The February 19, 2019, meeting of the Interoperability Standards Advisory Task Force of the Health IT Advisory Committee (HITAC) was called to order at 10:00 a.m. ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

Roll Call

Kensaku Kawamoto, co-chair, University of Utah Health
Steven Lane, co-chair, Sutter Health
Ricky Bloomfield, Member, Apple
Tamer Fakhouri, Member, One Medical
Cynthia Fisher, Member, WaterRev, LLC
Valerie Grey, Member, New York eHealth Collaborative
Ming Jack Po, Member, Google
Edward Juhn, Member, Blue Shield of California
Victor Lee, Member, Clinical Architecture
Leslie Lenert, Member, Medical University of South Carolina
Anil Jain, Member, IBM Watson Health
Clement McDonald, Member, National Library of Medicine
David McCallie, Jr., Member, Cerner
Arien Malec, Member, Change Healthcare
Terrence O’Malley, Member, Massachusetts General Hospital
Sasha TerMaat, Member, Epic
Andrew Truscott, Member, Accenture
Sheryl Turney, Member, Anthem

MEMBERS NOT IN ATTENDANCE
Tina Esposito, Member, Advocate Health Care
Raj Ratwani, Member, MedStar Health
Ram Sriram, Member, National Institute of Standards and Technology
Scott Weingarten, Member, Cedars-Sinai Health System

ONC STAFF
Denise Joseph, Public Health Analyst, ONC ISP Task Force Lead
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer
Call to Order

Lauren Richie called the meeting to order, conducted roll call, and turned the meeting over to the co-chairs.

Opening Remarks

Steven Lane reviewed the agenda, noting that the ISPTF will review the edits to the closed loop referral and care coordination recommendations and then transition to medication and pharmacy data (the next priority area identified by the ISPTF). While the ISPTF is initiating the discussion on medication and pharmacy data, there will be a change of the task force schedule that he asked Lauren Richie to share.

Lauren Richie shared that the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program notice of proposed rulemaking (NPRM) was released last week. She shared that there will be four tasks forces made up of HITAC members to provide comments on the NPRM. There will be a 60-day comment period for the NPRM, beginning when it is published in the Federal Register, and recommendations will be due at that time. During the time that these new task forces are developing comments to the NPRM, the ISPTF will be on hold. The ISPTF will reconvene at the end of April or early May.

Tamer Fakhouri shared that he has changed his role and has joined Livongo Health which is working on building solutions that empower people with chronic conditions. He will also continue to practice primary care at One Medical.

Final review: Closed Loop Referrals and Care Coordination Draft Recommendations

Steven Lane began the review of the edits to the closed loop referrals and care coordination draft recommendations. He added that he was hopeful that the time required to review the edits will be modest.

PRIORITY 1A

1A: Observations

- Current referral workflows are inefficient, fail to leverage available interoperability tools, leading to increased cost, delays in care and poor care coordination.
- Needed patient care may be delayed due to difficulty identifying who is available to accept a referral, and what is their availability.
- Patients simply given a phone number to arrange their own appointment may never follow up.
- Specialist may not receive the information required to efficiently and effectively care for the patient.
- Even when information is provided, if that information is not discrete data it cannot be easily ingested from the sending EHR system into the recipient EHR system causing expensive data transcription which can lead to errors and adverse events.
Important information may be lost, and unnecessary care delays introduced, due to the lack of closed-loop communications between referring providers and consultants.

1A: Recommendations

- There is promising work being done by the 360X Project to support closed-loop referrals that leverages C-CDA for clinical content, Direct protocols for transport, XDM for establishing context, and HL7 V2 messages for referral workflow. This has been successfully tested but is still in a pre-pilot stage.
- The success of 360X is dependent on specific patient identity management capabilities and the use of referral identifiers by EHR vendors.
- There are currently multiple potential methodologies for representing message context.
- FHIR supports provider directories, clinical and workflow messaging and could potentially provide an alternative transport mechanism to support referral workflows.

1A: Policy Levers/Responsibility

ONC
- Support 360X piloting via grants, contracts, certification requirement or facilitation and coordination
- Support FHIR-based efforts to address closed-loop referral and care coordination messaging needs.
- Include defined baseline closed-loop referral capabilities as a requirement for certification.

