Comments on:	Trusted Exchange Framework and Common Agreement (TEFCA) Qualified Health Information Network (QHIN) Technical Framework (QTF), Draft 2
Source:	US Office of National Coordinator for Health Information Technology (ONC) Sequoia Project as the ONC Recognized Coordinating Entity (RCE)
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Thank you for the opportunity to comment on this draft. We would also like to commend comments submitted by the Health Record Banking Alliance (HRBA) in response to this call for comments. HRBA's proposal offers an example of an efficient health information and exchange architecture based on Health Record Banks – one that puts the patient at the center, and in control, of health data/record flows pertaining to them.

Key Provisions from the January 2018 ONC Draft Trusted Exchange Framework (Introduction, pp. 3, 7):

"The 21st Century Cures Act's (Cures Act) focus on trusted exchange is an important next step toward advancing the establishment of an interoperable health system that:
- "Empowers **individuals** to use their Electronic Health Information to the fullest extent;
- "Enables providers and communities to deliver smarter, safer, and more efficient [**individual**] care; and
- "Promotes innovation at all levels." ...

"The vision we seek to achieve is a system where **individuals** are at the center of their care and where providers have the ability to securely access and use health information from different sources. A system where an **individual's** health information is not limited to what is stored in electronic health records (EHRs), but includes information from many different sources (including technologies that **individuals** use every day) and provides a longitudinal picture of their health." ...

[It then lists four important outcomes...]
A. "Providers can access health information about their **patients**, regardless of where the patient received care;
B. "**Patients** can access their health information electronically without any special effort;
C. "Providers and payer organizations accountable for managing benefits and the health of populations can receive necessary and appropriate information on a group of **individuals** without having to access one record at a time (Population Level Data), which would allow them to analyze population health trends, outcomes, and costs; identify at-risk populations [**cohorts of individuals**]; and track progress on quality improvement initiatives; and
D. "The health IT community has open and accessible application programming interfaces (APIs) to encourage entrepreneurial, user-focused innovation to make health information more accessible and to improve electronic health record (EHR) usability."
[Emphasis added.]

Comments on the Concept of TEFCA, QHINs and the QTF

1. Individual at the Center

As referenced above, it is notable that key provisions of TEFCA are *explicitly stated in individual-centric terms,* emphasizing that *"the vision we seek to achieve is a system where individuals are at the center of their care".* So the basic question: Do ONC and the TEFCA Recognized Coordinating Entity (RCE – The Sequoia Project)

believe that a complicated morass of networks and institution to institution interconnects offers a competent and responsive solution?

Either the individual is foremost and anchored at the center – and the supporting information infrastructure is thus designed – or not. In our evaluation of TEFCA and QTF Draft 2 we can't find a center, much less ascertain a locus for the individual. As far as we can determine, TEFCA and QTF Draft 2 anteicipat that fragments of individual health data/records are forever scattered in diverse forms and disparate datastores across the planet.

2. Trusted Exchange Bonds the Care Provider with the Cared For

TEFCA and QTF Draft 2 perpetuate a misperception common to nearly all strategies in this field. They presume that multiple (indeed myriad) inter-institutional exchanges will somehow lead to coherent ("integrated") individual patient care that is safe, effective, and efficient across all providers and health plans.

We are concerned that this constitutes a serious misadventure – *trying to solve an intrinsically individual-centric problem using an institution-centric approach*. The result in every case has been (and will continue to be) systems that can babble snippets to each other, but cannot effectively communicate. Communication relies on recurrent creation and conveyance of "data dumpsters" which are made available to patients/providers and left for each of them to ingest – assuming at each iteration the "dumpster" contains a complete rendition and that the recipient has time to rummage and the ability to create new understanding(s) on their own.

The "trusted exchanges" we need are not among institutions, but among the cared for and each of their care providers. With patient consent, such exchange enables providers to communicate both with their patient and with each other about their common patient. This is what patients and providers want and need.

There is nothing in the Cures Act that says the goal is to have hospitals integrated with doctors' offices and laboratories *per se*, yet the TEFCA and QTF Draft 2 formulas for how to achieve the individual-centric health care objectives are expressed in institution-centric terms. Meanwhile, the individual (and his/her health data/record) remains scattered – as dissonant and disconnected fragments – across these structures.

We believe this to be a profoundly flawed conception of the problem and its solution. Instead of working to solve fragmentation TEFCA and QTF Draft 2 demand its entrenchment – promoting schemes that have been proven repeatedly not to work at small or large scale – and distracting from consideration of solutions that are far simpler and more tractable. The answer to tackling unbounded complexity is not to champion or rationalize more of the same. The workings of institutions must no longer be advanced to act as proxies for the health and healthcare experiences of an individual.

3. Health Information Exchange Strategy – Coherence or Confusion?

The TEFCA and QTF Health Information Exchange (HIE) model requires that every system/device talk to every other system/device and from those exchanges expects that coherent individual information and care will somehow emerge. This cannot work in theory or in practice and the reason is simple. Interoperability (in this case dumping data from one system to another) is merely a technical capability. It IS NOT a model for how individual care is (or can be) managed nor for how the collective "system" is to (can) work to inform, guide, and monitor the overall health and care of each person. Clearly it is better if systems interact in common ways where appropriate, but standards for "data exchange" along with complex technical and governance frameworks are both misdirected and abidingly insufficient to the task.

Requiring systems to "talk to each other" does not help understand who needs to talk to whom and when, about what they need to talk, and what they mean when they exchange data. It may allow for many snippets of dialogue to be exchanged and even mass data dumps, but it cannot create a single, coherent, shared conversation that ensures each individual's overall health and care is safe, effective, and efficient or that system interactions and data flows are timely and competent (relevant, concise, actionable). Assumptions that this

capability will magically appear if only everything is connected to everything else are *prima facie* false and have been proven repeatedly to not work in practice.

