Consent: Challenges, Opportunities, and Future Direction

ONC Annual Meeting 2020
Monday, January 27, 2020

Rose-Marie Nsahlai, ONC (OS/OTECH)
Johnathan Coleman, Security Risk Solutions Inc.
Jay Nakashima, eHealth Exchange
Doug Burke, Cognitive Medicine
Daniel Chavez, San Diego Health Connect
John Moehrke, ByLight Professional IT Services
Consent: Challenges, Opportunities, and Future Direction - Speakers

• Panel Kick-Off: Rose-Marie Nsahlai, Office of the National Coordinator for Health Information Technology, Office of Technology, Security and Services Branch

• Panel Moderator: Johnathan Coleman, Security Risk Solutions, Inc.

• Panelists:

  • Jay Nakashima, eHealth Exchange

  • Daniel Chavez, San Diego Regional Health Information Exchange/San Diego Health Connect

  • Doug Burke, Cognitive Medicine

  • John Moehrke, ByLight Professional IT Services
Considerations for electronic consent in different settings

Opt-in, Opt-out

Regulatory Considerations, e.g. 42 CFR Part 2

Other Considerations, e.g. Granular Choice
eHealth Exchange
Jay Nakashima
eHealth Exchange

- Facilitates electronic exchange of patients’ medical information
- Improves the speed, quality, safety, and cost of patient care
- Informs clinical decisions when seconds and minutes matter
# eHealth Exchange

## We Connect

<table>
<thead>
<tr>
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<th>70,000 Medical Groups</th>
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<tbody>
<tr>
<td>All 50 States</td>
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<td>Three Federal Agencies</td>
<td>7,800 Dialysis Centers</td>
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<td>(DoD, VA, SSA)</td>
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<td>75% of U.S. Hospitals</td>
<td>8,300 Pharmacies</td>
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## Connecting federal agencies & the private sector in all 50 states

- Supporting more than 120 million patients

February 2020 connectivity with carequality-enabled HINs

61 Regional and State HINs
eHealth Exchange

Who Manages Consent?
Each eHealth Exchange Participant is responsible for adhering to applicable law, eHealth Exchange policies, etc before disclosing PHI

Complexities:
• Opt-in States
• Opt-in Providers in Opt-Out States
• Sensitive Conditions
• Consents vs Authorizations
ONC LEAP
Consent Registry Utility

Dan Chavez, Doug Burke
Today, facilities, not humans, determine what information is shared with whom, when and under what conditions.
Consent: Challenges, Opportunities, and Future Direction

Workflows:

Privacy
Medical
Social

Consent Registry Utility

Community

Exchange

Permission

Research

Advanced
A microservice providing an interface for inquiring about patient consent (backed by FHIR-based consent repositories)

**Request:**
Context of workflow (e.g., patient identifier, type of workflow, purpose of use,…)

**Response:**
Consent Decision, obligations and caveats, decision rationale (e.g., reference to the consent resource)
Consent Enforcement Point

Individual modules integrating with different application contexts to enforce consent decisions

- Capture and report the context of the workflow in the form of a query
- Receive and process the response
- Apply and enforce the decision in the workflow
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HL7 FHIR Consent

John Moehrke
HL7 FHIR Consent

- Consent Resource - useful for many consent types
- Positive and Negative - not just consent but dissent
- Not just classic consent - also Authorizations
- Depends on Local Policy meaning and enforcement
- Just captures and records facts
- Absence of a Consent means?
- Questionnaire may be used in workflow to obtain Consent
- Includes a RULE encoding customized to FHIR
Consent Maturity

1. Consent resource just points at scanned paper
2. Consent resource just points at QuestionnaireResponse
3. Consent encodes .provisions
4. Consent w/ depth .provisions (PERMIT vs DENY)
5. Consent using external rules encoding (XACML)

Vectors:

• Timeframe of validity
• Organization consent applies to
• Regulation consent applies to
• Local Policy agreed to
FHIR Consent

- Type - permit/deny
- Context affected
- Actors affected
- Data selection
- Obligations
Audience Q&A
Contact ONC

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