THE FHIR HIEDRANT

By

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CERTIFICATE OF APPROVAL

This is to certify that the Master's Capstone of

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.

Abstract

Background

Despite past attempts made to seamlessly integrate data from health information exchanges (HIE), utilization rates remain poor, as was demonstrated by a pilot study conducted at two busy emergency rooms in Indiana. The lack of functionality could be linked to the inefficiencies and workflow interruptions that occurred when users tried to access HIE data. Our goal was to find a software solution to these problems with the help of new Fast Healthcare Interoperability Resource (FHIR) specifications and Substitutable Medical Applications Reusable Technologies (SMART).

Methods

We developed an FHIR application called *FHIR HIEdrant* that could be launched with one click from within a clinician's normal workflow. The app automatically searches all outside medical records of patients appearing within the HIE and presents clinicians with the five most relevant data elements based on the patients' chief complaint. Our study of the app included a quantitative analysis of the longitudinal differences and a qualitative analysis of user feedback obtained through semi-structured provider interviews.

Results

During the development of the app, we encountered multiple roadblocks that caused project completion to be delayed from the initial estimate of six months to the actual timeframe of 18 months. Our quantitative analysis showed that the app increased HIE usage and our qualitative analysis gave us positive provider feedback and showed us different potential areas of improvement.

Conclusion

FHIR applications are a suitable means of integrating HIE data into an EHR workflow. The development and implementation of these applications de novo requires substantial up-front resources. These up-front investments can return improved HIE utilization.

The Problem

Health information exchanges (HIE) can potentially bring numerous benefits to healthcare systems, clinicians and patients (1)(2). These theoretical benefits, however, do not necessarily translate into practical gains (3). There are several reasons for this discrepancy, most importantly the fact that physicians do not use the HIE even if they have access to it. The goal of this capstone project is to further investigate the reasons for this failing.

This problem was discovered in our small-scale pilot study of HIE use in an emergency care facility in Indianapolis, Indiana. This study focused on the Indiana Network of Patient Care (INPC), the nation's largest inter-organizational clinical data repository and the primary platform supporting the Indiana Health Information Exchange (IHIE). The IHIE connects more than 100 hospitals, 14,000 practices and nearly 40,000 providers (4). Physicians access INPC through a Web-based platform called *CareWeb*. During a two-day study period in March 2017, we observed seven physicians over 17 hours delivering emergency care at both Eskenazi Health and Indiana University Health (IUH) Methodist Hospital, the two busiest emergency departments (>100,000 patient visits/year) in the city of Indianapolis. *CareWeb* was only accessed twice in a total of 70 patient encounters, despite its potential benefits (5). Based on interviews with physicians, we identified several barriers to HIE use, such as technical difficulties, time delays, having to leave the EHR to access *CareWeb*, as well as uncertainty about the presence and expected relevance of information.

Currently, clinicians most commonly access the information in an HIE by using a secondary system such as a Web portal, forcing them to interrupt their workflow. Even when the EHR automatically passes user credentials and/or patient contexts to the HIE application, the inherent disruptions have several negative consequences such as additional clicks and/or keystrokes, increasing the amount of time and cognitive effort needed to retrieve the desired information.

The goal of the FHIR HIEdrant project was to create a software solution to alleviate these problems.

Background

Local Infrastructure

The state of Indiana is home to a unique clinical informatics infrastructure. It is the location of the Regenstrief Institute and the Indiana Health Information Exchange, both of which are surrounded by a myriad of hospitals and healthcare systems.

The Regenstrief Institute in Indianapolis has been instrumental in the development of electronic medical record systems. The first, called Gopher, was developed and implemented in the 1970s for a public hospital, Eskenazi Health, formerly known as Wishard Hospital (6). After the development of the Gopher system, the Institute worked on integrating multiple electronic healthcare records from various hospitals into a health information network. These efforts blossomed in the 1990s with the creation of the first independent HIE in the US, the Indiana Health Information Exchange (IHIE)(4).

The Gopher and IHIE systems worked well together until 2016 when the Gopher system was phased out. With this sunset the Regenstrief Institute lost a connection to a collaborative partner, a clinical platform to develop and test their clinical innovations, and the unique opportunities which came with ownership of a homegrown research platform.

As a result of this transition, the Institute reinvented its pathways for clinical innovation. One of the pathways contained a new inter-organizational network for innovation, merging the following three partners: Regenstrief Institute (7) as the research institution, the Indiana Health Information Exchange (IHIE) (8) as the data broker, and the Indiana University Health hospital system (9) with a large vendor-based EHR system, Cerner (10). Although these organizations had previously worked together, this network created a new path towards innovation, development and implementation.

This network first decided to develop a new method of integrating HIE with Cerner and called the resulting collaboration the FHIR HIEdrant. This integration allowed physicians to review information from an EHR faster and more efficiently without changing the EHR workflow. This goal was achieved by constructing a SMART on FHIR application. Depending upon a patient's chief complaint, the application automatically searched the HIE and presented the five most relevant data items to the physician as a standard part of the EHR workflow.

SMART on FHIR

Two and a half years after the launch of the first iPhone, Harvard Medical School and Boston Children's Hospital received a grant to begin an interoperability project. Their goal was to develop a platform that enabled medical applications to be developed and then run effectively across different healthcare IT systems without needing modification. (12). The project, called Substitutable Medical Applications and Reusable Technologies (SMART), was tasked with developing an app similar to others available for the iPhone. Ideally, the SMART app could be downloaded from an online store into an EHR and subsequently solve a unique task.

To achieve a seamless integration of their application with a vendor EHR, SMART created a standard framework for authentication and integration of third-party applications. Also, SMART used common web terminology like Java and JavaScript and authentication terminologies like OAuth2 which allowed anybody with basic programming skills to build SMART applications.

SMART allowed access to the EHR while the Fast Healthcare Interoperability Resources (FHIR) regulated the data transfer. The FHIR framework, a new standard for healthcare data exchange, was an advancement from the previous HL7 standard (13). With the help of FHIR, SMART apps could request data from the EHR (e.g., patient identifiers and medication information) and write information into the EHR (e.g., notes and test results).

While the benefits of a SMART on FHIR application were easily identifiable, the drawbacks were not so apparent. In order to work flawlessly, SMART on FHIR apps required establishment of an effective and efficient infrastructure. Setting up the FHIR proved especially labor intensive, requiring a significant level of resources.

There were plenty of options available for the integration of third-party applications into the EHR(14). All of these alternatives allowed information to be extracted from the EHR and then written back into it. They were all highly customizable and had good performance profiles. The main drawback was that each application was EHR specific. They were each based on an individual EHR vendor and on the particular way in which the system was set up. This creates one-off solutions that were not easily adaptable to other contexts.

This lack of flexibility demonstrated by the alternative applications was the main reason we chose SMART on FHIR for our project. Since the IHIE was connected to 35 different health systems in the State of Indiana, our project results needed to be unconditionally scalable.

The FHIR HIEdrant

Overview

The FHIR HIEdrant application was designed to help emergency room physicians diagnose patients with a chief complaint of chest pain. Patients that present to an ER with chest pain more often than not have a history of similar symptoms for which they have been treated by different healthcare systems. Unfortunately, as the different electronic medical record systems were not integrated with each other, physicians could not access previous test results even though such information could enable quicker and more accurate diagnoses. Even in the rare cases in which ER physicians worked in hospitals connected to an HIE, such as the Indiana Health Information Exchange, our pilot study showed a lack of willingness to access it. The primary reason for this reluctance was the excessive length of time required to leave their current workflows, open up the web portal and begin searching for information. Our pilot study showed that ER physicians care for 11-15 patients per hour. This allows ER physicians to only spend an average of 4 minutes with each patient. Of course, the actual timeframe depends upon the patients' levels of acuity and need for care. However, minimizing the time spent with each patient is essential to cost containment. Saving time is so crucial in the ER that a physician might spend 20 seconds ordering a new test instead of 3 minutes searching for an old test result in the HIE web portal, especially since previous records might not exist.