CMS
- Align relevant programs, including MIPS, MSSP, patient centered medical home, etc., to reward activity that improves care through electronic closed-loop referral.

PRIORITY 1B

1B: Observations

- There is no standardization regarding what clinical data should be collected prior to referring a patient to a given specialist for a given problem or symptom.
- There is a need for specialty-specific standards regarding what information the “referred to” clinician requires from the “referring” clinician to provide an effective and efficient clinical response for a specific clinical issue.
- Payers have varying requirements regarding the information required and criteria that must be satisfied in order to provide prior authorization for referrals.
- This need is also relevant to transitions between care settings, such as from acute to post-acute care.

1B: Recommendations

- Clinical Data collected prior to and sent at the time of referring a patient.
- Identify an organization, or convene and support a collaboration, to develop and evolve recommendations for what clinical data consulting/receiving providers should receive/be sent in
order to optimize the efficiency and value of referrals/consultations for all parties (e.g., patient, referring provider, payer, referred to provider, other members of the care team). Begin with prioritizing the top 80% of referral diagnoses across specialties.

- Identify, catalog and, as necessary, manage and evolve best practice standard data elements necessary for collection and transmission to support efficient, patient-centric referral workflows and processes including associated prior authorization requirements.
- Potential collaborators:
  - America Medical Association (AMA) Integrated Health Model Initiative (IHMI)
  - 360X Project Group
  - Council of Medical Specialty Societies (CMSS)
  - Physicians’ Electronic Health Record Coalition (PEHRC)
  - Physicians Consortium for Performance Improvement (PCPI)
  - Health Services Platform Consortium (HSPC)
  - Healthcare Information and Management Systems Society (HIMSS)
  - EHRA Electronic Health Record Association (EHRA)
  - Da Vinci Project
  - Payer-Provider (P2) FHIR Task Force
- Consider piloting FHIR Argonaut Questionnaires when additional information, beyond top 80%, is needed.
- Explore the use of referral management apps (e.g., using SMART technology solutions) to support referral management workflows and the associated information exchange.

Discussion
- David McCallie suggested considering support for a SMART app for referral management.
- This discussion resulted in the addition of the following recommendation noted above:
  - Explore the use of referral management apps (e.g., using SMART technology solutions) to support referral management workflows and the associated information exchange.

1B: Policy Levers/Responsibility

ONC
- Convene and/or support stakeholders to profile minimal standards of clinical and administrative data required and desirable for clinical referrals, with exemplars in C-CDA and FHIR, including best practice guidance for display of those standards.
- Align the clinical referral profiles with the USCDI; specifically, allow for clinically relevant profiles of USCDI to be sent in clinical referral workflows.

PRIORITY 1C

1C: Observations
- EHR-integrated solutions for secure clinician-to-clinician patient-specific messaging are lacking, especially when clinicians work in different organizations or with different EHR/HIT systems.
- While currently required Transitions of Care messaging and 360X leverage Direct, this standard has been implemented inconsistently by EHR and other HIT vendors and operationalized inadequately by many providers and healthcare organizations.
The features and functions necessary to support the clinical usability of Direct messaging have been enumerated and prioritized (App Clin Informatics, Vol. 9 No. 1, 2018).

Direct interoperable features, functions, implementations, usage could be improved, and FHIR could potentially support secure clinical messaging and provide an alternative transport mechanism for these functions.

1C: Recommendations
- Clinician-to-Clinician Patient-Specific Messaging.
- Support and incentivize EHR and clinician user adoption of functionality necessary to fully utilize the capabilities of Direct and/or other compatible transport mechanisms for cross-organizational secure clinical messaging to support referrals and care coordination.
- Investigate how FHIR-based approaches can be developed and leveraged to support clinical messaging.

