Comments on:	Trusted Exchange Framework and Common Agreement (TEFCA), Draft 2
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Thank you for the opportunity to comment on the ONC Trusted Exchange Framework and Common Agreement (TEFCA), Draft 2. Our review of this Draft was done concurrently with our review of the ONC NPRM "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program" and thus a number of our comments are closely correlated.

General Comments

Key excerpts from the 21st Century Cures Act:

"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.]

1. Individual at the Center

First and most notably, key objectives of the 21st Century Cures Act 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".* In our review of TEFCA Draft 2 we expected to find the individual (patient or subject of care) at the

immediate center. Instead the individual is a far edge node, almost invisible and entirely peripheral to the Trusted Exchange Framework specified in Draft 2. Thus a fundamental conundrum – how to understand and interpret a proposal (this Draft) that is entirely disconnected from a most fundamental premise of the Cures Act.

We believe ONC should discard TEFCA (as drafted) and start over – ensuring that *the individual is foremost and anchored at the center* of the Framework. See comments following.

2. Trusted Exchange Bonds the Carer with the Cared For

TEFCA Draft 2 perpetuates a misperception common to nearly all strategies in this field. It postulates 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.

This strategy is flawed in theory – *it is trying to solve an intrinsically individual-centric problem using an institution-centric approach* – and it has failed in practice consistently and repeatedly over several decades. The result in every case has been (and will continue to be) systems that can babble snippets to each other, but cannot effectively communicate except by creating and conveying "data dumpsters" which are made available to patients/providers and left for each person to ingest – assuming they have time to rummage and the ability to create new understanding(s) on their own.

The "trusted exchanges" we need are not between institutions, but between the carer and the cared for. 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 Draft 2 formula for how to achieve the individual-centric health care objectives is expressed in institution-centric terms. Meanwhile, the individual (and his/her health 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 Draft 2 enforces 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 rationalize more of the same. The workings of institutions can no longer act as proxies for the health and care experiences of an individual.

3. Health Information Exchange Strategy – Coherence or Confusion?

The TEFCA 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 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. With not About

The whole aim of the 21st Century Cures Act (and thus by extension TEFCA) 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 Draft 2 the individual patient is incidental – and almost immaterial – seemingly a waning afterthought of TEFCA design.

Care is provided to individuals and hence health information and related conversations should 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*. 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 other 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, as part of 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. In addition, enforcing the TEFCA HIE model will undermine efforts to create the essential individual-centric infrastructure that is necessary for the health care system we aspire to have – and will undermine (if not fully contravene) the Cures Act focus on the individual at the center.

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

More on the IHR...

An individual's IHR is held on their behalf and used under the purview of a health record Custodian (new role), with permissioned access.

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. In essence the IHR becomes the point of integration within the whole health system for each individual.

a. 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.

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

c. 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'.

d. 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.

e. 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.

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

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

h. 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.

i. 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 central objective.

5. The Scatter Model

TEFCA relies entirely on the "Scatter Model" AND the proposition that it is possible to assemble a patient's 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 Comment 4. How much better foresight ONC might have to focus on how to engage patients in IHR accounts where all their health data/records can be directed and captured, typically after each encounter, using the Meaningful Use mandate for view/download/transmit. 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 proposes – 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 1000s 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: • Maintains an electronic account and address • Maintains/designates a single place to send/ store their records, e.g., after each encounter • Can direct their individual health data/records after each encounter (using MU provision for view/download/transmit)

	TEFCA Scatter Model	At the Center – Strengths of the Individual Health Record (IHR) Model
Broadcast query	Query goes to 10s or 100s of HINs, then on to 1000s, 10,000s, 100,000s of systems/devices	Query is directed to a single designated IHR custodian and account for each patient
Query response	• Response may be nothing, trickle or deluge • Response content may vary each time • Response may be minutes, hours or days later • You don't know what you don't know • 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	Managed at a single point by each patient, patient representative and/or IHR Custodian
Real-time + Continuous	[Not Applicable]	Sustained (24 x 7) support for individual health and care – monitoring and guidance

6. The TEFCA HIE Model is a "Spoiler"

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 stronger enforcement. TEFCA Draft 2 follows that belief. It is demonstrably wrong.

The HIE model is all about data massing and myriad exchanges and offers vanishingly little to facilitate the overall process of individual care. 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 to be 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 HIE model entrenches fragmented systems, data, and care. Patients remain scattered across the institutions with no place that is "theirs" within the overall health care system. This ensures that all of the potential improvements in care efficiency, efficacy and quality can 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, has been shown to be benefit-free. The new rules are just the latest retreat to the "rigorous standards relentlessly enforced approach". This has been tried over and over and has been shown to fail in every case. It is the wrong approach and cannot be morphed or finagled into the right one despite best intentions. This is why all previous generations of HIEs have failed as soon as stakeholders were asked to pay for them... not because the penalties were not high enough ($1,000,000 anyone?) but because the fundamentals are wrong and are unyielding to remedy.

7. 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/organizational 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 and impossible to

sit upon, 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 Draft 2.

It is also essential that the IHR is not seen as merely another participating source system. It is a different class of platform – an entirely new element of infrastructure. It is the locus of control for an individual's overall health and care. Because this is the only correct approach, it is not surprising that the IHR obviates the need for much of what HIEs aspired and failed (and will continue to aspire and fail) to do.

