

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

Preliminary Report

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Background

Patient-reported outcomes (PROs) and patient-reported outcome measures (PROMs) have emerged over the recent years with the goal of involving patients at the center of health care research, and improving their clinical experience. PROs can consist of any self-reported information from patients regarding their own health, quality of life, and physical or functional status after receiving treatment. PROMs refer to tools or devices that are used to record and report PROs (Weldring, 2013). In the past, PROs have been used more frequently for diseases that are difficult to cure, such as cancers, because patients' quality of life has a greater impact on their experience when the cure is not always successful. Collecting PROs has multiple benefits. First, it could serve as an important indicator of treatment efficacy that is difficult to be solely captured by clinical assessments. It also enhances communication between the patient and the care provider, which allows for more accurate treatment planning, increased patient satisfaction, and improved patient compliance and retention (Kluzek, 2021).

However, PROs have its associated drawbacks related to the subjectivity of the assessment. According to studies, patients have tendencies to overestimate benefits and underestimate risks. Because the data is self-reported, it could be biased, and selective reporting may occur. Patients' conditions may also fluctuate over time, so it is important to gather data regularly for a sufficient amount of time to accurately track treatment outcomes (Kluzek, 2021).

Benign prostatic hyperplasia (BPH), also known as prostate gland enlargement, could be a suitable disorder that could incorporate PROs in the course of its treatment. BPH is a urinary disorder that is common to men as they age, and causes multiple urinary symptoms, including but not limited to frequent urge to urinate, difficulty starting urination, weak urine stream, and inability to completely empty the bladder (Mayo Clinic, 2021). If symptoms exacerbate, it could cause further problems in the urinary tract or the kidneys. BPH affects approximately one third of men older than 50 years and 90% of men by age 85 years. It is also documented that more than 14 million men in the United States have symptoms of BPH. Globally, there are more than 30 million men who have BPH, making up a huge market (Deters, 2021).

When determining treatment plans, or identifying possible responses to the treatment given, patient testimony is used as one of the major factors that physicians take into consideration. Especially for urinary disorders like BPH, a patient's quality of life improvements and visible changes in their symptoms can be an indicator of treatment efficacy. However, as mentioned, PROs are not accurate as this information could be biased or incorrectly reported by patients. According to Dr. Chris Arett, the client for this project, approximately 20% of drugs used are ineffective due to inaccurate judgment of the patient's health, and patients still take drugs even if they have no effects on them. Therefore, it is imperative that a tool be employed to collect and synthesize evidence that could serve both the physician and the patient while determining the course of treatment. This tool, at early stages, could be applied in more visibly symptomatic disorders like BPH, but when combined with more robust functional health data, could be used for any other diseases to aid clinicians to make informed decisions.

Need Statement

A way to track intervention efficacy for patients with urological disorder to reduce overly excessive and ineffective use of drugs.

Project Scope

There is a need for a clearer way to track intervention efficacy to gauge treatment progress and prevent overuse of drugs resulting from inaccurate intervention efficacy assessment. Traditionally, efficacy of a medication or treatment has been largely determined by patient testimony. An easy-to-use method that tracks and records a patient's progress after treatment will be designed to aid clinicians make more informed treatment decisions. Features will be designed to motivate patients to actively record their symptoms. The prototype of the product that will be used to collect the initial patient data will be completed and deployed to patients and clinicians by December 1st. Data collected from patients will be processed, and algorithms will be implemented to develop a predictive model for treatment outcomes. The final product with predictive algorithms will be delivered on April 25th.

Key Stakeholders

The most direct stakeholders for this project would be the physician and the patient. The tool that will be created will aid the physician in their decision making process by providing an accurate status report of the patient's health. From this, the physician will no longer be required to base their judgment on the patient's testimony to prescribe drugs and plan out the course of treatment. The patient will be able to visually monitor their improvements while treatment progresses, and take an active role in the treatment. Visually witnessing improvements, or noticing signs of worsening could alert both the patient and the physician in a timely manner.

Even though the tool will be initially designed for use in urinary disorders, this technology could be further applied to many domains, such as other more complicated diseases, or drug development. Pharmaceutical companies may also benefit from this technology in the long run, since clinical trials during drug development also relies heavily on PROs, and an accurate way of measuring patient outcomes would be important for assessing drug efficacy. Also, the project

may have an impact on insurance companies and the government , as the tool will minimize unnecessary use of ineffective drugs, saving potential cost for both.