The FHIR HIEdrant solves that problem. Physicians are able to launch the application inside the EHR with one click. The app then searches the patient's entire chart at the HIE for test results and reports all relevant findings. It combines these outside test results into one view and presents them to the ED physician. This saves physicians a tremendous amount of time and improves patient care.

Front end

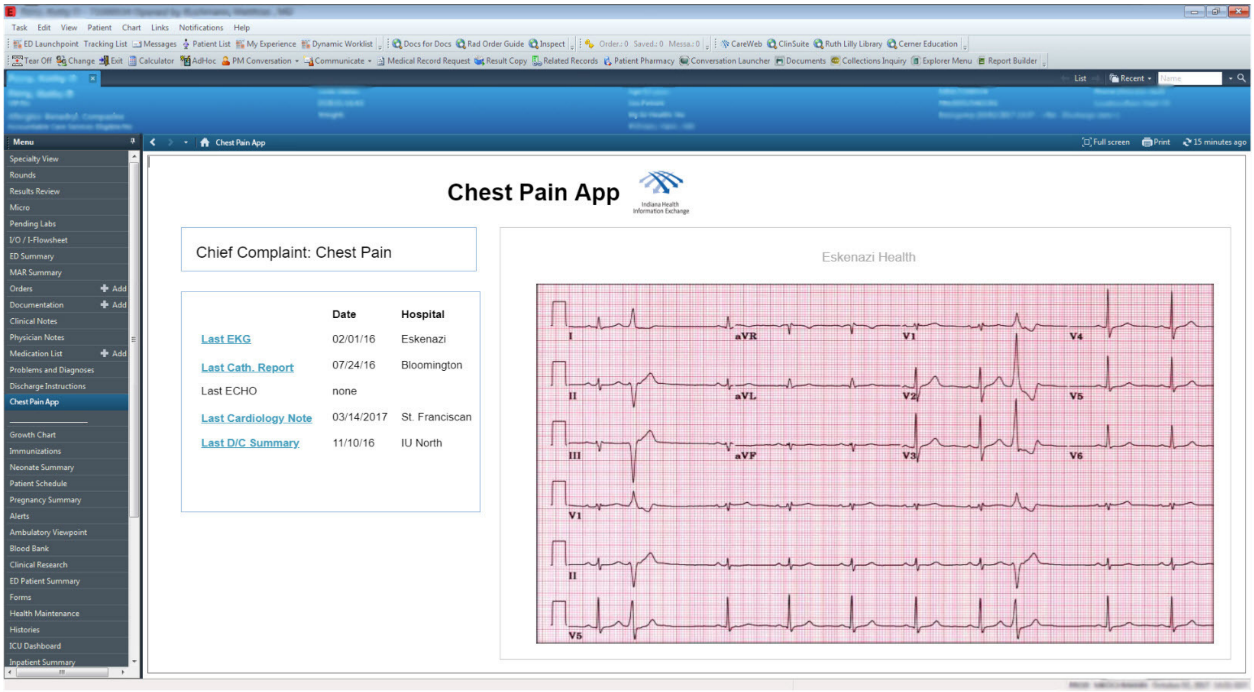

Figure 1: Screenshot of the FHIR HIEdrant launched in the EHR Cerner

Figure 1 shows the initial screen of the FHIR HIEdrant. The app is launched in the provider's electronic medical record system with one click on the left-hand menu. On the top, it displays the patient's chief complaint, such as chest pain. Below it shows five data items relevant to that complaint, e.g. last EKG, last cardiac catheterization report, last ECHO, last cardiology notes and last discharge summary from the hospital. In addition, it shows the date and the location for the creation of each data item.

With an additional click, the physician can display details, such as the actual EKG, on the right-hand side of the screen.

It is important to note that all potential data categories remain visible to the physicians even if tests were not performed or data is not found in the HIE. These missing pieces of information, signified by a gray area such as the last ECHO in the screenshot above, are still relevant. It is essential for an ED physician to to know which diagnostic tests have not yet been performed.

Back end

The back end of the system for the FHIR HIEdrant consists of four main components (see Figure 2) including:

- the hospital system IU Health with EMR Cerner;
- the Indiana HIE system with the INPC;
- the SMART app which links the two systems; and,
- the set of FHIR servers which contains the patient data and security authentication.

The SMART app communicates with the FHIR and an OAuth2 server in each institution. Figure 2 shows the details of the data flow process built within the FHIR HIEdrant. Figure 3 shows the implemented system architecture.

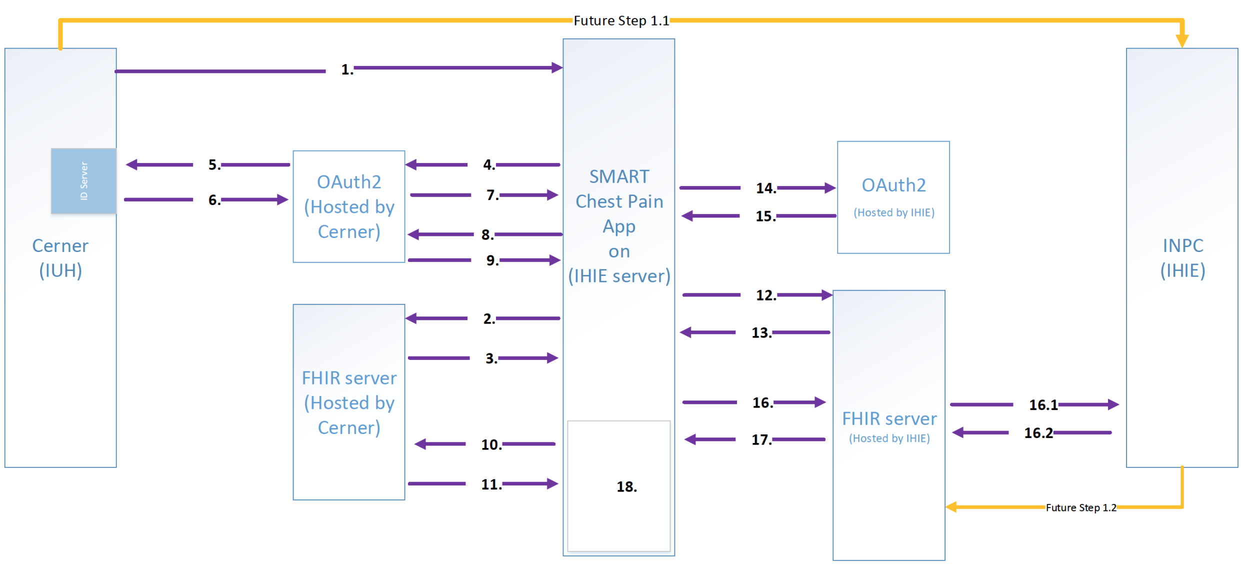

Figure 2: Data scheme for the SMART on FHIR app FHIR HIEdrant. The SMART App in the center connects to the two primary systems (IU Health's Cerner and IHIE's INPC) via their respective FHIR servers. The SMART uses OAuth2 as the authentication mechanism.

The data flow of the original architecture:

1. To begin work in the SMART app, the physician clicks on ‘Cerner’ in the Chest Pain app, located within the left banner inside the patient's chart. The SMART application was pre-configured to

work with two specific FHIR resource servers, including IU Health and INPC. Once accessed, Cerner uses the ID of the FHIR server to perform step #2. No information about the patient or the user is transferred.