The role of Custodian is key to making clear that the IHR is the individual's system. Specifically in relation to the TEFCA, the IHR should be positioned as the platform with which an individual's smartphone (or PC or tablet or smart watch) needs to interact. It allows individuals to participate together with their providers in a single coherent conversation about their health and care. It gives the individual the means to contribute to that conversation and not be merely the passive listener. This approach not only solves the data fragmentation issue that these rules are attempting to address, but also conforms with the needs of patients and families as set forth in the recent National Academy of Medicine Stakeholder Statement by Patient and Family Leaders. TEFCA Draft 2 does not address such needs.

8. Trusted Exchange without an Actual Source of Truth?

As formulated in TEFCA Draft 2, "trusted exchange" fails to start at (or even consider) the source of truth – the point where health data/record content is collected/originated. Given this omission, we believe this Draft misses the fundamental anchor point for successful interoperability and offers vanishingly little beyond a rehash of what is known (and well-proven) to have failed thus far.

9. Essential Characteristics/Properties/Qualities of Health Data/Records Carried via Trusted Exchange

Let's start with trust (or "trusted" – the "T" in TEFCA). This is very basic, but TEFCA must be open and explicit about what "trusted exchange" of health data/records really is. Let's consider essential characteristics and properties of health data/records that are the vital result of "trusted exchange" and which must always and clearly be evident at the point of end use – to the end user (e.g., clinician).

Essential characteristics of health data/records resulting from trusted exchange...	Properties Evident to End User
Actionable in support of real-time care delivery	Timely, Concise, Pertinent, Digestible, Comprehensible
With known clinical context: e.g., problem/complaint/symptom, diagnosis, treatment, protocol, status	Condition(s), Factor(s), Circumstance(s), Acuity
With facts, findings and observations regarding actions taken	Explicit, Specific, Cohesive
Associable with like information	Correlated, Comparable
Oriented in time: • What has happened (past, retrospective) • What is now in progress (present, concurrent) • What is anticipated, planned (future)	Chronological, Longitudinal
Oriented to actions taken: who did what when, where & why	Accountability, Transparency
Known and verified (verifiable) as to identity: • Subject: patient • Provider: individual and organization • Systems, devices and software	Identified, Attributed
Captured, consolidated from multiple sources	Integrated, Aggregated
Tuned for consistency: e.g., element names, data type(s), input/display/storage format(s), common units of measure, common vocabulary, common codes and value sets	Uniform, Congruent
Tied to the "source of truth", showing source and related details at point of data/record origination and at each point thereafter (including capture, verification/attestation, retention, transmittal, receipt, access/view...)	Factual, Authentic, Traceable

Essential characteristics of health data/records resulting from trusted exchange...	Properties Evident to End User
With known provenance	Source, Lineage
With known authorship, author's role and credential(s)	Ascription, Credence
Known to be unaltered since collection/origination	Immutable, Enduring
Known to be complete – or known to have missing elements	Whole or Partial
Known to be original – or known to be updated from original instance	Origin to Current Instance (data progression over time)
With measures/indicators (when appropriate) to show: • Quality, performance, outcome • Cost and value-based determinants	Efficacy, Effectiveness, Efficiency, Productiveness, Benefit

- *Evidence of truth (authenticity, accuracy);* is the
- *Basis of trust (assurance);*
- *For all end use(s) and to all end users.*

We believe there is nothing more important to demonstrating the value of "trusted exchange" than rigorous stipulation (in the common agreement) that essential characteristics and properties of trusted health data/records (as identified above) are consistently achieved, both in terms of the initial joining but also in ongoing management, assessment and assurance functions of all entities involved in the exchange of trusted health data/records. It is imperative that these characteristics/properties extend from the source, through exchange, to each end use and user. Nothing could be more critical. Otherwise there is little safeguard to prevent garbage in, then garbage out, and thus "distrusted exchange".

Measures to ensure qualitative assessment and assurance are far more important to "trusted exchange" than quantitative enumeration of transaction volumes, participating nodes, or volumes of data massed.

10. "Fitness for Use" and the End User's Affirmative Trust Decision

With regard to Comment 9 above, it seems obvious that these characteristics/properties are the same as those that demonstrate truth (traceable to the source of truth) and enable an affirmative trust decision by the end user. In other words, if these characteristics/properties are evident (or immediately accessible), the end user can readily determine whether the health data/records presented are in fact trustworthy and "fit for use" in terms of the intended purpose (whether for primary or secondary use).

We believe fitness for use (of exchanged health data/records) and the affirmative trust decision (by the end user) are the vital result of "trusted exchange" and must be established as explicit TEFCA tenets.

11. Unsafe at any Speed

To anyone involved in managing HIN or multi-system data flows, it is quickly evident that an exchange scheme of standards-based messages and documents across multiple disparate EHR/HIT systems often achieves something far short of trustworthy interoperability. The required exchange artifacts are routinely created as odd assemblages of fragmented, disjoint data sets/elements. Most all exchanged health information is subject to loss, alteration or error in the course of transmission from point of origination (source of truth) to each ultimate point of use. This often includes misidentification, disjunctions of content, context and meaning, detachment of chronology, provenance, consistency, useful classification and comparability, and *introduction of new safety risks*.

For example, the vital relationship between problems, diagnoses, complaints, symptoms, encounters, allergies, medications, vaccinations, assessments, clinical decisions, orders, results, diagnostic procedures, interventions, observations, treatments/therapies, protocols, transfers, referrals, care plans and status are often lost or become unrecognizable. Once again *safety risks are introduced* via exchange artifacts and exchange mechanisms.