We believe the problem needs serious reorientation through further deliberations about the form, facility and function of TEFCA.

4.1 With not About

The whole aim of the 21st Century Cures Act (and thus by extension TEFCA, QHINs and the QTF) is to ensure individuals get coherent, "joined-up" care. That can only be achieved if the individual is the conceptual design center of our information infrastructure. As we read QTF Draft 2 the individual patient is incidental, almost immaterial and seemingly a waning afterthought of TEFCA and QTF design.

Care is provided to individuals and hence health information and related conversations must align with that care. There must be a unique, shared place that brings together all dialogue and vital information involving the individual (patient) such that *providers can then talk with the patient rather than about the patient*. If that shared place exists, the providers can also use it to talk about the patient, but the patient will be able to access and join that conversation. This enables a common, shared conversation that can ensure each person's care is coherent across all those participating in their care – including the individual, their family and all care givers.

This requires a new class of infrastructure: an Individual Health Record (IHR) that is uniquely conceived to enable a common, fully-informed conversation about the overall health and care of the individual – across all providers and over extending time. The IHR is a persistent account of an individual's health and care, contributed to and used by all those participating in their care, *intrinsic to their duty of care*. It works with existing institutional systems such as hospital EHRs that will continue to manage detailed intra-institutional processes.

The IHR is not simply a repository of data, but an active platform that informs, guides, and monitors an individual's health and overall care. The IHR Model is based on the principle of sharing the "system of the individual" rather than merely data about the individual. Conceptually, an institution's systems talk to the "individual's system" rather than only to other institutions and thus – *providers talk with patients rather than about them.*

This reorientation of perspective and design obviates the need to even attempt the technical and organizational complexity envisioned by TEFCA and QTF. In addition, enforcing the TEFCA/QTF HIE model will *undermine efforts* to create the essential individual-centric infrastructure that is essential for the health care system we aspire to have – and stands to undercut (if not contravene) the Cures Act focus on the individual at the center.

Most fundamentally, *our solution needs to be designed around the individual and not around institutions*. It ensures individuals fully participate in the conversation about their health and healthcare. Design of the IHR Model asserts that coherent individual care is only possible when there is a "system" (center/locus) that is uniquely associated with each individual.

4.2 The Individual Health Record

An individual's IHR is held on their behalf and used under the purview of a health record Custodian (new role), with permissioned access. The Custodian serves to complement the idea of a patient-centered medical home – and the IHR "one-patient-one-record model" bypasses the intractable difficulties inherent in TEFCA's scatter model (further discussed in Comment 5 following).

In effect the individual's system is shared rather than snippets of data exchanged – institutional systems work with the IHR rather than being required to work with each other directly. *This changes an impossible-to-scale, infinitely-faceted, many-to-many connection/conversation/interaction model to a basic and readily implementable series of one-to-IHR connections.*

The IHR Model dramatically simplifies the arrangements. Indeed the IHR becomes the point of integration (yes, the single source of truth) within the whole health system for each individual.

.1 The IHR is a persistent account of what matters for an individual and is available for their care across providers and over extended time: the complexities of scattered records, brought together at some unspecified point in the future go away.

.2 The individual has a direct, complete way to access their own information and can fully participate in their own care.

.3 Through the IHR it is possible to continuously monitor the individual's health and care to help achieve the intended health outcomes, regardless of whether or not a particular institution or care-giver chooses to 'take a look'.

.4 The information agreement is between the individual and those providing care at the time of care, managed by a Custodian, and not between a complex of indeterminate and mostly likely unknowable set of institutions.

.5 Ensuring individuals have the enforceable right to be given information about the care they receive is essential, but this should be a standard part of clinical practice and the duty of care.

.6 As care progresses, institutions can enable their EHR/HIT systems, acting as directed by the individual's right to share their health information, to push new updates to the IHR as they become available (typically in real-time).

.7 It also aligns privacy and confidentiality with the wider responsibilities of clinical practice and duty of care.

.8 There is a clear model for managing cohorts of individuals (populations): with appropriate agreements and permissions, a Custodian can provide information on cohorts of individuals without requiring one-at-a-time access.

.9 Innovation and access to application programming interfaces (APIs) becomes a much simpler issue: simply interact with the IHR to participate.

All of these capabilities are exactly what the Cures Act set out to achieve. We believe this can only be realized by making individuals 'real' and central in our information infrastructure – thus advancing this approach as a fundamental objective.

5. The Scatter Model

TEFCA relies entirely on the "Scatter Model" AND the proposition that it is possible to assemble a patient's complete set of health data/records – in real-time – based on a broadcast or directed query mechanism. While it may be possible to broadcast a query for patient information in real-time, it is not feasible to expect that the query will reach – and get – an immediate response across all networks and from all EHR/HIT systems and devices where such information may reside.

For any number of reasons, delays could be measured in minutes, hours or even days. Further, there is a strong likelihood that it will be impossible to identify all possible locations where the data – and type of data – might be found (and ultimately retrieved) based on the query. From a practical standpoint, the requesting entity/clinician will always be in the position that they don't know what they don't know. They also don't know how long it might be reasonable to wait for query response(s).

