Project Definition:

This project ultimately aims to develop a software system *Patient Like Mine* ( PLM) search specific to Mayo Clinic, Rochester, Minnesota. PLM will be utilized by Physicians, Administrators and Researchers with the architecture allowing for a wide range of users. This software will initiate a search to identify patients that are similar to a certain patient of interest or a cohort of patients for both offline and near-real time clinical decision support on a large scale, using data distribution and integration frameworks and rule engines.

Currently, Mayo Clinic Rochester has a database that contains approximately 5,000 patients for postoperative colorectal surgery; therefore, for this *pilot project* we have selected postoperative colorectal surgery patients as our cohort. The most frequent postoperative complications with colorectal resections are surgical site infection, anastomotic leakage, intra-abdominal abscess, ileus and bleeding (1). These complications need to be diagnosed accurately as they affect patient outcome. For the scope of this project, we have selected post-surgical bleeding for the complication of interest. PLM searches will allow comparisons of bleeding *parameters* of the patient of interest with previous outcomes, with the potential capability of predicting a post-surgical bleed. The physician would have the ability to search pre or post operatively patients with similar parameters; however, for this project, we have selected post op day 2 for our search criteria.

PLM searches will be achieved by taking a wide range of complex data, defined by a template, that enable searches (queries) to extract and render relevant data visually.

1. *Complications in colorectal surgery: risk factors and preventive strategies.* **Kirchhoff, Clavien and Hahnloser.** 5, s.l. : Patient Safety in Surgery, 2010, Vol. 4.

Goals:

Intermediate :

1. Identify the stakeholders needs within the specified domain
2. Gain knowledge regarding functional and nonfunctional requirements
3. Provide an IEEE Requirements Specification Document to include use case and activity diagrams
4. Gain knowledge regarding software architecture and design and identify the specific needs for stated project
5. Provide a design document to include a top level component diagram, at least one fully specified APIs , sequence diagram, architectural pattern and a class diagram identifying the major architectural elements

Final:

1. Software development and design
2. Software testing
3. Software deployment

Development Strategy:

We have chosen an agile strategy for development due to the overall large nature of this project. The evolution through collaboration with the stakeholder and project advisors will be essential to developing a pilot project of an appropriate size.

**Milestones**

|  |  |
| --- | --- |
| Identify Project | September 04, 2014 |
| Meeting With StakeHolder ( Dr. Peter Li) | September 26, 2014 |
| In Class Presentation, Introduction to “Patient Like Mine” Software | October 2, 2014 |
| Draft For Use-Case/Activity Diagrams | October 8, 2014 |
| In Class Presentation, Requirements Document | October 23, 2014 |
| 1st Draft IEEE Requirements Specification Document | October 31, 2014 |
| Meeting with Project Advisors | November 6, 2014 |
| 2rd Draft IEEE Requirements Specification Document | December 1, 2014 |
| Final IEEE Requirements Specification Document to be submitted to project advisers | December 5, 2014 |
| 1st Draft Design Document to be submitted to project advisers | December 5, 2014 |
| Final Project Management Document to be submitted to project advisers | December 5, 2014 |

Prerequisites and Outcomes:

1. Meet weekly with Dr. Peter Li regarding “Patient Like Mine” Specifications
2. Meetings with Dr. Davide Sottara and Dr. Robert Greenes regarding software design and documentation requirements

Workers:

Stakeholder: Dr. Peter Li

Project Advisors: Dr. Davide Sottara, Dr. Robert Greenes

Teaching Assistant: Dr. Amol Bhalla

BMI 540 Class Participants:

William Caughey: System Engineer and Developer:

1. Attend weekly stakeholder meetings and BMI 540 classes
2. Identify and write-up nonfunctional requirements
3. Assist in the Use Case, Activity and Sequence Diagrams
4. Assist in the IEEE Requirements Specification write-up; in particular, sections 2 and 3
5. Contribute to the formal BMI 540 in-class presentations
6. Assist in all of the IEEE Requirements Specification document drafts 1, 2, and final
7. Assist in providing input for the Design Document and final write-up
8. Develop Risk Analysis for project management design document
9. Final In-Class Presentation: Design Document

Eric Holden: System Engineer and Developer:

1. Attend weekly stakeholder meetings and BMI 540 classes
2. Identify and write-up constraints for the system
3. Main developer for the Use-Case, Activity and Sequence diagrams
4. Assist in the IEEE Requirements Specification document write-up; in particular sections 2 and 3.
5. Assist in all of the IEEE Requirements Specification document drafts 1, 2 and final
6. Contribute to the formal BMI 540 in-class presentations
7. Main developer of the design document and final write-up
8. Develop Risk analysis for Project Management Design Document
9. Final In-Class Presentation: Design Document

Buffy Lloyd: Project Manager:

1. Attend weekly stakeholder meetings and BMI 540 classes
2. Identify and write-up functional requirements for the system
3. Organize meetings with stakeholder
4. Main researcher for domain of interest including identifying variables of interest for criteria of interest: postcolorectal bleed
5. Assist in the IEEE Requirements Specification document write-up; in particular section 1 and 2
6. Contribute to the formal BMI 540 in-class presentations
7. Assist in providing input for the design document and final write-up
8. Develop Project Management document including Gantt diagram, excluding risk analysis

Premises:

1. Develop a software system, PLM, which will be utilized by Physicians and Administrators initiating a search for postoperative day 2 colorectal surgery patients.
2. Software will initiate a search to identify patients that are similar to a certain patient of interest or a cohort of patients both offline and near-real time clinical decision support on a large scale, using data distribution and integration frameworks and rule engines.
3. Searches will be achieved by taking a wide range of complex data, defined by a template, that enable searches (queries) to extract and render relevant data visually.

Skills:

1. Computer Programming
2. Ability to work within a group
3. Communication ( high level required with Stakeholder)
4. Ability to quickly adapt and understand the domain and requirements by the stakeholder/s

Domain knowledge:

1. Literature review regarding:
   1. EASE Project ( Mayo Clinic, Rochester, MN)
   2. Post-Colorectal Surgery
   3. Complications related to colorectal surgery
2. Functional and Nonfunctional Requirements ( BMI 540 Course)

3. Software Design and Development ( BMI 540 Course)

Cognitive Modeling and Analysis:

1. UML- Use Case Diagrams
2. UML- Activity Diagram
3. UML- Sequence Diagram

Requirements analysis:

1. Functional Requirements
2. Non-Functional Requirements
3. IEEE Requirement Specification Document

Software architecture and design:

1. Component Layout
2. Interaction between components
3. API design
4. Architecture design including Client/Server

Documentation and communication:

1. IEEE Specification Requirement Document
2. Design Document

Constraints:

1. Novice educational background regarding software design and development
2. Limited man power

Time:

Allocated time for project is 16 weeks. An additional 16-30 weeks is required to develop and implement this software according to its specifications.

**Risks Analysis:**

The risks of this project can be categorized into technology, personal, organizational, requirement, estimation, and environmental risks. In what follows sections will be provided to discuss each section and risks that were identified.

Technology Risks

Technology risks can be defined as risks that arise from the system and its interactions. Risks that were identified were internal network failures, disconnects between PLM and EMR system, complications with physicians accessing PLM system, and rounding error during calculation. The round error during calculation would be considered a higher risk than the others.

Table 1 below presents these risks along with contingency plans, solutions, and frequency of solutions.

**Table (1)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Risk | Contingency Plan | Solution | Frequency | Avoidance |
| Rounding error during calculation | Temporary shutdown of PLM system. | Validation runs are required to determine if rounding is accurate and not producing errors. | It is suggested validation runs should be performed once every 6 months or when concerns arise that need to be resolved. | Validation runs every six months to validate that rounding errors are not occurring. |
| Disconnect between PLM and EMR system | User is notified that there is not a connection between PLM and EMR.  If this notification is given, a hard stop will be executed in PLM stopping physician from continuing execution. | Occasionally ping EMR system from PLM system.  Notify user if issues arise with communication. | Each time PLM systems accesses the EMR system to retrieve current patient information a ping should be executed. | The avoidance for this problem would come from the EMR system performing a ping to the PLM system - which is outside the scope of this project. |
| Complications with physician accessing PLM system | Notification is sent to user that PLM system is down. | Ping is sent to the PLM server when the physician is attempting to access the system. | Each time PLM is accessed a ping to the PLM server should be executed. | Have a notification when PLM server maintenance is scheduled with plenty of time in advance. |

*Table 1: Technology Risks for PLM System*

Personal Risks

Personal risks are risks that arise from personal using or interacting with the PLM system. The risks that were identified are administrator creating a bad template, deleting a useful template, alteration of a useful template, physician defines an inappropriate range/value/weight when executing a PLM search. Any risk that deals creating or altering a template is a high risk problem. The templates are the means by which search criteria are defined. The risks associated with deleting templates is a high risk but not seen as high as the risks with creating a bad template or altering a template that does not need to be altered. Inappropriate values specified by the physician would lead to searches returning less than optimal search results. This is a high risk problem because it affects the treatment of the patient.

Table 2 presents the personal risks along with the contingency plans, solutions, frequencies of solutions, and avoidance measures.