Unfortunately this is the routine result of double transformation of health information content typically occurring in one hop: source representation to exchange artifact (message, document or resource) to receiver representation. Each additional hop (via HIN or otherwise) only multiplies this deleterious effect. This is the sad but factual state of our health information ecosystem – a severe and continuing misadventure that TEFCA does not conceive to address. We believe this is a serious risk to clinical practice and patient safety that must not be ignored any longer.

12. What the Author Sees versus What the End User Sees

There are exchange schemes which ensure that what the author sees (at the point of origination), is what is retained in the source system, is what is exchanged, is what is retained by the receiving system, is what is presented to the ultimate user – but these are a rarity in the real world – where derivative health information is the norm, in fact encouraged by SDO "experts" and the government agencies that foster and promulgate their work into regulatory requirements.

(We don't cherish old technology like faxes and photocopiers but note that at least they reliably reproduce an exact copy of the original.)

In light of this situation it seems obvious that that the time has come to ensure what the author sees at the point of care/point of record entry origination is identical to what is available to each and every end user for each and every end use/purpose, even if some new derivative is offered. This should remain true whether the rendering comes from the EHR/HIT system that is the actual source of health record content or at some point downstream after that content has been exchanged – maybe one or even many hops away.

The following table shows the challenging paradigm of health data/record exchange between heterogeneous systems and the risk to fitness (for use/purpose) posed by data transformations.

<table>
<tr><th rowspan="2">Use</th><th rowspan="2">Purpose</th><th colspan="3">Health Record Content Exchange</th><th rowspan="2"><u>Post Exchange</u>
Fit for Use/Purpose?</th></tr>
<tr><td>Source</td><td>→ → →</td><td>Receiver</td></tr>
<tr><td rowspan="2">Primary</td><td rowspan="2">Clinical Care, Interventions and Decision Making</td><td colspan="3">Without Transformation
(<u>maintains/ensures fidelity to source</u>)</td><td>YES</td></tr>
<tr><td colspan="3">With Transformation(s)</td><td>Often NO</td></tr>
<tr><td>Secondary</td><td>Most Everything Else</td><td colspan="3">With Transformation(s)</td><td>Sometimes</td></tr>
</table>

The common practice of content transformation from source representation to exchange artifact to receiver representation must (at minimum) be accompanied by the original source rendering (what the author saw) as health record content moves downstream from the source – carried without alteration hop by hop.

We believe that before TEFCA is finalized it is crucial for ONC to convene the brain trust of healthcare providers, payers, clinical professional societies, the legal community, health information managers, medical malpractice carriers, EHR/HIT developers, standards developers and others to address and fully resolve this serious issue.

13. Basic Trusted Exchange Assessment 1 – Comparison Across Point(s) of Exchange

One basic form of trusted exchange assessment follows the pattern of collect, share and use.

Collect (at source of truth) →	→ **Share** (exchange) →	**Use** (if fit and trusted)
Input – Health data/records as collected (originated/retained)	= (identical) or ≠ (not)	Output – Health data/records as received, integrated & ready for use
What originated (began as)		What transpired (results as)
What the human (author) sees		What the human (end user) sees
↑	**Assessment – Measures Results of Comparison**	↑

We believe TEFCA, as purported to be the over-arching framework for "trusted exchange", is incomplete without clarity and focus on the pattern of collect, share and use (from the ONC Interoperability Roadmap), to thus include a specific plan for initial and ongoing assessment – *by comparison of health data/records* at the point of collection/origination to those manifest (as fit for use) at each ultimate point of use, after being shared/ exchanged.

14. Basic Trusted Exchange Assessment 2 – Comparison after Round-trip Exchange

A second form of "trusted exchange" assessment is based on a simple round-trip conveyance of health data/records (in order of A, B, C and D below).

System X	Exchange	System Y
A. Extracting from source health record entries, sends a clinical payload using any single or combination of exchange artifact(s)	→ → →	**B.** Instantiates payload in a new set of health record entries
D. Instantiates payload in a new set of health record entries	← ← ←	**C.** Extracting directly from those health record entries, sends the same clinical payload back using any single or combination of exchange artifact(s)
Assessment – Measures Results of Round Trip Exchange: Is there any loss of content, context, provenance, meaning or fidelity when comparing original System X record entries to System X record entries resulting from the round-trip (A + B + C + D)?		

Other Patterns: a) Reverse Roles of Systems X & Y b) System X → System Y → System Z → System X
Exchange Artifact(s): e.g., HL7 or NCPDP or X12 messages, HL7 CDA/CCDA documents, HL7 FHIR resources

We believe TEFCA, to demonstrate initial and ongoing assurance of "trusted exchange", must also stipulate the requirement for round-trip exchange assessment of health data/records, following the pattern shown above.

[Note that Trusted Exchange Assessment 2 was developed in collaboration with the Health Record Banking Alliance (HRBA) and members of the US Technical Advisory Group (TAG) to ISO TC215.]

15. Real-Time Safety Alerts

We believe that to enable "trusted exchange", TEFCA must include provision to identify, track and provide real-time alerts for identifiable safety risks occurring in the course of health data/record capture and exchange.

