Personalized Health Intervention Tracker Test (PHIT-Test) for Benign Prostatic Hyperplasia (BPH)

Verification & Validation Report

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Changes

The need statement, and team responsibilities have not changed since the progress report. However, the design specifications, project scope and design schedule have been altered. After discussion with the client, the function to compare and predict the course of treatment for one patient with another is irrelevant as the progression of the disease and treatment outcomes may vary across different patients. Also, the client suggested that the message capability should be redefined to sending text message notifications, as the original chatting function overlaps with the Epic system they are using and may cause unnecessary workload on the doctor's end. Moreover, the final medical verdict must be provided by the doctor to ensure safety of the patients, so the specification regarding "Data Analysis" will be striked. To account for this change, the design schedule has been altered. The updated development schedule would be to create the beta version of the website by April 8, and requesting the client to validate the product before April 22. The relevant sentence in the design scope has been updated to read: *"The prototype of the fully functional product will be completed and deployed to the client by April 8th."*

Verification Plan

Phittest is a web development project, so the verification process resembles that of website testing. Among all the design specifications, development time and cost do not require verification. The other specifications should each be fulfilled by one or more features of the website, or are related to user experiences. The detailed verification plan for each specification is listed in Table 1 below.

Table 1. Design Specification Verification Plan

Design Specification	**Verification Plan**
Accessibility	Responsive Web Design will be tested by testing the functions of the website from multiple devices (iOS, Android) and browsers (Safari, Chrome, Firefox).
Message capability	Three scenarios will be simulated: a) when a patient forgets to take the survey for one day, the website should alert the patient by a notification in the dashboard and a text message through Amazon SNS (Simple Notification Service); b) when a patient enters abnormal side effects for 7 consecutive days, SNS should send a text message to ask if the patient wants to notify the doctor; c) when a patient replies “Yes” to the previous scenario, SNS should alert the doctor. If message notifications are successfully sent and received in all scenarios, then it can be verified that the SNS functions properly.
Data visualization	A medication effect graph and a side effect graph should be generated from patients’ recorded data fetched from the database. Both graphs should clearly reflect the patient’s progress. This specification will be verified if the two graphs can be successfully generated.

Design Specification	**Verification Plan**
Patient compliance	Features related with patient compliance are the SNS function and the calendar, and the former could be verified in the previous specification. The latter feature will be tested by assigning one week of mock data (three days with records, one day without, and three days with record again) to the database. If the calendar shows two three-day streaks with a missing day in between, then its function must be verified.
Ease of use by doctors	The doctor's portal should have all its functions working as intended: a) when a doctor account is logged in, the person will be automatically redirected to the doctor's dashboard; b) the dashboard contains a list of patients, whose medication effect data and side effect data can be viewed as graphs.
Ease of use by patients	The patient's portal should have all its functions working as intended: a) when a patient account is logged in, the person will be automatically redirected to the patient's dashboard; b) in the dashboard, user can do the survey, which should have chained input radio buttons (i.e. new questions pop up based on the answer to the previous questions); c) the checkin calendar is in a conspicuous position; d) user can easily view and interpret their recordings in the result page .
Engagement time	This specification should be ensured by keeping the website simple and straightforward in the development stage. When the website is ready to launch, the developers should go over the daily routine of a patient and optimize the procedure if the engagement time is not the shortest possible.

Design Specification	Verification Plan
Accuracy of input	As discussed in the progress report, the accuracy of input could be achieved by using radio buttons instead of slide bars. Thus as long as radio buttons are used, this specification can be verified.
Easy to learn	The website should follow a straightforward design such that all features are instinctual to use. If a person using the website for the first time can learn the procedures in less than two minute and without confusion, then this specification is verified.

The process of web development requires much shorter intervals between testing and fixing. To ensure the success of the project, the verification testing, especially those testing plans that are directly related to the major functions of the website, will be carried out frequently. That way, the project could be delivered successfully. All major processes in debugging will be recorded adequately.

Validation Testing Plan

Validation for this website needs help and feedback from users. Users of the product can be divided into two groups, doctors and patients, and the product must meet the expectations of both groups. Doctors and patients will be invited to carry out the validation plan.

