HOW WILL THE PRO-EHR SYSTEM BE GOVERNED?

Questions

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WHAT SYSTEMS OF GOVERNANCE ARE REASONABLE FOR MANAGING PRO INFORMATION IN EHRS?

OPTION 1: DISTRIBUTED GOVERNANCE

EHR governance may be centralized, however most decisions about PRO implementation, oversight, and use is left to individual or group (department, subspecialty, program, etc.) users, or "end users".

**Any use of data for research purposes will still need to go through appropriate research oversight and review channels.

Advantages and Disadvantages of a Distributed Governance Model

- **Advantages:**
  - Allows different individuals or departments to adapt content and approaches to PROs to fit clinical needs
  - May encourage testing of pilot programs or projects
  - Ensures decisions about PRO implementation and use close to end-users

- **Disadvantages:**
  - Could lead to confusion or duplication
  - Patients may be asked to provide data to multiple similar PRO questionnaires with no coordination
  - May make cross-department collaboration more challenging
  - May confound reporting or research

OPTION 2: CENTRALIZED GOVERNANCE

An individual or group at the organizational level has oversight for most, if not all, decisions regarding PRO inclusion, implementation, and use in a given EHR.

Advantages and Disadvantages of a Centralized Governance Model

Advantages:
- Helps ensure that patients will not be subjected to multiple inquiries
- Provides a wider range of oversight and input
- Less likely to run afoul of regulatory oversight
- Can help set organizational goals and expectations for holistic, system-level adoption of PROs

Disadvantages:
- May inhibit use of different or more specialty- or condition-specific PROs
- Oversight could be bureaucratic and slow moving
- Resulting PRO data may be seen by clinicians as too general; not useful for patient care

OPTION 3: HYBRID

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 and Disadvantages of a Hybrid Governance Model

Advantages:

• Could be used in both centralized and decentralized institutional cultures

• Is flexible and may be optimal for emerging areas

• Allows for some experimentation within centrally agreed upon standards

Disadvantages:

• Could lead to confusion and disputes

• Could be misused to hinder local decision-making or to take advantage of imprecise rules

BEYOND INVOLVEMENT OF CORE CLINICIANS AND CLINICAL MANAGEMENT, WHAT GROUPS COULD BE INVOLVED IN GOVERNANCE OF PRO USE IN EHRS?

OPTION 1: USE THE PRE-EXISTING GOVERNANCE STRUCTURE FOR EHR

At a minimum, governance of PRO data in EHRs would include:

a) practice manager,

b) practice clinician, and

c) consultants or others to assist with IT and technical aspects of PRO use.

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.

Advantages and Disadvantages of an Existing EHR Governance Model

Advantages:

• Simple
• No new resources needed
• To the extent the organization has developed a thoughtful governance approach, can avoids duplication of effort, time, and administration

Disadvantages:

• Excluding patients increases the likelihood of patient and regulatory concerns

• Could constrain future use of patient-identified PRO data
• Oversight group will lack sufficient expertise in technical aspects of EHR implementation

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 and Disadvantages of a Direct Patient Representation

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

Disadvantages:
- Increases resource requirements to implement PROs
- Introduces new elements into advisory and/or decision-making
- Could be seen as making PROs a "special" category of data
- Might adversely affect participation in both research and QI
- Does not address concerns that PROs are unique data
- NOT taking governance into account explicitly for PROs may result in missed opportunities to set clear priorities

OPTION 3: ENGAGE A BROAD GROUP OF STAKEHOLDERS

Beyond patient involvement, governance structures may include 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. Examples of key personnel include:

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

In smaller practices this expertise may be consolidated.

Advantages and Disadvantages Broad Stakeholder Engagement

Advantages:

- Anticipates and provides means of addressing need to prioritize and control roll out of PROs
- Recognizes that there may be multiple organizations involved

Disadvantages:

- Will make governance group larger, complex, and more expensive
- Could lead to deadlocks or delays in reaching agreement
- May result in PRO data being considered as a special data for regulation
- IT logic may be needed to prioritize PROs to limit PRO administration to a single person at a specific point in time

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?