16. APIs or Bust?

TEFCA Draft 2 follows previous mandates that promote systems "talking to each other" by exchanging patient data in a specified "standard" format. It extends this approach by requiring these systems implement application programming interfaces (APIs) which define how data can be requested and then exchanged between systems point to point or across a network.

The premise is that this will somehow remove obstacles that are preventing health IT from addressing the major challenges facing health care today, in particular the fragmentation of individual care and health data/records captured in the course of that care.

The question is not whether there is a shiny new way to exchange data between EHR/HIT systems (as a successor to more traditional message and document exchange), but whether the resulting mélange offers anything better suited than previous incarnations of standards that produce little more (of substance) than mass dumps of often extraneous and inscrutable data (to the clinician who must view/comprehend them)? In other words, do APIs better provision information that is timely, concise, relevant and immediately actionable? If so, how? Or do APIs represent yet another contributor to clinician burden?

We believe APIs, today's "shiny bauble", must still prove their worth/benefit as substantively more than the latest fad.

17. Provenance

Given the attention to data quality/integrity found in TEFCA Draft 2, we find it curious that there is no mention of provenance. How can data quality/integrity be ensured without capture and continuous binding of all health data to its source and provenance details?

We believe provenance is essential to trusted exchange particularly as it demonstrates authenticity, continuity and traceability from source to use (point of origination to each ultimate point of access/use).

18. Burden Reduction or a Smothering Maze of New Requirements?

Promises to reduce burden are rendered meaningless as we contemplate TEFCA Draft 2 with its myriad, detailed and highly complex set of requirements. We believe essential objectives of the 21st Century Cures Act can be achieved with a vastly simplified approach, primarily by positioning the individual at the actual center, as described in preceding comments. Such approach not only unravels many of the complexities found in TEFCA Draft 2, it also offers substantial leverage to advance burden reduction.

From our assessment, the crush (and curse) of "burden" is felt most acutely by front-line clinicians at the point of care/point of service. TEFCA Draft 2 offers vanishingly little to those clinicians already severely impacted by burden delivered via top-down government mandates.

In January 2019 many industry views were submitted in response to the ONC call for comments on its Draft Strategy for Burden Reduction. We believe that the authors of this Draft should go back and read/review those comments and then make a serious attempt to recast TEFCA in light of industry input and advice regarding burden reduction.

Specific Comments

TEFCA Draft 2, Page 6, Introduction: "The Cures Act's 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 care; and
• "Promotes innovation and competition at all levels."

17. Ascension of the Individual

We agree that "the Cures Act's 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" and we believe the IHR Model clearly fulfills that objective for the individual – leaving aside the exponential multitude of complicated technical, governance and control mechanisms envisioned by TEFCA Draft 2.

18. Ascension of the Provider

We also agree that "the Cures Act's focus on trusted exchange is an important next step toward advancing the establishment of an interoperable health system that... enables providers and communities to deliver smarter, safer, and more efficient care" and we believe the IHR Model substantively achieves these objectives for the provider – without the myriad complexities of HINs, broadcast queries, multiple governance hierarchies and on (as proposed in TEFCA Draft 2).

TEFCA Draft 2, Page 4, Executive Summary, "The TEF and the Common Agreement will be distinct components that together aim to create technical and legal requirements for sharing EHI at a nationwide scale across disparate HINs. The TEF describes a common set of principles that facilitate trust between HINs. These principles serve as 'rules of the road' for nationwide electronic health information exchange. The Common Agreement will provide the governance necessary to scale a functioning system of connected HINs that will grow over time to meet the demands of individuals, clinicians, and payers. The architecture will follow a 'network of networks' structure, which allows for multiple points of entry and is inclusive of many different types of health care entities. Stakeholders have the option of participating at multiple levels of the TEF and Common Agreement exchange environment, as is appropriate for them."

TEFCA Draft 2, Page 7, An Onramp for Exchange, "The TEF and the Common Agreement seek to scale health information exchange nationwide and ensure that HINs, health care providers, health plans, individuals, and many more stakeholders can access real-time, interoperable health information."

TEFCA Draft 2, Page 8, An Onramp for Exchange, Support Nationwide Scalability: "The TEF and the Common Agreement aim to scale interoperability nationwide. This will be done by defining a floor of legal and technical requirements, which will enable stakeholders to access, exchange, and use relevant EHI across disparate networks..."

19. Will It Scale?

"The Common Agreement will provide the governance necessary *to scale* a functioning system of connected HINs...", also "*to scale* health information exchange nationwide and ensure that HINs, health care providers, health plans, individuals, and many more stakeholders can access real-time, interoperable health information", and "*to scale* interoperability nationwide". We believe these claims *to scale* are highly questionable given that there are NO other examples – across all industries, across all electronic computing schemes, across all nations – where success can be claimed with any approach similar to TEFCA.

TEFCA Draft 2, Page 7, An "On-Ramp" for Data Exchange: "Currently, there are more than 100 regional health information exchanges9 and multiple national level organizations that support health information exchange. While these organizations have made significant progress in advancing interoperability, connectivity across HINs is still limited due to variations in the participation and data use agreements that govern data exchange. This results in fragmentation and gaps in interoperability. It also means that HINs, health care

providers, health plans, and individuals participate in multiple forms of data exchange, which can be extremely costly and burdensome, in order to access all of an individual's data. According to a recent survey of about 70 hospitals, a majority of respondents indicated that they required three or more methods for exchanging data and about three in 10 hospitals used five or more methods to be interoperable. Continuing with the status quo is not enough to ensure all stakeholders have efficient methods for engaging in health information exchange."

