Leveraging Mobile Technologies to Communicate Genetic Testing Information

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Introduction:

By nature, genetic information is complex, hereditary, unchangeable, newly accessible, inconsistently characterized and somewhat predictive. Many of these aspects are unique to this field and have set it apart from other types of information used for diagnosis and treatment. The University of Washington Genetic Medicine Clinic (UW GMC) was one of the first medical genetic clinics in the world. For 60 years they have provided clinical guidance, genetic testing, and consultation. Certified genetic counselors, medical geneticists, and administrative staff all work together to server patients. The highly specialized nature of clinical genetics has resulted in portions of the clinic workflow operating outside the centralized hospital resources. These necessary internal administrative tasks have been developed piecemeal with an emphasis on basic functionality.

Within the UW GMC, all staff, from administration to clinicians, require specialized knowledge in genetics to carry out their functions. Third-party payors remain the predominant source of income for healthcare clinics and have tremendous influence over the workflow due to their ability to dictate requirements for successful reimbursement for services. Explosive growth in available genetic tests have meant there are over 70,000 clinical genetic tests covered by only 200 billing codes (NIH, 2018). This makes insurance providers require additional documentation to confirm the type and necessity of individual tests. The process of communicating with insurance and handling multiple appeals on behalf of the patient is burdensome and falls on genetic counselors forcing them to act as patient advocates.

The current clinical workflow requires highly specialized patient intake and scheduling, record retrieval and insurance authorization to be performed by clinic specific staff and/or the genetic counseling team instead of centralized UW medicine resources. Current patient billing practices mean that necessary activities with high time burden are not being covered by payers (such as return of results over the phone, insurance authorization and appeals process, as well as in-depth intake procedures). The clinic has a patient backlog and clinician time is not being well utilized.

Through a series of stakeholder interviews we were able to capture essential workflow processes,

potential breakdowns, as well as cultural and historical context. We modeled the workflow through the clinic using several frameworks to identify portions that could be addressed using mobile technologies.

Workflow Assessment:

The existing clinic workflow is depicted in Figure 1, represented as a swimlane activity diagram. Each lane represents an actor and each box represents an activity in the workflow, thus the presence of a box in a lane indicates which actor is primarily responsible for the activity. The process proceeds from left to right. Some of the key frustrations or potential breakdown in the workflow are highlighted in red brackets near the corresponding action.

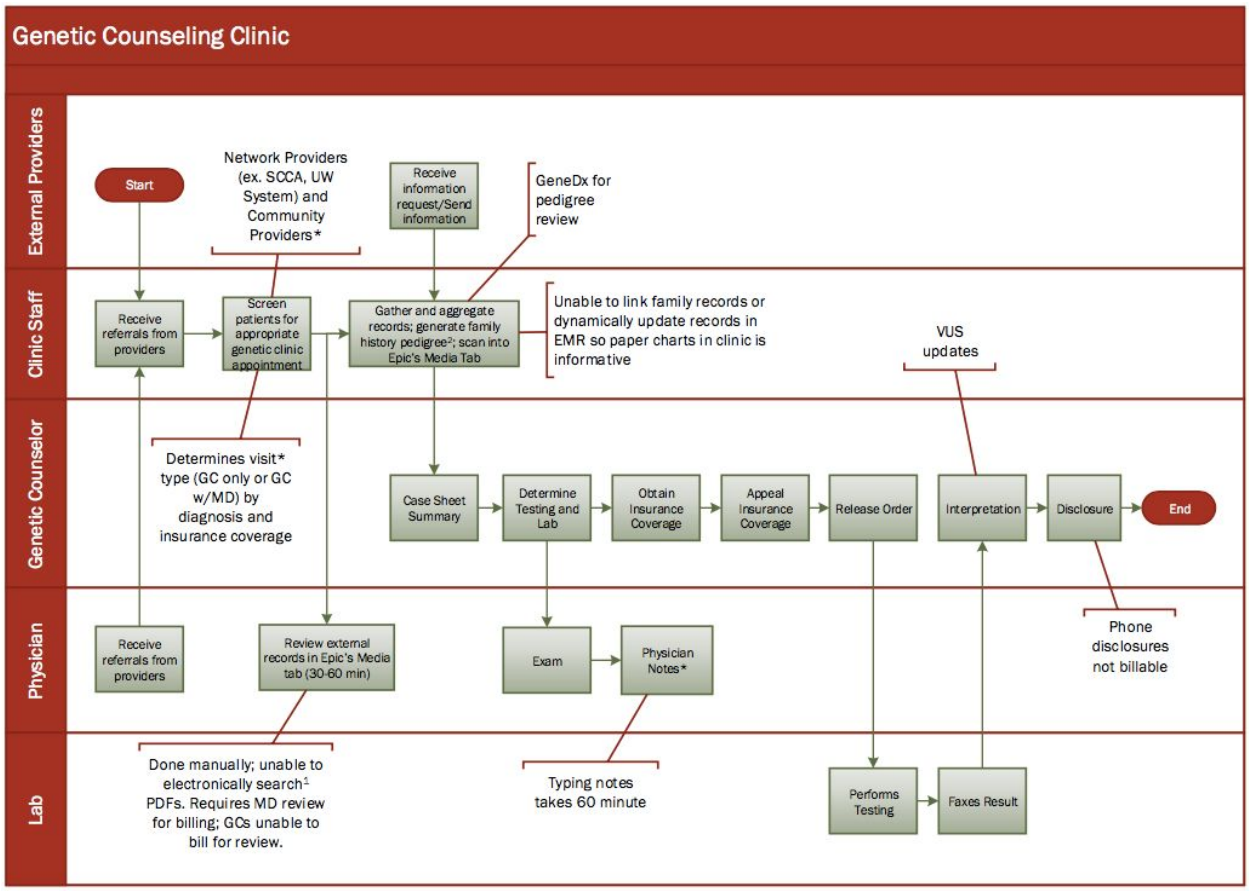

Figure 1. UWMC Genetic Medicine Clinic Activity Diagram

To determine the current workflow, we interviewed five individuals associated with UW GMC including: the Director of clinic operations and the Head of the Division of Medical Genetics, both practicing clinical geneticists; and three genetic counselors. These interviews highlighted different perspectives on problem areas in the workflow depending on clinic role. We were able

to explore these differences by developing personas (Appendix A, Figures 1-4). Compiling key issues from all stakeholder interviews suggest that the **three biggest areas to address were the initial patient intake process, insurance authorization process and return of results.**