2. The SMART application performs discovery by requesting the FHIR server's conformance statement. Using the ID from step one, the app requests the OAuth2 server URL from the Cerner FHIR server. This step does not occur in every instance since the SMART app can cache the information.
3. The FHIR server returns the conformance statement, which provides the needed endpoints for steps 4 and 8.
4. The SMART application creates an OAuth 2.0 authorization request, then directs the end user to the authorization server's endpoint via a browser. This request includes the scope needed in order to access FHIR resources.
5. The authorization server interacts with the IU health Cerner to verify identity and any other information required by the authorization server.
6. Cerner/ IUH provides any information needed by the authorization server to proceed. At this point, information about the provider is transmitted.
7. Authorization is sent via the OAuth 2.0 framework back to the SMART application.
8. The SMART application requests an access token using the authorization code.
9. The authorization server returns the access token.
10. The SMART application uses the access token to request the FHIR resources: Patient Name, MRN
11. The FHIR resource server returns the desired resources.
12. The SMART application performs discovery by requesting the FHIR server's conformance statement. Using the ID from step one, the app requests the OAuth2 server URL from the INPC

FHIR server. This step does not occur in every instance since the SMART app can cache the information.

13. The FHIR server returns the conformance statement, which provides the needed endpoints for steps 14 and 21.
14. The SMART application requests an access token from the authorization server. The authorization server uses the Jason Web Token (JWT). This means that the SMART App is pre-programmed into the OAuth2 server as an authorized client and therefore will automatically receive the access token.
15. The authorization server returns the access token.
16. The SMART application uses the access token to request the five chest pain data elements from FHIR resources.
    16.1 The FHIR server requests the data elements from the INPC.
    16.2 The INPC returns the data elements to the FHIR server.
17. The IHIE FHIR resource server returns the five data elements to the SMART app.
18. The SMART app displays these five data elements

Future Step 1.1: Upon a patient's arrival to the ED, a nurse registers the patient and enters the chief complaint. An ADT message is sent to the INPC with this information. This triggers the INPC to search the patient, index the chart, and examine the 5 data elements.

Future Step 1.2: The 5 data elements and the patient identifier are preloaded (cached) to the IHIE FHIR server.

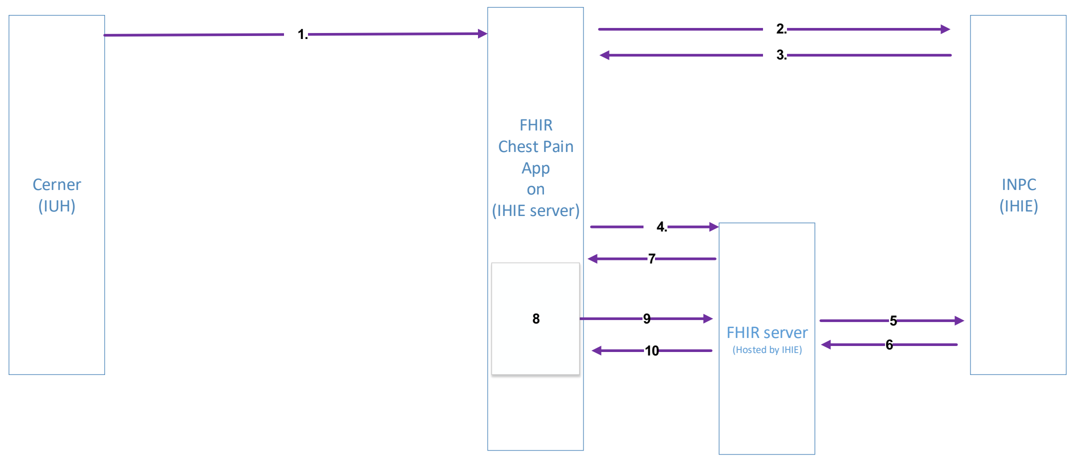

Figure 3: Architecture of the FHIR HIEdrant as implemented in production

Data flow of the actual implementation:

1. To begin work in the SMART app, the physician clicks on 'Cerner' in the Chest Pain app, located within the left banner inside the patient's chart. At the same time, the user's credentials are pushed through the single sign-on (SSO) to the app.
2. The FHIR app sends the SSO credentials to the INPC for verification.
3. The INPC verifies the user credentials to allow access to the data.
4. The FHIR application requests the five chest pain data elements from FHIR resources.
5. The FHIR server requests the data elements from the INPC.
6. The INPC returns the data elements to the FHIR server.
7. The IHIE FHIR resource server returns the information about the five data elements to the FHIR app.
8. The FHIR app displays information about these five data elements to the user.
9. The end user clicks on one of the data elements, e.g., an EKG, and the app requests the information from the FHIR server.

10. The FHIR server sends the information to the app, and it gets displayed to the end user.

Explanation of the differences:

Even without having expertise in the area, it is obvious that the differences between Figure 2, the initial architecture, and Figure 3, the implemented architecture, are striking. The actual implementation is a very abbreviated version of the original architecture. There are many reasons for this which can be summarized by one common goal: decrease the risk of project failure.

If the FHIR server is deleted from the implemented architecture in Figure 3, only the infrastructure of the IHIE remains. The only difference between them is the replacement of the FHIR app with the web portal of the Indiana HIE, *CareWeb*, in the center of the map as depicted in Figure 4.

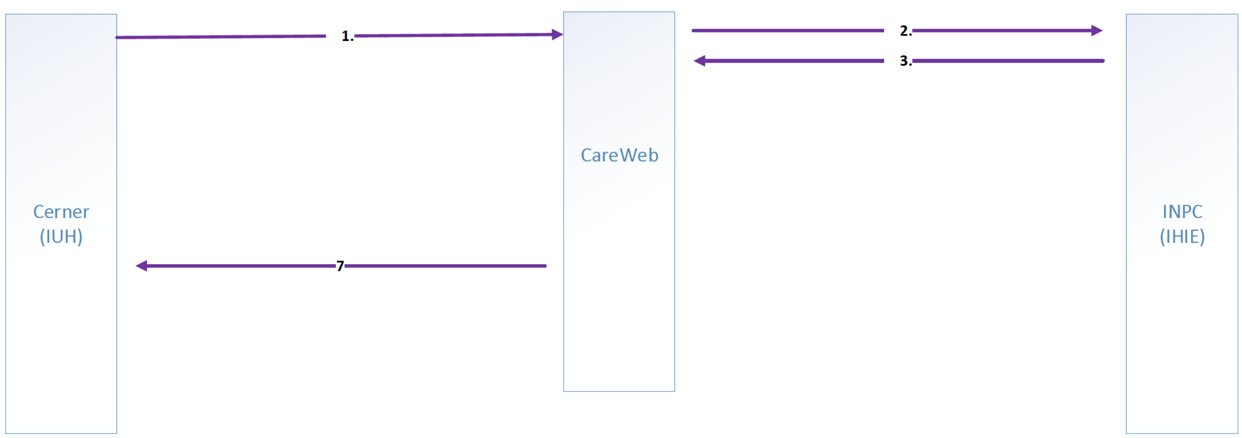

Figure 4: The underlying architecture of the Indiana Health Information Exchange. CareWeb is the web portal through which physicians can access the HIE.

Instead of building a new app that involves workflows from four new servers, the stakeholders concluded it would be easier to implement one new server/workflow at a time. They hoped to leverage as much infrastructure as possible from the old legacy system and prevent the application and implementation of new unknown software and IT. This decision was controversial, and the reasoning behind it will be discussed in the chapter 'Project Development and Roadblocks.'

The Project

Team

The project team for the FHIR HIEdrant consisted of representatives from four institutions: Indiana University Health (IU Health), Regenstrief Institute, Indiana Health Information Exchange (IHIE) and Cerner (Figure 5). Except for Cerner, each institution devoted development, management, and political leadership resources to the project. Cerner's role was that of a consultant.

