July 28, 2017

Via Submission to URL: https://www.healthit.gov/policy-researchers-implementers/interoperability/Proposed_Interoperability_Standards_Measurement_Framework_Public_Comments

Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
200 Independence Avenue SW
Suite 729-D
Washington, DC 20201

Subject: ONC Proposed Interoperability Standards Measurement Framework (Framework); published April 2017. URL: https://www.healthit.gov/policy-researchers-implementers/interoperability/Proposed_Interoperability_Standards_Measurement_Framework_Public_Comments

On behalf of the American Health Information Management Association (AHIMA), I am pleased to submit comments related to the ONC Proposed Interoperability Standards Measurement Framework.

The American Health Information Management Association (AHIMA) is the national non-profit association of health information management (HIM) professionals. Serving 52 affiliated component state associations including the District of Columbia and Puerto Rico, AHIMA represents more than 103,000 health information management professionals dedicated to effective health information management, information governance, and applied informatics. AHIMA’s credentialed and certified HIM members can be found in more than 40 different employer settings in 120 different job functions—consistently ensuring that health information is accurate, timely, complete, and available to patients and providers. AHIMA provides leadership through standardization of HIM practices, education and workforce development, as well as thought leadership in continuing HIM research and applied management for health information analytics.

AHIMA applauds ONC’s effort to “determine the nation’s progress in implementing interoperability standards in health information technology (health IT) and the use of the standards as a way to measure progress towards nationwide interoperability.”(p.3)¹

¹ Italicized text represents direct quotes from the Framework.
July 28, 2017
Page 12

AHIMA Comments

Our comments show that AHIMA is ready to work with ONC and the nation on the public-private approach to “achieving widespread interoperability.”

The following sections present our responses to the ONC questions (p.10).

We appreciate the opportunity to submit comments on Interoperability Standards Framework. We hope that you will continue to engage extensively with stakeholders on the Framework and we look forward to working with you to ensuring its successful implementation. Should you or your staff have any additional questions or comments, please contact me at pamela.lane@ahima.org; or (312) 233-1511 or Anna Orlova, Senior Director, Standards at anna.orlova@ahima.org; (312) 233-1140 if you have any questions.

Sincerely,

Pamela L. Lane, MS, RHIA
Interim Chief Executive Officer
AHIMA Comments on ONC Interoperability Standards Measurement Framework

GENERAL COMMENTS

Title
We would like to suggest a more precise title for the document. The current document presents two “measurement areas”/objectives such as

“1) Implementation of standards in a health IT product;
2) Use of standards, including customization of the standards, by end users to meet specific interoperability needs”

Those two items sound like survey questions that could inform the development of the Framework rather than a comprehensive Nationwide Interoperability Measurement Framework.

We suggest renaming the document by adding “building” or “toward” at the beginning of the title as follows:

Definitions
AHIMA is concerned that the document does not contain the formal definition of interoperability, interoperability standards, and interoperability measures. The terms of implementer and end user are used interchangeably throughout the document.

It is critical to define interoperability terms as well as the target audience for the successful implementation of the Framework.

In various comments that AHIMA provided to ONC in the past several years, we provided definitions and called for a nationwide consensus for fundamental terms including:

* Interoperability
* Interoperability Components: Semantic, Technical and Functional
* Interoperability Standards
* Use Case

Attachment A contains the list of AHIMA definitions for these terms.

SDO stands for Standards Development Organization not “Standards Developing Organization” as stated in the ONC Framework.

Interoperability Framework
In order to develop a measurement framework, there first has to be a framework to measure. The document refers to the ONC Interoperability Roadmap which itself does not contain a comprehensive interoperability framework.

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2 AHIMA Comments on the ONC Interoperability Roadmap. 2015. URL: http://bok.ahima.org/PdfView?oid=300817
It may be helpful to refer to the European Union (EU) Interoperability Framework below (Figure 1). Table 1 presents EU Interoperability Framework details by interoperability components [semantic, technical and functional (organizational and legal)].