See Comments 1-4. How much better foresight ONC (and its RCE) might have to focus on how to engage patients in IHR accounts where all their health data/records can be directed and shared, during or after each encounter? This allows subsequent queries to be directed to one place – an IHR – maintained by a trusted Custodian (such as a health record bank) and controlled by the patient (or their representative). We believe there are obvious and undeniable strengths to this approach versus what TEFCA/QTF contemplates – generally known as the "Scatter Model". See the following table and in particular the distinguishing advantages of the centered IHR Model:

	TEFCA Scatter Model	At the Center – Strengths of the Individual Health Record (IHR) Model
Basics	Patient data/records are managed across 10s and 100s of HINs and 100,000s of systems/devices, each of which maintains/manages: • Trusted software and storage • Accountability, authentication, authorization, consents, access control, audit mechanisms • Some fragment of the patient record	A designated and secure system which is: • Patient-controlled and provider neutral • Maintained by a trusted custodian organization Where the patient or their representative: • Maintain an electronic account and address • Maintain/designate a single place to send/store their records, e.g., during/after each encounter • Establish/maintain a single point of control, management and accountability for: authentication, authorization, consents, access control, audit mechanisms
Broadcast query	Query goes to 10s or 100s of HINs, then on to 100,000s of systems/devices	Query is directed to a single designated IHR Custodian and account for each individual (patient)
Query response	• Response may be nothing, trickle or deluge • Response content may vary with each subsequent query • Response may be minutes, hours or days later • You don't know what you don't know • You don't know whether your query has reached all relevant data sources • You don't know how long to wait	• Response is immediate • All relevant and permitted records are immediately available • You immediately know what you need to know
Confidentiality/ Authorization	Managed within a complex lattice of provider and HIN permissions plus patient consents	Managed at a single point by each patient, patient representative and/or IHR Custodian
Patient consent directives	Managed and kept current across 10s or 100s of HINs and likely dozens of providers (really?)	Managed at a single point by each patient, patient representative and/or IHR Custodian
Real-time + Continuous Monitoring	[Not Applicable]	Sustained (24 x 7) support for individual health and care monitoring and guidance – regardless of whether anyone chooses to take a look

6. Wither the TEFCA HIE Model?

See Comments 3 thru 5. The IHR Model is to share the platform and not merely exchange subsets of patient data. However, the pursuit of HIEs has for decades prevented the adoption of other models in the belief that all that is needed is more standards, more rigor and stronger enforcement. TEFCA and QTF Draft 2 slavishly follow that belief – yet it is demonstrably wrong.

The HIE model is all about data massing, myriad exchanges and data dumps – offering vanishingly little to facilitate the overall process of individual care and wellness. The benefits of the IHR in informing, guiding, and monitoring care can only be realized through direct interaction with the full IHR platform and with all of the source data building the IHR record.

While standards may be intended as a minimum specification, they all too often become a maximum level of achievement in the real world and thus result in an impoverished information environment. Paradoxically, the TEFCA/QTF HIE model serves to entrench and enshrine fragmented systems, data, and care. Patients remain scattered across the institutions with no place that is "theirs" within the overall health care system and

supporting information infrastructure. This ensures that most all potential improvements in care efficiency, efficacy and quality are impeded and may never be achieved. Giving every patient and physician a "data dumpster" of their information derived from a collage of systems, some well-behaved and others not so much, is largely shown to be benefit-free. It has been tried over and over and has produced no to meager benefit in every case. It is clearly the wrong approach and cannot be morphed or finagled into the right one despite best intentions. This is why all most generations of HIEs have failed as soon as stakeholders were asked to pay for them... because the fundamentals are wrong and are unyielding to remedy.

7.1 Coming of Age: The IHR as the Individual's System

See Comments 1-6. It is crucial that the IHR platform is correctly positioned as the individual's system – there to support the overall care of that individual across providers and over extended time. It must not be seen (or positioned) as a "health plan" system, a "provider" system, an "interoperability" system or any other such technical/institutional permutation. That is the IHR's greatest advantage – using a three-legged stool as an analogy – the IHR is the individual/patient "third leg" of the health information "stool", complementing the provider and payment legs. Without the IHR, the stool will forever be leaning over on two legs, awkward and unwieldy, no matter how "fat" the provider and payment legs get or how much bracing there is between the two of them. Unfortunately, that is the approach taken by TEFCA and QTF Draft 2.

It is also essential that the IHR is not seen as merely another participating system. It is a different class of platform – an entirely new element of infrastructure. It offers the locus of control and management for an individual's overall health and healthcare. Because this is the only truly feasible and comprehensive approach, it is not surprising that the IHR obviates the need for much of what HIEs have aspired and failed to do.

The role of Custodian is key to making clear that the IHR is the individual's system. Specifically in relation to TEFCA/QTF, the IHR should be positioned as the platform with which an individual's smartphone (or PC or tablet or smart watch) will interact. It allows individuals to participate together with their providers in a single coherent conversation about their health and care. It gives an individual the means to engage and contribute to that conversation – not merely as an impassive listener. This approach not only solves the data fragmentation issue the Cures Act is attempting to address, but also facilitates patient engagement. Neither TEFCA nor QTF Draft 2 address such needs.

7.2 The Problem Oriented Health Record (POHR)

The IHR concept leads to an obvious question. How are the contents of such a record to be organized? If an IHR is a mere compilation of existing records of different organizational schemes from multiple providers, it would be just as hard to navigate and use as those existing records — which are notorious for poor clinical functionality and usability.

The Health Record Banking Alliance (HRBA) has concluded that this fundamental issue can be addressed by use of an existing standard for organizing medical records (paper and electronic) known as the problem-oriented medical record (POMR). We refer to this standard as the problem-oriented health record (POHR), consistent with current industry usage of the term EHR rather than EMR.

By way of background, the concept of problem-oriented records was introduced in the 1960s. Two core components — problem lists and "SOAP notes" — have been widely adopted, and are thus familiar to current EHR users and health IT specialists.

In the 1990s when paper records still prevailed, a committee of the National Academy of Medicine (NAM, formerly the Institute of Medicine or IOM) considered the POHR for use with computerized patient records. The committee concluded:

> The committee unanimously believes that patient records should guide and reflect clinical problem solving and that the mere translation of current record formats, data, and habits from paper to

> computer-based systems will not alone produce the range of improvements in care potentially achievable in a truly reformed patient record system. … The committee did not reach unanimity regarding the choice of a single preferred record format … the committee did consider certain components of the POMR to be highly desirable in any computer-based record system. … Those who favored the POMR format argued that it is a general model that rests on a firm theoretical foundation …

The Computer-Based Patient Record: An Essential Technology for Health Care (National Academy Press, 1991, rev. 1997), pp. 90-91.

