Section 11: What are the Ethical and Legal Issues?

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USERS' GUIDE TO INTEGRATING PATIENT-REPORTED OUTCOMES IN ELECTRONIC HEALTH RECORDS

Relevant Questions

- What **consent** is required for **collection** of PRO data for integration in the EHR? Can patients opt out?

- What **consent** is required for **use** of PRO data **held in the EHR**, potentially for multiple purposes?

- Are there **liability** issues specific to PROs in EHRs?

Important Considerations

Ethical vs **legal** requirements

- Federal and local laws govern what is and is not **legally** required
- Ethical norms and principles, like respect for persons, establish a range of **ethically** appropriate and inappropriate actions
- Ethics and law are not always perfectly aligned, including as they relate to consent

Significance of activity **type**

- Legal and ethical consent requirements often vary depending on ***how*** and ***why*** data are being collected (e.g., for clinical, quality improvement, or research purposes)

Consent vs. Informed Consent

Consent

- Requires disclosure of information and individual authorization
- Level of information disclosure and type of authorization (opt in vs opt out) may vary

***Informed* Consent**

- Requires detailed information disclosure, assurance of individual understanding, and individual authorization

Consent & informed consent

- demonstrates respect for individual decision-making, and
- helps protect individuals from burdens or risks of harm that they did not agree to accept

Opt In vs Opt Out

OPT IN

An individual is not included in an activity unless (s)he indicates an interest in being included

Presumed exclusion

No PRO survey provided until written or verbal authorization is provided

OPT OUT

An individual is included in an activity unless (s)he indicates a desire to be excluded

Presumed inclusion

PRO survey provided but individuals can opt out by refusing to complete

Must consider implications of opting-in/out of both PRO **collection** and/or **integration** of PRO data into EHR

Consent to Collect and Integrate PROs in EHRs

Background:

- individuals can always opt-out of PRO collection by simply not providing information
- higher opt-out rates may reduce the usefulness of PRO data for research and other purposes

Options:

- No disclosure or authorization sought
- General (nonspecific) disclosure including opt out information
- Brief specific disclosure including opt out information
- Robust specific disclosure including opt in information

Consent to Collect and Integrate PROs in EHRs

Common **advantages/disadvantages** of various options:

- Efficiency of the process/ease of integration into routine practice
- Respect for the individual patient
- Individual understanding of the PRO survey
- Compliance with federal and local laws related to research, clinical practice, data use
- Need to obtain additional consent for future uses
- Need for systems to track consent preferences

Consent to Use PRO data stored in EHRs

Background: Consent requirements depend on

- **how** data will be used
- for what purpose(s) they were **originally** collected
- 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**

Options:

- No additional consent for data re-use
- General (nonspecific) disclosure about data re-use
- Specific disclosure and authorization (opt in) for data re-use

Consent to Use PRO data stored in EHRs

Common **advantages/disadvantages** of various options:

- Efficiency of the process/ease of integration into routine practice
- Respect for the individual patient
- Individual understanding of how data are being used
- Potential shortcomings of anonymous data (where required by option)
- Compliance with federal and local laws related to research, clinical practice, data use
- Whether data are being used in ways that are consistent with the original consent for PRO survey completion
- Need for systems to track consent preferences

Liability Considerations: General

A range of **liability** considerations should be evaluated by legal counsel of those seeking to integrate PROs in the EHR, including, but not limited to, those related to:

- data privacy and security
- reportable/actionable events
- human subjects research
- informed consent/notice and authorization
- handling of sensitive data (e.g., substance use/abuse)

Liability Considerations: Duty to Rescue

For some PROs, **“critical” or “panic” values** that signal a reasonable likelihood of current or future patient harm could implicate negligence and other liability concerns if not anticipated

Questions to consider when 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?

Key Information Gaps and 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 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?

Thank You