Project Plan: SafeSEX Screen

Author: Team Cranky Euler

1 Introduction

The objective is to build a web-based tool that recommend screening for Chlamydia and Gonorrhea in sexually active women age 24 years and younger and in older women who are at increased risk for infection.

2 Process Description

Authentication Service

The service should authenticate the user into the application. It should allow the user to login and logout of the application.

Input: Authentication information such as email, username e.t.c

Output: Authentication feedback, if successful, redirect to recommendation service, else inform user of the errors.

Patient Screening Recommendation Service

This service should provide recommendation to women on whether they should go for screening if they are likely to suffer from Chlamydia and Gonorrhea.

Input: Patient health information: age, demographriics, medical history, sexual history e.t.c

Output: Likelihood of suffering from Chlamydia, Gonorrhea,

whether or not they should go for screening, how often they should go for screening.

Integration with FHIR Screening Recommendation Service

This service will help doctors recommend patients for screening of Chlamydia or Gonorrhea if they are at risk based on data accessible through the FHIR API.

Input: Patients' medical history records, demographrics, sexual history

Output: Likelihood of suffering from Chlamydia, Gonorrhea, whether or not they should go for screening, how often they should go for screening.

3 Team

Team members:

Project Manager - Responsible for all aspects of project success.

Defining project, building work plan, assigning work, and overseeing execution.

Quality Assurance - Assures that project quality expectations will be fulfilled.

Sofware Developer - Responsible for building the project itself from a software perspective.

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4 Preliminary Questions

What are the features the tool needs to support?

How will it be used?

Are we limited in any way in terms of the technologies we can use?

How do we determine who is and isn't at risk of infection? Is that part of research that we should do? Is that out of scope for us?

Any specific design we have to follow?

Is our work affected in any way by the fact that another team (Terminators) is working on the same project?

5 Screening Decision Factors

Chlamydia and Gonorrhea are sexually transmitted diseases caused respectively by Chlamydia trachomatis and Neisseria gonorrhoeae. Both diseases are common among young, sexually active persons and if not treated properly they can cause severe complications especially among women(1). Reported infection rates have increased in the last 10 years because of the expansion of screening and better reporting systems (2). Patients infected with gonorrhea are more likely to be co-infected with chlamydia. It is recommended that a patient diagnosed with chlamydia or gonorrhea should consider screening for other STDs such as syphilis and HIV (3).

The purpose of this project is to build an application that recommends screening for both chlamydia and gonorrhea. Based on the research done and the references we will use the provided risk factors to determine if the application should or should not recommend a screening. In most cases Chlamydia and Gonorrhea infections are asymptomatic for both men and women. Screening is recommended for chlamydia every year for sexually active women aged under 25 years and for older women with risk factors or high risk sexual behaviours (4).

Screening for chlamydia and gonorrhea is not necessary for non sexually active persons. On the other hand, given the risks of these infections on young women, it is recommended to do annual screening for sexually active young women aged under 25 (based on (1) (2)).

We will consider other factors to recommend screening. If the patient shows symptoms (a combination of symptoms) of chlamydia or gonorrhea infections or they recently had a sexual partner who have STDs or STD symptoms, immediate screening is recommended no matter what is his age or gender. We will take into consideration the gender of the patient gender to determine the symptoms of chlamydia and gonorrhea.

If the patient is a woman older than 25 years, screening is recommended in certain conditions, if the patient has new or multiple sexual partners in the previous months and if the patient is pregnant and didn't have a screening in the last few months. More frequent screening (every 3 months) should be recommended for women patients that use drugs, or sex workers, or patients that exchange sex for money drugs (5).

Physical examinations.

Also available physical examination results obtained either via FHIR or the application UI can be considered for the recommendation. For example, PH of Vaginal fluid (LOINC code 48037-6) is associated with chlamydia (6), Oral lesions or Abnormal mouth tissue in last 7 days

(LOINC code 54873-5), Joint tenderness and swelling, cervical ectopy, Dysuria (LOINC code LA17661-2) can be a sign of infection.