I served as project leader for the team. Based on my credentials, I was able to work at all three institutions. I was doing clinical work at Indiana University Health, training in my clinical informatics fellowship at the Regenstrief Institute and working on my elective at the Indiana Health Information Exchange. I was the only team member in this position, which gave me a unique perspective and enabled me to appreciate the different points of view. For example, I understood the pressure that IU Health was under after their CMIO changed, the lack of progress on the Regenstrief site because one of the developers had serious family health issues, and the sudden chaos caused by the scrum master and the top developer at IHIE giving their two-week notices nearly simultaneously.

I also had a management role, sitting in on all strategy and budget meetings with the stakeholders as well as offering medical expertise required by the developers, i.e. teaching them the differences between the LOINC codes for EKG, stress EKGs, and EEGs.
Every week, I would meet up with my mentor Titus Schleyer to discuss the progress of the project or the lack thereof. Together we would develop strategies to overcome barriers which I would execute.

At the initiation of the project, team management and political leadership were heavily involved in mapping out a strategy, budget, and plan. Once the project was up and running, the number of team members was reduced from 27 to nine, and the remaining participants from IU Health, Regenstrief and

IHIE met weekly. This group was centered around the developer from each institution together with project managers.

A stakeholder meeting was held quarterly to discuss milestone development and the continued viability of the project.

Figure 5: The team members at the initiation of the FHIR HIEdrant project

Timeline

The project timeline was revised fairly soon after the initial project plan (Figure 6) and the modifications appeared in the actual project plan (Figure 7). Originally, we estimated that the project could be completed in 6 months. However, significant delays in the development and implementation of the FHIR server resulted in a new projected timeframe of 18-months. More detailed reasons for these changes will be discussed in the section on ‘Project Development and Roadblocks”.

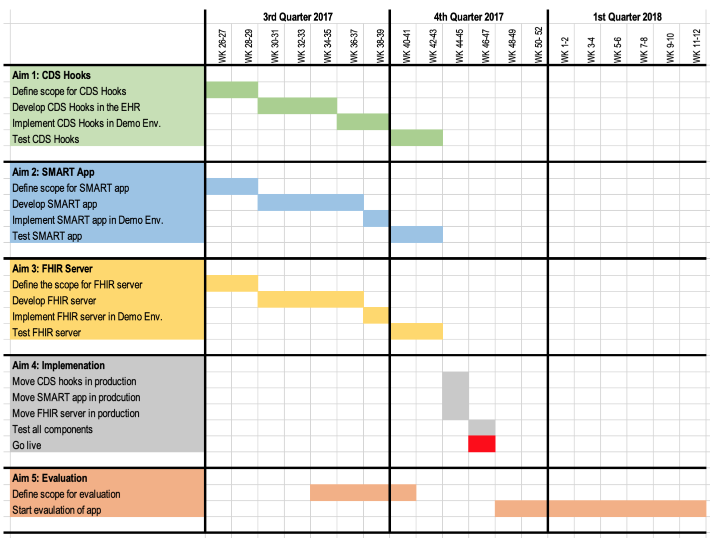

Figure 6: Initial project plan for the FHIR HIEdrant

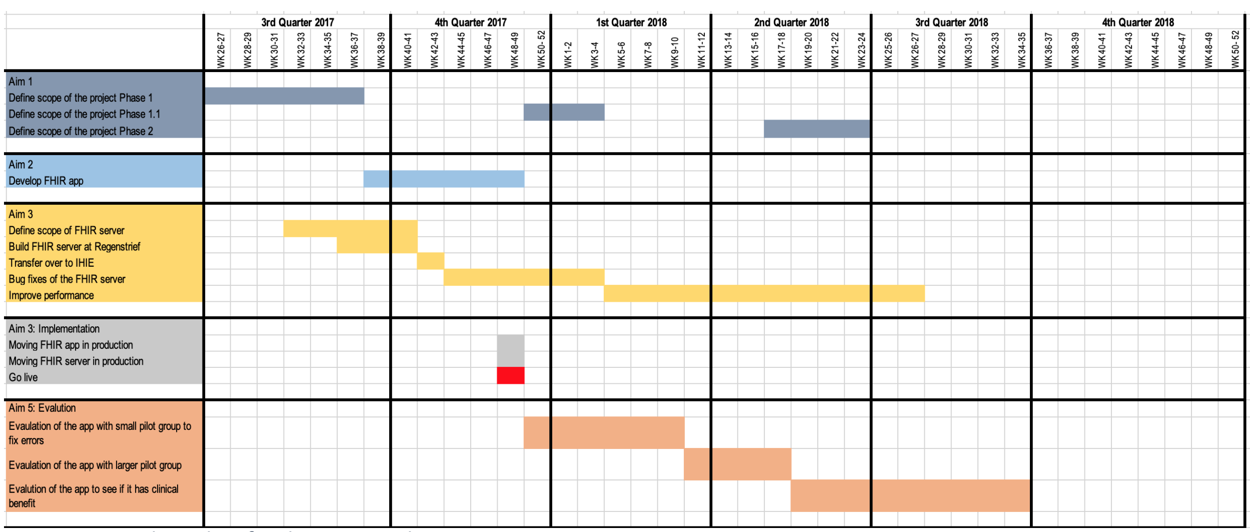

Figure 7: Actual timeline for the FHIR HIEdrant project

Phase 1 – Projected Completion Dec. 2017, Delivered March 2018

The goal of this phase was to develop a minimal viable product and proof of concept. The specifications included an ability to launch the app from the physician's home EHR and the display of five data items from the health exchange.

To achieve this goal, the product would not be a SMART app but rather a webpage loaded from the internal server of the health information exchange that pulled data from the FHIR server. It would leverage almost all of its functionality from the current web portal to the HIE called 'CareWeb' by using the same single sign-on (SSO) and VPN tunnels.

The following phases of this project are still ongoing:

Phase 2 – Date TBD

The goal of Phase 2 is to turn the webpage from Phase 1 into a SMART app by enabling user authentication via OAuth 2, as well as by setting up auditing and logging features to analyze app performance and user behavior. As mentioned in the Chapter 'SMART on FHIR', FHIR HIEdrant is intended to be a universal SMART app that can work with any EHR. For this purpose, the system requires universal authentication with OAuth2. In addition, we want to analyze how often users clicked on individual test results in the app to see if some specific data items, e.g., EKGs, are more critical than others.

Phase 3 – Date TBD

This phase will implement the SMART app at an institution other than IU Health with Cerner. The hospital chosen will preferably work with EPIC to make our application universally compatible with the two biggest HER vendors. In addition, we plan to broaden the scope of the display within the application to add other possible complaints as well as suggestions for pain management or screening for diabetes.

Budget

The initial FHIR HIEdrant project had a limited budget, with a maximum expenditure of $120,000 USD, and was only made possible due to the generosity of various participating institutions who offered in-kind services, volunteering the labor of their employees. IU Health offered the services of their developers at no cost to the project. The Indiana Health Information Exchange offered the work of their developers, project managers, and product managers at no cost as well. The only paid staff were two developers from Regenstrief (System Engineers II and IV). They worked for a total of 734 hours from July 2017 until June 2018, for a total labor cost of $45,000.

Project Development and Roadblocks

The following project development outline summarizes the main events that occurred and the decisions made during the FHIR HIEdrant project. This chapter will explain the differences between the proposed and the actual schedule, as well as the proposed and actual system architecture.