20. Missing Fundamentals

We agree that there remain substantial "fragmentation and gaps in interoperability" but this is not just a consequence (or lack) of "connectivity across HINs [that] is still limited due to variations in the participation and data use agreements that govern data exchange." We believe "fragmentation and gaps in interoperability" are due to lack (neglect) of focus on basic fundamentals of truth (authenticity, accuracy), trust (assurance) and end-to-end integrity of health information. See Comments 8-14.

TEFCA Draft 2, Page 25, Principle 1 – Standardization: "Adhere to applicable standards for EHI and interoperability that have been adopted by the U.S. Department of Health & Human Services (HHS), approved for use by ONC, or identified by ONC in the Interoperability Standards Advisory (ISA). HINs should adhere to federally adopted standards for EHI and interoperability. Specifically, HINs should first look to use standards adopted by HHS, then those approved by ONC through the proposed standards version advancement process as part of the ONC Health IT Certification Program (Certification Program), and finally, those identified in the ISA. In instances where none of the above references include applicable standards, HINs should then consider voluntary consensus or industry standards that are readily available to all stakeholders, thereby supporting robust and widespread adoption. Consistent adherence to these standards will ensure improved usability and access to EHI."

21. Technical Standardization is Not Enough

If only technical standardization were the answer – we'd be living the dream and basking in our (by now self-evident) success = nirvana achieved. Haven't we deployed/implemented most all these standards (referenced in the clauses above) for many years?

We accept that technical standards are important but we also know they are far from sufficient. The fundamentals remain missing and won't yield to new proclamations or fulminations. Let's remember that most all our technical standards, however expansive, are mostly unknown to the clinician user as they labor at the point of care/point of service. We don't pretend to be standardizing care or clinical practice, so everything the clinician does (and documents in their course of practice) must be transformed into the technical standards we use for computing. The reality of this transformation is that a lot goes missing or gets mapped (transformed) into something far different than was actually intended.

We believe technical standardization only takes us so far and is not, nor will ever be, sufficient enough to achieve true interoperability – in fact interoperability that is obvious to the front-line clinician in their everyday practice – routinely delivering health information that is timely, useful/usable, concise, relevant and actionable. See Comments 3, 6, 11 and 16.

22. Principles of Trusted Exchange and Interoperability

As we have advised in previous Comments, there are a number of issues bound to the objective to achieve safe and "trusted exchange" which are contingent on full interoperability. While we generally agree with the six "trusted exchange" principles in DRAFT TEFCA, we don't believe them to be complete as noted below.

Trusted Exchange Principle (TEFCA Draft 2, page 24)	Our Comments
Principle 1 – Standardization: Adhere to industry and federally recognized standards, policies, best practices, and procedures.	See Comments 3, 6, 11, 16 and 21.
Principle 2 – Transparency: Conduct all exchange and operations openly and transparently.	---

Trusted Exchange Principle (TEFCA Draft 2, page 24)	Our Comments
Principle 3 – Cooperation and Non-Discrimination: Collaborate with stakeholders across the continuum of care to exchange EHI, even when a stakeholder may be a business competitor.	---
Principle 4 – Privacy, Security, and Patient Safety: Exchange EHI securely and in a manner that promotes patient safety, ensures data integrity, and adheres to privacy policies.	Expand data integrity in "trusted exchange" to included essential characteristics, properties and qualities of health data/records as specified in Comments 9 and 27, 27.1 and 27.2.
Principle 5 – Access: Ensure that individuals and their authorized caregivers have seamless access to their EHI.	Expand "seamless access" to include patient-mediated exchange. See Comments 1-7.
Principle 6 – Population Level Data: Exchange multiple records for a cohort of individuals at one time in accordance with applicable law to enable identification and trending of data to lower the cost of care and improve the health of the population.	---
Principle 7 (new) – Certainty in Identity Matching	Establish formal mechanisms, automated and with manual verification (as necessary), to ensure correct identity matching.
Principle 8 (new) – Timeliness, Concision, Targeted, Relevant, Fit for Use and Actionable	As a key facilitator of burden reduction, establish formal mechanisms to ensure exchanged health data/records are timely, concise, targeted, immediately actionable, relevant and fit for, specific users and uses.

TEFCA Draft 2, Page 9, The Trusted Exchange Framework (TEF): "To support the Cures Act's goal of advancing health information exchange among health information networks, the TEF creates a common set of principles that are designed to facilitate trust between HINs and by which all HINs should abide in order to enable widespread data exchange. These principles are standardization; transparency; cooperation and non-discrimination; privacy, security, and patient safety; access; and data driven accountability."

23. TEFCA Principle 6 – What Happened to Data Driven Accountability?

Principle 6 (data driven accountability) is different than Principle 6 (population level data) as found on Page 24 and thereafter. We presume that "data driven accountability" is a leftover from TEFCA Draft 1 as it is not found elsewhere in the document.

TEFCA Draft 2, Page 16, The Common Agreement's Relationship to HIPAA: "Individuals, health care providers, health plans, and networks may not be willing to exchange data through the Common Agreement if smartphone app developers and other non-HIPAA entities present privacy or security risks because they are not obligated to abide by the HIPAA Rules. In order to meet the goals of the Cures Act as well as to help address these concerns and encourage robust data exchange that will ultimately improve the health of patients, the Common Agreement requires non-HIPAA entities, who elect to participate in exchange, to be bound by certain provisions that align with safeguards of the HIPAA Rules. This will bolster data integrity, confidentiality, and security, which is necessary given the evolving cybersecurity threat landscape."

