Interoperability MATTERS

an initiative of The Sequoia Project

Consumer Engagement Strategy Workgroup

Meeting Five

July 23, 2024

the sequoia project

CESWG Meeting Agenda – July 23, 2024

- Welcome – 2 minutes
- Workgroup charge – 5 minutes
- Meeting Five Recap – 10 minutes
- Presentation – Zoe Barber and Dave Pyke – 20 minutes
- Q&A – 10 minutes
- Open Discussion – Workgroup Direction – 30 minutes
- Meeting wrap up and next steps – 3 minutes

Welcome Consumer Engagement Workgroup Members!

- Henry Archibong, HealthMark Group
- Allison Aubuchon, WellConnector
- Jennifer Blumenthal, OneRecord
- Whitney Bowman-Zatzkin, RareDots
- Stephanie Broderick, Clinical Architecture
- Hans Buitendijk, Oracle
- Hugo Campos, Consultant
- Bart Carlson, Azuba Corporation
- Barbara Carr, Verisma
- Dan Chavez, Santa Cruz HIO
- Grace Cordovano, Enlightening Results
- Jeff Coughlin, American Medical Association
- Tammy Coutts, EHRA
- Dave Debronkart, HL-7 Patient Engagement
- Yssa DeWoody, Ring14
- Cathriona Dolphin-Dempsey, Stanford Health Care
- John Gaines, MatchRite
- Eddie Gonzalez-Loumiet, Ruvos
- Mike Graglia, Cure SynGAP1
- Thomas Grannan, Azuba Corporation
- Joe Hernandez, BluIP
- Jen Horonjeff, Savvy Cooperative
- Nabbil Khan, Lifeline Biosciences
- Shannah Koss, Koss on Care LLC
- Allison Kozee, MRO Corporation
- Jason Kulatunga, FastenHealth
- Amy Laine, Sandwych
- Virginia Lorenzi, The New York Presbyterian
- Tushar Malhotra, eClinical Works
- Desla Mancilla, BCBSA
- Shamekka Marty, Patient/Caregiver Advocate
- Josh Mast, Oracle
- Elizabeth McElhiney, Verisma
- Chrissa McFarlane, Patientory
- Lana Moriarty, ONC Tiffany O'Donnell, MRO Corporation
- Adaeze Okonkwo, Government of DC
- Melis Ozturk, IBM
- Eric Pan, Stanford
- Josh Parker, AthenaHealth
- AJ Peterson, Netsmart
- Sam Segall, Datavant
- Paul Seville, Deloitte
- Alexis Shaner, Hawai'i Pacific Health
- Stacey Tinianov, Patient Advocate/ Consultant
- Jaffer Traish, FindHelp
- Janice Tufte, Hassanah Consulting
- Brian Van Wyk, Epic
- Diana Warner, MRO Corporation
- Duncan Weatherston, Smile Digital Health
- Carol Zinder, inTandem Health

Sustainability & You:
A Call to Action for Workgroup Participants

The Sequoia Project is a 501c(3) non-profit working to improve interoperability for the public good. The Interoperability Matters Program -- including this workgroup – is made possible in part by member dues.

Please help us sustain the impact of our collective work by **identifying potential funding sources** that believe, like you do, in the power of cross-industry convenings to solve shared problems.

Perhaps your organization has a corporate foundation, or you are aware of relevant grantors or associations that may want to get behind this work.

Drop us an email at InteropMatters@sequoiaproject.org

Workgroup Charge

Consumer Engagement Strategy Workgroup

Workgroup Vision

Make health data work better for consumers!

Workgroup Goal

Work collaboratively to develop tools, propose solutions and recommend actions needed to ensure consumers can access, use and share their electronic health data in ways that will decrease patient workload and burden.

Personal Health Data – *What Patients Need*

Personal Access

All of my health information is readily accessible to me and my caregivers in one place when I need it

My patient portal makes it easy to find my visit reports, lab results, prescriptions and physician notes

I can access all of my health information from all of my physicians through a personal health hub of my choosing

It's easy for me to be able to do what I need with my data to manage my health and care.

