Patient-reported symptom monitoring: using (big) data to improve supportive care at the macro-, meso-, and micro-levels

Yan Wang[1,2], Matthew J. Allsop[3], Joel B. Epstein[4,5], Doris Howell[6], Bernardo L. Rapoport[7,8], Penelope Schofield[9,10,11], Ysabella Van Sebille[12], Melissa S.Y. Thong[13], Iris Walraven[14], Julie Ryan Wolf[15], Corina J.G. van den Hurk[16,*]

[1] Department of Health and Community Systems, School of Nursing, University of Pittsburgh, 3500 Victoria Street, Pittsburgh, PA 15261, USA

[2] Mckinsey & Company, 1 PPG Pl # 2350, Pittsburgh, PA 15222, USA

[3] Academic Unit of Palliative Care, Leeds Institute of Health Sciences, University of Leeds, 6 Clarendon Way, Woodhouse, Leeds LS2 9LH, UK

[4] City of Hope Comprehensive Cancer Center, 1500 East Duarte Road, Duarte, CA 91010, USA

[5] Cedars-Sinai Medical Center, 127 S. San Vicente Blvd., Pavilion, 7th Floor, Los Angeles, CA 90048, USA

[6] Princess Margaret Cancer Research Institute, 610 University Avenue, Toronto, ON M5G 2M9, Canada

[7] The Medical Oncology Centre of Rosebank, 129 Oxford Road, Saxonwold, Johannesburg 2196, South Africa

[8] Department of Immunology, Faculty of Health Sciences, University of Pretoria, Corner Doctor Savage Road and Bophelo Road, Pretoria 0002, South Africa

[9] Department of Psychology, and Iverson Health Innovation Research Institute Swinburne University, John St, Hawthorn, VIC 3122, Australia

[10] Health Services Research and Implementation Sciences, Peter MacCallum Cancer Centre, Melbourne, 305 Grattan Street, Melbourne, VIC 3000, Australia

[11] Sir Peter MacCallum Department of Oncology, University of Melbourne, Grattan Street, Parkville, Victoria 3010, Australia

[12] University of South Australia, 61-68 North Terrace, Adelaide, SA 5000, Australia

[13] Unit of Cancer Survivorship (C071), German Cancer Research Center (DKFZ), Im Neuenheimer Feld 581, 69120 Heidelberg, Germany

[14] Department of Health Evidence, Radboud University Nijmegen Medical Center, Geert Grooteplein Zuid 10, 6525, GA, Nijmegen, The Netherlands

[15] Department of Dermatology, Department of Radiation Oncology, University of Rochester Medical Center, 601 Elmwood Ave, Box 697, Rochester, NY 14642, USA

[16] Department of Research and Development, Netherlands Comprehensive Cancer Organization (IKNL), Rijnkade 5, 3511, LC, Utrecht, The Netherlands

*Correspondence to Corina J.G. van den Hurk. Email: C.vandenHurk@iknl.nl

Abstract

Purpose: This paper aims to provide a comprehensive understanding of the need for continued development of symptom monitoring (SM) implementation, utilization, and data usage at the macro-, meso-, and micro-levels.

Methods: Discussions from a patient-reported SM workshop at the MASCC/ISSO 2022 annual meeting were analyzed using a macro-meso-micro analytical framework of cancer care delivery. The workshop categories "initiation and implementation, barriers to adoption and utilization, and data usage" were integrated for each level.

Results: At the macro-level, policy development could encourage data sharing and international collaboration, including the exchange of SM methods, supportive care models, and self-management modules. At the meso-level, institutions should adjust clinical workflow and service delivery and promote a thorough technical and clinical integration of SM. At the micro-level, SM should be individualized, with timely feedback for patients, and should foster trust and understanding of AI decision support tools amongst clinicians to improve supportive care.

Conclusions: The workshop reached a consensus among international experts on providing guidance on SM implementation, utilization, and (big) data usage pathways in cancer survivors across the cancer continuum and on macro-meso-micro levels.

Keywords: Symptom monitoring; Real-world data; Supportive care

Introduction

Remote patient-reported symptom monitoring (SM) and alert algorithms have been shown to improve the clinical outcomes of cancer patients and survivors [1, 2]. However, there is significant variability in SM data collection and application during and following cancer treatments [3,4,5,6]. Implementation and utilization challenges, such as integrating SM into clinical workflows, are also identified in the literature [3, 7, 8]. While extensive research addresses the primary use of the individual's SM data in daily patient care [1, 3], secondary data usage at an aggregated level for research and decision-making remains underexplored. To further inform future studies, we will summarize information from the workshop, "Defining Common Methodologies for Patient-Reported Symptom Monitoring – Collecting and Using (Big) Data to Improve Supportive Care," associated lectures and focus group discussions at the MASCC/ISSO (Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology) 2022 annual meeting.

