Technical Barriers to HL7® FHIR® Solutions Scalability

The FHIR at Scale Taskforce (FAST) has identified a series of technical barriers that need to be addressed in order to scale Fast Healthcare Interoperability Resources (FHIR) as a ubiquitous technology that enables wide-scale clinical information exchange between providers, payers, and other stakeholders. These barriers include a lack of a FHIR endpoint locator, lack of common authentication and authorization approaches to ensure appropriate patient privacy, gaps in the ability to bridge patient identity across stakeholders, and a lack of industry wide governance and versioning for FHIR Application Programming Interfaces (APIs).

The FAST initiative brings together a highly representative, collaborative group of motivated healthcare industry stakeholders and health information technology experts who are working to analyze and synthesize the available solutions across the industry, and to further identify infrastructural and scalability gaps and barriers, with the objective to propose a suite of solutions that will accelerate FHIR adoption at scale.

The following technical barriers identified by the FAST team were found to impede the adoption of FHIR at scale and will be the basis for FAST-proposed scalability solutions:

1. Directory Services
2. Identity
3. Security
4. Testing, Conformance, & Certification
5. Versioning
6. Scaling
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DIRECTORY SERVICES

1. Endpoint Identification: No current standard or implementation provides a generally available method to find all FHIR endpoints and their associated capabilities (e.g., beyond just the capability statement).

2. Endpoint Characteristics: Currently no standard or implementation specifies and supports additional endpoint attributes (i.e., trust framework, authentication requirements, FHIR version(s), supported services, certification, and testing).

3. Currency & Accuracy of Directory Endpoint Information: Currently there is no agreed upon source or standard process for maintaining endpoint information and validating its accuracy. This creates uncertainty and the potential for inconsistent endpoint directory information.

4. Restricting Access to Endpoint Information: Certain endpoints may not be generally available (regardless of authentication) and any directory-service may need to restrict discoverability for those specific endpoints. This may be necessary to minimize attacks on these endpoints by malicious third parties.

IDENTITY

1. Use of Different Identifiers: Patient identifiers such as medical record numbers and insurance IDs are not meaningful beyond the boundaries of a specific organization, limiting their value in identity matching across organizations. Similar challenges exist with provider identifiers, though perhaps due to scale, this is a potentially less complex problem.

2. Cross-Walks Are Not Scalable: Small groups of organizations may exchange patient and provider rosters, thereby building a common and perhaps shared cross-walk for identifiers. This solution is not scalable at the national level, and real-time identification may be impacted by data latencies in maintaining cross-walks.

3. Custom Identity Matching Processes: Most organizations utilize custom processes, and any proposed solutions from FAST will need to accommodate this diversity.

4. Minimum Data Set: Reliably identifying patients across organizations may require a minimum set of data to be included in the transaction, which may not be available for all use cases.

5. Privacy: Considerations must be applied in developing recommendations on data to be returned in responses, including error messages.

6. Liability: Overlaps, overlays, duplicate records, and incorrect matches could require legislative consideration beyond technical recommendations.

7. FHIR Identifiers: Implementation Guides and FHIR resources may make patient identifiers needed to enable identity cross-walks optional.

SECURITY

1. Authentication & Authorization: Limitations on our ability to ensure, in a scalable way, that the requestor of information using a FHIR-based information exchange is appropriately authenticated and has the authorization to view and use the data requested.

2. Scale of Existing Processes & Tools: Techniques such as Open Authorization (oAuth) are widely accepted, but it is not clear how to scale and administer for broad use of FHIR.
5. Profiles That Are Version Specific: Profiles and implementation guides are version specific. This creates complexities when supporting multiple versions of FHIR and migrating from one version to the next, leading to substantial implementation issues.

6. Complexities Created by Extensions: A new version of FHIR introduces new content that impacts the definitions of the extensions or how the extensions are used in Implementation Guides/Resources.

