stakeholders are involved, (i.e. besides the initiators also the Flemish umbrella patient organisation, the scientific community, and the data registry owners (Sciensano, the Cancer Registry and the Intermutualistic Agency). It collects indicators for acute hospitals on the following domains: mother and childcare, orthopaedics, cardiology, breast cancer, stroke, patient experiences and hospital-wide quality; as well as for mental healthcare and assisted-living centres. Besides the provision of feedback and benchmarking reports to organizations and healthcare providers, for a selection of indicators the results are made public in an aggregated manner on the website www.zorgkwaliteit.be. The public reporting is organised on a voluntary basis and the website only allows to generate the results from three hospitals per report. On a monthly basis on average about 3000 unique visitors are counted but it has not been appraised who visits this web site and how they use the data from this website.

One of the domains included in the VIP² indicator set for which results are publicly available are PREMs. The PREMs were introduced under the leadership of the 'Flemish Patient Platform (VPP – Vlaamse Patiëntenplatform)'. The VPP developed, together with an academic centre, questionnaires to survey experiences of hospitalised patients in acute hospitals[151] and of both hospitalised and ambulatory patients in mental health services.[152] Both instruments were rigorously developed with much attention to the psychometric properties of the instrument as to the preferences of patients and healthcare providers. The instrument development process included: a scoping literature search to identify topics and instruments, focus groups with patients and experts to identify priorities, preliminary field test followed by extensive region wide testing

to test psychometric properties and fine-tune the wording and response categories.

The instrument for acute hospitals, is largely based on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS, see text box 3), and includes questions about: 'preparing for hospital stay', 'information and communication', 'coordination', 'respect', 'privacy', 'safe care', pain management', and 'participation'. There are also two general questions: one asks to rate the hospital from 0 to 10 (worst to best possible hospital) and one that asks if patients would recommend the hospital to friends and family. At the end of the questionnaire some demographic variables are questioned to allow for case-mix adjustments in the data analysis.

Acute hospitals participate on a voluntarily basis (but nearly all hospitals do so: in 2016: 48 out of 55 hospitals) with two measurement periods (March/April and September/October). There are clear instructions to collect the data (e.g. data collection should involve the entire instrument, patients with a sufficient knowledge of Dutch at surgical, medical, geriatric, maternity, and specialized unit ) but also a degree of flexibility (e.g. hospitals can add questions at the end of the questionnaire, data collection at the end of discharge versus after discharge). Hospitals are required to recruit a minimum of 150 adult patients per period and are asked to submit data within two months to the Flemish Agency for Care and Health (Flemish public administration). In 2016, the data from 31 892 patients collected by 48 different hospitals showed that 54.9% of patients rate their hospital 9 or 10 (min: 39.0%–max: 69.3%), which is far below US standards. In addition, large variability between Flemish hospitals exist.[151]

The main limitations reported are: the lack of response rates reporting; absence of case-mix adjustment and the absence of a mechanism to assess whether all completed questionnaires are transferred to the Flemish Agency for Care and Health. Case-mix adjustment, also retrospectively to allow assessment of evolutions over time, is being worked on and will still be solved in 2018. Another limitation in light of national policy initiatives (such as pay-for-quality) is that the questionnaire is not used in French speaking hospitals. Another limitation is that only top box ratings on the general question (respondents giving the hospital a score of 9 or 10 on a scale from 0 to 10) are publicly reported. Although in general all items of HCAPHS were strongly positively associated with the global rating, recent research suggest that the widely used cut-off point of 9 may not be the most optimal reflection of positive patient experiences with care. What's more individuals across populations appear to use the hospital rating scale differently which limits the use of these cut-off points (especially when comparing populations). While the global rating item might give a rapid overview of patients' experiences with a particular hospitals it is also worthwhile to report the scores on individual items.[153] The Agency is working on this issue and will report the scores on individual items from 2018 onwards.

The first version of the Flemish Patient Survey of Mental Healthcare, which followed a similar development process, includes 8 demographic items, 2 items reflecting global rating, and 35 core questions hypothesized to measure nine domains: information about mental health problems and treatment, participation, therapeutic relationship, personalized care, organization of care and collaboration between professionals, safe care, patient rights, result and evaluation of care, and discharge management and aftercare. Patients can only complete the questionnaire after at least 4 days of admission (psychiatric hospital, general hospital psychiatric ward, psychosocial rehabilitation, and psychiatric nursing home) or at least four sessions or contacts (sheltered housing, ambulatory public funded mental health services, and assertive community teams). A process evaluation showed that the clear communication about the objectives and contents of the questionnaire, the clear inclusion and exclusion criteria, and questionnaire length were appreciated. Nevertheless, the informed consent procedures were viewed as too complex and the availability of a Dutch version of the questionnaire only was considered as too restrictive. Moreover, the manual input was too time-consuming. This related to the main negative point, mentioned by a number of organizations, which was the short time span in which the data collection and uploading needed to be completed. Whereas several organizations indicated that they would prefer continuous measurement

of each discharged patient, a large majority (n = 35, 64%) indicated that it would not be possible to do two rounds a year. This would be too expensive and time-consuming.

Also for assisted-living centres, a survey was performed. All residents were asked to complete the questionnaire, but only about 40% were capable to do so. The survey ran for 3 years and was then abandoned for reasons of lack of feasibility (low response rates).

### Text box 3 –Hospital Consumer Assessment of Healthcare Providers and Systems - commonly used to measure patients' perspectives

The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) is the first national survey in the US with as purpose to standardize the collection of data to measure patient perspectives on hospital care. Patients' perspectives are measured on different factors, organized into nine topical areas: communication with doctors, communication with nurses, responsiveness of hospital staff, pain management, communication about medicines, discharge information, cleanliness of the hospital environment, quietness of the hospital environment, and transition of care. The survey includes also other questions such as variables that allow case-mix adjustment. Besides the general hospital survey also more specific surveys for the hospital care setting (e.g. the CAHPS Child Hospital Survey (Child HCAHPS) assesses the experiences of paediatric patients) or other care settings (e.g. nursing homes) exist.[154] The data allow objective and meaningful comparisons of hospitals, are publicly reported to give an incentive to hospitals for quality improvement and to create transparency and accountability. Patient care experience measures obtained via the HCAPHS are also increasingly included in pay-for-performance programs.[14] The instrument is available, validated and used in other countries.[155] It is often used in research and it has been shown that patient experiences are associated with several clinical outcomes and organisational factors (e.g. nurse staffing levels).[156]

The CAPHS surveys are collected via various ways (e.g. mail; phone; web-survey; in-person survey distribution; in-person interview). An evaluation of these different methods showed that:

- For traditional methods (mail or phone): the mail-only surveys compared to phone-only surveys are cheaper, and are less prone to measurement errors (e.g. social desirability bias). Yet phone follow-up can substantially improve overall response rates and respondent representativeness.
- For web-surveys: They are less expensive than traditional methods but yield lower response rates and are more likely to be filled in by younger, more educated, higher income respondents. Providing a mixed-mode of web with mail follow-up can increase response rates.
- With Interactive Voice Response, a pre-recorded voice (either human or digitized) presents the question and response options, and the respondent either presses a number on the phone keypad or speaks their response into the phone. Although in general response rates are low, this method enables to reach more socially disadvantaged respondents. In addition the problem of social desirability bias is small.
- In-person distribution of paper surveys is costly and may result in selection bias (unless outsourced to an independent company) and yield lower response rates compared to mail.[154]

**PROMs used are diverse**

Of the 49 reported PROMs used by hospitals, 26 were disease-specific validated PROMs (e.g. EORTC BR23, EORTC CR29 and EORTC QLQ C30, POKIS, REPOS, Knee Injury and Osteoarthritis Outcome Score (KOOS)), 8 were generic validated instruments (e.g. PROMIS, EQ-5D, SCL-90, SF-36), 8 were disease-specific self-developed or existing instruments with unknown validity and the remainders was unspecified.

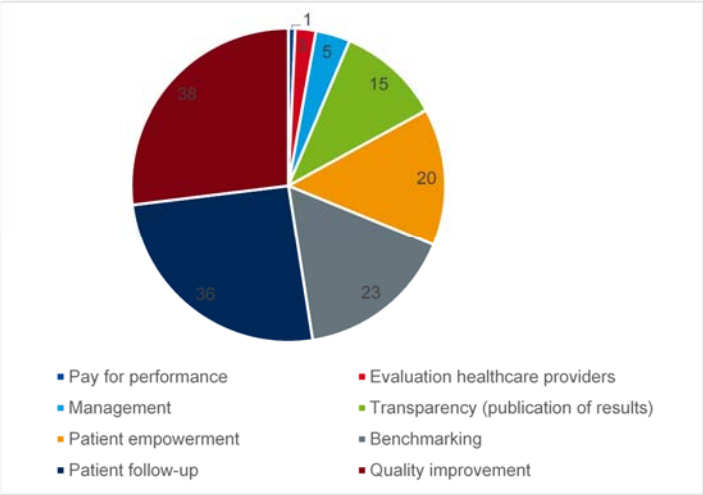
The other respondent categories (not from a hospital), mainly used disease-specific validated instruments (12 out of 16 reported PROMs used). These

included, for instance, the ACTIVLIM for neuromuscular conditions, the Reflux Symptom Index, the Voice Handicap Index, the KOOS; International Knee documentation Committee (IKDC) Subjective Knee Form, and the Tampa scale for Kinesiophobia.

PROMs are mainly used for specialised care, both for ambulatory and residential care. The exception is the use of generic PROMs in the Health Information Survey. Items included relate to perceived health in general, stress and wellbeing, presence of symptoms (based on a general symptom list) and general quality of life (EQ-5D-5L).

The purposes of collecting PROMs, as reported in the survey, are displayed in Figure 6. Quality improvement and patient follow-up was the most frequently checked response option, but PROMs also seem to be used often for benchmarking with other care institutions. Patient empowerment is closely related to the aspect of patient follow-up, as with the collection of the PROMs, healthcare providers can not only compare the evolution in the patients' health state, but they can also use the data to start a conversation with the patient, who is, in turn, better prepared because he/she has completed the PRO instrument. Furthermore, the government considers the current KCE study as an essential component of its empowerment policy[o]. This study is therefore designed in line with this aim.

**Figure 6 – Reported purposes of collecting PROMs (number of responses, all respondent categories together)**




### Implementation aspects

The most frequent mode of administration reported is still on paper (42%), followed by online via internet (21%) and by electronic means on-site (e.g. tablets) (13%). Face-to-face interviews (9%), telephone (8%) or e-mail (4%) are less often used.

Within the hospitals, it is usually the chief nurse, nursing director, medical director or, in hospitals with a specific quality assurance department, the quality coordinator, who are responsible for the data collection and the analysis, but the data collection itself is done by different kinds of people: chief nurses, nurses, psychologists, administrative staff, and data managers. The results of the analysis are usually available as a general

[o] DOC 54 2708/011

report (39%), a synthesis (27%), a feedback report (23%). Some respondents did not know what happened to the results of the analysis.

Hospitals and other institutions collecting PROMs take care of confidentiality and protection of the privacy of patients in several ways: through the privacy commission, anonymising and coding the data that are registered in the (secured) database, following the ISO27000 rules for security with internal audits, registering the data only in the patient's medical file.

Surprisingly, when asked whether any direct action was taken following the PROMs data collection and analysis, 44% answered "yes", 44% "no", and 12% "don't know". When respondents knew direct action was taken, the action related frequently to the individual patient management: e.g. symptom relief, collaboration with patient support team, change of treatment plan, but equally important were the lessons drawn for good practices in general. PROMs data analyses could lead, for example, to a revision of the interventions or techniques used, modification of care trajectories and better patient care across hospital departments. Also modifications in visiting hours for family and friends of the hospitalised patient was mentioned as an outcome of the PROMs analyses by one hospital.

## 4.2 Lessons learnt from a few Belgian case studies

The survey showed that different types of initiatives are taken in Belgium to collect data on patient-reported outcomes and experiences. The initiatives have different purposes and different designs. We aim at identifying the usefulness, hurdles and facilitators of implementing PROMs and PREMs for different purposes (micro, meso and macro) in Belgium. We selected 9 organisations with relevant experience as identified from the survey. The following criteria were used to select cases: inclusion of small and large initiatives, initiatives that implemented PROMs, PREMs or both, French-speaking and Dutch-speaking organisations, micro-, meso- and macro-level initiatives. This is by no means intended as a representative sample of all initiatives in Belgium. The main objective was to get a general idea of the status of PROMs and PREMs in Belgium and the experiences so far.

For each case, a site visit was scheduled to meet key-informants (clinicians such as nurses and physicians; quality managers; patient organisation representatives; civil servants). One researcher attended all site-visits and was accompanied by one of two other researchers (alternating each visit). During site visits information was gathered about barriers, facilitation and other implementation issues. We used a semi-structured interview guide to discuss the PROMs and/or PREMs initiative(s) with representatives of the organisations. The interview guide was based on a scoping review including papers (in first instance systematic reviews) such as Gleeson et al. 2016 (PREMs use in QI)[25], Antunes et al. 2013 (PROMs in palliative care)[157]. We focused on 'steps in the process of setting up a PROM or PREM initiative'[158] as well as 'main facilitators and barriers'.