This commentary will focus on addressing the implementation, utilization, and data usage of SM using a macro-meso-micro analytical framework of cancer care delivery for digital patient-reported data to inform decision-making [6]. At the macro-level, SM is implemented at the overall healthcare system level, and preferably, population-based data is used by government leaders to inform health coverage policies, such as provision, accessibility, and reimbursement. At the meso-level, SM is implemented at the institutional level, and the data is utilized for quality improvement across a whole disease site population and performance monitoring of

healthcare services. Finally, at the micro-level, SM is implemented in clinical practice, and this is the primary use of data to inform clinical decisions about an individual patient's care.

Table 1. Initiation and implementation, potential barriers to adoption and utilization, and data usage of symptom monitoring at macro-, meso-, and micro-levels

	Symptom monitoring
Macro[a]	**Initiation and implementation: create or review policies and regulations** • Assess existing evidence-informed programs or practices (e.g., evaluation of innovative medicines). • Involve consumers/intended users in the design and implementation process to establish data collection at the institutional level. • Share data and collaborate across institutions and countries for supportive care (e.g., improving interoperability of apps and electronic health records, standardizing core datasets of symptom monitoring, collecting big real-world data, and facilitating linkage using unique identifiers. • Initiate and facilitate international collaboration and data-sharing models for supportive care. • Regulate the price and reimbursement of EHR PRO tools • Regulate how companies that provide EHR technologies collect, use, and share patient data. • Develop approaches to mitigate the digital divide and macro-level health disparities to improve the accessibility and usability of ePRO approaches. • Add billing codes to respond to patient-reported symptom alerts to improve the accuracy and efficiency of alerts and the timeliness of patient self-management guidance. **Potential barriers to adoption and utilization** • Lack of evaluation of existing evidence-informed programs or practice. • Lack of reimbursement for symptom monitoring in health insurance. • Lack of collaboration and implementation programs to guide context-appropriate adaptation of supportive care between high and low-resource settings. • Lack of equity of access and differing quantity and quality of symptom monitoring resources in different regions and nations, influencing symptom monitoring adherence and engagement. • Lack of requisite interoperability, data sharing, or linking across institutions to enable data to be used on the macro level, such as dataset harmonization. • Potential different data protection regulations in different regions or countries. • Lack of flexibility of ePRO tools and potential to be cost-prohibitive. • Lack of understanding of the overall needs and preferences of patients experiencing new types of treatment, such as immunotherapy. **Data usage** • To inform healthcare policy, such as healthcare coverage, inclusion provision and reimbursement of healthcare services, capacity planning, and regulatory affairs.
Meso[b]	**Initiation and implementation: service change, clinical workflow adoption, and technical integration** • Adapt and adopt an evidence-informed program or practice to promote the preferred changes in symptom monitoring and management (e.g., standard operating procedures for alert triggers and refining existing alert management and algorithms). • Create a designated leadership that identifies remote symptom monitoring and management as a core service and engages key stakeholders, such as insurance companies. • Define success alongside monitoring and identifying barriers and facilitators to its attainment using hospital data. • Reconfigure workflows to embed symptom response in the service model, such as patient enrollment, clinical pathway responses to and management of alerts, a central pool (centralized triage) for handling symptom alerts, and standard operating protocols for symptom escalation. • Consider acceptability and sustainability (e.g., number of patients enrolled, clinicians' adherence to timely response) alongside monitoring adoption and implementation outcomes (e.g., implementation fidelity, future goals, and deliverables). • Choose a comprehensive technical infrastructure and applications that facilitate the collection, analysis, and presentation of patient-reported symptoms, alongside enabling timely patient feedback. **Potential barriers to adoption and utilization** • Poor system quality (e.g., malfunctions), integration, and a lack of foundational, structural, and semantic interoperability. • Lack of continuous support to clinicians and staff in the workflow and service-level changes, such as poor training and a lack of involvement in the development and implementation phases. • Poor data quality, storage, and security. **Data usage** • Use individual and aggregated data to combine with HRQoL and clinical data to guide quality improvement in routine care and clinical practice, decision-making and health technology assessment, performance monitoring, accreditation of different healthcare services or organizations, caseload evaluation, and future care planning.
Micro[c]	**Initiation and implementation: consumers' (patients' and clinicians') involvement** • Engage consumers from the start and throughout the codesign of a monitoring system to encourage its context-appropriateness and alignment with consumers' needs. • Communicate machine learning approaches in ways that aid interpretation, understanding, and trust by clinicians to promote adoption. • Tailor selection of ePRO questionnaire sets and timing for optimal relevance among patients with different characteristics. • Leverage the technology to adapt existing measures, such as exploring multimedia PROMs (mPROMs) with audiovisual components that may better suit mixed-literacy populations. • Train clinicians to assess, act, engage, and map clinical guidelines to symptom severity and provide patients with timely and actionable self-management advice.