24. Universal Safeguards

We applaud the Common Agreement stipulation that "requires non-HIPAA entities, who elect to participate in exchange... be bound by certain provisions that align with safeguards of the HIPAA rules" and agree that this should "bolster data integrity, confidentiality, and security, which is necessary given the evolving cybersecurity threat landscape." In our review of the Common Agreement, we see where the safeguards are described and we see these safeguards applied to HIPAA Covered Entities, Business Associates, QHINs, Participants and Participating Members, but we don't see specific language describing if/how "safeguards of the HIPAA rules" apply to "smartphone app developers and other non-HIPAA entities".

This is no small challenge, given that the envisioned health data exchange scheme is certain to involve software proffered by "smartphone app developers" and software in the realm of "non-HIPAA entities". This software (in the form of apps) will readily number in the 100,000s of unique instances.

We believe that in order for HIPAA safeguards to be viable and verifiable in all these instances, it will be necessary for a certification program to be established to build a national reference list of trusted applications which are then assured to qualify as nodes for trusted exchange.

TEFCA Draft 2, Page 18, Minimum Security Requirements: "To the extent the QHIN's risk analysis identifies any risks, vulnerabilities, or gaps in the QHIN's compliance with the HIPAA Privacy and Security Rules or other Applicable Law, the QHIN would be required to assess and implement appropriate security measures consistent with industry standards and best practices that it determines would be reasonable and appropriate to ensure the confidentiality, integrity and availability of the EHI that it creates, receives, maintains or transmits, and provide documentation of any such evaluation. This evaluation would not be required for Participants and Participant Members. QHINs are to evaluate their security program on at least an annual basis."

TEFCA Draft 2, Page 19, Minimum Security Requirements: "...regardless of whether they are a Covered Entity or Business Associate, Participants and Participant Members must take reasonable steps to promote the confidentiality, integrity, and availability of EHI, including maintaining reasonable and appropriate administrative, technical, and physical safeguards for protecting EHI; protecting against reasonably anticipated impermissible Uses and Disclosures of EHI; identifying and protecting against reasonably anticipated threats to the security or integrity of EHI; and monitoring workforce compliance."

TEFCA Draft 2, Page 28, Section 6.2 (A), Principle 4 – Privacy, Security, and Patient Safety: "Ensure that EHI is exchanged and used in a manner that promotes safe care, including consistently and accurately matching EHI to an individual.

"Certain health plans and health care providers, and their business associates must follow the HIPAA Rules to safeguard individual ePHI. However, EHI is increasingly collected, shared, or used by new types of organizations beyond the traditional health care organizations covered by the HIPAA Rules. Privacy and security should be a foundation for all health care stakeholders, including those that are not subject to HIPAA.

"Ensuring the integrity of EHI is paramount to providing safe care. When EHI is exchanged, safe care begins with correctly matching the data to an individual so that care is provided to the right individual based on the right information. Sophisticated algorithms that use demographic data for matching are the primary method for connecting data to an individual. To support accurate matching, HINs should agree upon and consistently share a core set of demographic data each time that EHI is requested. Likewise, participants of HINs should ensure that the core set of demographic data is consistently captured for all individuals so that it can be exchanged in a standard format and used to accurately match data.

"In addition to the importance of the integrity of demographic data, overall EHI integrity is a key component of promoting patient safety in electronic exchange. Where possible, standard nomenclatures should be used and exchanged in a data format that is consumable by a receiving system, such as a C-CDA or via FHIR APIs. Further, clinicians should update individuals' EHI in their EHR to ensure that medications, allergies, and problems are up to date prior to exchanging such data with another organization. To the extent possible, HINs should utilize testing and onboarding processes for their participants that seek to establish a high level of data quality."

[And noting that Sections 7.16 (page 59) and 8.16 (page 66) also address similar privacy, security, patient safety and data integrity requirements.]

25. Privacy, Security and Patient Safety

We applaud the inclusion of TEFCA Draft language (in the clauses above) that focus on critical issues of privacy, security, patient safety and data integrity. This is a strong and positive step forward from Draft 1. See Comments 9, 27, 27.1 and 27.2.

26. Core Demographic Data and its Source

While we agree that "HINs should agree upon and consistently share a core set of demographic data each time that EHI is requested", this requirement falls short if it only applies to HINs. HINs are typically not the source of demographic data and thus we believe this criteria should also be considered as a requirement for those entities and systems that source demographic data.

TEFCA Draft 2, Page 50, Data Integrity, in three sections: Section 6.2.2 (for QHIN); also Page 59, Section 7.16 (for Participant); also Page 66, Section 8.16 (for Participant Member): "Each [QHIN or Participant or Participant Member]'s security policy shall include the following elements to promote data integrity of all EHI that it receives, maintains or transmits:
"(i) Procedures to safeguard that EHI is not improperly altered or destroyed;
"(ii) Procedures to protect against reasonably anticipated, impermissible Uses or Disclosures of EHI;
"(iii) Procedures to maintain backup copies of systems, databases, and private keys in the event of software and/or data corruption, if the [QHIN or Participant or Participant Member] is serving as a certificate authority;
"(iv) Procedures to test and restore backup copies of systems, databases, and private keys, if the QHIN is serving as a certificate authority, so that the [QHIN or Participant or Participant Member] can retrieve data from backup copies in the event of a disaster, emergency, or other circumstance requiring the restoration of EHI to preserve data integrity; and
"(v) Procedures to document the methodologies and results of tests to restore backup copies of systems, databases, and private keys, if the QHIN is serving as a certificate authority. Such documentation shall be maintained in a manner consistent with 45 CFR § 164.316(b).