Identified steps included:

- Identify the goals for collecting PROMs
- Select patients, setting and timing of assessment
- Determine which questionnaire to use
- Choose a mode for administering / scoring the questionnaire
- Design processes for reporting results
- Identify aids to facilitate score interpretation
- Develop strategies for responding to identified issues
- Evaluate the impact of measuring PROMs on practice, including impact on patient empowerment

Topics relating to facilitators and barriers are:

- Support (e.g. from the management)
- Resources (available budget,..)
- Privacy and security
- Analysis and feedback
- Knowledge end users (e.g. basic statistics)
- Burden of data collection

- Patient involvement (in data collection)
- Patient involvement during the design of the project and questionnaire

Each interview was audio-recorded. Together with field notes the researchers made a transversal analysis based on these audio-recordings. This transversal analysis was first made by one researcher and next challenged by the two other researchers.

The following organisations were interviewed: les Cliniques Universitaires de Saint-Luc, le Centre Hospitalier de Wallonie picarde, UZ Leuven, Onze Lieve Vrouwziekenhuis Aalst-Asse-Ninove, Jessa ziekenhuis Hasselt, RIZIV-INAMI, het Vlaams Patiëntenplatform, PAQS, Santhea and BSM.

The findings from the interviews were used for a transversal analysis. Interviewees were informed that no in-depth analysis of their initiative would be reported, in order to allow them to talk freely about the advantages, disadvantages and difficulties of their initiative. This chapter thus describes the general lessons learnt from the experiences of these different organisations and should not be regarded as an exhaustive or complete analysis of all experiences with PROMs and PREMs in Belgium.

### 4.2.1 General observations

A first general observation from the cases is that, independent of the purpose of the PROMs or PREMs initiative, there is a large variability in (1) the extent of the initiative, (2) the standardisation of instruments, and (3) the embeddedness in the decision making processes. Secondly, all initiatives seem to struggle with the resource requirements for their initiatives.

Third, most initiatives in hospitals depend on the enthusiasm of some people within the organisation. While these individuals have a strong drive to improve practices, their dynamic attitude is not necessarily shared within the entire organisation. This might be explained by the fact that PROMs and PREMs are only at the early phases of development in Belgium and it will take time but also support (financial and managerial) to create a PROMs/PREMs culture within the healthcare system in general and the healthcare organisations in particular. Involvement of stakeholders in this endeavour is crucial.

In the following paragraphs, we describe each aspect of the PROMs and PREMs initiatives separately for the individual patient level, hospital level and macro level. On the individual patient level, PROMs and PREMs are collected to respond directly to the individual patient's reported experiences or outcomes during consultations or hospital care. On the hospital level, PROMs and PREMs are used to identify gaps and develop activities to improve patient experiences and quality of care for all or groups of patients receiving care in the hospital. On the macro-level, PROMs and PREMs are used to inform health policy decisions (e.g. reimbursement, financing), incentivize hospitals to continue to work on their quality of care through comparisons between hospital, inform citizens and (potential) patients, and describe population health.

### 4.2.2 Purpose of PROM and PREM data collection

In several hospitals PROMs are measured with a purpose of quality improvement of clinical care at service or hospital level (meso level) and individual patient care or shared decision making (micro level).

#### Individual patient level

One of the triggers for the implementation of PROMs in the *Hospital A* was the trend of increased home care for patients with chronic diseases such as cancer (e.g. chemotherapy at home). Systematically measuring PROMs from a distance helps to improve the clinical follow-up of these patients and avoid potential risks associated with health interventions provided at home (e.g. serious side-effects of medication). PROMs are felt to be able to improve the quality of care across the whole care trajectory. However, in most cases, PROMs are currently still only measured in a pilot project or study context.

#### Hospital level

Both PROMs and PREMs are used for **benchmarking** purposes and for **quality improvement**. Initiatives are taken by individual hospitals as well as by umbrella organisations (e.g. Santhea, BePPa, VPP), and independent research associations or service providers (e.g. PAQS, BSM). The

objectives of umbrella organisations and independent research organisations are mainly to support their members in their PROMs and/or PREMs initiatives, sometimes on very specific PROMs such as pain if this is the organisation's main focus (e.g. BePPa is the Belgian Paediatric Pain Association). They help, for instance, with the choice of instruments, coordinate collaboration between members, provide scientific support (e.g. statistical analysis, overview of the evidence-base for specific PROMs or PREMs) and perform benchmarking. They do not impose anything but inform and support member hospitals and other institutions interested in measuring patient-reported outcome or experiences for their own quality improvement projects. While the umbrella organisations do invest in creating awareness amongst their membership of the utility of PROMs and PREMs, they do not interfere with internal procedures, feedback and process changes. Members remain responsible for the actual implementation, data collection, feedback to personnel involved and planning of actions. Some organisations also perform the data analysis and provide the benchmarking as a service.

Physicians of two services at the *Hospital A* initiated PROMs measurement to measure the outcomes of their interventions but also to benchmark with other physicians performing the same intervention at other departments, hospitals, and even countries. Benchmarking **within the hospital** (e.g. comparing PREMs of different departments within the same hospital) is used to stimulate a kind of healthy competition. Benchmarking **with other hospitals** is done to identify areas where there still is room for improvement, but also to describe the quality of care in a hospital service towards (future) patients. It can be used for marketing but at the same time increase the average quality of care in the Belgian hospital sector, which will benefit public health. However, the limited standardisation of PROMs and PREMs used across hospitals hampers real benchmarking.

In the Flemish part of Belgium, VIP² has been implemented in the majority of Flemish acute hospitals. It involves the *Vlaamse Patiënten Peiling*, a set of questionnaires for different quality indicators in different domains (PREMs). However, not all hospitals report the results of the measurements in a transparent manner. The vision of the "Vlaamse Patiëntenplatform" is that the *Vlaamse Patiënten Peiling* should be considered as a barometer for the hospital, to identify the areas in which quality improvement is possible. It might be that further questioning of patients is needed to identify exactly how quality could be improved in these areas. Therefore, the more general macro-level VPP can give rise to meso-level initiatives.

In the French-speaking region of Belgium, a large initiative called "Projet ASPE" has been implemented in 17 hospitals and 40 sites collecting PREMs data. The project is coordinated by BSM, a private consultant with a long experience in PREMs. The objective of this project has never been to use the data for macro-purposes, but rather to support hospitals in their quality improvement initiatives. Nevertheless, the richness of the data collected (>25 000 questionnaires) allows statistical analysis that allow to identify procedural aspects that determine the satisfaction of patients (through factor analysis), which is relevant overall, not for one specific hospital. The initiative demonstrates that data collected with a meso-level objective can be used to improve quality of care overall, if the individual hospitals are prepared to use the outcomes for determining their quality improvement actions. This is voluntary.

### Macro level

Macro-level purposes include the monitoring of population heath, monitoring of the quality of care in hospitals, informing reimbursement decisions and informing payment models (e.g. pay-for-performance).

In Belgium, PROMs and PREMs are included in the Health Information Survey (HIS), allowing monitoring of patient health and experiences with healthcare. A generic PROM is used, the EQ-5D-5L, allowing monitoring on five general domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The EQ-5D-5L was introduced in the HIS for the first time in 2013 and is used a second time in 2018. The PREMs included in the HIS allow a general assessment of patient issues and organisational issues associated with health conditions and treatments. The benefits of having the PREMs and PROMs in the HIS are also that they might provide supportive information for public health activities, allow the monitoring of the general effect of major policy initiatives and allow the identification of patient groups (e.g. certain socio-economic groups) with a lot of room for

improvement. The results of the HIS are also used in the OECD Health at a Glance reports.

According to the representative of the RIZIV-INAMI reimbursement commission, PROMs could play an important role in reimbursement decisions, not only for individual reimbursement decisions such as in the context of the Special Solidarity Fund, but also for other types of decisions taken at the RIZIV-INAMI. The unmet needs commission (CATT-CAIT) has to judge the level of unmet need in a particular disease in order to judge whether a promising new drug is eligible for coverage through the unmet medical needs programme. PROMs could be informative for this purpose. For regular reimbursement decisions as well there is a place for PROMs. Whether new treatments should be reimbursed or not depends on their added therapeutic value. The appraisal of the added therapeutic value should also depend at least partly on outcomes that are relevant for the patients. The interviewee suggested that the reimbursement of a pharmaceutical product could be linked to the registration of PROMs in a central database to make this data collection happen. This would stimulate the registration of PROMs and would benefit the advisory committees at the RIZIV-INAMI who have to evaluate and re-evaluate after a few years the therapeutic value and cost-effectiveness of pharmaceutical products. Especially in the case of rare diseases, usually very little information on PROMs is available. Decision makers would benefit from a centralised database collecting the PROMs of all patients with the same rare disease. Also in the context of the managed entry agreements (art 81 conventions), the systematic collection of PROMs in patients receiving the products under convention, would provide very important information for the re-assessment after the contractual period.

In the context of pay-for-performance, the measurement of PROMs and PREMs besides structural and process quality indicators and other clinical indicators for measuring quality of care, performance and efficacy, is considered principally important. The use of PREMs in the context of pay-for-performance is foreseen for the near future in Belgium (included in the set of indicators for 2018). Part of the performance points used for this purpose will be based on PREMs.

### *4.2.3 Stakeholder involvement*

**Individual patient level and hospital level**

Success stories mainly come from organisations where the initiative was taken by the healthcare professionals involved in clinical care. A bottom-up approach seems to work better than a top-down approach. Also a multidisciplinary approach was mentioned by several interviewees as an important success factor. The advantage of a multidisciplinary working group is that different visions are present and a broader perspective can be taken (e.g. anaesthesiologists can have a different perspective than that of the nurses). Nurses also often take care of the data collection (invite patients to complete a survey, call patients to prepare a consultation etc), and sometimes provide support in the data analysis phase. It was noted by one interviewee that a different profile might be envisaged for these tasks. However, this would require a change in the curriculum of the training programmes for medical secretaries towards medical management assistance, as many of their former roles have disappeared due to the digital evolution. Medical secretaries can take up new roles to reduce the administrative burden of nursing staff.

IT support is often needed to ensure accessibility of the data, and clear reporting of results. Finally, juridical support is also crucial for a legally correct implementation of a PROMs and PREMs initiative.

An example was given of a multidisciplinary oncological consult (MOC), where radiotherapists, surgeons, medical oncologists and specialised oncology nurses work together on the definition and selection of the relevant outcome measures, and collaborated with the IT department to determine the measurement system and integration with the electronic patient file. Also the ethical committee was involved to approve the initiative.

The engagement of clinicians is also very important for the participation of the patients. If clinicians use the input provided by patients through the PROMs and PREMs in their clinical practice, patients are more likely to engage in the data collection initiative. When also patients were involved in the development of the PROMs or PREMs initiative, this likelihood may increase further. However, involvement of patients was not seen

systematically in all initiatives, although all interviewees agreed that it could be a plus. Those who do involve patients state that patient information and education is essential to ensure patient engagement. Much depends on the goodwill of clinicians to involve patients and other stakeholders, but also openness of the management to patient involvement. Some hospitals are still searching for a best practice approach for patient involvement. They start with small initiatives that will be evaluated in due time.

Although a bottom-up approach seems to work better than a top-down approach, in hospitals involvement of the management (including quality coordinators) is of crucial importance, especially to streamline the approaches across departments. Management obviously also plays a role in financing decisions.

Hospitals find it difficult to involve the general practitioners in their initiative. Not all general practitioners are open to transmural communication about severely ill chronic patients, because they feel confident that the patient is taken care off by specialists with knowledge that extends beyond theirs. Moreover, knowledge on specialised treatments is often lacking at the ambulatory setting, hampering an easy communication with this sector.

**Macro level**

When PROMs and PREMs are developed for macro-level purposes, it is important to involve patients in the development and implementation of measures to ensure relevance of the measures and applicability. Patients can also help to assess the user-friendliness of the feedback regarding e.g. the benchmarking on the web-sites of hospitals. VIP² is an example where the umbrella organisation of Flemish patient organisations (VPP) was involved.

For reimbursement decision purposes, patients should be involved in the design phase of clinical trials in order to identify the relevant PROMs to be collected.

### *4.2.4 Data collection methods and sources*

Data are collected in a variety of ways: paper, face-to-face interviews, phone, e-mail, web, apps. Pen and paper is still used relatively frequently in Belgium, although digital versions of the questionnaires are increasingly available and used by the institutions. Use of digital versions decreases the burden of registration (no personnel needed to scan or manually input the data into a database after completion of a paper questionnaire by a patient).

**Individual patient level and hospital level**

The same data collection methods are used for the meso level as for the micro level. The difference is the data handling: for micro purposes the data are kept individual, for meso level purposes, the data are aggregated at the level of the provider, service, organisation or patient group.

*Hospital B* provides a leaflet to patients, with a link and password to a secured web-portal to fill out a PROM. The *Hospital A* started to work with an electronic symptom app, primarily to monitor patients receiving care at home. The app was based on an existing paper symptom questionnaire and can be installed on a tablet or smartphone or a PC. Tablets are available at the hospital to allow the patients to complete the PROM at the hospital while waiting for his/her appointment.

The advantage of an app is that it can be installed on the patients' electronic device, and patients can fill it out every day at home. This allows for better preparation of follow-up visits, a conversation between the patient and a specialised nurse before consultation with the specialist physician, and use of the information by a multidisciplinary team to discuss the complaints of the patients. Moreover, apps could be designed as such that complications get a colour code, e.g. severe complication gets red colour, and alert systems can be put in place, e.g. when a red coded complication is mentioned, the patient is prompted to contact the hospital immediately. For the patient this gives the feeling that he/she is followed-up very closely. A reminder system to complete the PROM instrument can also be included as a feature in the app.