References

- **1.** Bébéar, C., & De Barbeyrac, B. (2009). Genital Chlamydia trachomatis infections. Clinical Microbiology and Infection, 15(1), 4-10.
- **2.** Workowski, K. (2013). Chlamydia and gonorrhea. Annals of internal medicine, 158(3), ITC2-1.
- **3.** Lyss, S. B., Kamb, M. L., Peterman, T. A., Moran, J. S., Newman, D. R., Bolan, G., ... & Ehret, J. (2003). Chlamydia trachomatis among patients infected with and treated for Neisseria gonorrhoeae in sexually transmitted disease clinics in the United States. Annals of internal medicine, 139(3), 178-185.
- **4.** Workowski, K. A., & Berman, S. M. (2011). Centers for Disease Control and Prevention sexually transmitted disease treatment guidelines. Clinical infectious diseases, 53(suppl 3), S59-S63.
- **5.** Cook, R. L., Wiesenfeld, H. C., Ashton, M. R., Krohn, M. A., Zamborsky, T., & Scholle, S. H. (2001). Barriers to screening sexually active adolescent women for chlamydia: a survey of primary care physicians. Journal of Adolescent Health, 28(3), 204-210.
- **6.** Das, S., Sabin, C., & Allan, S. (2005). Higher vaginal pH is associated with Chlamydia trachomatis infection in women: a prospective case–controlled study. International journal of STD & AIDS, 16(4), 290-293.

Use Case Model

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1 Use Case Diagram



2 Use Case Descriptions

2.1 User Login

<u>Requirements</u>: This use case must allow a provider to log in to the application with a unique user ID.

<u>Pre-conditions</u>: The user must have launched the application and already have an existing user ID on the local instance of the application.

<u>Post-conditions</u>: The user will be logged into the application and will be redirected to the main landing page.

Scenarios:

2.1.1: The user has logged and is taken to a main landing screen, where he can choose to view existing screening recommendations for existing patients or generate a new

2.2 Generate Screening Recommendation

<u>Requirements</u>: This use case must allow a provider to generate a chlamydia/gonorrhea screening recommendation from existing patient health records and manually-entered data.

Pre-conditions:

The user must have launched the application.

The user must be logged in to the application.

Post-conditions:

A new screening recommendation record will be created for a given patient and written to the application instance database.

The existing recommendation records list will be updated.

Scenarios:

2.2.1 Create New Recommendation Records(s)

The user will navigate to the "generate new recommendation screen".

On this screen, the user will need to enter patient details, including but not limited to:

Full name

Personal details

Sexual history

Other relevant information for chlamydia/gonorrhea screening purposes

Once the user is done editing the inputs listed aboved, he can submit the information, which will create a new record in the application's database instance.

In addition to using the manually-entered data, the

application will query the external FHIR API to get additional medical history for a given patient, which will be used to generate a patient recommendation.

After the screening recommendation has been successfully saved and updated in the application's database instance, a confirmation message containing the unique ID of the newly created recommendation record will be displayed. Furthermore, the screen will also display the following details:

Likeliness of a patient to have chlamydia or gonorrhea.

Recommendation for whether they should get screened for chlamydia/gonorrhea or not.

Recommendation for frequency of screenings.

2.3 View Patient Records

<u>Requirements</u>: This use case must allow a player to choose a cryptogram to choose a cryptogram from a list of available cryptograms, save/submit a solution to a chosen cryptogram, and see previously solved cryptograms.

Pre-conditions:

The user must have launched the application.

The user must be logged in to the application.

At least one patient recommendation record must exist on the application database instance.

Post-conditions:

The application will display a list of available patient recommendation records.

The application database instance will be updated when a record is deleted.

Scenarios:

2.3.2 Query Patient Data

The application will display a list of existing recommendation records, which the user can use to select a particular record to get additional information for that record.

Once a given record has been selected, it will redirect it to a page that displays the following information for that patient recommendation record:

Patient details e.g. full name, personal details.