Since the NAM Committee's analysis, no clear alternative to the POHR has emerged. In light of this history and HRBA's consideration of the POHR standard and its utility, we believe that the POHR should become a standard for organizing the contents of both EHRs and IHRs.

The difficulty, however, is that the POHR standard as a whole has never been well-understood or generally accepted, notwithstanding the widespread use of two of its core components (problem lists and SOAP notes). Moreover, subsequent development of the POHR standard for EHRs was never widely disseminated or discussed. This subsequent development included (i) advanced clinical decision support (CDS) tools intended to be used in conjunction with an electronic POHR, (ii) standards of care for clinicians and patients to jointly use these EHR and CDS tools with scientific rigor in medical practice, and (iii) new institutional arrangements for harvesting knowledge from medical practice and training/licensing clinicians. The original standard for problem-oriented paper records thus evolved to become a larger set of reforms for a true, integrated system of health and health care, as set forth in six books published from 1969 to 2021.

We are not advocating that ONC take regulatory action at this time to apply POHR standards to EHRs in general or IHRs in particular. Doing so would be premature. Instead HRBA believes that the entity best positioned to act is Health Level Seven International (HL7), which is the world's leading standards-setting organization for electronic health information. Indeed, HL7 has recently established a POHR Project, sponsored by the HL7 EHR Work Group and co-sponsored by the Patient Empowerment WG.

The HL7 POHR project's initial priority is developing standards of problem list management for provider EHRs in the existing "scatter model." Over time, the Project is expected to develop broader POHR standards for provider EHRs, and we stand among those who advocate similar standards for IHRs.

Additional Comments on Standing Up the CA and QTF

8. Common Agreement Update?

From recent presentations by ONC and The Sequoia Project leadership, we understand there is a new Draft of the Common Agreement (the CA in TEFCA), internally revised and circulated but not yet made public. Without availability of the latest CA Draft we wonder how this QTF Draft 2 might be positioned to fulfill CA provisions for QHIN internal governance, operations and external oversight. This includes the method and manner of qualification of QHINs and how such qualification may be borne, facilitated and monitored via the mechanism(s), stipulations and contingencies of QTF Draft 2.

We believe that with the latest CA Draft in hand, it would be possible to offer a much better evaluation of QTF Draft 2.

9.1 Trust is Paramount

Given TEFCA (Trusted Exchange Framework...) and its many facets, trust stands as the overarching principle/ objective. Without trust all is for naught. Trust equates to assurance and certainty and thus is fundamental to confidence and reliance for health data/record exchange. Thus:

- Trust is foundational
- Trust relies on more than assertion(s) or complacent participation in another's scheme
- Trust must be evidenced, not merely assumed
- Trust has a core constituency
  - Patients/subjects of health data/record content
  - Authors, verifiers/attestors of source health data/record content (including clinicians)
  - End users of health data/record content (including clinicians)

9.2 Chain of Trust

For health data/record exchange:

- Our chain of trust starts at the point of health data/record origination (data collection, authorship)
- Our chain of trust progresses, continuously and without interruption, to each point of health data/record use (consumption)
- Our chain of trust is supported by evidence of proper identification, capture, verification, retention, management, protection, exchange, access/use of health data/records

10. Trust Expectations

With regard to Comments 9.1 and 9.2 above, we took the opportunity to review particularly relevant clauses in ISO TC215 (Health Informatics) Standard, *ISO 21089:2018 Health Informatics – Trusted End-to-End Information Flows*. Derivative diagrams are included for reference in Appendices B-D.

Referenced are core constituents and their trust expectations with regard to how health data/records are managed (captured, retained, protected, exchanged and used) over their lifespan and at key lifecycle events, including exchange. Specifically with regard to core constituent perspectives:

- Subject (including patient) whose perspective is downstream (source → use): to whence do my health data/records flow and how do I trust that process?
- Author (including clinician) whose perspective is also downstream (source → use): to whence does my authored health data/record content flow and how do I trust that process?
- End user (including clinician) whose perspective is upstream (source ← use): from whence does my accessed health data/record content come and how do I trust that process?

11. Where the QHIN Fits and QTF Applies

As specified in ISO 21089 and broadly consistent with industry practice, health records are comprised of discrete entries. An entry typically documents/evidences an *action taken* to support individual health and/or provide healthcare. Actions include admissions, discharges, transfers, assessments, progress notes, care plans, orders, results, medication administrations, discharge plans and summaries, consults, care activities... Most all exchange artifacts (e.g., HL7 v2 messages, CDA/CCDA documents, FHIR resources) managed, processed and shared by QHINs *correlate to health data/records resulting from actions taken*.

Health record entry content has a lifespan within a system and across systems (via exchange). Thus, entry lifespans simultaneously support *two interlocking chains of trust*:

A. Retention chain: source → archive/deletion, i.e., starts at the source point of origination/retention and ends at the point of archive (to offline storage) or deletion; and
B. Consumption chain: source → use, i.e., starts at the source point of origination/retention and ends at each ultimate point of access/use (where health data/record content is consumed).

Each chain of trust starts at the point of origination/retention, is instantiated in the source system and then may extend across system boundaries via exchange. Successive lifecycle events occur within the health record entry lifespan, and may include points of: amendment (update), verification (and/or attestation), transformation/translation (e.g., to/from exchange artifacts (HL7 v2/v3 messages, CDA/CCDA documents, FHIR resources), to/from one human language to another), exchange, access/use, encryption/decryption, archive, deletion...