Phase 1 – Initiation of the project

The idea of supplementing the Indiana HIE with an FHIR server to enable new functions had been often discussed in meetings at Regenstrief prior to 2017. One of the Regenstrief investigators, Douglas Martin, MD, had even received a grant to build a prototype FHIR server for the INPC. In early 2017, Titus Schleyer, DMD resurrected the proposal. During a board meeting of the Indiana HIE, the potential advantages of an FHIR server were again discussed with the board members, including representatives of the different hospital systems connected by the HIE.

Instead of placing the topic on the IHIE agenda for 2018, the board members decided to create an ad-hoc group of representatives from the Regenstrief Institute, Indiana University Health, and IHIE to implement the FHIR HIEdrant. IU Health was chosen as to host the implementation system because it runs the most FHIR advanced EHR, Cerner, and it was the biggest client of the HIE.

Phase 2 – Agreement of the project scope

The project began in July 2017, and the first task was to develop the project scope. The work on this took place over the first two weeks. As all three parties had different incentives for joining the project, their goals were somewhat different. As a healthcare system, IU Health was most interested in creating an application that could reduce ER costs by decreasing the number of duplicatative tests while increasing the number of patients seen and improving safety. Regenstrief Institute, an academic research institution, wished to focus on the academic and research values of the project in order to attract future grants. IHIE wished to focus on creating and testing new IT solutions for the future and on satisfying the wishes of their biggest client, IU Health. To find consensus between these three parties was difficult as IU Health and Regenstrief endorsed the initial architectural model shown in Figure 2 and IHIE would not support any plan other than the implemented model shown in Figure 3. IHIE's biggest concern was not being able to deliver results to their client, IU Health, by the deadline. Since IHIE was the primary developer site and committing the most resources to the project, the group decided to narrow the scope and pursue the implemented model (Figure 3). They planned to implement the remaining steps of the project in the following phases. These discussions regarding project scope took about two months to finalize, which caused significant delays at the very beginning of the work.

Phase 3 – Development of the minimal viable product

The group agreed on the following distribution of work for the minimal viable product (MVP). The Regenstrief Institute would complete the work on the FHIR server that Dr. Doug Martin had already began with the grant he had received. During the course of the project, the FHIR server would be transferred to IHIE and implemented in their system. Concurrently, IHIE would build the FHIR app. IU Health would build a connection from their Cerner EHR to the FHIR app using a single sign-on (SSO).

An early problem occurred mid-project when IHIE received the FHIR server code from Regenstrief and the server failed to work. It was determined that the code template supplied by the HIE, used by the Regenstrief developer to build their FHIR server, was outdated. Therefore, large portions of the code written for the FHIR server were unusable and had to be rewritten. Eventually, the code for the FHIR server was fixed through several provisional solutions. The FHIR HIEdrant app was implemented on time, but it was inadequate and unreliable.

Phase 4 – Delivery of the MVP at the deadline

The delivery of the FHIR app met the agreed-on deadline of December 2017 but the product was so slow and full of errors that it was deemed unusable by the ER physicians. It took an estimated 20 – 30 seconds to load the application in the system. Users got timed out. In addition, data that physicians needed from

HIE were not displayed in the FHIR app.   The data elements that were displayed in the app with date and time could sometimes not be opened by the physicians. Physicians were frustrated as they might wait 30 seconds for the app to open only to find out that there was a test result in the HIE which the app could not display. They were then required to spend up to 3 minutes accessing the HIE web-portal to find the missing information.

Phase 5 – New project scope and outline for the new MVP

In January 2018, six months after project implementation and one month after the MVP delivery, the team spend another four weeks trying to decide how to fix the errors that occurred in the FHIR app and improve the app functionality so the end users would find its performance acceptable. The goal was an app launching in under five seconds.

The group wanted to repair the temporary fixes made to the FHIR server during the first round after it was delivered to IHIE from Regenstrief, improving the performance of the entire system.

Phase 6 – Feedback on MVP

In April 2018, five months after the delivery date of the original MVP, the modified MVP was delivered. This fulfilled all of the requirements that the three parties agreed to almost a year before. The app was still slow with a loading time of 10 -15 seconds, and had occasional errors, but it was user-friendly enough to be tested by a pilot group of 110 physicians in one of the busiest ER's in Indianapolis, IU Health Methodist ER. The results of this user evaluation can be found in the chapter 'System Evaluation.'

Phase 7 – Creation of MVP 2.0

Once the FHIR app was implemented, all three institutions agreed to continue their investment in the FHIR app. This work was supported by two grants funding work on the application, one direct and another indirect. Although the plan at the beginning of the project was to first create an FHIR MVP and then subsequently turn it into a SMART app, this proposal was now rejected. The many technical difficulties that the team encountered in the beginning, together with the improving performance, led to a decision to maintain the back end as it was, instead focusing on the clinical aspects of the app. The team felt that the FHIR HIEdrant would be more functional if it displayed the top ten most common ED chief complaints together with their associated data items from the HIE rather than displaying just one chief complaint. At the present time, this project is still ongoing.

Phase 8 – Upload to Boston SMART on FHIR App Gallery

As part of a side project, the Regenstrief Institute decided to make the MVP of the FHIR HIEdrant freely available by uploading it to the Boston SMART on the FHIR App Gallery. This work required extra developer hours from the Regenstrief site because the FHIR app needed to be converted into a SMART app which was compatible with the app gallery. The results can be viewed at https://apps.smarthealthit.org/app/chest-pain-application

System Evaluation

For our analysis of the FHIR HIEdrant, we combined quantitative analysis with a qualitative evaluation. The quantitative evaluation compared pre- and post-app implementation, analyzing the usage of the HIE in the intervention ED as compared to other ED's of IU Health which did not have access to the FHIR HIEdrant app. In the qualitative evaluation, we performed semi-structured interviews with the ED physicians in the intervention ED (see Figure 8 for the quantitative study design).

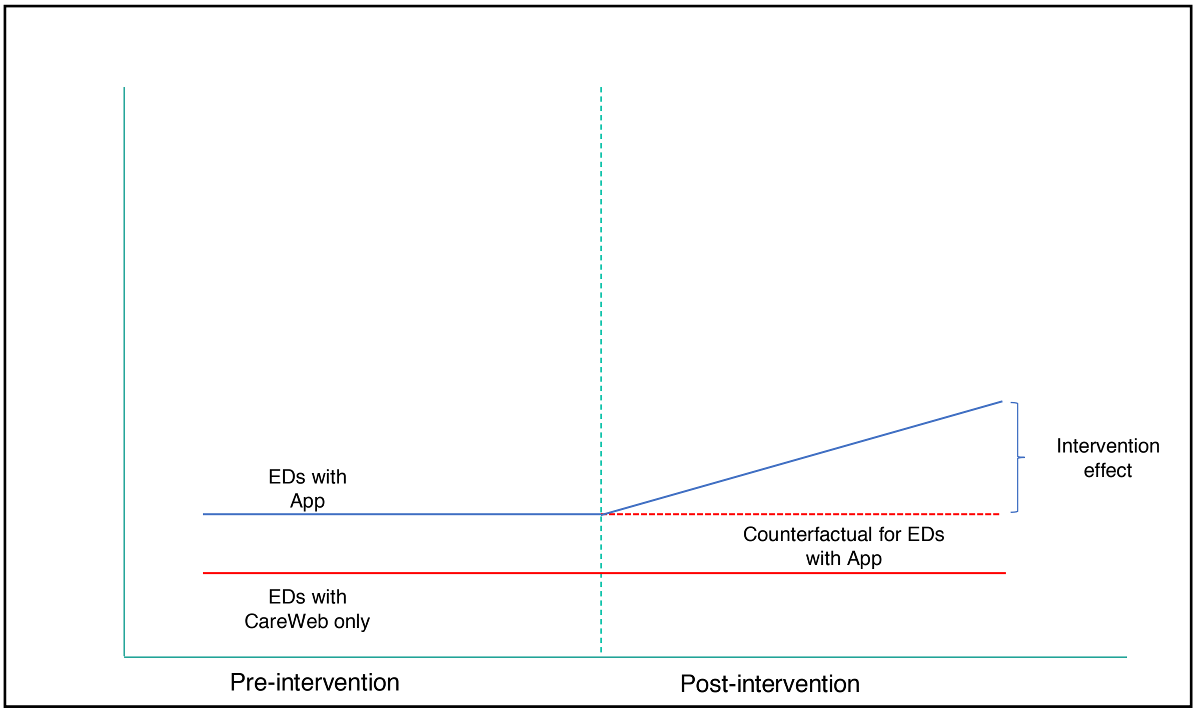

Figure 8: Illustration of the quantitative evaluation of the FHIR HIEdrant

Quantitative evaluation study

Our evaluation used a quasi-experimental, longitudinal study design to evaluate the relationship between *FHIR HIEdrant* usage and various outcomes related to clinical care in encounters with a chief complaint of *chest pain*.

