Dissertation Title

"To study the concept of Usability and User Centered Design Process to increase the adoption of Electronic Health Record in India"

A dissertation submitted in partial fulfillment of the requirements for the award of

Post-Graduate Diploma in Health and Hospital Management

by

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April, 2012

Abstract

With the advent of Health Information Technology, the rapid development and entry of a variety of EHR's in the market in recent years, Usability has become an increasingly prevalent topic. A series of reviews have been proposed by a number of HIT professionals, healthcare informaticians and researchers, which have clearly articulated design problems in the current generation of clinical applications.

The National Research Council (NRC) has asserted that today's clinical systems provide poor support for the cognitive tasks and workflow of clinicians. These problems can dramatically impact user acceptance and productivity. Patient safety is a prominent concern. The Joint Commission recently issued Sentinel Event Alert regarding technology-related adverse events. It was seen that out of approximately 25 percent of medication errors the overwhelming majority of these (82 percent) stemmed from CPOE and other data entry functions. Many studies have documented the issues of alert fatigue, screen fragmentation, terminology confusion and lack of appropriate defaults in CPOE and CDS systems.

Usability is the effectiveness, efficiency and satisfaction with which specific users can achieve a specific set of tasks in a particular environment. A system which adorns a good usability platter is easy to use and effective, it's intuitive, forgiving of mistakes and allows one to perform necessary tasks quickly, efficiently and requires a minimum of mental effort

Therefore this paper aims at illustrating the concept of USER CENTERED DESIGN principle and methods, as in how UCD can be adopted as a part of the Software Development Life Cycle Usability evaluation and testing and how an organization can acquire the USER MATURITY MODEL proposed by Earthy (1999) to become an usability centered organization which aims at developing products that provide a complete user experience.

The paper altogether is Qualitative in nature but some quantitative aspect has been included were a survey was conducted with doctors collecting certain usability requirements which would prove useful in the overall design process, and for taking their consent if they wish to be a part of our design process as the Main Users.

ACKNOWLEDGEMENT

I wish to express my deep sense of gratitude to Mr. Ahimanikya Satapathy, Founder & CEO, for giving me the opportunity to do my Dissertation at Fresco Informatics. He was very kind enough to spare his valuable time and provide me suggestions regarding the study to be undertaken.

I hereby take this opportunity to thank, Mrs. Asha Satapathy, Founder, Fresco Informatics for her valuable guidance & advice. Her willingness to motivate me contributed tremendously to my project.

Besides, I would also like to thank the entire survey population for their time and cooperation in carrying out the project work.

My sincere acknowledgement goes to Professor Indrajit Bhattacharya, Professor Anandhi Ramachandran & Professor Muthu Kumar for their kind assistance and support throughout my Dissertation Period.

Finally, an honorable mention goes to my family and friends for their understanding and supporting me in completing this project.

Thank You
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Abbreviations

- CDS: Clinical Decision Support
- CHR: Clinical Health Record
- CPOE: Computerized Physician Order Entry
- EHR: Electronic Health Record
- ESB: Enterprise Service Bus
- MPI: Master Patient Index
- PMS: Practice Management System
- SOA: Service Oriented Architecture
- SODA: Service Oriented Development of Applications
- UCD: User Centered Design
- UMM: User Maturity Model
- WOA: Web Oriented Architecture

Part 1 – INTERNSHIP REPORT

Introduction to Organization

Fresco Informatics provides extensive range of enterprise computing solutions, consulting services and technology products for the ever-changing world of business. The goal is to exceed the expectations of every client by offering outstanding customer service, increased flexibility, and greater value, thus optimizing system functionality and improving operation efficiency.

Fresco Informatics associates are distinguished by their functional and technical expertise combined with their hands-on experience, thereby ensuring that the clients receive the most effective and professional service. Fresco Informatics brings in a fresh and innovative approach to software products and services. Software systems are agile and hence Requirements continue to evolve throughout the life of the software system. Need of the hour is an adaptive and collaborative approach to software development. Hence Fresco chooses to follow agile practices like scrum.

Fresco team experts in the Open source and closed source enterprise technologies and products build over SOA, WOA and SODA. The team has contributed significantly to various open source initiatives such as Project Mural, Open ESB and Glassfish ESB.

Fresco EHR and MPI product suites empower and enables physician practices to provide effective and integrated care delivery. Fresco Informatics delivers the next generation of clinical care information systems solutions built upon best-of-breed and best-in-class healthcare software. The Fresco Informatics solution creates a foundation for heterogeneous communication amongst healthcare providers throughout the hospital as well as all caregivers within the Hospital Network.

Area of Involvement

The Internship Period was from 2nd January 2012 to 30th March 2012. During this Period, I worked as an intern in gathering & documenting the requirements for Fresco CHR for US Healthcare Project.

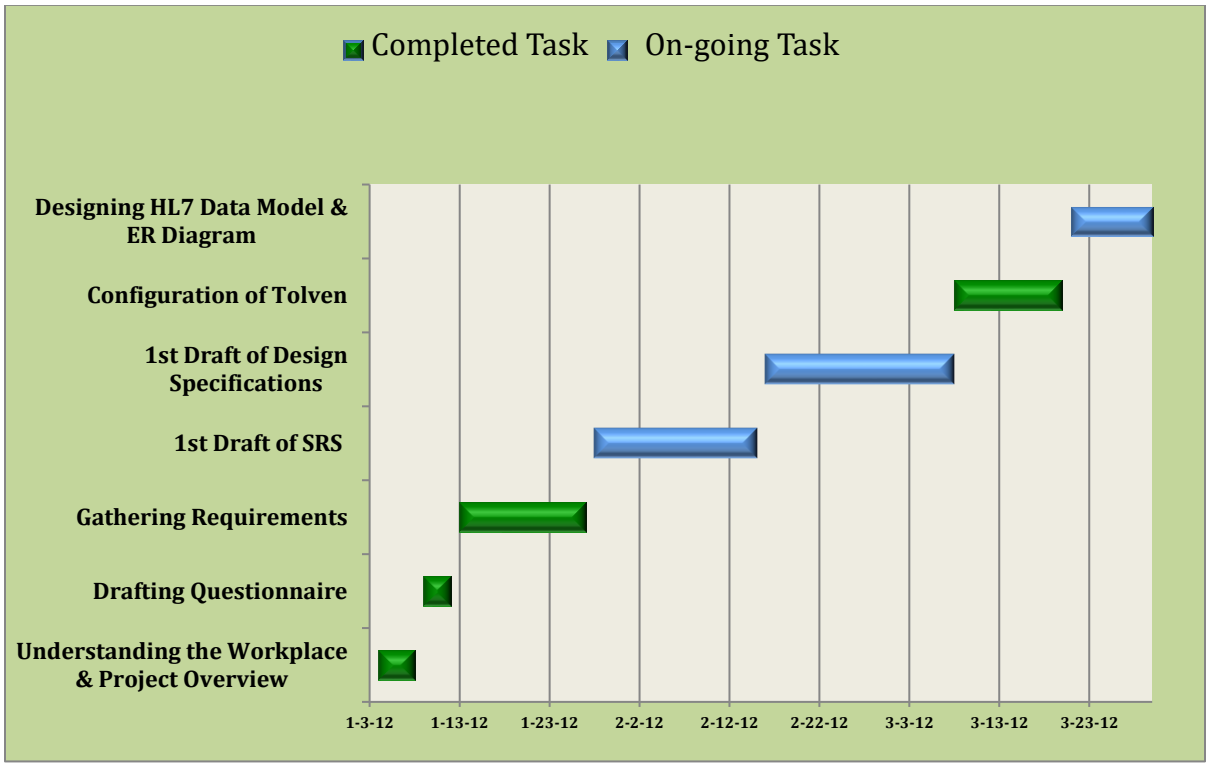


Figure 1. Gantt Chart showing the tasks undertaken

Fresco CHR Project Overview

Fresco Informatics delivers the next generation of clinical care information systems solutions in form of best-in-class healthcare software. The organization aims at providing a smart Practice management system apt for use at a clinical setup focusing on private practitioners who visit multiple clinics.

The Fresco Health practice management system comes with an Electronic Clinician Health Record, which enables authorized care professionals to capture information about their treatment

plans and findings. Clinicians can securely share the information that they have collected about their patients with other care providers.

The Fresco Informatics solution enables consumers to proactively ensure that their health providers have the latest information to guide them in their decision-making. The Fresco PHR provides the consumer with an intuitive web-based application where the patient can update his health related information in few quick and easy steps.

The following are the modules & applications in the Fresco CHR Project: -

- Authentication Module
- Appointment & Patient Registration Application
- Preferences Module
- Dashboard Application
- Consultation Application
- Billing Application

During my Internship Period, I was involved in the requirements gathering part from the Internal as well as External Resources for the development of Fresco CHR for the US Healthcare. Initially for the first week, I read through various Literature provided by the organization for coming up with Ideas & understanding the functionality of the system. Demo Versions of various CHR & PMS available were studied & understood to get hold of the functionality of the system.

The various CHR reviewed were: -

- Tolven CHR
- Vista EHR
- Practice Fusion
- Practo PMS
- EasyClinic Software
- Praxify
- CareCloud

Once, the functionality & the objective of the project were understood, requirements were gathered from a US Healthcare representative, who is involved in the building of CHR for US Healthcare. These requirements were validated with the requirements of the Internal Resources as well. Once the functional requirements were frozen for the first draft, Software Requirements Specification (SRS) was documented & sent for review to the Reporting Authority.

The format of the SRS Documented was as follows: -

- Introduction to the Organization & Product Profile
- Purpose of the Document
- Scope of the Document
- Major Stakeholders & their characteristics
- Product Features
- General Workflow of the Clinic
- Data Flow Diagram
- Functional Requirements
- Non-Functional Requirements
- Traceability Matrix
- System Architecture
- ER Diagram
- HL7 Data Structure/Data Model
- Use Cases & Use Case Description

First draft of SRS was completed by the end of first month, which is revised with small changes till date. After the SRS, System Design Specification with the data fields & characteristics were documented. Screens for the system were designed & the flow was presented in a PowerPoint presentation.

The tools used for all the documentation were: -

- MS Word
- MS PowerPoint
- MS Visio
- Lucidchart
- MockFlow

After the documentation, configuration of the existing CHR that is Tolven was undertaken. This involved documentation of Implementation Specification for US Healthcare Scenario. Various workflows involved according to the setup of the healthcare facility; that is; A Corporate Hospital & A Polyclinic were documented & was implemented in the existing Tolven CHR. Theses workflows were designed on the basis of my work experience & past knowledge gathered from the summer training experience & the information gathered from certain doctors. During this Period the developing team was also guided regarding the GUI & the design of the system for implementation of Tolven CHR.