Care Team Access

All of my data is readily accessible to all of my care team through their EHR, regardless of their practice affiliation

All of my physicians have access to all of the data about me that I choose to make available through their office electronic health record

It's easy for me to share all of my data with the providers, apps and researchers I choose

I am able to choose to not share specific types of health data with certain providers

Usefulness

I can understand my data and health information makes sense to me

My information is easy to read without straining my eyes

It is easy for me to see which of my lab values are out of range or if a specific test is negative or positive

My information is provided to me in language that is understandable to somebody without a medical degree

My information is accurate and its easy for me to correct inaccuracies

Awareness and Education

I understand my rights to data access, how and by whom my data is used and can advocate for myself and others

My provider makes it easy for me to understand my rights to data use and takes measures to ensure that I am able to exercise those rights.

My data access rights are clearly articulated in my patient portal and provider's office, so that I can see and understand them within the context in which that knowledge is relevant

My provider and patient portal makes clear what data is and is not shared with other providers in that health system or other health systems

Consumer Engagement Strategy Workgroup – Our Evolving Roadmap

1

Forming

- **Purpose** – what are we hoping to change?
- **Composition** – Who is participating?

2

Norming

Process – what should workgroup members expect?

Requirements – what are workgroup members asked to do?

3

Storming

Activity – what are we doing to achieve our purpose?

Deliverables – what are we going to produce?

We are here!

March

Meeting One

Workgroup Kickoff – Setting context

- How does health data dysfunction impact patients' lives?
- What are the key needs that need to be addressed to make data work for patients?

April

Meeting Two

TEFCA and IAS

- What does federal health IT policy dictate about personal access to health data?
- What are the barriers faced by a PHR company?

May

Meeting Three

ONC Director Micky Tripathi – Barriers and Solutions to Personal Access through TEFCA

- What are the specific policy and technical barriers?
- What are the solutions?

June

Meeting Four

Understanding IAS Options and Barriers – Insights from the PHR Frontlines

- Real world insights from a PHR founder
- What are the technical barriers and viable pathways to individual access?

July

Meeting Five

Policy Updates for IAS under TEFCA

- *TEFCA July 1 SOP update*
- Group discussion – what's next?

August

Meeting Six

Exploring Action

- Policy updates
- Options for simple, scalable solutions
- What are the gaps in IAS policy and/or practice that the CESWG can address?

September

Meeting Seven

Workgroup deliverables

- How can the CESWG advance IAS at scale?

Welcome our new Co-Chairs!!

Cathriona Dolphin Dempsey

Stanford Health Care

- Worked at Stanford Health Care for over 16 years.
- She spent the first five years as a nurse coordinator in the breast oncology clinic,
- Since 2013 she has worked on Health Information Technology Regulations, Quality Reporting, Interoperability, and other strategic organizational projects.
- She started at SHC as an IT analyst, progressed to project/program manager and now serves as the Manager of regulatory informatics.
- Led SHC's rapid onboarding to the Epic Research COSMOS database to support institutional research efforts and reducing provider burden efforts regarding patient messages.
- Registered nurse for more than 30 years and holds a master's degree in health informatics. She is PMI certified in project management and is a Six Sigma Lean Black Belt and Champion.
- In her current role at Stanford Health Care, Cathriona focuses on: Regulatory reporting and quality measure optimization, practices regarding Information Blocking/Sharing, FHIR exchange optimization and the implications of new regulations regarding artificial intelligence in healthcare.

