ONC Releases the Final 2016 Interoperability Standards Advisory

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The ONC 2016 Interoperability Standards Advisory has been published as scheduled in December 2015. And as was heralded by the Draft 2016 Interoperability Standards Advisory (ISA) released in the fall, the most substantial changes are in the format of the document. Concerns around maturity of standards and level of adoption have been addressed by addition of characteristics that are intended to provide a quantification of these characteristics for each listed standard. A total of six characteristics are included for each standard, which also reflect cost, regulatory requirements for the standard, and availability of testing. Read the HIMSS response to the 2015 ISA to further understand the changes between the 2015 and 2016 Advisory.

There is great risk of creating misleading concepts and misguided conclusions by assigning these characteristics to standards and implementation guides, particularly around maturity and level of adoption. Applying any characteristic to a standard as a whole is problematic at best and assigning values without strict criteria or data to substantiate those values is worse.

Standards maturity has become a buzzword of late, but trying to apply a two dimensional concept across all standards is ill advised. Such a single axis view of most standards is invalid in most cases, as both standards development maturity and implementation maturity are multi-axis concepts and are in most cases orthogonal to the adoptability and value of a standard for a particular use case. The rapid advancement of technology, in healthcare as well as other fields, along with innovative use cases associated with this advancing technology has led to new models of standards development and calls for new concepts of standards maturity. Standards are developed and adopted in parallel with innovative use cases that take advantage of new technology and the concept of a no longer has the meaning that it did in the past.

Balloting of standards as part of a consensus process remains fundamental to the idea of a standard, whether it is a messaging standard, a document standard, a terminology standard, or an implementation guide. But the process of stages of standards development progressing through draft standards that are piloted leading to a version that is normative or final is no longer viewed as the current process model. Indeed, the term DSTU (Draft Standard for Trial Use) is no longer part of the ANSI standards development model. I would suggest the current maturity model is something more akin to what I would term the "iPhone maturity model". Successive models are iteratively more mature and we have all come to understand that iPhone n+1 will have more functionality and more value than iPhone n. But we would hardly refer to iPhone n as a pilot. It is used in production and it has value. The HL7 FHIR® standard a case in point, as the first Release 1.1 already in production use for limited use cases and Release 2.0 expected to be in production use soon after its publication recently.

The value of a standard or implementation guide does not lie in the level of adoption of the standard as a whole, but rather in the implementation for a particular use case. Even if the value assigned to the adoption characteristic for a standard had some objective basis, it would have little relevance to the value of implementation for a particular use case. This is particularly true for Implementation Specifications which typically provide guidance on implementation of one or more standards for a particular use case. IHE profiles as an example may be adopted by an organization around the relevant use case because they provide value in terms of workflow efficiencies, improved care delivery, or

reduced cost, or other benefits. This is irrespective of the level of adoption across other organizations and whether the profile is considered to be in final form.

Members of the HIMSS Standards Advisory Task Force encourage dialogue in the community on this topic as we begin to address the ONC 2016 Interoperability Standards Advisory during the 90-120 day public comment period.   We look forward to your comments.