Managerial Task within the Organization

A project plan resource wise was made and is followed till date. The tool used for project management was Smartsheet Tool. This tool helps to manage the entire project well with timeline. The project plan cycle consisted of the following stages: -

- Project Initiation
- Project Planning
- Project Execution
- Project Evaluation
- Project Closure

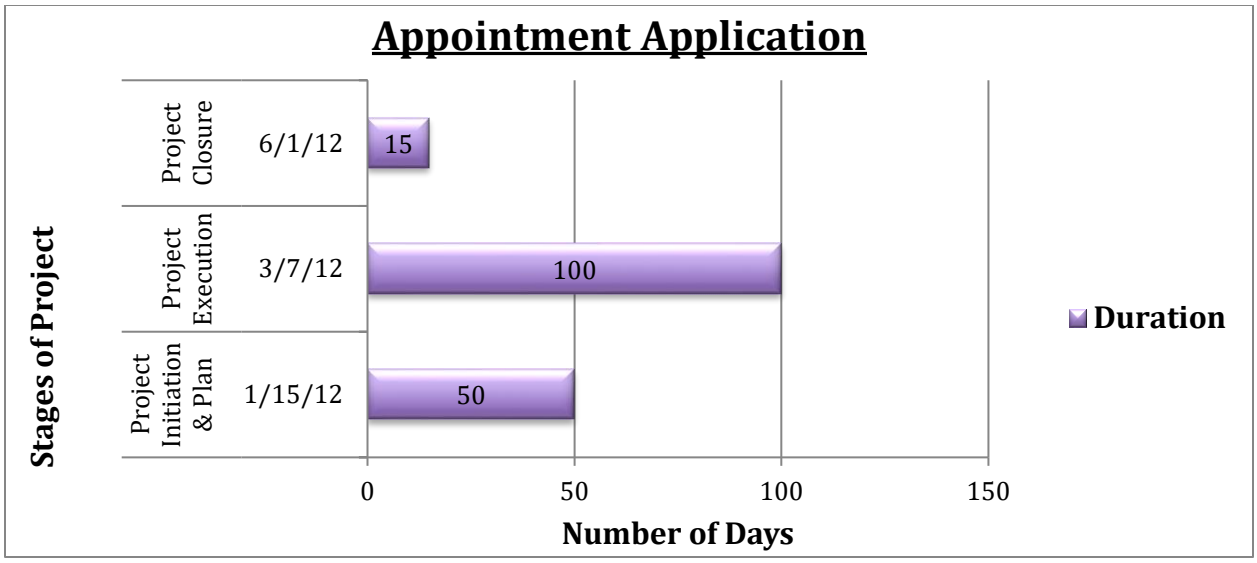


Figure 2. Start Date & Expected Number of days for completion of each phase

Project Initiation

This stage started on 4th January 2012 and took 50 days almost to get completed. The following were the task done during this phase: -

- Identify and document the need/objectives that the project will address.
- Define the objective, approach and controls of the project.
- Ensure a clear and common understanding of the deliverables that will be produced.
- Specify what work needs to be completed in order to produce the deliverables.
- Determine the type of skills that will be needed to complete the project.
- Estimate how long it will take. (The work breakdown structure)
- Obtain appropriate management approval for effort.

Project Planning

Once the project documentation was approved, effective project planning was done as a critical phase to successful resourcing and execution of the project activities. This stage included development of the overall project structure, the activities and work plan/timeline that formed the basis of the project management process throughout the project lifecycle. This Process helped in setting out the procedures that were used within the project for tracking progress, utilizing tools

and methodologies, communicating with the project team members, users and other stakeholders, and resolving issues, problems and addressing change requests.

The whole Fresco CHR Project was divided into different modules or applications. The current application undertaken is the appointment application, which was executed from 6th March 2012 and is estimated to get completed by 1st June 2012.

The project schedule involved 2 major steps:

- Estimate the effort (person-months), including a work breakdown structure (WBS)
- Estimate the schedule (calendar-months)

The Appointment Application, currently working is an online application, which can be used by both the doctors & the patients. This application was divided into the following sub-tasks:

- Login & Registration Page
- Doctor's Landing Page
- Patient's Landing Page

These tasks are sub-divided into small tasks, but because of the Organization Policy, these are not to be disclosed.

Learning from the Internship Period

The Internship Period gave me the hands-on experience with the product development life cycle in the healthcare industry. The major learning gathered from this period are as follows:

- SRS Documentation
- Design Specifications according to the User Interface
- HL7 Data Model
- Creating the Project Plan & Execution
- Interaction with the various clients involved
- Building the Project Proposal

PART 2- DISSERTATION

CHAPTER – 1 INTRODUCTION

Usability is the effectiveness, efficiency and satisfaction with which specific users can achieve a specific set of tasks in a particular environment. A system which adorns a good usability platter is easy to use and effective, it's intuitive, forgiving of mistakes and allows one to perform necessary tasks quickly, efficiently and with a minimum of mental effort which over shadows the tasks that every software does at the back end such as such as data retrieval, organization, summary, cross-checking, calculating, etc., thus improving accuracy and freeing up the user's cognitive resources for other tasks. (1,2)

Usability evaluation is a much wider and a complicated process than measuring the end user's satisfaction. The metrics, which helps us in determining the usability index comprise of measures of efficiency, effectiveness, cognitive load and ease of learning. The basic context of usability emerges from understanding the needs of the users, using established methods of iterative design, and performing appropriate user testing when needed. What we have in our hand is a wide variety of design and evaluation methodologies, both subjective and objective, which are continually growing in sophistication, all that we lack is the application of these methodologies in development of modern day Electronic Health Records.

1.1 EHR Design: The Constraints and Challenges

An EHR is a computer system composed of multiple, integrated applications enabling clinicians to order, document and store patient information. The term electronic health record (EHR) is sometimes, and incorrectly, used interchangeably. In contrast, an EHR is patient health information from multiple care delivery organizations' EHRs, comprising a patient-centric, longitudinal view of a patient's encounters with healthcare providers.

1.1.1 Complex Web of Information Needs:

Every EHR has a varied list of stakeholders, who have a wide range of complex information needs, varying from different care centers to care centers, among different administrative, financial and clinician groups, and from task to task within a group. On a whole there are around 50 physician specialties each having their own functionalities, work flows and corresponding software needs. Apart from this the ancillary staff such as Nurses, Medical assistants and other various support staff have their own set of requirements as a result each discipline has a number of different task scenarios in a working day, with each scenario demanding a different software interface design.

1.1.2 Mobile Work Condition:

Clinicians are often mobile, going from room to room, clinic to clinic, henceforth expecting full attention towards the software has always been a big ask for the clinicians. Their primary focus should be on the patient, and clinicians are often talking, listening or thinking while using the software. The clinical agenda differs from patient to patient and amongst all that which goes around interruptions are common. Moreover administrative and financial issues complicate even routine tasks followed by the impetus to measure quality of care, complicated by multiple standards.

1.1.3 Lack of Clinician-Developers Interaction:

The interaction between the end user and the developers is most important pre-requisite, despite the best of efforts towards taking the requirements and managing them the usability aspect require a great deal of interaction which is always challenging for EHR developers to get feedback or contribution in testing. Busy physicians allow only limited access for user-centered design work. Clinicians have other significant constraints that complicate usability evaluations, such as confidentiality concerns in all their encounters, the need to test in the actual work environment, and frequent interruptions in their workflow.

1.2 Rationale of the Study:

With the advent of Health Information Technology, the rapid development and entry of a variety of EHR's in the market in recent years, Usability has become an increasingly prevalent topic. A series of reviews have been proposed by a number of HIT professionals, healthcare informaticians and researchers, which have clearly articulated design problems in the current generation of clinical applications.

The National Research Council (NRC) has asserted that today's clinical systems provide poor support for the cognitive tasks and workflow of clinicians. These problems can dramatically impact user acceptance and productivity. Patient safety is a prominent concern in the literature.

The Joint Commission (formally known as Joint Commission on Accreditation of Healthcare Organizations) recently issued Sentinel Event Alert regarding technology-related adverse events.

This safety alert included EHRs, computer physician order entry (CPOE) and clinical decision support (CDS) systems. They reported that approximately 25 percent of medication errors. The overwhelming majority of these (82 percent) stemmed from CPOE and other data entry functions. Many studies have documented the issues of alert fatigue, screen fragmentation, terminology confusion and lack of appropriate defaults in CPOE and CDS systems.

Usability and User-Errors

User errors have a direct relationship to potential patient safety. User errors may be either errors of commission or errors of omission.

- Example, *errors of commission:* Selecting the wrong patient, wrong medication, wrong dosage or wrong encounter.
- Example, *errors of omission:*

➢ Overlooking or misinterpreting key data due to poor information display (e.g., overlooking critically abnormal lab result, or routinely dismissing a critically harmful drug-drug interaction warning).

➢ Failing to complete a task (perhaps due to interruption) such as transmitting orders or signing documentation.

1.3 Objectives:

- To discuss the usability of the EHR from the perspective of clinician users (physicians, nurses, and other associated providers) in the ambulatory, inpatient and acute-care environments.
- To study the basics of user-centered design, the core principles of usability and usability evaluation.
- To discuss the user centered design model and ways to apply the same during product development processes.

2.1 USABILITY

The International Organization for Standardization (ISO) defines usability as ―the effectiveness, efficiency, and satisfaction with which the intended users can achieve their tasks in the intended context of product use.

2.2 Usability Principles (1,5,8)

2.2.1 Simplicity

Simplicity in design refers to everything from lack of visual clutter and concise information display to inclusion of only functionality that is needed to effectively accomplish tasks. A "less is more" philosophy is appropriate, with emphasis being given to information needed for decision-making. The more complex an application, the more important this principle becomes.

2.2.2Naturalness

Naturalness refers to how automatically "familiar" and easy to use the application feels to the user. The factors that contribute to this feeling include terminology used in the interface and how well the design and screen flows map to the users tasks and expectations.

2.2.3 Consistency

External and internal consistency is important to the design of any application. External consistency primarily has to do with how much an application's structure, interactions and behaviors match a user's experience with other software applications. The more a user can apply prior experience to a new system, the lower the learning curve, the more effective their usage, and the fewer their errors. An internally consistent application uses concepts, behavior, appearance and layout consistently throughout.

2.2.4 Minimizing Cognitive Load

Cognitive load refers to the total amount of mental activity imposed on working memory at an instance in time. The major factor that contributes to cognitive load is the number of elements that need to be attended to. While this principle may sound a bit niche based as in its understood by specialized people who have the knowledge related to a field, and in this context it is essential for a complex, information dense software application. Therefore, Cognitive load is found increased by any aspects of a design that do not follow the principles of simplicity, naturalness and consistency.

2.2.5 Efficient Interactions

One of the most direct ways to facilitate efficient user interactions is to minimize the number of steps it takes to complete tasks and to provide shortcuts for use by frequent and/or experienced users. Apart from this other examples of designing for efficient interactions include:

- Auto- tabbing;
- Good default values;
- Large enough list and text boxes to limit scrolling;
- Minimizing the need for frequent switching between keyboard and mouse.
- Minimizing the amount of visual searching required for locating information and the distance the cursor must travel to make selections.