Electronic versions allow a graphical presentation of the results. For clinicians and for patients this can be an advantage. Surveys through a web portal allow direct integration in other databases, such as clinical registries or other centralised databases. Aspects of privacy are, however, very important for that matter.

The *Hospital A* assessed the app-system by comparing three weeks with paper version with three weeks with electronic version. All participants had a preference for the electronic version (even older patients). Patients experience more commitment because of the direct feedback. A similar experience was expressed by another hospital included in our study. Participation rates are high with the electronic versions of the questionnaires, even in elderly patients. Despite the positive echoes related to the use of an app from several hospitals, only two are actually using one and one hospital is in the process of developing an app for a specific PROM for pain measurement (*Hospital C*). Several hospitals still deliberately chose to continue using paper versions. Paper-based questionnaires are expensive in terms of printing, distribution and data input but do not require access to or skills in the use of digital technologies from respondents.

One hospital also uses phone-calls to collect PROMs data. This is a rather intensive and expensive approach, but is effective for initial non-responders and does identify patients with significant medical problems that would have gone unnoticed otherwise. It was highlighted that it would not be possible to generalise this approach, especially not for longitudinal follow-up of patients which requires frequent measurements.

Face-to-face interviews only seem to be used in exceptional circumstances, e.g. if e-mail or reference to web-portals is not possible or gives no response (e.g. costly, privacy issues).

**Macro level**

With respect to PROMs and PREMs that could in principle be used for macro-level purposes, differences in measurement approaches between settings is a concern. If data are to be used for funding, for instance, more guidance should be provided by the government (who completes the questionnaire, patient by himself, together with a nurse, when, etc.).

For the HIS, face-to-face household interviews are performed. This is a very resource intensive approach.

For reimbursement assessment purposes, data from PROMs registries or study-based PROMs data are used.

### *4.2.5 Integration of data in electronic patient records and registries*

**Individual patient level: integration in electronic patient records**

Integration of PROMs in the electronic patient records have the potential to integrate PROMs in a systematic manner in the healthcare service and as a routine action.[160] Integrating results directly into EHRs can help ensure that clinicians get this information at the right time.[160] Although promising, results remain inconsistent in terms of uptake (e.g. because of the considerable heterogeneity in how data is gathered ranging from patients printing and bringing checklists to clinic visits to automatic input via e-tablets of web-based interfaces).

While all hospitals included in our sample expressed an interest in integrating PROMs in the electronic health record of the patient, only one performed such integration for one of its PROM initiatives for one specific service.

**Macro level: integration in clinical registries**

The integration of PROMs in clinical registries is on the rise in Belgium. The continuing development of eHealth plays an important role in this evolution, as it creates opportunities that did not exist in the past. For example TARDIS is a registry for rheumatoid arthritis, which contains clinical and PROMs information. Reimbursement of specific pharmaceutical products is conditional upon the registration of these data in the registry. Linking reimbursement to data input helps routine PROM registration, and can at the same time benefit the advisory committees at the RIZIV-INAMI who have to evaluate and re-evaluate the therapeutic value of pharmaceutical products or other healthcare interventions. Especially in the case of rare diseases, decision makers would benefit from a centralised database collecting the PROMs of all patients with the same rare disease. In this context, the scientific institute of public health (WIV / ISP, currently Sciensano) is currently collaborating with the Belgian umbrella organisation for patients with a rare condition RaDiOrg to select the PROMs and PREMs to be included in the rare disease registries, e.g. the Central Registry of Rare Diseases, the Belgian Neuromuscular Disease Registry, the Belgian Cystic Fibrosis registry.

When clinical registries are set up on a national scale, they allow that the health outcomes from all patients within the specific field of the register are followed. These data can be used to assess treatment effectiveness, adverse events and variations in healthcare delivery and outcomes across providers, organisations and regions.[21] Generic but more often disease-specific PROMs are increasingly adopted in clinical registries next to clinical and physiological measures (e.g. vital parameters) and outcome indicators (e.g. adverse events).[21]

### *4.2.6 Measurement frequency*

The timing and frequency of the data collection depends on the purpose of the PROMs or PREMs measurement.[22]

**Individual patient level**

For micro-level purposes longitudinal PROM measurements are preferred, especially for chronic care patients. Longitudinal data collection with multiple data points over time is indicated to evaluate whether the PROM improved or declined over time. It is suitable to evaluate and monitor complex and ongoing interventions.[22] One of the initiatives measures the PROMs of its chronic patients (lung cancer) longitudinally and prospectively. This implies that from the very beginning of the disease management, patients are asked to complete the PROMs.

ICHOM suggests data collection time points in its guidance; e.g. at baseline, at 3, 6, 12, 24 and 36 months after surgery. These time points do not necessarily coincide with concrete appointments of the patient. In order to comply with the ICHOM guidance, patients might either be prompted at home to complete their PROMs at the specified time points, or the follow-up visits might be reschedules to synchronize with the time points. It should be noted that the frequency of measurement might influence compliance: if there are too many time points, patients might become discouraged.

Despite the advantages of longitudinal data, many hospitals ask patients to complete the PROM or PREM only once, e.g. after surgery, or at discharge, probably due to time and budget constraints. This is considered sub-optimal because it gives no idea about the evolution in the outcomes over time (e.g. after surgery, several days of measurement is considered essential).

**Hospital level**

There is quite a large variability in timing and frequency of registration amongst institutions. Some hospitals administer the PREMs the day before discharge from hospitals, others ask patients to complete the questionnaires after discharge (in particular when electronic means are used but also phone

calls are made for specific groups). Cross-sectional data collection is most frequent for PREMs.

**Macro level**

In the context of the HIS, recurrent cross-sectional measurements are performed (every 5 years). Because the sample of the general population varies across years, longitudinal data analyses cannot be performed.

The cross-sectional data are useful, for instance, to establish norms or reference data, or when different groups are benchmarked (e.g. comparing PROMs/PREMs between different socio-economic groups or regions). It facilitates comparisons but does not allow to evaluate the impact of a specific intervention on a change in PROMs or PREMs.

For the evaluation of the impact of a health intervention on patient outcomes, e.g. for reimbursement decisions, at least pre- and post-intervention data collection is needed and if possible longer-term longitudinal follow-up measurements (duration of follow-up depends on the condition). For some interventions, a pre-post measurement may be sufficient (e.g. uncomplicated joint replacement). This has not yet been set up in Belgium.

### *4.2.7 Population*

**Individual patient level**

On the micro level, PROMs or PREMs could be administered to specific patients or all patients from the target group (e.g. lung cancer) or all patients of a specific department (e.g. stroke, oncology). Currently, each institution decides by itself to whom to distribute the PROMs and/or PREMs. It really depends on the availability of resources and the purpose of the measurements. For clinical care purposes, it could be decided to focus in first instance on chronic patients or patients with multi-morbidity (the more complex cases).

**Hospital level**

Some institutions systematically ask all patients to complete the questionnaire, others distribute the questionnaires randomly to a sample of the entire patient population. Yet another possibility is to distribute the questionnaires only to the population of a specific department (e.g. oncology). It depends on the objective: if the aim is to compare providers within a specific service, all patients using that service should be invited to complete the PREMs or PROMs. If the objective is to improve or assess the service to a specific subgroup of patients, this subgroup should be targeted, independent of the provider who treated him or provided the service.

**Macro level**

Differences in implementation strategies between hospitals (not all hospitals asking all patients to complete the PREMs for instance) hamper comparisons between institutions. It is difficult to judge to what extent the data provided emerge from a representative population sample of the hospital.

Both generic and service-specific PREMs are implemented in Flanders by VIP² and in French-speaking Belgium by ASPE.

For reimbursement assessments, it is important to include patients getting the standard intervention as well as patients getting the new intervention when measuring PROMs.

### *4.2.8 Instruments*

The most common instruments to collect PROMS and PREMs are **surveys**. The type of survey and its contents depend on the level of its use. Macro-level surveys can be population surveys (e.g. in the context of the Health Information Survey), meso-level surveys can be surveys that are used in a hospital or several hospitals (e.g. standardised PREMs for benchmarking purposes) and micro-level surveys can be specific surveys administered as part of daily clinical routine (e.g. distributed during consultations). To be feasible and useful, PROMs should not burden patients too much. The data

should be easy to interpret and actionable (the right information for the clinician, hospital management or government).

### Individual patient level

For micro level purposes, usually condition-specific PROMs are preferred. However, for some diseases, ICHOM also recommends the use of a generic measure alongside a disease-specific PROM. Hospitals that use the guidance of ICHOM therefore implement both generic and disease-specific PROMs.

### Hospital level

There is a huge variety in instruments used in Belgium to measure patient-reported outcomes and experiences. The choice of the instrument is determined by the practicality.

For PROMs, both validated questionnaires (e.g. PROMIS, ICHOM standard sets) as self-developed questionnaires are used. The standard sets of ICHOM are perceived as very valuable, although some questionnaires are perceived as being too long and burdensome for patients. Therefore, one hospital included in our study works at a shortening of the questionnaire in a scientifically valid manner, with the help of an academic team. On the one hand, this may hamper the comparability between hospitals, but on the other hand the hospital considered it valuable to do the effort because others probably have the same concerns and are therefore reluctant to start using the ICHOM standard sets. With the shortened version, the hospital might set a trend in Belgium towards more feasible PROMs data collection. Another hospital made the same comment and decided to implement only part of the standard set in a specific patient population, to allow for a quicker and more feasible implementation. Another hospital mentioned issues with language versions. Some questionnaires are not available yet in French or Dutch and hence still need to be translated and validated in these languages. Other questionnaires, such as those of the EORTC, are also included in the ICHOM standard sets, and are available and validated in French and Dutch.

One hospital interviewed, listed a number of considerations that determined their choice of PROMs:

- The length of the questionnaire
- The use in clinical studies or by respected international organisations
- The possible integration in the electronic patient record
- Financial aspects related to the purchase of the questionnaire
- Scientific validity and usefulness for scientific research
- Generic nature (chosen by the hospital management) or condition-specific nature (chosen by clinicians)

For PREMs, regional differences are observed. In French-speaking Belgium, patient satisfaction questionnaires as proposed by (the PREMs working group of) Santhea or the patient satisfaction questionnaires and PREMs as proposed by BSM for the project ASPE are used. The PREMs working group of Santhea encompasses interested members who develop jointly an approach for measuring patient satisfaction in their hospitals. Actual implementation remains, however, the responsibility of the individual hospitals. No standardised or validated questionnaires are used; members of Santhea select the topics that are of particular interest to them, and can modify the questionnaires by consensus (e.g. shortening, reformulation, changing the order of questions). The questions included are primarily generic.

In ASPE, modification of the instruments by individual hospitals is not allowed. ASPE standardises the questionnaires for each domains considered (surgery, maternity, paediatrics, emergency services, …). The questionnaires are relatively extensive in order to provide specific information about the experiences and satisfaction of patients in particular wards.

The Flemish region mainly uses the PREMs proposed by the *Vlaamse Patiëntenplatform* in the context of VIP². With regard to these PREMs, one hospital raised a concern about the generic nature of the measures. The translation to concrete actions is hampered by the fact that the results of the data analyses are too vague. For example, what does it mean if 50-60% gives a very high score on the PREM, indicating “very satisfied”? Moreover,

some questions that are relevant for the hospital management are missing: e.g. food, comfort of the room, cleanness of the room, reception.

**Macro level**

For population health surveys, generic PROMs and PREMs are used.

For reimbursement decisions, generic PROMs complemented with condition-specific PROMs are preferred. Generic PROMs allow comparisons across diseases, whereas condition-specific PROMs give more detailed information on the domain in which a new intervention changes patient-relevant outcomes.

For the purpose of assessing the quality of care in healthcare institutions, domain-specific PREMs as well as generic PREMs are used.

Currently, PROM or PREM data were not yet used for reimbursement objectives.

### *4.2.9 Operational aspects*

A comment given by several interviewees was that informing the patient about the relevance of the data collection and the purpose is a very important operational aspect. This is independent of the purpose of the PROMs and PREMs. With better information, the participation increases. Another comment was that the number of questions and frequency of measurements should not be too high.

Also *vis à vis* the clinicians, good and convincing information is required to motivate engagement in PROMs or PREMs initiatives. One interviewee mentioned that clinicians always have reasons not to participate, but often the reasons given are incorrect: lack of time, patients do not want to fill out these questionnaires, no need for these data to improve my practice because I have sufficient experience to know what I must do. By showing the data, and involving patients in the development process of the PROMs/PREMs initiative, the beliefs of the clinicians might change.

**Individual patient level**

For the collection of PROMs and PREMs supporting staff is required. For example, at the *Hospital A* each oncology patient is seen by an onco-coach before his or her follow-up consultation to look and discuss the questionnaire filled out by the patient. Also for the follow-up PROMs measurements, a dedicated person is needed, in order to avoid reduced participation of patients who are symptom free (knowing that patients are symptom free is also important from a clinical point of view).

**Hospital level**

At the hospital level, several ad hoc initiatives are taken in the context of scientific projects. This has several advantages. On the one hand, it builds a solid scientific foundation for the initiative, because in the context of these projects a scientific literature review is performed to design the study and collect the data in a reliable and valid manner. This is often the aspect for which clinicians and hospital managers have insufficient time in their day-to-day practice. Moreover, if the scientific project is financed through a research grant or by other means, less resources are required from the hospital and the initiative becomes more feasible for the hospital to participate. On the other hand, project-based initiatives are often limited in time and initiatives heavily depend on the interest of researchers to develop further projects in this field. Therefore, project-based initiatives are not sustainable as they risk to fade away once the project is finished.

