Report

Data collection systems integrating PROMs and PREMs to support value-based decision-making

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This report was written by external researchers for the Health and Welfare Commissioner (CSBE). It aims to support the CSBE's efforts in assessing the performance of the health and social services system. The content and viewpoints expressed in this report are the sole responsibility of the authors. They do not represent the positions of the CSBE.

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Message from the Health and Welfare Commissioner, Joanne Castonguay

I have read this report on patient-reported outcomes measures and patient-reported experience measures (PROMs and PREMs) produced by Professor Marie-Eve Poitras, in collaboration with the Health and Welfare Commissioner (CSBE) with great interest. The report was developed within the PaRIS project of the Organisation for Economic Co-operation and Development (OECD), which aims to fill data gaps on healthcare system outcomes by asking patients themselves about the impact of the care received on their quality of life and well-being. The goal is to go beyond traditionally available data on resources and processes and focus on patient-reported data. Specifically, the CSBE contributed to the research funds for the Quebec component of the PaRIS project to enable Professor Poitras and her team to create an infrastructure to continuously collect and analyze data reported by Quebec patients in primary care.

This PROMs and PREMs development project is an excellent opportunity for the CSBE to obtain comparative data on the results of primary care from the patients' perspective. PROMs and PREMs place the users at the center of the process, seeking to optimize results that matter to them. This focus aligns with the CSBE's evaluation framework based on value for patients. This project also focuses on the adoption of standards by different jurisdictions to facilitate the comparison of results at the national and international levels. The results show that few jurisdictions have adopted such standards. To facilitate initiatives in this regard, this report describes the steps to be taken to adopt standards for comparable results, as well as the success factors for a successful implementation, in accessible language. For example, it seems that the leadership of clinical teams and central decision-makers are factors contributing to the success of the adoption processes of these standards.

Therefore, we invite Quebec decision-makers to take note of this report to provide direction to the actors in the health and social services system to integrate data, based on results that matter to patients in decision-making at the micro, meso, and macro levels.

Context of this report

As countries revamp their healthcare systems to make them more value-based, changes must be based on scientific evidence. Health outcomes and care experience reported by patients (PROMs and PREMs) are essential for identifying opportunities to improve the healthcare system. Since 2017, Canada, including the province of Quebec, has been participating in the OECD's Patient-Reported Indicator Survey (PaRIS) for patients with chronic conditions to address this gap. The objectives of PaRIS-OECD are 1) to systematically collect data on patients' experiences and health outcomes and 2) to present internationally comparable self-reported indicators on the experiences of care and perceived health of patients with chronic conditions following a consultation in primary care.

With a desire to share the PaRIS-Canada survey data for ultimate use in supporting clinical, organizational, or policy decision-making, the PaRIS-Quebec team, led among others by Professor Marie-Eve Poitras, presented the Quebec and Canadian initiative to the Office of the Health and Welfare Commissioner in the context of a presentation to various Quebec knowledge users. It is in this context that a series of exchanges happened between Professor Poitras' team and the team of the Health and Welfare Commissioner. From these exchanges emerged the following question: What are the main international initiatives for data collection systems integrating PROMs and PREMs and used by governments to support value-based decision-making?

Summary

Patient-reported data[1] inform about their perception of their health status (patient-reported outcomes - PROs) and their care experience (patient-reported experience - PREs). These indicators allow for the evaluation and improvement of the quality of care. Currently, their use by healthcare organizations is in emergence internationally. This emergence is explained by the interest in transitioning towards a value-based healthcare (VBHC) system. Establishing a data collection system that integrates patient-reported data promotes VBHC. The objective of this report is to describe existing data collection systems that integrate patient-reported data to support a transformation towards VBHC systems.

We conducted an environmental scan including interviews with international key informants and a scoping review guided by the methodology of the Joanna Briggs Institute. The results of both data sources were analyzed deductively and inductively using the conceptual frameworks of the Canadian Institute for Health Information and of Franklin et al. (2017). The analysis was conducted by two independent researchers. Themes found within both data sources were merged and synthesized. The themes informed the development of strategic insights and tactical considerations for the implementation of data collection systems integrating PROMs and PREMs to support value-based decision-making.

Twelve articles were included in the scoping review. Six interviews with eight key informants from six different countries were conducted. We found that the implementation of such systems in alignment with value-based systems disrupts current thinking patterns regarding data collection and use. Prior to their implementation, it is pertinent to adapt the systems to national and regional contexts in terms of governance, regulation, data security, and consent. It is also preferable to target segments of the population of interest rather than focusing on specific sectors of healthcare and social services (specialty, service, unit, hospital). During implementation, it is important to involve patients' representatives from the beginning and to implement strategies to support the engagement of all individuals involved in data collection. Support for data use and the implementation of a structured evaluative process in partnership with research communities are necessary. Finally, the process of using PROMs and PREMs results for value-based decision-making by governmental institutions is not yet precisely described. However, these systems already allow for practical changes in the field that may be proven beneficial for the quality of care and the performance of healthcare systems in the medium and long term.

[1] We use the terms "patients" to facilitate reading and support the concepts of PROMs and PREMs, but these terms here include all individuals who use healthcare and social services (patients, citizens, users).

Strategic insights

1. Implementing a system for collecting PROMs and PREMs in alignment with VBHC brings about a significant paradigm shift and disrupts current thought patterns regarding data collection and use at micro, meso, and macro levels.

2. Combining a bottom-up and top-down approach is necessary to achieve a homogeneous and balanced systematization of data collection.

3. Data collection systems that integrate PROMs and PREMs are an emerging innovation and its integration into the value-based decision-making process is still maturing.

Tactical considerations prior to implementation

1. Anticipate regulatory, confidentiality, data security, patient consent issues and needs.

2. Adapt to existing national or regional contexts regarding data collection systems governance.

3. Create a provincial framework to structure the implementation of local initiatives.

4. Prioritize a population segment-based rather than a sector-based (specialty, service, unit, hospital) data collection system.

Tactical considerations for implementation

1. Include patient representatives from the beginning of the initiative to achieve changes with and for the patients.

2. Select relevant PROMs and PREMs for all data users at micro, meso, and macro levels.

3. Support the engagement of all key stakeholders in the routine collection of data.

Tactical considerations to support the use and evaluation

1. Support the use of PROMs and PREMs at different levels (micro, meso, macro).

2. Establish a structured, objective, and independent evaluation process in partnership with research communities.

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Report

Introduction

For several decades, the performance of the healthcare system has been an important organizational challenge for governmental institutions. Currently, the healthcare system of Quebec is founded on a volume-based system which ultimately aims at reducing costs and mainly, fee-for-service payment models. This approach, although it optimizes the relationship between the quantity of services provided and the costs paid, is opposed to a value-based healthcare (VBHC) system which advocates the creation of value for the people treated and supports quality in the offer of services. The VBHC model represents an important innovation in healthcare systems (Porter & Teisberg, 2006). It helps reduce overall healthcare spending and ensures continuous quality improvement (Porter, M, 2017). This healthcare model is organized around patient needs and aims to improve outcomes that matter to them while optimizing the use of resources.

In Quebec, it is increasingly being argued that the migration of healthcare system governance from a volume-based approach to a value-based approach would enable the most cost-effective delivery of quality of care (Echevin, 2021). However, the performance indicators for this approach must be consistent with the measurement of value sought. One of the first steps in setting up such a system is the measurement of health outcomes on what matters to patients (Kaplan & Porter, 2011; Porter, M, 2017).

Patient-reported measures of health outcomes and experience of care, which will subsequently be referred to as Patient-Reported Outcomes (PROs) and Patient-Reported Experience (PREs), can inform us about what matters to them, and thus guide political and organizational decision-making regarding healthcare system governance. These measures are recognized as essential data in the improvement and evaluation of current healthcare systems (Medbery et al., 2019; Valderas et al., 2019). These indicators are captured using scientifically validated measurement tools. The measures must be reported by patients to enable us to know, on the one hand, the health outcomes (PROMs) and, on the other, how these people experience care in each context (PREMs) (Weldring & Smith, 2013).

PROMs

PROMs are recognized for their considerable benefits. PROMs promote patient engagement in their care, direct consultations towards what matters to them, and ensure better quality of care and follow-up (Campbell et al., 2022). The benefits of using PROMs and PREMs at an individual level are recognized; they provide specific information about patients' needs in terms of care and services (Campbell et al., 2022). However, the use of PROMs is much broader and goes far beyond an exclusively clinical application. Several PROMs tools exist and can be used at different levels (Al Sayah, Lahtinen, et al., 2021):

- Clinical environments: Individual health outcomes can facilitate patient communication with healthcare professionals, be used by healthcare professionals to inform clinical practice and improve patients' self-management of their health.

- **Organizations:** Patient health outcomes can be used to evaluate budgets, costs and the quality or performance of programs, health services and social services.
- **Policies:** Aggregated health outcomes can be used to complement conventional data sources (e.g., clinical-administrative data) to inform organizational and policy decisions, and to compare data between different regions.
- **Research:** Health outcomes can be used to assess the usefulness of the services offered in relation to the outcomes measured.

Thus, many stakeholders (decision-makers, clinicians, patients, research teams) can use PROMs to support their day-to-day work. They can take advantage of these outcome indicators to optimize clinical monitoring and evaluation, as well as political and organizational decision-making (Canadian Institute for Health Information, 2023). To achieve this, several types of health outcomes can be measured. These include (but are not limited to):

- Perceived health status
- Quality of life
- Health outcomes following surgery
- Pain level
- Disease progression
- Disease-specific symptoms
- General health-related symptoms

PREMs

Although largely less documented, PREMs also provide recognized clinical and organizational benefits (Canadian Institute for Health Information, 2022). Like PROMs, the use of PREMs goes well beyond clinical use. Several PREMs tools exist and can be used at different levels:

- **Clinical environments:** Individual experience data can be used to improve the management of the individuals' health condition, enhance the management of patients and improve the care provided (e.g., patient-centred care).
- **Organizations:** Patient experience data can be used to guide organizational decision-making related to improving care delivery, resource allocation or remuneration (pay-for-performance, reimbursement, etc.). (Jamieson Gilmore et al., 2023; Roland & Dudley, 2015).
- **Policies:** Experience data can be used to assess the performance of healthcare systems by comparing certain indicators such as access to care, continuity or coordination of care (Jamieson Gilmore et al., 2023).
- **Research:** Experience data can be used to assess the concordance between the services offered and the experience measured.

To assess system performance, several types of experiments can be measured. These include (but are not limited to):

- Physical and financial accessibility of care
- Communication between patients and clinicians
- Coordination, continuity and comprehensiveness of care
- Overall patient satisfaction with care
- Relationships with the healthcare team
- Technical and professional skills of caregivers

- Experience in organizing care and services
- Experience with support staff and professionals other than the healthcare provider
- Personal involvement at various levels (e.g., in care, in decision-making)
- Experience of clinical care and services provided

Context of the study

There is currently an international trend towards value-based systems transformation (EIT Health, 2020). This implies major changes at various levels of healthcare institutions (healthcare policies, management of healthcare facilities, relationships between clinician and patient). Consequently, implementing and evaluating this transformation requires structuring what needs to be collected from patients, and how this data will be collected, stored, processed, and used. This is why, to promote VBHC, an international emergence of data collection systems initiatives integrating PROMs and PREMs were developed. We defined as data collection systems any system or infrastructure enabling the collection, processing, storage, and us of data.

In the United States, PROMs are part of the mandate of payer organizations (the third party that pays all or part of the medical costs to the physician or reimburses them to the insured) (Forcino et al., 2020). In the United Kingdom, they are used to benchmark the performance of health and social care services and are included in a national register (Mjåset et al., 2020; Timmins, 2008). In Canada, the Canadian Institute for Health Information (CIHI) has advocated for a standardized pan-Canadian collection of PROMs (Terner et al., 2021). The Canadian Partnership Against Cancer (CPAC) recently coordinated the deployment of oncology PROMs in ten provinces/territories (Canadian Partnership Against Cancer, 2020).

