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Cover Page Footnote

We warmly thank members of the “Community of practice on patient engagement” in the Quebec province of Canada, on the experience and partnership of care and services for contributing to the development of this tool. This article is associated with the Policy & Measurement lens of The Beryl Institute Experience Framework (<https://www.theberylinstitute.org/ExperienceFramework>). You can access other resources related to this lens including additional PXJ articles here: http://bit.ly/PX_PolicyMeasure

An evidence-based tool (PE for PS) for healthcare managers to assess patient engagement for patient safety in healthcare organizations

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Abstract

In 1999, the Institute of Medicine had already warned that medical errors caused between 44,000 and 98,000 avoidable deaths per year in the United States. A similar situation was subsequently in 2000, documented in Canadian hospitals. According to a Canadian Patient Safety Institute report (2016), incidents in both acute and home care settings resulted in additional costs of \$2.75 billion each year. Research suggests that Patient Engagement (PE) for Patient Safety (PS) can help address this issue. However, the use of PE in various strategies to promote PS has yet to be fully integrated across healthcare systems in OECD countries. The aim of this study was to develop a tool for managers to assess PE strategies implemented at a health system level to enhance PS. Developing the tool involved 3 phases: (1) creating a framework; (2) building a first version of the tool; (3) validating the tool by an expert committee of PS and PE managers. The final tool consists of 81 questions, divided into four sections: (1) describing the healthcare organization (n=14); (2) gathering general information on PE strategies (n=15); (3) assessing different PE strategies for PS (n=49); and (4) describing the respondent's involvement in PS committees (n=3). The tool is currently being used (by healthcare professionals working in Risk Management (RM) or PS, or, by task groups that include patients) in a research study in Canada and France, to assist healthcare managers in monitoring the evolution of PE for PS at a system level.

Keywords

Patient engagement, partnership, participation, risk, risk management, patient safety, institutionalization, strategies, mechanism, factors, tools, change, patient partnership

Introduction

According to the Institute of Medicine (IOM), Risk Management (RM¹) is part of Patient Safety (PS) and can be thought of as “*freedom from accidental injury due to medical care or from medical error.*” [See Footnote 1] Already in December 1999, the IOM's report entitled “*To Err is Human: Building a Safer Health System*” revealed that medical errors² caused between 44,000 and 98,000 avoidable deaths per year in the USA. [See Footnote 1] In Canadian hospitals, similar evidence has been found, revealing that “*one in fourteen patients suffer from some form of harm, with a third of such cases being preventable.*” [See Footnote 2] Moreover, deaths related to incidents³ occur every 13 minutes, [See Footnote 3] and medical errors in both the acute and home care settings can cost \$6,800 per patient, resulting in additional costs of \$2.75 billion each year in Canada. [See Footnote 4] Estimated costs related to incidents and accidents⁴ in hospitals represent the costliest form of care, accounting for over \$58 billion per year across the country. [See Footnote 5]

That said, according to the “Safety is Personal” report from the Institute of the National Patient Safety Foundation in the U.S.A., patients and families can play a primary role in the prevention of medical errors and harm reduction.⁶ Indeed, studies related to both Patient Engagement (PE) and shared decision-making reflect the evolving and shifting role of patients and families in healthcare as they become more active, informed, and influential.⁷ A growing body of evidence supports that PE can lead to better health outcomes,^{7, 8} contribute to improvements in quality and PS,⁹⁻¹³ and help control healthcare costs.^{14, 15} For example, in a mixed method study by Taber et al.,¹⁶ a multidisciplinary quality improvement initiative concluded that engaging patients in follow-up analysis of their medication (e.g., reviewing discharge medication with patients) intake reduced medication safety issues by 40%, and was associated with 100% adherence with reconciliation,⁵ while seven-day readmission rates decreased by 50 %.¹⁶ Moreover, a systematic review summarizing the evidence from 55 studies¹⁷ concluded that patient experience is positively associated with activities such as adherence to recommended medication and treatments; the use of

screening services and immunisations, and fewer adverse events in general.¹⁷

Hence, PE – and that of the patient’s family and loved ones – are part of a new collaborative strategy, rapidly becoming a cornerstone for improving quality of care.¹⁸ Healthcare institutions wanting to build safer systems and control costs are increasingly setting PE goals to ensure higher levels of engagement from patients with regard to managing their own care and overall risk management in healthcare and social services.^{7, 8, 14, 19, 20}

In addition to the evidence above, Accreditation Canada (AC) (Canada’s healthcare institution accreditation body), in collaboration with the Canadian Patient Safety Institute (CPSI), stated in its 2013–2018 strategic plan that the organization’s main goal in PS is to encourage PE in order to support healthcare policy transformational change at organizational and system levels.^{21, 22} Thereafter, on January 1, 2016, AC standards were updated and clearly focused on the patient and family partnership approach. For instance, quality improvement teams and care safety are now deemed as incomplete without patients and their families being involved.²²

Despite these great strides and intentions, risk and PS managers in Canada have little to no evidence-based guidance on how to plan, implement, promote, evaluate and improve (thus, institutionalize) PE in healthcare establishments, particularly as related to PS at a system level. Moreover, no tools have been found which captured an overall system strategy of PE in PS in an entire healthcare organization or system.

