'Fixed with FHIR' Technical White Paper

by GigaTECH, LLC

Surfacing payor-based recommendations into the clinical workflow at the point of care.



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Introduction

The purpose of this paper is to document our team's experience using the Fast Healthcare Interoperability Resources (FHIR[™]) standards framework with our client. For this project GigaTECH architected and delivered a data driven Decision Support System (DSS) solution. With any modern health information exchange and interoperability endeavor the latest versions of FHIR is viewed as a compulsory component. Our client, an insurance company (the payor), who's initial FHIR-based DSS pilot presented 'payor-preferred' next best recommendation(s) at the point of care for patients diagnosed with Diabetes Mellitus (or more commonly known as Type 2 Diabetes). Critical to this effort was ensuring that the 'payor-preferred' recommendations were integrated into the clinician's conversations with the patient without increasing the clinician's burden or disrupting their preferred clinical workflow. The adoption and use of the FHIR standard to design, develop, and implement this pilot offered our team a secure and reliable means of developing a solution within a diverse healthcare information ecosystem. Moreover, architecting and implementing a data driven FHIR-based DSS for our client supports the future integration of 'next best action' recommendations into other Care Plans related to Chronic Care Management within their organization.

Our client had previously invested in developing an internal Healthcare Recommendation Engine (HRE) based on their comprehensive electronic view of the insurance member. This HRE could receive specific clinical information about a patient and would recommend the 'next best actions' based upon the HRE's analysis of its knowledge-based repository. The issue was that the payor's current business processes had, upon receiving recommendations from their HRE, sent unsolicited emails to the insurance member (patient) offering enrollment into a web-based therapy (WBT) program. This email campaign had poor patient response rates. The WBT program provides subscribers (patients) an online, customized diabetes treatment plan which is accessed on-demand from the patient's mobile device (or PC). The payor found that "92% of program participants with a baseline A1C of 9.0% or greater improved their A1C by an average of 2.7 points upon follow-up". This customized treatment plan has proven to be highly effective, however, due to its low enrollment rates, its effectiveness was limited to a small number of members with this diagnosis.

The payor led another analysis which proved that if a doctor, while discussing treatment options, were to recommend this online treatment plan, it would drastically increase enrollment rates. Our approach for this pilot was to give visibility to the clinician of this treatment option in a seamless, secure, and non-intrusive way at the point of care. GigaTECH, using our Prometheus[™] toolkit, architected a solution employing the <u>FHIR Clinical Reasoning</u> module leveraging the FHIR specification, the patient-view <u>CDS-Hook</u>, and a next best action <u>SMART on FHIR</u> enrollment application. Our solution integrated directly into the clinician's Electronic Health Record (EHR) display and passively presented the formulated recommendation. Once implemented, clinicians who used the enrollment SMART on FHIR app enrolled their patients over 55% of the time which resulted in the payor realizing a 400% increase in next best action enrollments. GigaTECH continues to work with our client to create more <u>FHIR Plan Definitions</u> and expand this capability for other HRE recommendations of next best actions. This interoperability between





automated clinical reasoning and advanced technical integration provides better and more consistent healthcare outcomes.

Defining the Problem

GigaTECH's approach for this pilot, was to methodically guide all stakeholders through an implementation lifecycle which started with a stated objective and resulted in a proven solution. A blended team methodology ensued, whereby clinicians, technicians, and administration unified through collaboration channels to build upon goals and objectives sought with this endeavor, all contributing to our ultimate success. GigaTECH's objectives were achieved through engineers leveraging our Prometheus toolkit and its five (5) distinct phases. Each phase of Prometheus is comprised of policies, services, and tools which were codified in a <u>FHIR Implementation Guide</u> (IG) describing the solution for all audiences. The result of Prometheus' 5 phases of execution was an EHR-agnostic FHIR-based healthcare data interoperability solution comprised of a payor CDS-Hook service, payor SMART on FHIR enrollment app and payor FHIR façade of their proprietary HRE data. A solution responsive to the payor's engagement strategy, operational environment, ubiquitous data availability, security, patient privacy, and complete with comprehensive documentation. The 5 distinct phases of Prometheus are represented in the graphic below:







Explore:

During the Explore phase, we help stakeholders define and document their interoperability requirements. Specifically, we identify the key data sources and their method of interface within the payor, provider, and patient model. We identify the key stakeholders, most importantly, the clinicians who often end up being the actual end users. We work with the client to identify their success measures, and any relevant metrics for the program. For our pilot these metrics were a mix of development and business measures such as cycle time, member enrollment percentage, and percentage of providers that use the application and recommend enrollment.