In 2017, the Organisation for Economic Co-operation and Development (OECD) launched the OECD PaRIS international initiative (https://www.oecd.org/health/paris/) aimed at developing and implementing PROMs and PREMs that are internationally comparable and standardized (OECD, 2019). Twenty-one countries are participating in this study, which is the first international survey of health outcomes and care experiences of adults with chronic conditions. It is also the first practice-based initiative in primary care. The objectives of the PaRIS-OCDE study are 1) to systematically collect data on patients' health outcomes and experience of care, and 2) to present internationally comparable self-reported indicators on the health outcomes and experience of care of patients living with a chronic disease treated in primary care.

Yet the use of these measures remains fragmented, and data collection systems integrating PROMs and PREMs are at different stages of implementation, ranging from pilot projects to large national initiatives (Prodinger & Taylor, 2018; Pross et al., 2017). Implementation is often the result of siloed local initiatives, leading to duplication and limited support (Ahmed et al., 2020). In addition, there may be differences in how these systems were implemented, for example, whether PROMS or PREMs were an integral part of their development or were introduced later into already existing systems. The great interest in PROMs and PREMs also leads us to reflect on how they were developed and how they will enable people with diverse profiles (gender, sex, ethnicity, income, social capital) to complete them and make appropriate use of their results. Implementation

difficulties linked to barriers at various levels (Nguyen et al., 2021) have led to low systemic adoption of PROMs and PREMs in Canada (Ernst et al., 2022; Gibbons et al., 2021).

In this context of transformation towards VBHC systems, it is essential to examine the main existing data collection systems integrating PROMs and PREMs. It is essential to describe them, while considering their use to support value-based decision-making, to guide their future development and implementation.

Objectives

Describe the main international initiatives of data collection systems that are integrating PROMs and PREMs and are being used by governmental institutions to support value-based decision-making.

Methodology

We conducted an environmental scan from July 2022 to October 2023. Environmental scans are an important public health tool to inform decision-making in health policy, planning and program development (Charlton et al., 2021). In particular, they are used to examine the current state of health and social programs and services, identify service strengths and gaps, assess patient and community needs, guide quality improvement initiatives, support clinical practice and professional education, and inform program and policy development.

For this project, the environmental scan consisted of 1) interviews with international key informants and 2) a scoping review (Charlton et al., 2021). Two frameworks supported our methodological approach:

1. CIHI's health data and information governance and capability framework (Canadian Institute for Health Information, 2020)
2. Franklin's framework (P. Franklin et al., 2017) to guide the collection and use of patient-reported outcome measures in the learning healthcare system.

1. Frameworks supporting the methodological approach

1.1. Health data and information governance and capability framework

Developed in 2020 by the CIHI, this framework aims to guide healthcare organizations in adopting a data governance structure that promotes continuous, reliable, and fit-for-purpose data collection. More specifically, it enables organizations to self-assess their governance structure and capabilities in health data and information, as well as helping them to build on existing skills.

The framework consists of four components covering the full range of capabilities (28) in health data and information (Figure 1). It is primarily the core capabilities, as identified by CIHI, that were used to develop the interview guide questions. They are named below according to the subject areas to which they belong:

Strategy and governance

This component defines the overall direction, accountability, and oversight of the data management program.

Targeted capabilities: roadmap, strategic governance model, operational governance model and risk management for health data and information.

Policies and processes

This component defines the activities for appropriate collection, processing, analysis and sharing of trusted health data and information.

Targeted capabilities: respect for privacy, security, access and sharing of health data and information.

Assets and standards

This component structures health data and information assets required by the policies and processes to enable strategic and operational outcomes.

Targeted capabilities: enterprise assets catalogue and content, enterprise data standards, enterprise data model and enterprise insight data for health data and information.

People and knowledge

This component empowers people, from stakeholders to the workforce to facilitate and improve processes, policies, designs and governance to be effective and sustained.

Targeted capabilities: health data and information stakeholder engagement plan.

Figure 1. Health data and information governance and capability framework

Note. From Canadian Institute for Health Information. CIHI's Health Data and Information Governance and Capability Framework. Ottawa, ON: CIHI; 2020

1.2. Framework to guide the collection and use of patient-reported measures in a learning healthcare system

Developed in 2017, the Franklin et al. (2017) framework (Figure 2) guides the implementation of PROMs in healthcare facilities. Specifically, it offers an implementation framework to ensure proper use of PROMs (right time, right indication) to generate valid and trustful data. Franklin's framework

recognizes the many challenges of implementing PROMs in a clinical context. According to this framework, the various elements that need to be considered when implementing a PROM are:

« Why PROMs? »

Many stakeholders value the collection and use of PROMs, but for different goals. In a learning healthcare system, PROM collection will meet the value proposition for all stakeholders, leading to efficient collection with the greatest utility of research-quality data within the healthcare delivery systems.

« Who? »

Individual patients in the clinic or populations with specific conditions.

« When, where? »

PROMs captured at time of patient care or directly from patients at home to ensure complete and timely data.

« What? »

Global and/or condition specific PROMs to quantify symptoms and health status, including relevant risk factors.

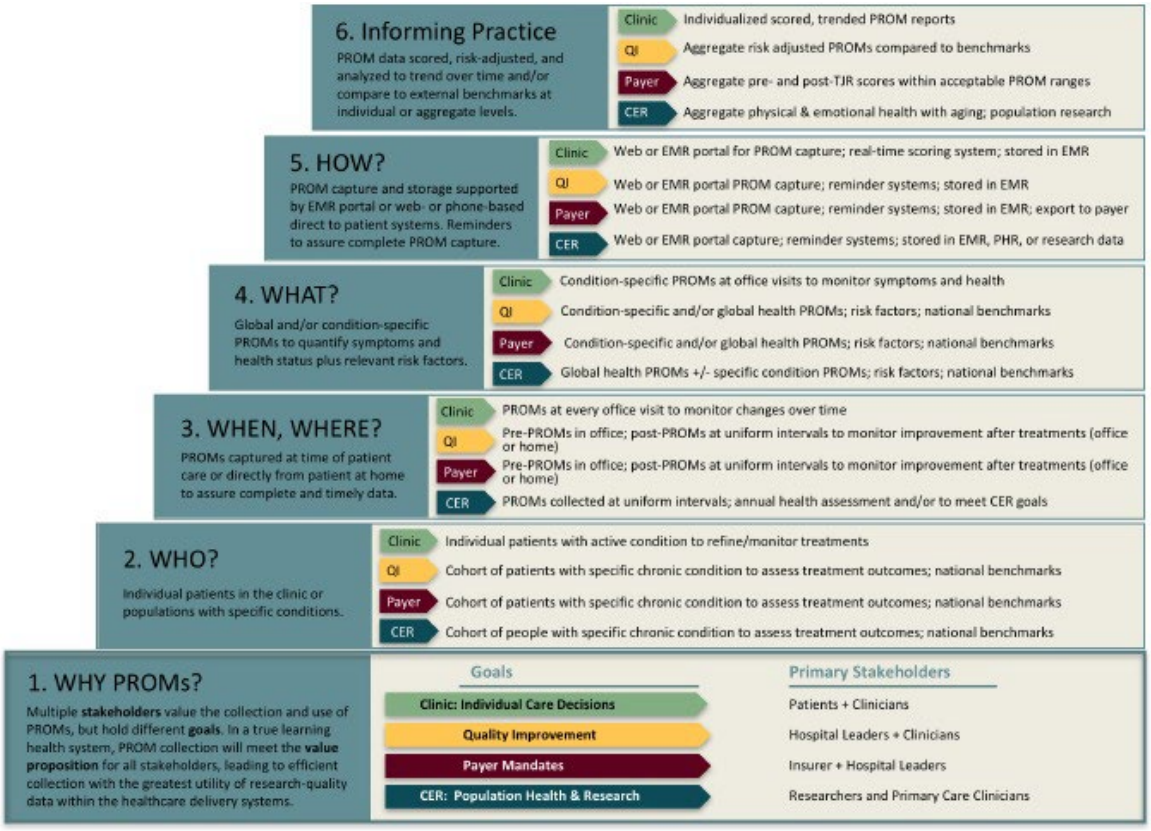
« How? »

PROMs are collected and stored supported by electronic medical records portal or web- or phone-based direct to patient systems. Reminders are sent to assure complete PROM capture.

« Informing practice? »

PROM results are scored, risk-adjusted and analyzed to establish a trend over time and/or make external comparisons on an individual or aggregate scale.

Figure 2. Collection and use of PROMs in the learning healthcare system. (P. Franklin et al., 2017)



This framework was initially developed in the context of collecting PROMs in orthopedics (P. D. Franklin et al., 2021). It is one of the most cited frameworks in the literature as a reference for PROMs collection (Maruszczyk et al., 2022; Nair & Wilson, 2019; Nelson et al., 2020; Ruseckaite et al., 2019). In this work, we have inferred its applicability for the collection of PREMs.

2. Interviews with international key informants

This aim of this qualitative step was to describe the main international initiatives involving the measurement of patient-reported outcomes and experiences of care for supporting governmental institutions' decision-making. Informants were identified in collaboration with Niek Klazinga, head of the OECD's Health Care Quality and Outcomes program, Dr Jean-Frédéric Levesque, an expert in the field through his experience in New South Wales, the research team's collaborative network and the Office of the Health and Welfare Commissioner (CSBE). A snowball selection was also carried out by asking participants if they could identify other potential key informants.

Participants were first contacted by e-mail. If the potential participant did not respond to the initial invitation, two reminder e-mails were sent out. Failure to reply after these reminders was considered as a refusal to participate. Interviews were conducted face-to-face or remotely,

depending on the availability of the people recruited. An appointment was arranged at a time and place convenient for the participant.

2.1. Data collection

An interview guide in French and English (Appendix 1 and 2) was developed based on the two conceptual frameworks presented above. An initial guide was produced, covering each of the main themes of the two frameworks: "Strategy and governance, Policies and processes, Assets and standards, People and knowledge" and "Why PROMs, For whom, When and where, What, How and Informing practice". It was then re-read and synthesized by PHRL, JFL and DR to improve understanding and to restructure the themes for greater coherence. The interview guide was then validated by a multidisciplinary team of seven researchers with expertise in implementing patient-reported measures and in patient engagement (PHRL, MEPo, MPG, MS, DR, JFL, NK). The final themes chosen were the structure of the data collection system, the target populations, the place, time and ways of collecting PROMs and PREMs, the type of PROMs and PREMs chosen, its type of use and its users. An initial test interview was carried out, following which, two themes were added: the patient's place and the challenges involved in collecting PROMs and PREMs outcomes. Participants were free to provide any documents informing the research team of the systems in place. The interviews were recorded using two audio and video recording tools (Microsoft Teams software and telephone). They were transcribed by a consultant using Microsoft Word.

2.2. Data analysis

Data were analyzed deductively and inductively. An initial analysis framework was created based on the conceptual frameworks and the interview guide by two researchers (PHRL, MEPe). The framework was then modified inductively using a thematic analysis: relevant verbatims were identified in the transcripts and assigned a code. The codes were put back into context and combined to develop the main themes of the analysis. Discrepancies in coding were resolved by the researchers to reach a consensus. MAXQDA analytical software was used for data management and coding.

3. Scoping review

3.1. Objective

The aim of this scoping review was to describe the main data collection system initiatives integrating PROMs and PREMs used by governments to support policy decision-making.

3.2. PICO model elements

Table 1. PICO Model Elements

Population	Governmental institutions, agencies, organizations and administrations
Intervention	Data collection system integrating self-reported data from patient or population
Comparison	None
Outcomes	Impact on policy decision-making, barriers and facilitators to implementation, improved quality of care, improved health outcomes for patients
Context	Healthcare system
Study design	All type of empirical studies (qualitative, quantitative, mixed)
Language	No restriction
Publishing year	No restriction

3.3. Study design

The scoping review was conducted according to the *Joanna Briggs Institute* (JBI) (Aromataris et al., 2020). The search strategy used the following databases MEDLINE, Embase, CINAHL, *Academic Search Complete*, PsycInfo et *Web of Science*. The protocol was recorded on *Open Science Framework* (https://osf.io/fn6wt).

