Users’ Guide to Integrating Patient-Reported Outcomes in Electronic Health Records

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INTRODUCTION

There is increasing interest in integrating patient-reported outcomes (PROs) in electronic health records (EHRs), but best practices for doing so are unclear. Recently, several meetings have reviewed the use of PROs in EHRs and identified barriers to routine collection of PROs for EHRs.

PROs are defined as the patient’s report of the impact of health, disease, and treatment from the patient perspective, generally collected via questionnaires. While there are both other types of patient-reported information (e.g., patient experience with care, alcohol use) and other sources of patient-generated data (e.g., fitness trackers, at-home blood pressure monitors), we are defining PROs specifically as patients’ direct reports of symptoms, functioning, health-related quality of life, and so on using standardized questionnaires. However, many of the issues addressed here also apply to other types of patient-generated health information.

In the EHR, PROs can be reported and used in the context of a patient’s other health data (e.g., laboratory reports, imaging studies, clinic notes) to promote patient-centered care in a number of ways – including individual patient management, quality of care evaluations, research, value-based purchasing, and population health. All of these applications of PROs can be facilitated by integrating them into the EHR along with the patient’s other health information. For the purposes of this project, we are defining an EHR as follows (modified from the Healthcare Information and Management Systems Society and Wikipedia):

The Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. The EHR gives patients, physicians and other health care providers, employers, and payers or insurers access to a patient’s medical records across facilities. The EHR has the ability to generate a complete record of a clinical patient encounter for use in care-related activities, as well as evidence-based decision support, quality management, and outcomes reporting.

To facilitate the inclusion of PROs in the EHR, and address the barriers to doing so, a multidisciplinary team was formed to develop this “Users’ Guide for Integrating Patient-Reported Outcomes in Electronic Health Records.” It addresses 11 key questions for integrating PROs in the EHR:

1. What strategy will be used for integrating PROs in EHRs?
2. How will the PRO-EHR system be governed?
3. How can users be trained and engaged?
4. Which populations and patients are most suitable for collection and use of PRO data, and how can EHRs support identification of suitable patients?
5. Which outcomes are important to measure for a given population?
6. How should candidate PRO measures be evaluated?
7. How, where, and with what frequency will PROs be administered?
8. How will PRO data be displayed in the EHR?
9. How will PRO data be acted upon?
10. How can PRO data from multiple EHRs be pooled?
11. What are the ethical and legal issues?

The target audience for this Users’ Guide is administrators, clinicians, researchers, information technology (IT) professionals and others who may be considering adding PROs to their EHR, or optimizing use of PROs in their EHR.

This initiative builds upon the International Society for Quality of Life Research (ISOQOL) “Users’ Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice” and uses a similar approach -- but focuses specifically on integrating PROs in EHRs. Rather than recommending one “right” way, various options are discussed in the context of their relative advantages and disadvantages. Notably, the distinctions are not always clear cut, and advantages in some circumstances may be disadvantages in others, and the impact of the advantages and disadvantages depends on how they are handled. Organizations can evaluate which approaches fit best within the context of their environment. Users who are unfamiliar with PROs may find it helpful to review the ISOQOL Users’ Guide first.

To illustrate the range of approaches for integrating PROs in the EHR, see Boxes 1-3, with different case studies. These cases represent examples of approaches and should not be generalized to all applications. They are not intended to be universally applicable to all PRO-EHR systems at their respective levels of integration.

For each of the topics covered in the Users’ Guide, it may make sense to implement more than one approach, as many of the options are not mutually exclusive. Each section of the Users’ Guide also identifies information gaps/research questions and useful references/resources. A compiled Bibliography of the references/resources is included at the end. Finally, the Users’ Guide provides a framework, which can facilitate collaboration by multiple institutions/groups to collect PROs in EHRs in a way that the data can be shared and pooled.

However, this is a Users’ Guide, not a Technical Manual, and integrating PROs in EHRs requires a multi-disciplinary approach. At the most basic level, the Users’ Guide should help those who are interested in integrating PROs in their EHRs think through the considerations involved, help them evaluate the various options and their relative advantages/disadvantages, and inform their decision-making regarding what will work best in their own environment. Implementing PRO-EHR integration will also require technical input and training for the IT builders and analysts.

This Users’ Guide is the product of a multi-stage process. First, we formed a Steering Group (Appendix 1), that advised on the overall strategy, developed a list of the key questions to be addressed in the Users’ Guide, and helped identify appropriate experts to address these questions. For each question, two experts with complementary backgrounds and expertise were selected, with the total group of 22 forming the Working Group (Appendix 2). Some
Steering Group members also serve as Working Group members. The Steering/Working Group met in person in September 2016 to review initial thoughts on the options for each of the questions, providing an opportunity for all of the experts to offer insights early on. A series of conference calls was held with the Steering/Working Group to review draft sections. In addition, the question list and draft Users’ Guide were circulated for comment, both within the Steering/Working Group and to external stakeholder groups, before being finalized.

We hope that this Users’ Guide will facilitate integration of PROs in the EHR, enabling use of PRO data for multiple clinical, research, and administrative applications, and thereby promoting patient-centered care.

**BOX 1: Full Integration**

Health System Alpha has an Electronic Health Record with a secure, tethered, web portal through which patients can view portions of their electronic medical record, communicate with providers, and complete PRO questionnaires. PRO measures can employ several core functions of the EHR.

**Providers**
- Can order PRO questionnaires to be completed ad hoc.
- Can order PRO questionnaires to be triggered for populations of patients with specific characteristics (age), diagnoses (stroke), or events (clinic visit, knee replacement surgery).
- PRO questionnaire scores are presented to clinicians using standard formats.
- Out of range PRO scores can trigger alerts and advice about things that can be done for the patient.
- PRO scores are integrated with other data within the EHR and can be presented and plotted alongside other clinical data elements like laboratory test results.

**Patients**
- Complete PRO questionnaires using the tethered portal, or via kiosks in the clinic, tablet computers in the waiting room, or hand-held devices like a smartphone.
- PRO questionnaire items are presented to patients using standard formats.
- PRO questionnaire scores and how to interpret them can be viewed by patients along with clinical test results, including trends over time.
- Patients receive limited advice tailored to their self-reported problems.

**IT Professionals**
- Require specific training to work within the EHR.
- A core set of PRO questionnaires are built into the most recent version of the EHR and can be activated.
- New PRO questionnaires can be added within the constraints of the EHR.

**Analysts/Researchers/Payers**
- PRO data can be extracted from the EHR and analyzed using statistical tools to produce reports for individual patients or groups of patients.
**BOX 2: Hybrid – Moderate Integration**

Health System Beta has a secure external web platform for PRO data collection, designed to interface with (bolt on to) an existing EHR’s clinical test results and patient identification databases. This application represents a combination of some non-EHR functionality with some technical integration with the EHR. Providers log in to the EHR to find a patient, and from there can additionally log in to the PRO website to order PRO questionnaires and view results; they can also log in directly to the website. Patients log in to a stand-alone PRO website to complete PRO questionnaires and view their results. Both patients and providers can communicate with each other about them via the PRO website.

**Providers**
- Have limited access to PRO data within EHR, have broader access to PRO data on external website. PRO scores are visible within the EHR as blocks of text or image files.
- Can order PRO questionnaires on external website to be completed ad hoc.
- Can order PRO questionnaires on external website to be triggered for populations of patients with specific characteristics (age), diagnoses (stroke), or events (clinic visit, knee replacement surgery).
- PRO questionnaire scores can be manipulated in a limited way within the EHR (e.g., limited ability to customize views but not able to plot alongside other clinical data elements like laboratory test results).
- PRO questionnaire scores can be viewed on the PRO website using standardized formats determined by the website programmers and can be analyzed using tools available there.
- Out of range PRO questionnaire scores on the PRO website can trigger alerts and advice about things that can be done for the patient via decision support that is built into the PRO website.

**Patients**
- Complete PRO questionnaires on website, or via kiosks in the clinic, tablet computers in the waiting room, or hand-held devices like a smartphone.
- Potential to collect PRO data using Interactive Voice Response (IVR) technology.
- PRO questionnaire items are presented to patients using standard formats determined by the website programmers.
- PRO questionnaire scores and how to interpret them can be viewed.

**IT Professionals**
- New PRO questionnaires can be programmed relatively easily by use of 3rd party software and added to the library of PRO questionnaires available on the website.
- Programmers must be familiar with the web design of the application.
- All PRO questionnaires are selected and programmed for use by PRO website programmers.
- Technical interfaces between systems must be set up and maintained by the health care organization IT staff. Changes in one system need to be retested for potential effects on integration with the other.
- Requires shared (or mapped) patient-identifiers in EHR and PRO systems.
Analysts/Researchers/Payers

- PRO data can be extracted for analysis for individual patients or groups of patients.
- Extraction of PRO data from PRO website does not require health system programmers, but may require PRO website system programmers.
- Integration of PRO data with other data from the EHR requires creation and merging of separate EHR and PRO databases, which requires database programmers.

BOX 3: Standalone – Low Integration

Health System Gamma has a secure external web platform for PRO data collection. Both patients and providers log in separately to the PRO website to access PRO data. Both patients and providers can view the results and communicate with each other about them via the PRO website. There is an interface with the health system patient identification system, which allows images of PRO data to be linked to the corresponding patient record in the EHR.

Providers

- Log on to the external website to order or schedule PRO questionnaires to be completed by individual patients or groups of patients.
- PRO scores can be printed out in hard copy for review.
- More difficult to order PRO questionnaires to be triggered for populations of patients with specific characteristics (age), diagnoses (stroke), or events (clinic visit, knee replacement surgery). This requires re-entry of information into the PRO system to trigger suggestions or automatic selection of questionnaires.
- PRO questionnaire scores are presented to clinicians using standardized formats used on the external website.
- Reports of scores are visible in the EHR as images.
- PRO questionnaires scores cannot be manipulated alongside other clinical data elements that are part of the EHR.
- Out of range PRO scores can trigger alerts and advice about things that can be done for the patient, on the external website.

Patients

- Complete PRO questionnaires online on the external website, or via tablet computers in the waiting room or hand-held devices like a smartphone.
- Potential to collect PRO data using Interactive Voice Response (IVR) technology.
- PRO questionnaires are presented to patients using standard formats determined by the website programmers.
- PRO questionnaire scores and how to interpret them can be viewed on the external PRO website.

IT Professionals

- New PRO questionnaires can be programmed and added to the library of PRO questionnaires available on the website.
- Programmers must be familiar with the web design of the PRO web application.
• All PRO questionnaires are selected and programmed for use by the website programmers.

Analysts/Researchers/Payers
• PRO data can be extracted for analysis for individual patients or groups of patients.
• Integration of PRO data with other data from the EHR requires creation and merging of separate EHR and PRO databases, which requires database programmers.

USEFUL REFERENCES/RESOURCES


1. **WHAT STRATEGY WILL BE USED FOR INTEGRATING PROS IN EHRS?**

Integrating PROs into the EHR facilitates their use by patients, providers, and researchers, yet poses challenges. Depending on the EHR vendor, there are options to administer assessments, including PROs, to patients. In addition, stand-alone PRO collection systems exist that can interface with EHRs to varying degrees. Finally, practices may choose to administer PROs with systems that do not interface with the EHR and manually enter or import the PRO data into the EHR. This section describes these three degrees of integration and summarizes the advantages and disadvantages to patients, providers, researchers, and administrators. The advantages and disadvantages listed will depend on the features of any particular system, do not apply to all systems in this category, and are not mutually exclusive between categories. The case studies in the Introduction provide illustrative examples of the range of options.

**OPTION 1: FULL PRO INTEGRATION WITHIN EHR**

Full integration occurs when a PRO assessment is collected as an internal part of an EHR system. PRO information is pulled from and pushed to the EHR in real-time (1) to inform/tailor PRO assessment and (2) to make integrated PROs available for broad use within the EHR in real-time, including for clinical decision support, longitudinal tracking in conjunction with symptoms and treatments, and seamless feedback to patients. PRO scoring can be automated. Some organizations may use a mix of full integration and stand-alone strategies for different purposes.

**Advantages:**
- **Patient:**
  - PRO data are collected in singular patient portal that collects all care information (e.g., appointments, laboratory values) and online communication with their providers
  - Flexibility of assessment location based on EHR vendor support (in-office, web-portal)
  - Real-time reporting of PROs to patient may be possible
  - Minimizes redundant information completion by drawing information from prior PRO completion or patient information (e.g., last visit date, chronic conditions)
- **Provider:**
  - One place for all PRO assessment actions (ordering, result review, follow-up)
  - Results presented alongside other clinical data (e.g., laboratory tests, radiology results, clinical notes)
  - Real-time scoring and reporting for immediate clinical use
    - Automated workflows for actions/follow-up
    - Alerts for high/low or actionable PRO scores
  - Standardized report formats that include longitudinal scores
  - Integration of medical history/EHR information available for reports
Can be initiated for long-term follow-up based on a trigger event (e.g., surgery, medication initiation, hospitalization) or for asynchronous collection (the collection of data that is not triggered by a clinical event)

- PRO completion can be done within the same workflow as other patient-facing data collection (e.g., review of systems)
- Real-time integration of content for clinical decision-making may be available
- Time saving for provider and staff over paper collection

• Research:
  - Can be extracted alongside other EHR data (e.g., tests, procedures, clinical data, events)
  - Possible to have extensive assessment-specific meta-data

• Administrative:
  - Part of the EHR system, there may be no additional contracts or costs
  - Standardized list of validated PRO questionnaires to select and use
  - Easier aggregation of PROs scores alongside other standard (non-PRO) performance measures
  - Automated reminders to complete PROs can be added into standard in-clinic workflow and within patient portals

Disadvantages:
• Patient:
  - Limited ability to change administration format
  - Remote home access requires a patient portal account with user name and password (as distinct from paper collection, in which this is not required)

• Provider:
  - Customizing PRO assessments beyond current available content and features (e.g., questionnaire, assessment timing and frequency) requires involvement of local EHR IT team
  - Presentation of PROs to patient and provider is limited by the capabilities of the EHR and customization may require involvement of local EHR IT team or additional external product

• Research:
  - Implementation of PROs (content, assessment frequency) may be focused on clinical utility
  - May not be designed for staff to identify and monitor missing PRO data (item-level or lost-to-follow-up)

• Administrative:
  - It may be difficult to customize PRO assessments across clinical settings
  - Restrictions often on launching additional, non-standard PROs (Requires additional resources or may not be possible depending on the system)
  - System may not easily allow for monitoring of missing PRO data
OPTION 2: PROS COLLECTED INDEPENDENTLY OUTSIDE OF THE EHR IN A SEPARATE SYSTEM
This is the broadest category, PRO collection is conducted via a stand-alone system that was likely either purchased from a 3rd party or developed internally. PRO information can be automatically placed in real time into discrete fields within the EHR through a specific interface and mapping. It can include an asynchronous pulling of information from the EHR to inform the PRO assessment. Scoring is automatic. Systems in this category can include the ability to provide automated feedback to the patient or provider. The advantages and disadvantages will depend on the system features used.

Advantages:
• Patient:
  o User interface is designed specifically for PRO administration
  o May provide more PRO reporting options and features. PRO content may be more easily configurable
  o Advanced PRO collection and reporting features
  o May minimize redundant information completion by drawing information from prior PRO completion or patient information (e.g., last visit date, chronic conditions)
• Provider:
  o Tailored reporting options for PRO results may be available
  o More specialized PRO content may be available out-of-the-box or PRO content may be more easily configurable
  o Real-time integration of content for clinical decision-making may be available
  o Asynchronous collection of PROs
  o Time saving for provider and staff over paper collection
  o Real-time scoring and reporting for immediate clinical use may be available
    ▪ Automated actions/follow-up
    ▪ Alerts for high/low PRO scores
  o Standardized report formats that include longitudinal scores
• Research:
  o Assessment-specific meta-data
  o Can be extracted separately or alongside other EHR data (tests, procedures, events)
• Administrative:
  o System may have dedicated technical support
  o Configuration is not dependent on EHR IT teams
  o New technology-based options (e.g., mobile apps) may be more quickly implemented

Disadvantages:
• Patient:
  o May not be clear that this is part of their care
  o Alerts/email reminders may be less “official” since they are not integrated within care workflows
Remote home access requires a user name and password (as distinct from paper collection, in which this is not required)

- **Provider:**
  - Missing PRO assessments (prior to visit) may not be easy to identify within the clinic workflow
  - Additional steps by the provider to access this separate system may be necessary to assign, administer, and review data
  - Workflow integration may require more staff oversight and specific training

- **Research:**
  - Complete data may require extracting data from two systems (EHR and PRO system)
  - Linking multiple data systems can be complex

- **Administrative:**
  - Integration of data requires additional information technology resources and expertise
  - Cost to maintain an independent PRO system may be higher than an integrated system
  - Updates or enhancements to the PRO system may require changes to the EHR system or integration tools in order to maintain compatibility
  - Security concerns collecting PROs within a separate system
  - Building additional PRO measures beyond the out-of-the-box standard requires additional resources or may not be possible depending on the system
  - Additional vendor agreements (beyond current EHR agreements) are necessary

**OPTION 3: MINIMAL SYSTEM INTEGRATION**

PROs are pushed uni-directionally from the PRO system into the EHR for storage. There is no bi-directional communication between the PRO system and the EHR. Methods can include: (1) a scanned document (e.g., PDF, JPEG), (2) entered into the EHR manually by a staff member, or (3) manually documented in the clinician note. PRO assessments can be paper-based or electronic, and patient feedback will be manual. This method may be used in conjunction with either option 1 or option 2 for patients who prefer paper-based assessments.

**Advantages:**
- **Patient:**
  - Paper-based collection may be more user friendly for individuals who are less comfortable using technology
- **Provider:**
  - Very low-cost up-front investment (e.g., paper assessments)
- **Research:**
  - Easier to establish PRO surveillance independent from the clinical care system (e.g., telephone, mailed surveys, or stand-alone electronic PRO collection)
- **Administrative:**
  - Less specialized technical supported for implementation, integration, and maintenance
Information can be uploaded to any EHR system that allows for attachments/pdf
Easy for different clinics to administer tailored and specialized PRO content

Disadvantages:
• Patient:
  o Possible redundancy in data capture between clinical sites of a health system
  o Potential for confusion regarding whether PRO assessment will be available to all members of their clinical care team (e.g., different specialties in the same group)
  o If PRO collection is paper-based, display options such as screen readers and text size adjustment are not available
• Provider:
  o Manual scanning or entry of data entry could delay in-visit use and result in less efficient clinic workflows
  o If there is no discrete data filing, PROs cannot be used for automated decision support
  o Administration relies on manual processes and workflows
• Research:
  o PRO information may not be structured, limiting secondary use and use with associated meta-data
• Administrative:
  o Manual identification of patient eligibility for PROs necessary
  o Relies on staff to track PRO administration across multiple patient visits
  o Lack of continuity across clinical settings
  o Additional vendor agreements (beyond current EHR agreements) may be necessary

KEY INFORMATION GAPS AND RESEARCH QUESTIONS
• What drives patient perception of benefit from PRO collection?
• Does greater system integration matter more than a more targeted, customized PRO collection system?
• Do PROs collected within or outside of a clinical encounter facilitate patient care?
• Do providers prefer EHR-integrated PRO reporting or PRO-specific systems?
• What system features facilitate and sustain PRO use by patients and providers?
• Which system design is more feasible and sustainable:
  o In community-based settings
  o For multi-morbid patients
  o By care setting (e.g., primary care vs. specialty care)
• What features in PRO collection and reporting are preferred by patients, providers, and researchers? Do these preferences differ by sociodemographic characteristics of patients?

USEFUL REFERENCES/RESOURCES
Acquadro C, Berzon R, Dubois D, Leidy NK, Marquis P, Revicki D, Rothman M. Incorporating the patient's perspective into drug development and communication: an ad hoc task force report of


2. **HOW WILL THE PRO-EHR SYSTEM BE GOVERNED?**

PRO Governance addresses which stakeholders oversee decisions related to selection, implementation, analysis, and use of PROs within the context of EHRs. Implicit in this discussion is the assumption that patient identified (person-level) PRO data may be used for applications beyond direct patient care such as patient-centered outcomes research.

Approaches to governing PRO information within EHRs will be strongly influenced by many of the other decisions and conventions discussed in this document. Specific considerations include the extent to which PRO information is fully integrated, or just “bolted on” the EHR; contractual and ownership issues related to PRO use; collection and analysis; whether PRO data are considered to be unique or an integral part of clinical records; and whether one concludes that the size of an organization should influence decisions about PRO governance. Institutional culture, including perspectives on stakeholder engagement and how the core EHR itself is governed are also likely to have a strong influence on governance decisions related to PRO-EHR integration.

The composition of the entities that own or operate the EHR and the practices itself is another influencer. The organization of medical practice is highly varied and makes any single approach to governance unworkable. No single governance model can encompass all the dimensions of solo private practice to large integrated practices with thousands of physicians in multiple settings from hospital to outpatient sites, or practice ownership models ranging from sole proprietorships to large for-profit corporations or various types of public ownership. Indeed, even within current EHR governance approaches, the oversight of PRO information in EHRs varies widely - from what might be seen as very loose oversight allowing many different groups to select, implement, analyze and use PRO data in EHRs - to highly structured, centralized control of nearly all elements of the EHR including PROs.

Finally, there are a substantial number of external factors that need to be taken into account, including those derived from legal, regulatory, and ethical considerations. Some of the legal issues are not yet resolved, such as who “owns” the information in an EHR, or more strictly defined, the medical record. Regulations such as the Health Insurance Portability and Accountability Act (HIPAA) and other medical privacy laws (legislative or case law) and norms such as the Federal Trade Commission’s (FTC’s) Fair Information Practice Principles (FIPPs) create an ethical and legal framework for uses of medical information that is developing slowly and is not yet applied consistently in governance and practice.

With these considerations in mind, this section reviews options for systems of governance and the various stakeholders who may be involved. Also see Section 11 for further discussion of the legal and ethical issues associated with PRO-EHR integration.
What Systems of Governance Are Reasonable for Managing PRO Information in EHRs?

As noted, governance of EHRs currently varies widely even between organizations of roughly the same size and complexity. In some organizations there are strict systems that control what content can be added to the EHR and how and when various modules in the EHR are introduced. In others, all or most decisions on which content to include are left up to individual or department-level users. Since there are trade-offs between distributed and centralized governance, the choice of which pathway to follow is likely to be highly variable based on organizational structure, leadership style, and mission. Even though this issue may be more critical in larger practices, it is important to consider in practices of all sizes.

OPTION 1: DISTRIBUTED GOVERNANCE

While there may be centralized governance of the overall EHR structure, in a distributed model, decisions about implementation, oversight, and use of specific PROs is left to individual or group (department, subspecialty, program, etc.) users. Thus, inclusion of different types of users or the extent of PRO use will be “governed” by end-users of the data. Any use of data for research purposes will still need to go through appropriate research oversight and review channels.

Advantages:
- Allows different individuals or departments to adapt content and approaches to PROs which may fit more closely with direct clinical needs
- May encourage testing of pilot programs or projects that can then be widely adapted by the full practice
- Ensures decisions about PRO implementation and use close to presumed data end-users

Disadvantages:
- Could lead to confusion or duplication if multiple – potentially incompatible - PRO questionnaires are used with the same patient by different departments
- Patients may be asked to provide data to multiple similar PRO questionnaires with no coordination between those requesting information
- May make cross-department collaboration more challenging
- May confound practice-wide quality reporting or research efforts

OPTION 2: CENTRALIZED GOVERNANCE

Using a centralized governance model, an individual or appointed group at the organizational level has oversight for most, if not all, decisions regarding PRO inclusion, implementation, and use in a given EHR.