We linked INPC usage log data to encounter data in order to identify encounters in which the clinician accessed a patient's clinical information in the HIE. INPC usage logs record all instances of users querying a patient's clinical information through *CareWeb* or the *FHIR HIEdrant*. In addition to INPC usage logs, we also used log files generated by the *FHIR HIEdrant* itself. The *FHIR HIEdrant* logs allowed us to distinguish between encounters in which patient information was accessed using *CareWeb* and those using the *FHIR HIEdrant*.

Evaluation Hypotheses

From the results of the pilot study described in the beginning of this report, we determined that the usage of patient information from the HIE was low, mainly due to the logistical and technical barriers to using *CareWeb*. The *FHIR HIEdrant* was designed to benefit the patient by removing these barriers so clinicians would increase their use of HIE information. The team believed that enabling physicians to retrieve key clinical information from the INPC with significantly less effort than was required by the lengthy *CareWeb* navigation process would make it easier for them to access important information. Thus, our primary hypothesis was:

> *HIE use in the intervention ED will increase after the implementation of the FHIR HIEdrant.*

Evaluation study

Study Design

A main component of the evaluation were semi-structured interviews conducted in-person, through video or on the phone. These interviews were designed in conjunction with a 1-page survey containing 22 closed-ended questions. We asked participants to complete these forms prior to the interview. Therefore, we obtained both qualitative and quantitative data. The questionnaire, described in further detail below, was based on the *Post-Study e-Health Usability Questionnaire (PSHUQ)*(15). We combined the semi-structured interview with a survey for several reasons. First, we wanted to make the interview process as efficient as possible, given that our participants were all busy ED physicians. Second, the survey instrument provided us with information that allowed us to summarize feedback quantitatively across respondents. Third, the interview component offered the opportunity to probe particular quantitative responses in more detail, helping generate a rich qualitative data set. Interviews took place at a location of the clinician's choosing, either in person or using Zoom teleconference/phone technology.

Participants

A total of 110 clinicians at the IUH Methodist ED had access to the *FHIR HIEdrant* during the study period from January 1 to August 1, 2018. Of those, 42 had used the *FHIR HIEdrant* at least once. We identified 28 target participants based on their rate of application use (light, medium or heavy users) as determined from application logs. Participation in the study was voluntary, and none of the clinicians were compensated monetarily.

Questionnaire

The survey instrument was designed to measure user satisfaction with the *FHIR HIEdrant*. It was based on the *PSHUQ*, an instrument that has undergone two rounds of validation (15,16). We added two questions each to the dimensions of *system usefulness* and *system/information quality* measured in the PSHUQ. In addition, we slightly adapted the original instrument to fit the objectives of our study.

The resulting instrument included 22 statements, of which 20 were coded on a seven-point, Likert-type scale, with possible answers ranging from *extremely agree* to *extremely disagree*. One of the statements was a *yes/no* item and the final statement could be answered *all of the time/sometimes/never*. Sample survey responses included:

System usefulness

"Overall, I am satisfied with how easy it is to use the Chest Pain Dashboard."

"I felt comfortable using the Chest Pain Dashboard."

System/information quality

"The Chest Pain Dashboard has all the capabilities I expected it to have."

"The information provided by the Chest Pain Dashboard helped me complete my clinical tasks."

System efficiency

"The response time of the Chest Pain Dashboard was adequate."

Potential system improvements

"The system could be improved."

We pilot-tested the survey with four of our participants. The results of this pilot test did not result in any changes to our instrument.

Data analysis

We summarized quantitative responses from the survey descriptively using simple counts for each statement/question. Mean response scores for each question were calculated by converting answer choices to numbers (*extremely disagree* = 1, *agree* = 2, … *extremely agree* = 7) and averaging the converted responses. In addition, the semi-structured interviews provided context for the four dimensions we intended to measure: *system usefulness*, *system/information quality*, *system efficiency*, and *potential system improvements*. This study was approved on November 27, 2017, by the Indiana University Institutional Review Board under the title *Evaluation of SMART on FHIR CareWeb Dashboard for Chest Pain* (protocol #1710793135).

Quantitative evaluation results

Our data sample included a total of 266,291 encounters within all emergency departments in the IUH system. We analyzed a 6-month period of encounters, including 3 months before and 3 months after the implementation of the FHIR HIEdrant in December 2017. Thus, the study period for encounters extended from September 2017 to March 2018. Overall, 20.2% of all encounters occurred in the intervention ED. Furthermore, over half (52.2%) of all encounters occurred after the FHIR HIEdrant was implemented. Chest pain was the most common chief complaint in all EDs, accounting for about 11.4% of all encounters. Clinicians did not use the INPC, either through CareWeb or the FHIR HIEdrant, in a vast majority (95.4%) of encounters. Compared to other EDs, the intervention ED had a greater INPC usage (10.55% vs. 3.2%, p <0.001) during our study period. When the INPC was used in the post-implementation period, the intervention ED was likely to have a higher usage (56.0% vs. 53.5%, p=0.006) than other EDs. In our regression analysis (see *Table 1*), the difference-in-difference estimator was significantly and positively related to INPC usage (OR:1.15; CI: 1.02, 1.30; p=0.026) suggesting that after the implementation of the FHIR HIEdrant, clinicians in the intervention ED used the INPC more than participants in other EDs.

	INPC usage		
Variables	***Odds Ratio***	***Confidence Interval***	***p-value***
Post	*1.05*	*(0.95, 1.16)*	*0.329*
Intervention	*3.38*	*(2.73, 4.20)*	*<0.001*
Post × Intervention (DID estimator)	*1.15*	*(1.02, 1.30)*	*0.026*

Table 1*: Estimates from the difference-in-difference analysis for INPC usage.* INPC usage refers to INPC usage through *CareWeb* or the *FHIR HIEdrant*. Post refers to the binary variable indicating the time period, 1: post-implementation; 0: pre-implementation. *Intervention refers to whether a given encounter was in the intervention ED or other EDs in the IUH system, 1: Intervention ED; 0: Other EDs*

Qualitative evaluation results

Of the 28 prospective subjects contacted through email, sixteen agreed to participate. The overwhelming majority (n=15) reported using the *FHIR HIEdrant* sometimes, while one person used it all the time. *Table 2* summarizes the quantitative responses to 19 other closed-ended questions. We report results by the dimension intended to be measured (*system usefulness*, *system/information quality*, *system efficiency*, and *potential system improvements*).