2.2.6 Forgiveness and Feedback

Forgiveness means that a design allows the user to discover it through exploration without fear of disastrous results. This approach accelerates learning while building in protections against unintended consequences. This is especially helpful if training is limited. Good feedback to the user supports this goal by informing them about the effects of the actions they are about to take. Forgiveness and feedback work together to reduce user errors and provide graceful recovery when mistakes are made. Good feedback also reassures the user that their actions have had the desired effect. Like consistency, these principles are standard in the design of any application, but of special importance in a clinical information system due to the impact they can have on user errors as well as cognitive load.

2.2.7 Effective Use of Language

The terminology used on display should always be familiar and meaningful to the end user's domain of knowledge. It should not contain any terms, which the user does not understand, or has no relevance to the work performed by the end user using the application or system. The use of Abbreviations and Acronyms should be only for well known accepted terminologies; therefore the vocabulary context is one of the most important aspects of deciding the usability of an application.

2.2.8 Effective Information Presentation

2.2.8.1 Appropriate Density

The density of information on a screen is a very important concept to be followed when designing any application. The information on a single screen should be arranged in such a way that it facilitates a major chunk in the decision-making process of the individual, too much of up and down scrolling, screen changes interrupt the user's decision-making process and affects the overall productivity.

The various characteristics that impact the visual density are as follows:

- Character count,
- Resolution,

- Font and font size and
- Grouping techniques.

Apart from these the screen elements used as accessories for denotation and navigation such as lines, buttons, controls, scroll bars and icons also contribute to density, which is yet another reason that simplicity is so important.

2.2.8.2 Meaningful Use of Colour

Colour is one of several attributes of visual communication. Skillful use of colour certainly contributes to a user interface that is pleasing in appearance. First and foremost, colour should be used to convey meaning to the user. This includes all aspects of information presentation, navigation, differentiation of screen areas and state representation of controls.

2.2.9 Readability

Screen readability also is a key factor in objectives of efficiency and safety. Clinical users must be able to scan information quickly with high comprehension. The pace and frequent interruptions in clinical workflow guarantee that decisions will sometimes be made based upon cursory screen review. Simplicity, naturalness, language use, density and colour all contribute to readability. A high contrast between text and background is also important.

2.2.10 Preservation of Context

Preservation of context is a very important aspect of designing a “transparent” application, as defined before transparency is about the uninterrupted user-experience in completing the task the user is looking to accomplish.

This means keeping screen changes and visual interruptions to a minimum during completion of a particular task. Visual interruptions include anything that forces the user to shift visual focus away from the area on the screen where they are currently reading and/or working to address something else, and then re-establish focus afterward.

2.3 USABILITY PRINCIPLES IN CONTEXT TO ELECTRONIC HEALTH RECORDS:

2.3.1 Simplicity in Context to Clinical Systems:

Clinical systems are complex as well as information dense–it is essential for efficiency as well as patient safety that displays are easy to read, that important information stands out, and that function options are straightforward. Simplicity as a principle should not be interpreted as "simple" in terms of EHR. Clear, clean screen design requires substantially more effort than cluttered displays; it also may mean that some complexity has been removed from the surface and moved "under the hood." Simplicity applies to any design regardless of the experience level of the target user.

2.3.3 Naturalness in Context to Clinical Systems:

The time with the providers is always limited, and during the implementation the provision of extensive training is always a big ask taking the fragmented timeframe the clinicians have. A good workflow design can contribute significantly to efficiency and reduce cognitive load. "Natural" workflow can vary dramatically from one specialty to another–or in an acute setting, from one department to another. An Ambulatory Department workflow is very different from that of an inpatient medical-surgical unit or to an emergency department workflow, so more consolidated and apt is the interface more is the adoption. Henceforth like simplicity, naturalness also contributes to error reduction.

2.3.3 Minimizing Cognitive Load in Context to Clinical Systems:

Clinicians have always had a busy atmosphere and are almost always performing under significant time pressure and in environments bursting with multiple demands for their attention. A plethora of information is kept at their perusal, which is exactly an indication of cognitive overload, which could negatively impact patient safety.

The 'mantra' for reducing cognitive load is "What is needed, when it is needed and Nothing Else". For example, when reviewing results of a lipid profile, the provider will want to see the patient's latest and prior results, the medication list, the problem list and allergy list all in the same visual field so that decisions and subsequent actions may be performed without changing

screens. Thus the display of information organized by meaningful clinical attribute relationships is one method of providing cognitive support to the user.

Moreover it has been observed that the user feels 'lost' within the application, as in there is no transparency what so ever, henceforth the Clinical system should not create any intrusive comments in the user's mind where he or she is in constant thought process of thinking HOW, WHAT, WHERE and WHATIF. These thoughts interrupt the basic thought and decision-making process, which the clinician is required to do at first place.

- **Memory vs. Visual Recognition**

Cognitive load is found to be increased if a user is required to rely on memory (recall) rather than visual recognition, if a user must try to remember information from one screen to another, what a button really does, or what name something is called as in an "orderable" list. High information density, poor feedback to the user and inadequate cues for data entry fields also affect cognitive load.

2.3.4 Effective Use of Language in context to EHR

- **No Technical terms on display**:

All language used in an EHR should be concise and unambiguous. The terminology used also must be that which is familiar and meaningful to the end users in the context of their work; no terms related to computers, technology, HL7, databases, etc. should appear in the user interface. This applies to everything: labels, descriptions, pick lists and error messages.

- **Abbreviations and acronyms**:

Abbreviations and acronyms should only be displayed when they are commonly understood and unambiguous. Information that must be spelled out but takes more space than available should have demarcations inserted to indicate there is more–with the full text available on mouse-over.

For efficiency, however, a larger number of common abbreviations and synonyms should be available to the user for the purposes of data entry and searching, expanding if necessary for display.

- **Structured Data Entry**:

A language issue specific to EHR design is the need to capture structured (discrete) clinical terms from provider documentation such as visit notes, allergies and problem and medication lists. This data is used to identify clinical relationships in patient records, drive decision support functions, eliminate redundant data entry and supply coded data elements to administrative and reporting functions.

The challenge with discrete clinical data entry is the presentation of structured terminology in the user interface. Vocabulary must be efficient to navigate, presented in terms familiar to clinical practice and at the appropriate level of granularity.

2.3.5 Effective Information Presentation in Context to EHR

- **Appropriate Density**

  The density of information on a screen is a very important concept to be cognizant of when designing EHR screens. In clinical applications, there can be so much relevant information to display it can be tempting to pack as much as possible onto a screen, but the amount of information and chances of an error run directly proportional therefore it is challenging to balance providing all the necessary information and limit the number of screen changes while maintaining an appropriate screen density. This criterion can be controlled while the designing but the actual balance is achieved once the users start using the system during the usability testing.

- **Meaningful Use of Colour**

Simplicity and consistency are both key principles in the use of colour. The use of a simple and consistent meaningful colour scheme is very important for designing screens for EHRs. Each colour should aim at portraying some information to the clinician, whether it's the process completion rate on the navigation bars, or any data coded in a specific colour, everything in the user's task area of the screen, needs to obey a meaningful colour scheme.

For e.g. if bright yellow is used as a “highlighter” colour to emphasize the name of the patient whose orders are currently being entered, then bright yellow should *only* be used as a highlight colour for key information. Inconsistent or gratuitous use of colour increases the likelihood of user error due to misinterpretation or oversight of important details; the meaning will be lost.

To accommodate users with colour-blindness, all meaning conveyed with colour must also be differentiated with a second visual mechanism (“redundant encoding”) such as font characteristics or fill pattern. For example, if red is used to display critical lab values then the characters should also be bolded, increased in size or some other characteristic. It is highly recommended that displays be designed in gray scale prior to adding colour to ensure that all meaning is represented. If not, the inability to differentiate colours also may lead to user errors that have patient safety consequences.

Usually the following colour scheme is universally accepted with the interpretations mentioned below:

- **Red:** Stop, Hot, Danger, Error, Extreme Warning, Severe Alert, Emergency, Alarm
- **Yellow:** Caution, Potential or Mild Warning, Requires Attention, Slow, Moderate Alert
- **Green:** Go, Safe, Normal, Good, Proceed
- **Blue:** Cold, Advisory

2.3.6 Preservation of Context concept in EHR:

As discussed before preservation of context is related to being simple and transparent, reducing the number of interruptions, screen changes and visual barriers is the main aim of this usability principle in context to EHRs.

For e.g. The most frequent violator is the dialog box, which also tends to obscure a significant part of the screen, a big dominant dialog box often puts off the clinician wherein the same information can be provided right adjacent to the control button or the trigger. All of these boxes should also be as small as possible without compromising their usability.

Another important guideline associated with preservation of context is that of directness. In part, this is a component of the "what-you-see-is-what-you-get" philosophy–if you change something on the screen, you should see the change immediately and in the format expected. An aspect of directness that sometimes falls through the cracks is to avoid "modes." In data entry, this sometimes occurs in the form of "viewing" vs. "entry" modes; these should not be separate. If a user is viewing information on a form that they have permission to edit, they should be able to do so, in context. This does *not* mean that information collected via a particular form (e.g., allergies) shouldn't be displayed elsewhere in the system as view-only. However, any data presented that is potentially user-editable, should have a mechanism for taking the user directly to the appropriate entry form if updating is desired.

2.3.7 Screen Form Factor Evaluation:

The selection of right form factor is also an important pre-requisite for mapping the usability context. The key in doing so is to strike the right balance to support all required functionality.

The first step, as an organization is to evaluate all business processes on a task-by-task basis to understand how your workers do their jobs on a daily basis. It is critical to also insure that your workers provide direct feedback as part of this process.

The second step is to consider what form factor, and what functionality, will best enable your field people to most effectively do their jobs: start with the business processes and tasks first, then map out the technology required.

Finally, there's one other key consideration to keep in mind, beyond physical dimensions, screen size, keyboard, and so on most different form factors will tend to have different operating systems. A device with a smaller form factor is likely to run a mobile OS such as Windows Mobile or Android, while a rugged tablet or laptop is likely to be running a full Windows operating systems.

The screen form factor in relation to the EHR was selected to be tablet based running on android operating system as well as iOS.

2.4 Common Misconceptions related to Usability:

Usability has been defined above, what exactly it is, but it is often misunderstood and the following section aims to distance usability from some common misunderstandings.

- **Usability is not User Acceptance Testing (UAT)**

User Acceptance Testing is the formal testing conducted to determine whether a software system satisfies its acceptance criteria and to enable buyer to determine whether to accept the system or not. UAT is designed to determine whether software is fit for use or not.

UAT involves taking use cases or procedures for how the system was designed to perform and ensuring that someone who follows the procedure gets the intended result. That is, UAT examines whether the system is capable of performing all specified functions but not necessarily how well the system supports users in performing those functions.