Thus, the objective of the study is to build a tool to assist healthcare managers in assessing system-wide integration of PE for PS practices, incorporating concepts of “Safety I” (situations that can go wrong) and “Safety II” (what goes right and the system’s ability to succeed despite conflicts, uncertainties and risks).²³ The tool was also intended to track change over time based on organizational best practices. Further validating the rationale for our research is the fact that, after the creation of our PE for PS assessment tool, in 2018, the CPSI released a guide to assist both patients/families and providers/organizations effectively partner to accelerate PS and quality efforts (in accreditation, regulations, etc.).²⁴

Consequently, this article presents the development of the PE for PS assessment tool at a system level by describing its creation process, and then discussing how it can be used by PS managers, risk managers or a task group in which patients are included, who wish to assess their PE strategies. The first part of the article presents the methodology used to create the tool in three phases. We then discuss the results and limits of our research, before formulating our conclusions.

Methodology

In order to build the PE in PS diagnostic tool, the research team followed a qualitative²⁵ validated process to ensure the questionnaire’s relevance, acceptability and reliability, internal validity and usability²⁶ according to a three-phased triangulation of: To ensure the questionnaire’s relevance, acceptability and reliability, the first two phases helped toward that objective: 1) structuring and identify themes (framework building); 2) creating a first version of the tool. To ensure the questionnaire’s internal validity and usability, the third phase was developed: 3) testing the validity and usability of the tool.

Phase 1: Structuring and identifying themes

Phase 1 firstly involved building a conceptual framework to anchor the tool around guiding principles of institutional theory (theory of change)^{27, 28} for better integration and institutionalization of PE for PS. Institutional theory seems best suited and relevant to our research questions since it integrates all research elements, including the enabling and inhibiting factors of change, which is related to change brought about by PE in terms of practice, strategies and mechanisms implemented by leaders within a given health institution. Published and grey literature were reviewed in order to better structure the conceptual framework around (i) PE best practices in healthcare institutions, (ii) factors enabling and inhibiting PE for PS, and (iii) available tools to measure PE for PS. Pertinent literature was identified through systematic searching of English-language published and grey literature covering the 2000 – 2016 time period. Our search targeted health management and social science literature using key words such as ‘patients OR users’ AND ‘engagement OR involvement OR participation’ AND ‘institutionalization or integration’ AND ‘patient safety OR risk management’. In addition to these resources, the research team reviewed internal documents on PE for PS from international organization websites such as CPSI, Accreditation Canada, the Institute for Healthcare Improvement (IHI), and the Health Foundation, because of their potential to influence PE for PS across healthcare organizations.

Phase 2: Creating a first version with support from two PS/PE experts

Phase 2 involved taking into consideration the conceptual framework’s structure and guiding principles with support from two PS/PE experts (one each working for the ministries of health in Quebec and France). Both experts commented on and reviewed all proposed questions in the tool by considering their respective governments’ priorities.

Phase 3: Testing validity and usability

Phase 3 consisted of testing the tool’s validity and usability by sending its second version to selected PS/PE experts. These experts came from three different types of

healthcare organizations in Quebec: (1) integrated university health and social service centres (free translation of *Centre intégré universitaire de santé et services sociaux* or CIUSSS); (2) non-university integrated health and social service centres (free translation of *Centre intégré de santé et services sociaux* or CISSS); and (3) university healthcare centres (UHC) which offer tertiary and quaternary care.

A total of five organizations, four in the province of Quebec, and one located in France (2 CIUSSS, 2 CISSS and 1 UHC) were selected based on their recognized work on PE and PS. The proposed tool was sent to each selected organization via email, and, more specifically, to a management duo (active at the management level) comprised of one person in charge of PE strategy and the other responsible for PS and RM. The expert duos were asked to answer all questions in the questionnaire by keeping in mind the clarity, the layout, the use, understanding and relevancy of the questionnaire, and if there are any questions missing or to be modified for better comprehension. Table 1 gives a detail of the seven questions asked the expert duos. At the end, all of their suggestions were taken into consideration in finalizing the tool.