Advantages:
- Helps ensure that patients will not be subjected to multiple inquiries from different areas within a large organization
- Provides a wider range of oversight and input from multiple players
• Less likely to run afoul of regulatory oversight with respect to inappropriate use of patient-reported data
• Can help set organizational goals and expectation for holistic, system-level adoption of PROs. This approach has the potential to increase the value of PROs and decrease patient burden by establishing and consistently implementing PROs based on principles such as a preference for using psychometrically valid, cross-purpose instruments when possible, rather than numerous specialty-specific PROs

Disadvantages:
• May inhibit use of different or more specialty- or condition-specific PRO instruments
• Oversight could be bureaucratic and slow moving in response to clinician and researcher needs
• Resulting PRO data may be seen by clinicians as too general and not useful for direct use with patient care

OPTION 3: HYBRID
In this approach, a core central entity provides a set of rules for implementing and using PRO data within the EHR and provides some level of oversight to ensure the rules are followed.

Advantages:
• Could be used in both centralized and decentralized institutional cultures
• Is flexible and may be optimal for emerging areas of EHR use of PROs
• Allows for some experimentation within centrally agreed upon standards

Disadvantages:
• If rules are not carefully constructed and monitored, could lead to confusion and disputes as to who is responsible for final decisions
• Could be misused in both directions, either to hinder local decision-making or to take advantage of imprecise central rules

_Beyond Involvement of Core Clinicians and Clinical Management, What Groups Could Be Involved in Governance of PRO Use in EHRs?_

At a minimum, governance of use of PRO data in EHRs would include the following (in some small practices “a” and “b” might be a single person): a) practice manager, b) practice clinician, and c) consultants or others to assist with IT and technical aspects of PRO use. In addition, other entities or stakeholders may be engaged in governing PRO use in EHRs.

OPTION 1: USE THE PRE-EXISTING GOVERNANCE STRUCTURE FOR EHR
The existing governance body and/or structure within the organization is appropriate to address PRO use in EHRs based on the assertion that there is already EHR information reported and in some cases recorded by patients (for example past medical history, family history, social history).
Advantages:
- Simple
- No new resources needed
- To the extent the organization has developed a thoughtful governance approach that represents all key organizational and community stakeholders, avoids duplication of effort, time, and administration

Disadvantages:
- Excluding patients increases the likelihood of patient and regulatory concerns over time
- Could constrain future use of patient-identified PRO data to direct patient care only
- Oversight group will lack sufficient expertise in technical aspects of EHRs, leading to implementation problems

OPTION 2: INCLUDE DIRECT PATIENT REPRESENTATION
Patient representatives or advocates are included as members of the governance group, or an advisory group to provide adequate oversight of PRO data for patient care.

Advantages:
- Anticipates patient and potential regulatory concerns
- If patients are included, may help engage patients in advocacy for PRO use within the practice, especially for direct patient care
- Helps promote patient-centered orientation in practice

Disadvantages:
- Increases resource requirements to implement PROs
- Introduces new elements into advisory and/or decision-making about use of PROs as a component of the EHR
- Could be seen as making PROs a “special” category of data - which may create barriers to collection and use
- Might adversely affect participation in both research and quality improvement projects
- Does not address concerns that PROs are unique data, that they are often specialty-specific, challenging to collect, and can be burdensome to patients
- NOT taking governance into account explicitly for PROs may result in missed opportunities to set clear priorities and consider the sequence by which elements of PROs should become part of the EHR and the sub-set of EHR designated as the patient’s medical record

OPTION 3: ENGAGE A BROAD GROUP OF STAKEHOLDERS
Beyond patient involvement, the presence or potential of an expanding array of PRO and similar data in EHRs could lead to a governance structure that includes a broad range of stakeholders and interests in governance. These represent not only “owners” and clinicians, but also those with skills and knowledge of EHRs, quality improvement and research personnel, as well as patients and/or patient advocates. In smaller practices this expertise may be
consolidated in small groups including those linked to the practice via contracting, consulting, or IT specialists. Some examples of key personnel include:

- Senior executive champions
- IT specialists
- Researchers
- Compliance officer
- Legal staff
- Quality improvement staff

Advantages:
- Anticipates and provides means of addressing need to prioritize and control roll out of PRO data collection tools of various types
- Recognizes that there may be multiple organizations involved in data collection (as with a commercial vendor), analysis (a different vendor, or internal) and use (internal, as well as for external purposes like pay-for-performance)

Disadvantages:
- Will make governance group larger and complex and more expensive
- Could lead to deadlocks or delays in reaching agreement
- May result in PRO data being considered as a special area for regulation around membership in governance or use in EHRs
- IT logic may be needed to prioritize PROs to limit what can be administered to a single person at a specific point in time

Use Case Example 1: In small practices that are affiliated with a research or quality improvement network, the governance of the EHR is often handled by one individual who is responsible for managing network participation. Within a network, some aspects of PRO selection and use are likely to be handled as a hybrid model with formal input and participation by researchers and others via the networks. Similarly, for small practices using patient-identified PRO data only for clinical and quality improvement within the practice, staff usually assumes that PRO data are simply one element of the EHR with oversight usually falling to the individual staff person or physician overseeing overall EHR use. While this person (or small set of practice participants) may have contractual or other relationships with various vendors, the control is centralized to one or a few individuals within the practice.
KEY INFORMATION GAPS AND RESEARCH QUESTIONS

- What is the range of current governance structures for EHRs and specifically for use of PROs in EHRs?
- How do various regulatory and legal issues affect or influence EHR governance, and where is further guidance needed to clarify expectations for governing the use of PROs in EHRs?
- Are core governance principles emerging to guide the selection, implementation, and use of PROs in EHRs?
- What are patient expectations for their involvement in oversight and governance of PRO-EHR use?
- What metrics could be used to evaluate the effectiveness of different models of governance?

USEFUL REFERENCES/RESOURCES


Segal C, Holve E, Sabharwal R. Collecting and using patient-reported outcomes (PRO) for comparative effectiveness research (CER) and patient-centered outcomes research (PCOR): challenges and opportunities. Issue Briefs and Reports. 2013: Paper 10. Available at: http://repository.edm-forum.org/edm_briefs/10.
3. **HOW CAN USERS BE TRAINED AND ENGAGED?**

For integration of PROs into the EHR, it is easy to first focus on technical solutions and forget the importance of the culture change. PRO data collection in clinical practice is a socio-technical task and needs to be based on training approaches, using insights from adult learning and behavior modification. Engaging both providers and patients in the process and educating them about the value of PROs and changes in their roles are essential to fully realizing the goal of PRO integration into health care interactions and decision-making. Each organization may wish to do a training needs assessment to better understand current technical skills and cultural attitudes to this change before designing a training implementation plan. It is optimal to design interfaces that are intuitive and require little-to-no training; active reminder systems may be considered as well. It is important to plan both initial training of providers when the implementation starts and to plan an ongoing training program and support. Ongoing support is essential as problems will arise that were not predicted initially, and adaptation and problem solving will ensure providers’ continued engagement. Furthermore, staff turnover will require ongoing training of new team members. Patient training may be initiated at many different stages of the care cycle and could be as simple as handing the patient a tablet to a more complex orientation to navigation around a patient portal. Beyond the scope of this document but important to mention is the potential impact of caregivers, social networks, and advocacy groups on patient’s perception of value from PROs. Training should include reminders that PRO data are to be treated with the same level of data security and privacy as all other EHR data. The options presented below are not mutually exclusive and the success of their adoption will depend on local conditions such as resources and staffing.

**What Training Is Required to Activate and Engage Patients (and Caregivers, Proxies)?**

**OPTION 1: APPOINTMENT SCHEDULER ACTIVATES THE PATIENT**

At the time of scheduling a clinic appointment, the scheduler informs patients that there is a questionnaire their provider would like to be completed prior to their visit and introduces patients to the option of using the online portal (see Introduction Full Integration Case Study), priming them about an e-mail link they may receive prior to the visit (see Introduction Hybrid or Standalone Case Study), or arriving early for the visit to complete the questionnaire on a tablet.

**Advantages:**
- Engages patients early on
- Encourages use of the portal which has other benefits in addition to questionnaire completion
- For patients who use the portal, there is less potential for disruption of workflows on the day of the appointment

**Disadvantages:**
- Scheduling staff may view this as extra work and be resistant to this additional task
- May increase the time needed to schedule a patient, slowing clinic throughput or putting extra demand on centralized call centers
• Scheduling staff may turn over frequently thus making training of them a challenge
• Will need to develop scripting for schedulers that highlights the benefits to patients and their care team
• Patients may be unwilling or unable to open a portal account and may arrive too late for the visit to receive initial training and complete a questionnaire
• Only applicable to PROs that are linked to a scheduled encounter (Full Integration Case Study-Box 1 in the Introduction)
• Scheduler may not have an active role in the workflow depending on how it is designed
• Requires identifying a standard set of measures that can be chosen for all patients or according to a specific set of instructions that the scheduler can implement
• May give less flexibility to the clinician in individualizing assessments based on patient status and diagnosis

OPTION 2: RECEPTIONIST ACTIVATES AND INFORMS THE PATIENT
Upon arrival at the clinic to check in for their visit, the receptionist educates/informs patients about the request to complete the questionnaire, explaining why it is important and how the data will be used. The receptionist may have a brochure to hand the patient or a video for the patient to watch. Receptionists can provide “just-in-time” support to patients for using a tablet or kiosk for questionnaire completion.

Advantages:
• In person explanation of the rationale for the request may be more likely to get the questionnaire completed
• If the organization has no patient portal, then “at check-in” is an alternate good time to approach the patient for this introduction
• Urgent needs identified through the questionnaire can be addressed at the visit rather than being overlooked or trying to contact the patient between appointments

Disadvantages:
• May be disruptive to receptionist usual workflows and result in longer queues at check-in
• Will need to develop scripting for receptionist that highlights the benefits to patients and their care team
• Requires identifying standard set of measures that can be chosen for all patients or according to a specific set of instructions that the receptionist can implement
• If patient does not arrive sufficiently in advance of appointment, this may delay rooming and disrupt clinic flow
• If receptionist turnover rate is high, then training of receptionist may be a challenge

OPTION 3: NURSE CHAMPION (OR MEDICAL ASSISTANT OR FLOW STAFF) ACTIVATES AND INFORMS THE PATIENT
At the point in the workflow when the patient is brought to the examination room, the designated PRO champion introduces the patient to the rationale for collection of PROs and guides the patient through completion of the questionnaire “just-in-time” support. They can
also introduce the patient portal to the patient and encourage/assist with sign up for the portal, if applicable.

**Advantages:**
- Care team member closer to the clinical encounter may be able to explain the value of PROs more convincingly than a receptionist or scheduler
- As a first walk through, this may provide better support to patients to overcome any technical obstacles such as signing up for the portal and navigation within the portal to locate the questionnaire (Full Integration Case Study-Box 1 in the Introduction)

**Disadvantages:**
- More labor intensive, uses higher cost staff
- Patient may be occupying an exam room which is more costly than waiting room space
- Nurse/medical assistant may not have access to the necessary links for partial or non-integrated solutions, if applicable
- Most applicable to PROs that are collected during an encounter

**OPTION 4: CARE MANAGER/HEALTH NAVIGATOR ACTIVATES AND INFORMS THE PATIENT REMOTELY**
Using appropriate algorithms, care managers/health navigators identify patients for whom PROs are desired and they contact the patient by phone or text. This can serve as an activation point or reminder as well as offer support to use the technology (patient portal or app) for PRO completion.

**Advantages:**
- Care managers/health navigators may already be reaching out to patients for other health related issues/testing/medication and can bundle into that call the reminder or introduction to PROs
- For many chronic conditions, these individuals may have established excellent rapport with patients, thus patients may be more willing to complete a questionnaire
- Can be linked to PRO collection asynchronous with any in person encounters/clinic visits

**Disadvantages:**
- More labor intensive, uses higher cost staff

**OPTION 5: PROVIDER ACTIVATES AND INFORMS THE PATIENT**
During the encounter, the provider introduces the patient to the idea of PROs, how PROs can play an important role in tracking patients’ health, the effectiveness of PRO interventions, and can request the patient to participate. The provider can establish the patient’s preferred modality of completing a questionnaire such as portal, tablet, and phone interview. As with all options, the provider can review results with the patient to reinforce the value in clinical care.
Advantages:
• An activated engaged provider may be able to explain the value of PROs better than others on the care team, including how s/he will use the data in practice

Disadvantages:
• More labor intensive, uses higher cost staff
• Only applicable if provider and patient have an encounter
• If provider contacts patient by phone for this activation, it is time consuming and does not generate revenue

OPTION 6: RESEARCH COORDINATOR ACTIVATES AND INFORMS THE PATIENT
A research coordinator enrolls patients in a study and as part of that enrollment introduces them to PROs, their value, and the modes that can be used for completion. If outside of the EHR, e.g., a national registry (Hybrid or Standalone Case Study in the Introduction), they can collect e-mail and other contact information for the patient.

Advantages:
• A research coordinator will have the training and time to engage the patient in PRO completion
• Can provide “just-in-time” training to patients for use of portal/website/app and provide troubleshooting support
• A research team will target high completion rates and likely spend additional time/resources to track down patients who are missing PRO data
• Can facilitate PRO collection asynchronous with clinical encounters

Disadvantages:
• Will need to develop scripting for research coordinators that highlights the benefits to patients and their care team
• This role may not be applicable to all organizations or clinical settings
• Additional cost for research coordinator

OPTION 7: PATIENT RECEIVES NOTIFICATION REQUEST/REMINDER VIA MAIL, SECURE MESSAGE, OR E-MAIL
An automated process can be developed using algorithms to define which patients should receive requests (initial activation) and reminders (established patients) for questionnaire completion. The system then sends out the notifications at predetermined times or time intervals.

Advantages:
• If automated process, will be less labor intensive for personnel and keep costs down
• Can facilitate PRO collection asynchronous with clinical encounters
Disadvantages:

- Without prior explanation or activation of the patient, this may be the least successful mode to engage patients resulting in low completion rates
- Inaccurate contact information for patients will result in missed opportunities
- May not be using the patient’s preferred mode for communication

Use Case Example 1: Institution X has fully integrated PROs in its EHR and they have an active patient portal. During clinic visits, patients are encouraged to sign up for the patient portal and provided with a brochure that explains all the things that can be done with the portal including completion of questionnaires. On the portal itself, there is a video that will help patients learn how to navigate around the portal as needed. Appointment reminders, both electronic and print, notify patients if they have a questionnaire to complete prior to their appointment. Using this approach has enabled a significant percentage of patients to complete questionnaires asynchronously from appointments and/or prior to appointments, thus resulting in less disruption of workflows on the day of the clinic visit. Patients who choose this option rarely require specific training. Those who present for appointments without having completed an assigned questionnaire are presented with a tablet by the receptionist and they complete the questionnaire in the waiting area prior to being escorted to the exam room. Little training is required in use of the tablet. If assistance is needed, then a member of the care team (not the receptionist) will assist the patient. The EHR immediately scores the questionnaire and results are available for review by the provider or other care team members immediately.

Use Case Example 2: Institution Y has a secure online system for PRO data collection via a website. The online system can interface with an existing EHR (so that reports can be viewed by providers from within the EHR), but also allows providers to view reports separately (via a secure login) which is a flexibility useful for multi-center projects or community providers. When patients attend the clinics a receptionist (or appointment scheduler or a researcher) introduces patients to the online system, registers them and issues a user name and password, and gives the patient a card. If patients lose the card, they are administered a new password to the old user name. Patients are shown how to use the online system in clinic and are provided with a booklet/manual explaining how to navigate through the PROs. Little further training is required as the online system is simple and intuitive. A dedicated phone helpline and email is given for ongoing technical support, if needed. Reminders to complete the PROs can be set up via email or text messages to encourage patients to use the system between appointments for monitoring symptoms or side-effects of treatments in real time.
**How to Convey to Patients the Value of Completing a PRO?**

**OPTION 1: DEVELOP SCRIPTS FOR DIFFERENT MEMBERS OF THE CARE TEAM**
Scripts are developed for different care team members any of whom may be in a position to “pitch” PROs to patients. Engage the care team members in the development of these scripts as an overall plan for care team education.

**Advantages:**
- Many members of the care team are equipped to introduce PROs to patients and motivate them to complete them

**Disadvantages:**
- Quality control will be a challenge initially with few care team members understanding the full value of PROs. Will need to coordinate this idea with training of care team
- In areas where a low volume of PROs are used, it may be difficult to ensure that the script is delivered authentically
- Care team members may be skeptical about PROs or not wish to spend time on extra work, and may communicate these attitudes to patients

**OPTION 2: DEVELOP MARKETING/INFORMATIONAL MATERIALS FOR PATIENTS**
If no materials are already available, work with the marketing and communications department of your organization to develop easily understood brochures, videos, and website content explaining, in easily understood language, the value of PROs. Inform patients that questionnaire responses will be recorded in their medical record just like other health care information.

**Advantages:**
- Materials that patients can take home to review, or review online, will help to reinforce content that was delivered verbally and provide them with answers to frequently asked questions

**Disadvantages:**
- Keeping the materials current may be a challenge
- Customizing materials for different health conditions may be labor intensive
- May be more useful at the launch of a PRO initiative than in a mature program

**OPTION 3: REVIEW AND DISCUSS RESULTS WITH PATIENTS**
Once a patient has completed a PRO in a clinical context, it is key that the results be reviewed with the patient just as one would do with any other medical test/study. By reviewing the results, explaining the scores (just as one would explain a blood pressure reading or HgbA1C) patients will learn to value the information and how it can be of assistance in tracking disease progress, of accurately conveying symptom burden to providers, etc.
Advantages:
• If PRO results are meaningful to the care team, members will be willing to exert the extra effort to obtain and review PROs
• If PRO results are meaningful and the results are thoughtfully explained to patients, patients will be much more willing to engage in future PRO completion

Disadvantages:
• Not all members of the care team will be sufficiently versed in the interpretation of the PRO scores
• Providers may find themselves too busy to discuss results
• Providers may not be aware that a PRO was completed, so may miss the opportunity to review results with patients

How to Incentivize Patients to Complete PROS?

OPTION 1: ENSURE THAT PATIENTS CAN USE THE TECHNOLOGY
Provide user support (help desk, email, and/or telephone contact number) and frequently asked questions so that patients are not intimidated by technology glitches.

Advantages:
• Ensures that patients who are motivated to complete PROs are provided the support that they need to overcome any technology barriers

Disadvantages:
• Requires considerable resources if the system is not designed to be intuitive, and if patients have limitations such as visual or cognitive impairment

OPTION 2: ENSURE THAT PRO RESULTS ARE REVIEWED WITH AND EXPLAINED TO PATIENTS
Create performance measures that track patient completion rates and provider review rates. Integrate these measures into normal performance review processes.

Advantages:
• Emphasizes the importance of PROs in clinical practice
• Ensures that patients’ efforts are acknowledged

Disadvantages:
• Requires considerable influence to engage leadership of all departments to hold providers accountable

OPTION 3: PROVIDE PATIENT FRIENDLY REPORTS/DATA DISPLAYS
PRO results and their interpretation are shared with patients either directly following completion or when visiting with the care team. Patients can review results on the portal just as they would blood pressure, weight, etc.
Advantages:
• Provides immediate feedback to patients and highlights usefulness of this new data stream

Disadvantages:
• Infrastructure for creating friendly patient facing reports is largely absent from EHRs
• The majority of PROs are lacking in materials for good explanation to consumers

OPTION 4: INTRODUCE DECISION SUPPORT FOR SELF MANAGEMENT
As patients learn to interpret PRO scores, they may welcome support and guidance on what actions can be taken to correct an abnormal score.

Advantages:
• Encourages self-management especially of chronic health conditions

Disadvantages:
• There is little existing content for what to do about abnormal PRO scores. New content would need to be developed and tested to understand what type of decision support is helpful to patients
• At present, the proportion of highly engaged patients who would take advantage of these features is unexplored
• Development of a robust algorithm for self-management can be time consuming

OPTION 5: ENABLE PATIENTS’ SELF INITIATION OF A PRO
Highly engaged patients may wish to monitor their own progress asynchronous with care team contact. Enable patients to order their own PROs and track results over time.

Advantages:
• Encourages self-management especially of chronic health conditions

Disadvantages:
• Infrastructure for creating this self-ordering is largely absent from EHRs even though they can measure their own glucose, take their own blood pressure, etc.
• At present, the volume of highly engaged patients who would take advantage of these features is unexplored
• A closed loop self-management system may require regulatory approval as a medical device
What Training is Required for Providers and Staff?
Theme: Incentivizing Participation and Identifying Motivators for Providers

OPTION 1: INTRODUCE GENERAL RATIONALE OF PRO USE AT DEPARTMENTAL MEETINGS/CLINICAL FORUMS
When launching a new PRO program, plan to share the important concepts, values, and “what’s in it for me” at departmental meetings, allowing time for questions and discussion. Identify what may motivate different providers.

Advantages:
• Opportunity to reach a wide range of staff and providers during regular meetings
• Receive endorsement from the organization as a whole
• Legitimates the project as part of a clinical routine for the organization
• Opportunity to present and discuss the project in full
• Finding out specific needs of staff
• Opportunity to identify early adopters

Disadvantages:
• Important staff members, including influential opinion leaders, may be missed
• Limited opportunity for detailed training in interpretation and use of results

OPTION 2: PROVIDE ONGOING SUPPORT TO USERS AND TRAINING TO NEW PROVIDERS
Once the data collection has started, make sure providers have access to ongoing support from expert users and simple training tools to refer to, such as online link to brief examples or pocket cards. One-to-one support in the initial phases of implementation should be considered, if possible. Be prepared for staff turnover, and have a brief introduction and training for new providers joining the team (individual or small group sessions).

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**Use Case Example 1:** Institution X has integrated PROs in a national registry such that patients can complete a PRO regarding their symptom score at any point in time that they wish. Doing so has enabled patients to self-diagnose worsening or improving symptoms. It has led to a change in standard intervals between clinic visits: historically patients were seen every 3 months and with PRO data it became apparent that for many patients less frequent visits can achieve optimal disease control.

**Use Case Example 2:** Institution Y has focused on optimizing data presentation for patients. Creative, easy to interpret data display has led to easier communication between patient and provider to track disease progress. It has also resulted in a different focus of discussion between providers and patients.
Advantages:
- Opportunity to individualize and tailor the support to provider’s values and needs
- Provides a forum to address concerns

Disadvantages:
- Time consuming as requires an available and knowledgeable trainer
- Has to fit in a busy provider’s schedule

OPTION 3: IDENTIFY A LOCAL CHAMPION (SUPER USER) WHO IS AN EXPERT PRO USER AND
ENCOURAGES WIDER ADOPTION
Find a local champion, preferably an opinion leader (a respected senior team leader), who helps
select PROs appropriate for the relevant clinical context and who starts PRO implementation,
accumulates experience and expertise, and then is in a position to influence other providers by
personal example or organizational changes.

Advantages:
- Providers are likely to be engaged if they see good examples and benefits
- Providers are more likely to be incentivized by a respected peer

Disadvantages:
- Dependent on finding early adopters for each clinical team and population
- The implementation in one clinical situation may be too specific and not transferable to
  other teams

OPTION 4: PLAN QUALITATIVE DEBRIEFS TO INDIVIDUAL PROVIDERS AND TEAMS
Once PRO data collection has started, find good examples and case studies demonstrating the
relevance of PRO data to patients, and discuss them with providers. Find out what motivates
providers. Can be done at formal meetings or informally when opportunities arise.