**European Union (EU) Interoperability Framework**

![European Union (EU) Interoperability Framework](image)

**Figure 1. European Union (EU) Interoperability Framework**

**Table 1. EU Interoperability Framework Details by Interoperability Components**

<table>
<thead>
<tr>
<th>EU Framework Layers</th>
<th>Functional Interoperability (Legal and Organizational Regulation and Policies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Legal and regulatory framework</td>
</tr>
<tr>
<td>2.</td>
<td>Organizational policies for information exchange needs and collaboration</td>
</tr>
<tr>
<td>3.</td>
<td>agreements</td>
</tr>
<tr>
<td>4.</td>
<td>Collaborative care and workflow processes</td>
</tr>
<tr>
<td>5.</td>
<td>Semantic Interoperability (Content)</td>
</tr>
<tr>
<td>6.</td>
<td>Information content and exchange structures</td>
</tr>
<tr>
<td>7.</td>
<td>Technical Interoperability (IT Infrastructure)</td>
</tr>
<tr>
<td>8.</td>
<td>Applications and services: Transport and exchanges services</td>
</tr>
<tr>
<td>9.</td>
<td>IT Infrastructure: Communication protocols including security and privacy</td>
</tr>
</tbody>
</table>

**Interoperability Standards**

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The ONC Framework refers to the ONC Interoperability Standards Advisory (ISA) – a list of standards relevant to health information exchanges using certified EHR technology. However, we believe that providing the list of standards is not sufficient to achieving trusted information sharing. True interoperability cannot be achieved without ALL these standards being harmonized to work together in an interoperability standard.

Attachment A contains the interoperability standards definition and the list of standards that must work together to enable semantic technical and functional interoperability.

The ISO Technical Committee 215 Health Informatics has been working on developing an interoperability standard - Reference Standards Portfolio (RSP) of individual standards - harmonized for a particular use case. For example, in collaboration with DICOM (Digital Communication in Medicine), SDO, ISO/TC215 has been working on the RSP for Clinical Imaging.  

**Use Cases**

Interoperability is a provider-specific asset/need. He (she) has to get “the right information, in the right form, in the right time.”

The current ONC Framework offers to count the use of standards in the HIT products. The main question, however, is: do these standards get the provider “the right information, in the right form, in the right time”?

Because the needs of providers are case-specific, there is a need to reinstate in the US the basic computer science use-case driven approach - the foundational methodology for documenting user needs. During 2005-2009, the American Health Informatics Community identified 152 use cases for which interoperability specifications were developed by the Health Information Technology Standardization panel (HITSP, www.hitsp.org). Attachment A contains the list of use cases and interoperability specifications developed in the US as well as the list of use cases that are under the development by the European Union.

We believe that the ONC Framework will benefit greatly from identifying/applying the use cases as specific examples for the measures of interoperability/information sharing via the means of HIT.

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Developing the ONC Framework
Methods and frameworks durable enough to support real progress in the daily working lives of providers could make a real difference and are sorely needed.

We propose that ONC should develop the interoperability measurement framework around the six layers identified by the EU Interoperability framework under semantic, technical, and functional interoperability (Figure 1, Table 1) using harmonized individual standards (Attachment A, Table A1) in a context of specific US national priority use cases (Attachment A, Table A2) solicited from the various HIT stakeholders and selected via a consensus-based process. AHIC and EU use cases (Attachment A, Table A2) and Meaningful Use use cases can be considered/re-evaluated as a start.

Based on the methodology referenced above, those measures for semantic, technical, and functional interoperability can be truly invaluable. AHIMA would be very interested in collaborating with ONC on developing the interoperability measurement framework.

RESPONSES TO ONC QUESTIONS

1) Is a voluntary, industry-based measure reporting system the best means to implement this framework? What barriers might exist to a voluntary, industry-based measure reporting system, and what mechanisms or approaches could be considered to maximize this system’s value to stakeholders?