Results

Phase 1: Structuring and identifying themes (Conceptual framework)

Theoretical framework and conceptual model based on a theory of change: the institutional theory

For this research project, the institutional theory was used not only to enable the construction of a conceptual framework (Appendix A - Conceptual Framework PE for PS), which sets out the different themes, principles and sections to be included in the tool for PE in PS.²⁷⁻³² Such an institutionalization process is initiated by establishment leaders,^{27,28} who give meaning to practices, and follows three steps. Knowledge acquisition (education, information) is followed by knowledge application and sharing by different healthcare providers (in this case, patients, HealthCare Professionals [HCP] and managers) through shared leadership and decision-making on key elements such as process design, care design, communication, training, and measurement.²⁷ Finally,

knowledge preservation is accomplished through various policies, evaluation systems, research programs, and support systems for the purpose of continued improvement.²⁷

In sum, the theoretical framework used to build our PE for PS assessment tool describes the different levels of strategies used by risk or PS managers across not only a continuum of knowledge but also multiple levels (strategic, organizational or tactical, and clinical). In addition, it shows enabling and inhibiting factors of institutionalization (integration) of PE for PS, in accordance with institutional theory pillars (regulatory and normative pillars, which are environmental elements, and the cognitive-cultural pillar defining the health organization).^{27, 31, 33, 34}

Literature review

A total of 85 articles and internal documents were found which related to PE for PS. Many of these articles concerned PE in specific health conditions or areas such as prenatal care³⁵ or PE in research.^{36, 38} In addition to these resources, the research team identified grey literature and internal documents (government articles and reports) on PE in PS from renowned Canadian and international groups.

Our literature review uncovered three main areas relevant to this project: i) implementation mechanisms and approaches for PE for safety; ii) enabling and inhibiting factors for PE for PS; and iii) available strategies for measuring PE for PS and RM at the organizational level. The research team placed particular focus on articles which included organizational level strategies, factors, tools, and were peer reviewed or systematic reviews. In total, 20 articles were retained related to strategies used for PE for PS at an organizational level.^{5, 7, 8, 11, 13, 17-19, 35-45, 47}

1. Implementation mechanisms and approaches

Our review of PE for PS revealed that PE can be considered as a continuum along which can be placed four types of patient and family engagement: informing, consulting, collaborating and co-creating. These four forms of engagement can occur in three different areas: clinical level,

Table 1. Questions asked to the duo of PE/PS experts

- Were the objective of the tool and the instructions for use clearly stated and helpful?
- Was the tool easy to use?
- Was the layout easy to follow?
- Were the questions easy to understand?
- Were there important questions missing or needing to be adapted?
- Do you think this tool will be useful for your organization? How long did it take you to complete the tool?
- Do you have any other comments on how to improve the tool?

organizational level and strategic level.^{7, 8, 12, 18, 19, 40-42, 46, 47} At the clinical level, patients can be informed and educated about risks related to medical procedures by HCPs,^{8, 12, 40, 41} managers or policy-makers. They can also be consulted about their experience, potential health risks or use of healthcare services.^{18, 40} At the organizational level, patients can collaborate to simply report adverse safety and quality events so that clinicians are made aware and can take immediate action if needed. Patients can also become members of RM or mortality and morbidity committees, task groups to analyze and evaluate incidents and accidents, and task groups overseeing incident and accident disclosure and reporting.^{7, 8, 19, 47} At the strategic level, patients can be consulted to develop various activities that can drive change in organizational culture, such as: reports providing transparent information on risks, benefits, and costs of care and treatment options; appreciation and rewards for care that fully incorporates patient and family engagement; identifying potential organizational research in which to invest; aligning incentives and penalties to support patient and family engagement; requiring patient and family engagement competencies for certification or accreditation; advancing patient and family participation through legislation; etc. Finally, co-creation between patients and professionals/managers and policy makers involves co-designing, for example, educational programs at all levels or new clinical pathways to increase patient safety.^{8, 18, 40, 41, 12} (Figure 1)

2. *Enabling and inhibiting factors*

Carman et al.,¹⁸ propose three sets of general factors that affect PE at the direct care or clinical level, organizational and strategic levels. The clinical level factors include patient characteristics such as values, knowledge, attitudes, beliefs and previous experiences. These factors can influence a patient's level of participation, just like others such as levels of education, health status, self-confidence and/or social status. Moreover, PE may also depend on HCPs and their relationships with patients.¹⁸ Indeed, HCPs may not have the incentive to include patients in their practice, especially if this has little to no impact on their remuneration model (no financial incentive), for instance.¹⁸ Additionally, there is a certain knowledge gap, or asymmetry, between HCPs and patients that may prevent both parties from addressing each other on equal terms. Patients may not be able to express themselves with as much precision about health conditions, which can hinder their ability to assert their point of view or to retain the interest of HCPs.⁷ For their part, HCPs are not always comfortable with the notion of sharing information or allowing input from patients to

question their practices. In fact, some may perceive patient participation as a hurdle in decision-making processes.⁷

The second set of factors, operating at the organizational level, concern its culture, internal policies and practices.¹² Developing specific targets with clearly-identified priorities (including: safety; effective evaluation or measures; tools to develop and adapt structures and processes to reduce dependence on individual vigilance; technological support for developing assessment measures, etc.) can help enable PE within healthcare organizations (HCOs).¹² Furthermore, when HCOs encourage the participation of relevant professionals by creating participation areas,^{12, 40} this leads to a greater sense of initiative and empowerment, encourages information sharing, and allows decentralized decision-making.⁴⁰ Creating a culture that supports partnership, as well as recognizing and flagging dangerous acts, is crucial.^{40, 48}

The third set of factors at the strategic level, concern the existence of influencing factors such as laws, regulations, policies and social norms, as well as available resources to support PE initiatives.^{12, 13, 40, 48}

3. *Measuring PE at the organizational level*

There are many ways to collect general PE information^{36-39, 43, 44, 49} (see Table 2). The literature revealed four main strategies to assess PE.