3.4. Research question

The scoping review was guided by the following research question:

What data collection systems integrating patient-reported outcome measures (PROMs) and patient-reported experiences measures (PREMs) are used by governmental institutions to support value-based decision-making?

3.5. Inclusion and exclusion criteria

The inclusion criteria were:

- ✓ Articles published in English or French
- ✓ Articles in whole or in part about a data collection system integrating PROMs and PREMs
- ✓ Supporting decision-making at regional, federal or national levels:
  - Conceptual use (gaining awareness of results)
  - Symbolic use (legitimizing or supporting predetermined positions)
  - Instrumental use (concrete use: program creation, performance evaluation, goal setting, etc.)

3.6. Bibliographic search strategy

The search strategy was developed by the team librarian specializing in systematic reviews (FB), in consultation with other team members. Its sensitivity was tested on a sample of five key articles that the search strategy should be able to identify. The bibliography of all included articles was examined for additional studies. Studies published up to December 2022 in English and French were included.

3.7. Study selection strategy and data extraction

Studies were selected using the bibliographic reference management tool *DistillerSR*. Initially, the titles and abstracts were screened by two independent reviewers (PHRL, WS) based on the inclusion criteria. A validation of the selection process was carried out on 50 articles by assessing the level of agreement of the reviewers regarding the relevance of titles and abstracts. Next, the full texts of the selected articles were assessed for eligibility according to the inclusion criteria. Articles whose full texts did not meet the inclusion criteria were excluded, and the reasons were documented. Disagreements between reviewers were resolved by discussion or by the intervention of an additional reviewer (MS).

3.8. Data analysis strategy

The reviewers used Franklin's framework and the themes of the interview guide used in the first step of the environmental scan (interviews) to create a data extraction grid (Excel spreadsheet). An initial test of the extraction grid was carried out on two articles, then the data from the included articles was extracted and synthesized by independent reviewers (PHRL, WS, EA). The final extraction grid collected data concerning the type of study, the region/country of study, the population concerned by the collection (who?), the type of PROMs or PREMs collected (what?), the means of collection (how?), the type and form of use (why? Informing practice?) and the macro-level users of the results.

3.9. Quality analysis

Quality analysis was not performed since it is not necessary in a scoping review methodology context (Aromataris et al., 2020).

3.10. Data management

Studies were selected using the *DistillerSR* web application (*DistillerSR*, 2011). Data extraction and analysis were performed using an Excel grid shared by Microsoft Teams.

3.11. Knowledge users' involvement

This review was carried out in partnership with the Office of the Health and Welfare Commissioner. Representatives of the Office were involved at key steps of the synthesis to gather their comments and suggestions.

Results

1. Key informant interviews

Six interviews were conducted with eight key informants between September 2022 and February 2023 (Table 1). One participant was recruited through a snowball effect (Welsh participant).

Tableau 2. Characteristics of Key Informants

Key informants	Country/region	Initiatives
Jean-Frédéric Levesque	Australia/New South Wales	Patient-Reported Measures Program
Solvejg Kristensen	Denmark	PRO Psychiatry
Francesca Ferre et Riccardo Novaro	Italy/Tuscany	The PREM and PROM Observatory
Dybvik Eva Hansen et Furnes Ove Nord	Norway	Norwegian Arthroplasty Register
Mark Wilkinson	England	NHS England PROM program
Hamish Laing	Wales	NHS Wales PROM program

The qualitative analysis categorized the themes as follows: data collection system governance strategy, data confidentiality and security, data collection system implementation, description of the PROMs and PREMs collection system, use of PROMs and PREMs results at different levels, and evaluation of the data collection system.

1.1. Data collection system governance strategy

Several governance strategies were developed, depending on the healthcare system and the pre-established organization. Most often, a steering committee was set up, including members of the government, project managers, clinicians and patient representatives. Project management could be carried out by the registries (Norway), by the project team in collaboration with the regional ecosystem (Tuscany, New South Wales) or by a governmental institution (Wales, UK).

Support from the national government varied. The government could lead the project, be a member of a steering committee, or simply offer financial support. All initiatives were supported by various expert annex committees: technical committee on self-reported measurements, committee on technological infrastructure, clinical committee, committee for the evaluation of research applications, etc.

It was reported by participants that a challenge exists in the management of health data, and that the implementation of a PROMs and PREMs data collection system was a significant cultural and

organizational change. In reality, this is a new health information collection system that requires a structured implementation approach.

« C'est tout un changement culturel et organisationnel que d'implanter ça dans nos systèmes. C'est quand la dernière fois qu'on a implanté un système d'information dans des contextes comme le Québec ou comme l'Australie? Ça fait des décennies, parce que nos systèmes d'information, c'est des héritages de systèmes construits graduellement où on a mis en place les systèmes de codification, etc. Puis là on arrive, puis on dit - on intègre un nouveau système d'information - et donc ça c'est un défi en soi. Parce que culturellement, ça posait des défis puis en réalité, c'était tellement différent comme système d'information que fallait un peu revoir et réinventer la gouverne de tout ça. »

– Free translation – "*It's a whole cultural and organizational change to implement this in our systems. When was the last time we implemented an information system in contexts like Quebec or Australia? It's been decades, because our information systems are inherited systems built gradually where we put in place coding systems, etc. And now we come along and say - we're integrating a new information system - and so that's a challenge in itself. Because culturally, it posed challenges and in reality, it was so different as an information system that we had to somewhat rethink and reinvent the governance of all this*."

1.2. Data confidentiality and security

The initiatives followed the current regulatory framework concerning data privacy and security ((General Data Protection Regulation (**GDPR**) in Europe, including the UK). Many systems used unique login credentials provided by the system (New South Wales) or based on unique national identifiers (myID in Denmark, national identity number in Norway). This was followed by a secure login with a password and double authentication (via mobile applications).

Subsequently, different levels of data access with their own identification process were identified. For example, in New South Wales, patients only saw their own data, clinicians only saw raw data or their patients' data only. Managers, on the other hand, saw only aggregated data without clinicians' identities. Consent was requested either on inclusion in the collection system by a professional, or on the first connection to the collection platform. The patient could withdraw consent at any time.

Finally, according to the participants, access to data for research purposes was highly regulated and sometimes involved cumbersome administrative procedures to the point that access was very difficult (England).

1.3. Data collection system implementation

All the initiatives were undertaken to transform healthcare systems towards a value-based healthcare system. On the one hand, governments were increasingly interested in the collection of PROMs and PREMs and on the other hand, clinical circles demonstrated a desire to have access to these measures for the follow-up and management of patients:

« So we have both these movements at the same time (local and national initiative). »

Initiatives generally had two main objectives:

- Improvement of daily clinical practice by using data from PROMs and PREMs (possibly integrated in an electronic medical record) for monitoring and management.
- Improving the quality, comparison and evaluation of the performance of health and social services systems.

It was, however, mentioned by a participant that the installation of such a program will not immediately lead to an improvement in the population's health status.

« Honnêtement là, quand le système a été mis en place, les gens pensaient qu'on allait simplement regarder les trajectoires puis qu'on allait voir à l'échelle populationnelle une amélioration d'état de santé à cause de nos programmes. Ça c'est un peu naïf évidemment, c'est pas comme ça que ça se passe dans la réalité pour toutes les raisons dont j'ai parlé. »

– Free translation – "*Honestly, when the system was put in place, people thought we would just look at the trajectories and see an improvement in health at the population level because of our programs. That's a bit naive, obviously; that's not how it happens in reality for all the reasons I've mentioned.*"

The implementations began with a pilot project, which was followed by an evaluation and an extension to other institutions or regions. The implementation was gradual in different structures and clinical settings, allowing the program to become known progressively and facilitating its extension. During the implementation, participants emphasized the importance of considering the local programs already in place.

« Un des enjeux qu'on avait c'est que ce programme-là se développait, mais sans qu'il y ait d'ajustement en parallèle de notre programme d'enquête populationnelle par exemple, ou des programmes plus locaux mis en place par les agences locales, et là on voyait bien que ça devenait un peu non coordonné. »

– Free translation – "One of the issues we had was that this program was developing, but there was no adjustment in parallel with our population survey program, for example, or with the more local programs implemented by local agencies, and it was becoming somewhat uncoordinated."

Within the implementation process, the level of patient involvement varied. It could be minimal (Tuscany) or more significant throughout the process (Denmark, New South Wales). In the latter case, patients expressed themselves separately from professional staff during system construction reflection workshops to be able to express themselves fully and freely. Patients were also present during the development of PROMs and PREMs questionnaires to select what they found most relevant and ensure the tool's comprehensibility. Then, they participated in testing the questionnaires to confirm their understanding and ensure they adequately supported clinical practice as expected. Finally, patients assisted in the evaluation of the system itself by reporting issues and providing critical feedback for improvement. This involvement is seen as a positive element of the process and the system:

« *And our initiative has gained so much respect because we've had patients' involvement, patient participation in every step, everywhere […] So it opens listening. So that we have been able to involve the patients and I've had [patient name] being my project assistant and a very, very tough patient*

advocate have been so valuable, I can only say I don't know where we would have been without her. And it's, I mean, it's been the biggest joy for me as a researcher to actually work together with her. And she's carried a lot of the scientific work on her shoulders in the way that we have agreed how to do things and design things together and she's a very practical down to earth person. So that's been very valuable. »

Furthermore, when the patient's engagement was lower, this decision was criticized retrospectively by the project leaders.

« *We have not been talking about patient participation. I believe mostly because we have not engaged directly with patients or patient associations in the design selection of the surveys. We have not really included patients or patient associations in our process. We have been giving back to them the results of our work. We have performed several focus groups with patients that have responded to the survey, but it was not a systematic involvement of patients and or patient associations, but we see that we need them, we should have them on board, they are asking us.* »

The collection systems targeted specific diseases or care trajectories of interest (hip and knee surgery, maternity, mental health, heart failure, etc.). A single population-based approach was proposed in the case of New South Wales (integrated care program). Generally, implementation initially focused on elective surgery pathways before expanding to care trajectories for patients living with chronic diseases. Additionally, it was noted that implementing such a system in primary care is challenging. Indeed, the high number of involved stakeholders and the need for a higher level of integration of technological infrastructure pose challenges.

1.4. Description of the PROMs and PREMs collection system

Selection and typology of PROMs

The process of selecting PROMs and PREMs was a significant part of constructing the data collection system. Among the various initiatives, the selection process was similar. It began with a literature review and was completed by expert opinions, field professional experiences, and previous institutional use or clinical study backgrounds. Participants reported drawing inspiration from other similar initiatives. Both generic and specific PROMs and PREMs were selected.

Subsequently, selected questionnaires could be enhanced by adding questions to adapt to the local context. For example, a PROM questionnaire could be supplemented by a section from a PREM questionnaire. In Denmark, a *de novo* questionnaire was constructed from various existing questionnaires. These questionnaires were then tested and validated within the given context.

Common precautionary elements during the selection of PROMs and PREMs were found across different initiatives:

- Clinical interest and systemic interest in PROMs and PREMs are different; therefore, selection was based on clinical needs (clinical scale) and evaluative or planning needs (systemic scale). Sensitivity to change for an individual differs from that of a population over a given period, and measure choices needed to be made according to desired changes (clinical vs. systemic).
- Measures should be sustainable and adaptable over time, as it is difficult to modify data collection once started.

- Questionnaires must be validated and adapted to the implementation context.

Data collection platform

The platform used for data collection was a significant concern in the various initiatives listed. It was notably mentioned that the choice of the provider developing the digital platform is crucial. In New South Wales, for example, despite a rigorous selection process, the provider was unable to meet expectations because the market was not sufficiently "mature".

Furthermore, this platform must be a modern tool adaptable to care contexts. It was advantageous to connect it with other existing data collection platforms and integrate it with patients' electronic medical records. One difficulty mentioned by those interviewed was the proliferation of these platforms for the same data collection. In Italy, there was one platform for data collection, another for sending questionnaires, and yet another for visualizing results. Teams were in the process of streamlining this setup. Sometimes, there were multiple platforms in the same region depending on different PROMs and PREMs collection initiatives and data collection in general.