The initial patient intake process is currently performed by one full-time and one part-time clinic administrative staff person. The intake process is detailed in a use-case diagram (Appendix A, Figure 5), involves screening referrals from external physicians, contacting patients to conduct phone-based family history, determining which specialty the patient falls into (cardiac, neurological, cancer, pre-natal, or metabolic), collection of external records for patients and pertinent family members, drawing a pedigree, and scheduling the patient with the appropriate team. Each of these duties requires specialized knowledge and expertise. In other clinics within the UW hospital, many of these tasks would be handled by central hospital resources such as scheduling, referral vetting, and records collection. However, the specialized knowledge and expertise required by the intake activities at UW GMC precludes using centralized hospital resources. In spite of this specialized workflow, the hospital is not willing to provide additional hiring resources and the end result is a backlog of patients waiting for intake/scheduling and unused time-slots for clinicians (see cultural model in Appendix A, Figure 6).

Insurance authorization is also a lengthy process that is currently performed by genetic counselors. Due to the high cost of genetic testing, insurance companies offer limited and specific coverage to their enrollees and have exacting procedures to ensure they are only paying for testing that meets their criteria. Because of the heterogeneity of insurance criteria, the genetic counselor must research which appointment types and tests are covered by each payor and send a detailed letter to the insurance company on behalf of the patient requesting permission to test. These authorizations are often rejected, initiating an appeal process. Rejection and appeal can be repeated multiple times. As with patient intake, in a typical clinic, this task would fall to central hospital resources, but here again, the specialized knowledge requires it be completed by the counselor or clinician, generally the genetic counselors (see sequence model Appendix A, Figure 7). Genetic counselors have attempted to reduce time-burdens by developing an internal flowchart and letter templates in an attempt to reduce the time-burdens of this process but it remains an issue that impacts morale.

When the patient's genetic testing results are received by the clinic they must be conveyed to the patient. Historically, patient results were returned and explained by genetic counselors in a follow-up appointment. In the case of a negative or inconclusive genetic testing result, patients found the time and monetary burden of an additional appointment frustrating. However, asking patients only to return if they have a positive test result can increase anxiety and harm. In response to patient concerns, the clinic communicates genetic testing results to patients over the phone, but the clinic cannot bill insurance for this time.

Finally, related to return of patient results, is the issue of variants of uncertain significance (VUS). A VUS is a rare genetic variant without sufficient evidence to classify it as clearly pathogenic or benign. However, as new evidence is generated, through research and patient reports, a variants status as a VUS can change. Variant reclassification can occur long after testing and initial return of results for the patient. The clinic currently has no way of automatically tracking VUS status changes, nor tracking patients impacted by the reclassification of such variants.

Design Rationale:

As a design team, we were able to brainstorm possible solutions to all three major issues. **In order to balance clinic needs, feasibility, and implementation, we decided patient cancer intake was the best problem point to tackle for this project.** It is the first bottleneck in the clinic workflow and there are process examples available from other genetic medicine clinics in the country. The cancer intake was decided upon because roughly 50% of the referred patients to UW GMC are cancer patients and its intake questionnaire implementation would be more straightforward.

Our stakeholder interviews revealed that some physicians consistently refer appropriate patients

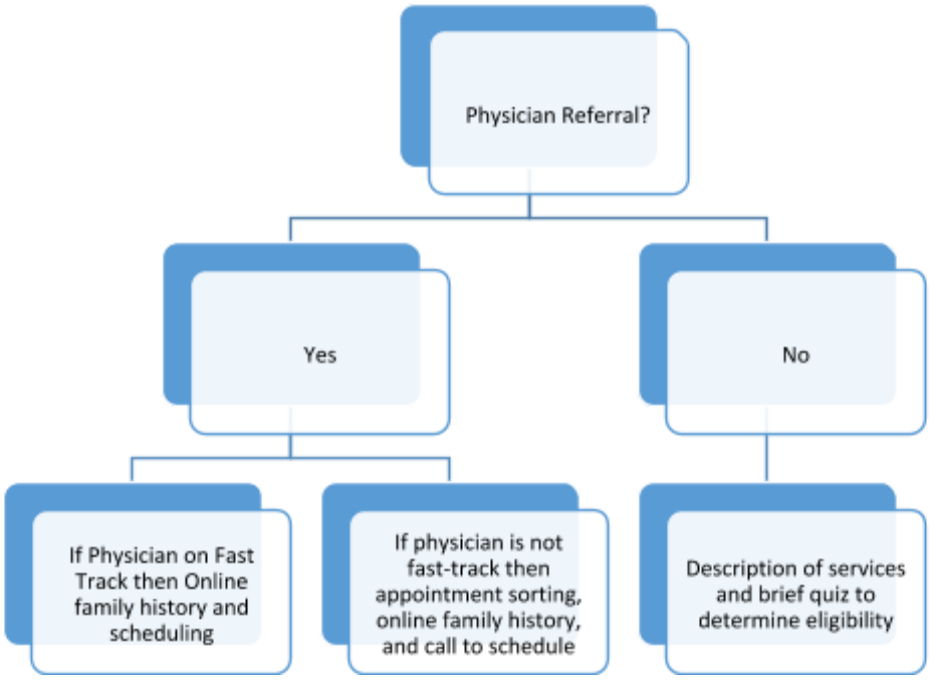

Figure 2. Physician Referral Workflow

and others who are less familiar with genetics do not. One idea proposed by the director of the clinic operations was creating a fast-track process for scheduling patients who were referred from certain physicians. This would reduce the need for additional vetting by administrative staff on all referrals and with an online tool for intake require only a scheduling phone call. We have developed the proposed workflow (Figure 2) that would allow administrative time to be better utilized by only making lengthy phone calls to patients who require additional screening.