A clear example of this is the project that was performed at a number of French-speaking hospitals by Mr Frédéric Bielen in the context of his PhD study. After the finalisation of the PhD, there was a continued interest from the hospitals, and the initiative got support from the Health Minister of the French-speaking region. A not-for-profit association Medsoc was set up to continue the work. In 2004 the support was removed, and the initiative continued under the umbrella of a newly established for-profit consultancy, called BSM. The initiative is self- sustaining, by means of participation fees of the hospitals. All hospitals are entitled to the same services, but are free to choose which ones they use.

The desirability of applying the SMART objectives when developing an implementation plan was mentioned by a few interviewees. SMART stands for “Specific, Measurable, Attainable, Relevant and Timely”. Applying the SMART objectives ensures focus, usability and applicability of the measurements.

Larger initiatives, covering several institutions or benchmarking with hospitals internationally, ensured standardisation of data collection within a specific field. For example, when ICHOM is used for choosing PROMs, the guidance from ICHOM with respect to the data collection is generally also followed.

**Macro level**

On the macro level the most important operational aspect is standardisation in the collection of data within the institutions. If this is lacking, the usefulness of the data for assessing the quality of care and for benchmarking is seriously reduced.

Another operational aspect raised was that patient associations and sickness funds could play a role in informing patients about the value of PROMs and PREMs for different purposes at different levels, in order to increase participation rates.

### *4.2.10 Data analysis and feedback*

**Individual patient level**

Only one hospital spoke about the type of data analysis and feedback on the individual patient level for one of its initiatives in a chronic patient population (oncology). A graphical presentation of the individual patient results is generated with a specific colour code. The main focus is on the evolution of the PROMs over time. The longitudinal information is also useful for the multidisciplinary oncologic consultations. The presentation with colours allows to focus immediately on the important problems during the consultation, which has a direct advantage for the patient.

**Hospital level**

One hospital produces feedback reports with aggregate data to the surgeons, per type of surgery. The analysis is performed on a central level. The feedback is given on white boards and action is prepared based on these feedback reports. The actual use of the white board feedback system as well as the implementation of the actions distilled from it heavily depends on the culture of the hospital unit. The presence of a quality culture is necessary to guarantee the success of the initiatives.

The linkage between the results and actions is very service dependent. Top-down initiatives lead less frequent to concrete actions than bottom-up initiatives. Critical success factors for translation of results to actions are engagement of the nurses and doctors, and support and motivation from the quality coordinator and management. Clinicians being able to ask for specific analyses is also expected to enhance the use of the results for quality improvement initiatives.

One hospital mentioned that the absence of integration in the electronic patient record hampers analyses on a more transversal level, as corrections for patient characteristics are not possible.

Three hospitals organise a yearly event for its physicians and chief nurses to present the results of their PREMs initiatives. This also offers the opportunity to thank the people who have made efforts to improve the quality of care in the hospital. One hospital also communicates about the initiatives through its own hospital journal.

In addition, one hospital also reports separately to each department on its performance in a graphical format. Monthly discussions are organised to explain critical success factors on the generic level and on the departmental level. Another hospital also organises feedback moments with departments. Based on this feedback, the chief medical doctor and the head nurse have to formulate at least three proposals for improvement each year. The possible action items are identified from a detailed analysis of factors determining the results, and ranked according to priority (highest impact factors get highest priority). The system has been accepted by the personnel and has now become part of the hospital culture.

**Macro level**

The analyses of the VPP data are performed by a thrusted third party and are coordinated by the *Vlaams Agentschap Zorg en Gezondheid*. Hospitals do not have access to the individual data of other hospitals, only to aggregated benchmark data, based on data provided by the patients. Demographic data was up until now not used in the analysis, but would become more important for case-mix adjustment if pay-for-quality approaches would be considered.

The VPP publishes the results of the analysis of two generic questions from the PREM per hospital online on zorgkwaliteit.be. Hospitals are free to decide whether they want their results to be published, but almost all hospitals decide positively. On the web-site people can compare every hospital to two other hospitals of their choice. Hospitals in addition receive more detailed results for each question, where the other hospitals' names are concealed. According to the VPP, it is the role of the hospital umbrella organisations to inform the hospitals on the good practices, with the VPP (*Vlaamse Patiënten Peiling)* as a barometer. Nevertheless, it is observed that the benchmarking data from the VPP are not often used for improvement of quality of care.

The VPP approach contrasts with the French-speaking region, where the two existing initiatives (Project ASPE and Santhea) do not publish any results, but makes the anonymised aggregated results available to all participating hospitals. Besides the aggregated results, each individual hospital also receives its own detailed results. The detailed data are sent to the general director of each hospital, who then decides to whom within the hospital he/she forwards the results.

The advantage of making all results publicly available is full transparency. However, the disadvantage is that the data provided might become biased, because hospitals do not want to appear on the website with bad results. As a consequence, the data become less useable for the purpose it tries to serve. Hospitals included in our sample expressed their doubts about the reliability of the results of the data analyses performed in the context of benchmarking activities, because of the differences in measurement frequency, data collection procedures etc. The latter differences may be induced by the eventual use of the data for publication. When PREMs would be used for pay for quality mechanisms, this should be taken into account. According to one hospital, this can only work if a centralised database is set up, where the data of patients are registered without passing through the hospital's own system.

The Vlaams Patiëntenplatform organises regular feedback moments with hospitals, where hospitals can indicate, through a participative methodology, any problem with the questionnaires, test protocols etc.

### 4.2.11 Impact

Small scale initiatives in one specific department attract the attention of other departments. This induces an interest to start with PROMs or PREMs. However, these initiatives require resources and these resources are limited. Not all interested parties can set up their own initiative. Reports on the impact of these initiatives ware not yet available.

On input level, the involvement of data nurses and the setup of a data management department is required. On the output level, it should be taken into account that data collection generates big data sets within hospitals that need to be managed. Resources need to be freed for this as well. One hospital hopes to be able to set up a data cell to support the physicians in data analysis and to sustain a uniform approach across the departments.

### 4.2.12 Barriers and facilitators

Throughout the discussions, interviewees highlighted several barriers and facilitators for the implementation of a useful PROMs or PREMs initiative. Other facilitators and barriers, as mentioned in the other countries or in the literature review, are analysed in the short report.

**Barriers**:

**Financial barriers**

- Lack of resources. For the application of PROMs and PREMs, personnel is required to organise and coordinate the measurements. Someone needs to provide the leaflets to patients, explain the objective of the PROMs and PREMs measurement, motivate the patients to participate, assist them if needed and encode the data or scan the completed questionnaires. For some applications, someone needs to call patients or send out emails.
  Most initiatives on the hospital level are financed by the hospital's own means. If additional staff is hired for coordinating and collecting data, this is also with the existing hospital budget. At *Hospital C*, recently a "patient experience officer" has been appointed to organise and coordinate PROMs and PREMs measurements at the hospital and to support the hospital management in using this information.
- Lack of provision of resources for the evaluation of the PROMs or PREMs initiative.
- Lack of time and knowledge to ensure scientific validation of the questionnaires in-house or financial means to outsources the scientific validation

**Operational barriers**

- Administrative burden, leading to
  - Lack of participation by physicians ("no time, always done it this way, patients don't want it")
  - Lack of participation by hospitals (e.g. VPP now has a high participation rate, but this required pro-active marketing strategies)
- Conflicting visions between clinicians regarding the features of the PROMs to be implemented
- Lack of knowledge about the international initiatives (like ICHOM) and distrust
- Lack of exchange between institutions – insufficient benefit taken from experiences in several institutions
- Lack of standardisation, both in instruments used (e.g. selection of different instruments or selection of only a few items from a standardised questionnaire), data collection (e.g. inclusion and exclusion criteria for patients, questionnaires filled out by family) and reporting (e.g. select only a few items to report upon), hampering comparisons between the results of institutions. Lack of standardisation in data collection induces a risk of selection bias in respondents (e.g. only positive patients included).
- Lack of participation by specifically vulnerable patient groups, e.g. elderly, refugees, emergency care patients
- Resistance from patients to the use of digital versions of PROMs or PREMs
- Lack of trust from the patients-side, e.g. due to questions regarding respect for privacy
- Timing of measurement as determined by ICHOM differ to follow-up consultations
- Compliance with privacy protection rules
- Duplication of work: having to register the same data in different databases (e.g. the electronic patient record and a clinical registry)
- Delays in feedback reports (e.g. within context of VIP², there is a delay of 6 months for the benchmarking reports) hamper linkage with actions in clinical practice

**Technical barriers**

- Lack of integration in the electronic patient record: information stored in different databases, e.g. clinical info is stored in the medical file, PROMs or PREMs are stored in a separate database or kept on paper
- Lack of IT support

**Methodological barriers**

- Lack of baseline data in some patients, which hampers comparative analyses.
- Difficulty to estimate at which time point best to include the patient (e.g. just after diagnosis?)
- Unavailability of other language versions. Availability of French and Dutch versions alone might be insufficient. Translation of a questionnaire requires validation process, which is time and resource consuming.
- Cultural barriers: questionnaire not adapted to differences in culture
- Selection bias due to the choice of the PROM or PREM and the administration route (e.g. older patients not able to complete a digital version; emergency patients not able to complete questionnaire at admission)
- Insufficient solutions to allow vulnerable patient groups to participate: e.g. questionnaire with pictograms for patients not speaking the language of the questionnaires, inclusion of specific questions that are relevant for patients with other cultural backgrounds
- Lengthy questionnaires

**Facilitators**

**Clear objectives**

- Clear finality of the registration of the data. Registration for the sake of registration will be counter-productive.
- *All* the data to be collected have a purpose and actually serve this purpose, there is no “noise”.

**Leadership and coordination of initiatives**

- Appointment of a coordinator with a clear task and function description, so that development is less dependent on motivation of single individuals
- Management support
- Gradual implementation
- Transparent and sufficient communication
- Sufficient financial and human resources
- Multidisciplinarity, including clinicians, nurses, patients, management, IT people, a statistician, data manager, administrative staff
- Peer-pressure to engage and participate

**Patient involvement**

- Involvement of patients in the development or choice of PROMs/PREMs:
  - Listen to patients
  - Create a longlist of domains and aspects that matter to patients
  - Remove factors that cannot be modified through quality improvement initiatives, or are not within scope
  - Check relevance and importance of selected domains and aspects with professionals and patients (patients’ voice most important in case of disagreement)
  - Translate short list in questionnaires
  - Develop test + implementation protocol
  - Pilot test



- Validate
- Involvement of patients in the establishment of a methodological approach for data collection
- Coordination of patient involvement initiatives (e.g. selection of patients for the developmental process)

**Technical support**

- Support from e-Health: creation of data storage modes that ensure privacy of the patients, integration into the electronic patient record
- Support from a central data analysis unit
- Avoiding duplication of work (automatic linkage with other databases, such as clinical registries)
- Creating a user-friendly, nice-looking application to complete digital PROMs and PREMs, with a secured log-in

**Communication and experience sharing**

- Communication towards the clinicians about the purpose for registration
- Coordination between different existing initiatives (cfr project ASPE in the French-speaking region; alternatively, a collaboration with Sciensano and HealthData.be could be envisaged)
- Organisation of meetings between centres to discuss experiences and best practices
- Better collaboration between tertiary care and primary care (reduce lack of trust and perceived division of labour issues)
- Positive attention, e.g. in public press and on internet, to centres who collect PROMs or PREMs data in a standardised manner and use the results to improve the quality of care
- Use of non-blaming tone: objective presentation of results of the analyses
- Timely feedback

**Education**

- Education of centres to ensure engagement
- Education of patients to ensure participation
- Education of health professionals to ensure engagement
- Availability of a web-site with an overview of tools to measure PROMs and PREMs in Belgium (validated French and Dutch language tools)
- Creation of a central place where patients can find information on PREMs results of hospitals in a user-friendly manner

**Methodological quality**

- Use of validated instruments, developed in collaboration with patients
- Involvement of external experts in the choice of the instruments (e.g. methodological expert, representative of relevant stakeholders for the identified purpose, this could be clinicians and nurses, but could also be policy makers or the society of chief medical doctors)
- Standardisation of data collection (which questionnaires, timing of data collection, representativeness of patient sample, alerts in case of missing data …)
- Risk-adjustment in the analysis of the data to take the impact of risk-factors (e.g. age, co-morbitities) into account and thereby avoid selection bias in data collection (collecting data only in ‘good’ patients)

# 5 DISCUSSION AND CONCLUSION

The discussion and conclusions of this work are included in the short report, along with the recommendations.