"Each [QHIN or Participant or Participant Member] shall report known instances of inaccurate or incomplete EHI to the Participant who is the originator of the EHI, and request that the Participant remediate such data integrity issues in a timely manner to the extent reasonably possible."

27. Assurance of Data Quality/Integrity is Vital

While we are pleased to see fresh attention to data integrity in TEFCA Draft 2, we do not believe it goes far enough.

A key point of reference is recent work by the Health Level Seven (HL7) Electronic Health Record Work Group (EHR WG) and their Reducing Clinician Burden (RCB) project. After substantial analysis, the RCB Project Team established a set of Vital Data Qualities...

Vital Data Qualities	**TEFCA Data Quality/Integrity safeguards must ensure common datasets and elements...**
Data is carried via a verifiable chain of trust from **source to end use**: • Starting as captured at the **source** (point of origination), then • Retained in the source EHR/HIT system, then • Transmitted from the source system, then • Received and retained by the receiving EHR/HIT system, then • Made available to each ultimate **end use and user** (point of access/use).	
• **Is it true and trustworthy?** Accurate, authentic, assured? • **Is it action-able?** Timely, current? Relevant, pertinent? Concise, succinct, to the point? Useful, usable? • **What is immediately *known*** (evident or knowable) regarding its content?	
***Known* and certain as to identity**: patient, provider (individual or organization)	Are associated with the correct identity and subject (of care/treatment)
***Known* to show clear relationship between data and actions taken** (i.e., actions taken to support individual health and to provide healthcare): • **Who did what when, where and why**	Show a clear relationship of datasets/elements with actions taken – who took what action, when, where and why
***Known* to retain clinical context and maintain vital inter-relationships** with/between (as applicable): • Problems, diagnoses, complaints, symptoms, encounters, allergies, medications, vaccinations, assessments, clinical decisions, orders, results, diagnostic procedures, interventions, observations, treatments/therapies, protocols, transfers, referrals, care plans and status	Show a clear relationship between dataset/element and its clinical context and vital inter-relationships (as noted in the ← left-side column ←)
***Known* as to source and provenance ("source of truth")**, with traceability to point of origination: human, device, software	Show dataset/element provenance with traceability to source/point of origination

Vital Data Qualities	TEFCA Data Quality/Integrity safeguards must ensure common datasets and elements...
***Known* as to accountable human authorship** (if applicable) with role and credentials	Show dataset/element authorship with role and credentials, as applicable
***Known* as to time orientation** (date/time of occurrence, chronology, sequence), and in terms of: • What has happened: past, retrospective • What is now in progress: present, concurrent • What is anticipated, planned: future, prospective	Show time orientation and chronology/sequence
***Known* to be verified (or not)** with evidence of verification, verifier(s), date(s)/time(s) and method(s)	Show evidence of dataset/element verification, as applicable
***Known* to be updated (or not)** with evidence of prior state(s), effective date(s)/time(s)	Show evidence of dataset/element update, prior state(s), effective date(s)/time(s), as applicable
***Known* to be unaltered** (maintaining fidelity to original/source content) or ***Known* to be altered/transformed** from source content/representation	Show evidence of dataset/element non-alteration or alteration, as applicable
***Known* to be complete** or ***Known* to be partial/pending** or ***Known* to be a snippet/fragment** with other essential details elsewhere	Show evidence of dataset/element completeness (or not), as applicable
***Known* to be comparable** (correlate-able, trend-able) to like data, having same/similar context	Have the same/similar context so as to be comparable, even/especially if sourced by separate EHR/HIT systems
***Known* to be consistent in terms of data definition and with corresponding data**: • Element name(s), data type(s), range, input/display/storage format, unit(s) and scale of measure	Have consistent data naming and definition, even/especially if sourced by separate EHR/HIT systems
***Known* to be sourced as structured (coded) content or not**	Show evidence of data source as structured content or not
***Known*, if coded, to include:** • Coding convention – vocabulary/terminology set or value set – and version	Show evidence, if coded, of coding convention and version
***Known* as to method and purpose of capture**	Show evidence of method and purpose of capture
***Known* as to how external data is integrated** with health data/records in the local EHR/HIT system	Include explicit representation of how external data is integrated with data/records in the local EHR/HIT system
***Known* as to how external data is integrated** among other health/data records from other sources	Include explicit representation of how external data is integrated among data/records from other sources

We know only too well that HINs and EHR/HIT systems can capture and propagate mass quantities of data. Claims of “interoperability” are also rampant. Timely, useful/usable, relevant and actionable information (particularly imports from external sources) is still an elusive commodity in the daily practice of many clinicians.

We believe emphasis on, and incorporation of, these vital data integrity qualities is essential to trusted exchange.

27.1. Immediate context

In conjunction with Comment 27, full context for each element is essential to trusted exchange.