Usability testing measures how well the system works (in human performance measures) when users actually use the system without the tight procedures dictated by test cases. The intended use and actual use can be two very different things, especially in the case of EHRs where actual users, environments, and situations may differ from defined use cases.

While usability testing some actionable feedback can be obtained, but not at the same level as watching representative users perform realistic tasks. Usability is fundamentally about behaviour, and for that the most important pre-requisite is that the user has to use the system.

- **Usability is not graphic or visual design**

Graphic design and visual elements can add value to the overall appeal of the system. However, simply applying a pleasing aesthetic to a poorly constructed application does not improve the functionality, the workflow, or the usability.

2.5 Usability and Utility: The Essential Comparison

Usability is not usefulness or utility. Utility refers to the existence (or absence) of feature or function necessary to carry out a specific task (e.g., does the EHR have the capability of recording vitals?) or Functional Requirements. Utility does not reflect whether a feature or

function is usable, simply that it is there. Usability is the ease with which those functions can be carried out.

While utility and usability are not truly independent, as a practical matter they can be considered as such. Some functions that are very useful may be very difficult to use. Others that are barely useful may be quite easy to use. The goal for the designer is to make all functions usable, but particularly those that are most useful.

When utility and usability are confused, it is often difficult to untangle the underlying user concerns. In the domain of EHRs, usability has, up to this point, been secondary to utility. It has been ensured that an EHR has all the features and functions have taken precedence over usability. As the number of features increases, the complexity also increases, demanding more attention to usability.

2.6 User-Centered Design Process in EHRs

The International Organization for Standardization (ISO) defines usability as ―the effectiveness, efficiency, and satisfaction with which the intended users can achieve their tasks in the intended context of product use.

This definition provides a number of components in a nutshell. The Usability monitoring establishes a framework for setting usability goals and specific evaluation measures for a given application, within this framework it measures certain attributes, which further help in comparing the application‘s progress over time as well as the comparison of competitor applications.

User-centered design is a bedrock principle for creating usable systems and devices. At its core UCD is a process that relies on systematic understanding of users and their environments, and iterative design and testing based on user performance objectives.

2.6.1 Stakeholders in USER CENTERED DESIGN PROCESS:

The stakeholders in a User centered design process have various roles in determining the functions and features of the EHR, through this process these stakeholders collaboratively work to represent the utility part into the best possible user interface. The following our the major stakeholders in the above mentioned process:

- Product manager or application manager programmers,
- Clinical experts (e.g., doctors and nurses),
- System & Business Analysts,
- Information architects,
- Visual designers.

2.6.2 Principles of the UCD Model: (1, 8, 9)

UCD serves to engineer improved usability and human performance into a system or device. UCD models have the following principles:

- Understand user needs, workflows and work environments
- Engage users early and often Set user performance objectives
- Design the user interface from known human behavior principles and familiar user interface models
- Conduct usability tests to measure how well the interface meets user needs
- Adapt the design and iteratively test with users until performance objectives are met

As an iterative process, UCD is a cycle that serves to continually improve the application. For each iteration, critical points and issues are uncovered which can be improved upon and implemented in subsequent releases.

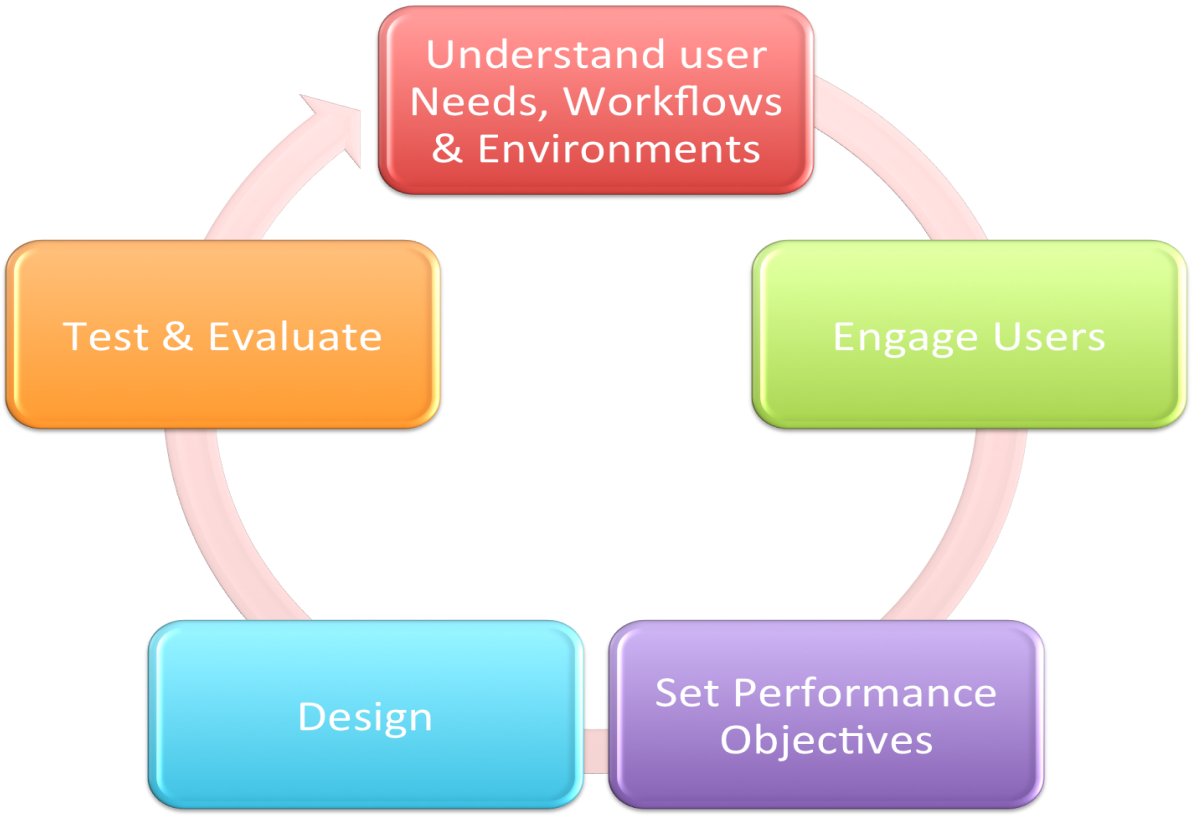


Figure 3. UCD Process

2.6.2.1 Understand the User:

*** Needs**

*** Workflows**

*** Environment**

- **Identify the Purpose**:

The most important pre-requisite for designing any interface is the purpose of that interface. Once the basic purpose is determined, it should be deep dived and all the associated tasks and sub tasks of the purpose should be listed accordingly.

For example,

Major Task or Purpose: a screen within an EHR is to be designed for Ordering of Prescriptions.

Associated Tasks and Sub tasks: Locate drug information, Interpret drug-drug interactions, and decide the dosage as per the patient requirements.

Therefore, the design of the EHR requires documentation of not only the high-level goal (i.e., place prescription order) but also all of the sub-goals and associated workflows.

- **Identify the User Environment**:

The user never works in a confined space or vacuum and when it comes to an EHR the scenario around the clinician can change every second. The EHR might be used in a quiet office, overcrowded noisy clinic, or in ways never considered by the designer. While the administrator has little or no control over where a device will be used, it is important that early in its development the administrator gathers sufficient information to understand the typical as well as the out-of-the-ordinary scenarios that may happen at any given time.

In short, design begins by understanding who the users are, their needs, typical workflows, and the context in which the system will be used.

2.6.2.2 Engage Users

It is a well known fact that that involving end users in EHR design is a good idea, but the most important catch is first, the starting point, with respect to user's EHR goals and objectives, is to gather information about:

- How is the EHR meant to fit within the practice or system, where will the EHR be used, how often, by whom,
- What is the intended user's experience is with similar devices, what level of complexity is an appropriate level, barrier to adoption, etc.

The data collected here should focus around examples of problems that the interface is intended to solve or outcomes that the users‘ envision. When we put the user goals in context of the environment it brings the design requirements into sharper focus, and it allows the design team to lay foundation for the design effort, by imbibing the user profiles, the context, and the scenarios around them.

Once the above information is gathered, early design prototypes should be presented to a small number of users (e.g., fewer than ten) for their reaction (e.g., early formative usability testing). These incremental design-test cycles are repeated with users until a solid vision is achieved. Users are engaged early during user research and preliminary design but also at each subsequent step such as design reviews and during usability testing.

Formative testing is done early in the design cycle with a small group of users to identify and prioritize major problems; Summative testing is done later in the design cycle with larger and more diverse groups of users and gathers real human performance data which is measurable in terms of variables associated with time.

2.6.2.3 Set User Performance Objectives

One result from qualitative work, developing application objectives, and early usability testing, is the formation of user performance objectives. Objective measures of success are important to decide when the interface has reached the appropriate maturity to be released. Typically, most user performance objectives are related to effectiveness (e.g., optimal and error-free performance), efficiency (e.g., speed), and satisfaction and subjective assessment.

In the UCD process, key performance measures are operationalized for target user groups such that core tasks (e.g., time to update any of the patient vitals on a particular screen) are given target values (e.g., less than 20 seconds by 90% of first-time users).

The Major Attributes for selecting the tasks as performance objectives are:

- **High Frequency and Importance:**
  The tasks should be those that are either high frequency, have high importance, or are difficult functions to perform.

- **Operational Performance Measures:**
  The performance measures should always be expressed in form of a factor which can be counted and compared such as time which can be reliably measured and will serve as the basis of comparison as well as identify where improvements have been made or further work needs to be done.

- **Diverse User groups:**
  The user groups and numbers of participants need to be specified. Learning criteria can also be taken into consideration depending upon user age, clinical experience, and their working behaviour and attitude towards use of software.

Once the development team agrees to the performance objectives, it continues to measure them through usability testing at points in the development process. One of the protocol that is often adhered to is that the interface is not released until all goals have been reached simultaneously as this ensures that all functions are working fine with none effecting the other in a sub-optimal way.

2.6.2.4 Include Human Behavior Principles and Familiar User Interface Patterns

Successful EHR design requires not only an understanding of users‘ needs, but also knowledge of the human factors design principles that ensure effective, efficient and satisfying usage.

The design guidance is built from evidence-based knowledge of human performance, from known best practices, and from commonly used interface patterns.

Amongst the above patterns many practices are detailed in design documents and design standards. Therefore having good knowledge of the users‘ tasks, environments, and human performance, skilled designers can make usable designs from the outset.

2.6.2.5 Conduct Usability Tests

Once the above steps have been accomplished, the designs must be tested with representative users under realistic contexts. The purpose of usability testing is to identify problems for repair during subsequent development and to measure user performance to ensure that the objectives are achieved; as described above testing with a small group is carried out i.e. formative testing, with this summative methods, must be used to ensure that the applications meet the user needs with respect to the performance objectives laid out in the beginning.