Advantages:
- A personal approach to individual providers encourages discussion and participation
- Encourages adult learning through experience

Disadvantages:
- Time consuming as requires a dedicated trainer
- Has to fit in a busy provider’s schedule

OPTION 5: PERFORM AUDITS AND PROVIDE FEEDBACK TO ORGANIZATIONAL AND
DEPARTMENT LEADERS
Plan and perform an ongoing audit, reviewing performance and providing feedback at
departmental meetings. It is important to focus on positive examples and emphasize benefits to
providers and patients.
Advantages:
• Encourages good performers
• Provides bench-marking opportunity
• Learning from experiences of others
• Receive endorsement from the organization as a whole

Disadvantages:
• Dependent on whether the organization (department) has existing meetings to review performance
• Can be perceived as “Naming and shaming” underperformers

OPTION 6: PERFORM AUDITS AND PROVIDE FEEDBACK WITH BENCHMARKING TO CLINICAL TEAMS AND INDIVIDUAL PROVIDERS
Plan ongoing review of performance and providing feedback to individual clinicians/clinical teams in comparison with others. Focus on good examples with benefits to both providers and patients.

Advantages:
• Opportunity to review details and plan changes
• Allows individual approach addressing concerns and celebrating success

Disadvantages:
• Can be resource intensive, requiring good infrastructure to analyze and feedback results

OPTION 7: ENGAGE STAKEHOLDERS TO REDESIGN THE WORKFLOWS AND SUGGEST SUITABLE TRAINING APPROACHES TO ALLOW SEAMLESS INTEGRATION OF PRO COLLECTION
Engage key stakeholders to review and re-organize (if necessary) the workflow in the specific clinical team/area to allow PRO completion by patients. Ask them to recommend training approaches that will work for their clinical team. Make sure they approve and “own” the redesigned workflow and the PRO implementation strategies.

Advantages:
• An opportunity to address concerns of the stakeholders and to meet their needs
• A planned structured approach

Disadvantages:
• Workflow redesign can be a big task, requiring expertise in management and administration of clinical processes
• Redesign may have extra costs and may require further organizational approvals (administrative or financial), possibly leading to delays
• Different stakeholders may have different priorities and needs; reconciling them may be difficult
OPTION 8: ENGAGE STAKEHOLDERS TO SUGGEST HOW TO BUNDLE PROS WITH ADDITIONAL SELF-REPORTED DATA THAT OFFLOADS WORK FROM PROVIDERS

Work closely with front line teams to identify additional patient self-reported data that offloads work from providers (for example review of symptoms, past medical history, health habits, family history) and facilitates documentation thus leaving more time for patient/provider interaction. Explain the benefits of this approach during providers’ training to motivate and engage them.

Advantages:
- As providers experience offloading of some elements of patient intake, rather than more work, they will more easily become motivated to continue this type of data collection

Disadvantages:
- Can be resource intensive to design the expanded questionnaire content
- Some providers will continue to ignore the data and repeat the same questions to patients

Theme: Training in Interpretation and Use of PRO Scores

OPTION 1: FACE-TO-FACE SMALL GROUP TRAINING WITH A FOCUS ON INTERPRETATION

Brief training in how the PRO scores are calculated and interpreted. Traditional PowerPoint presentation with brief case examples can be used. Can be delivered either in small groups (at existing departmental meetings) or individually to fit with the providers’ schedule. To be done at the start of the project, for each new staff member, and then ongoing support, as needed.

Advantages:
- Opportunity for questions and discussion
- A personal approach, which can be adapted to individual provider’s level of knowledge and understanding

Disadvantages:
- Can be time consuming
- Has to fit into individual provider’s schedule
- May not be possible for large organizations or departments
- Discussion in a group is less likely to address an individual’s gaps in knowledge and concerns

OPTION 2: FACE-TO-FACE SMALL GROUP TRAINING WITH A FOCUS ON HOW TO USE THE PRO SCORES

In-depth training session covering PRO score interpretation plus worked examples of how the results can be integrated and used in clinical practice. Address perceived barriers and concerns. Traditional PowerPoint presentation with brief case examples can be used. Trigger videos of cases can be developed to support discussion. Can be delivered either in small groups (at
existing departmental meetings) or individually to fit with the providers’ schedule. To be done at the start of the project, for each new staff member, and then ongoing support, as needed.

**Advantages:**
- Provides an opportunity for discussion and trying different approaches, based on theories of adult learning
- Engages providers in discussion

**Disadvantages:**
- Time consuming to prepare the training material, especially if using videos
- Can be difficult to find time for small group training in a busy clinical environment

**OPTION 3: MANUAL AND GUIDELINES ON INTERPRETATION**
Score calculation, interpretation, and worked examples to be developed in a written manual or a booklet. To be presented to providers at the start of the project and accompanied by pocket cards to aid interpretation.

**Advantages:**
- Can provide a comprehensive overview and training, yet allow flexible choice of topics
- Can be used as a reference

**Disadvantages:**
- Cannot address fully specific needs of individual staff members
- Limited opportunity for interaction and questions
- Didactic approach may be perceived negatively by providers
- Booklets can be lost easily

**OPTION 4: E-LEARNING PROGRAM ON INTERPRETATION AND USE OF PRO**
Score calculation, interpretation, and worked examples to be developed as an e-Learning program. To be completed at the start of the project. Link to the e-Learning to be available via the EHR (for example, on the screen displaying the PRO report), to ensure easy access to reference material, if needed.

**Advantages:**
- Can provide a comprehensive overview and training, yet allow flexible choice of topics
- Can be done on staff’s own time
- Will generate a formal record of provider training

**Disadvantages:**
- Cannot address fully specific needs of individual staff members
- Limited opportunity to ask questions
- Negative providers’ attitude to an increasing number of e-Learning programs
OPTION 5: INTEGRATE SCORE INTERPRETATION INTO THE PRO REPORT/DISPLAY IN EHR
The display of PRO scores in the EHR allows the user to view which questions were asked and the range of scores. If information is available, abnormal scores can be highlighted or information buttons provided. Reference values for the general population and specific patient groups can be provided.

Advantages:
• Builds on providers’ experience in interpretation of widely used clinical investigations (laboratory results)
• Simple approach which ensures consistency

Disadvantages:
• May not be suitable for providers with less knowledge or confidence
• May result in misinterpretation if not supported

OPTION 6: PROVIDE NOTIFICATIONS/ALERTS FOR PRO SCORES OF CONCERN (see Section 9 for more details)
Some established screening PRO instruments have well-defined critical values that in the EHR will trigger pages/e-mail/text message alerts to the designated individual(s) when such PRO values are reported. This approach provides “just-in-time” training to members of the care team that may be new to the PRO instruments.

However, some PRO measures may be used for monitoring and may not have established threshold levels and scores of clinical concern. Engaging clinicians in defining whether PRO scores of potential concern should be flagged in the display and potentially generate notifications is essential to ensure successful implementation and ongoing support.

Advantages:
• Immediate support for ongoing patient care
• Will incentivize patients who will see their reports being used by the providers

Disadvantages:
• Providers have concerns that when this approach is new to them, it will require re-design of services and may significantly increase their workload
• Concerns that providers may not be able to respond immediately, putting patients at risk
• Litigation concerns if unable to respond immediately to notifications/alerts

OPTION 7: TRAIN PROVIDERS IN THE USE OF DECISION SUPPORT TOOLS TRIGGERED BY ABNORMAL PRO SCORES
An abnormal PRO score can be linked to suggested clinical actions either briefly displayed in the EHR or via a hyperlink to related decision support tools, clinical protocols, or referral pathways. Engage providers in developing appropriate decision support tools or train them in their use.
Advantages:
• Immediate decision support for ongoing patient care
• Good clinical algorithms will improve decision-making and save provider’s time
• Will incentivize patients who will see their reports being used by the providers

Disadvantages:
• In patients with problems in multiple PRO domains this approach may result in a complex and time consuming decision support system(s)
• Algorithms for decision support tools need expert input and consensus, which may take a long time to develop and evaluate

OPTION 8: SET OF SIMPLE REMINDERS FOR PROVIDERS ONCE THE PROJECT IS ONGOING
Reminders on how to access the PRO scores, how to interpret the results, and how to use them in patient care can take various forms, as appropriate for the clinical setting. Examples are “pocket cards”, posters in clinic areas, and screen savers.

Advantages:
• Keeps providers engaged

Disadvantages:
• May be seen as an added burden in a busy clinical setting
• Requires a dedicated person to ensure reminders are available
Use Case Example 1: A cancer center has started routine PRO data collection on adverse events during chemotherapy via a secure online PRO system, with a standard set of symptoms/side-effects. PRO data are imported into the EHR via a custom interface and displayed in a tabular and graphic format. A brief PowerPoint presentation was prepared for standardized training of oncologists and nurses in how to access PRO reports in the EHR and how to interpret the scores. The key message to the providers was encouraging them to use the PRO data in the encounters, and to acknowledge and thank patients for their engagement. Evidence was presented that PRO data do not prolong the encounters and can help to focus the medical interview. The training was delivered in several ways:

1) At the initiation, the project leader presented the planned integration at key large departmental meetings to inform and engage providers.
2) The project leaders attended existing team meetings to deliver the training in small groups, keeping a record of all attendees.
3) Providers that did not attend were contacted and training was arranged at convenient times.
4) Once the project started, members of the project team were available in clinic areas to remind and encourage providers to use the new system.
5) The training presentation was made available via a hyperlink from the EHR screen displaying PRO reports.
6) When new providers joined the team, they were trained either in person or briefly introduced to the system in one-to-one training using the hyperlink in the EHR.
7) Laminated sheets with brief instructions on how to find and interpret the PRO reports were distributed in all clinic areas to act as reminders and quick reference guides.

After about 6 months into the project, an audit of the PRO data was presented at a large departmental meeting to show the value of the collected PRO data and give examples of positive impact on patient care.
Use Case Example 2: Institution Y has fully integrated PROs in its EHR, supporting collection of PRO data from patients via the patient portal, smart phones, and tablets at the time of the visit. Providers and staff have been trained how to “order” PROs either synchronous with an encounter or asynchronous via a message to the patient portal. Other providers have worked with the IT team to develop custom logic that will automatically attach a PRO to a visit or send out a PRO to a cohort of interest. Providers and staff have also been trained to know where to look in the EHR to find the results. This training has been done with a) small groups, b) one-on-one at the elbow support, c) peer-to-peer training, and d) the development of videos available on the organization’s intranet. The core PRO team has a dashboard to monitor PRO completion rates and, where there are low rates, can supplement training to those groups or individuals to troubleshoot. Providers and staff have also been trained how to use documentation tools to more efficiently find results and share them with patients. PRO score interpretation is built into the results report and several PROs have associated triggers to drive alerts and best practice advice within the EHR. In one instance, such advice was not provided and resulted in a temporary influx of consults to a supporting service. The problem was immediately addressed by re-visiting the training and alerts to ensure they were providing optimal support to frontline teams.

KEY INFORMATION GAPS AND RESEARCH QUESTIONS

• What conditions and which modes of communications are most effective to ensure high rates of PRO completion?
• What kinds of reminders/alerts are most effective for encouraging the care team to review results with patients?
• What is the optimal way to explain PRO results to patients – different scaling, different meaning of positive/negative scores, how to explain normative data or benchmark data?
• Which conditions and which modes are most effective to achieve the highest PRO completion rates? Does it vary by type of PRO, does it vary by patient clinical characteristics? Does it vary by whether clinicians effectively use the PRO information in their interactions with patients?
• What are the most common barriers to achieving high rates of PRO completion? E.g. technology issues vs. motivational issues?
• Which subpopulations of patients need the greatest support for PRO collection vs. those who will intuitively complete questionnaires with little assistance?
• What are the key incentives and disincentives for patients to engage in PRO completion?
• What kinds of decision support would be most useful for patient self-management in response to abnormal PRO scores? This will vary with the health condition, specific PRO used, and how actionable the PRO results are.
• How to decide which type of provider training and engagement works best for a given organization, team, or clinical situation?
• Do different providers groups have different training needs (physicians, nurses)?
• What is the role of decision support tools that may be based on PRO results?
• More evidence is needed on the benefits from PRO collection and display in the EHR for patients, providers, and health organizations (including cost-benefit ratio and cost-effectiveness).

USEFUL REFERENCES/RESOURCES


4. **WHAT POPULATIONS AND PATIENTS ARE MOST SUITABLE FOR COLLECTION AND USE OF PRO DATA, AND HOW CAN EHRS SUPPORT IDENTIFICATION OF SUITABLE PATIENTS?**

PRO measures capture important information about individual patient and population-level health. Advances in EHR technology allow for tailoring and automating outreach, capturing, and reporting PRO data to support clinical and administrative decision-making. The collection of PRO data depends on a number of factors (clinical context, intended use of PRO data, system(s) used for integrating PROs in EHRs, etc.). This section addresses how the EHR supports the inclusion of patients or populations of patients for PRO collection.

Another consideration in collection and use of PRO data is that data collection is determined both by the health care system, in identifying patients from whom PRO data is solicited, and by patients themselves in responding to requests for PRO data. Some patients may be particularly unlikely to respond because of factors such as health literacy, language barriers, or functional or cognitive limitations. Collecting PRO data from these patients is challenging, but can be enhanced by use of well-designed PRO collection systems, appropriate technology-assist options, or supportive processes. Concerns about data security and the intended use of data provided may also influence patient willingness to complete PRO measures. Efforts to engage patients in the design process will help identify strategies to address important barriers such as transparent messaging, providing patient controls for data sharing, and improved user-centered design. Similarly, analysis and interpretation of PRO data for low-response subpopulations should be based on methods that account appropriately for missing data.

We organize this section first by populations who might be targeted for PRO collection (options 1 and 2) and then by more tailored approaches based on patient needs and care (options 3 and 4). We recognize that it is possible more than one approach might be used.

**OPTION 1: ALL PATIENTS FOR WHOM PROVIDER/SYSTEM IS ACCOUNTABLE**

Collecting PRO questionnaires for all patients for whom a provider or health care system is accountable creates opportunities for routine assessment of PROs including patient symptoms, function, or health-related quality of life. One example is annual screening for depression across a patient population. This approach may be applied to ensure standard practices for routine assessments on domains of patient health not captured by available clinical tests, to support population health tracking on PROs, and even to conform to standards established by accountable care organizations or value-based purchasing contracts.

Advantages:
- Creates a culture for PRO capture for the health care organization and its patients
- Establishes routine expectations for staff, patients, and providers for PRO capture
- Provides routine screening and/or assessment of health-related quality of life, function, etc.
• Provides the ability to track population health on common PROs
• Provides an opportunity to incorporate screening measures (i.e., depression) required to comply with quality reporting programs mandated by payer organizations
• Allows for a known expected denominator for determining response rates to PROs when aggregating data for quality improvement or population health metrics

Disadvantages:
• The timing of PRO capture, if conducted at a predetermined time (e.g., annual) may miss important events/issues occurring between visits
• Scripted capture of PRO measures, without clear connection to patient care, may reduce rapport and/or openness in responding
• Workflows need to be flexible enough to fit the clinical objective of various PROs and a one-size-fits-all approach may not allow for flexibility
• Limited ability to collect information specific to particular conditions or treatments; need a tailored approach for this
• Patients without access to/competency in selected PRO data collection systems may require additional options (e.g., paper surveys, telephone response) and/or support to complete PRO questionnaires, adding to time and cost for completion
• Not all patients for whom a provider is responsible will be seen at regular intervals, raising concerns associated with low response rates and high missing data

OPTION 2: PATIENTS PRESENTING FOR CARE IN A DEFINED CLINICAL SETTING
Patients who receive care in specific clinical settings such as primary care, behavioral health, or specialty clinics allow for further targeted PRO collection based on a common setting. This provides an opportunity to assess PROs across a population of individuals. Under this approach, the EHR supports PRO collection by identifying patients based on location where care is received.

Advantages:
• Creates a culture for PRO capture
• The clinical setting or defined area of care provides an opportunity to blend generic and condition-specific PRO questionnaires appropriate to the care setting
• Allows for a known expected denominator for determining response rates to PROs when aggregating data for quality improvement or population health metrics

Disadvantages:
• Many patients have more than one condition. Burden on patients should be considered if every area is able to define its own specific PROs for collection
• Not closely tailored to the patient’s individual needs, because any real clinical setting has a heterogeneous patient population
• Interpretation will depend on who is seen in the clinic (HIV clinic vs. general primary care vs. orthopedic specialty clinic) unless population norms are available
OPTION 3: PATIENTS WITH A DEFINED CONDITION (E.G., PARKINSON’S DISEASE, HEART FAILURE, ETC.)

PRO data provide important information when administered to individuals with a specific condition or diagnosis, either a chronic condition or an episodic, time-bound condition. For example, it can provide information about the effects of a new treatment on a patient’s symptoms or function. PRO questionnaires are often developed for specific health conditions and evidence is more likely to exist to inform their use in practice.

Advantages:

• PRO questionnaires are frequently developed to provide information on patients with specific conditions or diagnoses
• Defining anchor events (e.g., initiating new treatments, set time points following diagnosis) for initiating PRO questionnaires may be clear
• Existing evidence on clinically important differences established for specific conditions provide actionable information for clinical care

Disadvantages:

• Some conditions may not have well-validated PROs with clear interpretation
• Need to have specific inclusion criteria linked to EHR data, with realistic assumptions about documentation completeness and accuracy. Simple criteria based on provider diagnoses may be affected by inaccurate encounter coding or problem lists. More complex criteria, perhaps involving laboratory or pharmacy data, may be challenging to implement
• Patients with multiple conditions may be overburdened
• Need to have timely identification of conditions. Conditions diagnosed or documented during an encounter will only result in timely PRO administration with tight integration of encounter data

Use Case Example 1: Population Driven PRO Capture: A health care system wants to screen all members for depression to ensure comprehensive care is provided. Screening occurs through routine collection of the Patient Health Questionnaire (PHQ-9), a widely used instrument for screening, diagnosing, monitoring, and assessing the severity of depression in clinical practice. Screening occurs for all annual well visits. For appointed visits, a PHQ-9 questionnaire is programmed and automated through the EHR-linked patient portal where individuals can complete the questionnaire online prior to their scheduled appointment with their health care provider. Patients who have not completed the questionnaire prior to the visit are asked the PHQ-9 questions at the point of care by the medical assistant. Automated scoring provides immediate results to the health care provider with recommended actions for treatment, including referral for care for patients with scores indicating depressive symptoms. An algorithm built into the EHR system schedules subsequent questionnaires based on results, including an annual recheck for patients with no signs of depression and a 3-month recheck for patients identified as needing additional attention.
• Defining specific uses for PRO implementation may require additional training or reminders when integrating into the clinical workflow if use is not frequent or part of routine practice
• Without a system for coordinating across PRO technology systems, patients receiving a condition-specific PRO questionnaire are likely to experience burden from inconsistencies in timing, mode of administration, frequency, length, etc. A system to coordinate across applications would need to include both governance and technical implementation

OPTION 4: PATIENTS WHO RECEIVE A SPECIFIC TREATMENT
PROs can provide data about outcomes following specific treatments or procedures. The EHR supports PRO collection by facilitating the identification of patients who are scheduled to, or have received, specific treatments or procedures. With programming, it is possible to assign PRO questionnaires at defined time points to support the goals of the activity.

Advantages:
• Allows for a targeted measurement strategy based on treatments received
• Existing evidence on clinically important differences established for specific treatments provide actionable information for clinical care and quality improvement
• Supports the ability to trend data on patient-reported domains relevant to the individual’s health and health care goals
• May support comparison of different care providers

Disadvantages:
• Some conditions may not have well-validated PROs with clear interpretation
• May require additional resources for follow-up if PRO assessment is required independent of the health care visit
• Establishing algorithms for treatment-specific PRO assessments may be required
• Limits comparisons to other treatments patients might receive for a given condition if not part of the scope for PRO assessment
Use Case Example 2: Tailored PRO Capture: A surgical practice wishes to assess symptoms and functional outcomes after total hip replacement, and to identify patients whose recovery is not as expected and may need additional care. They administer the Hip disability and Osteoarthritis Outcomes Score (HOOS) questionnaire upon referral for a surgical consult to establish a baseline score. Patients complete the survey electronically through a kiosk located in the surgical practice. The survey is administered prior to the surgical consult, allowing for automatically generated scores to be transmitted to the patient’s EHR. Results of the HOOS and other clinical data are assimilated and used by the surgeon and patient as part of shared decision-making about surgery versus conservative treatment. After the visit and a decision to proceed with surgery, follow-up surveys are scheduled for the patient to receive and complete online at 6 and 12 months after surgery. Patients completing the HOOS questionnaire after surgery with results that show incomplete restoration of function are scheduled for a follow-up visit and may be referred for additional physical therapy. In addition to patient care, the data are viewed and benchmarked quarterly as part of a national registry, to identify opportunities to improve the quality of care provided to patients.

KEY INFORMATION GAPS AND RESEARCH QUESTIONS

- Are certain populations excluded due to questionnaires used (cultural/language/accessibility issues)?
- Does PRO administration in clinical workflows change or bias patient responses, compared to administration in a research setting? For which patients?
- Is there a meaningful difference between cohorts who complete the PRO measures (or a given question) versus those who do not?
- What methods for data analysis best support/address missing data for different purposes?
- What impact does routine assessment of PROs in primary care have on patient outcomes and access to care, and does impact vary across patient populations?
- What PRO implementation strategies are most effective for managing patients with multiple chronic conditions?

USEFUL REFERENCES/RESOURCES

Implementation of PROs may vary based on EHR system, population followed, or context of decision-making. The selected resources are grouped into two categories: general and population-specific resources. General resources provide examples of PRO implementation across diverse populations. Population specific resources highlight examples of specific populations targeted for PRO capture leveraging diverse approaches to data capture.

General Resources


Population Specific Resources


5. WHICH OUTCOMES ARE IMPORTANT TO MEASURE FOR A GIVEN POPULATION?

This section concerns outcomes, which refer to what is being measured. Examples of outcomes are pain, fatigue, upper mobility, and social functioning. A later section (Section 6) deals with how the outcomes are assessed in terms of specific items and/or questionnaires.

Please note that some of the advantages and disadvantages of the various options below may differ depending upon the type of assessment used to measure the particular outcome. For example, while some might be concerned that generic outcomes may be less sensitive than disease-specific outcomes, the relative disadvantage might not exist if the generic outcome is measured using a computerized adaptive test that draws from a large item bank. Similarly, the advantages listed for any of the various options listed below may be irrelevant if the outcome is measured using a recall period (e.g., “In the past 7 days...”) that is not a good match for the intended goal of measurement in a particular setting.

This section is broken down into three subsections: (1) Which categories of PROs should be measured for a given patient? (2) How specifically should the PRO target a particular disease? and (3) What is the role of the EHR in tailoring outcome assessments? The options listed may not be mutually exclusive.

Which Categories of PROs Should Be Measured for a Given Patient?

Depending upon the scenario, there may be benefit for measuring any of several broad categories related to self-reported health including symptoms, functioning, social health/social support, general health perceptions, and/or health related quality of life.

OPTION 1: SYMPTOMS

A symptom is a subjective physical or mental experience caused by some underlying disease or health condition, or as an adverse effect (sometimes referred to as a side effect) of a health care intervention. Although symptoms and adverse effects are sometimes measured separately, it is often difficult for patients to accurately attribute an experience to disease vs. treatment. Therefore, it makes sense to combine these two categories. Examples of symptoms include pain, fatigue, anxiety, and depression. The measurement of symptoms has both advantages and disadvantages.

