HealthyMePHR

Enabling the patient to control the flow of their own medical data

Executive Summary

Background

The Healthcare Industry has long recognized the many benefits of sharing clinical data between clinical providers. More recently, numerous studies have shown that engaging patients in their health improves health outcomes and reduces healthcare costs. Interoperability has been a stumbling block for many years. Federal mandates have been issued and many vendors have attempted to solve the issues using varying approaches.

Changes in technology in combination with new standards offer innovative health data interoperability opportunities. The new HL7 FHIR standard supports APIs that are well known to most developers, and simplifies digital connectivity. OAuth is the well-known standard for authorizing individuals, and OpenID Connect provides a means to identify users. User managed access (UMA) is a protocol that enables an individual to control the authorization of data sharing and service access by others. HEART is focused on individual centered health data sharing, in contrast to institution centric sharing.

Vendors are embracing these new technologies, but it will take time to release all features, have medical institutions upgrade to the latest release, and then offer the solutions to patients and enable access to external providers. The fastest approach to change the modus operandi and allow Alice, a model patient, to share her health data is for Alice to store a copy of her clinical data and share it as she desires. Current protocol is for the clinical staff to initiate the sharing of data, which requires expensive software integration and overhead. With the patient at the center of sharing, the patient controls sharing health data specifics. If she has an upcoming appointment and knows the data is available, she can send that data to the new office and be assured they have it. She also has her data at her fingertips for easy reference. Impacts of this are enormous and represent disruptive technology.

For the purposes of this document we will use 'Alice' to represent our model patient.

Solution Summary

Using the HealthyMePHR, Alice would access her clinical data from her FHIR enabled Primary Care Provider and save it in her personal PHR. She would define her sharing policy, which would be stored in the access control component associated with her personal PHR AS. (Footnote: HEART is still defining this standard. This approach will be adjusted to support the final HEART standard.) When Alice defines her sharing policy she will be able to indicate (1) Who she will share with, (2) What parts of her medical data she is willing to share, (3) Sharing scope (Read/Write), (4) Expiration dates for sharing.

The HEART/FHIR enabled personal PHR would support an authorized user's electronic access to Alice's clinical data as indicated in Alice's sharing policy for that user. Since Alice has stored her data in a PHR that she controls, she can authorize and allow sharing as she wishes. While the rest of the industry catches up, Alice can begin benefiting from these new standards immediately.

HealthyMePHR includes these benefits initially, even while the broader HEART infrastructure grows:

- Having her own complete medical record available at her fingertips, on a web portal or smart phone, empowers her to engage in and manage her own wellbeing.
- Alice can manage her own sharing policy and allow approved parties access to her data
    - Share with parties she approves.
    - Share only desired components of her medical record
    - Authorize approved parties to access electronically
- When she visits a new provider, she needs an easy method to provide completed initial visit forms along with current clinical data, such as her problem list, med list, allergies, etc. The solution will allow the patient to fax her pre-visit forms to a new provider with the touch of a button, saving her from completing paper forms, yet again, and insuring conveyed data is accurate. Whenever that provider's system is capable of supporting FHIR based access, they can get the information electronically via the new standards.
- Alice can correct inaccurate information
- Alice can add important details to her copy of her record
- The solution will support importing a CDA in addition to providing a service to assist Alice in that process, as needed. (Added to support patient's whose PCP's EMR is not yet FHIR enabled.)

HealthyMePHR will be designed to work as a front end for existing PHRs. The initial solution will use existing open source solutions to demonstrate functionality and may partner with one PHR vendor for the generic product. Lush Group plans to partner with, and support, PHR companies that wish to HEART/FHIR enable their PHRs. As the HEART specification solidifies and the standard is approved, HealthMePHR will be updated to include the most recent specification. The Lush Group business is providing consulting and implementation services and plans to make developed technologies available to the broader market.
The web-based version of the solution will be sold on the product web site. Mobile versions will be available from app stores.

Target Audience
This solution is aimed at any consumer who has access to the internet and is interested in easily sharing their health data, understanding their own health data, and easing the transition from one clinical provider to another. It becomes very high value for any patient that sees multiple providers or has difficulty remembering details of their care, such as what medications they are taking, lab results or their complete problem list for instance. This is particularly important for individuals who use providers outside of a single EMR network. HealthyMePHR will help health care providers access clinical data provided to the patient by other members of the care team.

Methods and Technologies Used
The initial prototype will be a web-based application, usable on desktops, laptops, and mobile devices. Early in the product roadmap, a mobile app version will be available on cross-platform devices including iPhone, iPad, Android and Windows devices so that the patient has access to their own records on their own device.

The HealthyMePHR solution will access and share clinical data using FHIR and HEART standards. (FHIR, OAuth, OpenID Connect and UMA.) Refer to the solution overview diagram in the slide deck. Detailed implementation plans reflect current UMA publications as indicated in the ForgeRock diagram at

https://forgerock.org/openuma/. Lush Group is working with other HEART team members to resolve outstanding standard details that will impact this architecture.