PRIORITY 1D

1D: Observations
- Referral management and care coordination both require the ability to reliably identify and locate providers and to have an understanding of the messaging capabilities of each provider.
- Argonaut has published a provider directory implementation guide (http://www.fhir.org/guides/argonaut/pd/)

1D: Recommendations
- Provider Directories
  - Support the development and advancement of a nationwide standard for provider directories and their management to support referrals and care coordination, including cross-organizational clinical messaging. This should include information regarding:
    - NPI
    - Contact information, including Direct address(es)
    - Preferred method(s) of communication
    - Messaging capabilities supported for each communication method

PRIORITY 1E

1E: Observations
- Establishing the required governance for information sharing, enabling referral scheduling, etc., takes substantial effort and can be a barrier to closed-loop referrals and care coordination.
- Governance over Direct messaging is currently provided by DirectTrust, though this may not directly impact provider organizations’ decisions regarding implementation or support of this functionality.
• The Trusted Exchange Framework and Common Agreement (TEFCA) called for by the 21st Century Cures Act promises to provide a national framework and governance for connecting healthcare organizations and may be leverageable for this purpose as "snap-on" governance.

1E: Recommendations
• Governance
  o Include access to and governance of push messaging, and the associated technical and workflow requirements necessary to support referrals and care coordination, in the scope of the final TEFCA.

PRIORITY 2A

2A: Observations
• Referral management and care coordination currently rely on fax, telephone, and postal mail communication that does not automatically incorporate relevant information into patients' electronic medical records and clinicians' EHR workflows, with resultant process inefficiencies, and increased clinical and privacy risks for patients.

2A: Recommendations
• Automatically incorporate relevant patient information into EHR
  o Support efforts to transition to and eventually require secure, cross-organizational, cross-vendor, EHR-integrated electronic messaging between providers, patients, payers, and all care team members.

PRIORITY 2B

2B: Observations
• Patient-clinician messaging is currently supported principally within EHR-integrated patient portals.
• Patients desire the ability to utilize additional methods of secure communication that allow them to choose their preferred application interface to message with providers and other caregivers at multiple institutions or using multiple HIT systems.
• Any viable solution to support patient-clinician communications must fully integrate with EHR workflows.
• Early experience with patient-to-provider Direct messaging suggests that this is a feasible solution, but there has been little adoption by the provider community.
• FHIR could potentially support secure clinician-patient messaging.

2B: Recommendations
• Patient-Clinician Messaging
  o Support pilots of patient to provider messaging using multiple available technology solutions, e.g., Direct, FHIR.
Provide flexibility to individuals/patients to select the messaging tool(s) of their choice and to easily manage messaging with care team members utilizing disparate HIT solutions.

Viable messaging solutions will integrate with one another as well as with established clinician workflows for portal-based messaging.

Encourage consistency of policy solutions regarding the inclusion of patient-clinician messaging as a part of the legal medical record.

**Discussion**

- **Sash TeerMat** questioned whether the legal medical record needs to be considered. She thought there wasn’t consistency in how this is approached today. She questioned that this might be a policy problem.
  - **Arien Malec** commented that the result of patient secure messaging should be part of the clinical record.
  - This discussion resulted in the following recommendation (included above).
    - Encourage consistency of policy solutions regarding the inclusion of patient-clinician messaging as a part of the legal medical record.

- **Jack Po** suggested adding secure messaging integration.
  - **Steven Lane** added the following line to the recommendations for clarity (included above)
    - Viable messaging solutions will integrate with one another as well as with established clinician workflows for portal-based messaging.

**PRIORITY 2C**

**2C: Observations**

- Patient care is fragmented, inefficiencies and redundancies are introduced, and potential patient safety hazards are created due to the lack of coordination between care providers. A standard patient-centric, multi-stakeholder, multi-institutional care plan could help address this lack of coordination.
- There is some work in this area, but more foundational research and development are needed.

**2C: Recommendations**

- Multi-stakeholder, Multi-institutional Care Plan
  - Investigate various approaches, such as those based on the FHIR and C-CDA Care Plan.
  - Ensure that patient, caregiver and family goals and wishes are incorporated into the care plan.
  - Over time an app-based approach is likely to be beneficial to support this use case.

**Discussion**

- **David McCallie** expressed concern that over time an app-based approach will be necessary.
  - This discussion resulted in the addition of the following recommendation (noted above).
  - Over time an app-based approach is likely to be beneficial to support this use case.

**2C: Policy Levers/Responsibility**

- ONC, CMS, AHRQ, NIH
Sponsor R&D in this area, with a particular focus on the use of standards-based approaches to enable scaling.