Advantages:

- Symptoms can be highly informative for individual patient management in the clinical environment including facilitation of a diagnosis or assessing response to therapy, in part because clinicians are accustomed to dealing with them
- For clinical research, symptoms are the most proximate effects of a disease or health condition, and so are often more sensitive to changes in underlying health


• For quality assessment/improvement, symptoms can be indirect measures of quality processes
• Assessment of mental/emotional symptoms such as anxiety, depression, and anger may reveal important information which may not be readily apparent by solely measuring physical symptoms

Disadvantages:
• For patients with multiple diseases or health conditions, assessment of all relevant symptoms could be burdensome
• It may be difficult for the patient to determine whether a symptom is caused by a condition or disease versus therapy or intervention, with resulting implications for the best method of addressing those symptoms

OPTION 2: FUNCTIONING
Functioning refers to how well individuals can carry out activities that may be important for their daily living. Functioning pertains to several domains including physical functioning; psychological functioning; and social functioning. Examples of functions include lower extremity mobility, erectile function, cognitive ability, and the ability to fulfill social roles. Measurement of functioning has both advantages and disadvantages.

Advantages:
• Information about a patient’s functioning can inform individual patient management
• Functioning is typically absent from the patient’s clinical record, and so the addition of functioning assessments represents an important enhancement for individual patient management, research, and quality assessment/improvement
• Functioning can efficiently reflect the net effect of multiple underlying diseases/conditions and their associated symptoms
• For clinical research, functioning is an outcome that is important to multiple stakeholders
• Functioning is highly relevant for quality assessment/improvement, population health monitoring, and value-based purchasing
• Functioning is potentially observable and may be measured and/or corroborated by other procedures, including testing, and also by reports from others including family members and clinicians

Disadvantages:
• Wide range of possible functions requires prioritization to measure the functions that are most relevant for the goals at hand
• For clinical research, it is often more challenging to demonstrate the effects of interventions on functioning compared to symptoms. This is because functioning is further “downstream” than symptoms and is more influenced by characteristics of the person and his/her environment and may be influenced by baseline level of functioning
• A person’s rating of his/her performance on a certain function depends on whether s/he has had an opportunity to perform that function during the reporting period (e.g., may
not have been able to walk a block or more in the past 7 days because of cold weather). Interpretation of functional performance may be difficult if one does not know whether the opportunity for performance was present

**OPTION 3: SOCIAL HEALTH/SOCIAL SUPPORT**
Patients’ social health relates to their perceptions of social functioning including participation in relationships, social interactions, and perceptions of social support or isolation.

**Advantages:**
- Provides a more complete picture of patients and their day-to-day environment
- Can provide data on a broader definition of health that includes family and close personal contacts
- May identify additional resources that may be of assistance to the patient or that may be needed by the patient
- May reveal other factors that impact adherence to health care recommendations

**Disadvantages:**
- May reveal issues the health care team is ill-equipped to handle
- As was the case with functioning earlier, interpretation of social health may be difficult if one does not know whether the opportunity for social contact was present

**OPTION 4: GENERAL HEALTH PERCEPTIONS**
General health perceptions refer to the person’s overall evaluation of his/her health, including perceptions of improvements or decrements in health over time.

**Advantages:**
- General health perceptions often drive patients’ health decisions (e.g., to seek care, to discontinue use of a drug, etc.). As such, they are important to understand in the context of individual patient management and research
- Because of their generality and relevance to decision-making, measures of general health perceptions can be efficient and powerful predictors of patient’s behavior, and thus play a role in tailoring clinical interventions
- May have prognostic value independent of other clinical data

**Disadvantages:**
- Without measuring other types of outcomes, general health perceptions are less clinically actionable, although they may be an indicator of issues that need to be addressed
- Used as an endpoint in clinical research, general health perceptions may be poor proxies for the patient’s symptoms and functioning

**OPTION 5: HEALTH-RELATED QUALITY OF LIFE**
Health-related quality of life (HRQOL) is a broad construct that reflects the impact of a number of variables on a patient. Various models of HRQOL include variables such as biologic and
physiologic variables, symptoms, functional status, psychological well-being, general health perceptions, as well as individual and environmental characteristics. Some models include spiritual, societal, economic, and family-related domains; others group these under the broader construct of general quality of life. A global HRQOL score, in addition to other individual domain scores, may be a useful indicator of issues not otherwise addressed and thus may spur further investigation.

Advantages:
- Measures that provide an overall or global HRQOL score may provide additional information not reflected in the individual domains measured, such as physical, emotional, functional, and social well-being
- Afford the ability to compare HRQOL score across or between populations of patients with similar or different conditions
- A single-item global HRQOL score may quickly screen for an overall improvement or decrement in a patient’s condition

Disadvantages
- Clinicians may be uncertain how to provide specific interventions based on a global HRQOL score due to a lack of specificity regarding underlying issues contributing to patients’ perceptions of their HRQOL

How Specifically Should the PRO Be Targeting a Particular Disease Population?

OPTION 1: DISEASE-SPECIFIC OUTCOMES
Disease-specific outcomes are those outcomes that are attributed to a particular disease or health condition. For example, disease-specific outcomes for patients with psoriasis might include symptoms of itching, redness, burning, cracking, flaking, and pain. Note that in some situations, it might be beneficial to include assessments of both disease-specific and generic PROs.

Advantages:
- Disease-specific outcomes tend to have greater utility for individual patient management versus generic measures
- Patients who are administered disease-specific measures are more likely to feel that the questions are relevant to them
- Measures of disease-specific outcomes may have greater ability to demonstrate changes in health in both research and clinical care settings
- Focusing on a specific disease provides an opportunity to combine the use of generic and disease-specific measures

Disadvantages:
- The questionnaire burden will increase in proportion to the number of diseases/conditions the patient has
• For patients with multiple diseases/conditions, there could be redundancy among the multiple disease-specific outcome measures. For example, many measures of disease-specific outcomes include questions about pain.
• Questions that ask patients to attribute some experience (e.g., fatigue or social functioning) to a specific disease/condition may have questionable validity. While patients might be good reporters of their experiences, they are likely less able to pinpoint the specific underlying cause of their experiences. For example, a patient with heart failure, depression, and chronic obstructive pulmonary disease would have a very difficult time determining to what extent each individual disease affected his or her level of energy.
• Disease-specific outcomes have unclear relevance for patients who are being seen for a “well visit,” and as such may not have a specific disease or condition.

OPTION 2: GENERIC OUTCOMES
Generic outcomes are those that are relevant across a broad range of patients and healthy people. Examples of generic outcomes include fatigue/energy, pain, and physical functioning.

Advantages:
• Can be used for any person who comes in for a health care visit of any kind.
• There is a lower chance of redundancy among generic outcomes than disease-specific outcomes, making assessment less burdensome and more efficient.
• Because the same outcome is measured across different diseases/conditions, it makes it possible to compare outcomes across different types of patients (e.g., the fatigue of patients with heart failure compared to patients undergoing chemotherapy) and treatments.
• Generic outcomes can reflect the net effect of multiple diseases/conditions on the person’s well-being.
• The prior two advantages (comparability and net effects) make generic outcomes useful for health policy decisions about resource allocation across diverse health conditions.

Disadvantages:
• Might not be sensitive enough to detect changes or differences due to a specific disease.
• Might be considered less clinically actionable to specialty clinicians compared to disease-specific outcomes.
• Patients might not find questions about generic outcomes to be as relevant to their immediate health concerns.
What Is the Role of the EHR in Tailoring Outcome Assessment for an Individual Patient or a Particular Disease?

OPTION 1: EHR IS USED TO TAILOR OUTCOME ASSESSMENT FOR AN INDIVIDUAL PATIENT OR A PARTICULAR DISEASE
The EHR could tailor which PROs are assessed for a given patient or for a given disease in several ways. Tailoring could be based on other data within the EHR (e.g., diagnosis, laboratory tests, past PRO responses, sociodemographic data).

Advantages:
• Efficiency
• Potentially allows for tailoring of PRO items depending on the answer to screening questions (e.g., via computer adaptive testing)
• Can link to other data within the electronic record to trigger administration of a screening tool. For example, a low red blood cell count meeting a predefined level for anemia may trigger sending a patient a questionnaire about fatigue and shortness of breath
• May link responses to management pathways or clinical practice guidelines
• With multiple stakeholders having access to outcomes data within an EHR, may decrease potential redundancy of assessment

Disadvantages:
• Positive responses to screening items may lead to longer questionnaires, including some questions not relevant to the patient

OPTION 2: EHR IS NOT USED TO TAILOR OUTCOME ASSESSMENT FOR AN INDIVIDUAL PATIENT OR A PARTICULAR DISEASE
Generic outcomes are those that are relevant across a broad range of patients and healthy people. Examples of generic or disease agnostic outcomes include fatigue/energy, pain, and physical functioning.

Advantages:
• May allow for comparisons across patients or populations

Disadvantages
• May not capture all domains related to a specific health condition
• Patients may be dissatisfied or less likely to complete questions if they do not see the relevance to their particular condition

KEY INFORMATION GAPS AND RESEARCH QUESTIONS
• What is the optimal method of data collection and assessment of all relevant patient symptoms for a particular health condition(s) that minimizes patient burden and facilitates integration of data into the EHR?
• How does one determine the appropriate balance between administering generic and disease-specific measures depending on the clinical situation?
• What is the optimal way of displaying generic or disease-specific patient-reported data alongside clinician-reported observations/assessments within the medical record?
• Are there specific features that should be considered in identifying PROs for specific uses and do they differ with the application (e.g., over-arching, specialty-specific, condition-specific, procedure- or treatment-related)?

USEFUL REFERENCES/RESOURCES


Van Der Wees PJ, Nijhuis-Van Der Sanden MW, Ayanian JZ, Black N, Westert GP, Schneider EC. Integrating the use of patient-reported outcomes for both clinical practice and performance measurement: views of experts from 3 countries. Milbank Q. 2014;92(4):754-75.

6. HOW SHOULD CANDIDATE PRO MEASURES BE EVALUATED?

After determining the purpose and population(s) to target for PRO completion, the user faces the challenge of identifying which PRO measure(s) to select. In fact, the “user” is often not an individual or representative of a singular purpose such as clinicians, patients/caregivers, policy makers, payers, and/or researchers. In an organization such as an integrated delivery system or accountable care organization (ACO), there may be a strategic vision for harmonizing metrics across the care continuum as well as for population health management and/or value-based purchasing.

When selecting PRO measures, a balance of purposeful needs (e.g., clinical care, research, population health management) together with attributes of the PRO measure need to be considered. Relative value should be determined in order to justify potential burden on organizational staff/resources for data collection, on patients/caregivers for responding to questions, on clinicians for reviewing results, and payer requirements for PRO assessment.

Depending on the outcome of interest, PRO measure selection might entail choosing from a multitude of candidate instruments, or potential recognition of a lack of an ideal instrument for the identified purpose. There are several criteria to bear in mind with respect to PRO measure suitability, including: how a measure is defined, if the measure has been validated, its reliability and precision, whether a measure is in current use, length/brevity, respondent burden, clinical workflow burden, interpretability of score, licensing/cost, intended use, and availability of translated/culturally competent versions. Additional considerations include an approach to standardizing PRO measure use based on health system needs (ranging from population health management to advanced payment such as value-based purchasing, direct clinical care, through improvement/research activities) as well as for efficiency of PRO measurement and harmonization across the care continuum or multiple settings in a care delivery system.

PRO integration into the EHR may serve multiple purposes and be used in various contexts. The EHR is a query-able tool that houses important information about an individual patient to support decision-making and clinical treatment planning. As an amalgamation of crucial information, it becomes a trade-off in determining where and how to display clinically relevant information so that it is readily available to clinical care teams (and patients/caregivers in the case of an open notes structure or patient portal).

Selection of PROs for integration into clinical care is best done with multiple inputs. When collected in a clinical setting for clinical use, a process to integrate patients (and proxy caregivers in contexts where self-report is not feasible or sufficient) into selection of PRO measures may support relevance and appropriateness with the goal to reduce non-response. Inclusion of the clinical team perspective is important to understand if PRO data can be used to guide decision-making and impact the treatment plan during the clinical encounter. Analysts and/or health services researchers may play a role in providing guidance to providers on PRO...
measurement properties, evaluating whether the PRO data can be utilized to evaluate patient status over time, performance of the delivery system in improving health, and meeting potential reporting requirements.

Stakeholders may take a health system-wide, institutional, or work unit approach in PRO measure selection. Considerations include harmonizing PRO collection across a continuum of care, creating algorithms and/or designing data collection tools to reduce burden on respondents and staff, accounting for additional workflow decisions such as personnel to review PRO results, training on PRO interpretation and use, and monitoring whether intended intervention occurs based on score reports. Additionally, measurement of the reliability of the system and impact of PRO use at the level of the clinical unit, or the institutional level, need to be considered.

Criteria that may be employed to evaluate PRO measures for integration in the EHR are described below. Rather than advantages/disadvantages, for each criterion, positive and negative attributes are described.

**CRITERION 1: AVAILABILITY OF PRO**

**Positive Attributes:**
- Assessment of a proposed PRO allows for examination of key questionnaire/survey attributes such as definition, validity, language/cultural competence, number of items/duration
- Consideration regarding how candidate PROs may be tied to external payer, or policy requirements, or industry norming may result in better return on investment from an organizational perspective
- Crosswalk between legacy measures in the same domain may be available, enabling use of new, more efficient PRO measures rather than those used historically
- Identification of clinical champion(s) to support data collection and advocate for the use of candidate PRO(s)

**Negative Attributes:**
- Lack of measure/survey availability in desired area that meets key attributes
- Already collecting similar information in another format or point of contact (e.g., Hospital Consumer Assessment of Healthcare Providers and Systems [HCAHPS])
- Cost of licensing (vs. in public domain). For PRO measures not in the public domain, need to obtain permission from copyright holders, establish conditions of use (including use in the EHR), execute necessary licensing agreements, and secure budgetary approval to pay fees where applicable
CRITERION 2: MEASURE/QUESTIONNAIRE ATTRIBUTES

Positive Attributes:
- Validation in relevant populations, including consideration of cultural relevance and health literacy/numeracy
- Tested in multiple languages
- Evidence on achievable therapeutic response to support clinical relevance
- Solicits non-clinical information important for collaborative treatment planning
- Clearly defined with published evidence on reliability, feasibility, and utility
- Brief; length of survey
- Low measurement error (scores give a precise reflection of patient state)
- Computer adaptive test (CAT) option across linked modules (e.g., global health, physical functioning, depression)

Negative Attributes:
- Complexity that requires paper-based/alternative data collection mechanism
- Lack of evidence for validity in target population
- Reading level not aligned with target population
- Lack of evidence for clinical relevance or utility in care delivery
- Lengthy
- Recall period may not adequately capture variation in patient state during stated timeframe

CRITERION 3: STANDARDIZATION

Positive Attributes:
- Reduction in number of PRO questionnaires required to be programmed or implemented
- Increases feasibility of adoption of PRO collection or scale up across health system
- Potential for reduced respondent burden, if standard PRO can be used across clinical encounters
- Increased efficiency, reduced duplication of work to identify relevant thresholds for interpretation and intervention (in a given population or setting) based on a PRO questionnaire
- Selection of PRO questionnaires used in common data models facilitates participation in EHR based registries
- Streamlined training of end-users

Negative Attributes:
- Lack of differentiation of measures (and possibly scoring thresholds) by clinical setting
- May result in longitudinal trending challenge if switching from previously used measures
- Institution-chosen questionnaire may not fit the specific clinical needs
CRITERION 4: ABILITY TO POOL DATA ACROSS DIFFERENT QUESTIONNAIRES MEASURING THE SAME OUTCOMES

Positive Attributes:
• Flexibility in choice of instrument may allow use of questionnaires of greater clinical relevance
• Allows for greater autonomy in clinic/clinician/researcher selection
• Reduces transition to new questionnaires for settings historically collecting PROs
• No central standardization process required

Negative Attributes:
• Methodological challenges and lack of evidence in pooling such measures and/or composite scoring
• Potentially reduces ability to scale up PRO collection across clinical settings
• Increased resources needed to program questionnaires, determine cut points for health status, and thresholds for intervention
• Likely increase in respondent burden of data collection by patients answering different PRO questionnaires in different clinic settings assessing the same health domains
• Analysis requirements may delay time to generate longitudinal outcomes results

CRITERION 5: INTEGRATION INTO EHR

Positive Attributes:
• Ability to track repeated measures over time in equal periodicity if tied to encounters
• Ready access at point-of-care (POC) to support clinical care delivery
• Support improvement/research around care quality and efficiency as well as potential for proactive population management
• Opportunity to educate patients and clinicians on utility of PRO information, how it can be used, rationale for repeated measures
• Potential for clinical decision support to aid therapeutic response in a timely manner (e.g., for positive response to suicidal ideation in PHQ-9, expectations for response time would vary based on completion in-clinic [real time] vs. when remotely entered by patient [need disclaimer on expected response time])
• Complex PRO, e.g., with branching logic, may be facilitated by collection in electronic format
• Potential for CAT for certain outcome domains adds efficiency and decreases respondent burden by reducing the number of PRO items for completion
• Point of care data collection will positively impact response rates, particularly at follow-up when tied to clinic visits
• Supports direct, timely interaction on reported responses
• Clarity of purpose for PRO collection and defined clinical question should be basis of design and location to display PRO information for ready access
**Negative Attributes:**
- Complexity of PRO that requires paper-based/alternative data collection mechanism
- No uniformity in use such that scores may be entered into unstructured Progress Notes vs. a coded data field
- Inability to annotate scores with clinician comments or clarifications
- Multiple collection and presentation strategies (e.g., coded field and Notes) diminish ready access to information
- PRO information collected but not used, reflecting lack of purposeful collection, wasted effort, unclear or unmet expectations
- Variable functionality across available, vendor-based EHRs
- Risk of repeated collection of PROs across care settings
- Vendor-based EHR may not have capacity for real-time integration of data

**CRITERION 6: STAND-ALONE SYSTEM FOR DATA CAPTURE**

**Positive Attributes:**
- Potential for CAT algorithms to minimize number of items asked while maximizing accuracy of results will reduce respondent burden
- PRO additions may be considered outside of routine EHR adaptive programming requests across an organization
- Timely addition/deletion of PRO measures
- Potential for use of a patient portal behind a secure firewall with automatic follow up periods (depending on vendor)
- PRO deployment/completion not tethered to clinic appointment, reducing burden on in-clinic workflow for greater patient population coverage and equal periodicity in measures. Review/response to PRO would require review outside of scheduled appointments

**Negative Attributes:**
- Potential delay in accessing information stored in separate system or enterprise data warehouse (EDW)
- PRO collection mechanism may require alternatives (web-based, telephone, in person) to accommodate patient needs
- Need to build/buy solution to display scores in EHR, alternatively printing/scanning into medical record or accessing two systems (single sign-on integration)
- Limited available options for direct interaction with clinical team
- Use of CAT-based PROs requires more advanced technical capabilities

**CRITERION 7: STAKEHOLDER ENGAGEMENT**

**Positive Attributes:**
- Representative patient/caregiver involvement at the stage of PRO instrument selection is a key component for co-production of health care
• Clinical team involvement in PRO instrument selection enables consensus building and buy-in of intended end-users—a prerequisite for reliable clinician review and use of scores
• Early research/analyst involvement in planning will support selection of measures with evaluable data
• Pilot testing of questionnaires and technology platforms by end-user subgroups will support more successful roll-out

Negative Attributes:
• Obtaining patient/caregiver input requires specialized experience/expertise, may be time consuming, and input may not be generalizable
• There could be disagreement among and within stakeholder groups (clinical teams, patients, researchers) over relevance, purpose, and value
• Potential lack of congruence between PROs best suited for improvement/research vs. clinical care

CRITERION 8: RESOURCES AND WORKFLOW IMPACT

Positive Attributes:
• Attention to workflow considerations will reduce burden of collection, increase reliability of PRO capture, and reduce non-use of results
• Harmonization of PROs (i.e., avoiding inclusion of multiple PROs within the same domain) will enhance use, minimize data collection and respondent burden, and streamline PRO use training/education efforts
• Costs (e.g., licensing fees) can be balanced with consideration of benefits or value to the system and patient care optimization

Negative Attributes:
• Increased complexity in EHR, need to look across the medical record to coordinate and prioritize presentation of information—e.g., summary score vs. sub-component or item-specific scores
• Potential for inefficiencies in clinical encounter if there is no longitudinal measure reporting, requiring review of past encounters to assess individual-level trends
• Resources needed to audit system and provide feedback to providers and system managers, and for guidance on process improvements
• Lack of harmonization will increase burden on clinical teams and patients/caregivers
• Investment in planning and analysis burden in considering suitability parameters to determine whether a given PRO should be included or not
• Competing informational/patient contact priorities (e.g., post-discharge follow-up, HCAHPS/satisfaction surveys)
KEY INFORMATION GAPS AND RESEARCH QUESTIONS

- Gaining a sufficient database of selected PROs to conduct research necessary for interpreting score changes indicative of:
  - therapeutic response
  - need to change therapy

Such information on significant clinical change in addition to support of clinical care is needed for outcomes research and value-based purchasing.

- Need for crosswalks to longitudinally link historical, common construct data collection efforts together with harmonized measure set (e.g., SF-12 and PROMIS 10).

- Address issues of equal periodicity in monitoring change/progress at individual and population levels.

- How should a delivery system prioritize PROs in balancing data collection burden on clinicians and response burden for patients?

- Can we minimize respondent burden by aggregating PRO information from all patient contacts (e.g., post-discharge check-in, follow-up PRO) across collection methods (i.e., telephone, e-mail, clinic visits)?

USEFUL REFERENCES/RESOURCES

**Published Articles**


**Invited Commentary**

Published Reports


7. **HOW, WHERE, AND WITH WHAT FREQUENCY WILL PROS BE ADMINISTERED?**

*Should the EHR Coordinate the Administration of Questionnaires for Multiple Purposes (Research, Operations, and Clinical Care) and Across Different Stakeholders?*

As PRO measure collection expands, the burden of data collection will also increase for patients, especially in larger health systems or those with broad implementation of PRO collection. Synchronization of questionnaire deployment is becoming a progressively important consideration. When questionnaire deployment is synchronized, questionnaire administration is coordinated across clinical areas. For example, if a depression screen was collected in Clinic A, patients with an office visit in Clinic B the following day will not be asked to complete the depression screen again.

The effectiveness of synchronization of deployment is dependent on the degree that the content of PRO collection is standardized, such that the same questionnaires/scales are used to measure the same construct across clinical areas. Synchronization also requires some technical capabilities of the PRO-EHR system.

**OPTION 1: SYNCHRONIZATION OF ALL QUESTIONNAIRES ACROSS CLINICAL AREAS**

Questionnaire administration is coordinated across clinical areas. Patients are not asked to complete a questionnaire if it was previously completed within a specified time interval at another clinic.

**Advantages:**
- Reduces patient burden
- Reduces duplication of effort related to PRO deployment
- Allows providers to review data that are not collected at the time of the visit
- Reduces workflow disruption by decreasing the number/redundancy of questions patients are asked to complete at a given visit

**Disadvantages:**
- Dependency on technological capabilities of the PRO-EHR systems to deploy questionnaires in a synchronized way, track the deployment across contexts, and display the results across contexts
- To minimize patient burden, it is necessary for different stakeholders to agree on questionnaires that cover the same constructs. This may be especially difficult when questionnaires are deployed for different purposes (research, clinical care, operations)

**OPTION 2: DEPLOYMENT OF QUESTIONNAIRES ARE NOT SYNCHANTORIZED**

Questionnaires are administered independently within each clinical area without consideration of whether it was previously completed at another clinic.
Advantages:
• Less technically resource intensive
• No dependency on technical capabilities of PRO-EHR system

Disadvantages:
• Increased burden for patients seen in more than one clinic, which may increase patient frustration and reduce patient completion rates and satisfaction with the assessment collection process
• If different instruments are used to measure the same construct, limits the ability to compare different populations and use data for population health monitoring
• Increased workflow disruption

Should the PRO-EHR System Build in Quality/Error Checks?
Quality of patient data is critical when using aggregate data for research or using patient-level responses for clinical care. Quality of data is impacted by both nonsensical data (for example, 1-10 pain level response = “100”), or missing data (for example, non-answered questions preventing calculation of scale score). Quality/error checks can be considered a requisite for patient-entered data collection.