We identified the main issue(s) that needs to be overcome, which for our 'Fixed with FHIR' case study was displaying a proprietary store of recommendations to the clinician, for consultation with the patient who has been diagnosed with diabetes mellitus. This, noted as the 'next best action' is communicated within the medical community as leveraging evidence-based medicine and predictive analytics to improve health outcomes. The clinical recommendation our software displayed was derived by retrieving, in near real-time, the insurance benefit aligned with their specific insurance plan. Our engineering team took into consideration 'alert fatigue'. The term 'alert fatigue' describes how clinicians become desensitized to safety alerts due to the sheer volume of alerts presented. Our intent was to limit our impact to the provider's normal clinical workflow during the engagement process. Prometheus guidelines specify working within the boundaries of existing systems and data, such that we do not introduce more burden to the provider by attempting to have them learn a new product or move outside of their normal EHR system.

An output of this phase was a comprehensive backlog of user stories; derived through regular stakeholder engagements, documented business objectives, technical opportunities, and end-user workflow considerations. Documented business requirements are an input to subsequent phases within Prometheus, such as software development epics and user acceptance testing. As such, business requirements are specifically designed to provide critical solution objectives to support the next phase of development. For example, an overarching business objective for this client was: *"The payor seeks to surface next best action recommendations regarding a specific patient to the clinician during the encounter with the patient. This needs to be accomplished in an EHR agnostic manner while not requesting the provider to use a new system or understand the nuances of the patient's insurance. A clinician would then be able to request enrollment into the insurance-based benefit program with a single button click so as not to increase their burden."*

Architect:

This was our client's first foray with building and deploying a FHIR-based solution beyond the CMS Interoperability and <u>Patient Access Final Rule CMS-9115-F</u> (03/06/20). Through a series of 'customer engagements' we architected a Minimum Viable Product (MVP) that would serve as the basis for future FHIR-based solutions within their organization. In this case, our MVP centered around enrollment of patients into a next best action service that assists patients with the chronic disease of diabetes mellitus. Since this project was a greenfield capability, not relying on any previous business decision or





architecture, GigaTECH recommended a FHIR first approach. GigaTECH, leveraging the Prometheus toolkit, modeled the entire solution within a FHIR IG to showcase the system interactions for the clinician, EHR, payor CDS service, payor FHIR façade and payor SMART on FHIR enrollment application.

GigaTECH's FHIR architects designed a turnkey FHIR-enabled solution for this pilot where any EHR integrated with a payor defined patient-view CDS-Hook. This type of software enabled hook is specifically designed to be triggered when a clinician views a patient's chart within a FHIR-enabled EHR. Our FHIR architects also made use of the <u>clinical reasoning module</u> and US Core Implementation Guide (3.1.1 - STU3 Release US) to create a FHIR PlanDefinition resource for representing the overall recommendation for the diabetes mellitus patient population, supplementing our client's next best action database. The <u>PlanDefinition</u> resource allows for the definition of various types of plans as a sharable, consumable, and executable artifact of a pre-defined group of actions to be taken in particular circumstances. The PlanDefinition has an <u>\$apply</u> operation which allows the implementer to apply population level plan data to the context of an individual patient and create a care plan, represented by the <u>FHIR CarePlan resource</u>, for that individual. Clinicians now have immediate access to large samples of journaled treatments, specific to the patient's diagnosis, to aid them with continued care options.