7. FHIR Versioning of RESTful APIs May Differ From General Industry Definitions: Because FHIR uses slightly different definitions for versioning than the standard for RESTful APIs, it creates additional complexities for organizations that are implementing and supporting both FHIR API and other RESTful APIs not based on FHIR.

1. Maturity of Requirements: FAST team use case development identified a number of requirements in order to scale FHIR-based solutions. To establish testing and certification of FHIR at scale, these requirements must be documented in a format that provides clear understanding of what should be tested and certified.

2. Lack of Minimum Level of Conformance: Multiple stakeholders with varying degrees of maturity participate in FHIR-based information exchanges. To ensure industry alignment, testing and certification of FHIR-based solutions at scale are contingent upon a defined baseline FHIR conformance as well as addressing the scalability barriers in the development of applicable FHIR Implementation Guides.

3. Tooling: FHIR implementation is a complex process that requires validation of several layers of specifications. Development of FHIR is often done with limited testing confined to the specific implementation guide. Often these tests do not include validation of base FHIR resources or do not establish adequate validation. Independent validation through automated tooling can ensure a higher degree of conformance.

4. Timing: Testing of FHIR clients and servers should happen early and often. Encouraging use of FAST requirements as guidelines throughout the systems development process (test driven development) will become the foundation for successful interoperability using FHIR.

5. Certification Governance: There is currently no governing body to grant certification or determine readiness. A methodology needs to be defined that specifies the steps to achieve certification, what or whom is being certified (i.e., FHIR implementation approach or participants, stakeholders, and intermediaries), and the frequency of recertification.

1. Multiple Versions & Production: Trading partners may need to support multiple versions of FHIR with no guarantee of backward compatibility across versions except for those resources which are normative. Regulatory recognition of multiple versions of FHIR creates further confusion and challenges.

2. Continued Evolution of Standard: Supporting new functionality creates timing and adoption challenges (e.g., lag time to support new operations). Since vendors may support different functions at different times, the capability statement becomes an essential part of determining current endpoint support for specific functionality.

3. Variable Adoption of the Standard: Vendors adopt support for the ability to read or read/write specific resources. Maintaining capability statements and periodically pulling/processing statements are challenges.

4. Using Different FHIR Versions for the Record for a Single Patient: Depending on architectural models deployed for receiving and storing data, multiple FHIR versions may seriously impact decision support or negatively impact the ability to communicate the complete record to another entity.

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1. Testing, Conformance, & Certification Gap Analysis
Testing, Conformance, & Certification Solutions

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SCALING

1. **Multiple Current Interoperability Models:** Hybrid exchange models (e.g., spoke/hub, direct connections/point-to-point, and regionally interconnected spoke/hub) create challenges in adopting standards for scaling FHIR and implementing consistent approaches such as authentication, endpoint detection, standards for matching, and end-to-end performance.

2. **Lack of Predictability and Response Times:** Scaling real-time transactions requires infrastructure that may not be currently available through existing intermediaries. The lack of predictable end-to-end response time limits specific use cases where providers require a response prior to proceeding with diagnosis or treatment. Some intermediary models do not support end-to-end synchronous real-time applications. The industry will need to adopt synchronous FHIR front-end interfaces and migrate to near real-time backend solutions.

3. **Record Location:** Lack of a national patient record locator service limits the ability to discover all records for a given patient in a distributed service environment. There is no current process for universally discovering endpoints either in general or for a specific patient.

4. **Anticipating Increase in FHIR-Based Volume:** There are currently no models to predict the volume of FHIR-based transactions as FHIR is adopted broadly in the ecosystem. This may lead to unpredictable scaling and performance challenges. Adopting real-time (RESTful) solutions to solve real-time synchronous FHIR scalability is required by the industry. Payers and providers need to increase services (and related perception of reliability) to support significant increase in real-time transactions embedded in the clinical workflow.

Scaling Gap Analysis
Scaling Solutions