Recommendation information e.g. frequency of screenings, likeliness to have chlamydia or gonorrhea, screening recommendation (yes/no).

2.3.2 <u>Delete Existing Recommendation Records(s)</u>

Design Document

Team: Team Cranky Euler

1 Design Considerations

1.1 Assumptions

The purpose is to build a web-based tool that recommend screening for Chlamydia and Gonorrhea in a selection of patients. The app consists then of a doctor/provider facing portal with FHIR integraion that based on medical history for the patient and manual input about the patient can give insights or help decide whether or not they at increased risk of infection.

For this we will use FHIR Api to interact with the database either by querying or modifying, we may add some backend logic to help determine if the patient is at risk of infection or not.

The dependencies should be: SQL, python, python-flask, javascript, react js

1.2 Constraints

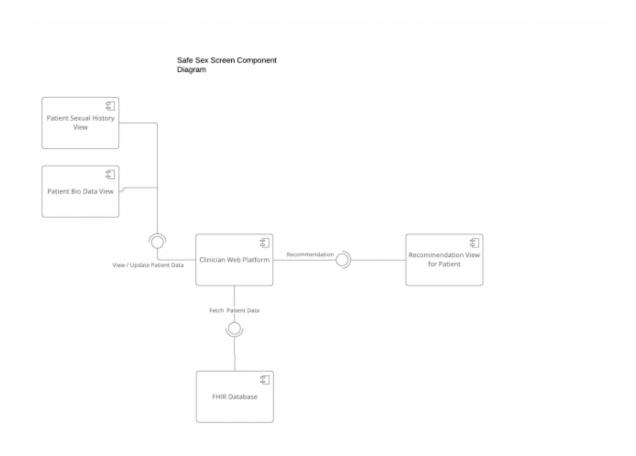
The lack of formal medical experience

1.3 System Environment

Software: Chrome/Firefox browser Hardware: Not applicable in our case

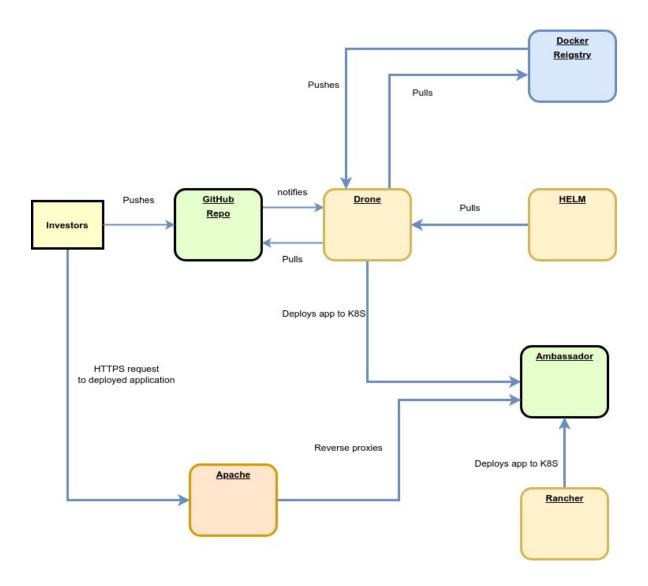
2 Architectural Design

2.1 Component Diagram

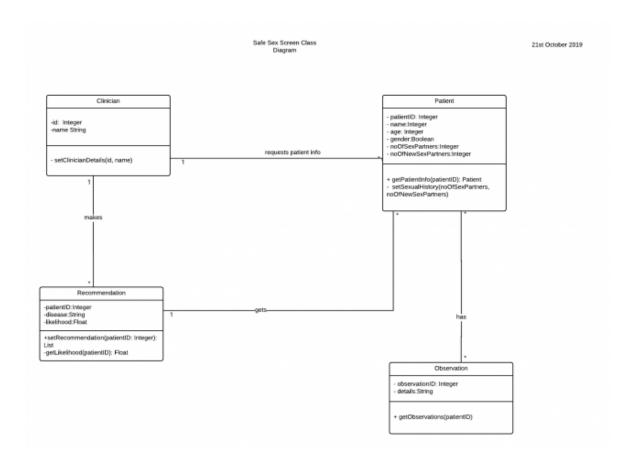


2.2 Deployment Diagram

Based on the HDAP lecture:

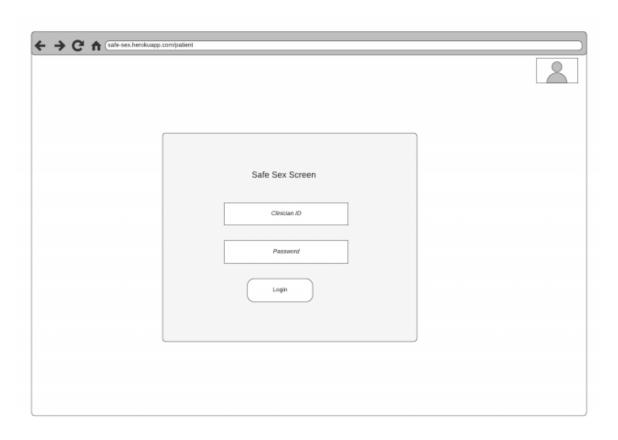


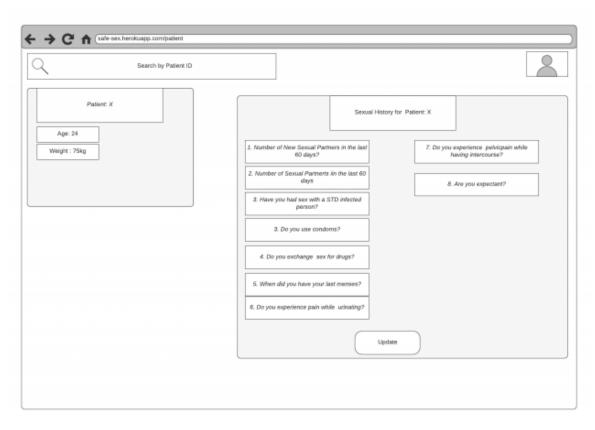
3 Class Diagram

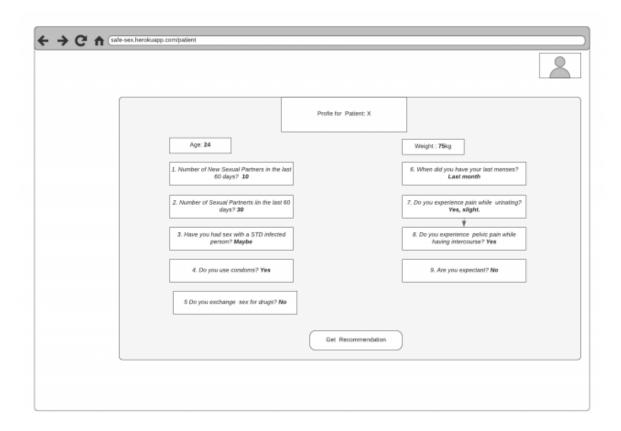


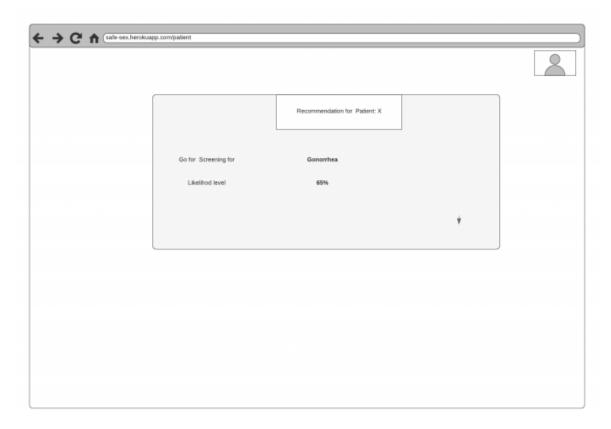
4 User Interface Design

These are very basic UI Design to get an idea on the things we may need to implement









5 Research Overview

Overview

Chlamydia is a sexually transmitted disease caused by a bacteria called Chlamydia trachomatis. It is an infection that usually affects young, sexually active persons. Chlamydia trachomatis is a bacteria responsible for most sexually transmitted infections [1]. In most of the cases, the infection is asymptomatic which means it has no symptoms in fact 70% of women and 50% of men chlamydia produces few or no symptoms and remains undetected. Chlamydia can cause complications if not treated, especially in young women.

