Gary L. Dickinson
Director, Healthcare Standards, CentriHealth
Co-Chair, HL7 EHR Work Group
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Comments to: Health Information Technology Standards Committee

So how did we find our way to this conundrum where the mandated set of Meaningful Use Stage 2 exchange standards don't actually ensure systems interoperate much less convey data that is fit for primary use – clinical care, interventions and decision making?

We will offer two perspectives in separate comments:

1) Let's start with the long-standing JCAHO definition for data integrity: accuracy, consistency and completeness. This definition was in place well before we injected IT into health records – but with IT the equation changed.

We now go to great lengths to transform authentic source content to the form and format we (standards and IT geeks) deem best for purposes of computability, exchange, reporting, big data or whatever. (I'm one of those geeks by the way.) We transform source health records and information to and from "standard" patient summaries, to and from "standard" exchange artifacts, to and from "standard" clinical information models. Each transform is an alteration and errors and omissions are often introduced.

In previous times the clinician controlled the exact content of the source record including precisely what was conveyed to the next clinician and patient care team, whether immediately or to the next shift or rounds, the next referral or the next transition of care.

This is no longer the case. Now the source record is largely indistinguishable as such. The binding of signature to original health record content is no longer obvious in most cases. What happens as source record content is sliced, diced, transformed and expurgated for various purposes – to and from exchange artifacts, digitized summaries and clinical information models – is typically locked invisibly away in the bowels of EHR systems and back-end exchange schemes.

So really IT has taken precedence over the clinician and his or her source clinical record. Now it's the algorithmic machinations of the IT geek who massages the data that have taken priority in place of the clinician whose source clinical content is being massaged.

Is this progress or have we lost our way? Why have we prioritized computability over authenticity? Why haven't we made primary use and authenticity of, and accountability for, source content paramount in all cases? Why haven't we seriously engaged the broader clinical community, bringing them to the forefront, to make sure we (the IT and standards geeks) get it right?

Why don't we recognize this as a clear and present danger to clinical integrity and most importantly, to patient safety?

It is our recommendation that the HIT Standards Committee carefully review the state of MU-mandated exchange schemes and the essential requirement for clinicians to control every aspect of their clinical information, ensuring truth (authenticity) and trust (assurance) end-to-end, from point of origination to each ultimate point of health record access/use.

2) Observe our pre-standards world – 1980s and before. For pair-wise interfaces, two parties would vie for whose specification would be the basis for a particular interface instance. By whatever process, one side wins out and a custom interface results. Mostly these interfaces are within the same provider enterprise and interfaced systems reside within common identity domains. Within these curated domains, software architectures may be heterogeneous but data content is almost totally homogeneous. Datasets, contexts, codes and value sets are precisely matched on both sides of each interface. And any interface can be precisely customized to the particulars of both systems and the common denominator between. If needed at all, this is single transformation model.

With the first publication of consensus-based clinical information exchange standards in the early 90's (by HL7 and others), the exchange standard became the baseline – but with the added burden that double transformations are now required in each exchange instance – to and from the exchange artifact. Still custom interfaces, still optimized between systems, still relying on the common denominator of identity, datasets, contexts, codes and value sets maintained within a single domain.

In 2014 with MU Stage 2, we have these same standards now designated as universal "interoperability" standards. Let's look at this closely:

Pre MU 2	Under MU 2 Mandate
• Known systems exchanging within common trust domain	• Potentially any pair, any sender, any receiver, at any time
• Standards are optional and baseline to what is exchanged	• Standards are required and describe everything exchanged
• Interfaces often optimized pair-wise	• Interfaces rarely optimized pair-wise
• Curated domains with common identities, datasets, contexts, codes and value sets	• Disparate identity domains • Often tricky identity matching • Widely disparate datasets, contexts, codes and value sets
• Often minimal transforms	• Often radical double transforms

Do we really believe these exchange standards are sufficient or even applicable to achieving interoperability? If so, why? And most importantly, why don't we recognize this as a clear and present danger to both clinical integrity and patient safety?

It is our recommendation that the HIT Standards Committee take a close and serious look at interoperability and MU 2-mandated exchange schemes and banish ill-suited paradigms. First establish what "primary use interoperability" really is, and how it might be successfully achieved – allowing health records and information to truly interoperate end-to-end, from point of origination and as an unbroken continuum to each ultimate point of access and use.