Brian Van Wyk

Epic

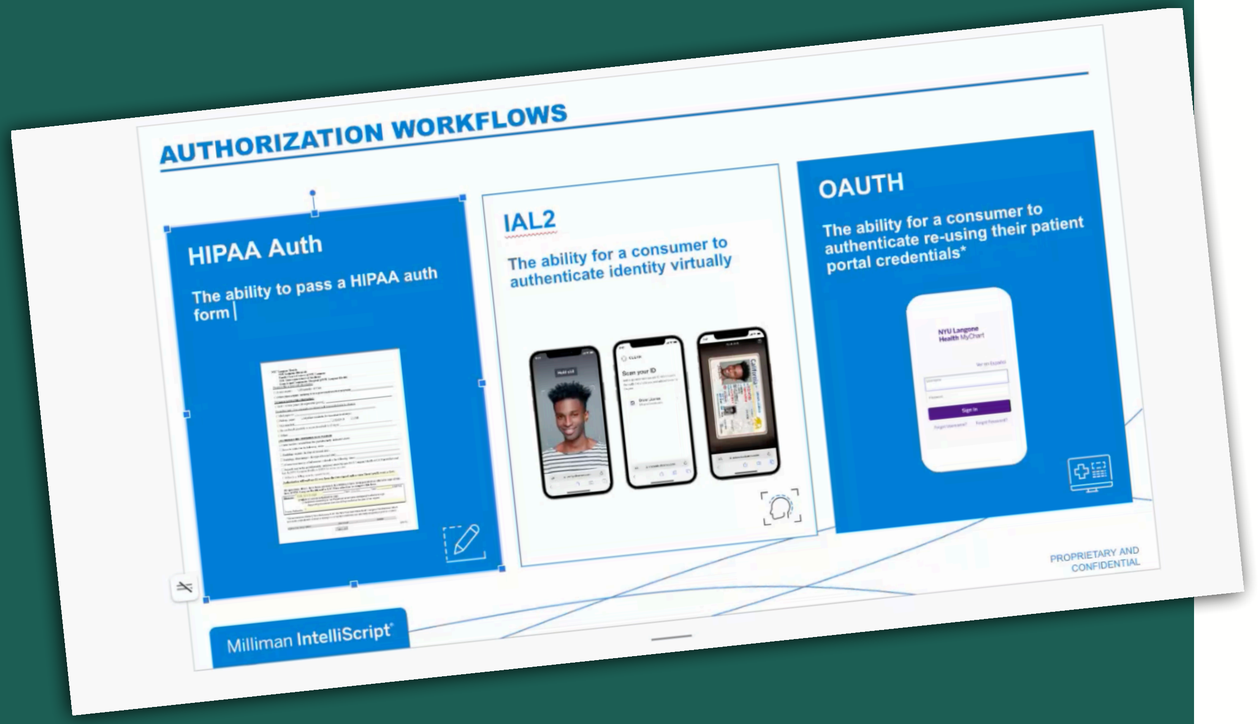
- Pronounced: Van (like the vehicle) Wyk (rhymes with bike, or Dick Van Dyke but not spelled that way)
- Title: Patient Experience
- Experience: 18 years with Epic
- Notable projects: 6 years on the Emergency Department application, displaying medication changes on the after visit summary, provider interoperability, patient engagement during an Inpatient admission, managing provider happiness and patient expectations as it relates to portal messaging

Meeting Four Recap

Overview of Jennifer Blumenthal's Presentation – Patient Access: Intent vs Implementation

1. *Authorization workflows*
2. *Authoritarian workflows under 21st Century Cures Act*
3. *Drawbacks*
4. *Improvement path*

Personal data access workflows



HIPAA authorization

- “Traditional” route for accessing data
- Patient requests data through provider
- “Manual” process
- Can be provided digitally – data dump