We are proposing an online family history questionnaire that would be completed by prospective patients prior to scheduling an appointment. Other UW medicine clinics such as the UW Medicine Weight-Loss Clinic require prospective patients to complete online modules prior to contacting central scheduling. The modules end with an online quiz that collects the patient's information. When the patient calls to schedule, the clinic has all necessary information to proceed. We are proposing a similar workflow whereby patients complete an online family history questionnaire similar to what would be asked during a phone call with the administrative staff. The questionnaire answers could be used to produce a digital pedigree or allow for the administrative staff to draw one without engaging in a lengthy phone call.

Pre-appointment questionnaires are common practice in specialty medicine. We found numerous paper examples mailed to patients at other genetic medicine clinics across the country (Appendix B). The advantage of designing this as a web-based form is that data can be collected in a structured format and used for other clinic task such as automatic pedigree generation, decision support, and may be able to interface with the EHR.

The goal of this design is to reduce the length of time administrative staff spends contacting prospective patients and collecting their information over the phone. We hope this design could be expanded so that the majority of family history information collection and patient intake could be completed online electronically allowing administrative staff to clear the patient backlog and reduce gaps in scheduling.

Proposed Design:

Fifty percent of the clinic's patients are seeking testing and evaluation for cancer genetics. Cancer genetics involve both genes that are related to hereditary cancer syndromes as well as specific mutations that change the course of treatment for people with existing cancer diagnoses. A variety of algorithms have been developed to identify possible hereditary cancers using family history alone.

We propose an online family history collection tool specifically tailored to cancer genetics. This tool could be used to screen eligibility for cancer genetics patients who have been referred

by external physicians who are not “fast-tracked” as well as collect family history information for the construction of a pedigree. Our proposed design includes the population of a digital pedigree similar to ones created using online free software such as Progeny, as seen in Figure 3. There is also an option to upload a GedCom file, if the patient chooses to do so. A GedCom file stores genealogical information which would be helpful in creating a pedigree.

The tool consists of a webpage based questionnaire that mimics the types of questions asked on traditional paper-based cancer genetics questionnaires, as seen in Figure 4. The dropdown options allows patients to easily complete the fields and also suggests suitable options. The most common types of cancers are included in the dropdown, but there is an option to add an unlisted cancer option, if necessary. Furthermore, the questionnaire allows the referred patient to schedule a time for the administrative staff to contact the patient for further questions. At the bottom of every page, there is a progress bar to highlight the length of the questionnaire.

After all the fields are completed, a pedigree is generated using the inputted information. The patient can then save and print the pedigree for their own use. Furthermore, the patient can also select a date and time that is convenient to receive a follow-up phone call with the clinic staff. By moving the patient intake prior to the phone call, the clinic staff will have more time to field calls and tackle the waitlist the clinic currently has.