One or both of the following options may be implemented.

OPTION 1: RANGE AND FORMAT CHECKS BUILT INTO THE PATIENT-ENTERED DATA COLLECTION SYSTEM
Range and format checks do not allow entry of nonsensical data elements.

Advantages:
• Reduces amount of unusable data
• Increases the proportion of completed responses that can be used in analyses or clinical care
• Reduces interpretation errors

Disadvantages:
• Requires programming effort

OPTION 2: SOME PATIENT QUESTIONS ARE “REQUIRED” TO MOVE TO NEXT QUESTION
Patients see a notation that a response is required before moving on to the next question.

Advantages:
• Reduces missing data
• Increases number of fully completed scales
Disadvantages:
• Does not allow patient preferences to opt-out of completing questions, which reduces patient autonomy and may cause patient frustration
• May reduce questionnaire completions
• Analysis of non-completed questions can provide information that can be used to improve PRO content
• May not be allowed by some institutions

Should Data from Multiple Modes Be Combined by the EHR for Presentation to Providers?
The availability of multiple modes of questionnaire administration such as office visit, patient portal, interactive voice response system, mobile apps, will improve with advances in technology and the growing collection of patient-reported outcomes. The ability for providers to view all questionnaire responses from different administration modes would improve provider workflow and allow providers to view trends in data over time. It is anticipated that some modes of administration, such as voice response system or mobile apps, may utilize technologies extrinsic to EHR.

OPTION 1: INTEGRATED REPORTING OF QUESTIONNAIRE RESPONSES COLLECTED USING DIFFERENT MODES OF ADMINISTRATION
A provider can view scores and/or responses from patient questionnaires collected using different methods of collection (for example: tablets, patient portal, or interactive voice response system). Aggregate reports of questionnaire responses contain data from different modes of administration. This requires that data elements are stored in the same place with the additional attribute of modality of collection.

Advantages:
• Allows providers to more efficiently track all patient responses over time and obtain a broader picture of the patient’s health status
• Allows flexibility in data collection, which may result in better completion rates as PROs can be completed via modalities that fit the needs of the given patient population/clinical scenario best

Disadvantages:
• Dependent on the technological capabilities of the EHR
• Data quality in different modes of collection may vary
• Responses collected using different modes of administration may not be comparable

OPTION 2: REPORTING OF QUESTIONNAIRE RESPONSES COLLECTED USING DIFFERENT MODES OF ADMINISTRATION IS NOT INTEGRATED
A provider cannot view scores and/or responses from patient questionnaires collected using different methods of collection on one data display.
Advantages:
- May be faster to deploy if not concerned with making sure multiple modalities all file to common data structures

Disadvantages:
- Less efficient for providers
- More difficult for providers to identify trends in questionnaires responses over time due to lack of integration

**Should the PRO-EHR System Collect Meta-data on How the PRO was Completed and by Whom?**

The inability of patients to complete patient-reported questionnaires due to physical or cognitive limitations or language barriers is a known limitation of patient-reported outcomes. Proxy responses, typically obtained from family caregivers, can be used in these instances. Proxies can answer questions from different perspectives. With the “proxy-patient” perspective, the proxy assesses a patient as the proxy thinks the patient would rate his or herself. In the “proxy-proxy” perspective, the proxy projects themselves as how s/he would respond if s/he was the patient. Responses may differ depending on the perspective taken by the proxy and the proxy should ideally be instructed on which perspective to take when answering questions.

In addition, health care providers may complete questionnaires by patient interview in cases where patients did not complete the electronic questionnaire or where patients started but did not finish all questions. Patients may respond differently to questions administered by an interviewer versus those they electronically complete themselves. The equivalence of proxy-reports and interviewer-reports with patient-reported data likely varies depending on the construct being measured.

One or more of the following options may be implemented.

**OPTION 1: PRO-EHR SYSTEM COLLECTS WHETHER QUESTIONNAIRE DATA WAS COLLECTED BY INTERVIEWER**

Meta-data on source of questionnaire completion is stored in the EHR and are available to the provider when viewing previously completed questionnaires and for use in reporting and data analysis.

Advantages:
- Allows analysis of clinical workflow and improved understanding of operational aspects of questionnaire collection
- Assists in interpretation of questionnaire responses
- Potentially allows for adjustment of scores for biases based on interviewer administration
Disadvantages:
• Dependent on the technological capabilities of the PRO-EHR system

OPTION 2: PRO-EHR SYSTEM COLLECTS WHETHER QUESTIONNAIRE COMPLETED BY CAREGIVER PROXY
Questionnaire set includes a question on who completed the questionnaire (patient, caregiver, or health care provider). An additional question may ask the relation of the person completing the questionnaire to the patient.

Advantages:
• Allows provider to interpret questionnaire responses in more accurate context
• May be necessary for some applications in research
• Potentially allows for adjustment of scores for biases based on proxy response

Disadvantages:
• Requires building and integrating an additional question within the questionnaire set
• Proxy responses can be completed by people with different relationships to the patient and caregiver roles. Definition of role of the caregiver proxy would require additional questions (i.e., “What is your relationship to patient?”, “How long have you known the patient?”)

OPTION 3: INFORMATION ON WHO COMPLETED QUESTIONNAIRE IS NOT COLLECTED AND STORED
No information is collected on who completed the questionnaire.

Advantages:
• Does not require additional resources

Disadvantages:
• Lack of this information may hinder utilization of data, especially in research
• Clinicians not provided with information that will help them interpret responses

How Can the PRO-EHR System Monitor Compliance/Alert to Missing Questionnaires?
Patient questionnaire completion rates are an important consideration. Low completion rates limit the effectiveness of collecting patient-reported data for clinical care and impact the ability to use data for aggregate analysis, such as quality reporting or research. Questionnaire completion may be impacted by patient-level factors such as cognitive or physical impairments, literacy, computer literacy, or language barriers, or operational factors such as clinical workflow, questionnaire content, or patient burden. Measuring completion rates is a necessary step to understanding reasons for suboptimal completion rates and developing interventions to improve performance. One or both options below may be employed.
OPTION 1: THE PRO-EHR SYSTEM GENERATES REPORTS OF COMPLETION RATES
This may entail regular group-level reports that can be used by providers and administrators, or it may consist of an individual-level tally of the proportion of questionnaires completed by a single patient, similar to a ‘no-show’ rate of a patient.

Advantages:
• Can be used for operational analyses and quality improvement activities
• Metric of success of questionnaire collection process

Disadvantages:
• Dependent on the technological capabilities of the PRO-EHR system

OPTION 2: THE PRO-EHR SYSTEM SENDS AUTOMATED NOTIFICATIONS TO THE HEALTH CARE TEAM WHEN PATIENTS DO NOT COMPLETE QUESTIONNAIRES
This may be in the form of a “best practice alert” or other notifications within the patient record or an email-like message to a recipient who can follow up with the patient. This may be especially important for questionnaires collected for research.

Advantages:
• Allows attempts to capture missing questionnaires in real-time

Disadvantages:
• Dependent on the technological capabilities of the PRO-EHR system
• Requires additional effort from health care team, can increase alert fatigue
• Utility of notifications is dependent on follow-through of collection attempt by health care team
• Feasibility of this approach unknown

When and With What Frequency Should PROs Be Obtained?
Clinical workflows for questionnaire administration will vary widely depending on the goal of data collection and specific questionnaires. It may be appropriate to deploy some questionnaires, such as health risk assessments or health-related quality of life questionnaires at specific intervals or tethered to specific visit types, whereas other questionnaires, such as those assessing symptoms, may be deployed in specific clinical situations, such as patients undergoing certain interventions. In instances when questionnaires are not completed at each visit, logistical issues arise in identifying which patients should be approached to complete questionnaires and what questions should be asked.

OPTION 1: QUESTIONNAIRES ARE ADMINISTERED TO ALL PATIENTS AT EACH VISIT
Specific questionnaires, identified by specific time interval since last completion and/or by diagnosis, procedure, or clinical situation are administered at a visit. In addition, a “base” questionnaire can be administered to all patients at the time of the office visit so patients always complete some questions at their visit. Alternatively, if no questionnaires need to be
completed, a message is displayed to the patient that there are no questions to complete at this time.

**Advantages:**
- There is a consistent questionnaire collection workflow for front desk/check-in staff and consistent setting for completion by the patient

**Disadvantages:**
- Potentially unnecessary questionnaire administration, which increases patient burden of data collection
- Patient satisfaction may decrease

**OPTION 2: QUESTIONNAIRES ARE DEPLOYED AT THE TIME OF A VISIT ONLY TO PATIENTS WHO HAVE BEEN IDENTIFIED AS REQUIRING QUESTIONNAIRE COMPLETION**

Specific questionnaires, identified by specific time interval since last completion and/or by diagnosis, procedure, or clinical situation are administered at a visit. Patients are given tablets at the visit only if there are questionnaires to complete.

**Advantages:**
- Minimizes patient burden
- May reduce workflow disruption/delays in patient through-put at clinic visit

**Disadvantages:**
- Method to determine which patients require questionnaire completion must be identified
- Requires additional decision-making by front desk staff or clinical providers
- May reduce completion rates if identification of patients requiring questionnaire completion is not consistently implemented
- Dependent on the technological capabilities of PRO-EHR system

**OPTION 3: QUESTIONNAIRES ONLY DEPLOYED REMOTELY**

Questionnaires are not administered at the time of the office visit. They are deployed remotely via patient portal or email invitation, only if the patient has a questionnaire that should be completed based on time interval since last completion, diagnosis, or other methods.

**Advantages:**
- No workflow disruption at office visit
- Only relevant questionnaires are administered to patients/minimizes patient burden

**Disadvantages:**
- Requires technological ability to deploy questionnaires electronically to patients
- Lower completion rates possible; requires patient willingness to provide data outside of a clinic visit in the requested mode of data collection
• Will not capture questionnaire data on patients who do not have their own device (computer/tablet/smart phone)
• If questionnaires are deployed through a patient portal, requires that patients be active on patient portal
• May require system to monitor questionnaire responses if they are clinically actionable

KEY INFORMATION GAPS AND RESEARCH QUESTIONS
• What is the validity of proxy responses when collected in routine clinical care?
• In what situations is remote deployment of questionnaires appropriate and/or adequate?
• Are there differences in responses to questions according to mode of administration?
• Is real-time notification of incomplete questionnaires feasible and does it lead to improvement in completion rates?
• How do you apply PRO data to improve patient care across different clinical scenarios?

USEFUL REFERENCES/RESOURCES

Data Quality


Proxy Responses

8. **HOW WILL PRO DATA BE DISPLAYED IN THE EHR?**

When displaying PRO data within the EHR, there is no established best approach, but rather a range of options that are not mutually exclusive. Although selecting among options is ultimately shaped by available resources and technical constraints, it is important for any approach to present PRO data effectively to maximize accurate interpretation and ease of use for clinical care. Other sections discuss related issues such as how PRO data are acted upon once reported by the patient. In this section, we focus on five key considerations for displaying PRO data for presentation within the EHR: 1) target audience and context of use; 2) presentation format; 3) distribution of PRO scores; 4) individual- vs. population-level scores; and 5) the complexity of the display.

**Target Audience and Context of Use**

The target audience is defined as who it is that primarily views the PRO data and within what context (e.g., use within clinical workflow, use at home by patients). There are two main target audiences for PROs within the EHR: clinicians and patients. Other audiences could include administrators and researchers (non-clinical users). When developing an approach for displaying PROs, it is important to consider the purpose, context of use, and experience of the target audience. Some approaches may need to target multiple audiences, such as when clinicians and patients share displays during clinic visits to review PRO data together.

**TARGET AUDIENCE: CLINICIANS**

Clinicians can use PROs for clinical care and the management of conditions in individual patients or populations of patients. For example, PRO scores can be embedded into clinic notes or documentation, be displayed in specific sections or tabs within the chart like laboratory results are shown, or be displayed on a separate screen within the EHR. PROs can also be integrated into registries to facilitate population health management, quality reporting, and inform treatment decisions (e.g., seeing how similar patients respond to treatment A vs. treatment B).

**Advantages:**
- Individual-level PROs can alert clinicians to adverse symptoms and changes in status, and foster communication of symptoms and facilitate interventions, such as counseling and treatment modifications
- PROs can help clinicians engage patients in monitoring their own symptoms
- Population-level PROs can support patient panel management to inform treatment decisions and shared decision-making conversations

**Disadvantages:**
- Interpreting PROs requires time and familiarity with standardized PRO questionnaires and scoring
• The introduction of PRO data could negatively impact clinical workflows without thoughtful process redesign, particularly if it is unclear what action(s) should be taken based upon PRO data
• Important information from PROs could be overlooked by clinicians if displays and workflows are not well-designed, which could potentially lead to risks to patient health and/or medical-legal risks for clinicians and organizations
• Population-level PROs may be difficult to interpret without accepted guidelines and metrics for using PROs as performance measures (e.g., clinically meaningful differences, reference ranges, measures of uncertainty, such as confidence intervals)

TARGET AUDIENCE: PATIENTS
Patients can use PROs for self-monitoring, self-management, and shared decision-making. PRO scores can be displayed in after-visit summaries or be displayed in a separate screen in the patient portal or personal health record.

Advantages:
• Individual-level PROs can engage patients in monitoring their health and conditions, empower them to discuss symptomatic problems with their care team, and inform their care decisions
• Population-level PROs could provide comparisons to similar patients to facilitate decision-making and behavior change

Disadvantages:
• Interpreting PROs requires sufficient literacy and numeracy, including graph literacy
• Patients may lack familiarity with standardized PRO questionnaires and scoring, which may make interpretation and use challenging
• Comparisons to other patients could be misleading without corrections for case-mix or other confounding factors, and could cause potential distress or disappointment if the patient is doing worse than other patients
• Patients may lack familiarity with the clinical relevance of PROs

TARGET AUDIENCE: OTHER AUDIENCES
Administrators can use PROs for quality improvement efforts. Researchers can use PROs to answer questions and advance science. There may be other potential target audiences that can benefit from PROs displayed in the EHR. These audiences might include payers, public health officials, government, or others. For example, PROs could be used to enrich administrative claims data for research.

Advantages:
• Population-level PROs could illustrate novel insights about the patient experience, differences between populations or interventions, or facilitate projections/predictions about outcomes and experiences
• Population-level PROs can be used to monitor or prompt changes in programs and interventions to improve symptom assessment and management
Secondary use of collected PRO data for comparative effectiveness research or quality improvement efforts offers efficiency when data are already collected as part of clinical care.

Disadvantages:
- Data privacy and security measures must ensure confidentiality
- Non-clinical use of PROs may require approvals (e.g., Institutional Review Board) that can take time and add complexity to the development and use of data displays
- Measures are needed to prevent data misuse and to protect vulnerable populations or patients with rare conditions where a patient could be identified or when disclosure of symptoms may have negative consequences (e.g., on insurance coverage, employment)
- PRO data collected for clinical care and used in a secondary analysis for performance or research purposes could be misinterpreted without sufficient clinical context, information about data quality (e.g., missingness or sparsity), or case-mix adjustments

Presentation Format

Most PROs are represented as scores rather than categorical values, which lend themselves to a wide range of approaches to presentation, including numeric and visual formats. When developing an approach for displaying PROs, it is important to consider the resources required to build or configure a particular presentation format within the EHR as well as the features required by the target audience, such as graph literacy and numeracy. Options also may be constrained to what is configurable within a given EHR system. Additionally, user needs and preferences, workflows, and context for using PRO data will influence which format is optimal. It can be helpful to understand under which conditions a particular format, or set of formats to toggle between, is most helpful.

OPTION 1: NUMERIC FORMATS

Text and tables are examples of numeric formats.

Advantages:
- Numeric formats provide PRO data specificity
- Configuring numeric displays is fairly simple because these formats are often standard features supported within EHR systems
- Clinicians are generally familiar with reviewing and interpreting numerical data displays

Disadvantages:
- Interpreting changes and trends in PRO scores can take time and effort, particularly if there is a large amount of data
- Numeric displays require more screen space to illustrate large amounts of data compared to visual formats
- Spotting abnormal scores or significant changes over time can be challenging unless data are flagged or highlighted
OPTION 2: VISUAL FORMATS
Graphs, charts, and pictographs are examples of visual formats.

Advantages:
• Graphs and charts can be easy and quick to understand because they make PRO data visually salient and allow for pattern recognition
• Pictographs can improve comprehension for people with limited literacy and numeracy
• Certain formats are well-suited for specific types of data, such as illustrating proportions with pie charts, trends with line graphs, or probabilities with icon array pictographs
• Visual formats can improve usability by patients and clinicians
• Certain formats, such as pictographs, may not require English proficiency

Disadvantages:
• Designing and building visual displays can require additional resources to configure or build custom features in EHRs with limited existing functionalities for visually representing PROs
• Interpretation, personal preference, and perceived level of understanding for graphical PRO displays are sometimes discordant between different types of users
• Complex visual formats may be more difficult to integrate into EHRs than the standard numeric formats that most EHRs support
• Some visual displays can obscure underlying PRO data points (e.g., raw data), which may be essential to clinical decision-making

Distribution of PRO Scores
The distribution of PRO scores refers to the spread of scores either over time or at a specific time point. Examples include longitudinal trends, cross-sectional comparisons, and change scores (e.g., improvement from baseline). When developing an approach for displaying PROs, it is important to consider the match between how scores are distributed and the intended use of the display by the target audience.

OPTION 1: LONGITUDINAL TRENDS
Longitudinal trends represent PRO scores from an individual or population over a period of time.

Advantages:
• Provides timeframe for examining changes in scores over time at-a-glance
• Facilitates estimating future projections of PRO data trends
• Many EHRs provide at least a rudimentary graphing feature to track scores over time

Disadvantages:
• Requires PRO data from multiple time points
• Missing data may not be appropriately represented, which could lead to misinterpretation of trends
• If contextual information is not provided, it may be difficult to understand changes in status over time in relation to events (e.g., medication or treatment changes, life stressors, etc.)
• Standards are needed for reference ranges and the number of time points to present for optimal interpretation of trends over time

OPTION 2: CROSS-SECTIONAL COMPARISONS
Cross-sectional data enables the comparison of PRO scores among individuals at a specific time point, such as the proportion of patients who report symptoms 6 months after receiving treatment.

Advantages:
• Provides insight into the magnitude of the impact of symptoms, treatments, or other factors at a single point in time
• Requires PRO data for only a defined point in time to describe prevalence or risk in a population

Disadvantages:
• Captures only the overall magnitude of the factor of interest without providing insight into the underlying cause or process
• A single time point does not capture relevant longitudinal trends

OPTION 3: CHANGE SCORES
Change scores represent the relative difference in PRO scores from one time point to another time point, which can provide a measure of the amount of improvement or decline.

Advantages:
• Enables an assessment of the magnitude of improvement or decline from a reference point, such as a treatment, surgery, or intervention
• Can potentially provide clinically meaningful differences, which can inform treatment decisions
• Requires PRO data at only two time points

Disadvantages:
• Captures only the overall magnitude of change without insight into the process or the underlying trend behind that change
• There may be discordance between a meaningful difference from the patient’s perspective and from the clinician’s perspective
• Evidence and standards are needed to identify clinically meaningful differences

Individual-Level Scores vs. Population-Level Scores

Individual-level scores refer to data from a single patient while group- and population-level scores refer to data from multiple patients. When interpreting these scores, one should
consider metrics such as clinically meaningful differences, confidence intervals, t-scores, and available reference ranges. The clinical context should also be considered (e.g., outpatient vs. inpatient, primary care vs. subspecialty).

**OPTION 1: INDIVIDUAL-LEVEL SCORES**
Individual-level scores represent PRO data from a single patient. A guidance document with recommended best practices for displaying individual patient data is forthcoming (personal communication: Claire Snyder, PhD).

**Advantages:**
- Useful for patient self-monitoring and self-management
- Useful for screening for conditions (e.g., depression), monitoring patient progress, informing treatment decisions, and for shared decision-making

**Disadvantages:**
- May require contextual information such as clinical thresholds or population data to aid interpretation
- Data privacy and security measures must be used to ensure confidentiality of PROs

**OPTION 2: POPULATION-LEVEL SCORES**
Population-level scores represent PRO data aggregated across multiple patients.

**Advantages:**
- Useful for shared decision-making to provide context about similar patients
- Useful for panel or population health management by clinicians or administrators
- Useful for practice and quality assessment (e.g., at the level of the clinician, clinic, or health care system)
- Could shift clinical practice towards higher quality care
- Can provide large scale insights into patient experience, treatment outcomes, natural course of disease and symptom experiences, and other discoveries

**Disadvantages:**
- May require contextual information, such as sample size, patient characteristics, time of measurement, clinical setting, or appropriate benchmarks to optimize utility
- Requires thoughtful selection of parameters around which to aggregate PRO scores, such as time of measurement, reference standards, and how to adjust for missing data and case-mix
- Data privacy and security measures must be used to ensure confidentiality of PROs (e.g., with small samples, children/adolescents, and individuals with rare conditions, mental health conditions, or reproductive health conditions)
- Outliers can skew the data and risk adjustment may be necessary
**Complexity of the Display**

The complexity of the PRO data display refers to the degree to which contextual detail and functionality are incorporated into the data display from simple (e.g., static) to complex (e.g., interactive). For example, a static display requires only that the user views data, whereas an interactive display may incorporate features that allow the user to dynamically toggle the format or filter the data. Some users may prefer additional details such as color to flag more severe symptoms, confidence intervals to communicate uncertainty, or other contextual data pulled from multiple data sources. Where capabilities for dynamic display of PRO scores exist, there may be additional opportunities for data presentation. Limitations in the complexity of current EHR displays of PRO data have motivated the use of external systems and platforms.

**OPTION 1: SIMPLE DISPLAYS**

Simple displays tend to represent just PRO data without contextual details and are generally static requiring no user interaction.

**Advantages:**
- May be quicker to interpret or use than displays with more details
- Minimizing detail can reduce cognitive burden
- Tend to require little prior knowledge to interpret or use
- Many patients and clinicians prefer to use simple displays
- Can be easier and less costly to configure and build simple displays within the EHR than complex displays

**Disadvantages:**
- Can lack details and contextual information that aids interpretation and comprehension of PRO data (e.g., seeing changes in medication use alongside changes in PRO scores)
- Can potentially lead to inaccurate interpretation
- Static displays may not meet users’ needs when further details and interactivity are desired

**OPTION 2: COMPLEX DISPLAYS**

Complex displays include additional contextual details and/or functionality to supplement PRO data, such as representing population means or interactive features within the EHR user interface (i.e., dashboard).