System usefulness

The overwhelming majority of respondents considered the system useful. In response to the four questions about *system usefulness*, 49 respondents either *extremely agreed* or *agreed*, while only 15 chose *somewhat agree*d or lower. Ease-of-use, as well as the ease of learning how to use the *FHIR HIEdrant*, were highly rated. This assessment was borne out by comments made during the interviews, which included:

> *"Just a button. Has a lot of info needed with one click."*
>
> *"Easy to get to but have to direct others to the link for the app. Intuitive once it is shown to them."*

System/information quality

System/information quality was rated lower than *system usefulness*. Here, the number of responses in the *extremely agree* and *agree* categories (n=79) were outnumbered by the ratings *somewhat agree* or lower (n=97). Some statements, such as "It was easy to find the information I needed," "The information provided by the Chest Pain Dashboard was easy to understand," "The information provided by the Chest Pain Dashboard helped me complete my clinical tasks" and "I liked using the Chest Pain Dashboard," were rated fairly high. However, the handling of and recovery from errors received quite low ratings. Two important statements, "The Chest Pain Dashboard has all the capabilities I expected it to have" and "Overall, I am satisfied with the Chest Pain Dashboard," had mixed responses. Illustrative comments were:

> *"Computer system is a hindrance takes a long time to load. Slower than expected, placement on Cerner nav. Is low and need to search for it. Needs to be easily available."*
>
> *"Errors would be when there is 'no data available' but its accessible other ways. No solution presented."*
>
> *"Early experiences tainted with lack of functionality and may be biased when speaking on newer experiences."*

> *"It has the last document, which is nice. Wish it would automatically pull up last cardio clinic note. Most often pulls general notes and discharge notes. Need notes with all chest pain information, such as meds."*

The response patterns in the *system/information quality* dimension corresponded to the progress of our development efforts. First, while implementation of the *FHIR HIEdrant* was conducted with the input of clinical informatics leadership at the IUH Methodist ED, we did not work closely with a large group of clinicians during development. Thus, most clinicians to whom the *FHIR HIEdrant* was made available were unlikely to have high expectations of the *FHIR HIEdrant*'s capabilities. In addition, the first version of the *FHIR HIEdrant* had significant problems in terms of return rates for clinical documents and other errors. Thus, we expected a highly negative assessment when respondents were asked about errors in the *FHIR HIEdrant*. In the subsequent version of the *FHIR HIEdrant* deployed in April 2018, the number of errors was significantly reduced, which was referred to in several participant comments.

System efficiency

The assessment of system efficiency was predominantly negative, with only nine responses of *extremely agree* and *agree* in response to statements about adequate response time and efficient use, while 23 responses were *somewhat agree*d or lower. This is illustrated by the following comments:

> *"Takes ten to thirty seconds. Would like an instantaneous response. Time outs and freezes the interface which makes me log out."*
>
> *"Twenty seconds is a long time, for a single EKG. Compared to multiple EKGs using the old method and was faster than finding a single EKG on the Dashboard."*

Again, our experience during the early phases of development validates these findings. In the first version of the *FHIR HIEdrant*, response times tended to range from 15 to 30 seconds, which was unacceptable to clinicians. In the second version rolled out in April 2018, we managed to reduce response times to between 10 and 20 seconds, with a mean of 15 seconds.

Statement	XA	A	SA	N	SD	D	XD	Mean
System Usefulness								
Overall, I am satisfied with how easy it is to use the Chest Pain Dashboard.	1	9	5	0	1	0	0	5.6
The Chest Pain Dashboard was simple to use.	4	9	2	1	0	0	0	6
I felt comfortable using the Chest Pain Dashboard.	6	6	3	0	1	0	0	6
The Chest Pain Dashboard was easy to learn how to use.	6	8	1	1	0	0	0	6.2
System Quality								
I could become productive quickly using the Chest Pain Dashboard.	4	4	4	2	2	0	0	5.4
The Chest Pain Dashboard gave error messages that clearly told me how to fix problems.	0	0	0	8	3	5	0	3.2
Whenever I made a mistake using the Chest Pain Dashboard, I could recover quickly.	0	1	0	12	1	2	0	3.8
The on-screen messages provided were clear.	2	5	2	5	1	1	0	4.9
It was easy to find the information I needed.	4	5	3	1	2	1	0	5.3
The information provided by the Chest Pain Dashboard was easy to understand.	5	8	2	1	0	0	0	6.1
The information provided by the Chest Pain Dashboard helped me complete my clinical tasks.	3	9	4	0	0	0	0	5.9
The Chest Pain Dashboard was pleasant to use.	4	4	5	2	1	0	0	5.5
I liked using the Chest Pain Dashboard.	3	6	5	2	0	0	0	5.6
The Chest Pain Dashboard has all the capabilities I expected it to have.	2	4	2	2	5	1	0	4.6
Overall, I am satisfied with the Chest Pain Dashboard.	1	5	5	2	2	1	0	4.9
Efficiency								
The response time of the Chest Pain Dashboard was adequate.	1	2	1	2	6	2	2	3.5
Using the Chest Pain Dashboard was efficient.	1	5	4	3	2	1	0	4.8
System Improvement								
The system could be improved.	4	6	4	2	0	0	0	5.8
The system is good as is.	1	1	4	2	3	3	2	3.6

Table 2: Summary of responses to 19 survey questions. XA=Extremely Agree, A=Agree, SA=Strongly Agree, N= Neutral, SD =Strongly Disagree, D-Disagree, XD=Extremely Disagree. Cells are shaded proportionately to the number of respondents.

Potential system improvements

There was strong agreement with the statement that the system can be improved. Ten participants either extremely agreed or agreed with the statement "The system could be improved," while only six responded *somewhat agree* or *neutral*. Only two responses extremely agreed or agreed with the statement "The system is good as is," while twelve agreed with the statement "I feel there are some drawbacks of using the Chest Pain *Dashboard*."

The question "I plan to use the Chest Pain *Dashboard* for all patients where it is useful" had an overall mixed but generally positive response.

Discussion of the evaluation

The key findings from our quantitative evaluation suggest that implementation of the *FHIR HIEdrant* resulted in an increase in overall HIE usage by the intervention ED. While we used a robust study design in our analysis, our findings should be interpreted cautiously.

A critical issue that influenced both the quantitative and qualitative analyses was the fact that we were evaluating "a moving target." After a suboptimal implementation in December 2017, we re-designed and re-implemented the *FHIR HIEdrant* in April 2018. As such, our quantitative evaluation is based on data from the earlier, non-optimized version of the *FHIR HIEdrant*. It is likely that this situation biased our overall findings towards the null (i.e., no change in HIE use in the intervention ED) which is contrary to our later findings. Further, in our analysis, we observed that clinicians used the *FHIR HIEdrant* in encounters where the patients had chief complaints other than *chest pain* such as abdominal pain, vaginal bleeding, gunshot wounds, intoxication, seizure, and flu. Given the broad-spectrum utility of some clinical information (e.g., discharge summaries) retrieved by the *FHIR HIEdrant*, it is possible that clinicians perceived the *FHIR HIEdrant* as an efficient way to access a variety of useful information. Findings from our qualitative interviews generally support this assessment. Concerning the implementation of the re-designed *FHIR HIEdrant*, several of our respondents remarked during the interviews that the *FHIR HIEdrant* “had gotten a lot better recently,” reflecting partial success of our software engineering efforts. In summarizing clinician attitudes about the *FHIR HIEdrant*, one of the project members remarked: “They love the idea; we just have to implement it better.” The findings of our qualitative study bear this out. Attitudes towards *system usefulness* were overwhelmingly positive, highlighting strong support for the method. While the view of *system/information quality* was partially positive, it was marred by less-than-optimal response time and errors in retrieving documents. Response time was also rated low in the *system efficiency* category, and the idea of *potential system improvements* was fairly uniformly supported.

Recognition

During its 18-month project phase the FHIR HIEdrant app received numerous awards and recognition, both from the startup community and from academia. Our work was presented at the following events. In general, Dr. Mattias Kochmann, as team leader, represented the research group.