**Table (2)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Risk | Contingency Plan | Solution | Frequency | Avoidance |
| Administrator created a bad template | Save copies of template database so we can rollback to a previous version | Before any creation of a template a hospital board approval will be required.  A set of criteria should be established that have to be met to create a new template. Some points of the criteria should include the need and purpose of the the new template.  This criteria also needs to include default values, ranges and weights in the template. | Any time a template is proposed to be added to the database.  Criteria for creation of a template should be reviewed once a year. | Hospital board approval |
| Administrator deleted useful template | Save copies of template database so a rollback can be performed if needed. | Before any deletion of a template a hospital board approval will be required.  Criteria needs to be established that define when a template can be deleted. Criteria should include reason for deletion and replacement options. | Any time a template is proposed to be deleted to the database.  Criteria for deletion needs to be reviewed once a year. | Hospital board approval |
| Administrator altered a useful template | Save copies of template database so a rollback can be performed if needed. | Before any alteration of a template a hospital board approval will be required.  Criteria for alterations should be established. Criteria should include need and purpose of alteration.  This criteria also needs to include default values, ranges and weights in the template. | Any time a template is proposed to be altered in the database.  Criteria for alterations should be reviewed once a year. | Hospital board approval |
| Physician defines inappropriate range, value, weight | Predefined ranges, values, and weights | Hospital board approved ranges, values, and weights. | Ranges, values, and weights will be reviewed every six months to determine if revisions are needed. | Hospital board approval |

*Table 2: Personal Risks of PLM System*

Organizational Risks

Organizational risks are risks that are risks that can be found inside the organization but outside technology. The risks that were identified were non-administrator individuals gaining access to the template database and non-system users gaining access to PLM system. These risks are low risk.

Table 3 presents the personal risks along with the contingency plans, solutions, frequencies of solutions, and avoidance measures.

**Table (3)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Risk | Contingency Plan | Solution | Frequency | Avoidance |
| Non-administrator gains access to template database | Log all users accessing the template database. This will allow administrators to determine who accessed the database, what was done, and when. | Have safety measures in place requiring identification and password from individual attempting to gain access.  Passwords should be changed frequently. Also, passwords need to meet criteria that will optimize security.  Furthermore, individuals who are given access to the database should be reviewed and updated. | It is proposed that every three months passwords should be changed.  At the time password changes occur individuals who have administrator access to the database should also be reviewed by the hospital board. | Changes to who has access to the database should be minimized. Meaning individuals who are administrators should be administrators together for a period time. This will minimize the number of hands who will have worked directly with the template database. |
| Non-system users gaining access to PLM system | Log all users accessing the template database. This will allow administrators to determine who accessed the database, what was done, and when. | Only individuals who work with patients should have access to the PLM system.  Passwords should be required along with some form of identification.  Passwords should be changed frequently and meet a set of requirements. | It is proposed that every three months passwords should be changed. | Changes to who has access to the PLM system should be minimized. Meaning individuals who are users should be users for a period time. This will minimize the number of hands who will have worked with the PLM system. |

*Table 3: Organizational Risks of PLM System*

Requirement Risks

Requirement risks are risks that arise from requirements not being met. The main requirement risk that was identified is a non-existent patient database. Table 4 presents the risk, contingency plan, solutions, frequencies of solutions, and avoidance measures.

**Table (4)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Risk | Contingency Plan | Solution | Frequency | Avoidance |
| Non-existent Patient Database | No contingency plan. As per the requirements for PLM, the patient database has to exist and able to communicate with PLM. | Patient Database exists | N/A | Before PLM system is implemented, ensure that patient database exists. |

*Table 4: Requirement Risks for PLM System*

Estimation Risks

Estimation risks are risks that arise from exceeding the estimated amount of time specified for execution. The main estimation risks that was identified is lag time. Table 5 presents the risk, contingency plan, solutions, frequencies of solutions, and avoidance measures.

**Table (5)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Risk | Contingency Plan | Solution | Frequency | Avoidance |
| Lag time on system accessing patient database | System timeout | Notify physician to adjust search criteria. | N/A | Board approved ranges, values, and weights. |
| Lag time on performing calculations | Display the currently completed results to the physician after a certain amount of time. | Notify physician calculations are not completed. Displayed results are only those calculations that have been completed. | Validation runs every 6 months to determine calculations can be performed within specified time. | Validation runs on calculations used by PLM system. |

*Table 5: Estimation Risks of PLM System*

Environmental Risks

Environmental risks are risks that arise from the environment in which PLM exists. The environmental risks identified were system does not have sufficient resources and operating system is incompatible. Table 5 presents the risk, contingency plan, solutions, frequencies of solutions, and avoidance measures.

**Table (6)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Risk | Contingency Plan | Solution | Frequency | Avoidance |
| System does not have sufficient resources | Notify physician that execution of PLM system is taking longer than expected. | Perform validation runs to determine if system has sufficient resources to execute PLM search | Validation runs every 6 months | Execute a preliminary trial of PLM hardware to ensure system has sufficient resources. |
| Operating system incompatibility | No contingency plan - PLM will not execute | No Solution - if system is not compatible with PLM hardware PLM will not execute | Preliminary trial to determine if PLM hardware is compatible with system when hardware or operating system changes | Execute a preliminary trial of PLM hardware to ensure system is compatible with PLM hardware. |

*Table 6: Environmental Risks of PLM System*