2.6.2.6 Iterative Testing

The UCD process ends when the user performance objectives are met through reproducible summative usability testing. The iterative design-test cycle requires the designer to objectively record and review the results, make changes accordingly, and then retest. If the design is built from a good foundation of user research and known user interface standards and conventions, the number of test iterations can be quite minimal. Usability testing must be built into the overall planning of application development.

From what all that has been discussed above we can observe that UCD as a process is more evolutionary than revolutionary in improving performance. The expectations from UCD should not be to produce incredible breakthroughs in human performance but significant improvement can be observed psychologically in the minds of clinicians that the product has been made keeping them in mind. However, often what is needed is solid incremental improvement, and this is where the UCD process is very beneficial.

2.7 UCD Methods

Figure 3 portrays a typical UCD methodology. The details of the process were covered in the previous sections, but on a practical level it is instructive to illustrate the process.

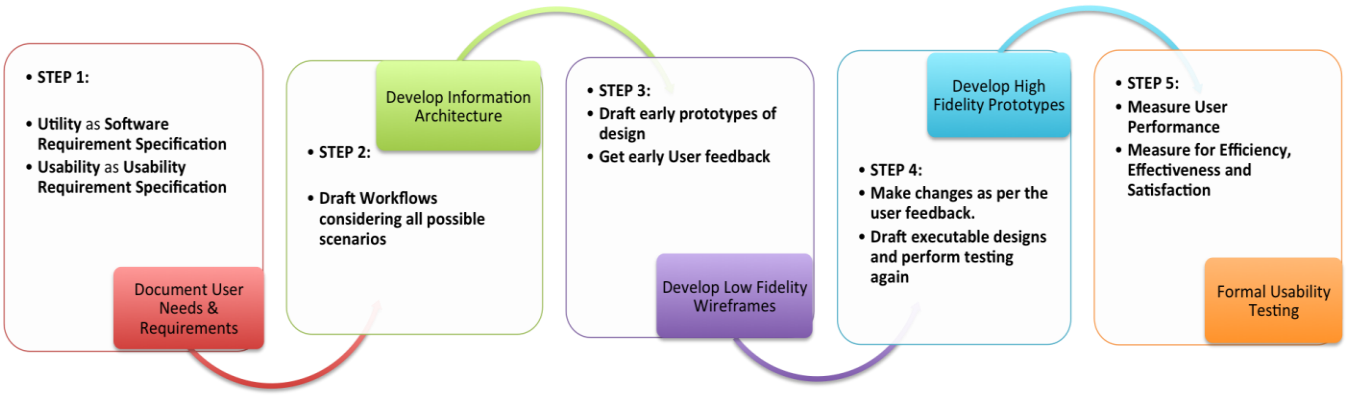


Figure 4. A User Centered Design Methodology

STEP 1: Document User Needs and Requirements

The designing of any system begins with understanding and documenting the user's needs and requirements and how they are to be fulfilled by the application in an abstract manner. For example, the application must be able to display the history of present illness, the history of past illness, social health data show all prior prescription and notes etc. and allow for writing of electronic orders for various investigations.

STEP 2: Develop Workflows to frame an Information Architecture

Once these requirements have been documented, the requirements are mapped into a set of workflows. The parameters, which have to be kept in mind while designing workflows, are as follows:

The most important thing which should be kept under consideration all the time is that whatever flow diagrams are being drafted these are totally user-centered and not system-centered; these requirements and process flows are at the user interface layer, not at a system or data layer.

The user interface involves the screens pre-dominantly, apart from that it also involves the flow across screens, the actions the user needs to take, the alert and error boxes, etc. and the workflow shall encompass all such events.

A completed workflow analysis is used to create information architecture. For instance, one process flow would demonstrate each of the data requirements and data flows (from the users' perspective) for a doctor writing an order for a blood test. The flow would include all starting conditions and assumptions, each step and action along the way, and all feedback the user would receive.

STEP 3: Draft Design Prototypes and Testing Iterations (Low Fidelity Versions)

Once the workflows are documented, the designers should come out with early prototypes of the design. These early prototypes translate the work flow diagrams and data needs to screen flows and screen images that are typically either low-fidelity images. Users will often have a difficult time reacting to workflow diagrams, but will have no trouble providing feedback on these prototypes.

At this juncture the concept of Usability Testing comes into existence, the outcome of that testing using the low fidelity designs may reveal certain flaws in the workflow analysis creating the need for adjustment. Usability testing at this stage is informal, often quite rapid, and involves few users. Designers use various wireframe tools such as Mock flow, which was used in our case to come out with low fidelity designs and later replicating them in html to test. The potential users (who have had no exposure to the application) would be given the task (e.g., ―Using these

screens please complete an order for Patient). Then the feedback will be used to make changes to the architecture and/or the screens.

STEP 4: Implement testing feedback and develop High Fidelity Version:

The iterative design-test cycle continues until enough confidence is gained to make a higher fidelity version – this time one that is executable and ready for formal usability testing.

STEP 5: Perform Formal Usability Testing:

The design screen would be turned into a fully functioning working prototype. Again, users would perform tasks; however, this time performance data would be recorded and formally documented. Once testing has occurred, the outcome of that testing is evaluated and often changes are required either to the user interface or to the information architecture and design. Adjustments are made until the performance criteria are met.

This method of iterative design and testing relies on increasing the fidelity of the prototypes as the design improves, and increasing the number of users involved during each iteration. Iterative testing is foundational to UCD. In the beginning, more informal, formative usability tests are needed to enable rapid turnaround of findings to the development team. As the interface matures, more formal, summative methods provide greater coverage of tasks and include more diverse user groups.

2.8 Usability Testing for EHRs (4, 5)

This section is intended to provide a primer on usability testing particularly when testing EHRs.

2.8.1 Basics of Usability Testing

Usability testing is a core component of user-centered design. The point of doing a usability test is to improve the EHR whether that means its workflow, navigation, screen layout, interaction, navigation, visual design, etc. It is not necessary to test the whole application at once except at the end of the design cycle prior to application launch. In fact, much like in software unit testing, usability tests should take place for portions of the user interface at very early stages. Early testing can be done with low-fidelity wireframes or paper prototypes of the application. Later, as

each portion of the application functionality is developed and tested, these units should be tested together up to the point of doing several use cases for an entire patient encounter. At the very end, usability testing of the whole application is conducted.

One should test early in the design/development process (formative testing) and continuously through to the final stages of development (summative testing). These two types of testing should be seen as ends of a continuum. They share the same goal (improve the user interface), but require different techniques and are driven by different measures. Formative testing finds major user interface bugs. It is rapid, iterative, informal, low cost, and qualitative. As more of the issues are discovered and corrected through formative testing, more controlled (i.e., summative) studies across broader sections of the user interface, with time and error recording, should be done.

Summative testing measures the application against benchmark or baseline performance, competing applications, and/or with the goal of ensuring the application is ready for launch.

It has been found in the previous studies that the vendors interviewed restricted their use of formal usability testing methods to the final design phase. In fact, usability testing should be a continuous part of the software development life cycle. Reserving testing until the end can be frustrating and counterproductive. A fully developed system has substantial organizational inertia built in, and the willingness to make substantial change is much lower because the cost is much higher.

Formative Testing	Summative Testing
Earlier and throughout the application life cycle when looking for major, high-level usability issues	Later in application life cycle when hard data are needed
Rapid	Formal Deliberative
Diagnostic	Used for verification of user performance
Iterative	-----
Used for bug fixes	-----
Qualitative	Quantitative

When approaching usability testing of EHRs, it is important to consider the

- The users are intelligent, highly trained, busy, healthcare worker and recruiting these participants is not easy but it is necessary.
- The users of EHRs are usually experiencing substantial mental workload when they use the applications.
- EHRs can rarely be tested under realistic conditions. Healthcare workers use EHRs in clinical settings. Most testing is done in a lab or office environment and does not have the atmosphere (or stress) of the real environment. The best guidance for this is to do formative testing in the lab or office environment. For summative testing, best efforts should be made to test in facilities that are similar to the actual setting.
- EHRs are complex applications that are often tightly integrated with other systems, therefore the successful results of the Lab testing might not replicate in the Field testing.

2.8.2 Essentials of Testing

This section covers several of the practical matters of usability testing.

Test Planning

The primary concern in testing is to make operational decisions about the objectives of the test, how to test the objectives, what data to record, and what is currently usable in the application and what needs improvement.

As the first activity, test team members should meet to ensure that the objectives, plans, methodology, resources, and timetables are properly aligned. The primary goals of the meeting will be to determine specific objectives for the test and understand the key questions and areas of interest.

Usability administrators create a test plan according to which the study is conducted. The plan is discussed with the key stakeholders and project team members and, if necessary, revised based on their feedback.

Project planning will include the creation of a timeline that will include major activities, when they occur, and who will perform them. The timeline is a valuable tool for project management though it will likely need editing and updating throughout the study.

Components of a Test Plan:

Test Plan objectives: Objectives are what stakeholders are hoping to learn and what decisions will be made based on the outcomes. Rubin (1994) provides examples of clearly worded user test objectives, such as:

- Can end users perform common tasks within established benchmarks (certain amount of time, errors, etc.)?
- Does the application contain major usability flaws that prevent completion of the most common tasks?
- During planning, the project lead must also assess available resources and capabilities,

assign responsibilities, and develop a timeline for activities. Resources that must be decided upon include:

- Budget: What financial resources are required for this study? Team members: Who has the skills and availability to be on the project?
- Location: Will you have access to a usability lab to conduct testing or will the test occur on-location?

Location is dependent on several factors such as accessibility of the team to potential participants, budget, time, and test application mobility (in other words, is the interface only available within a certain environment).

Test Objectives:

List the specific questions that the study has been designed to answer. For example:

Objective 1: To evaluate sample EHR application in terms of the user experience that it creates.

- Do users understand the navigation of the EHR and how the information is structured?
- Can users complete key tasks (e.g., use patient chart to find lab result) or do they require assistance?
- Do users understand the content in the EHR?
- Do users feel that the content meets their needs?

Test Application:

Describe the application including version number where appropriate and also include minimum requirements for computers that need to host the application, if necessary. For example:

- The application to be tested is sample EHR application, version 1.0.
- The test application may be run on laptop personal computer running a standard Internet browser.

Method:

Describe the methodology, including the participants, study design, tasks, and procedure. For example:

- Type of Participants

For e.g. 10 participants are recruited, all physicians, with 4 people having the experience of using an EHR before.

- Tasks for example:

- Find information in Patient Summary screen
- Check and record vital signs
- Look for interactions and allergies
- Add notes to patient chart
- Order investigations

Test Environment

Performance and Satisfaction Metrics:

These metrics describe the types of data that will be collected and analyzed. The measures commonly used in usability testing to evaluate effectiveness, efficiency, and satisfaction is as follows:

- **Qualitative measures**:

- Usability issues observed
- User comments

- Quantitative measures:
- **Effectiveness:**
- **Task Success and Task Failures**

A task is counted as a ‘Success’ if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis. The total number of successes are calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage.