Methods used for data collection

Data collection within the initiatives was primarily digitized (iPad in waiting rooms, websites, smartphones). Paper collection was also possible with secondary digital input, particularly to facilitate data capture from populations with lower digital literacy. Patients could be supported by a third party. However, it was reported that the paper collection method remained costly. Simultaneous collection with both PROMs and PREMs tools was possible. Collection could be carried out at patients' homes, in waiting rooms before consultations, or during hospitalizations.

Additionally, engagement at various levels (micro, meso, macro) of the collection was an important issue reported by all key informants. It was notably observed that: patient engagement was better when the request came from professional staff; professional engagement was better when they initiated the request autonomously, highlighting the importance of adopting PROMs and PREMs tools in daily practice; professional engagement could be lower due to scepticism about the usefulness of these measures at the meso and macro levels.

To address these challenges, several solutions were considered across the different initiatives:

- Accompany patients during data collection.
- Provide questionnaires in different languages (French, English, others).
- Co-create and make available support tools for patients and professional staff.
- Involve all healthcare professionals in data collection.
- Establish reminder systems for professional staff and patients to complete questionnaires.
- Create dashboards to monitor data collection.
- Regularly communicate with patients and professional staff (presenting the objectives of data collection and its benefits, training on how the system works at the regional level, presenting results and actual changes).
- Identify "champions" who promote the initiative at various levels of the healthcare system (micro, meso, macro).
- Identify voluntary structures and clinical environments to start implementation.

- Automate data collection procedures as much as possible.

1.5. Using PROMs and PREMs at different levels

The data were used at different levels within these healthcare systems (micro, meso, and macro).

At the micro level, the results supported discussions during consultations between patients and clinicians. The results contributed to monitoring and management by the clinical team and could be used by patients for self-management of their health.

At the meso level, managers could view aggregated data in the form of dashboards available at the unit or organizational level. These data allowed institutions to compare themselves with other healthcare facilities and health regions, promoting emulation and improving the quality of care. The availability of real-time data was seen as a strength of the system. Data were available in raw form to facilitate reading and understanding.

« So the real time visualization of data is another strength of our system. »

At the macro level, the use of data was primarily conceptual (knowledge of results) in the form of raw data presented in an epidemiological or statistical report. There was mention of using the data for financial resource management, quality improvement, and performance evaluation, but little was discussed about the process of using them in political decision-making. However, these data were used to make "small practical changes".

« *People are very fascinated when we report to them our work and they see also data and they see that some changes have been made based on the data, small, very small changes like very practical one.* »

Participants reported that the use and evaluation of data from PROMs and PREMs represented a real methodological challenge. How do we manage missing data? What indicators do we use for an allocative or evaluative perspective?

« Il y a beaucoup de défis méthodologiques associés à l'utilisation des PROMs, surtout dans une perspective évaluative, mais dès qu'on commence à mettre des tableaux de bord en place pour les cliniciens, on doit mieux traiter ces aspects-là. Puis dans nos analyses, on doit être en mesure de vraiment mieux comprendre ça. »

– Free translation – "There are many methodological challenges associated with the use of PROMs, especially from an evaluative perspective, and as soon as we start putting dashboards in place for clinicians, we need to better address these aspects. And in our analysis, we need to be able to really understand this better."

« On a des tableaux de bord descriptifs qui sont en place, mais on n'a vraiment pas atteint tout le potentiel analytique de ces sources de données-là, et la réalité c'est qu'à tous les niveaux du système de santé, on n'a pas des équipes qui ont les capacités actuelles pour vraiment en faire le traitement de manière avancée. »

– Free translation – "We have descriptive dashboards in place, but we really haven't reached the full analytical potential of these data sources, and the reality is that at all levels of the healthcare system, we don't have teams with the current capabilities to truly perform advanced processing."

1.6. Evaluation of the data collection system

Various evaluation strategies for the system had been put in place:

- Evaluation of the concrete use of the system.

This was the main evaluation described by the participants. In New South Wales, system dashboards had been created (How many patients enter the collection platform? How many patients start responding and abandon halfway through? How many clinicians should have asked patients to respond but did not send the request? Do the cohorts have the same proportions of patients who responded at home before the visit versus those who responded in the waiting room?). In Italy, two indicators were evaluated: the response rate and the percentage of patients covered by the program.

- Evaluation of the experience with the program itself through focus groups

Focus groups were regularly conducted within the initiatives to gather feedback on the experience from all stakeholders (decision-makers, managers, clinicians, patients).

- Summative evaluation (medico-economic).

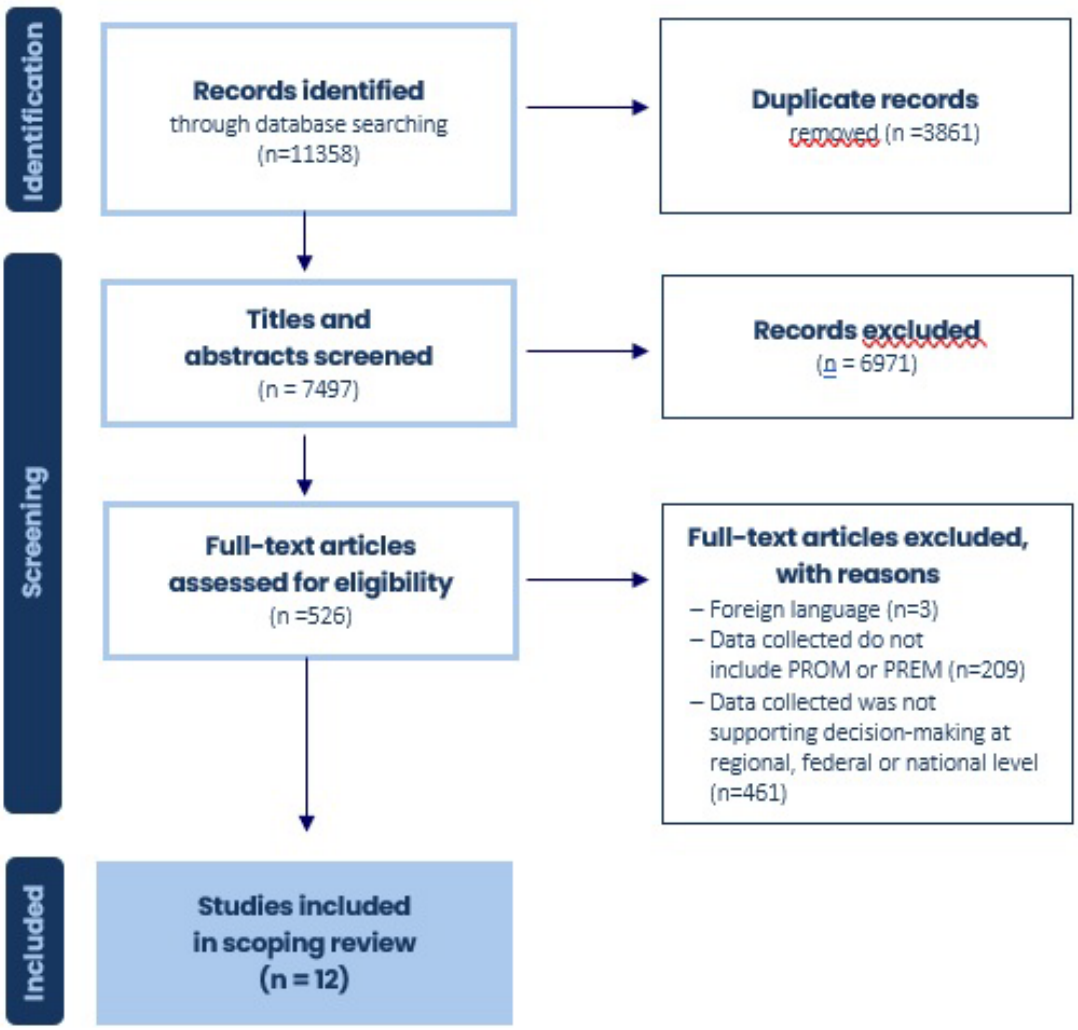
A summative evaluation is planned in two years in New South Wales to assess the system's impact and present the results to the Treasury Board, the project's investor.

2. Scoping review

2.1. Study characteristics

The research strategy identified 7497 articles in six databases (Figure 1). Following the process of selecting studies by title and abstract, 526 full-text articles were assessed for eligibility. Twelve articles met the inclusion criteria and were included in this scoping review (Al-Shammari et al., 2019; Bergerum et al., 2022; Cnudde et al., 2016; De Rosis et al., 2020; Devlin et al., 2010; Ernstsson et al., 2020; Feltelius et al., 2017; Glenngård & Anell, 2018; Kristensen et al., 2022; Olson et al., 2018; Pennucci et al., 2020; Stranne et al., 2020).

Figure 3. Scoping review flow chart



Six studies had a quantitative design, three a qualitative design, one a mixed-method design, one was a case study about national registers, and one was a research-action.

2.2. Description of the initiatives and the data collection system governance strategies

The initiatives of data collection system integrating PROMs and PREMs are shown in table 2.

The initiatives described in the studies were developed in six countries (Sweden, Italy, United-Kingdom, Danmark, Canada, Kenya). Half of the studies were conducted in Sweden. Within the articles, four types of governance could be described and depended on the local context: initiatives with national governance (England), initiatives with governance by an external third-party organisation in collaboration with the regional government (Italy, Canada), initiatives with governance based on national registers (Denmark, Sweden) and initiatives with governance by a local team (Kenya).

Some initiatives were only at the pilot-stage at the time of the publication (Kenya, Italy, Denmark, England), thus limiting the possibility of having recent data on these systems.

Table 3. Characteristics of included studies

Lead author	Country	Study design	Population	Which PROMs/PREMs are used?	How are PROMs/PREMs collected?
Al-Shammari et al., (2019)	Kenya	Quantitative	Pregnant women	ICHOM Pregnancy and childbirth standard set adapted for Kenya: ICIQ-SF, Wexner, PROMIS SFFAC102 and PHQ-2.	Digital platform on phone
Devlin et al., (2010)	United-Kingdom	Qualitative	Patients receiving surgery (unilateral hip replacement, unilateral knee replacement, groin hernia repair, varicose vein surgery and cataract surgery)	EQ-5D-5L; EQ-VAS; SF-36; VF-14; Aberdeen Varicose Vein Symptom Severity questionnaire; Oxford Knee Score; Oxford Hip Score	Paper-based
Bergerum et al., (2022)	Sweden	Qualitative	Patient from internal medicine, oncology, paediatric and rehabilitation	N/A	N/A
Cnudde et al., (2016)	Sweden	Quantitative	Hip and knee osteoarthritis	Visual analogue scale (VAS) hip pain; EuroQol 5; EuroQol VAS; Satisfaction VAS	N/A
Ernestsson et al., (2020)	Sweden	Case study (description of registers)	Patient with conditions related to the musculoskeletal system, nervous system, circulatory system, psychiatry, cancer, infections, pediatrics, obstetrics and gynecology, stomach and intestines, endocrine organs, skin diseases, rare diseases	EQ-5D-3L; EQ-5D-5L; EQ VAS	Paper-based, web-based or interview (telephone or face-to-face)
Feltelius et al., (2017)	Sweden	Quantitative	Patient with condition related to cardiology, neurology, multiple sclerosis (MS), stroke, rheumatoid arthritis, diabetes, prostate and breast cancer, ophthalmology	N/A	Web-based, paper-based
Glenngard & Anell, (2018)	Sweden	Quantitative	Patients having visited a provider in primary care	National Patient Survey	Web-based (link sent by e-mail)
Stranne et al., (2020)	Sweden	Quantitative	Patient with prostate cancer treated by radical prostatectomy	PROMs not specified: included questions on continence, erectile function and inguinal hernia formation	Web-based, paper-based
Kristensen et al., (2022)	Denmark	Qualitative	Patients with anxiety, affective disorders or psychotic disorders	PROMs were designed by a patient peer board to on well-being, social functioning and side effects of medication	Web-based
De Rosis et al., (2022)	Italy	Action research	Patients hospitalized in one of the hospitals of Tuscany or Veneto	PREM including questions on admission process, experience in the service, discharge phase	Web-based (link sent by e-mail or phone)
Pennucci et al., (2020)	Italy	Mixed-method	Patient with chronic heart failure	The Italian short version of the Kansas City Cardiomyopathy Questionnaire-12 (KCCQ-12); The KCCQ-12 scale; the Italian translation of the Self-Care Heart Failure Index (SCHFI) and a PREM (not specified)	Web-based (link sent by e-mail or phone)
Olson et al., (2018)	Canada	Quantitative	Patients receiving radiotherapy for bones metastases, for brain metastases, lung cancer, gynecological cancer, head and neck cancer	Questions from FACT BP, FACT-L, EPIC, PRO-CTAE, GI toxicity, EORTC QLQ Cx24, EuroQol EQ-5D-5L	Tablets or mobile phone with the help of a nurse