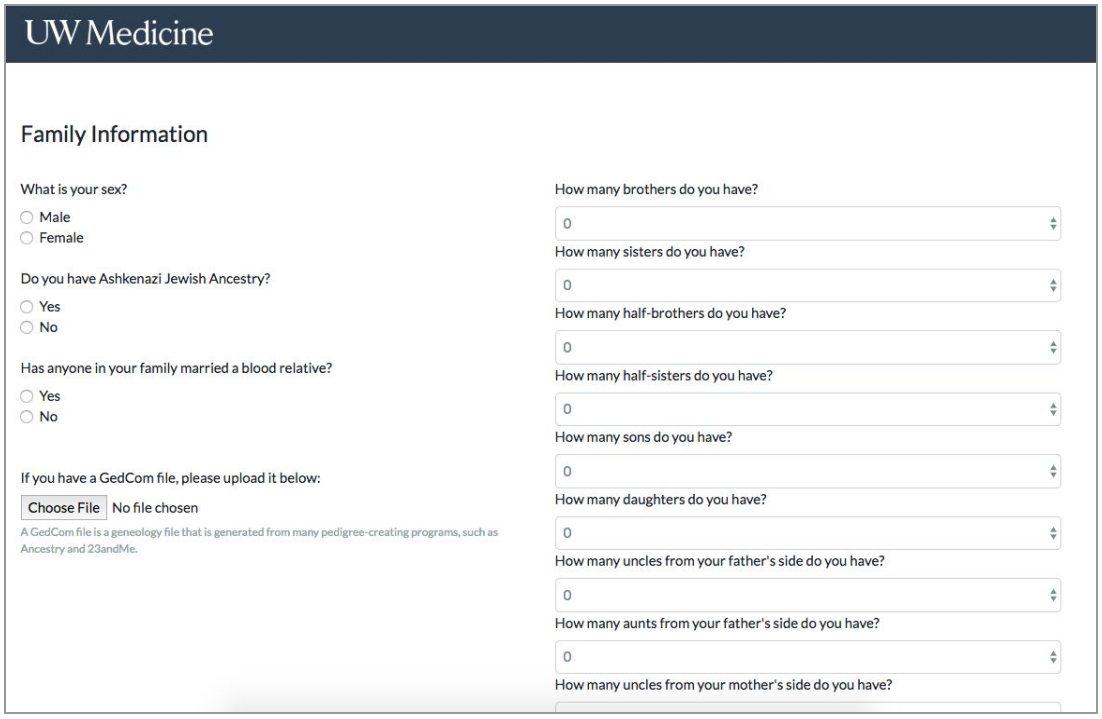

Figure 3. Family Information Questionnaire Page

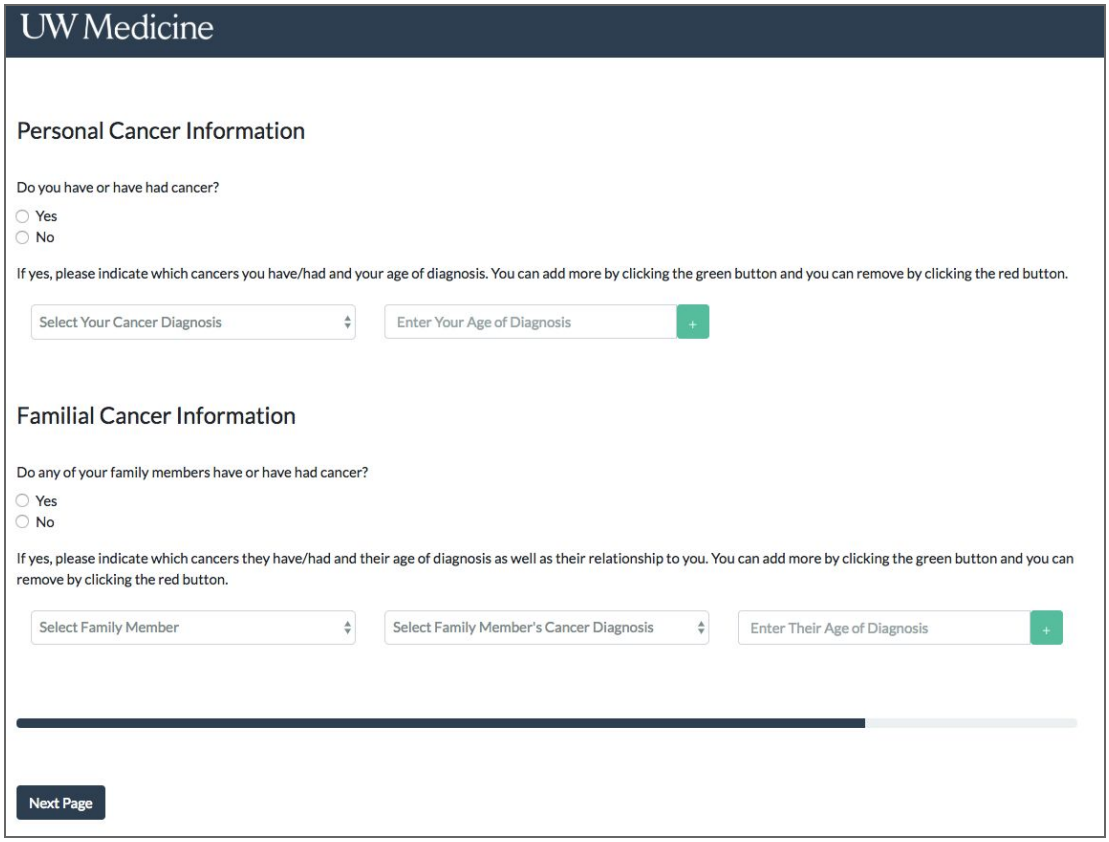

Figure 4. Cancer Genetics Questionnaire Page

Strengths:

This design has the strengths of fitting easily into the existing workflow. It has potential to be expanded and used as a means of establishing a relationship with new patients. Most patients that come to UW GMC will only visit the clinic once ever. So this tool is a basic questionnaire right now but it could be further developed into a patient facing resource that could build rapport, increase patient engagement and potentially reduce the clinic's no-show rate. A web-based application also has the advantage of being easy to edit or amend. The back-end data storage can be designed to allow for ease of transfer into the EMR.

Weaknesses:

We were unable during our stakeholder interviews to sit down with the UW GMC admins and therefore a lot of the design elements are speculation. It is possible for example, the questions in the tool do not match their own phone-based family history workflow. While the results of these questions address clinic needs, the actual tool would be patient facing and due to IRB restrictions we were not able to conduct any needs assessments nor preferences of the potential user.