If the participant abandons the task, does not reach the correct answer or performs it incorrectly, or reaches the end of the allotted time before successful completion, the task is counted as a ‘Failure’; it should be noted that no task times are taken for errors. The total number of errors is calculated for each task and then divided by the total number of times that task was attempted, although on a qualitative level, an enumeration of errors and error types should be collected.

- **Efficiency**
- **Task Deviations**

The participant‘s path (i.e., steps) through the application is recorded. Deviations occur if the participant, for example, visits an incorrect screen, clicks on an incorrect menu item, follows an incorrect link, or interacts incorrectly with an on-screen control. This path is compared to the optimal path. The number of steps in the observed path is divided by the number of optimal steps to provide a ratio of path deviation. Deviations do not necessarily mean failure – simply a less efficient method through the interface.

It is strongly recommended that task deviations be reported. Optimal paths (i.e., procedural steps) should be recorded when constructing tasks.

- **Task Time**

Each task is timed from when the administrator says ’Begin’ until the participant says ‘Done’. If he or she fails to say ’Done’, the time is stopped when the participant stopped performing the task. Only task times for tasks that are successfully completed are included in the average task time analysis. Average time per task is calculated for each task. In this case variance measures (standard deviation and standard error) are also calculated.

Task times are recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency.

- **Buffer time Allotment**:

Optimal task performance time, which is decided by expert performance under realistic conditions, is recorded when constructing tasks. The target task times used during the testing phase must be operationally defined by taking multiple measures of optimal performance and multiplying by some factor (e.g., 1.50). Therefore, if expert, optimal performance on a task was 100 seconds then allotted task time performance would be 150 seconds. This ratio should be aggregated across tasks and reported with mean and variance scores that allows some time buffer because the participants are presumably not trained to expert performance.

- **Issue based Matrices**

This is primarily used for formative testing) Usability issues (# issues found, % of participants who found an issue)

Severity ratings (rating assigned to usability issues that reflects the impact of each issue on the user‘s satisfaction and ability to complete tasks)

- **Self reported Matrices**

This method provides both quantitative and qualitative measures, which in turn provide insights about participant satisfaction)

For example: Post-task ratings (may be a Likert scale from 1 to 5 where, for example, 1 is very difficult and 5 is very easy) using System Usability Scale questionnaire, or any open ended questions.

- **Behavioural Matrices**

The user might add context to performance often, issues-based, and self-report metrics. Verbal (positive / negative) comments and non-verbal behaviour reported and interpreted.

- **Satisfaction**
- **Task Rating**

Participant‘s subjective impression of the ease of use of the application is measured by administering both a simple post-task question as well as a post-session questionnaire. The participant is asked to rate ―Overall, this task was: on a scale of 1 (Very Difficult) to 5 (Very Easy).

2.8.3 Analysis
Describe any analyses to be performed on the collected data.

2.8.4 Timeline
The project schedule, including test and deliverable dates

2.8.5 Selecting Participants
Based on the target user groups, the usability administrator can create a Screening Questionnaire for recruiting study participants. The questionnaire will identify individuals who meet defined criteria (e.g., hospitalists). The Screening Questionnaire also defines targeted breakdowns in terms of demographics and/or user profiles (e.g., age, gender, income, etc.). Individuals are recruited based on their responses.

Challenges in selecting participants:

The characteristics of the user groups make design and the design process of an EHR more challenging than that of other applications. In general, EHR users are highly educated and highly skilled: physicians in general and specialty practice, residents, hospitalists, nurse practitioners, nurses, lab technicians, administrative staff, etc. The design process must embrace the full range

of skills, knowledge, and experience that exists today in clinical practice. Specifically, during design and development, efforts must be made to include users from all relevant user populations.

When developing EHRs, it is important to ensure a sample of the population that exhibits a range of like characteristics, such as technology sophistication and acceptance of technology. Usability for groups at one end of the technology sophistication dimension often is much different than for those at the other.

As very few of the respondents were ready to be a part of our design team, hence the screening part was not considered.

2.8.6 Usability Testing Script

The usability administrator creates a moderator‘s guide with collaboration from the design/test team and formulates specific sets of questions and tasks that will be used during the usability test sessions. The moderator‘s guide can be a semi- structured interview script to aid in task administration and data collection.

As mentioned above in the task selection functions are then selected for usability testing according to several criteria: frequency of use, task criticality and complexity, and other issues such as difficult design areas, some compliance issues etc. A good moderator‘s guide includes tasks and questions that are in perfect alignment with the test objectives.

2.8.7 Running the Usability Test

The technical setup of a test can range from very high- to very low-tech. There are two main elements that must be included in test setup:

- A platform from which participants can access and experience the interface,
- Means for the administrator, note taker(s), and/or observer(s) to observe the participant actions, behaviors, and comments.

For EHR and other computer-based application testing, the equipment will likely consist of:

Desktop, laptop, or Tablet capable of running the test application, for the participant to use and ways for the administrator to view the participant‘s computer.

- Typically, a second computer or some other means for projection (monitor, TV, projector) can show the participant‘s screen.
- The test team and any stakeholders are able to see exactly what the participant is viewing and can observe the participant‘s actions.
- Software is available that can record the participant‘s screen along with other camera shots of interest.
- Often, a webcam/ small video camera is used to gather an audio and video recording of participant reactions and feedback.
- Note-taking tools may be electronic (e.g., structured spreadsheet or online survey collector) or hand written forms.

2.9 Organizational Maturity for Usability

An established UCD process ensures that designed EHRs are efficient, effective, and satisfying to the user.

The established UCD processes are followed by organizations that have a culture of usability. The degree to which the process of constructing usable experiences is systematized can be evaluated using a Usability Maturity Model. The purpose of such a model is both diagnostic and prescriptive. Within the Earthy (1999, 4) (model there are six levels that describe an organization's embrace of usability and user-centered design:

- 0 – Incomplete: Not able to carry out process
- 1 – Performed: Individuals carry out process
- 2 – Managed: Quality, time and resource requirements for process known and controlled
- 3 – Established: Process carried out as specified by organization, resources are defined
- 4 – Predictable: Performance of process within predicted resource and quality limits
- 5 – Optimizing: Organization can reliably tailor process to particular requirements

Each of these levels is cumulative and can be characterized by their use of data as a basis of decision-making, management support for usability, who is involved on the design team, and resources applied.

The following four dimensions can characterize usability maturity within organizations. These dimensions include

- Using data as a basis for decisions,
- Management support,
- The design team, and
- Resources.

Each dimension, as described in the following sections, has characteristics that will enable the organization to produce more usable applications.

- **Data as a Basis for Decision**

The traditional way of design and related guidelines are rarely sufficient to create outstanding experiences in applications as complex as EHRs. As complexity increases, the need to rely on user performance data provided from representative users in realistic contexts increases. It is easily claimed that an EHR is usable. However, such claims can and should be empirically tested given the right assumptions and the correct set of tasks. Therefore the reliance on user performance data to make improvements to the user interface and user experience is the best way to come out with an EHR that excels in usability.

- **Management Support**

Usability, as discussed at the outset, is not a well-defined term. Some organizations do not have a culture of usability. In organizations without a culture of usability there is little more than token thought given to ease of use, but as the organization matures and some layers of management begin to take usability seriously; usability activities (e.g., usability tests) then may become more formal and more regular. At the most mature levels, senior management of the company has a passion for the usability of the application. These senior managers understand the relationship between product quality and usability, as well as the relationship between brand identity and

usability.

These managers understand that the user interface to the EHR is the lens through which customers make critical purchase judgments about their application; in fact, the UI (User Interface) is their product. They also recognize that creating these user experiences requires a commitment to the necessary human resources, and to the UCD process.

- **Design Team**

It is assumed, in some less mature organizations, that programmers write the code and that the user interface is simply part of the code. But user interface design requires an in-depth understanding of the users, tasks, and context of use, which programmers often lack. Understanding this, many organizations rely on the expertise of staff clinical experts or outside clinical advisers to help design their EHR. Clinicians understand the contexts and use cases, and they themselves are users. Engaging clinicians is important and necessary, but it is often insufficient. Additionally, the number of clinical users is limited, and the way they are engaged (e.g., focus groups) can be inefficient at obtaining good data.

Organizations that best support user-centered design practices round out their design teams by employing experienced experts in human factors engineering and usability. These experts have knowledge of human capabilities with technology combined with expertise in user interface design (i.e., information architecture and wire framing). They also engage visual designers, who augment and extend the information architecture and the screen designs to improve performance. Usability experts and visual designers together with the business, software, and clinical experts are all part of a cross-functional team that lays a foundation for successful design.

- **Resources**

Commitment to usability requires resources -- human, time, and financial. In the design team dimension, it was pointed out that there are multiple members of the design team necessary to produce quality design. A UCD process does take time; however, the time is usually made up in the development phase. Less mature organizations may be impatient with the time required by the UCD process and feel rushed to start developing due to hard deadlines, but UCD executed well produces high quality user interface specifications that actually reduce time and reduce

rework because 'bugs' have been worked out before user interface development begins. Finally, mature organizations will dedicate sufficient financial resources toward having the right staff, facilities, and testing budgets to achieve the goal of a quality user experience.

2.10 FRESCO INFORMATICS @ USER MATURITY MODEL STAGE 2: MANAGED

The concept of Usability is not new at our organization; currently we are in development phase of an EHR product meant for clinicians which will be later on laced with more details to match up to the requirements of corporate hospitals.

The organization follows a User centered design process where all the steps are planned to be followed. Currently we have gathered all the user details in form of a **Software specifications document** which comprises of the **UTILITY** part, and besides that a **USABILITY REQUIREMENT** gathering exercise was conducted where the doctors were interviewed and their responses were analyzed to design the screens accordingly.

The requirements gathered related to Usability were incorporated into the Software requirements specifications document which has been attached in the appendix section.

Moreover, out of the 40 respondents, **5 clinicians** were ready to be a part of our UCD process and will help in determining the user experience along with the usability expert. Currently our developers are working on drafting **wireframes** and **low fidelity designs** and the soon the users will be contacted for their feedbacks.

CHAPTER – 2 METHODOLOGY

3.1 Sample Design

- Sample Unit: Practicing Clinicians in Bangalore
- Sample Size: **40 Doctors**
- Sampling Technique: Simple Random Sampling
- Sampling Area: Bangalore

3.2 Data Collection

A self-structured questionnaire was drafted & the primary data was gathered by sending the questionnaire through e-mail & also by direct interviews.

3.3 Data Analysis

Data was coded and analyzed in SPSS version 16.0, based on the responses FREQUENCIES were estimated to know the usability requirements of the doctors they expect in an EHR.