**Advantages:**
- Including information alongside PROs can contextualize scores to aid interpretation, such as clinical threshold/cut points, reference scores/ranges, minimally important clinical differences, significant changes in scores, population means, peer benchmarks, treatment changes or initiation, and patient comments or annotations
- Enables the presentation of PRO data alongside clinical data (e.g., graphing fatigue score against hemoglobin)
- Enables presentation of multiple PRO domains in a single “dashboard” or screen
• Enables inclusion of explanatory information, such as how the questionnaire is scored
• Interactive features can enable users to dynamically explore PRO scores and offer more detailed information about PROs (e.g., raw PRO data rather than summative score) than presenting all these data statically on a single screen
• Platforms that support complex displays provide the potential to integrate multiple sources of data and the opportunity to customize content and format to users’ needs

Disadvantages:
• Addition of contextual information and functionality can add time and cognitive load, can be distracting, and could negatively impact interpretation if not well designed
• Could require training for use, interpretation, and navigation of the display
• Likely to require additional information technology resources to configure or to custom build within EHRs since most only offer limited features and functionality for display of PRO data
• May need to build multiple interfaces to meet the needs of different target audiences (e.g., clinician vs. patient and primary care vs. subspecialty)
Use Case Example 1: Individual-Level Display: This report illustrates individual-level scores formatted visually in a line graph to show longitudinal trends in a patient’s functioning and symptoms. The target audiences of this report are clinicians and patients who can use the PRO data for patient care. This example is from an external PRO system that is not tethered to an EHR. This organization chose to create reports due to limitations of their current EHR functionalities for displaying PRO data. (Image reproduced from Snyder CF, et al. Cancer. 2017 Jan 13.)
Use Case Example 2: Population-Level Display: This report illustrates population-level scores formatted visually in a line graph to show longitudinal trends in physical function (left) and pain (right) scores for use in predictive analytics. PRO data was collected between April and December 2015 from 215 total hip replacement patients treated by three surgeons with a minimum 3-month follow up (mean 4.7 months). (Images courtesy of Ben Strong MD, and John Ginnetti MD, University of Rochester Medical Center)

KEY INFORMATION GAPS AND RESEARCH QUESTIONS

- How can user-friendly displays be designed to maximize accurate, timely interpretation and provide actionable information?
- What are optimal formats for displaying various types of PRO data to different audiences (patients vs. clinicians vs. administrators)? Do optimal formats vary across condition or PRO domains?
- What contextual factors and data are necessary to facilitate interpretation of PROs for clinical use?
- What standards are needed to facilitate PRO reporting in the EHR and clinical workflows?
- Where is the optimal location for PRO data and reports within the EHR and clinical workflows?
- Should any restrictions be placed on reporting PRO data for non-clinical use (e.g., privacy or confidentiality concerns for specific populations or conditions that would limit access to PRO data)? Should requests for PRO data be tracked?

USEFUL REFERENCES/RESOURCES

Published Articles


Snyder CF, Smith KC, Bantug ET, Tolbert EE, Blackford AL, Brundage MD; PRO Data Presentation Stakeholder Advisory Board. What do these scores mean? Presenting patient-reported outcomes data to patients and clinicians to improve interpretability. Cancer. 2017 Jan 13 [Epub ahead of print].

**Websites**


9. HOW WILL PRO DATA BE ACTED UPON?

Should Providers Be Required to Accept Data into the EHR?

OPTION 1: NO, PRO DATA SHOULD LIVE IN THE RECORD WITHOUT BEING “ACCEPTED” BY A PROVIDER

The volume of patient-generated data entering the system makes specific acknowledgement of every instance of patient information impractical and undesirable. If providers were to accept each PRO measure entry, alert/process fatigue may make this rote and make meaningful review of the information less likely.

Important considerations are:
1. That PRO data be visible as patient-entered, not to be confused with provider-entered or otherwise verified data. This allows viewers of the data to interpret it in the necessary context.
2. That other solutions are in place to capture alert-level values, if applicable (see below), in the event that a provider does not see the results in a timely manner.

Advantages:
• Better for provider workflow, reducing provider rejection of PRO initiatives
• Avoids “check-the-box” review of PRO data possibly contributing to more meaningful use of data
• This is not done consistently for all types of data for clinical use

Disadvantages:
• Requires that the presentation of data can differentiate between PRO data and provider-entered data (or a suitable workaround)
• Increases importance of systemic infrastructure for notification of alert-level value OR avoiding PROs that have potentially alertable responses

OPTION 2: YES, PROVIDERS SHOULD BE REQUIRED TO REVIEW AND ACCEPT THE DATA INTO THE EHR

The medical record must contain correct information, and therefore providers need to review patient-entered data before incorporating into the EHR. Though this is cumbersome, data accuracy and mandatory provider review of the data are important enough to warrant the additional time and effort.

Advantages:
• Ensures that providers will see all data provided by patients
• Makes it more likely that information in the record is correct
• Provides an opportunity for an option of provider annotation of the data

Disadvantages:
• Workflow is cumbersome, providers more likely not to use PRO at all
“Alert-fatigue” or “check-the-box” reviewing of these data is not meaningful review and does not achieve the stated advantages

When Should Different Kinds of Notifications Be Used?

It is important to emphasize that these choices are not mutually exclusive and different choices may be made by the same system for different PROs, different specialties, and different patient populations.

**OPTION 1: NO NOTIFICATION**

PRO measures may be considered akin to vital signs or historical information that flows into the chart with significant volume that do not involve notification for the appearance of this information. While no notification runs the risk of this information being missed, especially if it is new or captured in a different place from other clinical information, providers who are informed of where this information lives will learn to look for it when it is relevant. Abnormal values could be “flagged” in the record, similar to abnormal laboratory tests.

**Advantages:**
- Does not interfere with workflow
- No additional workload for providers
- May help to increase the awareness of clinicians about PROs

**Disadvantages:**
- Important clinical information may be missed by providers

**OPTION 2: STANDARD NOTIFICATION (NOT CONDITIONAL)**

PRO measure information is new, different from other types of data, and often clinically important, and providers can be notified every time a response is submitted. Notification for this will likely be “non-urgent” modalities such as email or clinical message. The notification should include the fact that a response was submitted, including the date and time, as well as the answers to individual questions and summary of PRO scores. Ideally, notifications would include the time trends showing how patients have changed over time. It is helpful to have a direct link to the chart/location so that providers can quickly access the patient record or additional information.

**Advantages:**
- PROs are less likely to be missed
- Does not interfere with workflow

**Disadvantages:**
- Likely to be large volume and therefore often ignored (it may be useful to use this method in low-volume settings)
OPTION 3: OPEN-ENDED “ALERT” (CONDITIONAL) NOTIFICATION
An “alert” notification is one that is conditional, meaning that it is based on a response, score, or change in score that warrants communication such as chest pain or severe/worsening depression. With an open-ended alert, providers are alerted, but the system does not ask them to electronically acknowledge or otherwise “close” the alert. Alerts to providers may be delivered at the same time as patient-facing communication with instructions on the best course of action to seek care. Various modalities can be used for “alert” notifications such as clinical message, email, text, page, or phone call.

Advantages:
- Enables responsive care based on real-time patient information
- Different modalities can be used for different levels of acuity, for example clinical message/email/text for low or medium acuity; page or phone call for higher acuity
- Less onerous to provider workflow than closed-loop alerting

Disadvantages:
- May be disruptive if done using page or phone
- Lack of “closed-loop” does not allow for documentation of the message having been seen or acted upon

OPTION 4: CLOSED-LOOP “ALERT” (CONDITIONAL) NOTIFICATION
An alert notification is one that is conditional, meaning that it is based on a result that warrants communication such as chest pain or severe depression. Closed-loop refers to the fact that a provider is alerted, and the system requires them to electronically acknowledge or otherwise “close” the alert. Alerts to providers may be delivered at the same time as patient-facing communication with instructions on the best course of action to seek care. Various modalities can be used for “alert” notifications such as clinical message, email, text, page, or phone call.

Advantages:
- Enables responsive care based on real-time patient information
- Because it is conditional, it will be lower frequency and may be more likely to garner attention
- Different modalities can be used for different levels of acuity, for example clinical message/email/text for low or medium acuity; page or phone call for higher acuity
- Closed-loop alerting ensures that a responsible party acknowledges or acts upon the result

Disadvantages:
- May be disruptive if done using page or phone
- Requires action and work. Often significant resistance to this option by providers, especially when the action step to be taken in response to the result is not clear
- May create legal exposure for providers if a loop is not closed
**What Modality of Alert Should Be Used?**

It is important to emphasize that these choices are not mutually exclusive and different choices may be made by the same system for different PROs, different specialties, and different patient populations.

**OPTION 1: EMAIL**
Non-secure email is likely not a viable option for a mature system, but may be used with 3rd party PRO systems that are not integrated with a health system’s clinical message system.

**Advantages:**
- Does not require integration with EHR
- Accessible by providers regardless of network access, virtual private network (VPN), clinical log-in
- Non-interruptive

**Disadvantages:**
- Not secure
- Not necessarily documented or tracked
- May result in a delayed response (i.e., not seen until provider checks the message)

**OPTION 2: CLINICAL MESSAGE WITHIN THE EHR**
Secure clinical messaging within the EHR is likely a highly viable option when PROs are collected using a system embedded in the EHR. It may also be utilized with the appropriate integration of a PRO data collection system with the EHR.

**Advantages:**
- Secure
- Documented
- Accessible at the moment that the provider is engaged in clinical work
- Non-interruptive

**Disadvantages:**
- May require clinical log-in, VPN, or network access, so may not be accessible in off-hours
- Not real-time

**OPTION 3: TEXT MESSAGE, SECURE TEXT MESSAGE, OR PAGE**
Many 3rd party systems and most EHRs can be integrated with texting platforms or a paging system. At the time of the result, an automated message is generated.

**Advantages:**
- Secure
- Documented
• Real-time
• Accessible

Disadvantages:
• Interruptive, possibly at inopportune times and out of context
• Often significant resistance to this modality by providers, especially when the action step to be taken in response to the result is not clear

Who Should Be Notified?

OPTION 1: THE PRIMARY CARE PROVIDER (PCP)
Most systems can easily identify the PCP. PCPs often consider themselves responsible for the overall health of the patient.

Advantages:
• Easily identifiable
• Likely to do something about the issue

Disadvantages:
• PCPs may refuse to get notifications for PROs that they were not involved in ordering
• Volume/workload overload for PCPs

OPTION 2: THE “ORDERING” PROVIDER
If a particular provider is the one to “order” or “assign” the PRO, often this person is identifiable electronically by the PRO system.

Advantages:
• Usually appropriate – the ordering provider likely wants to see the results

Disadvantages:
• There is not always an ordering provider or the ordering provider cannot be identified by the system

OPTION 3: A PROVIDER WITH AN UPCOMING APPOINTMENT
In some systems, PRO assessments are associated with an appointment. If so, the provider associated with the appointment may be identifiable electronically by the PRO system.

Advantages:
• Likely the appropriate person to receive the result
• Able to do something about the result in an upcoming visit

Disadvantages:
• Not technically feasible with many systems
OPTION 4: A NAVIGATOR OR ADMINISTRATOR
If the responsible provider rotates (e.g., front-desk coordinator OR nurses who share responsibilities for a pool of patients), an intermediary can receive, sort, address, and/or triage the messages to the appropriate provider, similar to functions of a call center.

Advantages:
- Can assist in ensuring that the appropriate person receives the result

Disadvantages:
- May be administratively cumbersome
- Navigator/administrator might not appreciate clinical context of the notification

OPTION 5: THE PATIENT OR DESIGNEE
Increasingly the patient and caregivers are the center of the care team, and in some cases, the patient should be notified about a particular result. It is possible that patients are responding with symptoms that they do not realize are dangerous for their particular context, for example angina and dyspnea in a patient with aortic stenosis. Alerting the patient is not mutually exclusive with other parties being alerted.

Advantages:
- Always identifiable
- Empowers the patient

Disadvantages:
- May be difficult to provide the full context of the result in an automated message and thus may lead to anxiety or confusion
- Patient may be prompted to seek care during off-hours

OPTION 6: PATIENT CHOICE
Similar to some portal messages, the patient can designate who receives the notification.

Advantages:
- The patient often knows which provider should receive a notification, and who s/he would like to inform

Disadvantages:
- There may not be agreement by providers with patients about which provider is appropriate to receive a notification

Should PRO Results Drive Clinical Decision Support in the EHR?

OPTION 1: YES
While PROs have great potential for use in aggregate, the use of PROs to improve the care of individual patients is essential for adoption. Providers resist being confronted by new
information without having a clear idea of what to do to remedy it. As such, translating PRO responses into possible action steps using clinical decision support is valuable. Decision support can come in multiple forms, including standard text showing a full table of scores and their implications, banners, or conditional alerts (sometimes called “Best Practice Advisories”). The underlying assumption is that how to interpret a particular PRO score is well-known, or at least that there is sufficient evidence for the effectiveness of an action.

Advantages:
- Improves adoption by providers
- Improves the care of patients and their subsequent engagement in their care, including the likelihood of completing PROs in the future

Disadvantages:
- There may be insufficient evidence to support action steps to take in response to many PROs
- Building the clinical decision support requires coming to some consensus among providers on the content (what the message is) and the behavior (when it should fire) of the decision support
- Building clinical decision support into the EHR, where it is most useful, can be time-consuming and costly, and require updating over time

OPTION 2: NOT YET
While certain PROs are well-trodden and the action steps to take in response to various scores are well-understood, most PROs do not fall into this category. In an era of “alert-fatigue” and proliferation of banners and messages, clinical decision support should be reserved for those instances where the action step is clear. As such, for most PROs, clinical decision support is premature at the current time. Clinicians will gain understanding and expertise with these PROs in the course of incorporating them into their care and, over time, algorithms may be more forthcoming.

Advantages:
- Does not require consensus building to determine the content and behavior of the clinical decision support
- Does not require build time and resources

Disadvantages:
- May limit adoption in clinical settings
- May miss opportunities to optimize care for patients with measurable symptoms or deficits in their function
Use Case Example 1: A large cancer center has integrated routine collection of symptoms following surgery into the EHR. A standard set of symptoms is included, such as pain, nausea, vomiting, constipation, diarrhea, fatigue, and physical functioning. Whenever a patient experiences a symptom at a moderate or higher level, or increased from the prior report, a notification is sent via email to the treating surgeon and a designated responsible nurse. No specific guidelines for how to respond are given to providers, although they are trained in the use of the system. The system is currently being modified to send the alerts through the EHR, to the same inbox as logged patient telephone calls and portal messages.

Use Case Example 2: A large pain clinic at a tertiary care hospital and multiple associated network sites enables patients to self-report pain and other symptoms regularly via a secure online portal. Symptom scores are imported into the EHR via a custom interface. Moderate or severe symptoms trigger a notification to the ordering provider through the provider’s EHR inbox. The provider is required to clear the notification within 72 hours.

KEY INFORMATION GAPS AND RESEARCH QUESTIONS

- How much additional work is required for providers to field notifications for PROs?
- What are the appropriate alert thresholds for notifications for various PRO measures?
- What is the optimal configuration to assure that an appropriate provider receives timely notifications?
- What are effective actions to take to respond appropriately to PRO scores that indicate a problem?

USEFUL REFERENCES/RESOURCES


10. **HOW CAN PRO DATA FROM MULTIPLE EHRS BE POOLED?**

When combining data collected by different groups, at different points in time, from different geographical locations, and using different software tools, one must be extremely careful to ensure that the data to be pooled are similar at some agreed upon level of consistency. There are many axes along which this consistency can be specified, including source and method of collecting the data, patient population queried, timeframe data were collected, and questionnaires used to collect the data. The rigor with which this consistency will be enforced is also dependent on many socio-technical factors, including composition and governance of the group, specific aims of the project, clinical workflows used, technical infrastructure, information management capabilities of the individual sites, and various ethical and legal issues that may arise. Sorting out these factors and their inter-relationships is an ongoing area of research for the applied biomedical informatics community. This section focuses on two distinct technical aspects of the problem: the software architecture used for pooling the data and the data model used to define the data to be shared.

**Architectural Considerations for Pooling PRO Data from Multiple EHRs**

There are two main software architectural approaches or strategies that can be used to aggregate and analyze PRO data from multiple sites: a centralized data warehouse or a federated/distributed data warehouse.

**OPTION 1: CENTRALIZED DATA WAREHOUSE**

A centralized data warehouse is used to store all the data that is extracted from each of the individual EHR systems and sent to a single, centralized data warehouse that is maintained by the data coordinating center.

**Advantages:**

- Simpler technically, and facilitates centralized quality control
- Assuming a strong local champion with experience working with the local data management processes, there is less risk of one site failing to return data or being delayed
- Facilitates data analysis by allowing the statistician to see which data were collected, which are missing, and to perform simple data quality checks at a more granular level
- Allows for additional data analyses based on intermediate results that may not have been initially planned
- Assuming that data are de-identified by site before submission to the coordinating center, the central data warehouse helps reduce potential problems associated with small sample sizes that may be more prone to re-identification. De-identification may, however, make it impossible to link data across sites, meaning researchers may not be able to achieve longitudinal data tracking or do later comparisons for additional research or quality measurement purposes. However, data linkage preserving methods exist which may allow data to be de-identified but still linked probabilistically
• Data analyses are easier to replicate or reproduce since data are retained in a single location/database
• Assuming that data are checked for quality to ensure their accurate translation before being loaded into the central data warehouse, assessment and characterization of data quality are more straightforward since it can be done on single source

Disadvantages:
• Requires that all sites address the legal, regulatory, and proprietary issues of sharing data outside their organization
• Requires all sites to agree on a standard data interchange format
• Requires all sites to agree on the types and potential values of data to be sent and then map their data as necessary to the standard values and formats
• Difficult to identify potential duplicate patients across study sites, though with associated duplicate assessment algorithms it may be possible. (Note: may be more or less important depending on likelihood of patients receiving treatment at multiple sites)
• If data are not de-identified before being sent to the central site, there is an increased risk of data breach since data are now located in two locations rather than one
• Sites may be reluctant to send patient-level data, unless guaranteed to be fully de-identified, outside of their system

OPTION 2: FEDERATED OR DISTRIBUTED DATA WAREHOUSE
The data for each site are extracted from the local EHR and kept in a locally maintained data warehouse at each site. Data analysis queries are then distributed to the local sites where they are run and only summary data from each site is sent to the data coordinating center for aggregation and summative analysis. The process of running the queries can be automated or done manually.

Advantages:
• Reduces organizational concerns about sharing potentially identifiable patient data, since the local organization retains control of all data and access to it
• No large centralized data warehouse is required, though a trusted or honest broker (i.e., an independent 3rd party that maintains the encryption keys required to de-identify the data, but not the actual data) may still be needed
• Local sites can audit queries performed against their database

Disadvantages:
• Requires all sites to agree on the mapping of local types and potential values of data to the standard values and formats
• Secure deduplication/overlay and record linkage is more challenging, though some methods for this have been described in the literature
• Difficult to ensure that data analyses were conducted accurately, or even similarly at each site
• Difficult to perform secondary data analyses based on intermediate findings
• May be difficult or impossible to replicate/reproduce data analyses, since there are dependencies on local data management and availability

**Common Data Model and Reference Terminology Critical for Pooling Data from Multiple EHRs**

In addition to the architectural decisions described above, pooling data requires two key components. First, it is important that the constructs to be pooled be represented in a common data model. Second, the actual data that represent those constructs to be pooled from each system must either be mapped to the common values for that construct or mapped to a shared reference standard. Another key consideration is the definition and use of meta-data, which are used to describe the data. Meta-data are critical in any future usage, aggregation, and mapping of PRO data. Although it is hard and time consuming to get consensus on a data model and meta-data, it is necessary; otherwise, the collected PRO data will have limited value when pooled. There are a number of possible approaches that must be considered when choosing or developing a common data model. The following are possible attributes of data models to consider, including:

• Granularity of data to be mapped and whether person-level analyses are supported
• De-identification or other limitations to the data sets (e.g., creating bins or categories of data rather than presenting specific values – age ranges rather than actual dates of birth; or only showing first 3 digits of ZIP code rather than all 5 digits)
• Specificity of data: are sequences, intervals, and episodes of clinical events for patients handled well (i.e., how was de-identification handled with respect to dates?)
• Clinical domain(s) covered by the data model
• Whether de-identification/de-duplication is supported by the data model
• Governance of the data model and how updates are reviewed, implemented, and disseminated
• Whether standard interoperability reference terminologies are supported by the model

There are currently hundreds of potential data models to consider. It is important to consider what each of these data models were designed for and how past decisions may affect the current project. The following examples are provided to illustrate how and why some of the attributes described above have been handled in: PCORnet v3.0, Consolidated Clinical Document Architecture (CCDA), I2B2’s SHRINE, and a project-specific data model created de novo. In addition to these examples there are other large, research collaborations that have developed common data models that could be extended to include PRO data which researchers should review before making a final decision, including:

• Observational Health Data Sciences and Informatics (OHDSI) has “been established as a multi-stakeholder, interdisciplinary collaborative to create open-source solutions that bring out the value of observational health data through large-scale analytics.” OHDSI is a federated system, where participating organizations map their data to the Observational Medical Outcomes Partnership (OMOP) Common Data
Model and researchers distribute SQL and R queries to sites. Learn more at www.ohdsi.org.

- Health Maintenance Organization Research Network’s (HMORN) Virtual Data Warehouse (VDW) is a “public, non-proprietary, research-focused data model implemented by 17 large, [integrated], health care systems across the United States.” The HMORN provides a governance oversight mechanism and extensive policies and procedures covering the VDW's content, development, implementation, and quality assurance activities.

- NLM common data elements. The National Institutes of Health (NIH) encourages the use of its pre-defined common data elements (CDEs) model by investigators involved in clinical research, developers of patient registries, and other types of human-focused research projects to standardize data quality and increase “opportunities for comparison and combination of data from multiple studies and across disparate EHRs” by other researchers. Learn more at https://www.nlm.nih.gov/cde/.

OPTION 1: PCORnet v3.0
A data model specifically developed by the Patient-Centered Outcomes Research Institute (PCORI) community that describes the semantics, or meaning of each data item, and in some cases the pragmatics, or context in which each data item was collected.

Advantages:
- Use of the standardized PCORnet v3.0 data model facilitates data sharing with others not initially involved in research project
- Ensures that data are commensurate (i.e., comparing “apples to apples”)
- This data model (as do several others) contains a special section for patient-reported outcomes, so transmission of them may be simpler and more accurate
- Is easy to access (as are most relational database management systems that implement fact-dimension, star schemas, or data mart style data models) using SAS which is a common data analysis tool

Disadvantages:
- Agreeing on the strict data definitions required by the PCORnet v3.0 model is difficult, time-consuming, and requires concessions on the part of all participating groups
- Organizations would have to specifically implement the PCORnet data model (they may already be implementing one of the other data models due to regulatory requirements or other projects)

OPTION 2: CONSOLIDATED CLINICAL DOCUMENT ARCHITECTURE R2 (CCDA)
A standard, general purpose XML-based clinical data interchange format that is commonly available in any ONC-ATCB (Office of the National Coordinator - Authorized Testing and Certification Body) certified EHR. It is routinely used to move data from one system to another, especially when the two underlying systems utilize different internal data models. It was designed to exchange the key clinical data required by another physician to care for a patient.
A potential alternative to CCDA would be HL7’s new FHIR (Fast Healthcare Interoperability Resources) standard, which may turn out to be simpler and faster than CCDA, while still maintaining similarly robust semantics. Currently FHIR is scheduled to be required by Stage 3 Meaningful Use in 2018.

**Advantages:**
- Widely available in any ONC-ATCB certified EHR, as CCDA is a widely used standard for clinical data interchange
- Most EHRs also have tools for viewing and reconciling information in CCDAs into the main clinical database, so this approach fits best in current clinical workflows, increasing the likelihood that clinicians may be able to view and import PRO data
- Robust tools for validation and testing of CCDA implementations are available
- Easily incorporates LOINC (Logical Observation Identifiers Names and Codes) codes which have been developed for many existing patient-centered outcomes research survey instruments

**Disadvantages:**
- Not designed to exchange PRO data, although it would be relatively easy to add this data type
- PRO data would likely be structured as generic observations, so enforcement of PRO-specific data constraints (for example, that all the elements of an SF-36 should be present, along with the various scale scores), which are actually handled by the data collection tool via the user interface, would be difficult

**OPTION 3: i2b2 – SHARED HEALTH RESEARCH INFORMATICS NETWORK (SHRINE)**
An open-source, XML-based, software network (based on the prototype model, Shared Pathology Informatics Network) that allows participating health care organizations to link their respective i2b2 instances for the sharing of obfuscated, aggregated counts of patients meeting selected inclusion and exclusion criteria for demographics, diagnoses, medications, and laboratory values. This network, called SHRINE (Shared Health Research Informatics Network) was designed to enable population-based research, assessment of potential clinical trials cohorts, and hypothesis formation for follow-up study by combining EHR-based information resources across health care organizations.