To understand how the QTF Draft 2 exchange paradigm fits, we follow health data/record content collected at the source (source of truth, point of origination) as it flows (is shared) downstream to each ultimate point of access/use, as shown in the Appendix A example. Along this (consumption) chain of trust may be multiple lifecycle events. QHINs and the QTF engage at Steps C-F of this sample sequence.

It is clear that *QHINs are intrinsic to, and comprise key links in, the chain of trust*.

[Appendix A is derived from specifications developed by the HL7 Electronic Health Record Work Group (EHR WG)/Reducing Clinician Burden Project, and is compatible with lifecycle events as specified in ISO 21089 (previously referenced), ISO/HL7 10781 Health Informatics – Electronic Health Record System Functional Model Release 2.1 and HL7 FHIR Release 4 Record Lifecycle Event Implementation Guide.]

12. Vital QHIN/QTF Role in the Chain of Trust

We searched for "trust" in QTF Draft 2 and found four instances, three of which are embedded in "trusted exchange framework". The fourth is part of this statement: "Protecting the privacy and security of health information is essential for building trust among participating entities." No argument with "protecting privacy and security" but we believe "trust" also extends to key aspects of data quality/integrity in serving the interests of "participating entities".

Trust is the overarching principle of TEFCA. There are certain qualities of trusted health data/record exchange that clearly stand as the responsibility and obligation of each Participant, Sub-Participant, HIN and QHIN in the chain of trust. In our example (following) we again use the collect/share/use paradigm, showing data flow from left to right. Evidence established in one step must be preserved and conveyed so that it is evident downstream to each ultimate point of use. Borrowing the old adage, our chain of trust is only (can only be) as strong as its weakest link.

Key Qualities to Ensure/Evidence End → End Chain of Trust		
Collect → at Source	**→ Share →** via QTF (QHIN→QHIN)	**→ Use** at End Use/User
Identity is evident, identity matching is assured: patients, providers (individuals & organizations), systems/devices	...is preserved and conveyed	...is evident and verifiable
Actions are taken to support individual health and provide healthcare • Bindings regarding who took what action when, where and why are evident • Bindings to data content and context are evident; content includes action-related facts, findings and observations	...is preserved and conveyed	...is evident

Key Qualities to Ensure/Evidence End → End Chain of Trust		
Collect → at Source	**→ Share →** via QTF (QHIN→QHIN)	**→ Use** at End Use/User
Chronology and timing are evident as to actions taken and data content/context: • Past, retrospective • Now, at present, concurrent • Future, prospective	...is preserved and conveyed	...is evident
Data content/context is identified as: • Data resulting from single action • Data snapshot of content/context at a point in time; data may result from multiple actions • Data summary of content/context over a period of time; data may result from multiple actions, may include value ranges	...is preserved and conveyed	...is evident
Composition by human author or assembly by software algorithm is evident	...is preserved and conveyed	...is evident
Who authored what when, where and why is evident – authorship is bound to content and context	...is preserved and conveyed	...is evident
If human author, their role and credentials are evident	...is preserved and conveyed	...is evident
Source (source of truth), origination and provenance is evident	• Source provenance is preserved and conveyed • If content is transformed during exchange, new provenance is added, preserved and conveyed	...is evident
If applicable, data content/context verifier is evident	...is preserved and conveyed	...is evident
If applicable, attestation (e.g., digital signature) is evident (confirming accuracy/completeness of content/context)	...is preserved and conveyed	...is evident
If applicable, signature/content binding is evident	...is preserved and conveyed	...is evident
Purpose of capture is evident	...is preserved and conveyed	...is evident
If known, intended recipient and/or purpose of use is evident	...is preserved and conveyed	...is evident
Content/context remains unaltered (from source) and is so evident	• Unaltered data content/context is preserved and conveyed • If data content/context is altered by transformation (e.g., to/from exchange artifacts), altered content/context is conveyed	...is evident
Data definition is evident: e.g., element names, data type(s), input/display/storage format(s), unit(s) of measure, vocabulary, code/value sets	...is preserved and conveyed	...is evident
Data content completeness or missing elements are evident	...is preserved and conveyed	...is evident
If applicable, update(s) to original content are evident, along with revision history	...is preserved and conveyed	...is evident
Data content originated as structured or unstructured is evident	...is preserved and conveyed	...is evident
Initial link in chain of trust is established	• Initial link in the chain is preserved and conveyed • Subsequent link(s) in chain of trust are added at each exchange hop, preserved and conveyed	...is evident
NOTE: Exchange artifacts include HL7 v2/v3 messages, CDA/CCDA documents, FHIR resources		

Another way to think of this:

Truth → captured as evidence in our chain of trust → ensures trust downstream to each end use/user.

We recommend that the QTF be revised to acknowledge and support the vital role of QHINs in the chain of trust, showing the mechanism(s) by which they preserve and convey evidence and key qualities in the course of health data/record exchange.

13.1 Data Transformed for Purposes of Exchange

We reviewed QTF Draft 2 to determine if/how data transformations are managed. We found no reference to this topic yet understand it to be a widespread practice. Data transformations routinely occur in the course of exchange as health data/record content is transformed from its source representation to exchange artifact representation to receiver representation. Exchange artifacts include HL7 v2/v3 messages, CDA/CCDA documents and FHIR resources. Data transformations often result in errors, alterations, loss/omissions and disjunctions.

We recommend that the QTF be revised to acknowledge the role of QHINs in data transformation. In certain cases, if QHINs disallow transformations and input health data/record content/context is thus identical to its output counterpart, QHINs should ensure this evidence is part of the chain of trust. In the case where QHINs perform transformation, the QTF should offer specific guidance on:

- use of widely recognized and validated transformation mappings,
- establishing provenance for any new data representations,
- creating audit log entries for transformation instances and for each instance where errors, alterations, loss/omissions and disjunctions were detected.