Survey-type tools examine specific components of PE, such as shared decision-making, supportive self-management (e.g. chronic disease management) and communication^{18, 39, 50} that can impact PS. Such tools have captured the development of PE in prenatal care.³⁵ They have provided a framework to describe PE in PS, to gain insight into patients' perspectives about their knowledge, comfort level and behaviors in promoting their safety while receiving health care in hospital.³⁷ They have also been used to assess the impact of engagement in research³⁸ or to evaluate patient and public involvement in health research.³⁶ These tools do not focus on PE for PS per se, but rather on self-management. Other survey tools at the organizational level assess the quality of PE or organizational culture which enables PE, trust, putting PE structures in place, etc.³⁹ The Public and Patient Engagement Evaluation Tool (PPEET), an organizational measure of its capacity for, and culture of, public and patient engagement,³⁹ does not specifically assess PE for PS despite the tool's evaluation of engagement more broadly.

Figure 1. Articles identified for PE in PS at the organizational level by the literature review

Furthermore, although these survey tools incorporate concepts of PE, none include the two concepts of PS,^{23, 51} that is, Safety I and Safety II, which are both necessary for a higher quality, safer and preventive healthcare organization.⁴⁰ For the Safety II, attention is also given to performance variability and adaptations that led to successful outcomes in the face of risk.²³ Thus, the existing survey tools found were not specific to PS.

The second strategy includes *interviews or focus groups* with patients, clinicians or managers to collect information about how PE is implemented by staff, as well as barriers to appropriate PE implementation.⁵⁰ Existing approaches were, again, not specific to PS.

Observing interactions is a third way to measure PE. This involves watching encounters between patients and HCPs to measure specific components of PE, such as communication or shared decision-making, rather than the broader concept of PE as a whole.⁵⁰ Once again, this strategy is mostly used to observe general interactions in PE, but not necessarily PE for PS.

The last approach involves *performance indicators*, such as the numbers of patients participating in intervention plans or on committees; the number and types of implemented policies involving PE for safety and RM; the types and documents designed for RM measurement created in collaboration with patients; the integration of PE indicators for safety and RM; and booklets / documents available on PE.⁵⁰

This literature review revealed four tools to evaluate PE at the clinical level in specific disease management areas and at the organizational level.³⁶⁻³⁹ (Table 2) That being said, there is a lack of tools which collect information on strategies / mechanisms at the system level of an entire healthcare institution, particularly in PE for PS integrating Safety I approach (incorporating RM practices), and safety II approach (incorporating preventative practices as well as best practices in PE in RM for PS).

Table 2. Tools to evaluate PE in PS at the organizational level

Title / Author / Year	Aim	Brief description	Where	Level
A 5-facet framework to describe patient engagement in patient safety / Duhn et al./ 2018	To gain insight into patients' perspectives about their knowledge, comfort level and behaviours in promoting their safety while receiving healthcare in hospital.	Open-ended questions were based on professional knowledge and common sense. The topics of some questions were informed by existing patient safety strategies and the study site's patient information booklet, as well as common clinical processes (e.g. administration of medication; diagnostic testing; staff hand washing). The questions were written at a Flesch-Kincaid grade level 5 to reduce the need for clarification and as part of best practice to facilitate patient understanding. The demographic questions included age; gender; reason for admission; length of hospitalization; health status; previous hospitalizations; and previous personal experience with adverse events in healthcare.	Kingston, Ontario, Canada	Organizational
Public and patient engagement evaluation tool (PPEET) version 2.0/ McMaster University / 2018	1) an Organization tool to assess the organization's capacity for, and culture of, public and patient engagement; 2) a Participant tool to obtain participants' assessments of key features of the engagement activity that they have participated in; 3) a Project tool to assess the planning, execution and impact of the engagement activity after it has been completed.	The Public and Patient Engagement Evaluation Tool (PPEET) includes three tools: the organization tool, the participant tool, and the project tool. When used together, the PPEET tools provide a comprehensive evaluation of public and patient engagement within a project and/or organization.	Hamilton, Ontario, Canada	Strategic, organizational and clinical
Methods and impact of engagement in research, from theory to practice and back again: early findings from the Patient-Centered Outcomes Research Institute (PCORI) / Forsythe et al./ 2017	To present PCORI's evaluation framework for assessing the short- and long-term impact of engagement; to describe engagement in PCORI projects (types of healthcare providers engaged, when in the research process they are engaged and how they are engaged, contributions of their engagement); and to identify the effects of engagement on study design, processes, and outcomes selection, as reported by both PCORI-funded investigators and patients and other stakeholder research partners.	An evaluation framework, as part of PCORI's evaluation plan, was developed with input from several groups representing diverse healthcare providers, including the PCORI Board of Governors, Methodology Committee, and its Advisory Panel on Patient Engagement. The full framework addresses all aspects of PCORI's work and operationalizes questions about PCORI's work in practice. The section focusing on the impact of engagement in research is the source of the research questions addressed and is organized into four areas: (1) description of engagement approaches; (2) effect of engagement on research processes and intermediate outcomes reflective of studies that matter to patients; (3) longer-term effects of engagement on achievement of PCORI's strategic goals; (4) impact of engagement in research on health.	Washington, DC, USA	Strategic and organizational
Evaluating patient and public involvement in health research: from theoretical model to practical workshop / Gibson A, et al./ 2017	To explore the practical utility of the theoretical framework as a tool for mapping and evaluating the experience of patient and public involvement (PPI) in health services research.	Three workshops were conducted with different PPI groups in which participants were invited to map their PPI experiences on wall charts representing the four dimensions of the framework. The language used to describe the four dimensions was modified to make it more accessible to lay audiences. Participants were given sticky notes to indicate their own positions on the different dimensions and to write explanatory comments if desired. Participants' responses were then discussed and analyzed as a group.	Bristol, England	Organizational