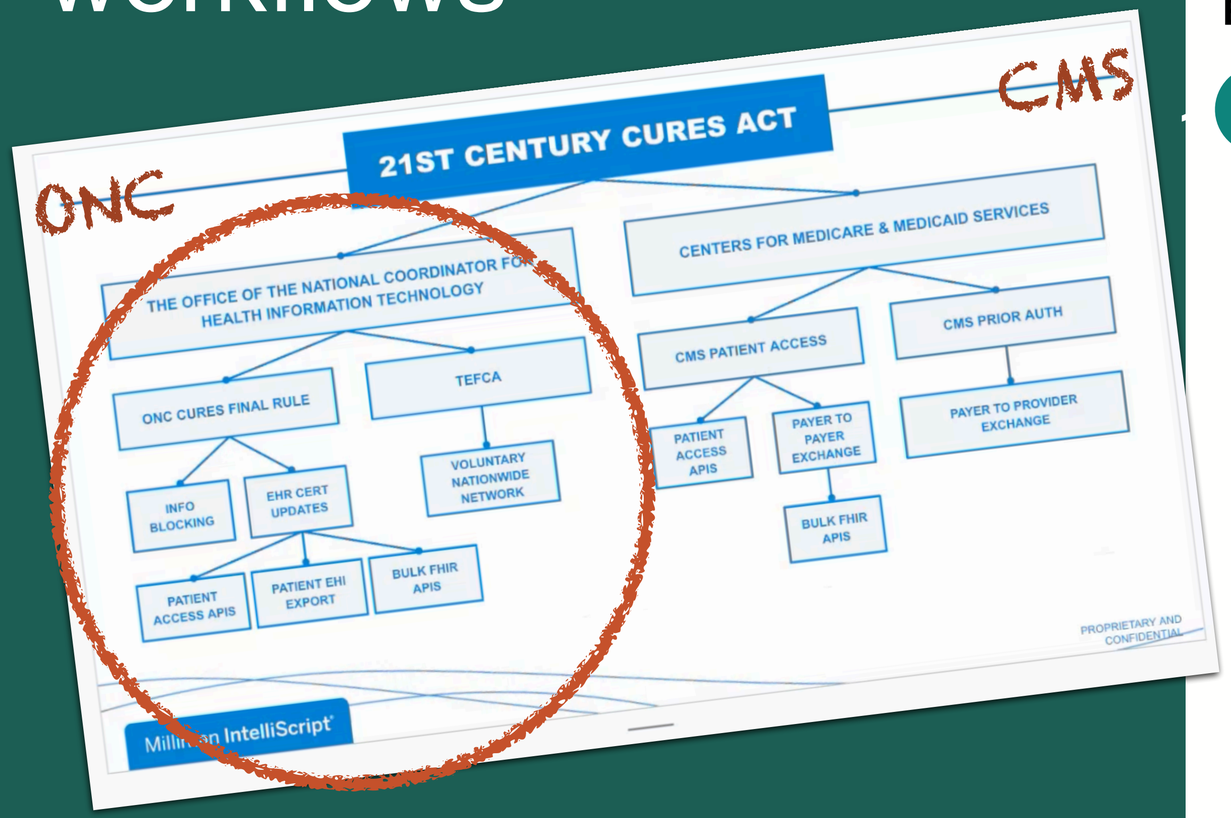
IAL2

- Standard for authenticating identity
- Developed by NIST – requires proof of identity
- Different “vendors” provide IAL2 technology
- Can be integrated into tech interface

OAUTH

- Enables consumers to establish identity with a technology platform/ provider through creating an account using accounts from other tech platforms that have established identity credentials

Personal data access workflows



Cures Act Final Rule

- Certification Standards for data access

TEFCA

- Network of networks (QHINs)
- Data exchange under trusted agreement and specifications

Cures Act Final Rule – Two components

1. Information blocking
2. EHR Certification updates

EHR Certification Updates – methods for patient data access

1 Patient EHI exports

What is it?

- Digital data dump

Issues

- Data elements vary
- Data difficult to use

Ways to improve?

- Enable API access/FIHR
- Require standard data sets

2 Direct API access/USCDI/ FIHR

What is it?

- Direct access to data
- Defined elements
- “Easy” build for developers

Issues

- “Easy” to build in friction
- Slow USCDI roll out –on V1

Ways to improve?

- Require easy portal credentials
- Incentivize FIHR adoption
- Expand USCDI faster

TEFCA

- Data exchanged through QHINs
- QHIN fees can be cost prohibitive for small developers
- Patient matching standards determined by each provider – concerns about HIPAA violation halted data flow to patients

Individual Access Services (IAS) in TEFCA

Zoe Barber, Policy Director, Sequoia Project

Dave Pyke, Technical Expert, Sequoia Project TEFCA Team

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TEFCA Timeline

Common Agreement Versions At-a-Glance

ONC TEFCA RECOGNIZED COORDINATING ENTITY

January 2022

Common Agreement V 1

The Common Agreement version 1 was the initial version of the Common Agreement and reflected policies developed with extensive public input.