AMIA Pitch IT – 1st prize

During the 2017 AMIA annual symposium, the academy held a competition to find the best health care IT innovation. The FHIR HIEdrant won the $5,000 first prize.

IU Health Safety – 1st prize

Each year, Indiana University Health holds a patient safety day. During this one-day long conference, students and fellows present their work intended to improve patient care within the IU Health network. The FHIR HIEdrant won first prize.

MedStarter Momentum – Top 3 finalist

MedStarter is a healthcare IT startup incubator based in New York City. It organizes the AMIA Pitch IT - a series of healthcare IT national and international competitions held throughout the year. MedStarter Momentum is the year-end contest where the finalists from each of the AMIA Pitch competitions in a single year compete for a final prize. The FHIR HIEdrant was one of the top 3 finalists.

Mira Award – Top 5 finalist

The Mira Award is an Indiana-based annual startup competition. In this competition, the best startups in Indiana compete in 10 different categories. The FHIR HIEdrant was one of the top 5 finalists in the category ‘Best Start-Up of the Year.'

AMIA 2018 Annual Symposium - Best poster award

At the annual symposium for the American Medical Informatics Academy, the FHIR HIEdrant won the best poster award for their submission titled *Leveraging FHIR to integrate information from a health information exchange directly with the clinical workflow in Cerner.*

AMIA 2018 Clinical Informatics Conference – Invited Speaker

At the Spring 2018 clinical informatics conference held in Scottsdale, AZ by AMIA, the FHIR HIEdrant was presented in the session: *Ignite Talks by the Clinical Informatics Fellows*.

Healthcare Informatics Health IT Summit Series – Invited guest speaker

This series of conferences with multiple venues is held throughout the year. A representative of FHIR HIEdrant was an invited guest speaker for the conference in Raleigh, NC.

IMO 2.0 – Invited guest speaker

Intelligent Medical Objects is the company behind the ICD code mapping and problem list generation for all major EHRs in the US. During their annual company event, a representative from FHIR HIEdrant was an invited guest speaker.

Xtelligent Media Value-Based Care Summit– Invited guest speaker

Xtelligent Media provides a series of high-value conferences on different topics throughout the year in the US. A representative from FHIR HIEdrant was an invited guest speaker at their 'Value-Based Care Summit'.

Perdue University Department of Pharmacy– Invited guest speaker

The University of Perdue in Indiana provides their pharmacy class with healthcare IT education. A representative of the FHIR HIEdrant was an invited guest speaker.

Scottsdale Institute Webinar – Invited guest speaker

Scottsdale Institute provides its members with a high-quality webinar lecture series about various healthcare IT topics. A representative of FHIR HIEdrant was an invited guest speaker for one their webinars

Regenstrief Work in Progress – Invited guest speaker

Each week, members of the Regenstrief Institute present their work to their colleagues from the Institute and Indiana University. A representative of FHIR HIEdrant was an invited guest speaker for this event.

Discussion and lessons learned:

The FHIR HIEdrant project was originally expected to be completed within six months but became an eighteen-month undertaking. This journey was paved with significant roadblocks but also gained noteworthy recognition from the clinical informatics and startup communities. To summarize the findings of this project and identify the lessons learned, the following three questions will be discussed:

1. Why was our initial vision for the app incompatible with the end product?
2. Why was project completion delayed?
3. Did the results of this project improve patient care?

Why was our initial vision for the app incompatible with the end product?

Our initial vision for the project was a fully functional SMART on FHIR app, and the end product was an FHIR enabled webpage. The latter is a step in the right direction, but even after 18 months, we have not achieved our vision of a fully functional SMART app.

One reason for this was that the three parties involved started from vastly different positions when it came to attitudes towards SMART on FHIR and resources. IU Health is a Cerner client. Cerner has been involved with SMART on FHIR for almost a decade now because the Boston Children's Hospital where the SMART technology was invented operates on Cerner. Therefore, IU Health had much greater knowledge about the subject and resources, and hence had higher expectations. The Regenstrief Institute had already built a grant-funded FHIR server before the projected started; the lead developer from the Regenstrief side had built multiple SMART apps in the past. A post-project survey showed that less than half of the project team (including the developer) on the HIE side has ever heard of or worked with FHIR or SMART. Nevertheless, it was the HIE that assumed most of the responsibility for this project by designing the FHIR app and implementing the server. None of the HIE employees worked full time on the project since their labor was donated by HIE. Therefore, it is understandable that the HIE reduced the project's plans to the bare minimum, especially since they were in a client-vendor relationship with IU

Health. Furthermore, even with the minimal project objectives, the goals were not achieved until five months after the original deadline. Needless to say, this reduced the confidence of the project partner, who became more reluctant to assume greater responsibilities in the next phase.

The lesson learned from this is that a project leader must identify the weakest link in the production chain and then determine causes of the shortcomings.

Why was project completion delayed?

The MVP of the project was due and delivered in December 2017, but it was not functional. A functional version of the MVP was delivered in April 2018, five months after the initial deadline. The delay was due to difficulties with the FHIR server implementation. The FHIR server code was developed at the Regenstrief Institute prior to the initiation of our work and then completed during the FHIR HIEdrant project. After the code was completed, it was handed over to IHIE for implementation. At that point, it was discovered that the code copy of the HIE that the Regenstrief developer used to build the FHIR server code was out of date. It took the IHIE team over five months to rewrite the FHIR server to make it compatible and increase its performance to be sustainable in a production environment. It is difficult to know whether this problem could have been foreseen, but it was apparent that the Regenstrief and IHIE developer did not work closely together. The IHIE developer team worked on a strict two-week sprint cycle. The Regenstrief developer team had an agile methodology set up but were easily disturbed by ad hoc requests. This asynchronous work resulted in a failure of the two developer sites to check in with each other regularly. As a result, IHIE just waited for the final product without being aware of what they would get.

Lesson learned: “Software is not like a seed that you can throw over the fence and expect it to bloom on the other side." If two software teams work on different parts of the same project, they have to work in the same sprint cycle and use the same data and code.

Did the results of this project improve patient care?

This is probably the most important question from this project and the most difficult to answer. The Regenstrief Institute invested around $50,000 in this project. However, the in-kind services provided by all the project members had a value of over $500,000. Feedback from the providers using the FHIR HIEdrant has been positive. On our surveys and in our pilot project, providers confirmed that the HIE was very useful for them and improved their patient care. The quantitative analysis showed that the FHIR HIEdrant facilitated the use of the HIE and that clinicians used it more frequently. Nevertheless, our evaluations, some of which are still ongoing, has not shown any improvements in cost, patient care or outcomes to date.

The FHIR HIEdrant received a lot of attention from the startup and academic sectors and obtained multiple awards. This recognition may not improve patient care tomorrow, but the focus placed on this issue might inspire others to build on our work, improving patient care in the future. Since both the code for the app and the instruction manual are freely available for download from the Boston SMART on FHIR app Gallery, we hope that this will ease the way for others to follow our path.

Lesson learned: It is extremely difficult to prove if software improves patient care and outcomes. Patient care and health outcomes are important and are affected by a myriad of individual factors. Clinical software only affects a few of the factors. Even though those changes can be significant, their effects might be completely diluted by unforeseen elements affecting the bottom line.

Conclusion

To address barriers to HIE use in the ED, we created an FHIR-based app that integrated clinical information from the HIE with the EHR. This task expanded from a six-month project into an 18-month journey in which multiple unforeseen hurdles had to be overcome. Our preliminary analysis suggests that the *FHIR app* increased HIE use in the intervention ED when compared to other EDs. Furthermore, while clinicians recommended improvements and requested additional features, they generally found the *FHIR app* useful.

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