In Denmark the infection rate of chlamydia is about 456/100 000 in 2007. It is reported that around 10% of women and 13% of men aged under 25 years have chlamydia infection (1). In 2015 more than 1M chlamydia infection cases were reported in the US (2) Reported infection rates have increased in the last 10 years, this is due to the expansion of screening and better reporting systems (2).

Gonorrhea is also a sexually transmitted disease, it is caused by a bacteria called Neisseria gonorrhoeae. Just like chlamydia it is most common among young, aged under 25 years and sexually active persons. It can be asymptomatic, especially in women (2).

Gonorrhea is the second most common STD. in 2015 more than 1M cases of Gonorrhea infection were reported in the US (2).

Chlamydia and Gonorrhea can cause cervicitis, urethritis, proctitis, and pelvic inflammatory disease (PID). It is crucial to prevent and detect these infections early in order to protect and improve the sexual and individual health of patients and of the community. (2)

Patients infected with gonorrhea are more likely to be co-infected with chlamydia (3). It is recommended that a patient diagnosed with chlamydia or gonorrhea should consider screening for other STDs such as syphilis and HIV.

Tests and Screening

There has been major advancements in chlamydia and gonorrhea detection in the past 30 years, there are different diagnosis method but cell culture remains as a reference.

Repeated NAAT test (Nucleic Acid Amplification Testing) is the most sensitive test for chlamydia and gonorrhea (2)(1).

There are other available tests with different costs, specificity and sensitivity. Examples of those tests are Cell culture and Nucleic acid hybridization tests. (1) contains more details about various tests for chlamydia diagnosis.

In most cases Chlamydia and Gonorrhea infections are asymptomatic for both men and women. The United States Preventive Services Task Force and Centers for Disease Control and Prevention recommend screening for chlamydia every year for sexually active women aged under 25 years and for older women with risk factors or high risk sexual behaviours (2)(4). They do not recommend routine screening for men because of lack of evidence, efficiency and cost-effectivness, but still suggest targeted screening in heterosexual men with high sexual activity, men in correctional facilities, adolescent and STD's clinics (2)(4).

Annual screening for gonorrhea is recommended for women aged under 25 years and for other women with increased risk factors (4). Those risk factors could be, having new or multiiple sex partners, not using protection, drug use, engaing in commercial sew work or living in communities with high disease prevelance.

Targeted screening is important for persons showing symptoms of chlamydia and gonorrhea or persons or children victim of sex abuse, or persons having intercourse with partners having STDs.

Screening Barriers

Majority of doctors do not follow the recommended routine screening for teenage and young women for various reasons. The physician belief, work environment, gender, opinion, ideology and commitment, influence his or her decision to proceed with chlamydia and gonorrhea screening or not (5). All these factors, along with the patient's lack of awareness can present barriers to the recommended screening.

Factors of higher risk of infection

In (2) Table 1 summarize some of History and Physical Examination Elements of Patients with Possible Chlamydia or Gonorrhea Infections, the following list summarizes the content of the table, these are the factors that can help determine the risk of infection:

Gender

Age under 25 and sexually active

Sexual contact with a person with an STD or STD related manifestation (symptoms)

Use of condoms

Number of sex partners in the past 60 days

New sex partners in the past 60 days

Environment with high STD diseases prevalence or not

Use of drugs

Exchange sex for drugs or money

Pain in joints or at sites of tendon insertions

Rash

Fever

Pharyngeal discomfort

Change in odor, amount, quality, color of vaginal discharge

Dysuria (painful or difficult urination)