GigaTECH FHIR architects worked with the payor and provider integration teams to define the alerting system within the EHR. With this pilot application, the Payor CDS-Hook service sent back the resulting next best action recommendation and alerted the provider using a passive alert. The passive alert notifies the provider directly from within the patient's EHR but in no way obstructs the provider's workflow. This allows the provider to take actions based upon patient dialog as opposed to forced steps through the application. In this case, the action that can be taken by the provider is to open a complementary SMART on FHIR application to enroll the patient in the diabetes mellitus management program provided by the payor.

The Next Best Action Decision Support graphic (below) provides a pictorial view of this interaction. GigaTECH employed a FHIR Façade Model to transform the payor based proprietary HRE data to FHIR for communication to the EHR. We performed a field-by-field mapping to verify compliance with the FHIR standard and ensured our solution remained EHR agnostic. The SMART on FHIR application was designed by GigaTECH's FHIR architects while the UI itself was developed by UI designers in collaboration with provider clinical champions and select end users, utilizing a <u>user centered design</u> (UCD) process. Our custom solution communicated the converted payor data to the CDS service and SMART on FHIR application as required. This provided the interface to our client's proprietary next best action database for diabetes mellitus.







Additionally, the SMART on FHIR application received insurance benefits data specific to individual patients. This was accomplished using a CDS-Hook standard application context approach for supplying contextual data from a CDS-Hook service to a SMART on FHIR application. Our SMART on FHIR application was designed to allow the provider to see relevant information about the patient with diabetes mellitus and then either enroll them into the diabetes mellitus monitoring program, decline the enrollment, or state that it was not medically necessary. FHIR interoperability was codified in FHIR profiles and code systems which defined the interchange. We defined all code systems, value sets, and profiles which govern this exchange and provided comprehensive documentation in a FHIR Implementation Guide (IG) for our client.

Create:

During software construction or the Create Phase, GigaTECH was tasked by the client to take a shared approach to solutions development. This approach enabled our team to train the client developers in FHIR implementation best practices. GigaTECH led the development of a standalone CDS-Service used for early proof-of-concept and integration testing with the EHR. CDS Services are notified by pre-registered triggering activities, or CDS Hooks, that contain context parameter data and are designed to provide a near-real-time response. GigaTECH established a pilot/development environment within our





custom-defined domain to create CDS Services and for data storage needs. We employed a '<u>continuous</u> <u>delivery'</u> based approach and used GitHub Actions pipelines making it possible to build and share workflows via reusable steps. These pipelines were configured to automatically deploy containers to AWS (Amazon Web Services) <u>Fargate</u>. Fargate is a serverless compute engine that eliminates the need to provision and manage servers. AWS Fargate allowed us to deploy and manage these containers in a secure pay-as-you-go environment. This approach allowed us to develop in parallel while the host production environment was being prepared. These resources provided a baseline for the functional and technical requirements for the development and testing environment that the client team used to create the resulting production CDS service.

GigaTECH created the SMART on FHIR application for enrollment into the insurance-based benefit program. Again, employing continuous delivery based on GitHub Actions pipelines which were setup to automatically deploy client-side code to AWS S3. AWS S3 provided us with a scalable environment with the security, compliance, and audit capabilities necessary for this project. All software development across this project was managed utilizing a <u>Scrum Methodology</u>, depicted in the following diagram.







We utilized a 1-week cadence for our sprints and regular demos which afforded our product team an opportunity to discuss: progress, tasks or stories which are more challenging and paused efforts which needed addressing. GigaTECH led integration testing using standard FHIR based sandboxes, such as those provided by CDS-Hooks.org and Logica-Health. We successfully performed integration testing to and from the provider QA endpoints as well as to and from the payor QA endpoints, culminating with all services being publicly available at our client's quality assurance (QA) endpoints. During the Prometheus Create phase, a number of products/services were created:

- AWS hosted CDS service for EHR proof of concept testing
- AWS hosted Smart on FHIR enrollment app
- Customer hosted CDS-Hooks service based on SMILECDR
- Customer hosted FHIR Façade which was built to call the restful API to MLS
- Customer hosted restful API layer to MLS
- Customizable development and test environments
- Secure, automated continuous deployment pipelines