Phase 2: Building a first version

Following our conceptual framework, the first version of our tool contained 91 questions, separated in four sections:

1. Section 1 (n=16 questions) is related to the healthcare organization characteristics. It describes knowledge preservation policies, and the structure of RM and PS inside the organization;
2. Section 2 (n=16 questions) includes general questions on PE strategies and mechanisms in the healthcare organization. This section describes knowledge acquisition among the different task groups and structures in place to engage patients and their families;
3. Section 3 (n=56 questions) includes specific questions on PE strategies and mechanisms for PS in the

healthcare organization. The section pertains not only to knowledge acquisition, but also knowledge application and sharing within the different task groups and structures in place to engage patients and their families for RM and PS. The second part deals with knowledge preservation within PE policies for PS, as well as indicators and structures in place (regarding support systems, transparency and indicators used to maintain and institutionalize PE for PS);

4. Section 4 (n=3 questions) includes questions on the general appreciation of PS and the involvement of the respondents in PS committees in the organization. This section relates to knowledge acquisition, knowledge application and sharing and knowledge preservation (see Table 3 for more information).

During the month of September 2016, this first version of the tool was sent to the Ministry of Health and Social Services of Quebec (MSSS), the quality and ethical directorate, and to the Ministry of Health and Solidarity of France (the General Directorate of Healthcare Services (free translation of *Direction générale de l'offre de soins*)). The objective was to align the tool's questions with government priorities and to be sure that an important element had not been omitted. Both governments advised to integrate more questions related to PE-sensitive performance indicators for health outcomes and costs. In total, 55 questions were modified with respect to their wording, 13 were deleted and 3 questions on indicators were added. Thus, the second version of the tool had 81 questions instead of the initial 91.

Phase 3: Testing validity and usability

During September 2016, a second version of the tool was sent to five duos of experts on PE/PS, each from five different HCOs in Quebec. One duo even filled out and analyzed the tool alongside a patient who was part of their

team. After one week, a conference call was organized with each site to discuss the questions. One researcher (UAG) led all calls with the expert duos, which lasted between 45 and 60 minutes: To ensure the questionnaire's internal validity and usability, some questions were answered:

1. Relevance of the tool and questions and question comprehension: All respondents mentioned that the tool helped guide actions and could be used as a self-assessment tool for healthcare institutions. The tool is best used as a team of health care professionals (an expert in PE, RM and or PS and a patient advisor): "The tool helps us really frame our strategies and could be used as a self-assessment tool for healthcare institutions [...] It will be used for sure".
2. The tool's layout: The layout was reworked by adding specific titles to sections and spaces for comments underneath each question.
3. Important questions missing or to be adapted: Questions were added and adapted to word questions and use certain terms that were more appropriate for the Quebec context (e.g. using the term "users" instead of "patients"). Other advice was to include questions associated to policies, training, simulations, and collaboration strategies with different departments, community organizations or other entities such as an internal user committee in relation to implementation of PE in RM.
4. Clarity of instructions and of the questions: The tool's instructions were said to be clear and well understood by the team of PE professionals and patients, or PS professionals and patients, or both.
5. Time spent answering questions: The average time to complete the tool was 55 minutes.