For example, blood pressure should include the following elements of *immediate context*, including provenance:

Who (actor)	Patient or subject of care
	Performer, who measured blood pressure
	Author of health record entry (who may be different than performer)
	Provider: individual practice or organization
What (action taken)	Systolic, diastolic and/or mean measurement
When	Occurred at: date/time/duration
	Recorded at: date/time
Where	Body location, sampling site
	Physical location – e.g., exam room, bedside
	Recorded at: network address and/or device ID
Why	Rationale for, or purpose of, measurement
How	Method – e.g., inflatable cuff with auscultation by stethoscope
Under what circumstance(s) or condition(s)	At rest, pre/post exercise or other condition

To be complete and to establish trust (assurance) and truth (authenticity, accuracy), we believe TEFCA must specify that each element of health information is carried together and tightly coupled with its *immediate context*.

27.2. Extended Context

Following on Comments 27 and 27.1, *extended context* shows key relationships beyond the immediate measurement (for example, extending the context of our blood pressure example):

Context	Blood pressure measurement occurring as:
a) Basic vital signs panel	Part of a vital signs panel (e.g., heart rate, respiratory rate, body temperature, pulse oximeter) as might be captured from the same patient, by the same performer, at the same date/time
b) Inpatient vital sign monitoring	Part of a vital signs panel (as detailed in "a" above), as might be performed hourly in an inpatient setting
c) Outpatient history and physical assessment	Part of a vital signs panel (as detailed in "a" above), performed in an outpatient clinic, in conjunction with a history and physical assessment
d) Weekly monitoring – to rule in/out hypertension	Weekly follow up visits measuring vital signs (as follow up to "c" above) to determine if patient has hypertension (high blood pressure), performed in an outpatient clinic for four successive weeks
e) Weekly monitoring – post hypertension diagnosis	Weekly follow up visits measuring vital signs to assess effectiveness, dosage levels and possible side effects of medication prescribed after patient was diagnosed with hypertension (as follow up to elevated BP levels detected from monitoring described in "d" above)

To be complete and to establish trust (assurance) and truth (authenticity, accuracy), we believe TEFCA must specify that each element of health information is carried together and tightly coupled with its *extended context*.

TEFCA Draft 2, Page 26, Principle 1 - Standardization: Adhere to industry and federally recognized technical standards, policies, best practices, and procedures: "HINs should, to the extent possible, ensure that the data exchanged within their own network and with other HINs meets minimum quality standards by using testing and onboarding programs to verify minimum quality levels. HINs may consider using tools, such as ONC's C-CDA scorecard tool for testing the technical conformance of C-CDAs or the Patient Demographic Data Quality Framework (PDDQ) to evaluate the quality of patient demographic data. They may also consider developing tools to test the quality of data exchange using Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®) APIs. These types of testing programs can help ensure that high quality data is exchanged both within and across HINs."

28. Minimum Quality Standards and Levels

While we appreciate that "HINs should, to the extent possible, ensure that the data exchanged within their own network and with other HINs meets minimum quality standards by using testing and onboarding programs to verify minimum quality levels.", we are uncertain as to what is meant by "minimum quality standards" and "minimum quality levels". We believe these "minimum quality standards/levels" and related testing requirements should be made explicit and closely align with the Vital Data Qualities specified in Comments 27, 27.1 and 27.2.

29. End-to-End Testing

It is unreasonable to accept that quality standards/levels only apply to data once it hits the HIN. For data to be found timely, useful/usable, relevant and actionable at each ultimate point of access/use, it must be demonstrable that data quality standards/levels were achieved/maintained throughout its lifespan. This requirement necessitates more than snapshot testing but rather end-to-end testing – from source to use.

Testing is a relative term. In all work done over the past 30 years, testing mostly required the provider of data to demonstrate that all fields in a message or document are populated to the specified format. Such testing is very unlikely to check the faithfulness to care or source of the content including:

- Validity of data (authentication/verification)
- Provenance of each contributing element (a real problem for patient summaries where data elements are amalgamated from multiple sources and points in time)
- Amendments (updated/corrected from its initial instance)
- Completeness with respect to expectation of care
- Context of care including the care coordination process

All these are necessary to ensure that a received health data/records are timely, useful/usable, relevant and actionable for clinical practice and immediate care needs. In the current environment, most of these requirements remain substantially beyond the capabilities of data exchanges (or dumps) across HIEs.

We believe it is crucial to test Vital Data Qualities (see Comments 27, 27.1 and 27.2) not as the static output of a source system but rather in real world scenarios from source to use – point of data/record origination to point of data/record access/use (across one or more points of exchange). This ensures that fidelity to source can be tested (and ensured), not at a single point or within a single system, but rather end-to-end.

TEFCA Draft 2, Page 45, Section 3, Data Quality and Minimum Necessary and Section 3.2, Data Quality Characteristics: "To help confirm that QHINs exchange accurate patient demographic data that is used for matching, QHINs shall annually evaluate their patient demographic data management practices using the then applicable PDDQ Framework. The first such evaluation shall be conducted within eighteen (18) months after the QHIN has executed the Common Agreement."

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30. Short Shrift to Data Quality?

Although Section 3 (above) is focused on Data Quality and Minimum Necessary, only Section 3.2 describes data quality and then only with regard to the quality of "demographic data that is used for matching". We are perplexed that this important topic is given such short shrift. See Comments 9, 27, 27.1 and 27.2 above.