The GigaTECH team created the initial test plan/scenarios for all services to be deployed within the production environment. The customer ensured synthetic data was available in each environment to run and execute the test scenarios. All products/services went through:

- Unit testing which had to be at least 85% coverage
- Proof of concept testing in the development environment
- Integration testing in the test environment
- Acceptance testing in the pre-prod environment
- Final deployment to the production environment

Again, utilizing Prometheus, GigaTECH designed the security framework protecting the interchange of PII and PHI data. While some advanced <u>FHIR exchange capabilities</u> were considered, such as the UDAP Cross organization access profiles, they were ultimately rejected based upon the current state of FHIR maturity for production level applications with those standards. Consequently, GigaTECH defined the exchange using the trusted certificate approach outlined in the CDS-Hooks specification and extended it to support a cross organizational SMART on FHIR application.

Implement:

Once the software was fully built and acceptance tested, GigaTECH worked with our client to roll out the resulting solution within targeted pilot locations. Pilot locations were identified early in the process and remained actively informed throughout the project. These pilot locations met the criteria of having a business need for the application, were active in providing initial and incremental requirements, provided UI suggestions, provided a clinical champion for continuous feedback and improvements, and agreed to collect usage statistics. The client's governance committee ratified the application prior to production implementation, validating the training plan and training delivery process, approving the deployment and acceptance checklists, and adding value to the process we identified for obtaining user feedback and Key Performance Indicators (KPIs) to be used for continuous process improvements.





Consistent with Prometheus principles, clear and inclusive communication was instrumental within our production implementation successes. The Provider offices knew when and why the application was being utilized, they were trained on its usage, and understood how to collect and communicate effectiveness statistics. They had a sense of ownership in the entire process and were eager to report on KPIs and workflow improvement suggestions. These pilot sites utilize various EHR instantiations and have slightly different workflow processes. This was also a criterion for pilot sites as to thoroughly test EHR agnostic application performance and usability. As expected, the application performed as advertised, increasing eligible patient enrollment into the diabetes mellitus program as a next best action over 400% from the initial baseline that was identified before our application roll out.

Our customer coordinated with their provider network from a technical standpoint deployment into production. They also coordinated with them from a business standpoint to ensure the provider network CDS governance committee was on board and signed off on the project. With GigaTECH's assistance and support, the customer:

- Built a training plan for the pilot site and pilot providers
- Performed training with the pilot site and pilot providers
- Built a deployment checklist
- Built an acceptance checklist
- Built a process to obtain feedback from the pilot providers and interviewed the pilot providers
- Built demos to inform both the provider network and client executive leadership
- Defined metrics and KPIs to collect and to capture feedback and success/failure rates of the services

A structured approach to coordinating the communications in and between the customer, stakeholders, development team, operations personnel, any additional sub-contractors and/or subject matter experts and the customers provider network was a critical component of our team's success.

Sustain:

With the pilot successfully implemented the focus has turned to supporting and maintaining the application currently in production. The GigaTECH team currently maintains a Tier 3 support role during the Sustain Phase, fixing any anomalies with the software, engaging in consulting/advising with stakeholders, training client developers, and architecting the next set of 'next best action' capabilities. Our client established a help desk capability specifically for this project, established a <u>JIRA board</u> for recording defects, collected project metrics and associated KPI's, trained new medical personnel with regards to application usage, and established a prioritization schema for process and capabilities improvements.

Through the Prometheus Sustain Phase, team GigaTECH has stayed in close contact with the pilot site personnel. We ensured the security aspects of the application continue to protect PII/PHI, tweaked our documentation when items were unclear to the various audiences' disciplines, hardened our configuration management approach, and provided suggestions for technology and capability





improvements. We also continued to learn from stakeholders about what their goals and objectives are for effectively managing the continued care for their patients. This is valuable input for the expansion of our application to best serve the next best action, and for the successful continuation of this platform for the many thousands of additional use cases within the medical ecosystem. Continued communication between our team, the client, and the pilot sites have identified areas for improvement and more importantly expansion and implementation of this technology. The need to continue exploring the possibilities inherent in extending this revolutionary capability for other use cases is obvious. Subsequently we've engaged this client to build upon our success by extending their foothold within these new capabilities to supporting 'next best action' involving nicotine cessation.