PRIORITY 2D

2C: Observations
- Real-time text messaging is increasingly being used to support clinical communications both within and between clinical organizations. Such messaging is often performed outside of the EHR without creating permanent documentation of the associated clinical decision making or communication.

2C: Recommendations
Real-time text messaging
- Explore the usage of and development of standards for the use of secure real-time text messaging that supports appropriate integration with EHR documentation and workflows.

1: GENERAL OBSERVATIONS

1: Observations
- There are similarities between the technology needs to support Referrals & Care Coordination and Orders & Results. These closed loop exchanges share a number of common processes:
  o Initiator provides information to provoke a specific action from the responder
  o Responder reacts to this information by:
    - Requesting additional information (clarification)
    - Messaging regarding the progress of the request
    - Messaging management to ensure completion of the exchange (“closing the loop”)
  o Examples of Closed Loop Exchanges include:
    - Test orders/results
    - Referral request/response
    - Transitions of Care
    - Shared Care Plan (longitudinal care coordination)

1: Recommendations
- Identify opportunities for harmonization/unification of technology standards and governance support of the various instances of closed loop exchanges.

2: GENERAL OBSERVATIONS

2: Observations
- Closed loop referrals between ambulatory providers are but one example of a Transition of Care (ToC) workflow. Other examples include:
  o Request for outpatient testing
Transitions to, from and between EDs, acute care facilities, ambulatory surgery centers, LTPAC facilities, home/community care providers, etc.

Each of these workflows may require:
- Specification of sender and receiver
- Specification of urgency
- Specification of whether transition is meant to be temporary or permanent
- Requested response, e.g., acknowledgment of receipt, returned test result, referral/care report, etc.

2: Recommendations
- Identify opportunities for harmonization/unification of technology standards and governance support of the various instances of Transitions of Care.

3: GENERAL OBSERVATIONS

3: Observations
- There are many custom interoperability solutions that use different approaches, e.g., HL7 v2/v3/CDA, FHIR, and Direct. This adds cost and complexity.

3: Recommendations
- Actively seek out and identify opportunities to consolidate, simplify and render cost-effective the health IT interoperability landscape.

3: Policy Levers/Responsibility

ONC
- Commission effort(s) to identify functional overlap between standards and identify opportunities for consolidation and/or harmonization.
- For individual ONC-funded projects, consider including required and/or optional tasks for exploring such cross-use-case harmonization and de-duplication in the project scope.

4: GENERAL OBSERVATIONS

4: Observations
- There are areas of health data interoperability where there is no clear single best approach, and multiple potential approaches that can be taken.

4: Recommendations
- ONC should avoid "picking winners" prematurely and remain open to potential alternative approaches which may ultimately be superior for a given problem or in a larger context that considers various use cases (e.g., by avoiding the need to maintain separate infrastructure for multiple use cases).

4: Policy Levers/Responsibility
ONC

- Convene practicing clinicians, HL7, DirectTrust, Argonaut Project, EHR vendors, and other relevant stakeholders to identify specific use cases that would warrant a standards evolution path to allow applicable functionalities currently available in Direct to potentially also function in FHIR.
- Develop certification criteria and associated CMS programmatic changes to allow a flexible transition to the appropriate use of the FHIR standard where this technology is deemed superior for a given clinical use case.

Discussion

- Terry O’Malley asked about the next steps for the ISPTF.
  - Steven Lane shared that it provides a transition to the Interoperability Standards Advisory (ISA) and how it has evolved. He shared that Steve Posnack stated at HIMSS that there might be a standing group focused on defining interoperability use cases that may help identify what is next and help ensure that the work identified continues. He noted that this will be discussed with ONC leadership.

ISA Summary of the 2019 Reference Edition on Medication & Pharmacy content, Carmen Smiley, IT Specialist, Office of Technology

Steven Lane transitioned to a presentation from Carmen Smiley to provide an update regarding the changes that have been made to the 2019 ISA.