3.4 Limitations of Study

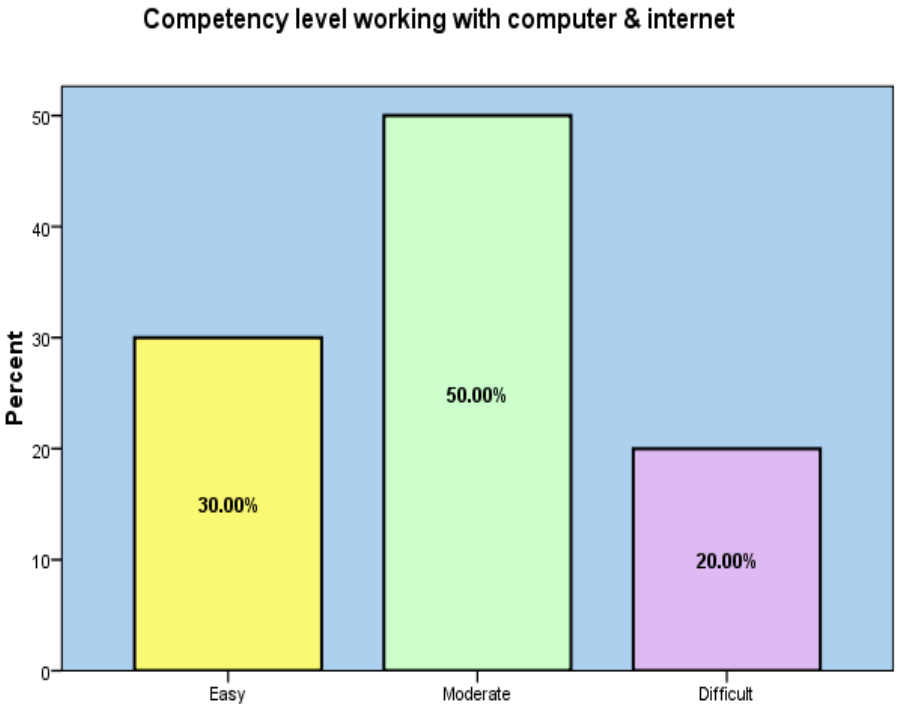
Gathering response from a large number of doctors under time constraints was difficult. Therefore, small sample size was one of the limitations for this study.

The analyses below will show the various the results of various questions answered by the doctors, based on the analyses the system design specifications will be documented.

CHAPTER 3 – RESULTS & FINDINGS

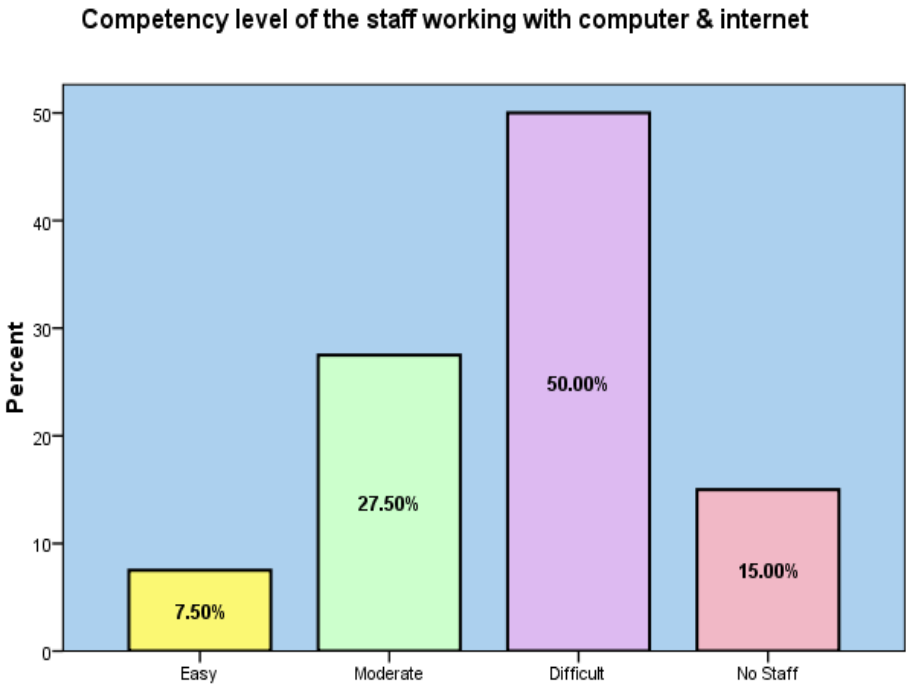
✓ Competency Level with Computers

Competency level working with computer & internet			
		Frequency	Percent
Valid	Easy	12	30.0
	Moderate	20	50.0
	Difficult	8	20.0
	Total	40	100.0



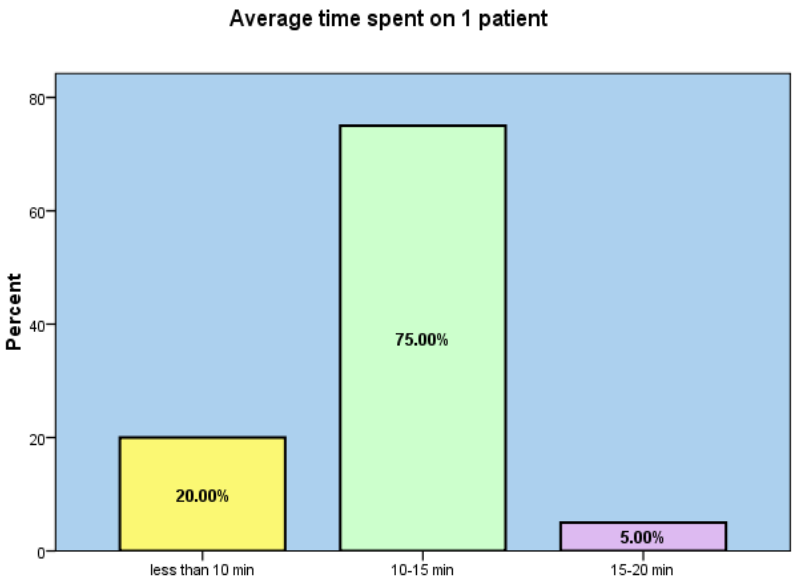
✓ **Competency level of Staff with using computers**

Competency level of the staff working with computer & internet			
		Frequency	Percent
Valid	Easy	3	7.5
	Moderate	11	27.5
	Difficult	20	50.0
	No Staff	6	15.0
	Total	40	100.0



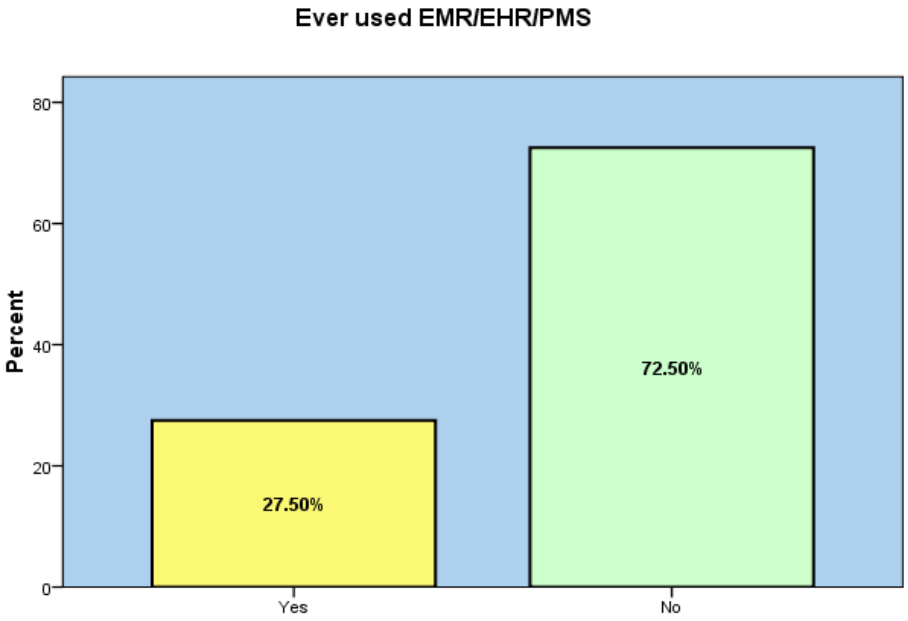
✓ **Average time spent on each patient**

Average time spent on 1 patient			
		Frequency	Percent
Valid	Less than 10 min	8	20.0
	10-15 min	30	75.0
	15-20 min	2	5.0
	Total	40	100.0



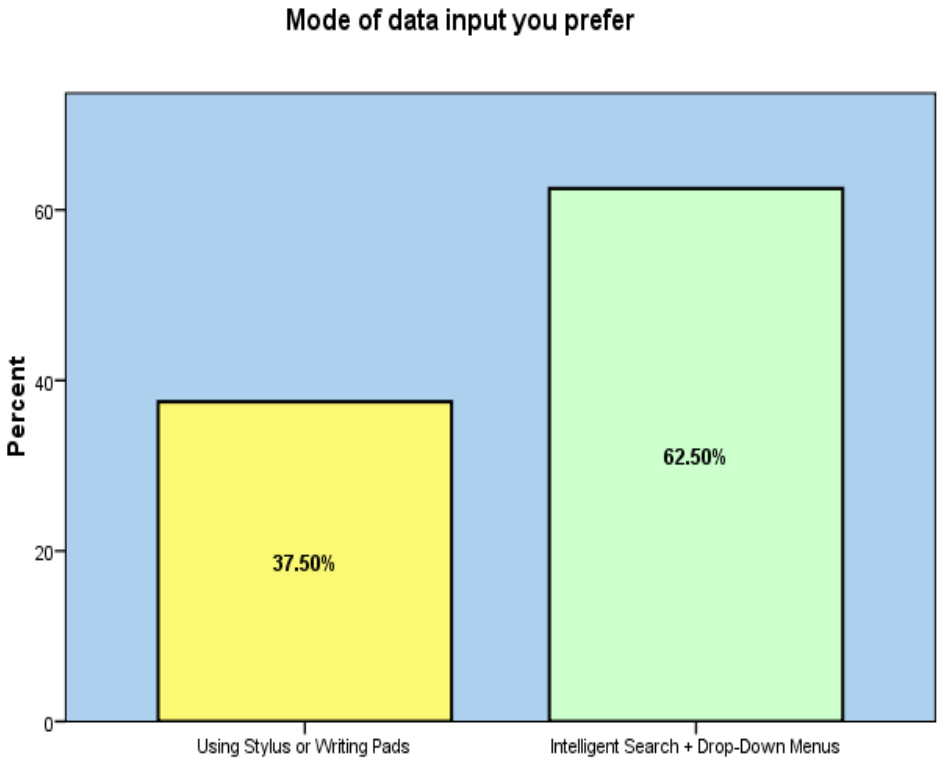
✓ **Have you ever used EMR/EHR/PMS?**

Ever used EMR/EHR/PMS			
		Frequency	Percent
Valid	Yes	11	27.5
	No	29	72.5
	Total	40	100.0