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# APPENDICES

# APPENDIX 1. EVIDENCE ABOUT IMPACT: REVIEW OF REVIEWS

## Appendix 1.1. Search strategy

### *Appendix 1.1.1. Ovid MEDLINE*

Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily, Ovid MEDLINE and Versions(R)

Search Strategy:

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1 Patient Reported Outcome Measures/ (1148)

2 Patient Outcome Assessment/ (3927)

3 PROM?.ab,ti. (3134)

4 (patient? adj2 report* adj2 (outcome? or measur*)).ab,ti. (13263)

5 1 or 2 or 3 or 4 (18722)

6 "patient? report* experience? measur*".ab,ti. (57)

7 "patient? experience? measur*".ab,ti. (91)

8 PREM?.ab,ti. (327)

9 Patient Satisfaction/ (77347)

10 (patient? adj2 report* adj2 (experience? or measur*)).ab,ti. (5869)

11 facilitator*.ti,ab. (20786)

12 barrier*.ti,ab. (247574)

13 implement*.ti,ab. (401258)

14 impact.ti,ab. (803717)

15 effect*.ti,ab. (6353582)

16 5 or 6 or 7 or 8 or 9 or 10 (95065)

| | |
|---|---|
| 17 | 11 or 12 or 13 or 14 or 15 (7239976) |
| 18 | 16 and 17 (38578) |
| 19 | limit 18 to systematic reviews (2719) |
| 20 | limit 19 to yr="2010 -Current" (1959) |
| 21 | (effect* adj2 (outcome? or measur* or evaluation)).ab,ti. (54205) |
| 22 | 11 or 12 or 13 or 14 or 21 (1434870) |
| 23 | 16 and 22 (15118) |
| 24 | limit 23 to systematic reviews (1217) |
| 25 | limit 24 to yr="2010 -Current" (908) |

### *Appendix 1.1.2. Cochrane*

Date Run: 06/12/17 15:16:22.157

| ID | Search | Hits |
|---|---|---|
| #1 | MeSH descriptor:[Patient Reported Outcome Measures] explode all trees | 82 |
| #2 | MeSH descriptor:[Patient Outcome Assessment] explode all trees | 321 |
| #3 | PROM?:ab,ti | 124 |
| #4 | (patient? near/2 report* near/2 (outcome? or measur*)):ab,ti | 213 |
| #5 | "patient? report* experience? measur*":ab,ti | 0 |
| #6 | "patient? experience? measur*":ab,ti | 1 |
| #7 | PREM?:ab,ti | 259 |
| #8 | MeSH descriptor:[Patient Satisfaction] explode all trees | 11369 |
| #9 | (patient? near/2 report* near/2 (experience? or measur*)):ab,ti | 81 |
| #10 | #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 | 12244 |
| #11 | facilitator*:ab,ti | 1262 |
| #12 | barrier*:ab,ti | 8666 |
| #13 | implement*:ab,ti | 20475 |
| #14 | impact:ab,ti | 65091 |
| #15 | effect*:ab,ti | 567985 |
| #16 | (effect* near/2 (outcome? or measur* or evaluation)):ab,ti | 9898 |
| #17 | #11 or #12 or #13 or #14 or #15 or #16 | 607430 |
| #18 | #10 and #17 Publication Year from 2010 to 2017 | 273 |

## Appendix 1.2. Critical appraisal of reviews

### Table 11 – Evaluation of studies according to the AMSTAR instrument

| Author | ams1 | ams2 | ams3 | ams4 | ams5 | ams6 | ams7 | ams8 | ams9 | ams10 | ams11 | ams12 | ams13 | ams14 | ams15 | ams16 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | PICO research questions | A priori design | Selection of study designs explained | Comprehensive | Duplicate study selection | Duplicate data extraction | List excluded studies | Adequate detail | Risk of Bias assessment | Funding sources | Approapriate statistical methods | Impact Risk of Bias on meta-analysis | Risk of Bias taken into account in discussion of results | Heterogeneity | Publication bias | Conflict of interest |
| **Antunes et al. 2014** | | | | | | | | | | | | | | | | |
| **Boyce and Browne, 2013** | Yes | No | Yes | Partly | No | Partly | No | Partly | Partly | No | N/A | N/A | Yes | No | N/A | Yes |
| **Boyce et al. 2014** | | | | | | | | | | | | | | | | |
| **Chen et al. 2013** | Yes | No | Yes | Partly | Yes | Yes | No | Partly | Partly | No | N/A | N/A | Yes | No | N/A | Yes |
| **Etkind et al. 2015** | Yes | No | Yes | Partly | Partly | Partly | No | Partly | Partly | No | N/A | N/A | Yes | No | N/A | Yes |
| **Gleeson et al. 2016** | Yes | No | Yes | Partly | Partly | Partly | No | Partly | Partly | No | N/A | N/A | No | No | No | Yes |
| **Holmes et al. 2016** | Partly | No | Yes | Partly | Yes | Yes | No | Yes | Partly | No | N/A | N/A | Yes | No | N/A | Yes |
| **Howell et al. 2015** | Partly | No | Yes | Partly | Partly | Partly | No | Partly | No | No | N/A | N/A | No | No | N/A | Yes |
| **Kendrick et al. 2016** | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | Yes | Yes |
| **Kotronulas et al. 2014** | Yes | No | Yes | Partly | Yes | Partly | No | Partly | Partly | No | N/A | N/A | Yes | No | N/A | Yes |

## Appendix 1.3. Evidence tables

**Table 12 – Summary of systematic reviews (1)**

| Study | Sources searched | Years searched | Number of studies included (per study type) | Countries included in the review |
|---|---|---|---|---|
| **Antunes et al 2014** | Medline, PsychInfo, CINAHL, Embase and British Nursing Index | From 1985 till August 2011 and updated on 19 March 2012 | • 26 studies within 31 articles<br>• Qualitative design (n=4)<br>• Quantitative methods (n=7) | • UK (n=11); USA (n=7); the Netherlands (n=2); Australia (n=1); Canada (n=1); Israel (n=1); Italy (n=1); Malaysia (n=1); Vietnam (n=1) |
| **Berger et al. 2013** | PubMed, Scopus, PsycINFO, Sociological Abstracts, Web of Science, EconLit, Anthropolgy Plus | From inception till January 20, 2013 | • 25 studies (observational studies) | • The Netherlands (n=1); Italy (n=1); US (n=23) |
| **Boyce and Browne, 2013** | Pubmed and the Cochrane Library; screening of reference lists and a citation search from previous reviews | From inception till February 2012 | • 17 RCT's (11 cluster randomised trials) | • USA (n=13); UK (n=2); The Netherlands; Germany |
| **Boyce et al. 2014** | Pubmed, PsychInfo, CINAHL | From inception till August 2013 | • 16 studies (qualitative designs) | • UK (n=9); Sweden (n=3); Australia (n=2); USA (n=1); Canada (n=1) |
| **Chen et al. 2013** | Scopus | January 2000-October 2011 | • 27 studies<br>• RCT (n=16); interrupted time series (n=2); descriptive (n=9) | • USA (n=11); Canada (n=3); Australia (n=3); The Netherlands (n=3); UK (n=5); Germany; Norway |
| **Corsini et al. 2017** | Medline, Pubmed, PsychInfo, Cochrane Library, CINAHL, Scopus, Joanna Briggs Institute EBP Database, Google Scholar | From inception till July 2015 | • 11 studies on 7 international monitoring systems | • The Netherlands (n=1); USA (n=3); UK (n=1); Australia (n=2) |
| **Etkind et al. 2015** | Medline, Embase, CINAHL, BNI, | From 1980 to 2013 | • 16 studies (10 RCT's; 1 controlled trial; 5 descriptive studies) | • Not reported |

| Study | Sources searched | Years searched | Number of studies included (per study type) | Countries included in the review |
|---|---|---|---|---|
| | PsycINFO, and gray literature (Reference lists and unpublished literature, personal contacts) | | | |
| **Gillam et al. 2012** | Medline, Embase, PsychINFO | From January 1, 2004 to July, 31, 2011 | • 94 studies (not stated) | • UK |
| **Gleeson et al. 2016** | Medline, CINAHL, PsycINFO, Cochrane Libraries | From 1990 to May 2015 | • 11 studies (2 RCTs; 9 qualitative designs (6 qualitative follow-up studies, 3 evidence-based co-design approach) | • North America (n=5); UK (n=5); the Netherlands (n=1) |
| **Greenhalgh et al. 2017** | Embase, Health Management Information Consortium, Medline | ? | • 58 papers for review of aggregate PROMs and performance data<br>• 36 papers for individual review | • ? |
| **Groen et al. 2015** | Medline, Scopus, PsychINFO | From January 1990 up to April 2014 | • 26 studies (11 reviews, 9studies on psychometric evaluation of a questionnaire on patient empowerment; 6 qualitative studies) | • Not reported |
| **Holmes et al. 2016** | MEDLINE, EMBASE, PsycINFO, PsycARTICLES, Cochrane Library and Web of Science, Google Scholar, UK Clinical Research Network Portfolio Website, screening of reference lists and a key author search, | From 1985 till January 2015 | • 13 studies using critical interpretative synthesis method to analyse both qualitative and quantitative study findings: 2 qualitative studies; 1 mixed method; 2 RCTs; 2 non-randomised trials; 2 case series; 1 case report; 1 cross-sectional survey. | • Brazil (n=2); Ireland; Canada (n=2); USA(n=5); Sweden; UK; France |
| **Howell et al. 2015** | Ovid Medline, CINAHL and PsycINFO | 2003-September 2013 | • 30 studies of which 16 primary studies about the impact RCT (n=4); non-randomised trials | • Not reported |

| Study | Sources searched | Years searched | Number of studies included (per study type) | Countries included in the review |
|---|---|---|---|---|
| | | | (n=3); descriptive and qualitative (n=9); and systematic reviews (n=4);. | |
| **Kendrick et al. 2016** | Cochrane Depression Anxiety and Neurosis group specialised controlled trials register, the Oxford University PROMS Bibliography (2002-5), Ovid PsycINFO, Web of Science, The Cochrane Library, and International trial registries. Grey literature; Reference lists | initially to 30 May 2014, and updated to 18 May 2015 | • 17 studies (13 RCT+4cRCT) | • USA (n=9); Ireland; Sweden; Norway; The Netherlands (n=2); Germany (n=3) |
| **Kotronulas et al. 2014** | Medline, EMBASE, CINAHL[Cumulative Index to Nursing and Allied Health Literature], PsycINFO, and PBSC; reference lists; | Inception – May 2012 | • 26 articles, 24 studies: 20 RCTs, 4 controlled trials | • USA (n=7); Canada (n=3); Australia (n=4); The Netherlands (n=4); UK (n=5); Germany; Norway; Sweden |
| **Nama et al. 2013** | The Cochrane Gynaecological Cancer Review Group's Trial Register ; CENTRAL, Medline, Embase | 1985 to November 2012 | • All identified studies excluded | • / |
| **Yang et al. 2018** | Medline, Embase, CINAHL, PsychInfo, Cab Direct, CDSR | Inception-? | • 43 articles: 16 RCTs, 6 quantitative cohort studies, 1 quantitative cross-sectional study, 3 surveys, 15 qualitative studies, 2 mixed methods studies | • USA (n=18); UK (n=9); the Netherlands (n=6); Australia (n=3); Canada (n=2-; Germany (n=2); France (n=1); Italy (n=1); New Zealand (n=1); South Korea (n=1) |

**Table 13 – Summary of systematic reviews (2)**

| Study | Research Question/objective | Population | Intervention | Results | Authors' conclusion |
|---|---|---|---|---|---|
| **Antunes et al 2014** | To identify barriers and facilitators to the systematic implementation of PROMS in palliative care clinical practice, to identify needs and other comments of clinical teams regarding the routine use of PROMs and to identify lessons learned on the process of implementation of PROMs in clinical practice. | • Adult patients with advanced disease in palliative care settings | • Implementation of PROMs in clinical setting | • No interventions studies of implementing facilitators to overcome barriers when using PROMs<br>Implementation process:<br>• Lessons learned: a need to acknowledge interpersonal relationships between clinical team members and the ongoing emotional and cognitive processes that occur in each individual<br>• Barriers: fear of change, feeling of assessment, work open to criticism, fear of added work<br>• Facilitator: leadership, ownership of the measures, providing (timely) feedback, preparation phase of reassurance and coordinator, education, selection of measures | *Successful implementation of PROMs should be tailored by identifying and addressing potential barriers according to setting. Facilitators (a coordinator, taking into consideration the ongoing cognitive and emotional processes of each individual, educational component) could promote ownership and correct use of the measure by clinicians, potentially improving practice and the quality of care provided through PROM data use in clinical decision-making.* |
| **Berger et al. 2013** | To assess the impact that public reporting, which will be extended to the outpatient setting, has on patient outcomes and disparities | • Hospitals (n=16), nursing homes (n=5), emergency rooms (n=1), health plans (n=2), home health agencies (n=1) | • Effect of public reporting on patient outcomes, disparities, patient choice | • Only 1 study reported on public reporting of PREMs: mixed effect of PR on patient-reported satisfaction and other measures of patient experience | *The evidence of the impact of PR on patient outcomes is lacking, with limited evidence that PR has a favourable effect on outcomes in nursing homes. There is little evidence supporting claims that PR will have an impact on disparities or in the outpatient setting.* |
| **Boyce and** | To assess the impact of | • Feedback to physicians (n=14); | • Feedback from PROMs to healthcare | • **Group-level (=)**: NS<br>• **Patient-level (=/+)**: | *In conclusion, the use of PROMs as a quality improvement tool is a* |