2019 Edition Reference ISA

Updates included in the 2019 Reference Edition ISA based on numerous changes made to address public comments received, including but not limited to:

- Allows a Prescriber to Prescribe Medication Using Weight-Based Dosing
- Allows a Prescriber to Request a Patient’s Medication History from a State Prescription Drug Monitoring Program (PDMP)
- Updates since the 2019 Edition Reference ISA, including but not limited to:
  - Specialty Care and Settings functionality (opioids and pediatrics)
  - Allows a Prescriber to Send a Prescription to a Pharmacy for a Controlled Substance
  - Allows a Prescriber to Communicate Drug Administration Events
  - Allows a Prescriber to Communicate with a REMS Administrator
  - Allows for the Exchange of State Prescription Drug Monitoring Program (PDMP) Data

Specialty Care and Settings

- New functionality supports "Specialty Care and Settings" to display a list of interoperability needs supporting particular care needs or settings, including Opioids (prevention and treatment) and Pediatrics.

21st Century Cures Act NPRM
• 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program
  o Proposes an update to electronic prescribing (eRx) SCRIPT standard in 2015 Edition from NCPDP SCRIPT v10.6 to NCPDP SCRIPT 2017071
    ▪ CMS recently finalized its Part D standards to NCPDP SCRIPT 2017071 for eRx and medical history, effective January 1, 2020
    ▪ ONC and CMS have maintained complementary policies and aligned standards to ensure that the current standard for certification permits use of the current Part D eRx standards
    ▪ New eRx standard will eventually become the baseline for ONC Health IT Certification
    ▪ ONC will continue to reference the current transactions included in § 170.315(b)(3) and propose to require all of the NCPDP SCRIPT 2017071 standard transactions CMS adopted

New eRx Certification Criterion § 170.315(b)(11)
  • Create new prescriptions (NewRx, NewRxRequest, NewRxResponseDenied)
  • Change prescriptions (RxChangeRequest, RxChangeResponse)
  • Cancel prescriptions (CancelRx, CancelRxResponse)
  • Renew prescriptions (RxRenewalRequest, RxRenewalResponse)
  • Receive fill status notifications (RxFill, RxFillIndicatorChange)
  • Request and receive medication history (RxHistoryRequest, RxHistoryResponse)
  • Ask the Mailbox if there are any transactions (GetMessage)
  • Relay acceptance of a transaction back to the sender (Status)
  • Respond that there was a problem with the transaction (Error)
  • Respond that a transaction requesting a return receipt has been received (Verify)
  • Request to send an additional supply of medication (Resupply)
  • Recertify the continued administration of a medication order (Recertification)
  • Complete Risk Evaluation and Mitigation Strategy (REMS) Transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse)

Discussion of Next Priority Topic: Medication & Pharmacy Data

Steven Lane in Clem McDonald’s absence shared Clem’s concerns with reviewing medication and pharmacy data next because he felt there is a lot that is happening to move things forward. He was concerned that this might not be the item of the greatest need based on the progress that is already being made.

Other members of the group did not express concern; therefore, Ken Kawamoto proceeded with the discussion.

Ken Kawamoto reviewed the comments shared by the ISPTF members in the shared excel document to identify challenges and potential solutions. He asked each member to review the information they added into the document.
Terry O’Malley noted that structured sig is beyond what long-term post-acute care (LTPAC) needs at this point. He commented that basic use cases that are well established should be the baseline.

- **Steven Lane** noted that in Terry’s comments there are items such as dose, frequency, time of last administration that would benefit from structure sig. This is what allows a computer to know how much a patient is receiving at a certain point in time. He shared that structured sig would allow systems to provide more detailed dose and lifetime dose-related clinical decision support (CDS) and improve the efficiency of transferring and reconciling medication information between systems.

- **Arien Malec** commented that medication history comes from pharmacy benefit managers (PBMs) which comes from claims data and does not include sig information. There are gaps in standards for sig information. There is utility to be able to compute dosing.

- **David McCallie** added that there is a distinction between templated sigs and structured sigs. Computable is another variation, vendors are able to tease apart a free text sig into structured components, but it does not fit into the definition from the National Council for Prescription Drug Programs (NCPDP).

- **David McCallie** questioned whether Arien was in support of/against structured sig.
  - **Arien Malec** commented that it is important to make sure that the unstructured sig gets to physicians. There also needs to be a directive to make sure there is utility of taking on structured sig. There is the ability to capture value in some of the easy cases up front.
  - **Steven Lane** shared that laying out a path forward for structured sig, beginning with being able to share the data that does exist is important, as Arien noted.