AHIMA believes that such a reporting system will not advance interoperability. Rather, it will provide information on what standards are in use in the HIT products which we already know from the annual public feedback on the ONC ISA. We are also concerned the reporting system will not assure that standards included in the ISA are used in a harmonized way as interoperability standards.

We also question whose responsibility it will be to report the measures. Vendors? IT staff at the organization, e.g. CIO? Providers, e.g., CMIOs? Public health agencies (local, state, and federal) must also be included as respondents.

Additional concerns include:

- If public reporting is implemented and the reporting is voluntary, what methods would be used to determine the completeness and accuracy of the reported items?
- The current standards tracked on CHPL are only a snapshot of items that can be monitored and the standards for CEHRT established to date only minimally assess the functionality and do not assess standardization of reporting effectively.
- Basic statistics would indicate that by not having a comprehensive reporting of all stakeholders the results would likely be skewed. Smaller organizations would likely have fewer resources and may not submit; therefore the stronger vendors with more robust functionality would be representing the entire environment.
• If the reporting is voluntary, at what point would it be statistically significant? What will the measurement be?
• If the reporting is not certified there is a concern that there will be variability in responses based on the perspectives of the responders. With this variability, there will not be accurate comparisons or ability to determine compliance.
• The enlistment of vendors and some of the large health organizations could be a preferred avenue to address concerns over reporting responsibilities; however, it is important that public health also have a seat at the table.
• Objective 1 seems designed to further the health IT developer / exchange network add-on subscription and membership programs. Given the lack of demand fostered by the costs of these add-on programs, positioning non-provider as gatekeepers may actually discourage adoption.
• Will there be any incentive for voluntary participation?

2) What other alternative mechanisms to reporting on the measurement framework should be considered (for example, ONC partnering with industry on an annual survey)?

Integrating the Healthcare Enterprise (IHE), with its Connectathon testing of interoperability standards, as well as the HIMSS Certification Program are the best ways to assure that the correct standards are used in HIT products to assure interoperability. Specific annual surveys can be developed around the IHE Connectathon and HIMSS Certification Program in collaboration with various stakeholders (professional organizations and SDOs) to track use and usability of individual standards and interoperability standards in HIT products.

ONC may partner with affected stakeholders on qualitative studies that identify whether and how entities actually are exchanging specific information and are able to use that information for business and clinical purposes. These studies will help identify impediments and successful strategies to resolve these impediments and document the benefits of interoperability.

3) Does the proposed measurement framework include the correct set of objectives, goals, and measurement areas to inform progress on whether the technical requirements are in place to support interoperability?

AHIMA is troubled that the proposed framework does not include the correct set of objectives, goals and areas. It is unclear what the survey will measure or how the two measurement areas are different from each other. AHIMA is also concerned that there are a series of unanswered questions including: who is supposed to do the reporting, who are the end users, and why is the customization of standards is brought up (customization introduces variability, which then hampers interoperability)?

More importantly, the ONC Framework and survey do not appear to address the issue of “Do we have the standards that we need?”

In our general comments above, we propose the alternative approach for developing the interoperability measurement framework as follows:
1. Develop a US Interoperability Framework (see EU Framework as an example)
2. Define US priority use cases (see Table 2 for US and EU use case examples)
3. Identify standards portfolios by use case and by framework components (see ISO/TC215 Standards\textsuperscript{11} as example)
4. Develop conformance criteria for interoperability standards testing and implementation
5. Develop the measures for interoperability based on approach stated in items 1-4 above

Additional concerns include:

- How objective 2 could be completed by the end users. Unless this became a mandate that included certification for the vendor and there is no extra cost in the deployment, organizations may not be willing to pay more to receive this functionality.
- Regarding “Track the use of standards by end users in deployed systems (i.e., which standards are most commonly being used and understand how often and in what manner standards are customized during implementation),” it would be of great value to also study WHY customization is occurring. Generally customization happens when a healthcare organization determines what is inherently available does not meet the workflow or information that is needed at point of care. Once baseline data is obtained there may be themes that will demonstrate gaps and omissions in standards that currently exist.
- Regarding measures: "volumes" of use should be reported in context of some denominator. We suppose a meaningful denominator would be "number of potential transactions," although we do not know how practical such a number is to articulate.
- The measures focus solely on generation of data, but not on receipt. We are not sure that successful receipt can be quantified, but if the reporting is voluntary, then it is reasonable to ask for a subjective assessment of "degree of successful “ingestion” <comprehension> of data sent," where "successful" includes both receipt and semantics (i.e., received as intended). See reference to qualitative studies above.