Lower abdominal or pelvic pain

Pelvic pain with intercourse

Date of last menses

Pregnancy

Abnormal Intermenstrual bleeding

Urethral discharge, dysuria, testicular pain (for men)

Physical examination

Oral examination for lesions

Joint examination for tenderness and swelling

Rectal examination for mucosal friability, purulent discharge, perianal lesions

Inguinal, femoral, epitrochlear cervical nodes for swelling and/or tenderness

Pelvic speculum examination for vaginal pH, fluid characteristics, purulent discharge at the endocervix, cervical ectopy

Pelvic bimanual examination

The above mentioned factors can help decide whether or not to

proceed with a screening for chlamydia and gonorrhea. Using this research overview, the above list and additional research if needed we will decide the factors that we will use in our application to determine whether or not to recommend a screening.

References

- **1.** Bébéar, C., & De Barbeyrac, B. (2009). Genital Chlamydia trachomatis infections. Clinical Microbiology and Infection, 15(1), 4-10.
- **2.** Workowski, K. (2013). Chlamydia and gonorrhea. Annals of internal medicine, 158(3), ITC2-1.
- **3.** Lyss, S. B., Kamb, M. L., Peterman, T. A., Moran, J. S., Newman, D. R., Bolan, G., ... & Ehret, J. (2003). Chlamydia trachomatis among patients infected with and treated for Neisseria gonorrhoeae in sexually transmitted disease clinics in the United States. Annals of internal medicine, 139(3), 178-185.
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Test Plan

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1 Testing Strategy

1.1 Overall strategy

Our testing will encompass unit and integration tests. Unit tests will mostly be for the backend functionality to ensure the core functional logic is implemented such as using patient-provided data to determine the risk level of Chlamydia or Gonorrhea. Integration tests will be used to test the whole system as a whole once most of the functionality has been built in. For our unit tests, we will use chai and mocha Javascript libraries. The UI will mostly involve manual testing by the QA lead.

1.2 Test Selection

We will employ white box testing techniques in the project which will involve working with the source code. We will focus on independent testable features such as authentication, addition of patiient information and fetching recommendation details. We anticipate that most of our tests will be unit tests.

1.3 Adequacy Criterion

We will strive to achieve 70% test coverage as measured by tools such as Istanbul to test this coverage.

1.4 Bug Tracking

We will track bugs by creating Github issues with label *bug* in our assigned Github repository. This will ensure visibility to the whole team as well as our TA.

1.5 Technology

We will use chai and mocha testing libraries for our unit tests. We hope to use Selenium for the test of our web application as well if time allows.

2 Test Cases

Preliminary test cases:

Purpose	Steps to perform the test	Expected result	Actual Result	Pass/fail
Test that an entering correct username results in a successful login	On the login screen of the app, type in the username of the provider and press the log in button	Success		
Test that entering incorrect username results in unsuccessful login	On the login screen of the app, type in the username of the provider and press the log in button	Error. Incorrect username.		
Test adding patient data into the system	On the home page, upon a successful login, the provider can enter patient information.	Patient data is successfully saved.		
Test that a correct recommendation is given for screening of Chlamydia	Add a new patient or search for a new patient whose sexual history that matches a symptom of Chlamydia.	Success. Go for screening for Chlamydia once every 6 months.		
Test that a correct recommendation is given for screening of Gonorrhea	Add a new patient or search for a new patient whose sexual history that matches a symptom of Gonorrhea.	Success. Go for screening for Gonorrhea once every 6 months.		
Test that a correct recommendation is given if no symptoms or Chlamydia and Gonorrhea are found	On the recommendation screen, the patient should enter their bio information and sexual history that is not at risk,	Success. It looks like you're safe. No need for screening. Check back in 6 months		
Test that we can fetch a list of patients from the FHIR api.	On the home page, click patient data.	Patients data is returned if available.		

Information Sheet

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Link to Gantt Chart

Our chart can be found here.

Link to GitHub Repo

Our Repo can be found here.

Thank You!