Audit log entries should show input data content/context and data content/context resulting from the transformation, as appropriate.

13.2 Data Not Transformed

In some cases, source internal representation = exchange representation = receiver internal representation, in which case transformation is typically unnecessary. It's possible we'll see more of this as FHIR matures and more software systems use FHIR resource instances as – or alongside – their internal (native) data representation.

Ideally health data/record content/context and the author's digital signature are bound together at the source/point of origination and this encapsulation is fully maintained throughout the course from source to use. In this case data transformation is not appropriate as it would break the signature binding/encapsulation. Note that the author's digital signature is distinct from the digital signature that may be applied by a software system. Both are important as we seek more robust integrity measures for health data/record content/context which clearly evidence the source of truth – throughout our end→end chain of trust.

14. Provenance

We searched QTF Draft 2 for "provenance" but no match was found. Provenance is crucial to trust and most any intended use of health data/record content exchanged.

We recommend the QTF be revised to acknowledge the role of QHINs in proper preservation and conveyance of provenance and related details. As noted in previous Comment 13.1, all data transformations occurring in the course of exchange by QHINs create a new representation/instance of health data/record content with its own provenance. Such should be added to the chain of trust, preserved and conveyed to all downstream recipients.

15. Accountability

We searched QTF Draft 2 for “accountability” but no match was found. Accountability ties directly to the role(s), responsibilities and obligations of QHINs as health data record content/context is preserved and conveyed under their control. This is a specific area where it would be ideal to review (and likely reference) the latest CA to verify the QTF is appropriately addressing and ensuring QHIN accountability provisions.

In any case, we recommend the QTF be revised to acknowledge the role of QHINs in fulfilling vital accountability principles.

16. Safety, Patient Safety

We searched QTF Draft 2 for “safe”, “safety” and “patient safety” but no matches were found. Safety and more specifically patient safety are key objectives for any entity or process managing health data/records, including exchange. This stands as another important topic that is clearly applicable but difficult to review and provide useful comments without access to the latest CA and thus to ensure that CA and QTF are in lock step with relevant safety requirements.

We commend ONC and note their development of extensive guidance around HIT safety and safe practices: https://www.healthit.gov/topic/safety/safer-guides

We recommend the CA and QTF reference and/or incorporate relevant guidance to ensure QHINs deploy and engage vital safety practices.

17. Testing and Quality Assurance

While we appreciate the testing strategy outlined in QTF Draft 2, we also believe that a much more comprehensive and robust testing/assurance approach is needed – one that covers the entire course of the health data/record lifespan following both the retention chain and the consumption chain (as described in Comments 11 and 12). This also serves the interests of QHINs as they demonstrate/fortify their position as a valued/valuable component in the lifestream of health data/record flow from source to use.

18. Questions that Remain

- Why does there seem a bias/belief that QHIN/QTF requirements stand isolated from source and end use/user requirements for health data/records?
- Is there a bias/belief that health data/record content, context and quality can be enhanced after the point of origination?
- Have the CA and QTF gone far enough to avoid the all-to-frequent occurrence of garbage in/garbage out?
- Can end use/user trust (be assured) that the health data/record content they receive (via QHINs) is properly identified (as to subject/patient)? Authentic/accurate? Properly attributed (as to source/authorship/ performer of actions taken)? Complete? In proper context? Relevant? Timely? Consistent and comparable? Properly defined (in terms of name/description, form, format, range, value/code set)? Fit for particular purpose of use? If so, how so?
- Should QHINs screen inbound health data/record streams for specific attributes which ensure data quality/integrity, trust (assurance) and usability? If not, why not?
- Rather do QHINs best serve as dumb pipes, i.e., whatever is sucked in at one end is summarily discharged/dumped out the other?
- In what regard do QHINs and the QTF add value to health data/record exchange? Or instead, is their value in doing no harm?

Appendix A – How do We Ensure End-to-End Fidelity as We Collect, Share and Use Clinical Documentation?

Derived from HL7 Electronic Health Record Work Group - Reducing Clinician Burden Project
How Do We Ensure End-to-End Fidelity as We Collect, Share and Use Clinical Documentation?

	Sequence	Flow	Instance	Sample End-to-End Information Flow with Lifecycle Events (LEs) supporting Clinical documentation --------- Lifecycle Event References: a) ISO 21089:2018 Trusted End-to-End Information Flows; b) ISO/HL7 10781:2021 Electronic Health Record System Functional Model Release 2.1; c) HL7 FHIR Release 4 Record Lifecycle Event Implementation Guide	
Collect	A	▼	1	**LE - Documentation is Originated By Clinician or End User** Clinical content/context instance - as rendered to/viewed by the authoring clinician	← What the Author sees
		▼	2	**LE - Documentation is Retained by Source System** Clinical content/context instance - as stored in source EHR/HIT system database	
Share	B	▼	3	**LE - Documentation is Transformed - Exchange Pre-Processing** Clinical content/context instance - as transformed into exchange artifact **LE - Documentation is Transmitted** Clinical content/context instance - as transmitted by EHR/HIT system system	
		▼		**Clinicial Content Exchange - from Source to QHIN 1**	
	C	▼	4	**LE - Documentation is Received by QHIN 1** Clinical content/context instance - as received by the QHIN 1 **LE - Documentation is Transformed - Exchange Post-Processing** Clinical content/context instance - as transformed from exchange artifact **LE - Documentation is Retained by QHIN 1** Clinical content/context instance - as stored in the QHIN 1 database	
	D	▼	5	**LE - Documentation is Transformed - Exchange Pre-Processing** Clinical content/context instance - as transformed into exchange artifact **LE - Documentation is Transmitted by QHIN 1** Clinical content/context instance - as transmitted by QHIN 1	
		▼		**Clinicial Content Exchange - from QHIN 1 to QHIN 2**	
	E	▼	6	**LE - Documentation is Received by QHIN 2** Clinical content/context instance - as received by the QHIN 2 **LE - Documentation is Transformed - Exchange Post-Processing** Clinical content/context instance - as transformed from exchange artifact **LE - Documentation is Retained by QHIN 2** Clinical content/context instance - as stored in the QHIN 2 database	
	F	▼	7	**LE - Documentation is Transformed - Exchange Pre-Processing** Clinical content/context instance - as transformed into exchange artifact **LE - Documentation is Transmitted by QHIN 2** Clinical content/context instance - as transmitted by QHIN 2	
		▼		**Clinicial Content Exchange - from QHIN 2 to Each Receiver**	
	G	▼	8	**LE - Documentation is Received** Clinical content/context instance - as received by receiving EHR/HIT system **LE - Documentation is Transformed - Exchange Post-Processing** Clinical content/context instance - as transformed from exchange artifact **LE - Documentation is Retained by Receiving System** Clinical content/context instance - as stored in receiving EHR/HIT database	
Use	H	❖	9	**LE - Documentation is Accessed/Viewed by Receiving Clinician or End User** Clinical content/context instance - as rendered to/viewed by end user/clinician	← What the End User sees