Specific Design Requirements with Metrics

Data Collection:

- Obtain clear patient consent before data collection
- Numerical or categorical input preferred to textual input when recording patient symptoms. Data to be collected everyday includes but not limits to:
 - Features from the American Urological Association Symptom scoring sheet
 - Features from the Bladder Symptom Diary

Functions to implement:

- User can leave a message to the doctor at anytime
- The doctor will be notified when the American Urological Association symptom score of the patient has been below the average by 25% for 7 consecutive days.
- Having a modulated main page that has sections of
 - summary of user's data points
 - entrance to different recording pages
 - comparison charts between user's data points and the predicted medicine efficacy
 - entrance to the communication platform
- A reward system to motivate patients to record every day

User Experience:

- User should learn how to use this product within 5 minutes of training
- User engagement time should take less than 2 minutes a day (excluding time to communication with the doctor)
 - Login process should be smooth and kept under 15 seconds

- All recording can be finished within one minute's time
- Less than 45 seconds for users to read the interpretation of their data
- Users can visualize their progress and medicine efficacy comparing with average data
 - A line chart on the main page showing both the average combined score and the user's score
 - When clicking into the visualization page, user can see comparison figures in more detailed categories

Technical:

- Accessible from different devices and browsers including Chrome, Safari, Microsoft Edge, Firefox, etc.
- Visualization algorithm calculates and displays all relevant data points

Web Security:

- Collection and storage of data must be HIPAA compliant
- Use secure web browser and use hashed passwords
- Protect against SQL injections and cross-site request forgery

Data Analysis:

- Integrate machine learning tools (TensorFlow, etc.)
- Train model using previous survey data provided by the client and the data collected by the initial deployment of the application
 - 70% of the data will be used for training, 30% for testing

Existing solutions

Multiple solutions have been attempted to alleviate such problems with inaccurate PROs, and to prevent excessive use of ineffective drugs. Some existing solutions to track the intake of medicine include using a pillbox and pill reminder applications. With a pillbox patients can organize all pills they need for one day in one box and take every pill from it everyday. It is

an indirect reminder for patients to take medicines, working especially well when multiple medicines are taken at the same time. Pills reminder apps such as Express Scripts (6), which is designed to manage prescriptions online, can set daily reminders and order refills directly. Patients can set the medicine schedule by themselves, and if the patient misses a dose the app will send alerts to the patient.

Symptom tracker spreadsheets can also record everyday medicines and symptoms. Patients can easily download the spreadsheet from the website and write their daily symptoms. Patients can store these daily paper spreadsheets in the organizer and give to doctors when it is necessary. However, this method relies highly on patients' self-discipline, and will often fail if patients have insufficient knowledge background in medicine.

Medicine tracking apps such as MyTherapy (6) can track the overall health such as blood sugar, blood pressure, heart rate and temperature and share them with doctors. Some apps have an artificial intelligence system to answer some basic medical questions. Apps will also remind patients to avoid the specific food according to their treatment. The basic food information such as calories is provided.

Some research groups are trying a tracking system for diabetes-related nerve pain to help patients starting new medicines (8), which will give automatic survey phone calls to patients. Such a system asks patients how their medicines were working. If a patient reports that the medicine is not working, the patient's doctors will receive an alert message and reach out to the patient.

Some Hospitals have healthcare keep reports of patient satisfaction dashboard (7), which provide the data including patients' follow-up rate. These reports can also be provided to medical companies or the government, indirectly showing the efficiency of treatment.

In recent years, electronic data capture (EDC) systems have been under active development to collect patient health data online. One example is a cancer symptom and machine-learning based adverse event predicting tool developed by Kaiku Health. According to

their research, they have been able to improve the quality of life of patients and increase overall survival of cancer patients (2).

Preliminary Design Schedule

Red = All

Yellow = Kaixin Pan

Green = Crystal Shin

Blue = Evelyn Xu

	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
Meet with the client and discuss project ideas	Red							
Initial draft of need statement and project scope	Red							
Decide project idea	Red							
First presentation		Green						
Learn programming language		Red						
Second presentation			Yellow					
Meet and discuss progress with the client			Red					
Third presentation				Blue				
Initial application development		Red	Red	Red				
Deliver initial app to the client and get feedback				Red				
Make changes based on the feedback					Red			
Learn machine learning tools				Red	Red			

Second phase of development (ML)								
Final testing								
Project delivery								

Organization of Team Responsibilities

Crystal Shin and Evelyn Xu will both be responsible for website development, with Crystal focus more on backend and Evelyn focus more on frontend and user experience design. Crystal will also be in charge of external communication. Kaixin Pan will take the role of secretary, literary researcher and time keeper, while providing support to Crystal and Evelyn in programming. All three people should commit and push code to Github in a timely manner, and update their parts in LabArchive.

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