Related QTF Version: 1
Related FHIR Roadmap Version: 1

December 2023

Common Agreement V 1.1

The Common Agreement version 1.1 included changes required by HHS prior to TEFCA exchange going live. *This is the version in operation as of the official launch of TEFCA exchange.*

Related QTF Version: 1.1
Related FHIR Roadmap Version: 2

July 2024

Common Agreement V 2.0

The Common Agreement version 2.0 includes enhancements and updates to require support of HL7 FHIR® based transactions.

Related QTF Version: 2 – DRAFT
Related FHIR Roadmap Version: 2

Transition from Version 1.1 to Version 2.0

ONC TEFCA RECOGNIZED COORDINATING ENTITY

- **TEFCA is currently live on Common Agreement Version 2.0 for QHINs**
- Applicable Flow-Down provisions are applied to Participants and Subparticipants
- There is a transition period to allow for adoption of the new Framework Agreements by those who are already live
  - 60 days for the Common Agreement
  - 180 days for the Terms of Participation
- During the transition, all TEFCA connected entities can engage in TEFCA Exchange for approved Exchange Purposes
- QHINs are responsible for adding new TEFCA connected entities to the RCE Directory as they sign the Terms of Participation

May 2024

- May 1: Common Agreement and Terms of Participation published in Federal Register

June/July 2024

- July 1: Common Agreement 2.0 is effective for QHINs (60 days after publication)
- RCE and newly designated QHINs sign version 2.0
- Final QTF version 2.0 published and expected to be in production
- Facilitated FHIR SOP expected to be published and in production
- New Participants and Subparticipants sign the Terms of Participation

Summer 2024

- Additional SOPs are released on a rolling basis

December 2024

- Dec 27: Terms of Participation compliance date for any Participant / Subparticipant that signed a flow down agreement prior to June 30th

https://www.federalregister.gov/documents/2024/05/01/2024-09476/notice-of-publication-of-common-agreement-for-nationwide-health-information-interoperability-common).

Expected SOP Batch Release

ONC TEFCA RECOGNIZED COORDINATING ENTITY

Published July 1, 2024

- QHIN Technical Framework (QTF) Version 2.0
- Facilitated FHIR Implementation SOP
- Individual Access Services (IAS) Provider Requirements
- Governance Approach SOP
- Delegation of Authority SOP
- Expectations for Cooperation SOP
- Exchange Purposes SOP
- RCE Directory Service Requirements Policy SOP
- Security Incident Reporting SOP
- XP Implementation SOP: Treatment

Expected Summer/Fall 2024

- XP Implementation SOP: IAS Demographic Matched
- XP Implementation SOP: Public Health
- XP Implementation SOP: Health Care Operations
- QHIN Security for the Protection of TEFCA Information (TI)
- Participant/Subparticipant Additional Security Requirements SOP
- QHIN Onboarding & Designation/Application SOP
- QHIN Application SOP
- Updated Governance SOP

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IAS Exchange Purpose

Exchange Purposes: IAS

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TABLE 2. REQUIRED RESPONSE AND PERMITTED FEES

Authorized XP	XP Code	Required Response (Yes/No)	Permitted Fees (Yes/ No)
Treatment	T-TREAT	No	No
TEFCA Required Treatment	T-TRTMNT	Yes	No
Payment	T-PYMNT	No	Yes
Health Care Operations	T-HCO	No	Yes
Public Health	T-PH	No	Yes
Electronic Case Reporting	T-PH-ECR	No	Yes
Electronic Lab Reporting	T-PH-ELR	No	Yes
Individual Access Services	T-IAS	Yes	No
Government Benefits Determination	T-GOVDTRM	No	Yes

- **Individual Access Services (IAS):** the services provided to an Individual by a QHIN, Participant, or Subparticipant that has a direct contractual relationship with such Individual in which the QHIN, Participant, or Subparticipant, as applicable, agrees to satisfy that Individual's ability to use TEFCA Exchange to access, inspect, obtain, or transmit a copy of that Individual's Required Information.
- **Individual Access Services Provider (IAS Provider):** each QHIN, Participant, and Subparticipant that offers Individual Access Services (IAS).
- **Individual:** has the meaning assigned to such term at 45 CFR § 171.202(a)(2).