Potential barriers to adoption and utilization

- Low awareness of ePROs among consumers, both patients and clinicians.
- International, national, and regional digital divide, social disparities, health service inequity, and variations in the influence of digital health literacy on patients' adherence and engagement.
- Patients' concerns regarding data security, handling, usage, and fear of exploitation.
- Increased patient burden to complete routine and standard questions.
- Failure to integrate patients' inputs and prioritize individual goals.
- Disbelief and distrust in AI models and approaches when algorithms are used to alert and generate self-management guidance.
- Insufficient time investment from clinicians.

Data usage

Aggregated data

- To build AI prediction models to support clinical decisions and improve supportive care, such as improved patient outcomes (e.g., clinical, HRQoL, costs), health risk detection, triage, and intervention.
- To inform the design, development, evaluation, and revision of symptom monitoring.

Individual data

- To understand patients' needs and preferences to improve communication between patients and clinicians (e.g., to prioritize unmet needs).
- To gain longitudinal insights into current and previous results to inform clinical practice and support decisions for patient care (e.g., treatments, goals of care, continuation, the addition of interventions, and supportive care).
- To provide real-time tailored patient feedback through automatically generated alerts and appropriate interventions.

[a]Focuses on the healthcare system and policy; [b]focuses on the implementation framework on the institutional level; [c]focuses on the individual patient

PRO Patient-reported outcomes, ***ePRO*** electronic patient-reported outcomes, ***PROM*** patient-reported outcome measures, ***mPROMS*** multimedia patient-reported outcome measures, ***EHR*** electronic health record, ***HRQoL*** health-related quality of life

Methods

The MASCC workshop was conducted as a preregistered session, open to all attendees. Presenters initially delivered information on various topics, after which participants engaged in semi-structured, round-table discussions organized into sub-groups. The collaborative discussions covered SM initiation and implementation, barriers to adoption and utilization, and data usage across the macro-meso-micro levels (Table 1). The workshop attracted 25 participants (clinicians, nurses, researchers, and patient advocates) from diverse countries, each bringing a unique experience level in remote SM. The content analysis of the discussion was conducted by one author (YW), with validation of the results performed by the senior author (CH).

Results

Table 1 illustrates the workshop-discussed aspects of SM for "initiation and implementation," "barriers to adoption and utilization," and "data usage." At the macro-level, implementation of SM requires examination of critical issues, including symptom assessment scales, existing disparities in healthcare access and digital literacy, the number and quality of healthcare services available, and SM resources at different institutions and regions. Social disparities (e.g., socioeconomic status, internet access, age) must also be considered due to their strong association with patients' health and digital literacy, which could affect their SM adherence and involvement [9]. Furthermore, the broader constraints of the health system in the context of a country should be considered, with a need for policies to guide the implementation and adaptation of programs from high- to low-resource settings.

Data usage, policy development, utilization of funds for health care, and modification at the macro-level, such as healthcare coverage, could be supported by recent large-scale real-world data at the meso- and micro-levels. Additionally, the use of data at the macro-level can only be realized if international collaboration is established and data is standardized and freely shared across institutions, regions, and countries. This could be complicated as different countries might have different data protection regulations. Crucially, data sharing at the macro-level necessitates the usage of standard methodologies to ensure data quality and protection.

Therefore, at the meso-level, institutions should pursue agreements with electronic health records and patient-reported technology companies to facilitate and enable data collection and sharing. Additionally, policies are necessary to allow individuals to control their data, including the right to access and correct. For countries with health insurance, implementing billing codes that respond to symptom alerts can improve the accuracy and efficiency of alerts by streamlining the identification and tracking of specific symptoms. Lastly, macro-level data informing explainable artificial intelligence (XAI) requires enhanced training with diverse real-world examples. This promotes micro-level SM data integration. Moreover, leveraging macro-level data identifies and mitigates biases in AI models, ensuring unbiased explanations across demographics thereby enhancing clinical care delivery at the meso-level.