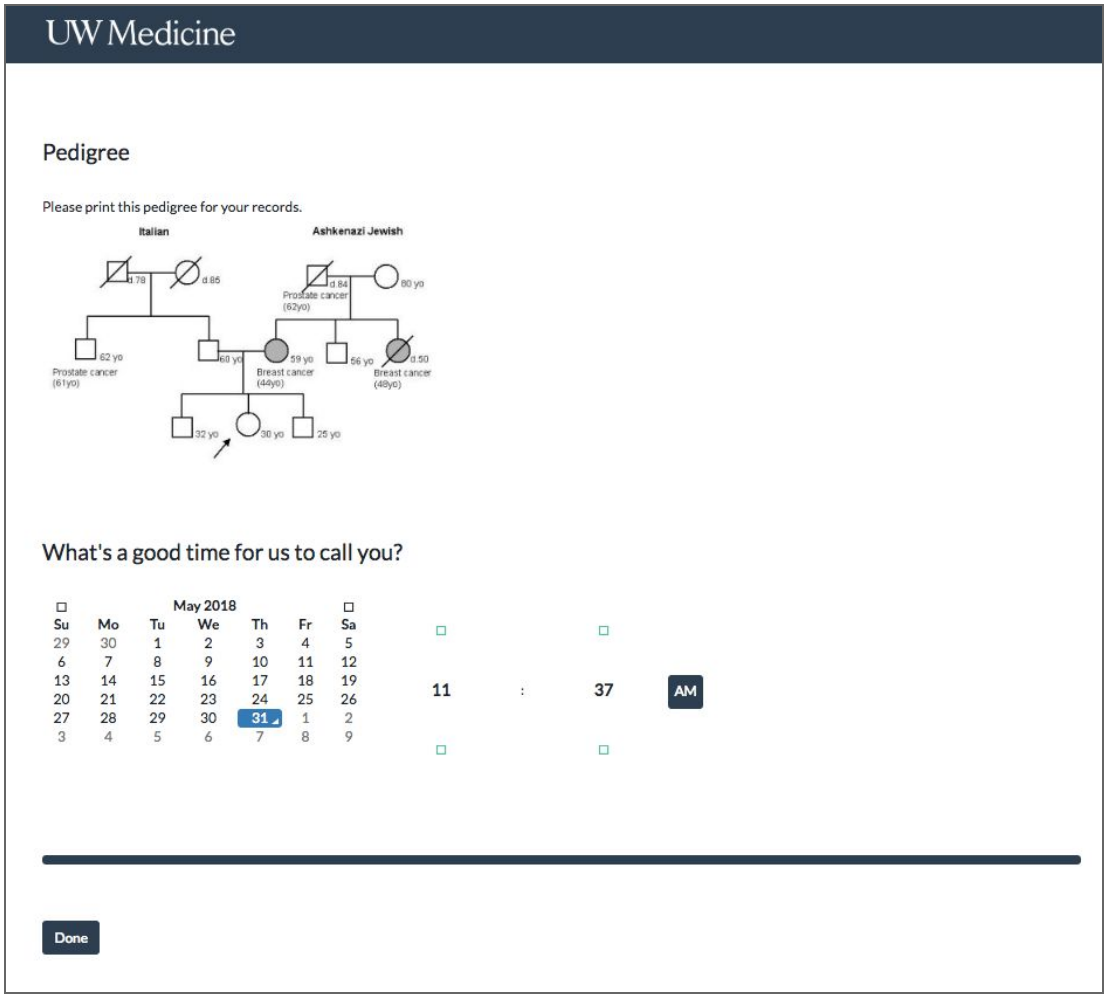

Figure 5: Pedigree Generation

Unsolved issues:
Our tool focused primarily on cancer genetics but that is only 50% of patients at the clinic. Ideally this tool would be expanded to allow for online family history and relevant pre-appointment data to be collected for all patient types.

Implementation Difficulties:
Collecting patient data online requires HIPAA compliant servers and secure data transfers. We did not explore the current standards when designing this or if any there is any existing UW policies that would impact this application.

Evaluation:

Though the primary goal of our proposal is to improve clinical efficiency, many overlapping factors impact a clinic's workflow, positively and negatively. Introduction of new processes can

also have a negative effect of impeding workflow as well. Therefore it is important to identify metrics that can be clearly attributed to our proposal and improve clinical efficiency without negatively impacting the clinic's current process.

In order to evaluate the form's utility without causing undue hardship on the clinic, we propose conducting an initial pilot roll-out of the form. Results from the pilot will allow us to make adjustments as necessary for future revisions and improvements. For the pilot phase of our proposal, two evaluation criteria will be used to measure clinical workflow improvement: efficiency and effectiveness. Efficiency will be evaluated quantitatively based on the percent of patients who submit the online form. Effectiveness will be evaluated qualitatively by perceived utility of the completed pedigree.

The measure of efficiency for our proposed intake form for cancer patients will be based on the number of patients who submit the online intake questionnaire over the total number of cancer patient referrals received by the clinic, within a two week period. A higher percentage of patient intake completion rates may lead to greater efficiency of clinic staff and workflow.

However, one of the primary challenges for clinic staff is to ensure appropriate and accurate pedigree creation. The accuracy of pedigree creation serves as a link to our measure of effectiveness. In fact, the extent to which clinic staff and genetic counselors are efficient in their respective professions depend upon the accuracy of the patient created pedigree. If patients produce pedigrees that require extensive revisions by clinic staff or genetic counselors, this can hamper clinic processes further and lead to additional delays. Therefore, qualitative assessment by clinic staff and genetic counselors of patient pedigrees from the intake form is necessary to evaluate the effectiveness of the proposed intake questionnaire.

For each patient generated pedigree, clinic staff and genetic counselors will be asked two questions to provide their perspective on the utility of the patient generated pedigree. The first question will be anchored to likert scale responses. The second question gives staff and counselors the opportunity to expand upon and detail their approval or disapproval of the patient generated pedigree; hence it is an open-ended question that allows for free text. Both questions are listed below:

Question 1: How useful was the patient generated pedigree?

Very Useful	Somewhat Useful	Moderately Useful	Minimally Useful	Not Useful at All

Question 2: Were there any modifications that you had to make to the patient generated pedigree?

Additional metrics that can be gathered beyond the pilot phase of our evaluation includes measuring the amount of time it takes for clinic staff and genetic counselors to complete the intake process for newly referred cancer patients on revisions of our proposal. Prior studies found that genetic counselors spend an average of seven hours on each new patient case (McPherson et al., 2008; Williams et al., 2014). Williams et al. found that genetic medical history intake takes an average of 45 minutes. Heald et al. provide a detailed list of tasks separated by pre-visit, in-person, and post visit tasks that may be useful for future review and further comparisons. Reductions in time or tasks listed from these studies through our proposed intake form may serve to validate improvements in clinical efficiency within UW's Medical Genetics Clinic thus supporting one of NSGC's Strategic Initiatives of identifying 'existing and needed tools and technology to support the efficiency of genetic counsellors.'

Conclusion

Workflow analysis and stakeholder interviews revealed several points where mobile technologies could be leveraged to reduce workload on administrative staff, increase clinic efficiency and provide better services to patients. We identified three major areas where changes in workflow and development of new technologies would achieve these goals including patient in-take, insurance authorization and return of results. We have proposed a potential design solution to revamp patient in-take by making an online tool accessible by patients that would collect family history and develop a patient pedigree. This data would all be collected and stored electronically for easy merge with EMR and reduce time spent by clinic staff on these tasks. Evaluation of this tool would rely on surveys with administrative staff on the tool's perceived usefulness and improved patient workflow.