Imagine...
• The child's game of "telephone" where a simple phrase is whispered in the ear of the first child and then repeatedly whispered one to the next down the line. After a few "whispers" the phrase often becomes convoluted or nonsensical.
• What happens when clinical content/context follows a typical information flow (per the exchange example on the left), algorithmically instantiated in up to nine (9) instances (separate representations) from the point of origination (source) to the point of use (consumption).

How might it be possible to ensure that what the author sees/intends (at the point of origination) is the same as what the receiving end user sees?

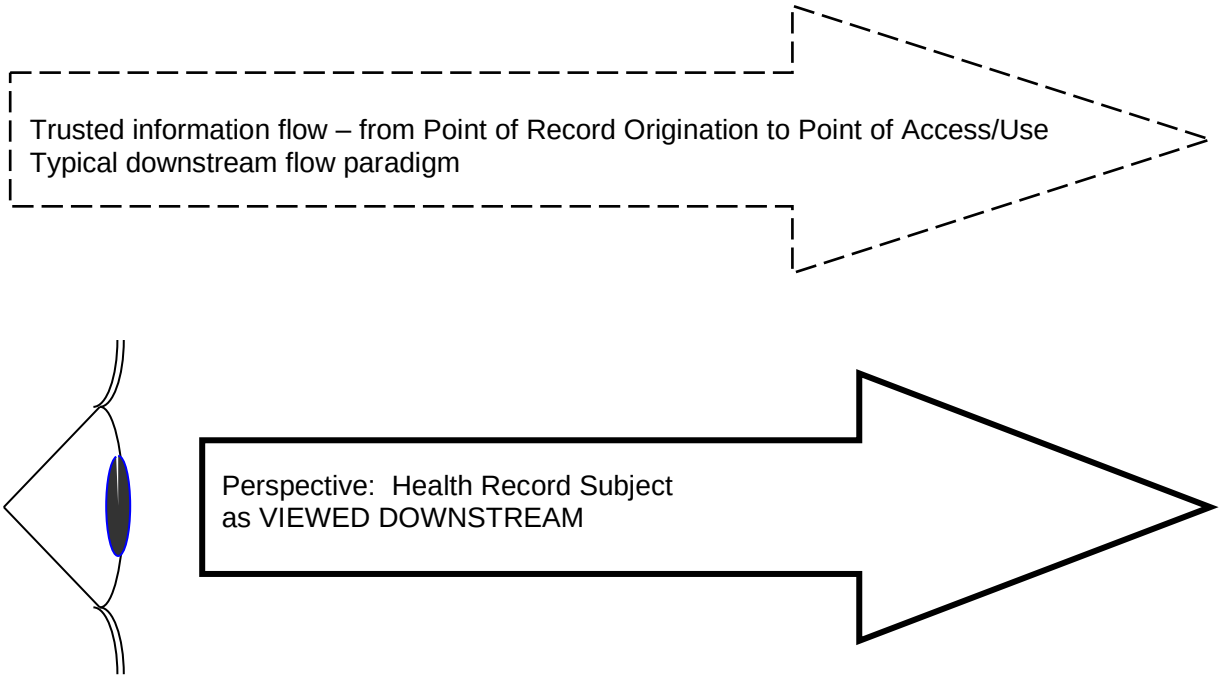
Clinical Documentation is captured during the course of care and comprises discrete entries in the electronic health record. Each entry has a lifespan with one or more lifecycle events occurring during that lifespan. A typical collect/share/use flow **sequence (A-H)** including lifecycle events is shown in this example, starting at the source/point of origination and continuing to the ultimate point of access/use (via QHIN exchange).

Instance (1-10) shows lifecycle events as they might occur in end-to-end flow - certain of which may involve content/context transformations, resulting in the creation of a new instance or representation of the clinical documentation. Discrete instances serve particular purposes (as noted above) including those which render user interface display(s), enable database retention and facilitate exchange. Transformations may introduce errors, alterations, omissions and disjunctions at each new instance. Note that transformation(s) may be unnecessary in some cases (e.g., when FHIR resources are the native data representation within source, QHIN and receiving systems).

Exchange Artifacts include HL7 v2/v3 messages, CDA/CCDA documents and FHIR resources.

Appendix B – Health Data/Record Subject Perspective – Downstream Information Flow

Derived from ISO 21089:2018, “Health Informatics – Trusted End-to-End Information Flows”



As the health data/record subject (e.g., patient)…

How might I be assured of (trust) the persistent integrity and authenticity of my health record and its content? Throughout its lifespan and at each record lifecycle event?

How might I be assured that access/use of my health record is based on principles of "need to know" and “minimum necessary”?