| Study | Research Question/objective | Population | Intervention | Results | Authors' conclusion |
|---|---|---|---|---|---|
| **Browne, 2013** | providing healthcare professionals with feedback (patient and group level) on patient-reported outcome measures (PROMs) | other including psychologists, nurses and social workers (n=3)<br>• Mental health (n=7); functional status (n=5); rheumatoid arthritis; oncology; general health; asthma; liver disease | professionals at Patient-level (management tool: n=10; screening tool: n=5; mixed: n=1)<br>• Feedback from PROMs to healthcare professionals at group-level (n=1) | 1 study with overall significant effect (mgt tool)<br>6 studies (mgt tool:n=5) with at least one result favouring the intervention for a subgroup (n=2) or specific domain (n=6)<br>• **Setting:**<br>Most of studies with favouring results concern the outpatient setting (n=6) for a specialised patient population while only 1 out of 8 studies in primary care found favouring results<br>• No clear pattern in **type of PROM** | *highly versatile and complex intervention. The effectiveness of PROMs feedback seems to be related to the function of the PROM. However, the evidence regarding the impact of PROMs feedback on patient outcomes is weak, and methodological issues with studies are frequent. The use of PROMs as a performance measure is not well investigated.* |
| **Boyce et al. 2014** | To synthesise qualitative studies that investigated the experience of healthcare professionals with using information from PROMs to improve the quality of care; to synthesise the findings about the barriers and facilitators to their use | • Primary care (n=5); hospital care (n=4); hospice care (n=2); mixed settings (n=4); unclear setting (n=1)<br>• Physicians (n=4); nurses (n=2); therapists (n=1); mixture of HC professionals (n=8); unclear population (n=1)<br>• Mental health (n=7); palliative care (n=5); oncology (n=1); acute care (n=1); respiratory medicine (n=1); rheumatoid arthritis (n=1) | • Facilitators and barriers related to the implementation of PROMs in clinical setting | • **Practical considerations (around data collection process and the effective use of the information)**<br>**Barriers:** workload associated with collecting and analysing data; difficulty or ease of PROMs administration; questionnaire not user-friendly; lack of collaboration between colleagues; lack of clear guidelines on the data collection process (patient eligibility, timing, frequency and location of administration) and analysis and interpretation; lack of training on how to recruit patients, deal with difficult scenarios and effectively use the information; lack of statistical support for the analysis and interpretation of the data; support required from the wider service; use of technology when it slowed down the process<br>**Facilitators:** data collection facilitated when user-friendly questionnaires; flexibility needed in the data collection process due to variability in the acuity of patients; appreciation from the | *Professionals value PROMS when they are useful for the clinical decision-making process. Practical barriers to the routine use of PROMs: correct infrastructure not in place before data collection, use disruptive to normal work routines. Technology can play greater role in processing information. Attitudes to the use of PROMs may be improved by engaging professional in the planning stage of the intervention and by ensuring a high level of transparency around the rationale for data collection.* |

| Study | Research Question/objective | Population | Intervention | Results | Authors' conclusion |
|---|---|---|---|---|---|
| | | | | management for the additional work; involvement from the management in the process; appropriate training; time to become familiar with the measures prior to implementation; support during the initiation stage of data collection; use of technology for data collection and dissemination of the findings<br>• **Professionals' attitudes**<br>**Barriers**: no transparent objectives for data collection; professionals not open to receiving feedback or changing their clinical practice<br>**Facilitators**: /<br>• **Methodological considerations**<br>**Barriers:** need for more sophisticated feedback on a clinically important change; need for aggregated data about effectiveness of treatments to complement data about individual patients; compromised validity of measurement; sensitivity to accurately detect a change<br>**Facilitators:** interpretability of PROMs data; graphic presentation of the results<br>• **Impact on patient care:**<br>**Barriers:** clinical value questioned (no new information from the results); intrusive nature of collection on patient's privacy and doctor-patient interaction, capacity to narrow focus of consultation and opportunity cost; distressed patients; potential to damage patient-clinician relationship<br>**Facilitators:** improvement of care processes by improvement in | |

| Study | Research Question/objective | Population | Intervention | Results | Authors' conclusion |
|---|---|---|---|---|---|
| | | | | communication, patient education, joint decision-making, screening for health issues, monitoring changes and stimulating better care planning; complement to their own clinical judgement and to stimulate professional development; research and audit tool; ability to build patient confidence in the competences of the professional, to manage patient expectations and to assist in handing responsibility back to the patient. | |
| **Chen et al. 2013** | What are the impacts of PROMS (cancer patients) with regards to:<br>Provider behaviour;<br>Organisational changes for improving processes and models of care;<br>clinical outcomes; and<br>patient experience of are (e.g. self-care).<br>What mechanisms are involved in the | Adult cancer patients in outpatient, inpatient and outreach settings | Composite PROMs that are routinely collected | **Patient-provider communication (+)**<br>21/23 studies report positive findings (including RCT). 1 study – (ceiling effect); 1 study = (low cancer severity)<br>**Monitoring treatment response (+)**<br>Increased monitoring in 11/11 studies especially for patient symptoms, side effects and toxicity.<br>**Detecting (+)**<br>15/16 studies report positive findings. 1 RCT (=)<br>**Patient behaviour**<br>No studies<br>**Patient management (+/=)**<br>13 studies (+); 4 studies (=)<br>**Patient satisfaction (+)**<br>13 studies (+); 3 studies (=): ceiling effect?<br>**Health outcomes(+/=)** | *There is growing evidence supporting the routine collection of PRO to enable better and patient-centred care, especially in cancer settings. Despite the strong evidence in supporting the notion that the well-implemented routine collection of PROs enhances patient-provider communication and improves patient satisfaction, and growing evidence supporting ideas that it also improves the monitoring of treatment response and the detection of the unrecognised problems, the evidence-base was weak for its impact on changes to patient management*<br>*and improved health outcomes and non-existent for changes to patient health behaviour, strong and effectivequality improvement, increased transparency,* |

| Study | Research Question/objective | Population | Intervention | Results | Authors' conclusion |
|---|---|---|---|---|---|
| | link between PROs and the impacts identified?<br>What factors moderate the extent of the impacts identified? | | | 13 studies (+), especially symptoms, side effects and toxity are improved, followed by emotional well being; 2 studies (=)<br>**System performance and quality improvement**<br>No studies<br>**Moderating factors**<br>Sufficient intensity of feedback (multiple times over a sustained period of time), targeting multiple stakeholders (doctors, nurses, allied health workers, as well as patients) with simple, clear, graphical and longitudinal meaningful interpretation of the results, and providing sufficient training for both health professionals and patients. (+)<br>Complex issues (e.g. depression ) routine screening and feedback may need to be integrated with other strategies (e.g. decision-making aids, education, clear management plans and clinical pathways) (+/=)<br>More pronounced effect amongst subgroups with more severe problems at baseline (+/=) | *accountability, public reporting and better healthcare system performance.* |
| **Etkind et al. 2015** | The aim was to systematically review evidence on capture and feedback of PCOMs (patient-centered outcomes) in palliative care populations and determine the effects on | Palliative care setting | Routine use of PCOMs (patient-centered outcomes): capture and feedback | **Process and outcomes of care**<br>Increased reporting/recognition of symptoms (+); greater congruence between patient and professional HRQOL scores (+); larger number of actions taken based on HRQOL data (+); improved psychological and emotional HRQOL for patients (+/=) and carers (+/=) but found no improvement in symptom burden (+/=), and no change in overall HRQOL (=)<br>**Acceptability** | *We have presented evidence that implementation of PCOMs in palliative care improves processes of care and psychological and emotional HRQOL. To date, the evidence for impact on psychological outcomes is only moderate, but it does indicate that PCOMs data capture and feedback can positively impact patients' health status. However, there is evidence that PCOMs feedback* |

| Study | Research Question/objective | Population | Intervention | Results | Authors' conclusion |
|---|---|---|---|---|---|
| | processes and outcomes of care | | | patients found the intervention ''helpful in discussing important issues/telling professionals how they were feeling'' and ''would use PCOMs feedback as part of standard care''(+)<br>Acceptability to professionals with mixed results (±) | *does not appear to improve overall HRQOL in palliative care. The evidence for these conclusions predominantly stems from oncology settings. To aid implementation projects, future work should investigate other disease areas and particularly other settings of care relevant to palliative care patients.* |
| **Gillam et al. 2012** | To assess the impact of the Quality and Outcomes Framework on the quality of primary medical care | Primary medical care | Pay-for-performance scheme | | *Observed improvements in quality of care for chronic diseases in the framework were modest, and the impact on costs, professional behaviour and patient experience remains uncertain.* |
| **Gleeson et al. 2016** | Explore how patient-reported experience measures (PREMs) are collected, communicated and used to inform quality improvement across healthcare settings | A full range of patients populations from children through to the elderly and staff (from healthcare practitioners to senior managers)<br>General practice (n=3) and (n=6) acute or chronic care hospital settings | Use of PREMs to inform quality improvement + facilitators and barriers | **5 studies reported facilitators and/or barriers**<br>• **Data collection**<br>**Barriers:** lack of understanding and expertise; poor specificity of results; timing of feedback<br>**Lessons learned:** need for staff training in data analysis and statistics to facilitate full understanding and use of results<br>• **Organisation**<br>**Barriers:** lack of time or resources to collect, analyse or act on data; competing priorities; an organisational culture or staff resistance to QI improvement initiatives; lack of engagement or support for change from management | *Findings suggest there is no single best way to collect or use PREM data for QI, but they do suggest some key points to consider when planning such an approach. For instance, formal training is recommended, as a lack of expertise in QI and confidence in interpreting patient experience data effectively may continue to be a barrier to a successful shift towards a more patient-centred healthcare service.* |

| Study | Research Question/objective | Population | Intervention | Results | Authors' conclusion |
|---|---|---|---|---|---|
| | | | | **Facilitators:** working in a culture supportive of improvement, change and patient views; management support and encouragement; allowing dedicated time for staff to discuss results and plan improvements; evidence-based co-design for patient involvement; ward-specific survey to facilitate sense of ownership over improvement actions; using national publicly reported survey as an incentive to use PREM results<br>• **areas for improvement**<br>**Most popular:** changes to processes for admissions or waiting times; producing educational materials for patients<br>**Least popular**: upgrading infrastructure; changing clinician behaviour | |
| **Greenhalgh et al. 2017** | To identify the ideas and assumptions underlying how individual and aggregated PROMs data are intended to improve patient care; to review the evidence to examine the circumstances in which and processes through which PROMs feedback | Mix of populations and care settings | • Feedback of aggregate PROMs and performance data (feedback and public reporting of PROMs, patient experience data and performance data to hospital providers and primary care organisations)<br>• Feedback of individual PROMs data (feedback of PROMMs in oncology, palliative care and the care of people with mental health problems in primary and secondary care settings) | **Aggregate PROMs and performance data** | *PROMs data act as 'tin openers' rather than 'dials'. Providers need more support and guidance on how to collect their own internal data, how to rule out alternative explanations for their outlier status and how to explore the possible causes of their outlier status. There is also tension between PROMs as a QI strategy versus their use in the care of the individual patients; PROMs that clinicians find useful in assessing patients, such as individualised measures, are not useful as indicators of service quality.* |

| Study | Research Question/objective | Population | Intervention | Results | Authors' conclusion |
|---|---|---|---|---|---|
| | improves patient care | | • Design of review: realist synthesis | | |
| **Groen et al. 2015** | To define the conceptual components of patient empowerment of chronic disease patient (cancer survivors) and to explore the contribution of existing and new IT services to promote empowerment | Cancer survivors | IT services (electronic PRO services) | **Attributes of empowerment**<br>**Positive contribution of ePRO services (+)**: the opportunity to identify personally relevant issues and health goals; providing knowledge of personal symptoms and physical and psychosocial functioning by providing graphic overview of symptom and QoL scores; identification of personal needs and psychosocial problems by providing graphic overview of symptoms and QoL scores, with or without reference values; when ePROs are fed back to patients with coaching statements, it may improve the effectiveness of the encounters with health professionals | *IT services may especially contribute to empowerment by providing knowledge. The components of empowerment could be used to develop IT services for cancer survivors.* |
| **Holmes et al. 2016** | The review aimed to identify all relevant evidence and examine any emerging concepts from published findings as a first investigation of the potential impact(s) of implementing ROMs in routine clinical practice on the process and outcome of healthcare for | Patients with non-malignant pain | Five constructs:<br>• Assessment of patient;<br>• Decision making;<br>• Therapeutic relationship;<br>• Tracking process and evaluating and changing treatment;<br>• Potential implications for outcomes; | **Assessment (=)**:<br>Inconclusive, qualitative research raises concerns about validity of PROMs and its subjective nature (e.g. patient capable to assess pain?). (Qualitative)<br>**Decision making (+/Q)**<br>Contributes to decision making process especially for choosing a treatment, develop an individualised treatment plan and set goals. No quantitative results available.<br>**Therapeutic relationship (+/Q)**<br>Improves patient-physician interaction and patient involvement (Qualitative).<br>**Evaluating and changing R/ (=/+)**<br>Unclear impact. Conflicting opinions (Qualitative) and mixed findings on referral | *Due to the poor quality, lack of generalisability and heterogeneity of these studies, it is not possible to provide a comprehensive understanding of how PROMs may impact clinical treatment of non-malignant pain. The literature suggests that PROMs enable pain assessment, decision-making, the therapeutic relationship, evaluation of treatment and may influence outcomes. Further research is needed to provide better evidence as to whether PROMs do indeed have any effects on these domains.* |