HealthyMePHR will be built to work with FHIR enabled PHR's providing the additional back-end functionality to meet the additional HEART and HealthyMePHR requirements. (In the first iteration we will use existing open source components to accelerate the process. We are currently evaluating HSPC and C2S open source.)

The initial data set will be the common clinical data set, which is already supported by the Argonaut project and implemented in many EMR/PHR servers. In addition to the common clinical data set, the system will include a list of medical providers, ability to store scanned insurance cards, local pharmacy info, and a vitamin/supplement list, all of which can be entered by the patient.

The back end process will be a cloud-based solution, including data and housed in a secure Azure environment, allowing it to easily scale while maintaining required security. Only Alice and those she approves will have access to her data. The solution will make use of Consent2Share concepts and lessons learned through their prototypes and testing. This product will be tested against and certified with the major EMR vendors.

The Lush Group has already created a SMART on FHIR prototype multi-platform app and has successfully connected to SMART, EPIC, Cerner, and CareEvolution sandbox servers. (Refer to slide deck for visuals.) The core FHIR resources defined in the Argonaut project have been implemented and tested against these systems. The Lush Group has deep experience with OAuth. They have used OpenID, FHIR and SMART on FHIR in this prototype, and have been active participants in both the Argonaut project and the HEART WG efforts. The Lush Group additionally has years of experience in developing web based apps and back-end systems and has the resources and experience to apply to this project.

The current Lush Group FHIR prototype application could be enhanced and made available as a provider tool to demonstrate the system solution create by HealthyMePHR.
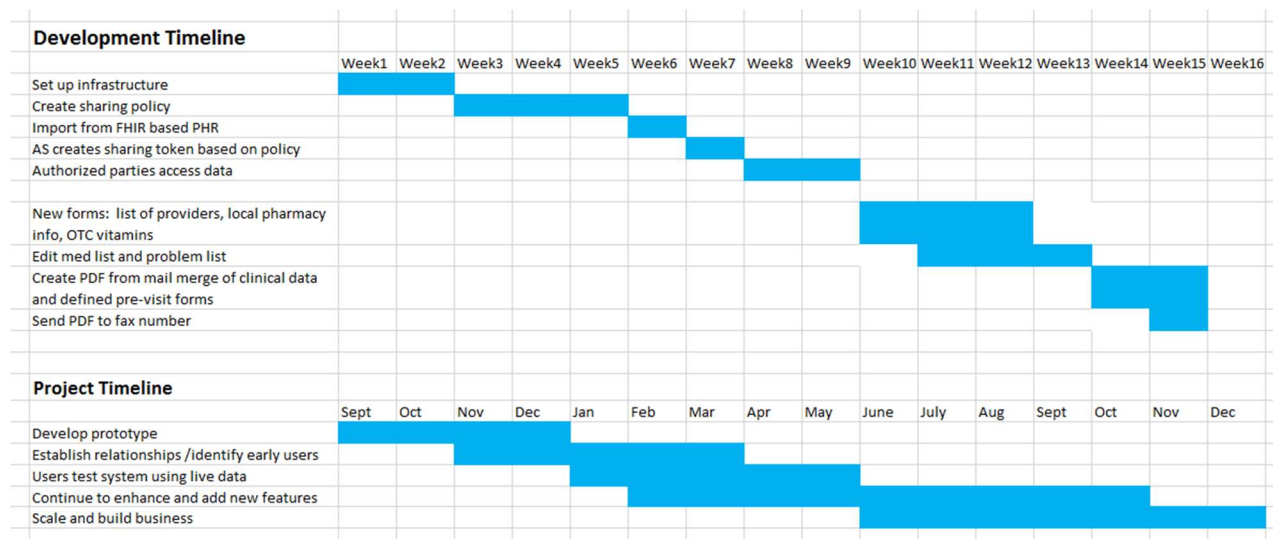
Financial Overview

Profit and Loss Summary

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Revenue	$0	$86,988	$512,450	$1,749,800	$4,424,500	$8,249,000
Lush Group Contribution	$90,860					
Challenge	$5,000	$70,000				
Investment		$80,562	$88,150			
Total Revenue	$95,860	$237,550	$600,600	$1,749,800	$4,424,500	$8,249,000
Development Costs	$95,360	$100,000	$150,000	$200,000	$250,000	$350,000
Other Salaries	$0	$0	$120,000	$120,000	$120,000	$120,000
Other Expenses	$500	$137,550	$330,600	$411,000	$422,600	$443,200
Total Expenses	$95,860	$237,550	$600,600	$731,000	$792,600	$913,200
Gross Profit	$0	$0	$0	$1,018,800	$3,631,900	$7,335,800
Net cash position	$0	$0	$0	$1,018,800	$4,650,700	$11,986,500

Year one will be financed through company overhead. Subsequent shortfalls will be met by investments partner relationships and loans as needed. Challenge funds will be used to offset development costs.