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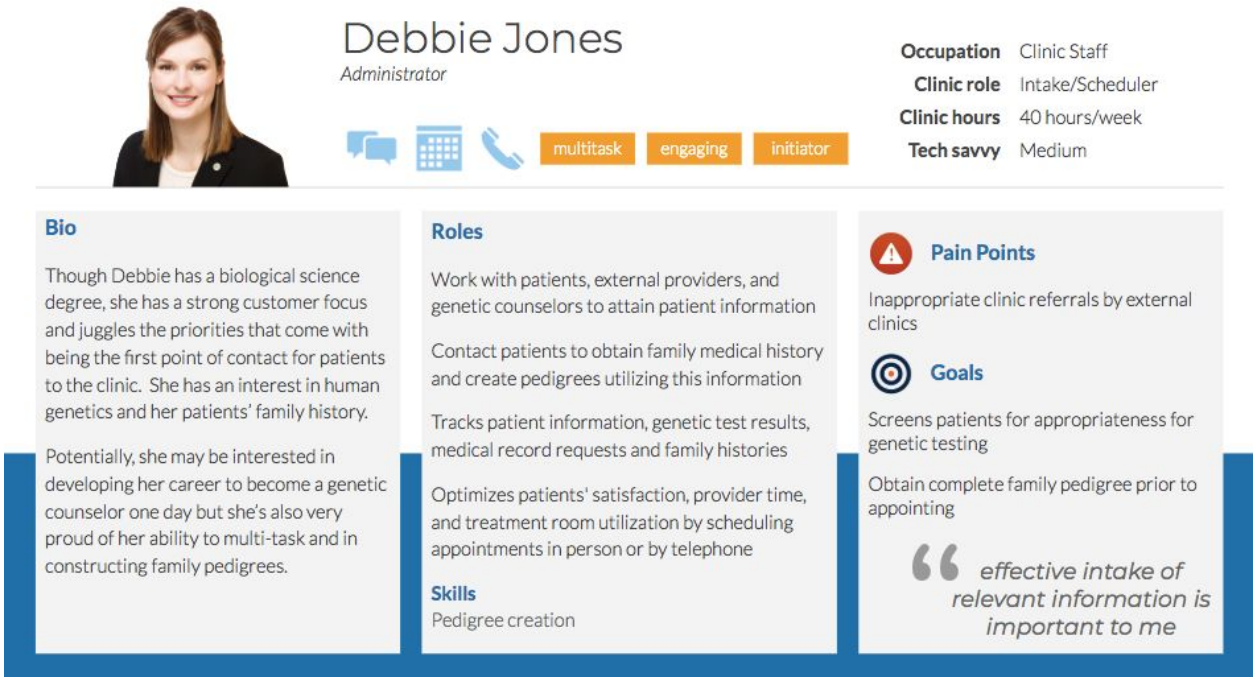
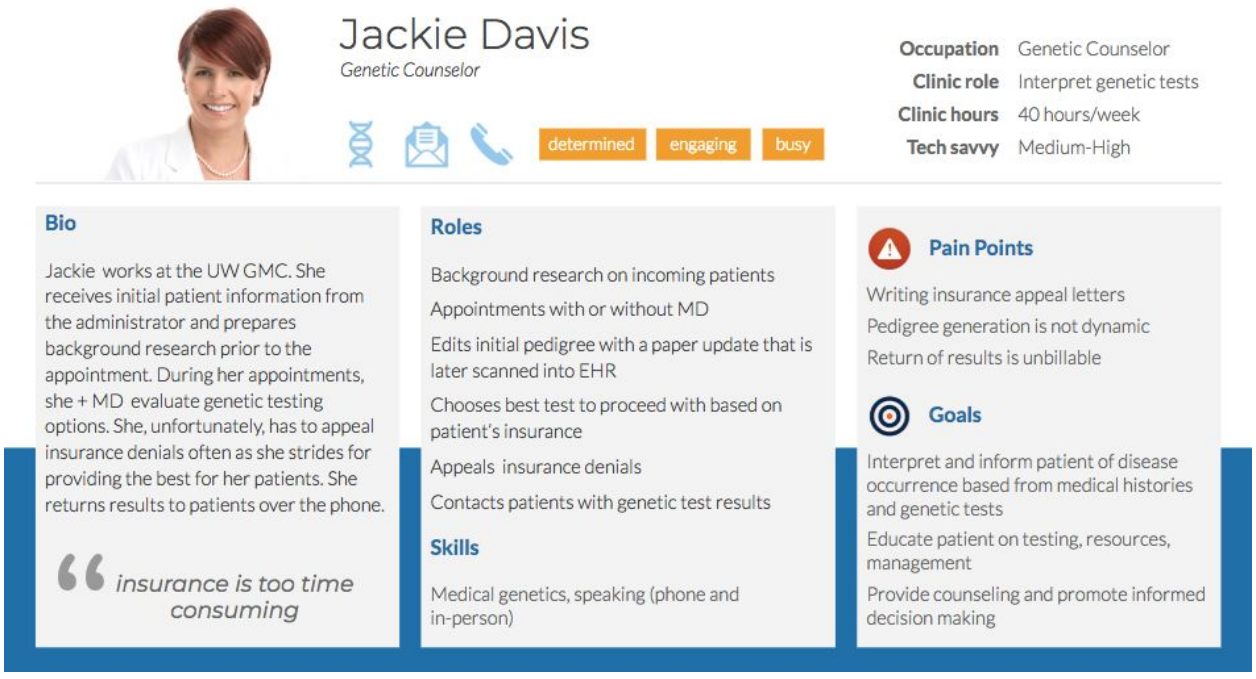
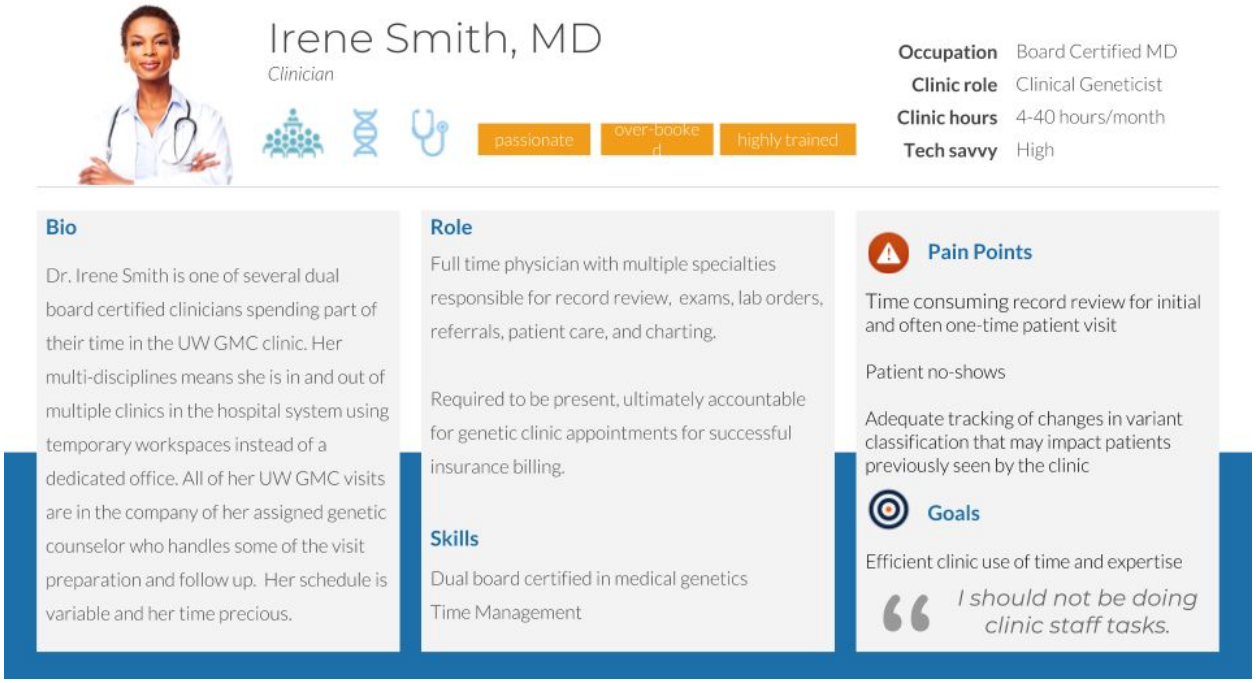
Appendix A (Figures):