2.3. Facilitators and barriers to implementing the data collection system

Various implementation facilitators were described. It was possible to implement these systems without investing additional resources or increasing the workload of professional staff (Olson et al.). The facilitator most often cited in the various initiatives was the use of champions at different levels of the system, but particularly at the clinician level. Having convinced champions promoting the initiative was a major facilitator. A second facilitator was the inclusion of patients in the design and implementation of the data collection system (Kristensen et al.). Several other facilitators were mentioned: communication via different information tools (posters, leaflets in the departments) (De Rosis et al.), communication about the initiative, training and support for clinicians (Kristensen et al.). Finally, allowing teams flexibility in their approach to data collection, for example by identifying their own solutions, facilitated appropriation and implementation (Olson et al.).

Various barriers to implementation were also described: concerns and resistance to implementation from the clinical teams, administrative and logistical difficulties, lack of training, time constraints, lack of collection tools, budget limitations and limited administrative and human resources.

2.4. Selecting PROMs and PREMs

The studies selected described data collection systems in a variety of contexts, including follow-up for orthopaedic surgery, cardiac pathology and cancer (Table 2). Most of the data collection systems described in the studies integrated PROMs. De Rosis et al. (2020) and Glenngård and Anell (2018) presented the collection and use of a PREM. However, in De Rosis et al. (2020), the PREM was part of an initiative combining PROMs and PREMs.

The PROMs selected were often specific to the trajectory studied. They could be associated with a generic PROM, specifically the EQ-5D-5L, which was used in four studies (Devlin et al., Cnuddle et al., Ernestsson et al., Olson et al.). The data collection systems described were sometimes connected with other clinical data systems (England, Swedish registers) or administrative data systems (England, Swedish registers, Kenya). Several strategies were used to select the PROMs and PREMs: a PROM was developed in collaboration with a committee of patient partners, followed by several rounds of validation (Kristensen et al.); an existing PREM questionnaire was enhanced using closed and narrative questions (the questions were worded positively to mitigate negativity bias), enabling the collection of quantitative and qualitative data (De Rosis et al); tools from the pregnancy and childbirth toolbox produced by the International consortium for health measurement (ICHOM) were adapted to the local Kenyan context (Al-shammari et al.). In this case, the tools selected had been validated with expert resources and stakeholders from both private and public sectors.

The choice of tools also depended on its intended use. Devlin et al. (2010) explained that the EQ-5D was chosen for the UK PROMs programme because it was widely used for medico-economic evaluations. Moreover, patient preferences and choices had to be considered. Finally, Al-Shammari et al. described the challenge of potentially acquiring a user licence for certain tools, which are not on freely accessible (cost, accessibility).

2.5. Collecting data from PROMs and PREMs

The data were collected using various channels: web-based, telephone surveys, and paper-based. Swedish registers used all these tools, but most initiatives employed a web-based strategy, except for the English pilot study (published in 2010). The choice of a web-based strategy was particularly justified in the article by De Rosis et al. (2020), as data collection via postal surveys or paper-based are expensive and time-consuming; telephone surveys required brief questionnaires and can produce interviewer-bias or selection bias. Therefore, the web-based strategy appeared to be the best option. Web-based methodology also required brief questionnaires but could be accessible across multiple platforms (web, applications). Additionally, the authors described an increase in digital literacy and the use of smartphones and Internet across all populations, including older adults.

Furthermore, data collection could be supported by completion reminders and engagement from clinical teams.

2.6. Using PROMs and PREMs

Hypothetical intentions for the use of different systems were often present, but a concrete description of the use of these data for decision-making by national or regional institutions were only briefly detailed in the included studies (table 3).

Table 4. Use of PROMs and PREMs Data

Lead author	Who uses PROMs/PREMs for decision-making?	What type of use?	What form does the data take?
Al-Shammari et al., (2019)	Kenyan government	Benchmarking on social and health services performance, quality improvement	Aggregated data and statistics
Devlin et al., (2010)	United-Kingdom Department of Health (DH)	Benchmarking on social and health services performance, quality improvement	Aggregated data, reports and statistics
Bergerum et al., (2022)	National Quality Registers	Benchmarking on social and health services performance, quality improvement	Aggregated data
Cnudde et al., (2016)	National Quality Registers, National board of Health and Welfare, Sweden statistics	Performance measure of social and health services, quality improvement, establishing guidelines	Aggregated data and report
Ernestsson et al., (2020)	National quality registers, governmental institutions, health professionals	Benchmarking on social and health services performance, quality improvement, economic evaluation, evaluation of interventions, individual patient consultations	Aggregated data in real-time and annual report
Feltelius et al., (2017)	National quality registers, National board of Health and Welfare	Quality improvement, policy decision-making	Aggregated data in real-time and annual report
Glenngard & Anell, (2018)	Regional government	Performance measure of social and health services, quality improvement	Aggregated data and statistics
Stranne et al., (2020)	National quality registers, governmental institutions, health professionals	Benchmarking on social and health services and quality performance, quality improvement	Aggregated in real-time
Kristensen et al., (2022)	National registers	Quality improvement	Aggregated data
De Rosis et al., (2022)	Regional government	Benchmarking on social and health services and quality improvement	Aggregated data in real-time and annual report
Pennucci et al., (2020)	Regional government	Benchmarking and measure the performance of health-care providers	Aggregated data in real-time and annual report
Olson et al., (2018)	British Columbia Cancer Agency	Quality improvement	Report

The data from the collection systems were mainly used to benchmark the different health services or facilities with each other, to improve the quality of care and for data analysis for research purposes. None of the data sources selected described a process for using PROMs and PREMs data for value-based decision-making.

However, PROMs and PREMs were often used at the clinical level to support clinician-patient communication, shared decision-making, monitoring, and patient self-management. The results could be used to make small, tangible changes at local level in the short term, but could lead to improvements in the long term (Olson et al.). The use of real-time data could enable these changes to be made quickly and accurately (Italy).

2.7. Presenting data to the knowledge users

The way the data was presented was a key aspect in the various empirical studies, since it affects interpretation, the perception of usefulness and the actual use of the data. The data in these tools (scores, sub-scores, thresholds) are very complex to interpret (Devlin et al.). The data had to be presented in a way that was clear, intelligible, relevant and informative for those using it (decision-makers, clinicians, patients). It was necessary to remember that one way of presenting the data was not necessarily right for everyone.

Presentation in the form of real-time data was often preferred (De Rosis et al., 2020; Ernstsson et al., 2020; Feltelius et al., 2017; Stranne et al., 2020). It allowed immediate feedback of results to users. In particular, the data were easier for clinicians to remember. This made it possible to act quickly to problems and make lasting changes (De Rosis et al.). The use of real-time data was seen as an important and positive innovation by clinicians and managers.

Furthermore, it was reported that these data were only relevant to clinicians if they concerned the patients in their service. Indeed, there was no available support to clinicians for quality improvement by using aggregated data. In addition, data were sometimes added to patients' electronic medical records or other data sources to facilitate their use by clinicians (Kristensen et al.). Annual reports were also produced for decision-makers and other reports were made available to the public (Cnudde et al., 2016; De Rosis et al., 2020; Devlin et al., 2010; Ernstsson et al., 2020; Feltelius et al., 2017; Olson et al., 2018).

2.8. Evaluation of the data collection system

Several ways of evaluating the system were proposed in the various articles selected. Al-Shammari et al. described a process using quarterly meetings between clinicians from the participating centres to identify weaknesses and areas for improvement in the system implemented. Kristensen et al. described a participatory qualitative approach involving three groups of informants: patients, clinicians and managers. Finally, the Italian authors described the use of two performance indicators for the data collection system estimating appropriation and the response rate.

Synthesis of the results emerging from the two data sources

The objective of this work was to describe the main initiatives of data collection systems integrating PROMs and PREMs and used by international governmental institutions to support value-based decision-making. First, the interviews with key informants made it possible to present a summary of the description of the various systems according to six main themes: the governance strategy of the collection system, confidentiality and data security, the implementation of the system, the description of the PROMs and PREMs collection system, the use of PROMs and PREMs at the different levels and the evaluation of the system itself. Secondly, common themes were found in the scoping review, which made it possible to complete the qualitative results on: the governance themes, by presenting the initiatives according to four models (national, external third-party organization with regional collaboration, registries, local); the implementation of collection systems, by describing its barriers and facilitators; the description of the collection system, by detailing the selection and collection of data; and the system evaluation, by presenting various strategies. In addition, the scoping review has added new themes by developing the notions of presentation and use of results. It is interesting to note that due to the emergence and innovation of data collection systems integrating PROMs and PREMs, we did not find any evidence to accurately describe the use of PROMs and PREMs in the value-based decision-making process.

Then, the convergence of these different results allowed us to establish solid foundations for the implementation of PROMs and PREMs collection systems and thus to establish three strategic insights and nine tactical considerations for the implementation of these systems. Some are innovative in the context of this emerging theme, others refer to notions that have already been developed and supported in literature. These insights and considerations are necessary elements in the reflective process for the deployment of such a system in the Quebec context.

Strategic insights

1. Implementing a system for collecting PROMs and PREMs in alignment with the VBHC brings about a significant paradigm shift and disrupts current thought patterns regarding data collection and use at the micro, meso and macro levels

The implementation of data collection systems integrating PROMs and PREMs is used to support the transformation of healthcare systems towards VBHC. Our work indicates that the collection of PROMs and PREMs is a disruptive change in the context of health data collection. By definition, these data are collected directly from patients, who are an integral part of the collection process. Yet, to date, most data collected has come from administrative data or directly from clinicians.

There is currently a global transformation of healthcare systems with a paradigm shift that involves the desire to put patients at the centre of the healthcare system (patient-centred care, value-based healthcare) (Kidanemariam et al., 2023). The concept of patient-centred care has changed the way healthcare has been understood and delivered until now. It has shifted the focus of healthcare system delivery from the perspective of decision-makers and clinicians to the perspective of patients. Until now, outcomes reflecting patient priorities have traditionally been poorly measured in clinical practice, compared to clinical outcomes such as survival rates, for example (Van Der Wees et al., 2014; Wu et al., 2010). At the clinical level, this paradigm shift has resulted in the implementation of PROMs and PREMs tools as well as the concept of shared decision-making. At the organizational level, VBHC, while supporting this approach, had mixed results in supporting a patient-centred approach (Kidanemariam et al., 2023). The inclusion of PROMs and PREMs is therefore a first step towards assessing the implementation of VBHC, based on their perspective. In addition, patient participation in the process of developing and implementing these data collection systems, integrating PROMs and PREMs (in combination with the clinical and policy vision) could provide a better understanding of which specific measures are important for the population of concern (tactical consideration for implementation No. 1). This would ultimately lead to results that really matter to them, in a way that is sustainable for the healthcare system.

Thus, it seems relevant to put in place different strategies to promote collaboration among all stakeholders throughout the process. For example, creating a steering committee within the structures that includes patients, clinicians and decision-makers, conducting focus groups to evaluate the system or the selection of measurement tools, or supporting the engagement of knowledge users at the various levels.

