AEGIS.NET, INC. (AEGIS)

Since 1996, AEGIS has provided trusted advisory leadership and support to its customers. In 2008, AEGIS implemented a process-driven methodology that reflects the best practices of Deming, CMMI, ITIL, and ISO 9001/20000-1/27001. This is called the “AEGIS Shield Methodology,” and it underpins the company’s disciplined approach to deliver maximum value that is scalable and repeatable. Healthcare interoperability thought leaders for 15+ years, the AEGIS Health IT team employs the AEGIS Shield Methodology, along with Touchstone, its HL7® FHIR® validation ecosystem, to help teams deliver FHIR integrations on time and on budget.

Goal

To change the Context of Testing: Integrating testing disciplines into HL7 FHIR Implementation Guide creation to improve FHIR implementations and resulting interoperability

Opportunity

To demonstrate the value of applying the AEGIS Shield Methodology to infuse a testing mindset and employ a robust and collaborative testing approach throughout the lifecycle of a FHIR Implementation Guide

Project

The Problem

As the FHIR implementation community scales, the barriers to consistently producing interoperable solutions using FHIR become more prevalent. Implementer effort required to interpret FHIR Implementation Guide (IG) content grows exponentially as the community grows and teams try to implement multiple FHIR use cases.
The need for clear requirements is not unique to FHIR (nor to healthcare); creating crystal-clear requirements that minimize the need for interpretation is universally difficult. In healthcare, ambiguous requirements are barriers to interoperability and pose significant risks to patient safety. The industry needs to minimize ambiguity in the FHIR IG language to realize the full potential of FHIR adoption, support interoperability and preserve the safety of patients.

Despite the best efforts of IG authoring teams, most FHIR IGs require active interpretation by implementers. Needing to guess what requirements authors really meant is a recipe for implementations that do not talk to each other.

FHIR IGs lack consistency in how requirements are expressed. Some have a list of “SHALL” statements that are easy to spot; others have explicit and implied requirements scattered throughout the document.

**Hypothesis**
Applying the “How do we test this?” thought processes to IG content will result in clearer IG requirements and improve the implementation process.

Asking this question causes the team to think about IG content in a fundamentally different (and deeper) way than the default state of describing how they envision system implementation.

In both cases, the team describes what they want, but having to answer the “How do we test this?” question forces the team to concretely describe what they mean, resulting in a clear path for implementers by providing them with requirements that require little (or no) interpretation.

**Approach**
For this case study, AEGIS looked at FHIR implementation guides in various stages of development and applied a rigorous analysis process, along with close collaboration with IG authors and stakeholders to identify testable requirements.

Standardizing how an artifact is tested requires an iterative testing approach that shows the link between each part of the process. The test approach outlines the step-by-step process from requirement gathering to executing a test script.
A well-articulated and executed test approach ensures a consistent method of testing the IG before publication and supports more interoperable implementations. The test approach includes:

Selecting the Source Artifact, e.g. an IG

- Analyzing the requirements in the source artifact (the requirements act as the starting point for the testing process)
- Developing test cases from the requirements
- Obtaining approval from the artifact author/technical lead on the developed test cases
- Creating test scripts from the approved test cases
- Quality Assuring (QA) the test scripts
- Deploying the test scripts for public consumption
- Calibrating the test scripts based on feedback from the community of users

Incorporating a testing approach into the IG authoring process results in published IGs that have gone through the necessary rigor to ensure requirements are clearly defined. Clearly defined requirements reduce the ambiguity of implementation. Consistency of implementations improves interoperability.

Findings
Using the Shield Methodology test approach, AEGIS identified clear-cut requirements as well as those that were vague and left to interpretation. Test cases were developed based on objective requirements, and for those requirements that were more subjective, feedback was provided to the IG authors via the HL7 JIRA.
system. Once the test cases were approved, the necessary technical details needed to support the testing methodology were defined and test scripts were written, QA’d, and deployed for further use and testing by the community. This entire process provided a testable and replicable path for implementation as well as an insight into those IGs where requirements were confusing, or lacking.

Incorporating a test approach into IG development provides an extra level of validity, further helps identify and refine requirements, and generates valuable test artifacts for the community of IG implementers. This level of validation provides the needed proof that the IG can be operationalized.

Implementation of any solution, particularly those that involve complicated systems, presents a prioritization, resource, and financial risk to an organization.

Identifying and incorporating ways to accelerate the adoption and implementation of published IGs is fundamental to the goals of HL7, the health IT community, and most importantly patient safety. The goal of producing readily implementable IGs in a consistent way furthers interoperability, reduces implementation burden, ensures patient safety, and brings additional value to the work being done by HL7 and the community of dedicated volunteers.

Moving Forward

Supporting and utilizing a testing approach requires a shift in the way IGs are developed, balloted, and implemented.

By changing the context of testing, the industry will drive the shift forward. This will require short- and long-term planning and strategies to ensure the testing activities support the future direction of FHIR IGs.

For example, validating that FHIR implementations are “Continuously Interoperable” by incorporating testing into operating practices will minimize interoperability entropy as time passes. IGs will need to be validated in the context in which they will be operating, which in some cases will require that IG implementations be stitched together in a continuous operational workflow.

This drives the need for testing across the healthcare continuum, and that evolutionary advance will require testing with simulated ecosystems.

The fact that we can anticipate these sophisticated scenarios is an exciting reminder that the HL7 FHIR standards are a game-changer for healthcare interoperability.

For additional information about improving the FHIR IG development process, check out Implementable FHIR IGs: The Missing Manual.