Summary

GigaTECH successfully delivered a data driven DSS solution which employed the FHIR R4 standard. The FHIR R4 standards contains both normative and trial use content. While normative content is backward compatible, trial use content may still change as those resources are honed by implementer support. To mitigate the risk of non-normative content changing, our solution adhered to existing IGs such as US Core, Clinical Practice Guidelines (CPG), and Clinical Reasoning. The solution presents 'payor-preferred' next best recommendation(s), based upon the patient's insurance benefits and provider type, and is delivered at the point of care for patients diagnosed with Diabetes Mellitus. The 'payorpreferred' recommendations were integrated directly into the clinician's EHR and clinical workflow to reduce any burden or disruption. GigaTECH's client, a healthcare insurance company, had minimal experience with the FHIR standard beyond the rollout of 21st Century Cures Act rule at 45 CFR 170.215 based FHIR API standards. Teaming with GigaTECH allowed our customer to take the concept of their Healthcare Recommendation Engine (HRE), in their proprietary format, and make that information available within any provider's Electronic Health Record (EHR) system.

The web-based Diabetes program, which is now recommended by the clinician at the point-of-care, provides patients an online, customized diabetes treatment plan that is accessed directly from a patient's mobile device or Personal Computer. The payor discovered that 92% of patients utilizing this program with a baseline A1C of 9.0% or greater improved their A1C by an average of 2.7 points. This customized treatment plan has proven to be highly effective. We architected and created a standards-based interchange for CDS Services between a payor and provider that was EHR agnostic and was put into production in less than 6 months from concept. Our approach was to give visibility to the clinician of this treatment option in a seamless, secure, and non-intrusive way at the point of care.

GigaTECH, using our proprietary Prometheus[™] toolkit, architected a solution employing the FHIR Clinical Reasoning specification built on top of the FHIR specification, the patient-view CDS-Hook, and a next best action enrollment SMART on FHIR application. Our solution integrated directly into the clinician's EHR display and passively presented this recommendation. Once implemented, the payor realized a 400% increase in next best action enrollments, and clinicians whose EHR used the enrollment SMART on FHIR app enrolled their patients over 55% of the time. GigaTECH continues to work with our





client to create more FHIR PlanDefinitions and expand this capability for the thousands of other HRE recommendations of next best actions.

Health Level 7® (HL7) Fast Healthcare Interoperability Resources® (**FHIR**) has been identified as the foundational standard for health data exchange, supporting the 21st Century Cures Act rule at 45 CFR 170.215. FHIR provides the data standards for internet data exchange via secure application programming interfaces (APIs), regardless of proprietary data formats or EHR sponsored operating systems. HL7, an international standards organization, also identifies the guidelines for healthcare organizations to share and process information between systems in a uniform and consistent manner. As the Cures Act, signed into law on December 13, 2016, becomes increasingly enforced, payors, providers, labs, pharmacies, and clinics are increasingly obligated to comply with patient's rights to ubiquitous access to their health information.

FHIR is a cornerstone to this revolutionary concept of healthcare data interoperability, it is and will continue to change the way healthcare professionals collaborate across medical domains and about the continued and coordinated care of individual patients. FHIR will also greatly enhance population health statistics, accelerate clinical research bringing effective treatments to market quicker. Additionally, FHIR allows federal compliancy with evolving laws and mandates while being less intrusive on existing data and infrastructure, provide for an easy means to share data within a mobile-friendly environment, and is an effective solution to data sharing within the healthcare ecosystem. GigaTECH has the knowledge and experience to guide your organization through FHIR discovery and implementation. Contact us to learn how we can assist in a productive and cost-efficient way.