2. Combining a bottom-up and top-down approach is necessary to achieve a homogeneous and balanced systematization of data collection

Our work has highlighted that, in this dynamic of transformation towards VBHC, not only decision-making institutions such as governments or ministries are implementing these systems, but also that clinical communities are developing their own initiatives in parallel. Strategies vary by country (Steinbeck, 2021): the Netherlands has a predominantly bottom-up presence with top-down financial support; Denmark has a bottom-up implementation with top-down recommendations; England has essentially a top-down implementation but also some bottom-up initiatives; and Australia has essentially a bottom-up implementation but also state initiatives as in New South Wales. Thus, it is important to take into account the local initiatives for the collection of PROMs and PREMs already in place.

The existence of these two opposed dynamics in tension will require a search for a balance and therefore tends towards a systematization of collection. This balance could be achieved by combining a bottom-up force from the clinical community and a top-down force from the decision-making community in order to structure all initiatives within the framework of a learning health system model (Enticott et al., 2021).

In addition, it has been shown that the learning health system model can be an effective model for creating bridges between silos of disciplines, professions or different levels of the healthcare system (micro, meso and macro) (Enticott et al., 2021; Melder et al., 2020). It can also facilitate the resolution of complex problems that are often faced by healthcare system actors in order to achieve better outcomes.

Finally, a bottom-up and top-down implementation approach would provide a structure while leaving room for flexibility to adapt to local initiatives and thus move towards a successful implementation in the Quebec context. This approach would also make it possible to standardize data collection practices and, ultimately, improve the potential for using the data (benchmarking, evaluation of intervention, clinical research). From a more global perspective, this approach would also create links between silos across Canada and internationally.

3. Data collection systems that integrate PROMs and PREMs are an emerging innovation and its integration into the value-based decision-making process is still maturing

The two previous observations indicate the emergence of a paradigm shift and new challenges. To address them, emerging methods such as collection systems integrating PROMs and PREMs are being developed under the impetus of governments as well as clinical settings. The initial objective

of our study was focused on describing initiatives using PROMs and PREMs results to support value-based decision-making. The notion of using PROMs and PREMs was therefore at the heart of our work. Across all initiatives, the use was presented at different levels (micro, meso, macro). However, no elements were found concerning the processes of using PROMs and PREMs results in value-based decision-making. Generally, only a generic presentation of use objectives at different levels was addressed within the scientific literature (e.g., "benchmarking on health and social services performance" or "quality improvement").

However, this observation is not surprising. Indeed, the concept of VBHC remains a recent concept described by Porter and Teisberg in 2006 (Porter & Teisberg, 2006). The MeSH (Medical Subject Headings - used in the MEDLINE database) keyword "Value-Based Health Care" was only introduced in 2023. The concept of PROMs and PREMs, for its part, also emerged concomitantly (Cella et al., 2007; FDA, 2009; Patrick et al., 2007). The term "Patient-Reported Outcome Measures" was only introduced in this same database in 2017 (no introduction of the concept of "Patient-Reported Experience Measures"). The use of these measures as evaluation tools in VBHC is an emerging concept but one of growing interest. Consequently, various international initiatives for data collection systems integrating PROMs and PREMs have been developed recently and are at different stages of implementation. The various systems are not yet fully deployed and are in the process of maturing (Steinbeck, 2021). This could explain the lack of concrete elements on value-based decision-making processes. It was mentioned by a participant during interviews that immediate changes should not be expected. Indeed, there are a multitude of barriers and issues that must be resolved upstream in order to have an efficient decision-making process: the inclusion of patients throughout the process (tactical consideration for implementation No. 1), the time for patients to appropriate the tools, but also the necessity of good data quality, their readability, presentation, and interpretation (tactical consideration to support the use and evaluation No. 1).

However, currently, there are clinical and management uses of PROMs and PREMs that enable practical changes directly in the field, on a smaller scale, particularly thanks to real-time data systems that enable short- and medium-term improvements (Gibbons et al., 2021; Graham et al., 2018; Larsen et al., 2011; Wright et al., 2017). The addition of these concrete, small-scale changes could enable long-term improvement.

Tactical considerations prior to implementation

1. Anticipate regulatory, confidentiality, data security, patient consent issues and needs

Our work highlights that, first of all, it is necessary to anticipate and adapt to the local regulations in place regarding data confidentiality and security. For European initiatives, one of the major challenges was ensuring that data collection systems complied with the European GDPR, which posed significant difficulties.

In Quebec, Law 25 (*Projet de loi 64, 2021*) modernizing legislative provisions regarding the protection of personal information aims to promote transparency and help citizens better control the use of their personal information. This law is inspired by the GDPR and requires, among other things, that consent must be requested in simple and clear terms that patients be properly informed when personal information is collected, that they be notified in the event of a confidentiality incident involving their personal information if the incident poses a risk of serious harm, and that they be informed of their right to have their data erased and delisted.

In Quebec, Law 25 (*Projet de loi 64, 2021*) and the new Law on Health and Social Services Information (*Loi sur les renseignements de santé et de services sociaux*. RLRQ, R-22.1) (not yet in effect) set out the legal framework applicable to the collection of data integrating PROMs and PREMs. Law 25 applies to any collection of personal information carried out by a public body or on its behalf, or by a private enterprise or on its behalf. Moreover, data from PROMs and PREMs, being health data, are considered "sensitive" personal information. Sensitive personal information is information that, "due to its nature, particularly medical, biometric or otherwise intimate, or due to the context of its use or communication, (...) generates a high degree of reasonable expectation of privacy" (Gouvernement du Québec, 2023a). Thus, when a public body wishes to obtain the consent of the concerned individual to use sensitive personal information for a purpose other than what it was collected for, or when it wishes to disclose this information, the consent must be expressly given. Express consent requires a positive action from the individual, such as filling out a form, responding affirmatively to a question, or ticking a box (Gouvernement du Québec, 2023b). However, a public body may use this sensitive personal information for the purposes of study, research, or statistics to evaluate performance or measure the quality of products and services offered, with a view to continuous improvement (Gouvernement du Québec, 2023c). He can also use this information if it is depersonalized to serve the public interest, for example, by conducting research on a specific topic related to his mission to develop a new program or service.

However, this aspect is controversial in Europe regarding the framework provided by the GDPR (Gefenas et al., 2022; Wiertz & Boldt, 2022). There is an ethical debate around the different consent models concerning the collection and use of sensitive personal data for study or research purposes (Wiertz & Boldt, 2022). The question is whether consent should be understood as broad, as is traditionally the case in research in Europe, or whether consent should be understood according to narrower consent models (dynamic consent) (Gefenas et al., 2022; Hallinan, 2020). Indeed, consent allows patients to be informed about the objectives of the study or research, to compare them with their own values, to take ownership of these objectives, and to help the project team achieve the objectives by providing their data if they wish. The disadvantage of broad consent is that at the time consent is given, the quantity and quality of future studies conducted from this data are unknown. It is therefore not possible to inform subjects about the scope of the research, the personal benefits and risks, the research agents, or the funding of future research studies (Caulfield & Kaye, 2009). Consequently, although projects for study or research purposes may benefit from the use of data without consent for reasons of public interest, this could compromise the benefits identified which were initially targeted, particularly in a value-based approach (Geller et al., 2022; Wiertz & Boldt, 2022).

In light of these elements, it is considered important to reflect on this notion of consent regarding sensitive data such as PROMs and PREMs in the context of VBHC to ensure good ethical practices. To this end, several consent models could be considered.

For example, for greater transparency and autonomy in the management of health data by patients for research and evaluation purposes, a new approach through meta-consent could be studied. This concept proposed by Ploug and Holm (Ploug & Holm, 2016) is based on the idea that people should be asked how and when they want to be presented with a consent request to use their personal health data. This model takes into account preferences in terms of values, vulnerability, and trust. It allows for an active role of patients in the consent process and adds transparency to the use of health data. By indicating their preferences, patients can choose different types of consent depending on different research projects. For example, broad consent can be given for all cancer-related research. In the event of conflicting preferences, it is possible to indicate a prioritization of the different consents.

The work of the Interdisciplinary Research Group in Health Informatics (GRIIS) has evaluated the relevance and acceptability of such a model in the Quebec context (Cumyn et al., 2021). They conclude that this model is favorably supported by the Quebec population. It is considered the best approach in the context of research on personal health data (Geller et al., 2022). However, this model has limitations in managing conflicts between consent preferences and in choosing different types of consent. This is why Geller et al. (2022) developed a model inspired by meta-consent: the value-based consent model. Additional consent and refusal options have been added and are offered for each category and subcategory of research subjects. Thus, according to the authors, this model provides a more precise matrix of preferences, better considering the values and preferences of individuals.

2. Adapt to existing national or regional contexts regarding data collection systems governance

In our work, it was shown that the governance strategies of data collection systems for initiatives varied according to the national or regional governance contexts in place. Some initiatives were essentially part of national governance (England, Wales), others relied on external third-party organizations in collaboration with regions or provinces (Tuscany, New South Wales, British Columbia), or relied on national registers (Norway, Sweden, Denmark).

The notion of healthcare systems governance has recently been explored through a report by the CSBE on the transformation of healthcare systems governance (Denis & Téhinian, 2023). It defines governance as aiming to "articulate a set of actors and organizations in a situation of distributed capacities to achieve goals deemed desirable from a collective perspective." This report recalled that one of the current elements of healthcare systems governance is the search for a balance between centralization and decentralization. Some systems are opting for active governance at different levels of the healthcare system and valuing decentralized bodies (multi-level governance), and others are relying on greater centralization. Denis and Téhinian (2023) noted that the governance of the healthcare system in Quebec resembles a highly institutionalized system and, consequently, "its transformation requires change management and an effort of organizational development on the scale of the healthcare system."

Furthermore, as described in our strategic insight No. 1, healthcare systems are transforming into value-based systems to take into account what matters to patients. The transformation of these systems will therefore lead to transformations of the overall governance, which should be done with and for patients. This is especially true as the aspects of co-development and co-creation are essential elements in the transformation of healthcare system governance to adapt to the needs of patients (Denis & Téhinian, 2023). Consequently, governance inspired by what is being done in New South Wales or Tuscany, or perhaps even in Wales, could be adapted for the implementation of such a system in the Quebec context.

Nevertheless, Quebec has its own specificities, and the entire provincial context must be considered. Indeed, considering the context is a key determinant of the successful implementation of PROMs and PREMs data collection systems (Greenhalgh et al., 2018). Additionally, understanding the resources, existing legislation, and the necessary structure to support the future initiative should be done before any initiative to integrate PROMs and PREMs.

3. Create a provincial framework to structure the implementation of local initiatives

There are currently bottom-up and top-down dynamics in the implementation of PROMs and PREMs data collection systems (strategic insight No. 2). A balance needs to be found within this dynamic. In this context, provincial frameworks for PROMs and PREMs collection initiatives would

provide a development framework for harmonizing use practices at the provincial level, while leaving freedom for construction, integration and appropriation at the local level. Some frameworks have already been proposed, notably the one proposed by CIHI in 2021 for the collection of PROMs in the Canadian arthroplasty context (Canadian Institute for Health Information, 2021) and those proposed at the time of the Montreal Accord in 2013 (Ahmed et al., 2017; Arbuckle et al., 2017; Bartlett et al., 2017; Bartlett et Ahmed, 2017; Bingham et al., 2017; Mamiya et al., 2017; Mayo et al., 2017; Noonan et al., 2017; Sawatzky et al., 2017).

Montreal Accord on patient-reported outcomes use series (Bartlett et al., 2017)

In November 2013, a broad cross-section of healthcare system key stakeholders (patients, patient advocates, researchers, clinicians, policymakers, research funders, and regulatory and public health representatives) gathered in Montreal for a workshop on the needs, priorities, strategic partnerships and resources required to create a sustainable national PROMs collaborative network. The one-and-a-half-day workshop consisted of presentations, interactive debates and small group sessions to reach consensus using the nominal group technique. The research presented at the workshop, the views and reactions expressed, and the emerging themes from the consensus vote were then developed by the authors in eight manuscripts.