| Study | Research Question/objective | Population | Intervention | Results | Authors' conclusion |
|---|---|---|---|---|---|
| | non-malignant pain. | | | patterns and medication prescriptions (Quantitative).<br>**Potential implications for outcomes (=/+)**<br>Inconclusive quantitative results<br>• Significant impact on pain levels in one RCT but not in another (although some effect was shown on pain related to strenuous activity)<br>• No significant impact on patient satisfaction and health status. | |
| **Howell et al. 2015** | What is the impact of the routine use of PROMs on outcomes at the patient, provider, and system levels. What are the barriers and enablers influencing clinical uptake of PROMs in routine care | Cancer patients or cancer survivors | • Routine use of PROMs in clinical practice | **Patient-level**<br>• Patient satisfaction (=): Positive effect (SR) but not always significant (2 RCT). Ceiling effect with high satisfaction levels in I and C group;<br>• Perceived QoC (=/+): unclear;<br>• Well-being (= or +): some favouring results, but mostly null findings;<br>• Symptom management (+): indications for increased self-management and improved clinician's attention to symptom severity;<br>• Acceptability (+) by patients is high.<br>**Provider/clinical practice**<br>• Patient-clinician communication (+): positive effect with more discussion of symptoms, emotional well-being etc.<br>• Early detection and symptom monitoring (): positive effect on monitoring and detecting otherwise unreported symptoms;<br>• Clinical decision making (+): indications for changes in referral patterns (e.g. to psychologist in case of emotional | *PROMs use in routine cancer clinical practice is growing with improvements on essential care processes shown but a number of implementation barriers must still be addressed. The lack of standardization in PROMs used in cancer organizations may make it difficult to use these data for quality monitoring in the future.* |

| Study | Research Question/objective | Population | Intervention | Results | Authors' conclusion |
|---|---|---|---|---|---|
| | | | | distress) and medication prescriptions (e.g. analgesia) but not confirmed in an RCT;<br>• No impact (=) on length of consultation.<br>**Enablers and barriers**<br>Barriers: time constraints (e.g. not enough time to address issues that arise from PROMs); lack of training; liability issues (e.g. PROMs reported by patients electronically between visits); perception that PROMs may be 'intrusive' in the clinical setting.<br>Enablers for clinicians: integration with clinical practice guidelines; automatic 'flagging' of clinically important scores; incorporating the service-user perspective into development; longitudinal interpretation of what signifies a clinically important difference.<br>For patients: length and complexity of the scale; translated and culturally meaningful version; ensuring that the PROM addresses issues relevant to patients and cancer type, stage, and phase of the cancer journey; patient comfort level with technology; the degree of disability; disease-specific questions and simplifying scales (e.g. scale with verbal descriptors) | |
| **Kendrick et al. 2016** | | People with common mental health disorders | • Feedback of PROM scores to clinician, or both clinician and patient (intervention)<br>• No feedback of PROM scores but coding is possible (comparator) | **Mean improvement in symptom scores (=)**<br>9 studies - Outcome Questionnaire-45 (OQ-45): no evidence of a difference (mean difference (MD) -1.14, 95%CI -3.15 to 0.86)<br>3 studies - Outcome Rating Scale (ORS): no evidence of a difference (standardised mean difference (SMD) -0.07 95% CI- 0.16 to 0.01) | *We found insufficient evidence to support the use of routine outcome monitoring using PROMs in the treatment of common mental health disorders (CMHDs), in terms of improving patient outcomes or in improving management. The findings are subject to considerable uncertainty however, due to the high* |

| Study | Research Question/objective | Population | Intervention | Results | Authors' conclusion |
|---|---|---|---|---|---|
| | | | | Other outcome measures: mixed results in 4 studies.<br>**Health- related quality of Life (=)**<br>No significant results (2 studies)<br>**Adverse events (=)**<br>No immediate suicide risk (1 study)<br>**Social functioning (=)**<br>No significant results (1 study)<br>**Changes in the management of CMHDs (+/=)**<br>No significant differences in changes in drug therapy (2 studies)<br>Mental health referrals significantly more likely in the feedback group (OR 1.73, 95% CI 1.11 to 2.70) | *risk of bias in the large majority of trials meeting the inclusion criteria, which means further research is very likely to have an important impact on the estimate of effect and is likely to change the estimate. More research of better quality is therefore required particularly in primary care where most CMHDs are treated. Future research should address issues of blinding of assessors and attrition, and measure a range of relevant symptom outcomes, as well as possible harmful effects of monitoring, health-related quality of life, social functioning, and costs. Studies should include people treated with drugs as well as psychological therapies, and should follow them up for longer than six months.* |
| **Kotronulas et al. 2014** | This review examined whether inclusion of PROM in routine clinical practice is associated with improvements in patient outcomes, processes of care, and health | Adult (>18y) patients with active anticancer treatment | • Routine use of PROMs in cancer care | **Physical symptoms (+/=)**<br>Reduced symptom prevalence and severity in 7 CT (of which 6 RCT): mainly clinically sometimes statistically significant.<br>**Quality of life (±)**<br>NS findings in 9 RCTs and conflicting evidence in 3 other studies.<br>**Psychological symptoms (=)**<br>No changes reported<br>**Supportive care needs (±)**<br>Tackling patient needs (mixed findings) | *The use of PROMs in clinical practice seems to be most effective in increasing patient satisfaction with communication about emotional concerns. Discussion of POs during consultations may increase and, in some studies, is associated with improved symptom control, increased supportive care measures, and patient satisfaction. Additional patient-related outcomes could be usefully addressed in future trials, including perceived* |

| Study | Research Question/objective | Population | Intervention | Results | Authors' conclusion |
|---|---|---|---|---|---|
| | service outcomes during active anticancer treatment. | | | **Medical decisions made/advice given/changes in treatment/referrals made (+/=)**<br>Referrals to psychosocial clear (initial effect but not at follow up), effect for analgesia prescriptions in case of pain, effect for diagnostics and therapeutics services for emotional and social concerns.<br>**Patient outcomes discussed during consultation (+)**<br>Patient outcomes such as emotional problems, social and sexual functioning are discussed more often.<br>**Acceptability by health professionals (HP) (+)**<br>**Moderate to high** (e.g. identify issues of concern and to guide discussions with patients)<br>**Patient satisfaction with intervention (+)**<br>High satisfaction with intervention<br>**Awareness of patient outcomes HP (+/=)**<br>Nill finding or effect (e.g. ADL, QoL, pain)<br>**Timing of referrals (+)**<br>Earlier refferals found in 1 RCT and 1 controlled trial<br>**Health services outcomes (=)**<br>**No difference (**one exception: group of breast cancer patients**)** | *self-care self-efficacy, social activity, work limitations, or survival. Patients and healthcare professionals are willing to engage in the routine use of PROMs during anticancer treatment. However, it is paramount that PROM intervention implementation is effective and incorporates strategies that increase patient adherence to the actual use of PROMs and HP engagement in the active incorporation of PROM feedback during encounters with patients.* |
| **Nama et al. 2013** | To evaluate the effectiveness of PROMs as an alternative to routine follow-up | Women after treatment for gynaecological cancers | • PROMs or QOL questionnaires versus traditional follow-up with multiple visits to the hospital | **All identified references excluded** | *We found no evidence to make an informed decision about PROMS for follow-up after gynaecological cancer. Ideally RCTs which are multicentre or multinational or both,* |

| Study | Research Question/objective | Population | Intervention | Results | Authors' conclusion |
|---|---|---|---|---|---|
| | to identify recurrences, affect overall survival and assess psychological benefit | | | | *or well-designed non-randomised studies are needed that use multivariable analysis to adjust for baseline imbalances, to compare follow-up strategies and improve current knowledge.* |
| **Yang et al. 2018** | To identify mechanisms through which PROs facilitate patient-clinician communication in the adult oncology population | Adult oncology population | • Use of PROs | **Usefulness of PROs in facilitating communication**<br>• In 37 of 43 studies increase in communication following PRO implementation: discussion of symptoms in general, discussion of patient care, treatment plans, emotional function, discussion of health-related quality of life issues<br>• More heterogonous results on improvements in discussions on daily function, psychosocial problems, patient pain, fatigue<br>**Mechanisms**<br>Increases symptom awareness; prompts discussion, streamlines consultation; facilitates inter-professional communication<br>**Patient health outcomes**<br>Contradictory results on patient management<br>**Facilitators and barriers**<br>**Barriers** : technical problems with administration and completion of questionnaires, patients being too ill to comply with instructions, patients not believing PROs to be personally useful, difficulty quantifying care experience using PROs, lack of reminders to complete questionnaire, limited | *Our review suggest that PROs facilitate patient-clinician communication through various mechanisms that could perhaps contribute to improvements in symptom management and survival. The impact of PROs on clinical outcomes, however, remains poorly studied.* |

| Study | Research Question/objective | Population | Intervention | Results | Authors' conclusion |
|---|---|---|---|---|---|
| | | | | reimbursement and incentives for clinicians, PROs not directly assessing relevant health issues, patients and physicians finding PRO use to be inconvenient and too time-consuming<br>**Facilitators**: increased education of the clinician and the patient, taking into account the patient preferences, organisational issues (less than 20 questions, 10 min in length, electronic device, administered in clinic, private and comfortable space to complete questionnaires, questionnaires tailored to them and to cancer type, presentation issues (summaries, visual representations of PRO data), explicit identification of symptom thresholds and provision of concrete management guidelines | |

*+ (signifies a positive finding); = (signifies no statistically significant findings)); =/+ (signifies mixed results with positive and null findings); ± (signifies mixed results with positive and negative findings); - (signifies a negative finding); /Q (only based on qualitative studies).*

# APPENDIX 2. SEARCH STRATEGIES FOR THE THREE COUNTRIES

Search strings used for Google-searches on December 1st, 2016:

### France

**PROMs - English:**

Care PROM* OR "Patient Reported Outcome*" outcome* OR satisfaction patient OR patients OR client* implement* filetype:pdf OR filetype:doc OR filetype:docx OR filetype:ppt OR filetype:pptx site:.fr 2006..2016 -RCT* -trial* -local

**PROMs - French:**

Santé PROM* OR “Résultats rapportés par le* patient*” OR “Résultats déclarés par le* patient*” OR “Résultats rapportés par le client” OR “Résultats déclarés par le client” OR “Patient traceur*” satisfaction OR resultat* patient OR patients OR client* instauration OR implément* filetype:pdf OR filetype:doc OR filetype:docx OR filetype:ppt OR filetype:pptx site:.fr 2006..2016 -ERC* -RCT* -essai* -local -locale

**PREMs - English:**

Care AND (PREM* OR “patient reported experience*”) AND experience* AND (patient OR patients OR client*) implement* filetype:pdf OR filetype:doc OR filetype:docx OR filetype:ppt OR filetype:pptx site:.fr 2006..2016 -RCT* -trial* -local -outcome*

**PREMs - French:**

Santé PREM* OR “Expérience rapportée par le* patient*” OR “Patient traceur*” expérience* patient OR patients OR client* instauration OR implément* filetype:pdf OR filetype:doc OR filetype:docx OR filetype:ppt OR filetype:pptx site:.fr 2006..2016 -ERC -RCT* -essai* -local -locale -résultat*

## The Netherlands

**PROMs - English:**

Care PROM* OR “Patient Reported Outcome*” outcome* OR satisfaction patient OR patients OR client* implement* filetype:pdf OR filetype:doc OR filetype:docx OR filetype:ppt OR filetype:pptx site:.nl 2006..2016 -RCT* -trial* -local

**PROMs - Dutch:**

Zorg PROM* OR “Patient Reported Outcome*” OR “patiëntgerapporteerde uitkomsten” OR “cliëntgerapporteerde uitkomsten” uitkomst* OR tevredenheid patiënt OR patiënten OR cliënt* implement* filetype:pdf OR filetype:doc OR filetype:docx OR filetype:ppt OR filetype:pptx site:.nl 2006..2016 -RCT* -trial*

-lokaal -lokale

**PREMs - English:**

Care AND (PREM* OR “patient reported experience*”) AND experience* AND (patient OR patients OR client*) implement* filetype:pdf OR filetype:doc OR filetype:docx OR filetype:ppt OR filetype:pptx site:.nl 2006..2016 -RCT* -trial* -local -outcome*

**PREMs - Dutch:**

Zorg PREM* OR “patient reported experience*” ervaring* patiënt OR patiënten OR cliënt* implement* filetype:pdf OR filetype:doc OR filetype:docx OR filetype:ppt OR filetype:pptx site:.nl 2006..2016 -RCT* -trial* -lokaal -lokale -uitkomst*

## United Kingdom

**PROMs:**

Care PROM* OR “Patient Reported Outcome*” outcome* OR satisfaction patient OR patients OR client* implement* filetype:pdf OR filetype:doc OR filetype:docx OR filetype:ppt OR filetype:pptx site:.uk 2006..2016 -RCT* -trial* -local

**PREMs:**

Care AND (PREM* OR “patient reported experience*”) AND experience* AND (patient OR patients OR client*) implement* filetype:pdf OR filetype:doc OR filetype:docx OR filetype:ppt OR filetype:pptx site:.uk 2006..2016 -RCT* -trial* -local -outcome*