**Advantages:**
- Standard data storage model freely available to any organization currently running an i2b2 data warehouse
- Some organizations (i.e., those participating in the National Institutes of Health’s Clinical and Translational Science Award (CTSA) program) already have an i2b2 data warehouse, and may participate in one or more SHRINE networks
- Robust, easy to use query tools are available
- Clinical data can easily be integrated with PRO data
Disadvantages:
• Not specifically designed for PRO data, so some modifications would be required
• SHRINE is focused on retrieving counts rather than detailed data, so some analyses would not be possible
• Many health care organizations (and therefore sources of patient data) do not have an i2b2 data warehouse, therefore limiting their participation and potentially biasing the samples represented to populations served primarily by academic medical centers

OPTION 4: PROJECT-SPECIFIC AD HOC DATA MODELS
The team creates a new data model for each project that includes all and only the data required for a specific research project.

Advantages:
• Ensures that all and only the data required for their project is extracted and exchanged
• Minimal work is required at the inception of the network

Disadvantages:
• Requires additional personnel with specific training in design, development, and implementation of data models
• Considerable new work is required for each project

Use Case Example 1: Dr. Jones is interested in looking at SF-36 scores for patients with diabetes before and after initiation of a new therapy (Therapy X). Because Therapy X is relatively new and not used commonly at her organization, she would like to conduct a query across multiple organizations that share data through a patient-centered outcomes research network. She uses the SHRINE query tool to construct a federated query that identifies patients who are taking Therapy X and who have at least one SF-36 assessment recorded before and after initiation of the drug. The SHRINE tool helps her determine that four organizations in the network have patients that match her inclusion criteria, and she sends a manual request to each organization for medication and SF-36 data. Analysts at each organization manually retrieve these data and send them to Dr. Jones using the PCORnet data model.

This use case uses a federated architecture and SHRINE data model for the initial query, and then a distributed manual query with the PCORnet data model for fetching detailed data.
**Use Case Example 2:** Dr. Hernandez has just received a new, multi-site PCORI contract to study patient-reported outcomes following knee replacement surgery. During the project kick-off meeting the project’s steering group charges an informatics sub-committee with developing a plan for pooling patient-reported outcomes data describing their activities of daily living for all patients who have had knee replacement surgery. The group decides to use the Knee Injury and Osteoarthritis Outcome Score (KOOS) as their primary PRO resource. After much discussion, the group determines that they will not be able to create a centralized data warehouse, so they begin designing a virtual data warehouse along with a project-specific data model that consists of pre-configured SAS queries that each site will run at the end of the month to identify patients and collect their KOOS measurements pre- and post-surgery. Each site then sends a data summary to the central coordinating center that consists of the number of patients operated on, a small set of summary statistics describing this patient population including gender breakdown, age, and body mass index, along with the mean and standard deviation of the KOOS measurements in the 1 month before surgery and at 1, 2, and 6 months post-surgery.

*This use case uses a distributed data warehouse, a project-specific data model along with summary SAS queries to pool data across EHRs.*

**KEY INFORMATION GAPS AND RESEARCH QUESTIONS**

- How can patient record linkage and de-duplication be achieved across sites?
- How resistant are these sharing methods to re-identification attacks?
- What level of trust is needed between organizations sharing PRO data?
- Is it acceptable to depend on a trusted intermediary to distribute queries and data, or is a decentralized approach preferred?
- How robust is the PCORnet v3.0 data model for various PRO data resources?

**USEFUL REFERENCES/RESOURCES**


Observational Health Data Sciences and Informatics. https://www.ohdsi.org/.


11. WHAT ARE THE ETHICAL AND LEGAL ISSUES?

The integration of PROs in EHRs potentially expands the uses of these outcomes, including the number and types of individuals who can access and use PRO data, which raises several ethical and legal questions. Uncertainties relating to patient consent as well as data protection, access, and use can arise.

For purposes of this section, “consent” is defined as the process of 1) disclosing basic information about an activity and 2) providing individuals with the opportunity to authorize their participation in, or the contribution of their personal information to, the activity. From an ethical perspective, consent processes demonstrate respect for individual decision-making and help protect individuals from burdens or risks of harm that they did not agree to accept. In situations where an individual does not have (or may have limited) capacity to consent, additional protections may be required. From a legal perspective, specific requirements associated with consent and data use can vary depending on, among other things, the type of activity being pursued (e.g., health care delivery, research, or quality improvement) and jurisdictional considerations (e.g., the applicability of different federal, state, and local laws). For example, patient consent to receive medical care generally implies consent for the use of the patient’s health-related information for the purpose of providing the individual with health care; however, it does not imply consent for research use of the same information.

For human subjects research, both federal and some state laws specify unique consent requirements. At the federal level, the “Common Rule” [45 CFR 46], issued by the Department of Health and Human Services, defines requirements for the protection of human research subjects for certain types of activities, including informed consent requirements and the conditions under which an Institutional Review Board (IRB) may permit a waiver or modification of those requirements. The U.S. Food and Drug Administration (FDA) has separate legal requirements for clinical investigations subject to FDA jurisdiction that also seek to protect human subjects [21 CFR 50]. When activities are conducted outside the United States, other countries’ laws and regulations are also likely to be implicated.

Where patient data are collected and/or used for local improvement of health care operations, value-based purchasing, or population health purposes, such data uses are most often described to patients though notices of privacy practices or other disclosures provided, typically at the outset of patient care encounters.

In this section, we review some of the core consent-related considerations and options associated with integrating PROs into EHRs and describe several additional legal considerations that largely remain unsettled at this time. The advantages and disadvantages raised in this section incorporate a combination of ethical, legal, and practical considerations.
What Consent Is Required for Collection of PRO Data for Integration in the EHR? Can Patients Opt-Out?

Individuals who collect PROs for integration into the EHR should consult others within their institution to understand consent-related norms, policies, and requirements. Below we describe a number of different options for disclosure and authorization to assist clinicians, researchers, and others as they prepare for these discussions. Importantly, while the law, in many instances, governs what is and is not legally required with respect to consent for research, quality improvement, and clinical practice, ethical norms and principles, like respect for persons, may provide additional justification for certain approaches to consent that may extend beyond legal requirements. Similarly, practical considerations, such as the need to anticipate future uses of PRO data, may also provide a justification for certain models of disclosure and authorization.

Additionally, with respect to PROs, it is worth noting that these outcomes are generally collected through structured survey instruments. Therefore, individuals can always opt-out of PRO collection for clinical care, quality improvement, or research by simply not completing the survey and generally should be informed of this option. However, it is important to note that higher opt-out rates may reduce the usefulness of PRO data for research and other purposes. Therefore, it is important to consider how to balance these different considerations when selecting an approach to disclosure and authorization. In some situations, it may also be possible to allow individuals to opt-out of having their PRO data included in their EHR. The feasibility of this option will likely depend, to some extent, on the level of PRO integration within the EHR (see Introduction Case Studies).

Finally, where PROs are being collected and used in such a manner that evokes the need to obtain patient authorization under the Health Insurance Portability and Accountability Act (HIPAA), some of the consent options outlined below (e.g., Options 3 and 4) are likely to be more conducive to the integration of consent elements with the additional required components of HIPAA authorization.

**OPTION 1: NO DISCLOSURE OR AUTHORIZATION SOUGHT**

Individuals would be provided a PRO survey, or asked the survey questions, but would not receive any information about the purpose of the survey or how the data collected could be used or integrated with the EHR. No written or verbal authorization would be sought.

**Advantages:**
- This option may be expedient for both the individuals fielding the survey and those completing the survey
- This may be consistent with the way information is collected during clinical encounters

**Disadvantages:**
- Individuals eligible to complete the PRO survey may find this disrespectful
• Individuals may be hesitant to complete the survey accurately if they do not understand the purpose of collecting the information and who will have access to it
• This may not comply with federal, state or local laws and policies depending on the purpose of the data collection. Research uses of data in particular are likely to be limited under this option
• Additional consent may be required for EHR integration or future uses of the information once in the EHR

OPTION 2: GENERAL (NONSPECIFIC) DISCLOSURE INCLUDING OPT-OUT INFORMATION
All patients in a health care system would be informed generally that the system sometimes fields PRO surveys to collect data for clinical, quality improvement, and/or research purposes, that the data will be linked to EHRs, and that individuals do not need to complete the survey if they do not wish to. If this approach is used, decisions need to be made about whether the institution would allow individuals to opt-out of receiving all versus particular PRO surveys, and whether individuals can also opt-out of having PRO data integrated with the EHR. If either or both options are made available, institutions must also decide whether the process of opting-out would be active, e.g., an individual must affirmatively indicate preference(s), passive, e.g., an individual who fails to respond to a certain number of PRO surveys would not be invited to participate in future surveys, or both. Determinations must also be made concerning how often individuals will be reminded about this institutional policy, and through what patient information delivery system(s).

Advantages:
• Individuals are provided the opportunity to become aware of the general reasons PRO data are being collected and that that data will be linked to EHRs
• This option is relatively efficient and can be integrated with standard clinical care workflow

Disadvantages:
• Some individuals may be more likely to opt-out of PRO collection due to lack of clarity about present or future specific data uses, or, where applicable, the inability to keep PRO data separate from the EHR. This might prevent some groups of individuals from benefiting from their PRO data being used by their clinicians
• A reliable means for tracking initial and future opt-out requests is needed
• A general disclosure may be insufficient for particular types of research uses and additional consent may be required for future uses of the information once in the EHR

OPTION 3: BRIEF SPECIFIC DISCLOSURE INCLUDING OPT-OUT INFORMATION
This option differs from Option 2 in that it also requires the provision of information about the reason(s) for fielding a specific PRO survey, who will have access to the information collected, and the implications of integrating PRO data with the EHR. If, after reviewing this information, individuals decide to complete the survey, this demonstrates their authorization for the specific use described in the disclosure statement, and not more. Given this limitation, institutions may wish to consider presenting patients with the option of also permitting their data to be used for
additional particular purposes in the future without re-consent. Finally, as with Option 2, decisions will need to be made about whether individuals can also opt-out of having PRO data integrated with the EHR.

Advantages:

• Individuals are likely to have a greater understanding of the specific purpose(s) for which data are being collected and of what will happen to data once collected, including who will have access
• This option may be viewed as more respectful of individual decision-making as it provides more information to help individuals decide whether completing the survey is consistent with their interests
• This option is likely to be more consistent with a larger number of data uses

Disadvantages:

• The additional disclosure may lengthen the amount of time required to complete the survey
• Individuals may have more questions after reviewing the information, necessitating the creation of additional resources to address those questions
• The approach necessitates a reliable means for tracking initial and future opt-out requests, and, where relevant, authorizations of future data use

OPTION 4: ROBUST SPECIFIC DISCLOSURE INCLUDING OPT-IN

Prior to completing a PRO survey, information would be disclosed to patients consistent with Option 3 above and consistent with Common Rule or other relevant human subjects research regulations concerning the required elements of informed consent. Individuals eligible for the data collection activity would be asked to affirmatively indicate their willingness to participate (express authorization), e.g., with a signature or other acceptable form of authorization, prior to completing the PRO survey.

Advantages:

• This option provides the greatest amount of information and accommodates patients who wish to have access to a significant level of detail about data collection and use
• This option is consistent with the widest range of data collection activities, such as when PRO data are being collected and integrated in an EHR as part of a randomized clinical trial

Disadvantages:

• The additional information and documentation of patient authorization (opt-in requirement) may further lengthen the amount of time required for individuals to complete the survey
• This approach may be less practicable in particular contexts, e.g., where PROs are collected via automated interactive voice response systems, or in the context of tight clinical workflows
• As with other options, this approach necessitates a reliable means for tracking patient preferences regarding participation, integration (where feasible), and future data use.

**What Consent Is Required for Use of PRO Data Held in the EHR, Potentially for Multiple Purposes?**

As with other EHR data, once PRO data are integrated into the EHR, they could have a variety of uses. The need for additional consent for use of existing PRO data in the EHR depends on how the data are to be used, for what purpose(s) they were originally collected (for example, whether they were collected for clinical or research purposes), whether they are de-identified, the level of risk associated with the proposed data use, and any other relevant specifications or limitations of original disclosures and authorizations (see above). Individuals should first review the terms of any underlying (previous) consent before considering the below options for re-use of existing data. As with all other questions addressed in this chapter, guidance on consent requirements and appropriate data use should be sought locally.

**OPTION 1: NO ADDITIONAL CONSENT FOR DATA RE-USE**

PRO data in the EHR would be re-used without additional notification and authorization from the individuals who provided the data.

**Advantages:**
- This approach can be easily integrated into routine practice and operations and is the least time and resource intensive
- This approach is consistent with norms for clinical practice and health care operations, where PRO data were originally collected for health care purposes
- It is also consistent with some forms of research where data are de-identified

**Disadvantages:**
- If data are being used in ways inconsistent with original consent/disclosure specifications or in ways that could generate risk to individuals, this option may be inappropriate
- If data are de-identified or anonymous, it may be difficult or potentially impossible to retrieve additional data of interest or concern from the same patients or link PROs with other current and future patient data

**OPTION 2: GENERAL (NONSPECIFIC) DISCLOSURE ABOUT DATA RE-USE**

All individuals in a health care system would be informed that the system sometimes uses existing PRO data stored in EHRs for clinical, quality improvement, and/or certain types of research. If this approach is used, decisions need to be made about whether the institution would allow individuals to opt-out of allowing their PRO data to be re-used for specific purposes, and if so, what patients would need to do in order to opt-out. The system also needs to consider how it will ensure that all individuals receive the notice and how often individuals will be reminded about this policy.
Advantages:

- The advantages of option 1 (above) generally apply here as well
- This approach provides individuals with additional information on how their PRO data are being used to improve health care

Disadvantages:

- Individuals may lack full understanding of how PRO data are being used
- If given the option to opt-out, some individuals may do so due to lack of specificity about uses. A reliable means for tracking opt-out requests will also be needed
- If data are rendered de-identified or anonymous, it may be difficult or potentially impossible to retrieve additional data of interest or concern from the same patients or link PROs with other current and future patient data

OPTION 3: SPECIFIC DISCLOSURE AND AUTHORIZATION (OPT-IN) FOR DATA RE-USE

When an individual is eligible for an activity involving his or her PRO data from the EHR, that individual would be informed about the activity, including any possible risks of harm or benefits, and will be asked to provide authorization for the use of data. As described above, the level of information disclosed could vary. Investigators and institutions would need to consider if written authorization is required, or if verbal or other forms of authorization is sufficient, depending on the nature of the data use.

Advantages:

- Individuals will have a greater understanding of the specific purpose for which the data are being used
- If the use of data is not consistent with the specifications of the original consent, this option is more respectful of individuals because it provides them with more information to help them decide whether the data use is consistent with their interests

Disadvantages:

- This option may be difficult to integrate into clinical settings and may not always be practicable
- This option is the most resource intensive
- This option requires a system for tracking authorizations

Are There Liability Issues Specific to PROs in EHRs?

A range of liability considerations should be evaluated by legal counsel of those seeking to integrate PROs in the EHR, including those associated with data privacy and security, human subjects research, reportable events, and informed consent/notice and authorization, among others. Many of these issues, such as the need often to establish Business Associate Agreements under HIPAA, are not specific to integration of PROs in EHRs, though they are applicable to the context. Other legal concerns may arise where patients are under the age of majority, where they have limited or no capacity to provide consent, or where PROs are
collected under substance use treatment programs that are subject to additional regulatory oversight.

It is not the intention of this section to provide legal advice or a comprehensive review of liability issues. When PROs are integrated into an EHR, a range of concerns are likely to arise related to the obligations of providers to review and act upon PRO information that has the potential to inform diagnosis, prognosis, or treatment (see Section 9). Here, we draw attention to one particular potential liability (and ethics) issue which, while also not unique to PRO integration in EHRs, is often of concern for individuals and institutions considering integration. The issue relates to “critical” or “panic” values which primarily implicates negligence law and legal considerations associated with the concept of a “duty to rescue.” To further illustrate the issue, one might consider the example of a patient whose scores on a PRO questionnaire are consistent with severe depression and the report is not acted upon by providers or the institution for whatever reason. Questions may arise relating to whether providers or the health system may be liable for subsequent patient self-harm or suicide. A related concern may arise in situations where a PRO provided information that should have led the provider to suspect a particular diagnosis. For example, if a somatic symptom PRO included information on pain, numbness, and tingling that did not meet a particular severity threshold (so not indicating a "critical" value) but that still was highly suggestive of nerve impingement that was missed and led to permanent disability. Indeed, such liability concerns may arise across any number of validated PROs that signal a reasonable likelihood of current or future patient harm.

Questions to consider by institutions and others involved in developing alert systems and response policies include:

- Is the “value” one for which providers typically receive alerts and are obligated to respond outside the PRO context?
- How imminent and likely is the potential harm?
- How well positioned is the provider or system to respond?
- What constitutes reasonable care, or a reasonable response, in a given situation?
- How can actions and decisions be most effectively documented?

Answers to these, among other questions are all likely to be relevant to liability determinations. The nature and degree of integration of PRO information into the EHR is also likely to influence liability assessments in a variety of ways, as is the reliability and validity of the PRO value itself and the system’s alert capabilities. Further complexity is likely to arise around distinguishing values that are critical from those that are abnormal but not urgent, as well as differentiating what is generally considered as critical from that which is critical (or normal) for particular patients.

**KEY INFORMATION GAPS AND RESEARCH QUESTIONS**

- What if patient self-reports conflict with provider judgment? What is the evidentiary value of the conflicting reports?
- Are there situations in which a patient’s provider should be prohibited from viewing PROs that are collected for research purposes and integrated into an EHR?
• Where multiple models of disclosure and authorization meet legal requirements, how should the other considerations relevant to informed consent be balanced in deciding on which approach to use?
• Do legal obligations relating to access to health records and data differ for PROs pre vs. post integration into an EHR? For example, who should have control over disclosure of PRO data to insurance companies and/or disability benefit programs?

USEFUL REFERENCES/RESOURCES


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## Appendix 1: Steering Group Biographies

<table>
<thead>
<tr>
<th>Ethan Basch, MD, MSc</th>
<th>Dr. Ethan Basch is an oncologist and health services researcher who directs Cancer Outcomes Research at the University of North Carolina. His research focuses on patient-reported outcomes (PROs), and his group established that up to half of patient’s symptom side effects go undetected during cancer treatment and clinical trials -- and that patient engagement and questionnaires substantially improve detection. His team created a system for the National Cancer Institute to collect patient-reported side effects during cancer trials. He is also involved in efforts to bring PROs into comparative effectiveness research, routine care, and quality improvement. He is a member of the National Cancer Institute’s Board of Scientific Advisors, PCORI Methodology Committee, Co-Chair of the Alliance Health Outcomes Committee, and an Associate Editor at JAMA.</th>
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<tr>
<td>Jason Gerson, PhD, Patient-Centered Outcomes Research Institute</td>
<td>Jason Gerson, PhD, is the Associate Director for Comparative Effectiveness Research (CER) Methods and Infrastructure team at the Patient-Centered Outcomes Research Institute (PCORI). He is responsible for providing intellectual and organizational leadership in designing and implementing new CER methods and infrastructure initiatives, evaluating proposals, and monitoring programs and grants. Before joining PCORI, Gerson was a senior officer at The Pew Charitable Trusts, where he led research activities on a number of drug safety and innovation issues. Before that, he was a commissioner’s Fellow at the Food and Drug Administration (FDA), working in the Office of Pediatric Therapeutics on regulatory science, policy, and ethical issues related to pediatric medical product development. Prior to joining the FDA, Gerson was a faculty member in the Department of Epidemiology at the Johns Hopkins Bloomberg School of Public Health. During that time, he served as a co-investigator on a project assessing how evidence about the biological mechanisms underlying therapeutic interventions (drugs and devices) is incorporated into the broader evidence base for those interventions. Earlier in his career, Gerson worked in the New York City Mayor’s Office of Health Policy and the New York City Administration for Children’s Services designing, implementing, and evaluating health services for a number of populations, including the city’s foster care children. Dr. Gerson received an AB in bioethics from Brown University and PhD in health policy from the Johns Hopkins Bloomberg School of Public Health.</td>
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<tr>
<td>Erin Holve, PhD, MPH, MPP</td>
<td>Dr. Erin Holve is Director of the Department of Health Care Finance’s Health Care Reform and Innovation Administration (HCRIA) within the District of Columbia Government. HCRIA creates and tests new delivery system and payment models among Medicaid providers with the goal of enhancing health care quality, improving care and outcomes, promoting health equity, and enhancing the value and efficiency of DHCF’s programs. In this role Dr. Holve also chairs the DC Health Information Exchange Policy Board and oversees the District’s Medicaid EHR incentive program. Dr. Holve has more than fifteen years of experience in health policy and health services research. She is a widely published and cited author of reports and peer-reviewed articles on health insurance access, as well as health IT infrastructure. Dr. Holve holds a Ph.D. in health services research from the Johns Hopkins School of Public Health and masters' degrees in public health and public policy from the University of California, Berkeley.</td>
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<td>David R. Hunt, MD, FACS</td>
<td>David Hunt is a general and vascular access surgeon who currently serves as the medical director for health IT adoption and patient safety in the Office of the National Coordinator (ONC). At ONC, he focuses on patient safety, health care disparities, and strengthening programs that promote the effective and safe implementation of electronic health records. Beyond his surgical practice, Dr. Hunt has years of hands-on experience at all levels of information technology from programmer to systems analyst and software developer. While working at the Centers for Medicare and Medicaid Services (CMS) from 2002 – 2007, he led two of the largest surgical quality and patient safety programs in the nation, the Surgical Care Improvement Project (SCIP) and the Medicare Patient Safety Monitoring System (MPSMS). Dr. Hunt was awarded a bachelor’s degree in biochemistry from the University of Rochester (NY) and a medical degree from the Howard University College of Medicine. He completed his residency in surgery at Howard University and became a diplomate of the American Board of Surgery in 1991. Practicing in both private and academic settings, Dr. Hunt served as a Clinical Assistant Professor of Surgery at Howard University, chair of surgical peer review at various hospitals in the Washington metropolitan area, and has been a fellow of the American College of Surgeons since 1993.</td>
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| Nancy Smider, PhD | Nancy Smider, PhD, is the Director of Research Informatics at Epic. She focuses on Epic’s electronic health record system as an enabling and accelerating technology in support of the clinical research mission of organizations. Nancy also leads Epic’s annual Research Advisory Council conference which draws over 350 attendees from more than 135 of Epic’s customers, providing a broad perspective on the research-related efforts of leading healthcare organizations across the country and globally. Nancy earned her PhD in 1993 from the University of Wisconsin, Madison. She did her Post-Doctoral fellowship in health services research, after which she accepted a position as a Research Scientist at the University of Wisconsin, School of Medicine, where she continued her work as part of a multi-disciplinary team examining biopsychosocial models of health and disease. A significant component of this research program focused on individual differences in outcome trajectories as measured by participant self-reported assessments. She joined Epic in 2001. |

| Ashley Wilder Smith, PhD National Cancer Institute | Ashley Wilder Smith, PhD, MPH, is Chief of the Outcomes Research Branch at the National Cancer Institute. Dr. Smith’s program of research focuses on developing, advancing and promoting investigations related to understanding and improving patient reported outcomes (PRO) and quality care for cancer patients, survivors and families. Dr. Smith is the Chief Science Officer of a trans-NIH cooperative agreement that supports the availability and implementation of PROMIS®, the NIH Toolbox®, Neuro-QOL, and ASCQ-Me™. Under this initiative, these four person-centered health outcome assessment systems are now offered through an integrated platform for automated use in one research resource. Dr. Smith earned her MS and PhD degrees in Health Psychology in 1999 and 2002, respectively, from the University of Pittsburgh. She completed an NCI Cancer Prevention Fellowship, which included earning an MPH in Epidemiology, also from the University of Pittsburgh. |

