Implementer Leader/Topic Plan Template

1. Use Case Driven Approach to C-CDA Implementation Guides
2. When creating an Implementation Guide without an Use Case it is difficult to know how to use the specification.
3. I am going to present real examples of using an Implementation Guide with and without a good Use Case and the resulting outcomes.
4. I have examples of using the eICR spec without a clearly defined Use Case and with a clearly defined Use Case and outcomes for both.
5. Prior to this meeting, please review the IG Quality Criteria.
6. New IG Quality Criteria will be added that all IG’s will include Use Cases. Implementers will be introduced to the new IG Quality Criteria.

A Tale of Two Projects

eICR – Digital Bridge Project
- Initial Implementation of eICR
- Generalized the implementation criteria
- Triggering was vague
  - Initial process was manual
  - A method for maintenance was becoming unwieldy
- Submission
  - Another manual process
- Content
  - Lacked clarity around required, recommended, and optional content

elCR – CDC Covid Reporting
- Used the elCR IG for COVID-19 reporting
- Defined a specific use-case for which this IG would be used
  - Specified what criteria should trigger the use-case
  - Specified when the use-case should be triggered
  - Specified what content was needed
  - Specified how to transmit the content back for public health reporting
- Byproduct
  - Created a solvable problem that can be used for additional public health reporting conditions
C-CDA standards-based development

At what point of non-compliance does the standard cease to be ‘standard’?
- When I stepped into IP Development from Consulting 5 years ago, we were still trying to correct issues with C-CDA r1.1 for MU2 and then had to code C-CDA r2.1 for MU3 which included new document templates.
- We had to develop some ITI tools.
- There was also a project for eICR.
- It was a mess.

None of this takes into account any of the tools that the teams developed for clients to manage their templates.
This also does not account for any of the effort determining how we needed to handle these documents once they were created.

Electronic Initial Case Reporting (eICR)

We started this work over two years ago
We developed to the eICR standard
We have been working with the standard for over two years.

The solution has been deployed to our customers.
A technically accurate solution. It was not easy to deploy.

We also did some work on FHIR for update mechanisms.
Create the development team to build the solution
Define a rollout model for a rapid deployment
Define a cloud-based approach for broad rollout vs. client-by-client rollout.

Electronic Initial Case Reporting (eICR) – COVID-19 Use Case

Set up contact from CDC
Work to adopt for COVID
Set up Case
Start Case
Define teams
Create the initial case data
Define a critical infrastructure dashboard

Implications for HL7 C-CDA Implementation Guides

- Exacting standards vs. limiting innovation
- Collecting, Storing & Processing of Documents
- Storytelling Power of C-CDA

Subjective, Objective, Assessment, Plan (SOAP) model

**SOAP**

- **Subjective**
  - Basic CCD – at check-in; demographic; patient states
- **Objective**
  - A more complete CCD – after any provider inputs their findings; anything the provider discerns or observes during their visit with the patient either from instrumentation, viewing, listening, some other form of sensing, or problem data
  - History & Physical
- **Assessment**
  - Discharge Summary – After a visit, the provider’s final assessment, including diagnosis.
  - Procedure Note/Operative Note
- **Plan of Treatment**
  - Care Plan – A care plan document the provider creates with goals, procedures, instructions, other follow-up

Good Examples of Use Cases

- Healthcare Associated Infection
  - One of the most successful CDA products
- Last IAT – topic came up repeatedly…
  - John D’Amore’s “Life to Death in C-CDA”
  - Linda Michaelson’s “Payer Section”
  - Emma Jones “Clinical Notes”
Quality Criteria

In our Quality Criteria, we have:
- Title Page, Templates, Inheritance & References, Value Sets, Examples, Extensions
- And then: Components of the final publication package
  - Criterion - The Implementation Guide
  - Criterion - At least one file containing a conformant sample CDA document.
  - Criterion - Extension schemas (where applicable) should be present or pointed to.
  - Criterion - Automatable Validation rules (e.g. schematron, Java code, etc.)
  - Provide validation, either on a website or stand alone tool, for templates contained in an
  - Option, provide the test package used to validate the tool.
  - Nowhere do we have Criteria for Use Cases

Where do we go from here?

As an implementer, we need to make sure we have a solid use case in place before we develop with a standard. To that end, it is inherent on the implementer community to share relevant use cases with HL7 to inform not only new template design and Implementation Guide Documentation, but also to provide context for existing guides. As a member of HL7, I would personally like to see more of that included in the Implementation Guide. I do not believe it needs to be dictated that a template mandates a specific use case, but I do think we could do more to identify the how & when portion of use cases, or at least provide good example use cases.

Motion for Consideration

Motion that the IG Quality Criteria be updated to include specifics of one or more use cases that would be relevant for the IG.

Furthermore, I would add that the SDWG provide guidance on what constitutes this Use Case criteria. (e.g.)
- A description of the Use Case
- A well-defined example
- Defining how/when it will be used
- A process flow from beginning to end