**Victor Lee** agreed with Arien. To the extent that it makes sense to define standards or help people find standards that are not being used.

**Ken Kawamoto** shared the items he entered into the spreadsheet (the challenges he entered are noted below).

- More information than medication identity may be needed, e.g., for opioids morphine milligram equivalence calculations (dose, quantity, frequency, etc.).
- Medication dispense data is not universally available, and currently not available via Fast Healthcare Interoperability Resources (FHIR).
  - **Ricky Bloomfield** noted that it could be asked that both the National Drug Code (NDC) and RxNorm codes get sent. For Argonaut one coding system has been asked for, but having both if available would be useful in this case.
  - **Arien** noted that RxNorm would be preferred.
  - **David McCallie** noted that a systematic approach is needed. The pharmacy side uses NCPDP and FHIR is not used. There are a lot of opportunities for improvement. This is a systems problem, not a standards problem.
  - **Terry O’Malley** shared that the pharmacy is pushing to be the central source of truth for medications. Assuming a central source emerges, how do we standardize?
    - **Arien Malec** shared that the standards are not good because they don’t establish the status of reconciliation or provenance.
    - **David McCallie** noted that this is something that could be solved but again expressed concern that this is a systems issue.
• Identifying whether patients were on a particular drug: National Library of Medicine (NLM) RxNav application programming interfaces (API) does not return RxNorm codes for discontinued drugs, potential to create gaps in prior medication analysis.
• Medication reconciliation: Similar medication data entered by different sources are difficult to reconcile.
  o David McCallie questioned if he was identifying a standards gap.
  o Ken Kawamoto assumed that standards would be an aspect.
• Interpretation/calculation using medication sig components: A lot of sigs are in free text.
• Prescription drug monitoring program (PDMP): Access and cost.

Cynthia Fisher shared that patients and physicians need access to know the real price of their prescriptions including of the net negotiated price along with their personal share of the pricing, be it from deductible, the percentage of share, and out of pocket.
• David McCallie commented that there are efforts in the works to help resolve this. For costs, there are services that vendors have embedded, but they do not include standards. The CARIN Alliance has an active project where there is a push to use standards to go directly to consumers.

David McCallie shared two items he entered in the spreadsheet, but he noted that they may already be addressed.
• There is a functional need for prior authorization.
• Portable prescriptions, there isn’t any way to “forward” the eRx to an alternate pharmacy, should the patient desire to fulfill the prescription elsewhere (e.g. lower cost, out of supply, inconvenient access, etc.).
  o Clem McDonald noted that Rx transfer request response and confirm is in the NPRM.

Steven Lane concluded the recommendations discussion.

Lauren Richie opened the lines for public comment.

Public Comment
There was no public comment.

Comments in the public chat
Andy Truscott: My comment there was yes, you have many airline apps... but there is Saber or Apollo as industry standards.

Gay Dolin: I agree with the forward-thinking approach to app based dynamic care plans - FHIR PoC at the connectathon has already been accomplished several times as well as Use Case in the HIMSS Interoperability showcase. However, the C-CDA Care Plan, which represents a snapshot in time of care - just like CCD - could feed these apps and should not be completely precluded.

Carmen Smiley: https://www.healthit.gov/isa/electronic-prescribing

Gay Dolin: I believe Clem is not suggesting NO structure in a substance/Medication Administration, but rather the degree to which the details are standardized in the exchange message in FHIR or C-CDA
Gay Dolin: not that it should not be captured in structured way in the HER

Gay Dolin: That’s it!

Gay Dolin: Capture structure in the EHR -- DO NOT represent that to the n’th degree in exchange messages

Gay Dolin: standards can contain persistent identifiers - it depends on how they are implemented (and probably more guidance is needed

Carmen Smiley: Re ePA: the new SCRIPT standard supports this

Next Steps and Adjourn

Steven Lane asked the ISPTF members to continue to add their comments on medication and pharmacy data into the shared spreadsheet. He reminded the ISPTF that the group would meet again once the review of the NPRM is complete.

The meeting was adjourned at 11:35 a.m. ET