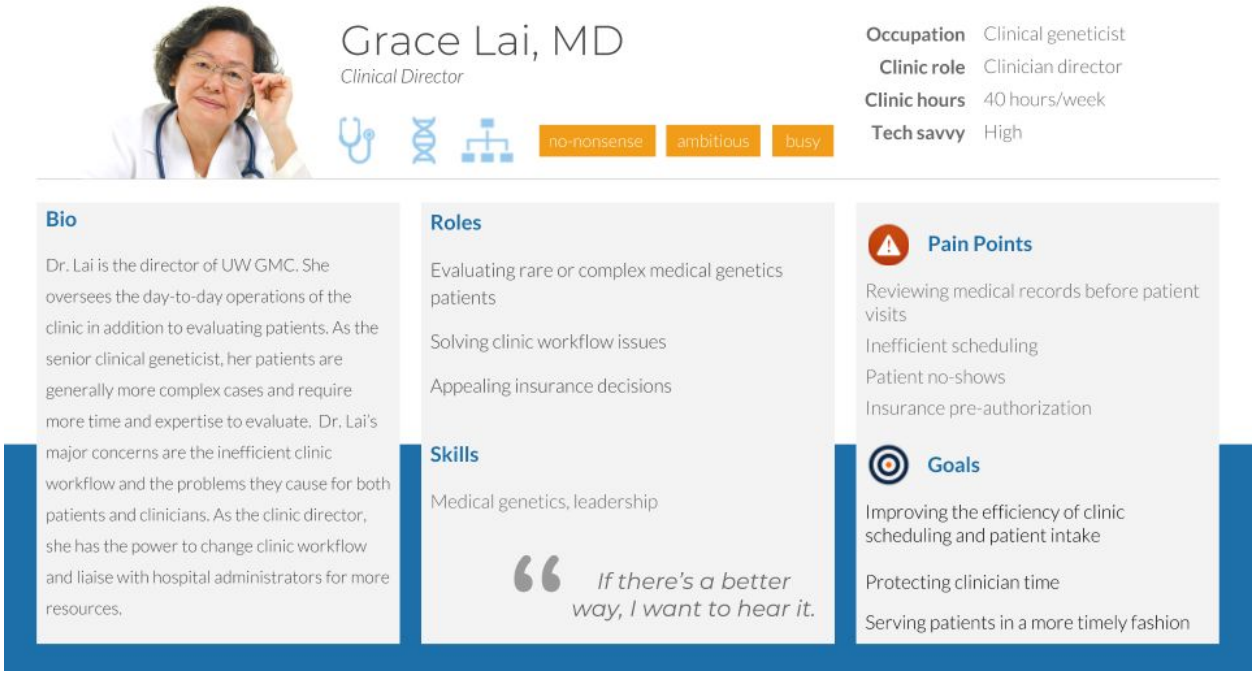
Appendix Figure 1: Administrator Persona



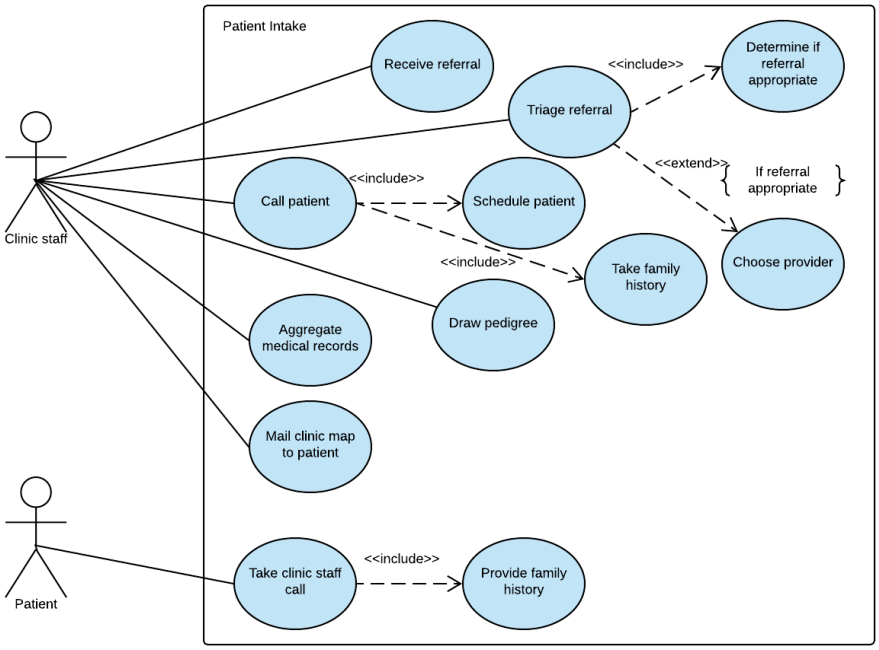
Appendix Figure 2: Genetic Counselor Persona