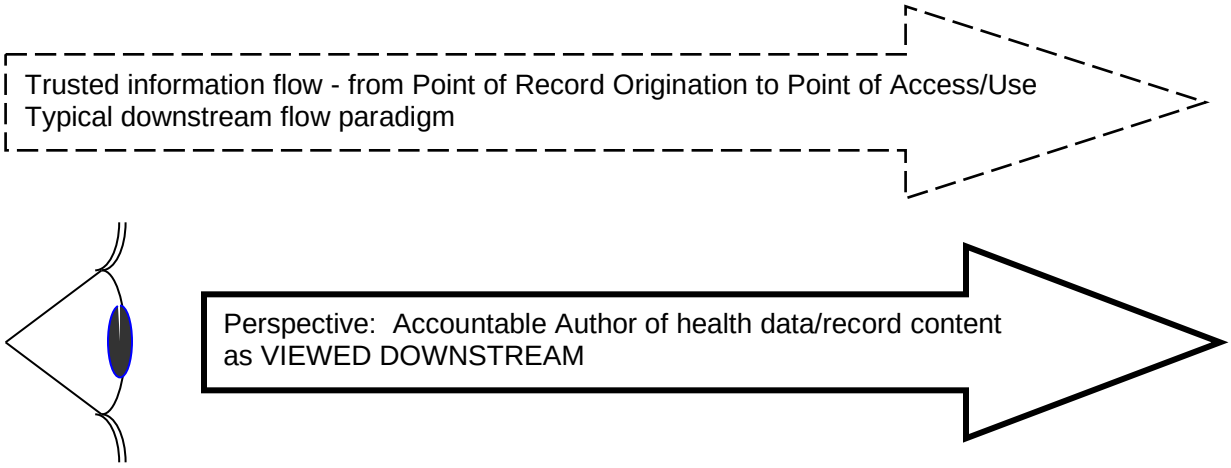
How might I be assured that routine access/use of my health record is according to my consent agreement? Other disclosures according to my specific authorization?

With regard to my health record, how might I be assured (trust) that accountable actions by accountable parties are ascribed, authenticated and traceable, including key points in the record lifecycle:

- Record origination, update, verification, transformation/translation?
- Record access/use?
- Record disclosure and transmittal?
- Record receipt, retention and stewardship?
- Record de-identification or aliasing?
- Record archival, loss or destruction?

Appendix C – Health Data/Record Author Perspective – Downstream Information Flow

Derived from ISO 21089:2018, “Health Informatics – Trusted End-to-End Information Flows”



As an accountable provider of health(care) services (as ascribed in the health data/record)…
As an accountable author, scribe and/or verifier of health data/record content…

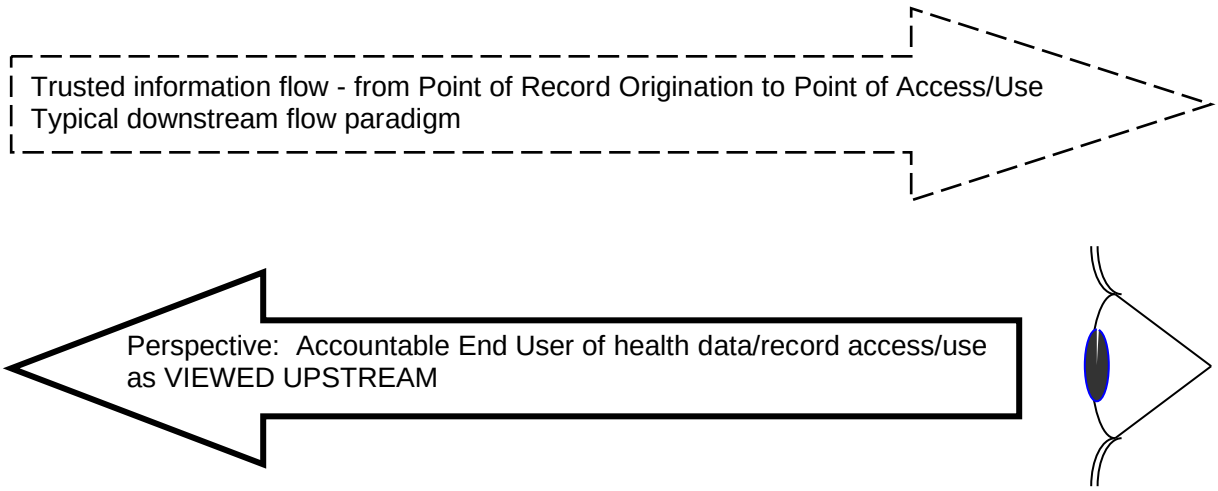
How might I be assured of (trust) the persistent integrity and authenticity of health data/record content/context ascribed to me? Throughout its lifespan and at each record lifecycle event?

With regard to health record content ascribed to me, how might I be assured (trust) that subsequent accountable actions by accountable parties are ascribed, authenticated and traceable, including key points in the record lifecycle:

- Record origination, update, verification, transformation/translation?
- Record access/use?
- Record disclosure and transmittal?
- Record receipt, retention and stewardship?
- Record de-identification or pseudonymization?
- Record archival, loss or destruction?

Appendix D – Health Data/Record End User Perspective – Upstream Information Flow

Derived from ISO 21089:2018, "Health Informatics – Trusted End-to-End Information Flows"



As an accountable end user (including clinicians) of health data/record content…

How might I be assured of (trust) the persistent integrity and authenticity of health data/record content/context which I access and use?

With regard to health data/record content, how might I be assured (trust) that accountable actions by accountable parties are ascribed, authenticated and traceable, including key points in the record lifecycle:

- Record origination, update, verification, transformation/translation?
- Record access/use?
- Record disclosure and transmittal?
- Record receipt, retention and stewardship?
- Record de-identification or pseudonymization?
- Record archival, loss or destruction?