Required Information

ONC TEFCA RECOGNIZED COORDINATING ENTITY

- For Individual Access Services, beginning December 31, 2024, Required Information is, at least, the USCDI v1 data classes and data elements that the Responding Node maintains. If the Responding Node is controlled by a Health Plan, the Responding Node MUST also share individual claims and encounter data (without provider remittances and enrollee cost-sharing information) that it maintains. Additional details on implementation specifications for Required Information are provided in the QTF and applicable XP Implementation SOP(s). For the avoidance of doubt, prior to January 1, 2026, the QTF does not require USCDI data to conform to USCDI vocabulary standards.

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Common Agreement Section 10

Section 10 Individual Access Services

Section 6 of Terms of Participation

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- **Individual Access Services Offerings:** Any QHIN, Participant, or Subparticipant may elect to be an IAS Provider
- **Individual Consent:** Individuals using IAS through an IAS Provider must complete an IAS Consent. The IAS Consent shall include, at a minimum: (i) consent to use the Individual Access Service; (ii) the Individual's acknowledgement and agreement to the IAS Provider's Privacy and Security Notice; and (iii) a description of the Individual's rights to access, delete, and export such Individual's Individually Identifiable Information.
- **IAS Provider's Privacy and Security Notice**: IAS Providers must obtain express, documented consent to a Privacy and Security Notice, as detailed in the IAS Provider Requirements SOP.
- **Additional Security Requirements for IAS Providers:** IAS Providers must meet security requirements for all Individually Identifiable Information it maintains.
- **IAS Incident:** If an IAS Provider reasonably believes that an Individual has been affected by an IAS Incident, it must provide such Individual with notification without unreasonable delay and in no case later than sixty (60) days following Discovery of the IAS Incident.
- **Survival for IAS Providers:** the IAS Provider's obligations in the IAS Consent, including the IAS Provider's requirement to comply with the Privacy and Security Notice and provide Individuals with rights, shall survive for so long as the IAS Provider maintains such Individual's Individually Identifiable Information.

Related SOPs

IAS Provider Requirements
XP Implementation SOP: IAS: Demographic Matched

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Standard Operating Procedures (SOPs)

SOP: Individual Access Services (IAS) Provider Requirements

Standard Operating Procedure (SOP): Individual Access Service (IAS) Provider Requirements

Version 2.0

July 1, 2024

Applicability: QHINs, Participants, and Subparticipants that offer Individual Access Services

Purpose: IAS Providers are required to obtain the Individual's express documented consent in connection with IAS via a written Privacy and Security Notice.

SOP Sections:

1. Common Agreement References
2. SOP Definitions
3. Purpose
4. Procedure
   - 4.1 Written Privacy and Security Notice and Individual Consent
   - 4.2 Consent to Sale
   - 4.3 Content of Notice to Individual of TEFCA Security Incident or Breach of Unencrypted Information (IAS Incident)

SOP: Individual Access Services (IAS) Provider Requirements

ONC TEFCA RECOGNIZED COORDINATING ENTITY

Definition:

- **Material Change(s) to the Notice:**
  - *"a change to the Privacy and Security Notice that results in the Use and Disclosure of Individually Identifiable Information by the IAS Provider in a different manner than when the Individually Identifiable Information was collected or otherwise obtained…"*

IAS Privacy and Security Notice

- An IAS Provider must obtain the Individual's express documented consent in connection with IAS, including acknowledgment of and agreement to the IAS Provider's written Privacy and Security Notice ("Notice") that describes the privacy and security practices used to safeguard Individually Identifiable Information