# APPENDIX 3. TARGETED WEBSITES (SEARCHED DECEMBER 2016- FEBRUARI 2017)

| Country and organizations | Websites (URL) |
|---|---|
| **United Kingdom** | |
| British Orthopedic Association | https://www.boa.ac.uk |
| British Spine Registry | http://www.britishspineregistry.com/ |
| Department of Health | https://www.gov.uk/government/organisations/department-of-health |
| Government | https://www.gov.uk/ |
| Government Web Archive | http://www.nationalarchives.gov.uk/webarchive/ |
| INVOLVE | http://www.invo.org.uk/ |
| King's Fund | https://www.kingsfund.org.uk/ |
| London School of Hygiene and Tropical Medicine | https://www.lshtm.ac.uk/ |
| My NHS | https://www.nhs.uk/service-search/performance/search |
| National Health Service (NHS) | http://www.nhs.uk/pages/home.aspx |
| National Health Service England | http://www.england.nhs.uk |
| NHS North of England Commercial Procurement Collaborative | https://www.noecpc.nhs.uk/ |
| National Institute for Health and Care Experience (NICE) | https://www.nice.org.uk/ |
| National Institute for Health Research (NIHR) & INVOLVE | http://www.nihr.ac.uk/ |
| National Joint Registry | http://www.njrcentre.org.uk/ |
| Picker Institute Europe | http://www.picker.org/ |
| Private Healthcare Information Network | https://www.phin.org.uk/ |
| PROMs 2.0 | http://proms2.org/ |
| Royal College of Surgeons | https://www.rcseng.ac.uk/ |
| The Health Foundation | http://www.health.org.uk/ |
| **Netherlands** | |
| Dutch Health Care Institute (Zorginstituut Nederland) | https://www.zorginstituutnederland.nl/ |
| Dutch Institute of Clinical Auditing (DICA) | https://www.dica.nl/ |
| Federatie van Medisch Specialisten | http://www.demedischspecialist.nl/ |

| | |
|---|---|
| Gezondheidsraad | https://www.gezondheidsraad.nl/ |
| IQ Healthcare - Radboud University Medical Centre & IQ PROM | http://www.iqhealthcare.nl & http://iqprom.nl |
| NIVEL | http://www.nivel.nl/nl/ |
| Nederlandse Federatie van Universitair Medische Centra (NFU) | http://www.nfu.nl/ |
| Nederlandse Vereniging van Ziekenhuizen (NVZ) | https://www.nvz-ziekenhuizen.nl/ |
| Patiëntenfederatie Nederland | https://www.patientenfederatie.nl/ |
| Rijksoverheid | https://www.rijksoverheid.nl/ |
| Santeon ziekenhuizen | http://www.santeon.nl/ |
| Stichting Miletus | http://stichtingmiletus.nl/ & https://www.patientervaringsmetingen.nl/ |
| Tilburg University (Research portal) | https://pure.uvt.nl/portal/ |
| University of Amsterdam | http://www.uva.nl/ |
| UvA-DARE (Digital Academic Repository) | http://dare.uva.nl/ |
| Erasmus University Rotterdam, RePub (Publications) | https://repub.eur.nl/ |
| Zorgverzekeraars Nederland (ZN) | https://www.zn.nl/ |
| **France** | |
| Comité d'Evaluation de Diffusion des Innovations Technologiques (CEDIT) | http://cedit.aphp.fr/ |
| COMPAQ-HPST | http://compaqhpst.fr/fr/ |
| French National Authority for Health (HAS) | http://www.has-sante.fr/portail/ |
| Hôtel Dieu University Hospital Paris | http://www.hotel-hospitel.fr/ |
| Institut national de la santé et de la recherche médicale (INSERM) | http://www.inserm.fr/ |
| UPMC University Paris (Department of Rheumatology) | http://upmc.fr/ |
| **International** | |
| European Observatory on Health Systems and Policies | http://www.euro.who.int/en/about-us/partners/observatory |
| EuroQoL Group | http://www.euroqol.org/ |
| International Consortium for Health Outcome Measurements (ICHOM) | http://www.ichom.org/ |
| Organisation for Economic Co-operation and Development (OECD) | https://www.oecd.org/ |
| World Health Organization (WHO ) | http://www.who.int/en/ |

# APPENDIX 4. EXPERTS (RESPONDENTS) CONSULTED FOR THE THREE COUNTRIES

**France**

- Prof. Etienne Minvielle, Titulaire de la Chaire de Management, Ecole des Hautes Etudes en Santé Publique (EHESP)
- Martine Bungener, économiste, sociologue, directrice de recherche émérite, CNRS − CERMES3
- Dr. Catherine Grenier, directrice de l'amélioration de la qualité et de la sécurité des soins, HAS
- Dr. Arnaud Fouchard, Adjoint au chef du service, Direction de l'amélioration de la qualité et la sécurité des soins, HAS

**The Netherlands**

- Drs. Barbara van Leiden-Vriens, Programma Kwaliteit, Zorgverzekeraars Nederland
- Dr. Philip van der Wees, Radboud University Medical Centre

**United Kingdom**

- Jenny King, Associate Director Research, Picker Institute Europe
- Dr. Angela Coulter, Senior Research Scientist, Health Services Research Unit, Nuffield Department of Population Health, University of Oxford
- Prof. Nick Black, Dept. of Health Services Research and Policy, London School of Hygiene and Tropical Medicine

# APPENDIX 5. DATA EXTRACTION TEMPLATE

| Variable | Description | Picklist |
|---|---|---|
| **Country** | France (FR), Netherlands (NL), United Kingdom (UK) | FR<br>NL<br>UK |
| **Source** | Source of document | Google search<br>Targeted websites<br>Snowballing<br>Experts |
| **Date** | Search date | Date (YY-MM-DD) |
| **Author** | First author of document or name of publishing organization | Author (last name) or name of organization |
| **Year** | Publication year | Year |
| **Title** | Title of document | Title |
| **Type** | Type of document | Report/ study findings<br>Presentation<br>Statement/ opinion<br>Standard, protocol or guideline<br>Study protocol<br>Other |
| **URL Document** | Hyperlink of document | Hyperlink (www) |
| **Language** | Language of document text ( | Dutch<br>English<br>French |
| **Organization** | Type of organization(s) that published the document | Government<br>Health agency<br>Health insurance company<br>Professional organization<br>Patient organization<br>Special interest group |

| | | |
|---|---|---|
| | | Research institute<br>University<br>Collaboration<br>Other |
| **URL Organization** | Website of organization | URL (www) |
| **Experts** | Country experts, experts who contributed to the document | Names, titles, affiliations and e-mail addresses |
| **Subject of document** | Content of document | Study/research<br>Implementation<br>Policy<br>Etc. |
| **Type of information** | Type of data reported in the document | Quantitative<br>Qualitative<br>Mixed mode<br>Other |
| **PREM/PROM** | PREM, PROM or both | PREM<br>PROM<br>Both |
| **Name PREM/PROM** | Name of PREM/PROM | Name |
| **Type of PREM/PROM** | Type of PREM/PROM | Generic<br>Disease specific<br>Both |
| **Type of disease specific** | Type of disease specific PREM/PROM | Reumatology<br>Low Back Pain<br>Other |
| **Description of PREM/PROM** | Description of instrument | Describe the instruments as defined in the document |
| **Setting** | Health care sector or type of care providers that apply/use the PREM/PROM | Primary care<br>Hospitals<br>Rehabilitation centers<br>Nursing homes<br>Home care<br>Social services |

| | | |
|---|---|---|
| | | Allied health care<br>Other |
| **Scale** | Scale of implementation | National<br>Regional<br>Local<br>Selection of care providers<br>Mixed<br>Other |
| **Aim** | Objectives and scope | Clinical practice (communication, shared decision making, disease management)<br>Quality improvement<br>Benchmarking<br>Public reporting/ transparancy<br>Patient choice<br>Governance/ accountability<br>Reimbursement<br>Etc. |
| **Stakeholders** | Organizations involved (name, type, profit / non-profit, etc.) | Describe the organizations involved in implementing the PREM/PROM, as defined in the document |
| **Specialism** | Medical specialism (if applicable) | General practice<br>Orthopedic surgery<br>Rheumatology<br>Eye care<br>Dermatology<br>etc. |
| **Population** | Target population(s), type of patients, in-/exclusion criteria and patient/ client characteristics (disease/ disorder or functional impairment; mean age, gender distribution, etc.) | Describe the population as defined in the document |
| **Type of patients** | | General healthy<br>General diseased<br>Low Back Pain |

| | | |
|---|---|---|
| | | Reumatoid arthritis<br>Specific diseased other |
| **Method** | Method of data collection: design (longitudinal/cross-sectional), qualitative or quantitative, sampling (consecutive/all or random, selection criteria), timing and number of measurements (pre-and post-) etc. | Describe method as defined in the document |
| **Period** | Implementation/ evaluation period (data collection/ measurements) | Describe the period(s) as defined in the document |
| **Participation and response** | Number of organizations and participants involved, response percentage | Number of organizations and patients/clients, response % |
| **Implementation** | Findings regarding implementation (level/phase etc.) | Describe overall findings regarding implementation as defined in the document |
| **Facilitators** | Findings regarding facilitating factors | Facilitators as defined in the document |
| **Barriers** | Findings regarding impeding factors | Facilitators as defined in the document |
| **Type of effect** | Effects of using PREM/PROM as described in the document | Clinical practice<br>Disease management<br>Quality improvement<br>Policy<br>Governance<br>Reimbursement<br>Accreditation<br>Legislation<br>Competition<br>Etc. |
| **Practice effects** | Reported effects on clinical practice and quality improvement | Describe effects on practice as defined in the document |
| **Policy effects** | Reported effects on healthcare policy, legislation, accreditation, stakeholder involvement, reimbursement, market competition etc. | Describe policy effects as defined in the document |
| **Public reporting** | Public reporting of PREM/PROM measurements: communicator systems (e.g. website or report) and audience/ users (e.g. patients, physicians, organizations, health insurance agencies, regulators, government, etc.) | Describe the mode and audience of public reporting as defined in the document |
| **Financing** | Financial issues regarding measurements with PREM/PROM (reimbursement of measurements, payment for results, financial incentives, etc.) | Describe financing as defined in the document |
| **Legislation** | Legislation relating to the measurement of PREM/PROM | Describe relevant legislation, as defined in the document |

| | | |
|---|---|---|
| **Recommendations** | Recommendations regarding implementation of PREM/PROM | Describe recommendations as defined in the document |
| **Conclusions** | Added value, limitations, recommendations, policy implications, etc. | Describe conclusions as defined in the document |
| **Lessons learned** | Summary of lessons learned | Describe lessons learned as defined in the document |
| **Remarks** | Any other remarks (i.e. comments of author or researcher) | |

# APPENDIX 6. SURVEY PROGRAMMES AND INSTRUMENTS (PROMS/PREMS) IN THE UK

| Programmes and instruments | Start | Aim | Description | PROMs / PREMs |
|---|---|---|---|---|
| **NHS National patient experience survey programme**<br>**Surveys/questionnaires:**<br>**GP patient survey**<br>**Inpatient survey**<br>**Outpatient survey**<br>**A&E survey (Accident & Emergency services)**<br>**Children and young patients survey**<br>**Community Mental health survey**<br>**Maternity survey**<br>**Cancer survey** | 2001/2002 onwards<br>(integrated into the NHS Outcomes Framework in 2011) | Improve quality of services, reduce variations between trusts, benchmarking, quality monitoring, commissioning (pay-for-performance), regulation/ inspection and national monitoring. | Systematic collection of patient feedback across a wide range of NHS services.<br>The survey questions are cover five 'domains' or aspects of care:<br>• access and waiting<br>• safe, high-quality co-ordinated care<br>• better information, more choice<br>• building better relationships<br>• clean, comfortable and friendly place to be.<br>Together with an 'overall patient experience score' (originally used as a Public Service Agreement indicator of departmental performance against nationally set goals). | PREMs<br>(later also PROMs, e.g. EORTC in Cancer survey, 2011) |
| **National PROMs programme**[4, 148]<br>**Generic PROM:**<br>**EQ-5D-3L™**<br>**Condition-specific PROMs:**<br>**(not for groin hernia):**<br>**Oxford Hip Score (OHS)**<br>**Oxford Knee Score (OKS)**<br>**Aberdeen Varicose Vein Questionnaire** | 2009-2012<br>(integrated into the NHS Outcomes Framework in 2011) | Routine collection of national PROMs data among patients undergoing elective interventions, in order to monitor performance, understand and investigate variation, and inform commissioning decisions and conversations with provider trusts. | Four surgical procedures were chosen to be included in the national PROMs programme, mandated in the NHS Outcomes Framework (2011 onwards):<br>- Total hip replacement<br>- Total knee replacement<br>- Varicose veins surgery<br>- Groin hernia surgery | PROMs |
| **NHS Patient Experience Framework**<br>**(see https://www.gov.uk/government/news/a-framework-for-nhs-patient-experience)**<br>**Patient Experience Questionnaire:**<br>**A short, 19-item core questionnaire on the experiences of patients with NHS health care services.**[162] | 2011 onwards | To guide the measurement of patient experience across the NHS, outlining elements which are critical to the patients' experience of NHS Services. | Reflecting 8 domains, based on the Picker Institute's Principles of Patient-Centred Care:<br>• Respect for patient-centred values, preferences and expressed needs<br>• Coordination and integration of care<br>• Information, communication, education<br>• Physical comfort<br>• Emotional support | PREM |

| | | | | |
|---|---|---|---|---|
| | | | • Welcoming the involvement of family and friends<br>• Transition and continuity<br>• Access to care | |
| **Friends and Family Test** | 2013 | Voluntary feedback tool for online, real-time comments on NHS services, also providing a summative score (overall rating). | Comments on hospital services and a summative score (5-point rating). | PREM |