Furthermore, one of the main barriers to the implementation of PROMs and PREMs in clinical settings is that clinicians sometimes feel that this measure is not clinically relevant (Bull and al., 2022). If this is the case, clinicians might not 1) use this measure to support continuous quality improvement and 2) support the routinization of data collection from PROMs and PREMs by patients. Ultimately, this would hinder the systematization of data collection and the establishment of a sustainable structure for data collection and use. Thus, it is essential that the data collected make sense for decision-makers, clinicians, and patients. Everyone must appropriate the different tools and their results within the framework of their respective practices. This vision is consistent with the values promoted by VBHC.

With this in mind, the implementation should be gradual, and it is suggested to evaluate the results of pilot programs before a provincial expansion. The deployment conditions and the necessary resources must also be studied. Two types of support can be offered, as observed in New South Wales. Asynchronous support, such as a website with resources presenting the program, and synchronous support, such as a team composed of individuals dedicated to the gradual implementation, going on-site to offer technical, organizational, and educational training.

4. Prioritize a population segment-based rather than a sector-based (specialty, service, unit, hospital) data collection system

All the initiatives in our study presented approaches by population segments. The targeted segments were those considered priority populations based on various performance indicators (e.g., elective surgeries in the United Kingdom; elective surgeries, heart failure, and maternity in Italy; elective surgeries, heart failure, maternity, diabetes, chronic obstructive pulmonary disease, bronchiolitis, or falls in the elderly in New South Wales). The approach by population segments is described in the literature as preferable for organizing healthcare practice rather than an approach by specialty, service, unit, or hospital (Varela-Rodríguez et al., 2021). This approach is particularly interesting when aiming to transform systems towards VBHC by starting implementation in high-priority sectors where costs are high. However, a population segment approach solely focused on high healthcare costs, or a physical condition can present certain limitations (Langton et al., 2020). For example, two patients with chronic heart failure might have different needs related to various social determinants of health. Thus, these population segments could be defined by the homogeneous grouping of patients with common needs (Chong et al., 2019; Langton et al., 2020). In Quebec, recent political decisions aim to improve the performance of home support services. People with loss of autonomy using home services would be a good example of a population segment of interest in the Quebec context. Thus, care experience and perceived health could be data collected within the care pathway of people with loss of autonomy, regardless of the sector in which they receive care or services, including home services.

Additionally, it is essential to consider populations with adverse social determinants of health, who are at higher risk of having perceived poor health or a less favorable care experience. This will prevent the over-representation of satisfied populations or those with good outcomes. For example, patients with intellectual disabilities or low literacy levels are sometimes excluded from PROMs and PREMs data collection (Kroll et al., 2014). There is also a lower response and satisfaction rate among vulnerable patients, the unemployed, or young people (Imam et al., 2014; Tam et al., 2023). Moreover, most PROMs or PREMs are not validated or adapted for the previously mentioned populations, even though these populations often have extensive and complex care needs and are at risk of poorer health outcomes. Efforts must be made to ensure that appropriate initiatives are put in place for these populations to obtain valid, inclusive, and representative results. A more population-based approach that also promotes equity in the completion of PROMs and PREMs by patients could therefore be interesting.

Also, a segment-based approach is not sufficient and raises the issue of multiple data collections for populations included in several segments. Approaches focusing on the overall experience of the person could help resolve these issues. For example, our work described two population-based approaches with the case of New South Wales (integrated care program) (Agency for Clinical Innovation, 2017) and the PROMs and PREMs observatory in Italy (De Rosis et al., 2020). The segment-based approach remained predominant within the various initiatives.

Finally, a mixed approach currently seems the most relevant in the context of VBHC with:

- Short- and medium-term programs to target priority population segments.
- Population-based programs allowing for long-term improvements.
- The deployment of data collection and completion strategies that promote adherence from everyone, including people with adverse social determinants of health, who are often underrepresented in large-scale data collections.

Tactical considerations for implementation

1. Include patient representatives from the beginning of the initiative to achieve changes with and for the patients

The current report described that the inclusion of patients was variable across different initiatives, ranging from inclusion throughout the entire process to more moderate interventions. However, it was acknowledged by key informants that their involvement had a very positive effect and that their absence was a significant limitation.

The current transformations in healthcare systems are being carried out with the aim of putting patients at the center of the care system (patient-centered care objectives, value-based healthcare) (Kidanemariam et al., 2023). This consideration should also be applied to developing and implementing these data collection systems integrating PROMs and PREMs. Some countries, such as Denmark (Kristensen et al., 2022), have included patients throughout the entire process. Patients had participation actively (governance, questionnaire development and testing phases, system evaluation, etc.) but were separated from clinicians, at their request, to express themselves fully and freely.

This finding is even more important since a systematic review conducted in 2023 showed that patient engagement at the organizational level lacked maturity in VBHC (van der Voorden et al., 2023). Indeed, it was mentioned that patient involvement in VBHC was mainly done through questionnaires or interviews conducted by a research team. Higher levels of patient participation, such as advisory roles, co-design, or collaboration teams, were rare. No examples of higher levels of patient engagement (co-leadership by patients of care improvement committees) were found. Consequently, the authors recommended that VBHCs adopt patient engagement at all levels to ensure that their values are at the heart of these initiatives.

2. Select relevant PROMs and PREMs for all data users at micro, meso and macro levels

The results of our work indicate that the process of selecting PROMs and PREMs was similar across different initiatives, including a literature review, expert opinions, or inspiration from other initiatives.

The chosen questionnaires should be neither too long (leading to a lower response rate among patients) nor too short (risking a lack of discrimination for interpretation and clinical relevance). Additionally, it has been proposed that a PROM or PREM should only be selected if it provides high-quality evidence of content validity (qualitative evaluation with patients) and sufficient internal consistency (quantitative psychometric evaluation) (Prinsen et al., 2016). Special attention is needed when selecting these tools for use in a VBHC context. It is important to select tools that measure outcomes that matter to patients.

However, expecting to find the perfect PROM or PREM is unrealistic (Chiarotto, 2019). The tools should be broad, validated for different populations, cultures, and languages (Chiarotto, 2019; Kroll et al., 2014). Ideally, according to the authors, the selection should be based on studies comparing different tools for a given population, but such studies are rare. Most often, tools are selected because their psychometric data are considered sufficiently good or because they are widely used without any recent tools showing superiority. However, even when widely used, some of these tools may not meet the minimum required scientific standards (Derriennic et al., 2022). Therefore, selection must be careful. Moreover, it is possible to choose to develop a tool in the absence of a sufficiently valid tool for a specific population and context. It would be preferable to ensure the methodological rigor of selecting and evaluating tools before integrating them in quality assessment or resource allocation programs. Finally, the questionnaires should be pre-tested in advance with the target population (Al Sayah, Jin, et al., 2021; Deshpande et al., 2011).

Additionally, the process of selecting PROM or PREM tools should find a balance to meet the needs of all stakeholders (patients, clinicians, and decision-makers). The collected data must help patients in self-management, clinicians in clinical decision-making, and decision-makers in value-based decision-making. Identifying constructs that address the different needs is an essential step in selecting these tools.

Finally, the frameworks mentioned in tactical consideration prior to implementation No. 3 could provide best practice guidelines to address these quality issues (questionnaire completion time, content validity, internal consistency, transferability to different contexts, and respect for stakeholders needs).

3. Support the engagement of all key stakeholders in the routine collection of data

Data collection requires the use of a digital collection platform. Our work finds a proliferation of these platforms for several initiatives in the same location or even for the same initiative (platform for data collection, for sending questionnaires, and for analyzing results). The proliferation of these platforms presents a significant challenge for systems where the ideal would be to have a common platform to address organizational, security, and engagement challenges in data collection.

The use of multiple platforms or systems may hinder the engagement of key individuals in this paradigm shift (strategic insight No. 1), for which the engagement of all parties is important. Indeed, the engagement of patients and clinicians is a strong challenge of these new data collection systems and must be anticipated to provide responses upstream. For example, certain populations such as patients living alone or those with cancer are less inclined to respond (Adjei Boakye and al., 2022).

The engagement of clinicians is also crucial. Some findings suggest that without this engagement, there can be no improvement in patients' outcomes (Austin et al., 2019). There is also some mistrust among clinicians, who find these measures too subjective and are skeptical about their use for resource allocation, penalties, or bonuses (Berlin, 2021). This also represents an additional burden for them and a heavy administrative cost (Qaseem et al., 2021).

Finally, studies suggest that if patients and clinical teams understand the value of PROMs and PREMs information and how they will be used, they will be more inclined to participate in the data collection process (Boyce et al., 2014; Squitieri et al., 2017). In the UK, for example, explanatory videos are made available to clinicians to introduce PROMs to patients and support them in their use (Wolpert, 2014).

To address these challenges, several courses of action are conceivable:

- Accompany patients during data collection.
- Provide questionnaires in different languages (French, English, others).
- Co-create and make available support tools for patients and professional staff.
- Involve all healthcare professionals in data collection.
- Establish reminder systems for professional staff and patients to complete questionnaires.
- Create dashboards to monitor data collection.
- Regularly communicate with patients and professional staff (presenting the objectives of data collection and its benefits, training on how the system works at the regional level, presenting results and actual changes).
- Identify "champions" who promote the initiative at various levels of the healthcare system (micro, meso, macro).
- Identify voluntary structures and clinical environments to start implementation.
- Offer incentives for data collection rather than performance (Steinbeck, 2021).
- Automate data collection procedures as much as possible.

Tactical considerations to support the use and evaluation

1. Support the use of PROMs and PREMs at different levels (micro, meso, macro)

Within the various initiatives, PROMs and PREMs were used at different levels (micro, meso, macro). At the micro level, patients had access to their own self-reported measurement results to promote involvement and self-management. At the meso level, the creation of real-time results monitoring dashboards was a common model within the various initiatives. Finally, at the macro level, regular publication of public reports on PROMs and PREMs results was important to ensure transparency in the healthcare sector and provide easily accessible and understandable information to patients. However, for public reports to support care improvement processes and patient empowerment, it was necessary to establish solid implementation experiments beforehand.

Indeed, the results of systematic reviews regarding the benefits of using PROMs are mixed (Boyce et al., 2014; Squitieri et al., 2017). A potential advantage is found particularly when using data to evaluate the quality of care at the organizational or system level (clinical management) or when the tool evaluates an outcome related to a clinical intervention (individual decision). Similarly, the correlation between PROMs scores and individual clinician performance is not established, mainly due to external factors that can influence this correlation (Qaseem et al., 2021). Their interest in comparing performance between clinicians therefore seemed limited. In 2022, a systematic literature review found little or no effect of aggregated PROMs data on improving the quality of care (Dorr et al., 2022). However, the authors clarified that all necessary conditions for successful implementation were not met.

Furthermore, reading and interpreting these results are real challenges for proper use. Indeed, it has been shown that the way results are presented is an important aspect of their use. Data must be presented in an informative, relevant, and understandable manner for those who use them (Vallance-Owen et al., 2004). There are methodological and technical challenges to overcome to ensure that the right information is available in the right format and accessible by the right means at the right time (Ahmed et al., 2017).

It is therefore important that clinicians, managers, and decision-makers are adequately trained in the use of these tools and the dangers of overinterpreting their results (Wolpert, 2014). In this context, presenting the conditions of use and strengths and limitations for the decision-making process is particularly useful, especially as these training sessions are well received. Finally, the use and interpretation of these data could be enhanced when they are associated with classical

healthcare system data (administrative and data reported by clinicians) (Al Sayah, Lahtinen, et al., 2021). Moreover, it is essential to deploy multimodal interventions to support the use of PROMs and PREMs by knowledge users in order to maximize their use and effects (Powell et al., 2015; Waltz et al., 2015).