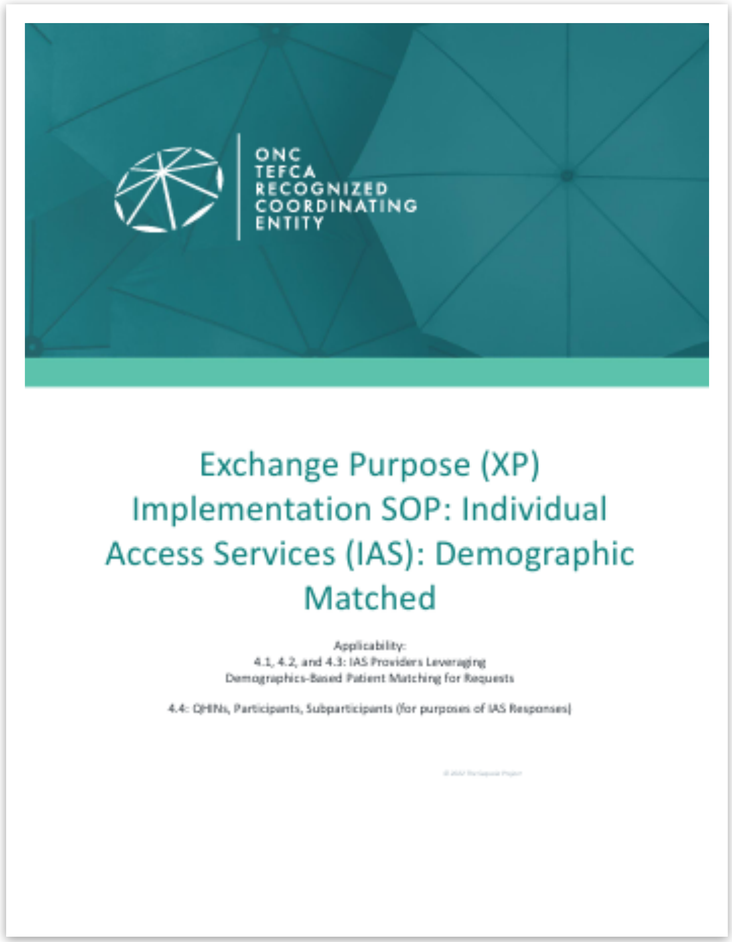
Consent to Sale

- If an IAS Provider intends to 1) sell, 2) receive remuneration in exchange for Individually Identifiable Information, or 3) use Individually Identifiable Information for targeted advertising or other marketing purposes, the IAS Provider must obtain the Individual's prior, express, and documented consent
- Consent to Sale may be obtained with the consent to the Notice but must be labeled as such and separate from the consent to the Notice

Content of Notice to Individual of TEFCA Security Incident or Breach of Unencrypted Information