1. Validation from doctors

   Doctors' expectation is to track the treatment effect and side effects of the medication for patients, give patients helpful feedback, and prompt them to connect with the doctor if the

results are suboptimal. Doctors also need to have access to the data from patients to conclude the effect of a specific treatment.

The first step of the validation from doctors is to invite the client, a doctor, to see if he can realize how to use this website easily and clearly. A specific survey will be designed by asking questions about the learning time and uncomfortable or unreasonable place on the website.

The second step is to check if the data gained by the website fits the client's expectations. The survey will ask them if some data is unnecessary or missing. Also, the survey will ask if the display of data is clear and easy to read. As the website will send alerts to patients if their treatment is suboptimal, he will help to decide if the alert is sent in the correct condition.

After getting the survey back, a meeting will be scheduled to discuss the survey with the client.

2. Validation from patients

   Few things need to be validated by patients, including their user experience, their ideas about data analysis results, and their engagement time. The patient’s expectation of the website is that it should be easy to use, easy to learn, take a small amount of time to fill out the survey, and provide useful visualization of their progress. Before inviting and conducting validation with real patients, some students in WashU will be first invited for user experience. Then, real patients will be invited with the help of the client, Dr. Arett. A survey will be designed for patients from different backgrounds and ages to record four pieces of information.

a. Level of difficulty for patients in various technology or physical situations to access the website.
b. Whether the patient would be willing to continue using the website after at least five times of use.
c. Time required to learn how to navigate through the website for the first time.
d. Timeliness and usefulness of the data visualization and health suggestions provided by the website.

The survey will also ask users about whether they have any suggestions or improvements for the website. If any of the validation process fails, additional changes will be made to address the needs of the users and will be validated again for its correct function.

Discussion of Approval Process

Since medication history is considered a part of medical records, the project must be HIPAA-compliant. The guidelines from HIPAA that are directly related to the project are: 1) Train all workforce members in medical records security procedures; 2) Identify and proactively protect against anticipated security threats; 3) Implement hardware, software and procedures to monitor access. Since the project only involves minimal data from the patient's medical records (it only requires current medication information) and most of the data collected are related to the patient's subjective assessment of their symptoms, the product will not require a specific approval process. Also, the product is not classified as a medical device, as the product will not deal with data obtained by physical examinations or lab results. The data collected will be survey answers about patients' symptoms, and this falls under the category of a health tracker, which does not fall under FDA's regulated medical devices. Once the product is developed, the website

will only be accessible by the client, and the client, as a healthcare provider, has access to his patient's records. Currently, there is at least one member of the team who is trained for HIPAA, and other members could also receive training. The website's security will also be considered seriously to comply with the regulations of HIPAA. Most importantly, the website must ask for patient consent before asking to provide the information regarding their medication.

Current Project Status

Currently, the website is under development. The Github repository has been created and can be accessed by all of the group members. The members have cloned the repository and have the ability to work in parallel with one another on multiple Git branches. The user database has been configured and users can log into the website. The team has had a meeting with the client to finalize the survey questions and the content of the website. So far, the Django web framework is suitable for the project as it does not require as much development time as compared to other web frameworks. Django has an array of built-in security measures that would aid with the development of a secure server. The group members are well-trained with Django so the developmental process for the pages is expected to go smoothly.

In addition to developing the website's features, the team is also working on hosting the website on a domain for public visit. Currently, a naive prototype containing only the index page is running on Amazon Lightsail Cloud Server. The Lightsail platform was chosen because it can not only automatically configure networking, access and security environments, but also has a template for Django projects. However, in the most recent meeting with the client, the chat function was changed to the message notification function, which will be realized through the Amazon Simple Notification Service. This change in the definition of message capability will

incur changes to the hosting server, because according to research so far, Lightsail cannot utilize Amazon SNS. Therefore, the team is researching for new ways to host the website on a domain. Thus far, the Amazon Elastic Compute Cloud (EC2) is the top choice, for it has the best ability to incorporate various AWS services to the server. Still, whether to migrate from Lightsail to EC2 or not has not been determined yet, and is subject to further discussion and research.

Works Cited

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