2. Establish a structured, objective, and independent evaluation process in partnership with research communities

Several evaluation strategies for the data collection system have been proposed in our work:

- Evaluation of the concrete use of the platform using monitoring dashboards on the process (response rates, use rates by clinicians).
- Evaluation of the project experience itself through focus groups.
- Independent medical-economic evaluation of the program.

These strategies were also found in the literature, particularly by contacting patients and clinicians to assess their use of the system and its measures (Watson et al., 2021). Additionally, patients could contribute to the evaluation and improvement of the system itself by reporting issues and providing critical feedback.

The structure of an evaluation process is essential for any implementation of innovation and is important to ensure the efficiency of the system (Bauer et al., 2015; Bourassa Forcier et al., 2023). In implementation science, Bauer et al. described three types of evaluations that can be associated with each other: process evaluation, formative evaluation, and summative evaluation.

- Process evaluation describes the characteristics of the use or non-use of what is being implemented. Data are collected before, during, and/or after implementation and analyzed by the research team without feedback to the implementation team and without the intention of modifying the ongoing process.
- Formative evaluation uses the same methods as process evaluation, except that the data are transmitted to adapt and improve the implementation process.
- Summative evaluation is a compilation of the impact of the implementation strategy once completed. Summative evaluation measures typically assess the impact on care processes (for example, increased use or quality of targeted practices) or help characterize the economic impact of implementation and its effects.

It then appears essential to determine the object of evaluation, whether it is related to the implementation and use of PROMs and PREMs or the effects at different levels of PROMs or PREMs use (micro, meso, or macro). In 2023, the Quebec report on innovation projects revealed that the indicators used to determine added value are mostly volumetric and financial: they notably include the number of users, the number of emergency room visits avoided, the number of hours of services or care, and operating costs (Bourassa Forcier et al., 2023).

Given these different elements, it seems pertinent to consider an evaluative model that combines Bauer et al.'s (2015) three modes of evaluation and that allows understanding both the implementation and use process as well as the effects. However, the choice of this evaluative model should include the essential components of VBHC. Practically, these strategies could include all the devices found described within the various initiatives. For example:

- Process evaluation of the use of the data collection system using process tracking dashboards (response rates, use rates by clinicians).
- Formative evaluation of the user experience through discussion groups involving all users.
- Evaluation using health-economic studies on the effects of the data collection system integrating PROMs and PREMs.

Finally, in order to carry out these evaluations, a partnership with communities of researchers is desirable. Indeed, scientific rigor and multidisciplinary expertise are pillars of learning health system models aimed at improving healthcare services and care (Enticott et al., 2021; Menear et al., 2019). Thus, an evaluation of data collection systems by independent and experienced teams in this field would allow for a healthy and continuous improvement of PROMs and PREMs data collection systems.

Conclusion

Our environmental scan, combining interviews with key informants with a scoping review, allows for robust findings regarding the description of data collection systems integrating PROMs and PREMs to support value-based decision-making. Based on these solid foundations, three strategic insights and nine tactical considerations have emerged.

Indeed, it has been observed that the implementation of such systems in alignment with VBHC brings about a significant paradigm shift and disrupts current thinking patterns regarding data collection and use. This is an emerging innovation, and both governments and clinical environments are developing their own initiatives. A balance is needed between these bottom-up and top-down approaches to achieve a consistent systematization of data collection. Thus, various international initiatives are still maturing, and some elements are only minimally developed. In particular, the process of using PROMs and PREMs results for value-based decision-making by governmental bodies is yet to be fully described. However, these systems are already enabling practical changes in the field that could be beneficial for the quality of care and the performance of healthcare systems in the medium and long term.

Prior to the implementation of these systems, it is therefore pertinent to adapt to national and regional contexts regarding data governance, consider regulatory and data security issues and consent needs, and also create a provincial framework to structure the development and implementation of local initiatives. Additionally, it is preferable to target segments of the population of interest rather than focusing on different sectors of health and social services. During implementation, it is important to involve patient representatives from the beginning, establish strategies to support the engagement of all individuals involved in data collection, and select relevant tools for everyone. Finally, support for data use at various levels (micro, meso, macro) and the establishment of a structured evaluation process, in partnership with research communities, are necessary for the sustainable use and operation of data collection systems integrating PROMs and PREMs.

Ultimately, the patient-reported measures are essential information for a VBHC system. Integrating these data into a data collection system constitutes a significant innovation, for which upstream work and reflection must be carried out to structure the implementation of the data collection system and its subsequent use. The insights and considerations presented in this report can support the implementation of such systems in the Quebec context.

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Appendix 1: English Interview guide

Objective: Describe the main international initiative of measurement system including PROMs/PREMs and used for policy-making (in order to provide the information to structure PROMs/PREMs measurement data system in Quebec)

What measurement initiative including PROMs and PREMs are already in place in countries/in region?

I. Presentation of the participant

⇨ Can you introduce yourself (age, nationality, education, profession and current assignments)?

Starting question

⇨ What is the status overall and the history of PREMs measurement in your country/region? Is there any PREMs initiative?

⇨ What is the status overall and the history of PROMs measurement in your country/region?

II. Structure and architecture of the measurement system

1) Strategy and Governance

⇨ What are the desired outcomes?
⇨ What is the strategy/direction behind this measurement system in order to achieve the desired outcomes? What is the need/the aim of this initiative?
⇨ What is the governance model (who is responsible for it/driving it, how is it monitored?)

2) Policy and Process

⇨ How are compliance, security, privacy and confidentiality of data ensured?

3) Assets and Standards

- ⇨ How are the databases structured (inventory, data paths (input, output)?
- ⇨ What are the standards for data content and exchange? (HL7 norm?)
- ⇨ What is the organizational data model (diagram, glossary, technical data dictionary)?
- ⇨ What are the analytical practices to support decision-making related to the production of this data (production of indicators, algorithms, reports by the organization?)

4) Efficiency and sustainability

- ⇨ What strategies have been developped to support and improve the efficiency and sustainability of the process? (collaboration, training, communication (internal/external))

III. Process applied to PROMs/PREMs and its management

1) What is the typology of use of PREMs and/or PROMs at different levels?

a) Decision-making level (individual decision, clinical management, health care policy, population-based health) and what are the types of users?

b) Type/application/function? (clinical (patient and clinician), quality improvement, resources management (management, reimbursement, reprioritization, financial incentive), assessment and research)

2) What patient populations are targeted by these measurement systems?

3) How is the collection of PROMs and PREMs going?

a. Where and when are PROMs and PREMs collected (home, office, hospital, primary care; before/after consultation?)

b. What method of collection (paper, phone, website, tablet, personal computer?)

c. What about data access and security?

d. What about consent to data collection?

4) How were the PROMs and/or PREMs selected (which ones were selected, by whom and why)? Is there a governance structure (do you manage the introduction of new questionnaires or can people use the tool themselves and integrate their own questionnaire)?

IV. Analysis and use of data

⇨ Do you have a framework for analysing these data? If so, which one?

V. Place of the patient

⇨ How involved is the patient throughout this initiative (design, selection, development)? (if not developed before in the interview)

VI. Challenges of information systems including PROMs and PREMs

⇨ What are the challenges and success factors of developing information systems that include PROMs and PREMs?
⇨ Is there any other initiative? Were you inspired by other initiative?

Appendix 2: French Interview guide

Question de recherche : Comment est construit et utilisé le système de mesures utilisant des PROMs et des PREMs?

I. Présentation du participant

⇨ Pouvez-vous vous présenter? (âge, genre, nationalité, formation, profession et missions actuelles)

II. Structure et architecture du système de mesure

⇨ Pouvez-vous décrire comment le système de mesure a été construit/son architecture?

1) Stratégie et gouvernance

⇨ Quelle est la stratégie/l'orientation derrière ce système de mesure afin d'obtenir les résultats voulus?
⇨ Quel est le modèle de gouvernance? (Qui en a la responsabilité/le pilote? Comment est-il surveillé?) Quel est l'implication des patients dans ce système?

1/Carnet de route général en matière de données et d'information sur la santé (HDI)/de la mise en place de ce système (vision, orientation, valeur stratégique)

2/Modèle de gouvernance stratégique en matière de HDI

3/Modèle de gouvernance opérationnelle en matière de HDI (rôles et responsabilités)

4/Gestion des risques en matière de HDI

2) Politique et processus

⇨ Comment la conformité, la sécurité, le respect de la vie privée et la confidentialité des données sont assurés?

1/Politique et processus de respect de la vie privée s'appliquant aux HDI (gouvernance, gestion des consentements, gestion des incidents)

2/Politique et processus de sécurité des HDI (évaluation de la vulnérabilité des données, gestion des menaces et des risques)

3/Politique et processus liés à l'échange de HDI ainsi qu'à l'accès à celle-ci (accès aux données par différents organismes, confidentialité?)

3) Actifs et normes :

⇨ Comment sont structurées les banques de données (inventaire, cheminement des données (provenance, sorties)?

Quelles sont les normes relatives au contenu des données et à leur échange?

Quel est le modèle organisationnel des données (diagramme, glossaire, dictionnaire des données techniques)?

Quelles sont les pratiques analytiques permettant l'aide à la prise de décision (fiables et éthiques) liées à la production de ces données? (production d'indicateurs, d'algorithmes et de rapports par l'organisme?)

1/Contenu et répertoire des banques de données et d'informations sur la santé de l'organisme

2/Normes de données organisationnelles

3/Modèle de données organisationnel

4/Pratiques liées aux enseignements tirés des données et de l'information sur la santé de l'organisme

4) Personnes et connaissances

⇨ Quelles stratégies ont été mises en place afin de favoriser et d'améliorer l'efficacité et le maintien du processus? (collaboration, formation, communication (interne/externe))
⇨ Comment le système de mesure a-t-il été implanté/déployé et maintenu? Quelles sont les structures du processus qui ont été mises en place pour soutenir l'utilisation des différentes personnes visées?
⇨ Est-ce que le système lui-même a été évalué? Évaluation interne/externe?

Plan de collaboration avec les intervenants en matière de HDI

III. <u>Processus appliqué aux PROMs/PREMs et à leur gestion</u>

1) Quelle est la typologie d'utilisation des PREMs et des PROMs aux différents niveaux?

a) Niveau décisionnel? (décision individuelle, gestion clinique, politique de soins, santé populationnelle) et quelles sont les types d'utilisateurs?
b) Type/application/fonction? (guide décision clinique (patient et clinicien) particulière, amélioration de la qualité, décision d'allocation et de planification (gestion,

remboursement, reprioriser les choses, incitation financière), évaluation et recherche)

2) Quelles populations de patients sont ciblées par ces systèmes de mesure?

3) Comment se passe la collection des PROMs et des PREMs?

a. Où et quand est-ce que les PROMS et les PREMS sont recueillis? (maison, cabinet, hôpital, en première ligne?, avant/après la consultation?)
b. Quels modes de collection? (papier, téléphone, site internet, tablette, ordinateur personnel?)
c. Quid de l'accès et de la sécurité des données?
d. Quid du consentement au recueil des données?

4) Comment les PROMs et PREMs ont été sélectionnés? (Lesquels ont été choisis, par qui et pourquoi)? Est-ce qu'il y a une structure de gouverne? (est-ce que vous gérez l'introduction de nouveau questionnaire ou les gens peuvent utiliser eux-mêmes l'outil et intégrer leur propre questionnaire?)

5) Quels sont les types d'utilisateurs des PROMs et PREMs? (ex : utilisation par milieu hospitalier et soins de première ligne dans un système unique, le PROM doit suivre le patient)? Comment les PROMs et les PREMs sont utilisés dans la pratique et par qui? (score individuel, suivi de tendance, comparaison avant/après intervention, associations avec d'autres indicateurs?)

IV. Analyse et exploitation des données

Avez-vous un cadre d'analyse de ces données qui permettrait de guider le développement d'indicateurs et des mesures? Si oui, lequel?

V. Place du patient

Quelle est l'implication du patient tout au long du processus (design, sélection, développement)? (si non abordé)

VI. Défis des systèmes d'information incluant des PROMs et des PREMs

Quels sont les défis liés au développement des systèmes d'information incluant des PROMs et des PREMs?