Development Plan and Timeline

HealthyMePHR will use an open source PHR for the core PHR requirements. The UI for the patient to define their consent will be based on the open source Consent2Share project and will make use of lessons learned from that project. Added functionality to the core PHR will include storing the patient consents, and enhancing the AS to support UMA standards and responding to the patient's policy wishes. FHIR based access to the external EMR will utilize prior Lush Group work in the FHIR prototype project. Functionality that will make the solution more usable to the patient while the industry evolves will be added at the end of the prototype phase and may not be included in the initial prototype.

Development Timeline

	Week1	Week2	Week3	Week4	Week5	Week6	Week7	Week8	Week9	Week10	Week11	Week12	Week13	Week14	Week15	Week16
Set up infrastructure	■	■														
Create sharing policy			■	■	■											
Import from FHIR based PHR						■	■									
AS creates sharing token based on policy								■								
Authorized parties access data									■	■						
New forms: list of providers, local pharmacy info, OTC vitamins										■	■	■				
Edit med list and problem list												■	■			
Create PDF from mail merge of clinical data and defined pre-visit forms														■	■	
Send PDF to fax number																■

Project Timeline

	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
Develop prototype	■	■	■													
Establish relationships /identify early users			■	■												
Users test system using live data					■	■	■	■	■							
Continue to enhance and add new features										■	■	■	■	■	■	■
Scale and build business																■

HIPAA Compliance

All components of the HealthyMePHR will follow HIPAA compliance requirements. It is the intent to host systems in Microsoft Azure that provides HIPAA compliant servers. All data in motion will be encrypted. Audit trails will record all activity. The HEART specification includes user authentication and focuses on secure access. All personal will be trained and follow HIPAA compliance rules. A comprehensive backup and recovery plan will be published. HIPAA compliance will be reviewed regularly to validate conformance.

Success Metrics

- Ten patients will use HealthyMePHR to access their medical record from their primary care provider and store current data in the HealthyMePHR. Patients will create policies that provide specific users access to their medical data and/or share their medical data by sending to the desired provider.
- At least two of the patient's specified partners will access and review medical data electronically.
- At least 5 patients will refer to their own medical data when asked medical questions, such as 'What medications are you taking.'
- At least three patients will eliminate the task of completing initial visit forms by using this system to fax their information to the new provider.
- This solution will position the patient for future sharing, but we acknowledge that the industry will lag behind this functionality initially. If a provider uses any FHIR enabled app to access Alice's data, that will be another big win.

Potential Risks

- The HEART WG is still specifying HEART. While they are making progress, the initial specification of HEART is not complete. Our initial solution will evolve as the standard is defined and becomes stable.
- We want to encourage Alice to review and correct her medical information. She may not always do that accurately. We will evaluate mitigation options during the prototype stage.
- Many physicians may not initially trust data coming from the patient, in contrast to data coming from another physician. We hope to convince them by demonstrating other benefits.
- We have challenges that need to be explored during the prototyping phase and incorporated into the solution.
    - Support for a provider directory, including FHIR endpoints
    - Ability to exchange endpoints between sharing partners
    - Clinical data reconciliation issues
    - Storing of clinical data from multiple sources per patient
    - We recognize that key features will need to be added early in the product lifecycle

Participants/Team

This proposal is presented by Lush Group, Inc., a software development company of 28 years, located in Jamestown, RI.   The Lush Group has developed large scale solutions in addition to smaller mobile applications. They recently developed a SMART on FHIR prototype multi-platform mobile app, working with the Argonaut project. Team members are either employees or consultants of the Lush Group. Below is the background of team members by role.

- Nancy Lush is a healthcare innovation thought-leader and wellness advocate. Over 35 years, she has a broad depth of experience in software and product development. Nancy and her teams have been responsible for the development of major systems, including integration, interoperability, mobile apps, web-based apps, data-centric solutions and analytics. She is equally adept at business and operations. She is a repeat entrepreneur, having founded her first product company in the 80's, and has been involved with numerous startups throughout her career. Nancy has over 20 years in the healthcare industry, has been active in both HIMSS and interoperability task forces, has been Chief Technology Officer for an electronic medical records company, and is passionate about improving health and wellness while reducing the cost of healthcare.
- The Product Manager/Business Development resource has deep experience in innovation, startups, healthcare interoperability, software development, product management and leadership. He is technically strong in his own right and has the capability to manage the product from concept to a scaled solution.
- The Lead Engineer has over 15 years in software development, including developing back end systems, APIs, RESTful services, web based apps, and mobile apps. He has implemented a SMART on FHIR multi-platform mobile app.
- The UX designer is an expert at user communication, experience design processes and mobile interfaces. She has 8 years of experience in healthcare with a leading healthcare vendor.
- We use an experienced customer service organization with an established support system. That group will undergo additional training to support this solution.
- In a later phase, Lush Group plans to partner with PHR companies as the business is developed.