Based on the above comments, a third version of the tool (see Table 4), totalling 81 questions, was resubmitted for

Table 3. Theoretical framework sections based on institutional theory

<p>(1) Knowledge acquisition</p> <p>Knowledge is created for patients, HCPs, and different strategic managers (e.g. through workshops, training and education on disease management, RM / safety, and on PE in risk management / safety);</p>
<p>(2) Knowledge application and sharing</p> <p>Managers involve and engage patients in different task groups, committees and teams for shared decision-making on process design, care design, communication, training, and measurement (e.g., reporting and disclosure process for medical errors, PE in PS and quality improvement plans, processes, monitoring, etc.). Patients could also be engaged in incident management (immediate response, disclosure, analysis, follow-up, shared learning, engagement in quality and safety committees, assurance reviews, implementing recommendations, etc.).¹⁴</p>
<p>(3) Knowledge preservation</p> <p>Managers and the healthcare institution not only engage patients in the creation of different PE policies, evaluation systems, research programs, and support systems, but also create a culture of safety, transparency, and collaboration among teams (which include patients). An evaluation framework containing measures and indicators is developed as well.</p>

Table 4. Final layout of the tool (81 questions)

Section 1	General questions (Number of questions = 14)
Knowledge preservation* - -	› People working in patient engagement (PE) in patient safety (PS)
Descriptive questions about the organization	› Number of years employed
	› Training received
	› Structure of PE in PS: e.g., department responsible for PE in PS
Section 2	Questions related to PE strategies in general (Number of questions = 15)
Knowledge acquisition*	› PE activities
	› Structure and strategies used to engage patients
	› Organization and committees
Knowledge application and sharing*	› Training
	› <i>Simulations</i>
	› <i>Collaboration with different departments or community organizations</i>
	› User committee
Knowledge preservation*	› Indicators: implementation, planning and performance
	› Transparency
	› <i>Policies</i>
Section 3	Questions related to RM and PS (Number of questions = 49)
Knowledge acquisition*	› PE activities
	› Structures used to engage patients
	› <i>Organization and committee</i>
Knowledge application and sharing*	› Training
	› <i>Simulations</i>
	› <i>Collaboration with different departments or community organizations</i>
	› User committee
Knowledge preservation*	› <i>Indicators (implementation, planning and performance)</i>
	› Transparency
	› <i>Policies</i>
Section 4	General information of the implication of the people answering the tool (Number of questions = 3)
Knowledge application and sharing & knowledge preservation*	› <i>Participation of management in PS committees</i>
	› <i>Additional comments</i>

*These titles do not appear in the tool; they are intended to provide structure to the reader of this article, according to the guiding principles of the institutional theory of change within the conceptual framework for the integration of PE for PS.

final approval to the committee of experts composed of the 5 Québec duos of PE and PS managers. (Table 4)

Discussion and Limits

A patient engagement tool for patient safety

This tool is the first to be dedicated to managers or task groups (which could include patients) to assess different strategies meant to enhance PS, as well as to track change over time. The tool finds its originality in the fact that risk/PS managers, in collaboration with patients, can assess PE, and then support and deploy strategies and mechanisms based on best practices in order to optimize efforts for PS and results within the organization and

inter-organizations. It integrates PE strategies for PS at different governance levels of the organization, supported by a change management theory which helps decision makers / leaders / managers integrate strategies into their organizational practices over time. Additionally, the tool can help accreditation organizations assess institutions' PE for PS over time. Moreover, the tool also exposes positive deviants or best practices (using not only a "Safety I" but also a "Safety II" approach)²³ through its data collection on factors, mechanisms and strategies implemented in the HCO which help fully institutionalize (integrate) PE for the enhancement of PS.

Updated with complementary tools

In fact, since the tool was created in 2016, our research team has been able to adapt and integrate into the tool many points mentioned in the literature review (from 2016 to 2018) such as the literature on “Engaging Patients in Patient Safety – a Canadian Guide” which came out in 2018,²⁴ (p. 63) and other contemporary tools such as that used by the American Institute for Research,⁵³ which contains an inventory of PE measures at the organizational level. According to the latter organization, key elements for measuring PE at the organizational level include leadership support, participation of patients and families in organizational partnership, having policies in place, and the type of structures set up to enable patient and family participation. This Institute also mentions tools available to measure and collect data, ongoing initiatives, and how to recruit patient partners and health professionals who support PE structures. Indeed, all of the above-mentioned elements were incorporated in our PE in PS assessment tool. Despite not being specific to PE in PS at the organizational level, such elements assisted our validation of various sections of our assessment tool.

The preliminary user testing and confirmation of tool’s face validity

To ensure that the tool fulfilled its intended objective, the research team followed and met a set of qualitative criteria.²⁵ As a first qualitative criterion, the project’s internal validity (i.e., whether conclusions drawn through the tool’s questions are warranted or not) was enforced through the tool’s questions: 1) their relevance for the HCO (i.e. did the questions help HCOs structure PE initiatives in PS; and did the tool help risk and safety managers track change and initiatives of PE in PS?); and 2) whether solicited experts were able to understand and answer questions posed by the tool and felt that all important components were present. Moreover, data from the literature review which informed the tool’s development were drawn from multiple international data sources and were subjected to a rigorous critical analysis. The construction of the tool was carried out by triangulation of: (1) the combined use of a conceptual framework and a literature review; (2) the construction of a first version of the tool and its alignment with cross-jurisdictional priorities; and (3) mobilizing experts in PE and PS to test the tool and its usability.

As for transferability, the tool is currently being used in a province-wide research project and was sent to all integrated healthcare institutions in Quebec (n=24).