*We appreciate the previous service on the Steering Group of Jamie Skipper, PhD, and Caroline Coy, MPH, from the Office of the National Coordinator for Health Information Technology.
| Claire Snyder, PhD  
Claire Snyder, PhD, is Professor of Medicine and Oncology at The Johns Hopkins School of Medicine, with a joint appointment in Health Policy & Management (Bloomberg School of Public Health). She directs the Johns Hopkins program for Building Lifestyle, Outcomes, and Care Services Research in Cancer (BLOCS). Her research focuses on the quality of cancer care and, in particular, how patient-reported outcomes (PROs) such as health-related quality of life can be used to improve individual patient care. She is currently President of the International Society for Quality of Life Research (ISOQOL). Previously, Dr. Snyder worked at the National Cancer Institute and edited Outcomes Assessment in Cancer: Measures, Methods, and Applications (Cambridge University Press). She began her career in the private sector at Covance Health Economics and Outcomes Services Inc. Dr. Snyder received a BA cum laude in Public Policy Studies with a certificate in Health Policy from Duke University. She received a Master of Health Science in Health Policy in 2000 and a PhD in Health Policy & Management in 2005 from the Johns Hopkins Bloomberg School of Public Health. |
| --- |
| Matt Stiefel, MS, MPA  
Matt Stiefel directs the Center for Population Health in Kaiser Permanente’s Care Management Institute. He was a 2008-09 fellow with the Institute for Healthcare Improvement, and continues as a faculty member for various IHI initiatives, including 100 Million Healthier Lives. Matt joined KP in 1981 as a medical economist, and later held management positions in KP Northwest, directing planning, marketing, and medical economics. He joined the Care Management Institute as the director of measurement in 1998 and became the associate director of CMI in 2000. Prior to KP, he served as a policy analyst on the Carter Administration Domestic Policy Staff and in the US Department of Health, Education and Welfare, and as a local health planner in the San Francisco bay area. He completed an MS in epidemiology from the Harvard School of Public Health in 2013, holds an MPA from the Wharton School, and a BA in psychology from Stanford. |
| Mellanie True Hills, CSP  
Mellanie True Hills, CSP, is an atrial fibrillation and heart disease survivor, internationally-known author and speaker, non-profit CEO, and passionate advocate for patients. She is founder and Chief Executive Officer of the American Foundation for Women’s Health and StopAfib.org, a global atrial fibrillation patient advocacy organization. Her personal mission is to create a Stroke-Free World. She has testified before the FDA, convened the Atrial Fibrillation National Health Policy Roundtable, served on the Patient Council of the National Patient-Centered Clinical Research Network (PCORNet), and co-chairs the global Sign Against Stroke in Atrial Fibrillation Task Force. StopAfib.org collaborates with the American Heart Association on MyAFibExperience.org, a personalized community for those living with AF. Mellanie is the author of three best-selling and multiple award-winning books, speaks at medical conferences worldwide, is a regular contributor on patient perspectives to medical publications, and has been featured by hundreds of media outlets around the globe. She holds the highly-prestigious Certified Speaking Professional (CSP) designation from the National Speakers Association. Previously, she led the creation of one of the first corporate web sites, JCPenney.com, was a high tech executive at Dell, an executive strategist at Cisco, a world-renowned Internet strategy consultant, and a syndicated business journalist. |
Kevin Weinfurt, Ph.D., is Professor of Psychiatry and Behavioral Science at Duke University Medical Center and a faculty member of the Duke Clinical Research Institute. Dr. Weinfurt is also a Professor of Psychology: Social Health Sciences, a Senior Fellow of the Duke Center for Aging, and a Faculty Associate of the Trent Center for the Study of Medical Humanities and Bioethics. Dr. Weinfurt received his undergraduate degree from Loyola University of Chicago and did his graduate work in psychology at Georgetown and Oxford University. Dr. Weinfurt conducts research on measuring patient-reported outcomes, medical decision making, and bioethics. He has served as chair of the National Institutes of Health’s study section on Health Services Organization and Delivery. Dr. Weinfurt was the PI of the Duke site for the NIH PROMIS Network, where he led the development of the PROMIS SexFS measurement system for self-reported sexual function and satisfaction. He is currently chair of the Symptoms of Lower Urinary Tract Dysfunction Research Network, and is co-PI of the NIH Collaboratory Coordinating Center. Dr. Weinfurt also co-directs Duke’s Clinical Research Training Program, in which he teaches a semester-long course in patient-reported outcomes. Dr. Weinfurt has also taught courses in introductory psychology, judgment and decision making, the psychology of medical decision making; and multivariate statistics.

Albert W. Wu is practicing internist and Professor of Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health, with joint appointments in Epidemiology, International Health, Medicine and Surgery, and the Carey Business School. He is Director of the Center for Health Services and Outcomes Research, and the PhD Program in Health Services Research. He was the first to study PROs in HIV/AIDS clinical trials and led patient reported outcome assessment for the NIH AIDS Clinical Trials Group and other national studies, and developed leading PROs in the field. He led PRO assessments related to intensive care, surgery, eye disease, asthma, and chronic kidney disease. He was President of the International Society for Quality of Life Research. He has been a thought leader on the incorporation of PRO data into the electronic health record, and was co-developer of PatientViewpoint, an early webtool to allow providers to routinely order PRO questionnaires as lab tests. He is Director of the EPIC Questionnaire Working Group for Johns Hopkins Medicine. He was Vice-Chair of PCORNet PRO Taskforce and leads PRO measurement for the PCORI-funded PaTH Clinical Data Research Network. He has a BA and MD from Cornell University, MPH from University of California, Berkeley, and was a Robert Wood Johnson/Veterans Administration Clinical Scholar at University of California, San Francisco.
## Appendix 2: Working Group Biographies

<table>
<thead>
<tr>
<th>Name</th>
<th>Position and Institution</th>
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<tr>
<td>Joseph Ali, JD</td>
<td>Mr. Ali is Research Scholar II, Johns Hopkins Berman Institute of Bioethics and Associate, Department of International Health, Johns Hopkins Bloomberg School of Public Health. His research includes efforts to improve understanding of emerging ethics and regulatory challenges in health policy and systems research. In the United States, he served as co-lead of the Ethics &amp; Regulatory Taskforce for PCORnet – the National Patient-Centered Clinical Research Network. In this role, he contributed to the design and development of systems and approaches to support national patient-centered comparative effectiveness research. Internationally, he is leading a project exploring the ethical, legal and societal issues that arise in mobile phone-based non-communicable disease surveillance in low- and middle-income countries. For the past 10 years, he has also supported capacity strengthening, training and collaborative partnerships in research ethics, particularly across sub-Saharan Africa.</td>
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<tr>
<td>Ethan Basch, MD, MSc</td>
<td>Dr. Ethan Basch is an oncologist and health services researcher who directs Cancer Outcomes Research at the University of North Carolina. His research focuses on patient-reported outcomes (PROs), and his group established that up to half of patient’s symptom side effects go undetected during cancer treatment and clinical trials – and that patient engagement and questionnaires substantially improve detection. His team created a system for the National Cancer Institute to collect patient-reported side effects during cancer trials. He is also involved in efforts to bring PROs into comparative effectiveness research, routine care, and quality improvement. He is a member of the National Cancer Institute’s Board of Scientific Advisors, PCORI Methodology Committee, Co-Chair of the Alliance Health Outcomes Committee, and an Associate Editor at JAMA.</td>
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<tr>
<td>Judy Baumhauer, MD, MPH</td>
<td>Dr. Baumhauer serves as Associate Chair of Academic Affairs and Professor, Division of Foot and Ankle Surgery, Department of Orthopaedics at the University of Rochester. In addition to providing clinical care, she holds the position as the Medical Director of the PROMIS for the UR Health Care System and is a board of director of Accountable Health Partners, ACO for the Rochester Region. She received her BS from Springfield College in Massachusetts; her MS in Biology from Middlebury College and her medical degree from the University Of Vermont College Of Medicine. She completed orthopaedic residency at the Medical Center Hospital of Vermont and a Fellowship in Foot and Ankle Surgery at the Medical College of Wisconsin. While working as an Attending at the University of Rochester, she obtained a MPH degree from the University of Rochester Department of Community and Preventive Medicine. Dr. Baumhauer is the past president of the ABOS, AOFAS; and EOA. She has chaired and presented at many regional, national and international courses, published over 100 papers and chapters and her research interests include outcomes assessment and clinical trials design. Dr. Baumhauer is a deputy editor for Clinical Orthopaedics and Related Research (CORR) and a reviewer for Foot and Ankle International, American Journal of Bone and Joint Surgery, and the journal of Orthopaedic Research.</td>
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Jim Bellows is Managing Director, Evaluation and Analytics in Kaiser Permanente’s Care Management Institute. His team produces metrics, program evaluation, and applied research that powers system-wide care delivery improvement initiatives by characterizing opportunities, learning what works, producing data that drives performance, and assessing impact and value. His work builds Kaiser Permanente’s capabilities as a learning health care organization, and is done in close collaboration with a wide range of clinical and operational partners. He directs use and adaptation of a wide variety of qualitative and quantitative methods to produce knowledge for improvement and for spread of successful practices, and facilitates translation of results into strategy, design, and practice. He earned his PhD in health services research and health economics from the University of California at Berkeley. He was a Lecturer at UC Berkeley for four years, teaching health care quality improvement and quality measurement.

Arlene Chung, MD, MHA, MMCi is an informatician, health services researcher, internist, and pediatrician. She is an Assistant Professor of Medicine and Pediatrics at the University of North Carolina at Chapel Hill (UNC) School of Medicine, and is a member of the Lineberger Comprehensive Cancer Center and the UNC Program on Health and Clinical Informatics. She is board certified in the new medical subspecialty of clinical informatics. Her research focuses on the integration of patient-reported outcomes (PROs) and other patient-generated health data (PGHD) into the electronic health record and patient portal, implementation of PROs/PGHD into clinical workflows, and on interactive data visualization. She has extensive experience with the design and development of patient-facing software systems, including the Crohn’s and Colitis Foundation of American Partners Patient-Powered Research Network patient portal that integrates PROs, social media, electronic health records, and wearable device data. She is an inaugural member of the NIH Precision Medicine Initiative Cohort Program’s Institutional Review Board, which oversees the landmark million-person cohort study that seeks to collect genomic, electronic health record, and wearable device data. She also serves on the ASCO PRO/PGHD Interoperability Workgroup.

Dr. Michele Halyard is a Professor of Radiation Oncology at Mayo Clinic with expertise in the treatment of breast cancer and head and neck cancer. She is also the Suzanne Hanson Poole Vice Dean of the Mayo Clinic School of Medicine, a national medical school with campuses in Minnesota, Arizona, and Florida, and serves as the Dean for the Arizona campus of the Mayo Clinic Medical School which will open in July 2017. Her research focuses on the use of patient reported outcomes in clinical practice. Dr. Halyard served as the Vice Chair of the Patient Reported Outcomes Quality of Life (PROQOL) committee of the North Central Cancer Treatment Group and also served as a Vice Chair of the Health Outcomes Committee of the ALLIANCE cooperative group and as the Co-Chair of the International Society for Quality of Life Research Clinical Practice Interest Group. Dr. Halyard was a coauthor of the ISOQOL User’s Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice.
Dr. Hartzler is an assistant investigator at Kaiser Permanente Washington Health Research Institute, where she leads a research program on the human-centered design of personalized health technology. Her research focuses on the ways technology can empower patients through collaboration with peers, providers, and other health system stakeholders. Combining patient-generated health data, social computing, and participatory design, Dr. Hartzler’s recent projects include visualizing patient reported outcomes in personalized dashboards to facilitate patient-provider collaboration, text mining in online health communities to connect patients with peer mentors, and designing genome-guided decision support tools to promote shared decision making. This work spans consumer health informatics and human-computer interaction, drawing upon social science foundations, and has received 4 best paper awards and 4 honorable mentions at premier medical informatics conferences. Dr. Hartzler holds a PhD in biomedical informatics and a bachelor of science in psychology from the University of Washington.

Rachel Hess, MD, MS is a Professor of Population Health Sciences and Internal Medicine and the founding Chief of the Division of Health System Innovation and Research (HSIR) at the University of Utah Schools of the Health Sciences. As the director of HSIR, she brings together individuals from across the University of Utah to develop, test, and implement novel approaches that improve health outcomes for the population. She is also the principal investigator of one of the original 11 PCORnet Clinical Data Research Networks, PaTH. Dr. Hess’s implementation work uses health information technology to engage patients in their care. She has examined the impact of providing patients with guideline-based feedback regarding their health behaviors and health-related quality of life on patient activation and behavior change. Dr. Hess has overseen the development and successful implementation of multiple technology-based programs in primary care, including UPMC’s efforts in the electronic collection of patient-reported information as part of routine clinical care throughout the health system. Dr. Hess completed her undergraduate work in mathematics at Washington University, received her medical degree from the University of New Mexico, completed her residency training at Temple University, and completed her general internal medicine and women’s health fellowships at the University of Pittsburgh.

Dr. Erin Holve is Director of the Department of Health Care Finance’s Health Care Reform and Innovation Administration (HCRIA) within the District of Columbia Government. HCRIA creates and tests new delivery system and payment models among Medicaid providers with the goal of enhancing health care quality, improving care and outcomes, promoting health equity, and enhancing the value and efficiency of DHCF’s programs. In this role Dr. Holve also chairs the DC Health Information Exchange Policy Board and oversees the District’s Medicaid EHR incentive program. Dr. Holve has more than fifteen years of experience in health policy and health services research. She is a widely published and cited author of reports and peer-reviewed articles on health insurance access, as well as health IT infrastructure. Dr. Holve holds a Ph.D. in health services research from the Johns Hopkins School of Public Health and masters’ degrees in public health and public policy from the University of California, Berkeley.
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<th>Roxanne Jensen, PhD</th>
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<td>Georgetown Lombardi Comprehensive Cancer Center</td>
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<td>Roxanne Jensen, Ph.D., is an Assistant Professor at Georgetown University in the Department of Oncology and a member of the Cancer Prevention and Control Program at the Lombardi Comprehensive Cancer Center. She received her B.A. from the University of Pennsylvania and Ph.D. in Public Health from the Johns Hopkins Bloomberg School of Public Health. Dr. Jensen was a PROMIS Network Investigator leading large-scale analyses validating the use of PROMIS measures in cancer patient populations. She has conducted multiple studies evaluating methodological and operational barriers present when integrating patient-reported outcomes assessment into clinical practice. She is currently a KL2 scholar developing electronic patient-reported symptom reports specifically for patient use.</td>
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<th>Irene Katzan, MD</th>
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<td>Cleveland Clinic</td>
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<td>Irene Katzan MD, MS is a neurologist and Director of the Cleveland Clinic Neurological Institute Center for Outcomes Research and Evaluation. She has a background in evaluating the outcomes of care in stroke and other neurological diseases and in modifying systems to optimize patient management across healthcare venues. She is also the Medical Director for Patient-Entered Data at Cleveland Clinic. She led the development and implementation of the Knowledge Program initiative to collect patient-reported outcomes information at the point of care. Currently health status information is collected electronically in over 100,000 clinical encounters each month.</td>
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<th>Carolyn Kerrigan, MD, MHCDS</th>
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<td>Dartmouth-Hitchcock Medical Center</td>
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<td>Dr. Kerrigan has more than 30 years of diverse leadership experience as a clinician, educator, researcher, healthcare leader and mentor with significant accomplishments in systems redesign, quality improvement, physician performance measurement, strategic planning and teambuilding. Dr. Kerrigan received her bachelor's degree and medical training at McGill University in Montréal, Québec. Her specialty training is in plastic surgery with subspecialty training in hand surgery. She practiced in Montréal for 12 years and at Dartmouth-Hitchcock for 20 years. She received her Masters in Health Care Delivery Science from Dartmouth College in 2013. Dr. Kerrigan is currently teaching in the MHCDS program and coaching quality improvement to diverse frontline teams both inside and outside DH. Under Dr. Kerrigan’s leadership, Dartmouth Hitchcock Medical Center has implemented a system wide program to integrate patient generated health data and self-reported outcome assessment in clinical practice.</td>
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<th>Danielle Lavallee, PharmD, PhD</th>
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<td>University of Washington</td>
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<td>Danielle Lavallee, Pharm.D., Ph.D., is a research assistant professor in the Department of Surgery at the University of Washington. Dr. Lavallee leads CERTAIN Patient Voices, an initiative to incorporate the patient perspective into both quality and research activities through the capture of patient-reported outcomes and active patient engagement. In this role, she manages a survey center which specializes in supporting survey development, methods for direct-to-patient surveying, and data collection for research studies and technology surveillance. Dr. Lavallee is leading work within UW Medicine to strategically implement the collection and reporting of patient-reported data in a manner to support both clinical and patient decision-making. Dr. Lavallee holds a Doctor of Pharmacy from the University of Kansas and a Ph.D. in Pharmaceutical Health Services Research from the University of Maryland, Baltimore.</td>
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<td>Esi Morgan, MD, MSCE</td>
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<td>Greg Pawlson, MD, MPH</td>
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<td>Lucy Savitz, PhD, MBA</td>
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Dean F. Sittig is the Christopher Sarofim Family Professor of Biomedical Informatics and Bioengineering in the School of Biomedical Informatics at the University of Texas Health Science Center in Houston, TX. He received his PhD in Medical Informatics from the University of Utah. His research interests center on design, development, implementation, and evaluation of all aspects of clinical information and communication systems. He is working to improve understanding of both the factors that lead to success, as well as, the unintended consequences associated with various forms of health information technology. Most recently he has focused his efforts on developing guidelines for the safe and effective implementation and use of electronic health records (EHRs) that are based on an 8-dimension socio-technical model that he developed with Hardeep Singh. This work lead to the development of the SAFER guides that were designed to help healthcare organizations conduct pro-active risk assessments of their EHRs. He has co-authored the following books, “Improving Outcomes – A Practical Guide to Clinical Decision Support Implementation”, “Clinical Information Systems: Overcoming Adverse Consequences”, “Electronic Health Records: Challenges in Design and Implementation” and most recently “SAFER Electronic Health Records: Safety Assurance Factors for EHR Resilience” and “Clinical Informatics Literacy: 5000 Concepts That Every Informatician Should Know”.

Professor Galina Velikova is an academic Medical Oncologist at the University of Leeds and Leeds Teaching Hospitals, UK with over 15 years track record of successful patient-centred research using electronic Patient-Reported-Outcome Measures in daily practice and clinical trials. She currently leads a National Institute for Health Research (NIHR) 5-year Programme Grant for applied research on patient self-reported symptoms and toxicity, using an online reporting system (QTool), uniquely integrated in electronic records, along re-designed care pathways for remote monitoring during cancer treatment to improve patient safety. She has experience in leading collaborative research, both nationally and internationally, such as Quality of Life sub-studies of international breast cancer trials (TACT2, SUPREMO). She is involved in the implementation in NHS, locally of holistic needs assessment for cancer patients (NICE supportive & palliative care guidelines) and nationally contributes to the National Cancer Survivorship Initiative. She is a practicing oncologist (Consultant in Medical Oncology) with clinical work focused on systemic treatment of breast cancer patients with early and advanced disease. Professor Velikova is past Chair of British Psychosocial Oncology Society, EORTC Quality of Life Group; and past President of International Society for Quality of Life Research (ISOQOL).

Dr. Wagle is a Medical Director at Partners HealthCare, working in the Divisions of Population Health Management and Quality Safety and Value. He leads the system’s efforts on Ambulatory Quality including performance, quality improvement, quality innovation, and value demonstration. For the last five years, he has led the development of the Partners Patient Reported Outcomes Measurement program, which has grown to include hundreds of thousands of data collections across dozens of specialties throughout the Partners network. For the last four years, he has led the transition to more clinically defined quality measures including the use of clinical registries and EHR data. Recently, he has led the effort to create new quality measures where they are needed in primary and specialty care. He earned his bachelor’s degree in biochemistry magna cum laude from Harvard University and received his M.D. from Harvard Medical School cum laude in the Harvard/MIT Division of Health Sciences and Technology where he was awarded a Howard Hughes Fellowship to conduct translational research in the field of lipid and carbohydrate metabolism. After his experience in two startup ventures, he earned an M.B.A. with high distinction as a Baker Scholar and Dean’s Award recipient from Harvard Business School where he focused on health care management. Dr. Wagle practices primary care at Brigham and Women’s Primary Physicians.
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<th>Name</th>
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<td>Kevin Weinfurt, PhD</td>
<td>Duke Clinical Research Institute</td>
<td>Kevin Weinfurt, Ph.D., is Professor of Psychiatry and Behavioral Science at Duke University Medical Center and a faculty member of the Duke Clinical Research Institute. Dr. Weinfurt is also a Professor of Psychology: Social Health Sciences, a Senior Fellow of the Duke Center for Aging, and a Faculty Associate of the Trent Center for the Study of Medical Humanities and Bioethics. Dr. Weinfurt received his undergraduate degree from Loyola University of Chicago and did his graduate work in psychology at Georgetown and Oxford University. Dr. Weinfurt conducts research on measuring patient-reported outcomes, medical decision making, and bioethics. He has served as chair of the National Institutes of Health’s study section on Health Services Organization and Delivery. Dr. Weinfurt was the PI of the Duke site for the NIH PROMIS Network, where he led the development of the PROMIS SexFS measurement system for self-reported sexual function and satisfaction. He is currently chair of the Symptoms of Lower Urinary Tract Dysfunction Research Network, and is co-PI of the NIH Collaboratory Coordinating Center. Dr. Weinfurt also co-directs Duke’s Clinical Research Training Program, in which he teaches a semester-long course in patient-reported outcomes. Dr. Weinfurt has also taught courses in introductory psychology, judgment and decision making, the psychology of medical decision making; and multivariate statistics.</td>
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<td>Danielle Whicher, PhD, MHS</td>
<td>Patient-Centered Outcomes Research Institute</td>
<td>Danielle Whicher, PhD, MHS, is a Program Officer for the Clinical Effectiveness Research (CER) team at the Patient Centered Outcomes Research Institute (PCORI). She is responsible for developing funding announcements and managing PCORI funded research contracts. Whicher is also a staff liaison to the PCORI Advisory Panel on Rare Disease and a co-editor for the journal Value in Health. Before joining PCORI, Whicher was a project coordinator at the Johns Hopkins Berman Institute for Bioethics. In this role, she worked on research designed to engage patients and other stakeholders in conversations about appropriate approaches to disclosure and authorization for enrolling participants in CER studies. She has authored a number of manuscripts on policy, methods, and CER-related ethics issues, including issues around informed consent and the routine integration of patient reported outcomes in electronic health records. Whicher received an MHS in health policy and management and a PhD in health policy and management and bioethics, both from the Johns Hopkins Bloomberg School of Public Health.</td>
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<td>Adam Wright, PhD</td>
<td>Harvard Brigham &amp; Women’s Hospital</td>
<td>Adam Wright is an Associate Professor of Medicine at Harvard and a Senior Scientist at the Brigham and Women's Hospital. Dr. Wright's research focuses on making EHRs safer and more effective through better design, improved clinical decision support and harnessing clinical data to drive a learning healthcare system. In addition to research, Dr. Wright teaches Harvard's introductory biomedical informatics courses, and also teaches medical students. He has a PhD in biomedical informatics from Oregon Health and Science University and a BS in mathematical and computational sciences from Stanford.</td>
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