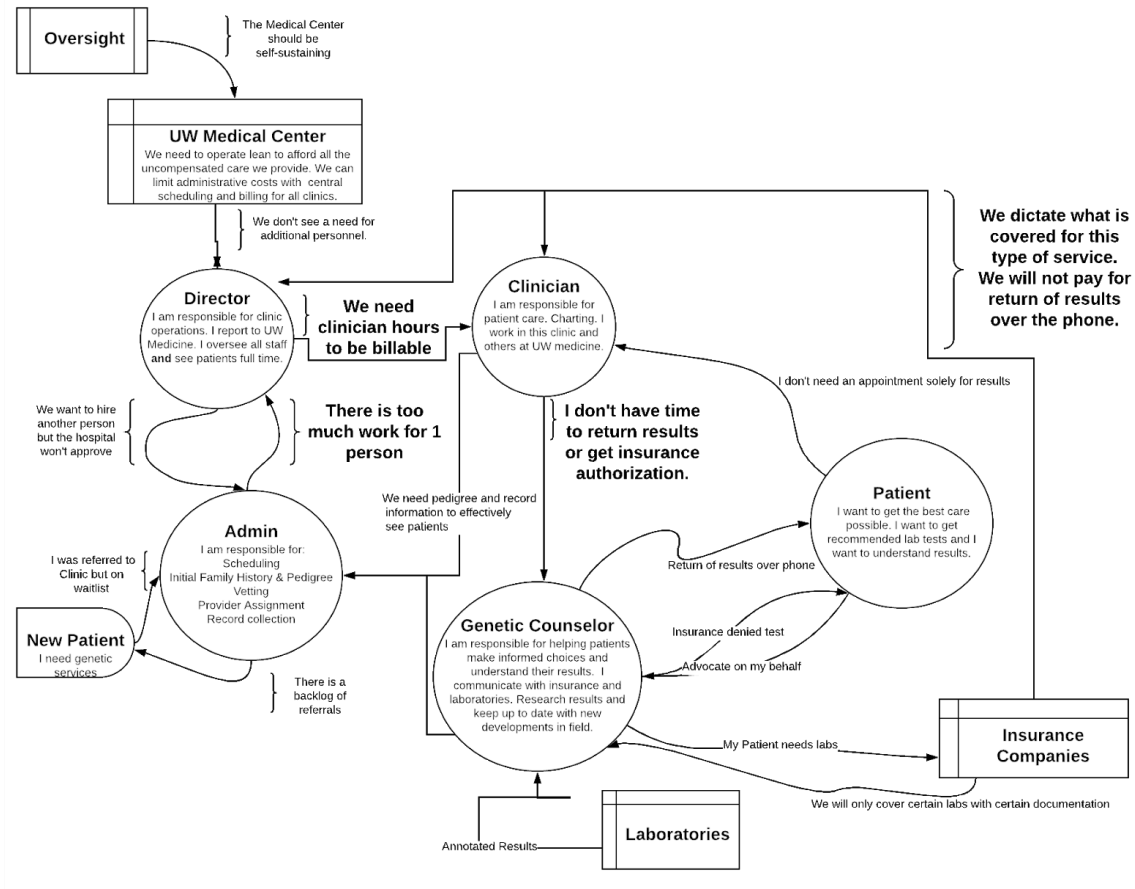
Appendix Figure 3: Clinician Persona



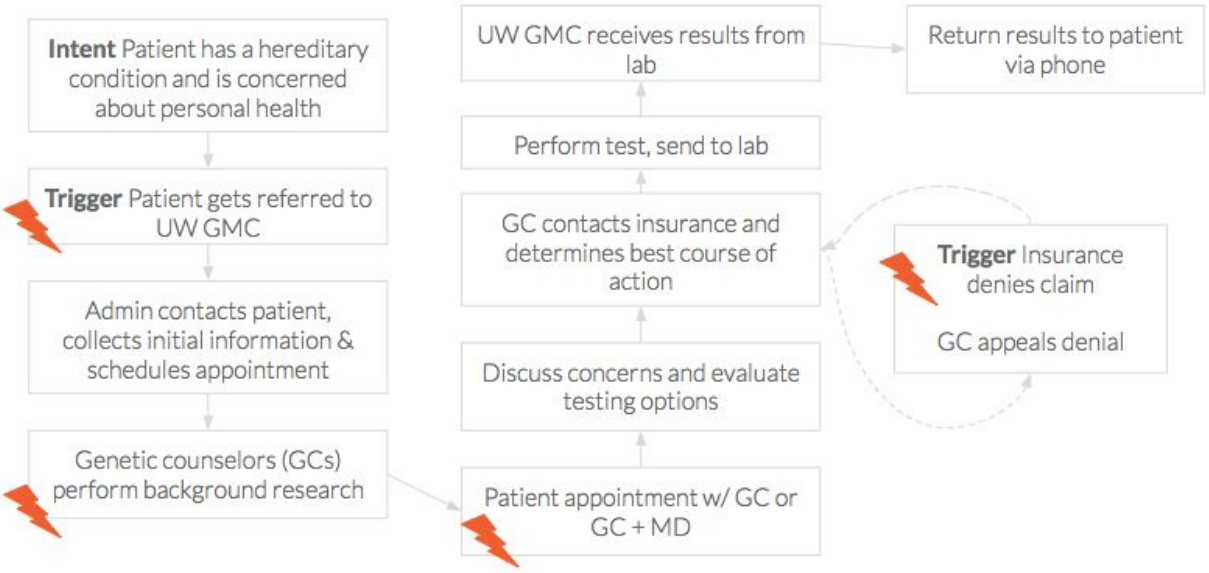
Appendix Figure 4: Director Persona



Appendix Figure 5: Use-case Diagram



Appendix Figure 6: Cultural Model



Appendix Figure 7: Sequence Model

Appendix B: Sample Genetic Clinic Cancer Intake Forms