At the meso-level, the workshop determined that efforts should be directed toward service and clinical workflow changes during the implementation process rather than focusing solely on monitoring technology uptake. This requires service reconfiguration and the use of best practices in remote SM service, along with behavior change that involves appropriate clinician training and sufficient support to ensure they use the data effectively for personalized treatment plans and improved access to supportive care. Examples include standard operating procedures for responsibilities in handling alerts, linking to triage recommendations [10], or rearranging deployment of clinical staff or materials. As a result, institutes should use a multidisciplinary care model and form a team with a designated leader. This team should recognize SM as a core service, assess the cost of care and potential cost savings, engage critical stakeholders, incorporate strategies to enhance patient engagement and adherence, and ensure that the service benefits patients rather than just an entity for data collection [11]. Furthermore, this team should pay attention to the continuous support for clinicians, nurses, and other personnel, as well as adequate system integration, data quality, security, and usage to promote the viability of SM at the meso-level.

While micro-level data can inform SM's design, development, and revision at the meso-level, establishing a robust infrastructure at the meso-level is imperative. This infrastructure should encompass data storage, security, privacy, ownership, and a standardized methodology for data analysis on a larger scale. These infrastructure and methodological considerations should be integral to future SM implementation processes. Finally, data usage at the meso-level could emphasize benefits from combining symptom outcomes with health-related quality-of-life data and clinical data to assist institutional quality improvement, performance monitoring, accreditation of different healthcare services, caseload evaluation, and future care planning. These opportunities apply to the whole cancer patient population in a hospital.

At the micro-level, workshop discussions highlighted the importance of utilizing technology in SM to personalize individual patient needs, such as scheduling the frequency and timing of questions, providing individualized feedback, and introducing self-enrollment via open-source apps. The workshop also emphasized care equity and assistance for vulnerable and underserved patient populations, such as using passive monitoring with wearables, multimedia patient-reported outcomes measures, or tailoring the content and presentation of questionnaire items for cancer patients with low literacy [12], elderly, or comorbidities. Additionally, to ensure that new interventions are implemented appropriately, researchers need to understand the essential patient needs [13,14,15,16] and meaningfully co-design with patients and healthcare providers throughout the development and implementation of SM approaches. This is why the discussion at the workshop could have benefited from more significant involvement of patients and patient advocates. While the ease of use versus validity of SM tools was not explicitly discussed, we acknowledge the inherent tension between these attributes. Addressing this tension in future

studies is crucial to facilitate large-scale data usage at the meso-level, where valid data are required. While the workshop did not discuss data protection and medical device regulations for SM, we also acknowledged the potential variations across different countries that might introduce barriers to adoption [17].

Lastly, the discussion highlighted the importance of micro-level SM data for developing AI decision support tools. This comprises models that anticipate symptom worsening and the frequency of follow-up care based on symptom burden throughout the treatment phase. With follow-up including clinical and patient-reported data and novel statistical techniques (e.g., latent class growth modeling and joint modeling) [18], researchers may be able to detect inherent subgroups that may not have been otherwise identified. However, healthcare professionals must understand, trust, and value decision support technologies to accept and utilize these tools at the micro-level [19]. Therefore, transitioning towards more explainable AI is necessary to make these models more interpretable for clinical practice.

Conclusion

Understanding the pathway of SM implementation, utilization, and (big) data usage across macro- to meso- and micro-levels is required to optimize its role in symptom prevention and management. Key stakeholders must be involved early in SM co-designing at all three levels, including patients, clinicians, institutions, government, and payors. Policies are needed at the macro-level to encourage data sharing and international collaboration, including exchanging methods for SM, supportive care models, and self-management. To assist the long-term implementation of SM, institutions should appoint a team to adjust clinical workflow and service delivery to guide a thorough technical and clinical integration at the meso-level. Finally, at the micro-level, SM must be individualized with real-time patient feedback and trust and understanding of AI decision support tools that are practical and pragmatic and foster use by clinicians to improve supportive care.

Contributions

All authors contributed to the conception and design as speakers and contributors to the workshop and discussed the current manuscript's primary outcomes. The first draft of the manuscript was written by Yan Wang, supervised by Corina van den Hurk, Julie Wolf, and Matthew Allsop. All authors commented on previous versions of the manuscript and have read and approved the final manuscript.

Competing Interests

Dr. van den Hurk received institutional implementation and research grants for symptom monitoring from AstraZeneca, Boehringer-Ingelheim, Bristol Myers Squibb, Ipsen, and Merck. Dr. Doris Howell is on the Scientific Advisory Board of Carevive Systems, Inc. and has been a consultant to this company in previous years.

Data Availability

The data that support the findings of this study are available on request from the corresponding author.

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