The tool’s limits

One of the limits of our PE for PS tool is the fact that, as created, it was not intended to be used by patients alone but rather by healthcare professionals and managers working in RM or PS or by a task group (on which patients might be present). However, if a patient were to

be part of a working group, he or she would be capable of answering the tool alongside healthcare professionals as a team or as part of a trio. In fact, one of the expert teams in Quebec who tested the tool during phase 3 involved a patient advisor.

Secondly, our tool does not address the quality and culture of PE within the organization in detail, nor how PE could instill trust in an organization. Rather, it focuses more on what should be done in order to institutionalize PE in PS. The tool can be used in a complementary manner alongside other tools in order to evaluate such aspects in more detail. These other tools include the American Institute for Research inventory of PE measures at the organizational level,⁵³ and the Evaluate Team Collaboration Skills tool, a toolkit for not only engaging patient and families at the planning level, but also assessing collaboration over time by taking into consideration diversity, structure of participation, and trust.⁵⁴ Other complementary tools are the Engaging Patients in Patient Safety guide which provides strategies for organizations that need to implement PE in PS,²⁴ and the PPEET³⁹ which assesses the quality of PE at the organizational level through “integrity of design and process.”

Thirdly, the tool’s focus on PE for PS assessment in Quebec’s integrated healthcare context may limit its applicability to non-Canadian settings and to healthcare organizations that focus on smaller and more specific populations. While the tool principally relies on Canadian experience, we attempted to balance this aspect with an extensive review of the international literature, which also informed our work, and by diversifying the groups testing the tool through participating partner organizations (e.g., from major urban centres as well as regional referral centres). Also, by involving a counterpart from France, an international setting was included in our research. Participating practice partners in France have already begun to use our PE for PS assessment tool. The tool could potentially be used, in translation, by any healthcare organization in the world.

The limits identified above reflect a balance between the application of rigorous methods and relevance to practitioner needs. In light of the considerable investment being made in PE for PS in HCOs around the world, this early step is critical for ensuring that this rapidly evolving field is supported by a strong foundation of evidence. As we continue to experiment with this tool, we expect it to be not only used by managers in PE and for PS, but also by teams that bring together PE/PS managers and patient advisors. Understanding how the tool is perceived by managers, patients and the public will contribute to its improvement over time. You can access the assessment tool here: (Appendix B - Questionnaire PE for PS -French version).

Conclusion

The fairly preliminary user testing and confirmation of the PE for PS tool face validity by experts gave birth to the development of a tool which has implications for practice and research. This tool which assesses for the first time PE strategies in patient safety supports decision-making by healthcare leaders and updates existing PE for PS modalities. There is no other such tool available at present to collect this type of information at the organizational or system level. The tool also offers an opportunity to allow managers in collaboration with patient's advisors in health care organizations to track PE changes in safety strategies over time by repeated assessments within the organization. PS/RM and PE Managers can use this tool to gain an important PE perspective on safety, capturing areas of weakness that might otherwise go unreported or unidentified. Furthermore, such a tool can be used to compare results and to develop standards or best practices for PE in safety improvement. Currently, as part of its "Global Patient Safety Challenge", the WHO encourages healthcare institutions around the world to "*reduce the level of severe, avoidable harm related to medications by 50% over the next five years.*"⁵⁵ Our tool could be adapted and adopted by healthcare institutions taking on the WHO's challenge, and could be integrated into international standards or even best practices of PE for safety.

While the PE for PS assessment tool is currently in French (Appendix B - Questionnaire PE for PS -French version), an English adaptation will be soon available since a pilot project has been completed in English-speaking provinces in Canada during the Fall 2020 as well as a psychometric analysis of the tool. An article presenting the adaptation of the French version of the tool to the English version will be published in 2021. As evidenced by existing research, patient and family engagement offers a promising pathway towards better, safer healthcare, as well as improved population health.

Declarations

Ethics approval and consent to participate: The research protocol was approved by the University of Montreal ethics committee and the *Centre de Recherche du Centre Hospitalier de l'Université de Montréal*. Approval number: MP-02-2017-6814 -- CÉR CHUM Number: 16.189.⁴⁰

Consent for publication: We received a signed consent form from all 5 duos participants who took part in our study, and who are also involved in ongoing research projects.

Availability of data and material: All data generated or analyzed during this study are included in this article, and the end result is the assessment tool which is available in

French. You can access the assessment tool here (Appendix B - Questionnaire PE for PS - French version)

Conflicts of interest: None to declare.

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Authors' contributions: Both of the first authors (UAG and MPP) were involved in building the tool. UAG performed data analysis, interpreted the literature review and carried out the interviews. MPP assisted with identifying themes and elements which were important to consider. MPP connected the team with experts in RM / safety and PE. UAG was responsible for writing the study protocol, assisted by MPP. KB reviewed the article and helped in building the methodology of the English version of the questionnaire. MRG, helped with the literature review of the article.

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Questionnaire PE for PS - French version

You can access and review the full questionnaire as supplemental information here.