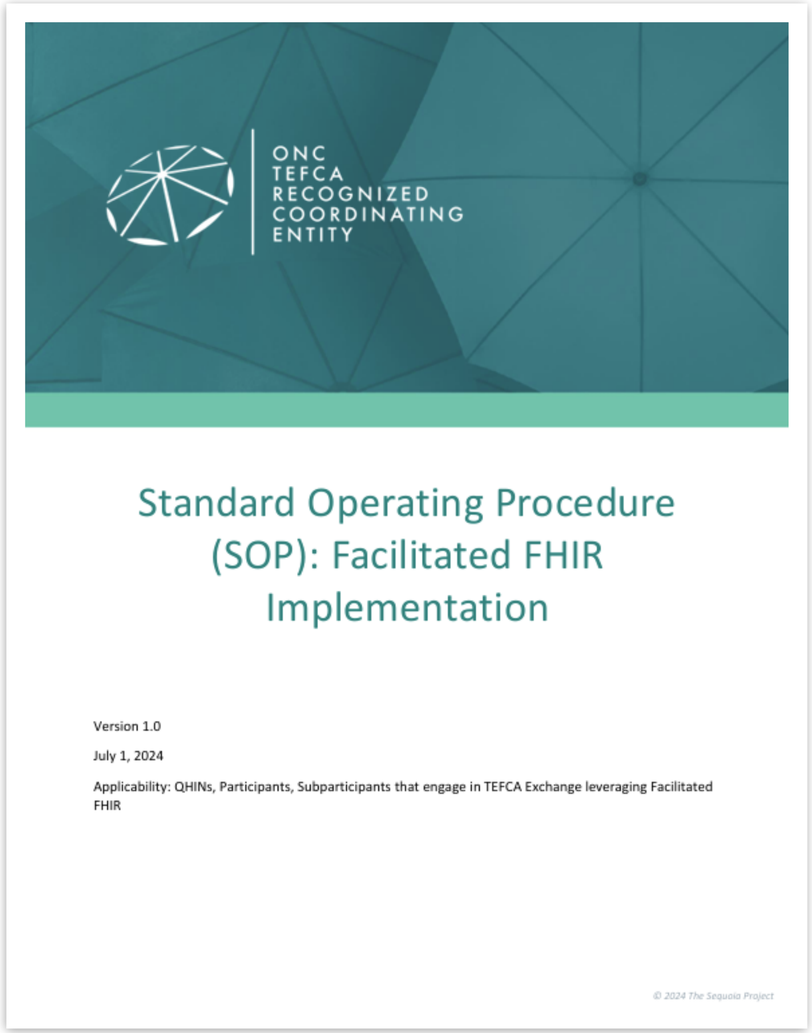
- Brief description of what happened
- Description of the type of Individually Identifiable Information involved
- Steps Individuals should take to protect themselves
- Brief description of what the IAS Provider is doing to investigate, mitigate and protect against further incidents
- Contact procedures

DRAFT IAS XP Implementation SOP: Demographics Matched



1. Common Agreement References
2. SOP Definitions
3. Purpose
4. Procedure
5. Appendix A— Patient Request Identity Verification Policy

Facilitated FHIR Implementation SOP Version 1.0



1. Common Agreement References
2. SOP Definitions
3. Purpose
4. Facilitated FHIR Query Scenario
5. Use Case Steps
6. Procedure

IAS Query Requirements

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- IAS Queries must use the IAS XP Code T-IAS
- IAS Providers MUST work with a Kantara-approved Credential Service Provider
- IAS Providers MUST verify identities of Individuals to Individual Assurance Level 2 (IAL2)
- IAS Providers MUST authenticate Individuals to at least Authenticator Assurance Levels 2 (AAL2)
- IAS Providers MUST demonstrate that Individuals have proven their identities by including an IAL2 Claims Token in all transactions

IAS Using Demographics Matched

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- IAS using demographics matched can be done using either FHIR or IHE protocols
- Verification of an Individual using demographics must include (where available) the following demographics:
  - The first name, last name, DOB, address, city, state, zip
- Verification should also include sex, middle name, suffix, email, phone number, SSN, ZIP+4, and other verifiable identifiers
- Historical name and/or address may be included if validated by the CSP
- Changes to address, etc. must be validated with the CSP, and a new token issued, prior to any further queries.
- IAS Query Response is required when a Query includes the appropriate IAL2 Claims Token, and achieves an acceptable demographics-based match based on responder policy MUST Respond

IAS Using FHIR Credentials

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- Until January 1, 2026 QHINs, Participants, and Subparticipants can determine their own exchange partners and Exchange Purposes for FHIR-based exchange
- FHIR-based exchange allows for IAS Queries using either demographics or credentials to verify identity
- The IAL2 token must accompany the authentication and authorization request for FHIR access, even if credentials are also provided
- If the authentication and authorization request does not return the FHIR Patient id for that patient, a demographic match (using the FHIR $match operation) may be performed and must use the same demographics verified by the CSP.
- Use of credentials in the request (user and password) is an automatic required response

Questions?

Open Discussion – Direction for CESWG

Interoperability MATTERS
an initiative of The Sequoia Project

the sequoia project

Thank You!!

Contact Us

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For additional information visit our website.