4) What, if any gaps, exist in the proposed measurement framework?

AHIMA suggests the following gaps exist in the proposed measurement framework:

1. Absence of definitions
2. Absence of US interoperability framework to measure against
3. Absence of US priority use cases to measure the interoperability usability (outcomes) against
4. Absence of the list of standards that are needed to support specific user needs in the use case, so it is not known what standards do we have versus what standards do we need to support clinical needs in HIT products
5. Limitation of ONC ISA that contains the list of standards but not the harmonized interoperability standards list to be implemented as a package in the HIT products to be interoperable

6. Absence of national conformance criteria for interoperability standards testing and implementation to address/minimize “variability of standard implementation”

7. Focus on how to measure (survey) without the clear metrics of what to measure

5) Are the appropriate stakeholders identified who can support collection of needed data? If not, who should be added?

No, AHIMA is concerned that the target audience for the proposed survey is not clear. (See comment above on who is supposed to report the measures? Vendors? IT staff at the organization, e.g. CIO? Providers, e.g., CMIO? Public health agencies (local, state and federal) have to be included as respondents.)

We suggest that the selection of "health IT developers and exchange services" as the most reliable data holders is unwise. Should such stakeholders be identified as the most reliable data holders, it could further drive these parties to create various added layers of fees and memberships to further the "data holding" mission they perceive the federal government to be tasking them to fulfill. The added layers of fees and memberships sought by health IT developers and exchange services only defer and suppress standards implementation and use. For example, it is not unusual to find a single provider asked to pay $1,000 or more each month to join a "preferred exchange service," or to ask their health IT developer to activate some "preferred standard."

AHIMA suggests, other stakeholders should include professional associations (American Health Information Management Association, American Hospital Association, American Medical Association, American College of Surgeons, American Academy of Pediatrics, Medical Group Management Association, American Osteopathic Association, and the Joint Public Health Informatics Task Force) and many others who represent clinical user perspectives.

6) Would health IT developers, exchange networks, or other organizations who are data holders be able to monitor the implementation and use of measures outlined in the report? If not, what challenges might they face in developing and reporting on these measures?

Many organizations have reported not utilizing exchange because they have received data that is unreadable, cluttered, containing extraneous information that is not needed, and not consumable.

The stakeholder list has to be expanded to include professional associations (see above) and SDOs. The latter may conduct their own studies on use and usability of their standards.

7) Ideally, the implementation and use of interoperability standards could be reported on an annual basis in order to inform the Interoperability Standards Advisory (ISA), which publishes a reference edition annually. Is reporting on the implementation and/or use of interoperability standards on an annual basis feasible? If not, what potential challenges exist to reporting annually? What would be a more viable frequency of measurement given these considerations?

An important question that should be addressed is how soon after ONC receives the information will the results be available? Timeliness of the data would make it more meaningful.
In other words, why wait for an annual survey? Why not enable continuing feedback on the standards use via online tools? Do we need to wait a year to declare that the standard should not be used? How much damage could be done when using that standard in the product during the year? Again, we suggest that ONC review IHE Connectathons results which report problems with existing standards within a week after the event putting standards developers to work to fix the standard.

8) Given that it will likely not be possible to apply the measurement framework to all available standards, what processes should be put in place to determine the standards that should be monitored?