List of Abbreviations

AE: Adverse Events

CISSS: integrated health and social service centres (free translation of *Centre intégré de santé et services sociaux*)

CIUSSS: integrated university health and social service centres (free translation of *Centre intégré universitaire de santé et services sociaux*)

CPSI: Canadian Patient Safety Institute

DQEPE: Directorate of Quality, Evaluation, Performance and Ethics

HCP: Healthcare professional

HCO: Healthcare Organizations

IOM: Institute of Medicine

MSSS: Quebec's health and social health ministry

OECD: Organization for Economic Co-operation and Development

PE: Patient engagement

PS: Patient Safety

PP: Patient partner

PPEET: Public and Patient Engagement Evaluation Tool

RM: Risk Management

UHC: university healthcare centre

USA: United States of America

WHO: World Health Organization

Footnotes

[1] The World Health Organization (WHO) and its conceptual framework for the International Classification for Patient Safety (ICPS), define risk management (RM) as "*activities or measures taken by an individual or a healthcare organization to prevent, remedy or mitigate the occurrence or reoccurrence of a real or potential (patient) safety event*."^{11, 48}

[2] A "medical error" (or simply *error* here) is a *failure to carry out a planned action as intended or an application of an incorrect plan. Errors may occur through doing the wrong thing (commission) or by failing to do the right thing (omission), at either the planning or execution phase*.³⁹

[3] An "incident" is a situation in which harm was caused but no damage occurred.³⁹

[4] An "accident" is a situation in which harm was caused and damage occurred.³⁹

[5] The process of comparing a patient's medication orders to all of the medications that the patient has been taking.

This reconciliation is done to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions.

<https://www.ncbi.nlm.nih.gov/books/NBK2648/>

Appendix A. Conceptual Framework of PE for PS

Regulating pillar	Cognitive-cultural pillar			Normative pillar
	Knowledge acquisition	Knowledge application and sharing	Knowledge preservation (culture is installed)	
Micro or clinical level of engagement	<u>Patient and family education / information and preparation on PE in risk management (structure-process, roles)</u> - Educate and prepare patients, families and staff to engage with health care organization and systems through the implementation of support mechanisms (Educate about culture of no-blame and risk management; organization structure, tools available, etc.) <u>Clinicians / leadership education / information and preparation on PE</u> - Educate and Integrate patient and family engagement into the healthcare professions curriculum (role learning) - Develop standardized patient and family engagement competencies	- Patients report adverse safety and quality events (rapid response teams, etc.) - Patients and families are invited to coach / train other patients with their disease management and risks identification Patients and families are able and capable to report health risks and incidents / accidents related to their health. - Patients are part of clinical teams - Mechanisms to support communication of adverse events	- Develop continuously curriculum / training programs in PE in risk management. Develop training programs that explain roles, explain organizational structure, quality and risk management improvement processes - Support systems in communication. Mechanisms that help Clinicians elicit, understand, and respect patient perspectives and concerns (active listening, patient coach, etc.) - Available resources in PE (booklet, guide, jobs in PE, etc.) - Clinicians' task and job description integrate PE - Develop recruitment that enable the ongoing identification and selection of effective patient and family advisors	
	Role learning, health literacy & knowledge, education, competency			Factors
	Measurement: 1- Implement additional measures of patient-level experiences, goals, and outcomes. Patient-reported outcome measures. Capture patient and family experiences and satisfaction with Decision-support tools and the outcomes of shared decision making via, for example, the use of a direct feedback loop.			Indicators
Meso or organizational level of engagement	- The organisation asks patients about their experiences when tackling services, planning, design in risk management (surveys are used)	- Patients are engaged on different group work tasks, committees in risk management.	- Documents exist in eliciting structure care processes to support patient and family involvement in care planning and self-management (e.g., Dedicate staff and create departments to oversee work with patient and family advisors Patients co-lead safety and quality improvement committees) - Communication and technology to coordinate activities in-between departments - Quarterly reports on PE in risk management / ongoing activities, etc.	
	Practice, culture (risk management, culture of no blame)			Factors
	Measurement: 1- Implement measures that assess the process of patient and family engagement—how and to what extent engagement occurs. 2- Create feedback mechanisms (using measures) to help plan patient care, provide real-time, personalized feedback to clinicians and organizations, and drive changes. 3- Conduct research on how engagement leads to outcomes, including improved health, quality, cost, or staff satisfaction.			Indicators
Macro or strategic level of engagement	- Provide access and transparency on annual report concerning information about risks, benefits, and costs of care and treatment options	- Patients and families are on the board of Directors and user committees and share decision	- Develop organizational policies that specify families as full members of the healthcare team. - Policies about transparency (information about risks, benefits, cost of care and treatment options, access to medical record) - Provide recognition and rewards for care that fully incorporate patient and family engagement - Require patient and family engagement competencies for certification or accreditation.	
	Policies, transparency, access to information (report, board of directors)			Factors
	Measurement: 1- Policies in place, 2- measures that evaluate number of decision taken with patients and families, 3- availability and access of report			Indicators