AHIMA questions why it would difficult to apply the measurement framework to all available standards. The purpose of having the Interoperability Measurement Framework is to ensure the end users (clinicians) expectations in HIT products are met. With the proper standards harmonization methodology, robust interoperability components and supporting standards harmonization/testing/certification infrastructure, interoperability is achievable. See AHIMA’s proposed steps in question #3 to make this happen. Most importantly, the provider and public health communities should be engaged in this part of the conversation to assist with prioritization of what information will be truly valuable to be shared and integrated, i.e., setting up the US priority use cases.

9) How should ONC work with data holders to collaborate on the measures and address such questions as: How will standards be selected for measurement? How will measures be specified so that there is a common definition used by all data holders for consistent reporting?

We recommend that ONC clearly define “data holders.” We believe this requires additional clarification as “data holder” could be construed broadly. For example, each patient is now a data holder.

To select standards for measurement, we recommend that ONC launch a public-private partnership, similar to HITSP in 2005-2009, and re-instate the HITSP standards harmonization methodology as follows:

1. Identify priority business cases and interoperability use cases
2. Define interoperability needs and measures by use case
3. Select standards to support the use cases
4. Harmonize selected standards by addressing the gaps and overlaps
5. Develop interoperability specification – an assembly of harmonized standards that will work together to address use case interoperability needs
6. Test interoperability specification and improve standards as needed
7. Certify interoperable standards-based products
8. Measure the interoperability outcomes against the metrics developed in #2

10) What measures should be used to track the level of “conformance” with or customization of standards after implementation in the field?
The customization of standards is constantly brought up in various questions. What does ONC mean by “customization of standards after implementation”? Customization is happening today due to the lack of the use of standards in HIT products. Customization will phase out when the standards-based HIT solutions replace current ones.

Table 4 presents proposed measures for semantic, technical and functional interoperability by standards type. In order to implement these measures, ONC should collaborate with the industry to guide the development of the interoperability standards testing tools, e.g. IHE Connectathon’s tools.
<table>
<thead>
<tr>
<th>HIT Standards Categories</th>
<th>Examples</th>
<th>Examples of Interoperability Measures</th>
<th>Method of Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Semantic Interoperability</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Standards</td>
<td>Vocabularies and terminologies (e.g. ICD, SNOMED, LOINC)</td>
<td>Valid codes and mappings</td>
<td>HIM Mapping Audit</td>
</tr>
<tr>
<td>Information Content Standards</td>
<td>Reference information models (RIMs), templates, datasets</td>
<td>Valid content</td>
<td>IHE Connectathon Object Checker</td>
</tr>
<tr>
<td><strong>Technical Interoperability</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information Exchange Standards</td>
<td>Message-based, structured document-based, e-mail-based standards, IT standards</td>
<td>Valid content successfully delivered</td>
<td>IHE Connectathon Integration Testing</td>
</tr>
<tr>
<td>Identifiers Standards</td>
<td>National Provider Identifier (NPI)</td>
<td>Valid record components are found and assembled</td>
<td>IHE Connectathon Integration Testing</td>
</tr>
<tr>
<td>Privacy and Security Standards</td>
<td>Access control, consent directives, other</td>
<td>Correct information is available to those who need to know</td>
<td>HIM Release of Information Audit</td>
</tr>
<tr>
<td><strong>Functional Interoperability (Organizational and Legal)</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Functional Standards</td>
<td>Procedures, work processes (workflow, dataflow), checklists, use cases</td>
<td>Correct information is available to those who need to know in a right time and form</td>
<td>HIM Compliance Audit</td>
</tr>
<tr>
<td>Business Standards</td>
<td>Guidelines, best practices</td>
<td>Information supports business needs</td>
<td>HIM Compliance Audit</td>
</tr>
</tbody>
</table>
Attachment A: AHIMA Definitions

Interoperability. AHIMA supports the HL7 definition of interoperability as follows:

"Interoperability" means the ability to <capture, manage*>, communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks in various settings, and exchange data such that clinical or operational purpose and meaning of the data are preserved and unaltered. 12

Levels of Interoperability. HL7's approach to interoperability is based on the following three interoperability components (pillars):

1. Semantic interoperability—shared content
2. Technical interoperability—shared information exchange infrastructure
3. Functional interoperability—shared rules of information exchanges, i.e., business rules and information governance ("the rules of the road").13

The European Union Interoperability Framework developed in 2015 is consistent with the technical, semantic, and functional (organizational and legal) components of HL7 interoperability components (Figure 1, above).14,15

Interoperability Standards are special products of standards harmonization activities — a meta-standard (standard about standards), an assembly of standards, interoperability specifications, interoperability guidelines, reference standards portfolio, etc.— that define how individual standards have to work together to enable interoperability between information systems for a specific healthcare domain (care coordination, radiology, laboratory, pharmacy, data reporting, population health, etc.). Interoperability standards are harmonized and integrated individual standards constrained to meet healthcare and business needs for sharing information between organizations and systems.16

The term interoperability standards was introduced in 2005 by the Health Information Technology Standards Panel (HITSP, http://www.hitsp.org).

Table A1 presents the list of individual standards categories by interoperability components.

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13<Capture, manage> were added by AHIMA to the HL7 definition.


True interoperability cannot be achieved without ALL these standards being harmonized to work together in an interoperability standard.

The ISO Technical Committee 215 Health Informatics has been working on developing a Reference Standards Portfolio (RSP) of individual standards harmonized for particular use case. For example, in collaboration with DICOM (Digital Communication in Medicine), SDO, ISO/TC215 has been working on the RSP for Clinical Imaging. ¹⁷

**Use Cases**

We believe that the ONC Framework will benefit greatly from identifying/applying the use cases as specific examples for the measures of interoperability/information sharing via the means of HIT.

During 2005-2009, the American Health Informatics Community identified 152 use cases for which interoperability specifications were developed by the Health Information Technology Standardization panel (HITSP, www.hitsp.org). Table A2 presents the list of use cases developed in the US and European Union.

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<table>
<thead>
<tr>
<th>HIT Standards Categories</th>
<th>Examples</th>
</tr>
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<tbody>
<tr>
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<td>Guidelines, best practices</td>
</tr>
<tr>
<td>Breakthrough (Business Cases)</td>
<td>EU Antilope Project Business Cases</td>
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<tr>
<td>EHR laboratory result reporting</td>
<td>Laboratory</td>
</tr>
<tr>
<td>Biosurveillance</td>
<td>Referral and discharge reporting</td>
</tr>
<tr>
<td>Emergency response</td>
<td>Patient summary</td>
</tr>
<tr>
<td>Consultation and transfer of care</td>
<td>Multi-disciplinary consultations</td>
</tr>
<tr>
<td>Medical home</td>
<td>Participatory healthcare (chronic diseases)</td>
</tr>
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<td>Remote monitoring</td>
<td>Telemonitoring</td>
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<td>Radiology</td>
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<tr>
<td>Medication management</td>
<td>Medication</td>
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<td>Maternal and child health</td>
<td>Neonatal care management</td>
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<td>Immunization</td>
<td>Immunization</td>
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<td>Consumer empowerment</td>
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<td>Patient –provider secure messaging</td>
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<td>Public health case reporting</td>
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<td>Newborn screening</td>
<td></td>
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<tr>
<td>Clinical research</td>
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19 European Union (EU). Antilope Project. URL: [https://www.antilope-project.eu/front/index.html](https://www.antilope-project.eu/front/index.html)
20 eStandards. eHealth Standards and Profiles in Action for Europe and Beyond. Quality in Interoperability: Contribution to the EU eHealth Interoperability Framework. Deliverable D2.1. Extension of the eEIF: Five New Use Cases URL: [http://www.estandards-project.eu/eSTANDARDS/assets/File/estandards_D2_1%20Extension%20of%20the%20eEIF%20Five%20New%20Use%20Cases%20V1_3.pdf](http://www.estandards-project.eu/eSTANDARDS/assets/File/estandards_D2_1%20Extension%20of%20the%20eEIF%20Five%20New%20Use%20Cases%20V1_3.pdf)