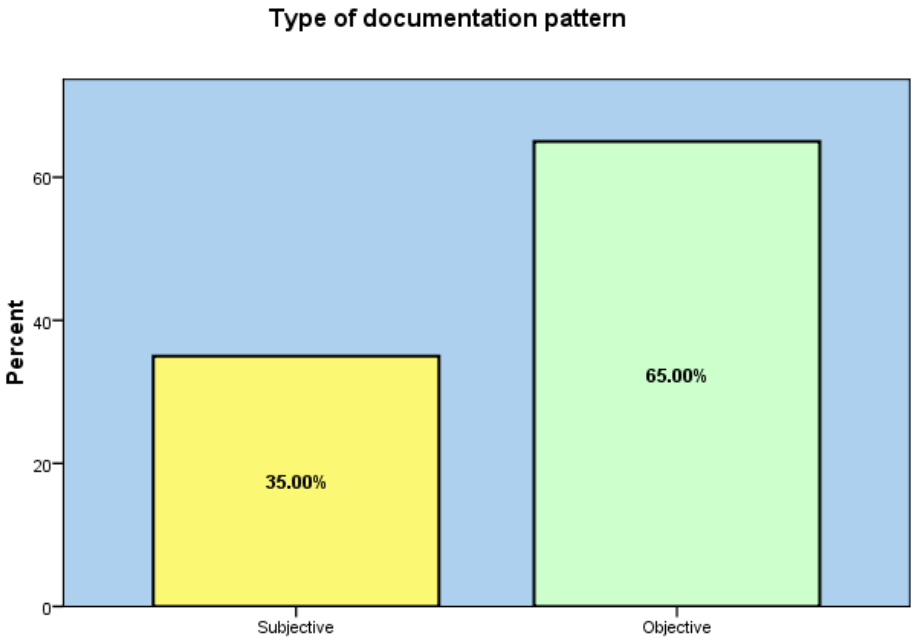
✓ Mode of Data Input

Mode of data input you prefer			
		Frequency	Percent
Valid	Using Stylus for Free Text	15	37.5
	Intelligent Search + Drop-Down Menus	25	62.5
	Total	40	100.0



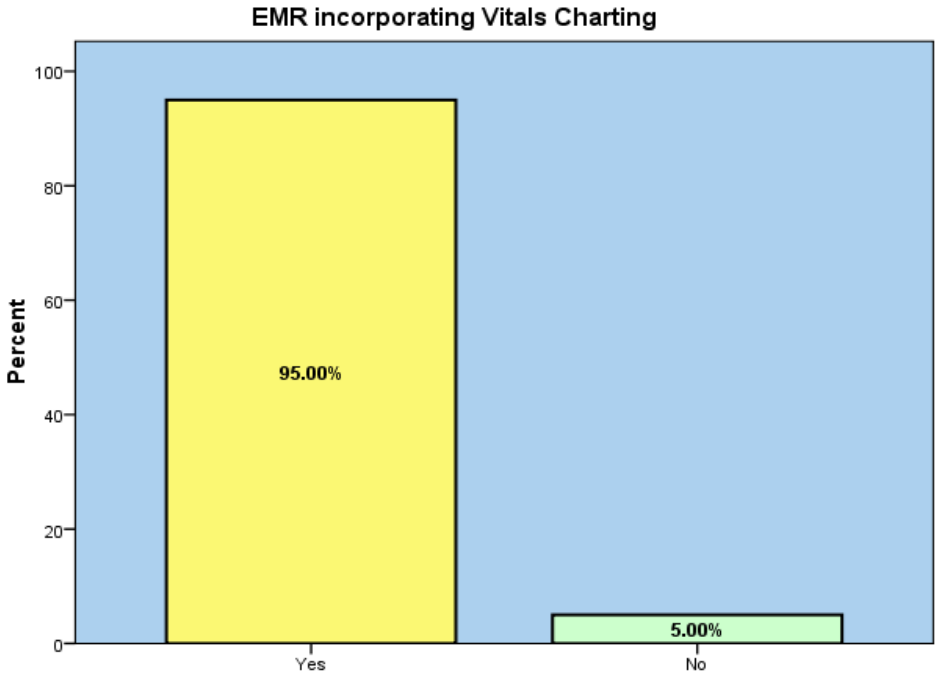
✓ **Type of documentation pattern**

Type of documentation pattern			
		Frequency	Percent
Valid	Subjective	14	35.0
	Objective	26	65.0
	Total	40	100.0



✓ **Do you want Vitals Charting in an EMR/EHR?**

Want Vitals Charting			
		Frequency	Percent
Valid	Yes	38	95.0
	No	2	5.0
	Total	40	100.0

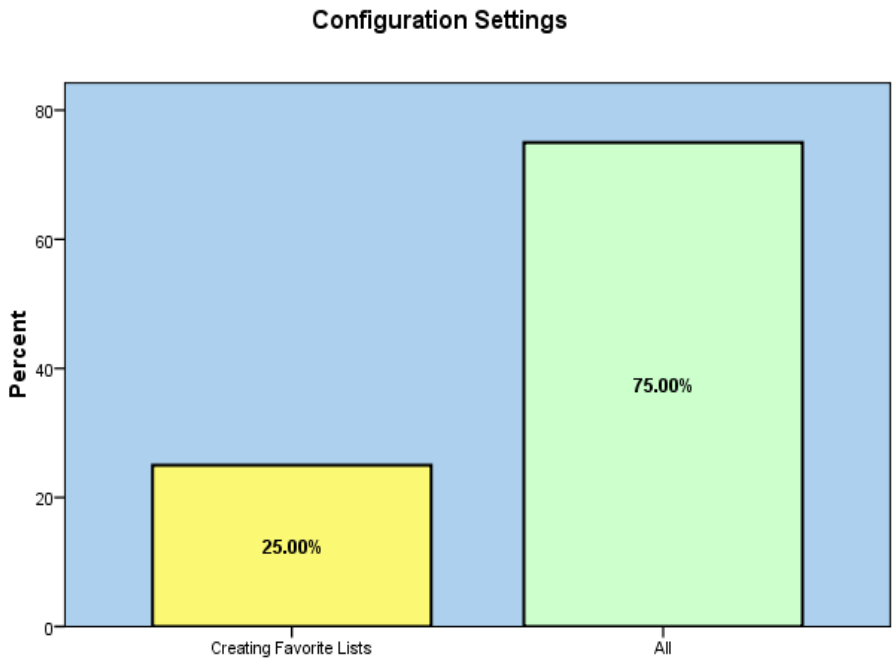


✓ **Do you want an EMR to incorporate Patient dashboard with complete summary**

Patient Dashboard with complete summary			
		Frequency	Percent
Valid	Yes	40	100.0

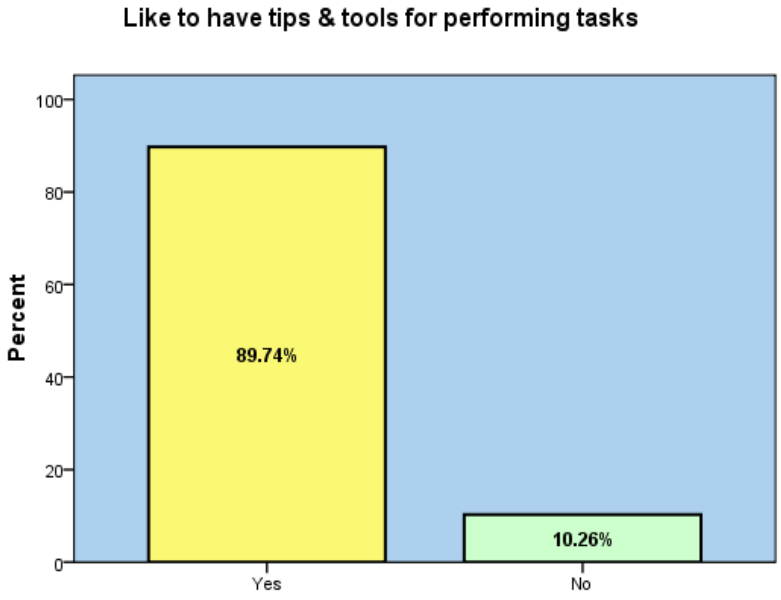
✓ **Configuration Settings**

Configuration Settings			
		Frequency	Percent
Valid	Creating Favorite Lists	10	25.0
	All	30	75.0
	Total	40	100.0



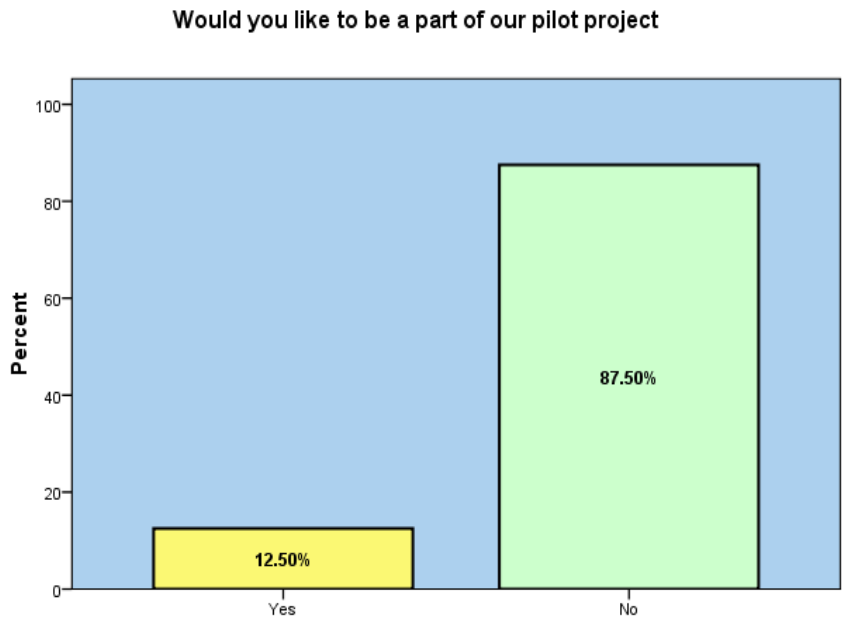
✓ **Do you like to have tips & tools for performing tasks?**

Like to have tips & tools for performing tasks			
		Frequency	Percent
Valid	Yes	35	87.5
	No	4	10.0
	Total	39	97.5
Missing	System	1	2.5
Total		40	100.0



✓ **Would you like to be a part of our Pilot Project?**

Would you like to be a part of our pilot project			
		Frequency	Percent
Valid	Yes	5	12.5
	No	35	87.5
	Total	40	100.0



Once the low fidelity wireframes are designed taking the usability aspects proposed by the majority of doctors as a part of this questionnaire, the participant doctors of our design team will be called for their feedback and from there onwards the other stages of UCD cycle will be carried on to develop and obtain a complete user experience through our EHR.

CHAPTER 4- RECOMMENDATIONS & CONCLUSIONS

User-centered design is a bedrock principle for creating usable systems and devices. At its core UCD is a process that relies on systematic understanding of users and their environments, and iterative design and testing based on user performance objectives.

The Usability monitoring establishes a framework for setting usability goals and specific evaluation measures for a given application, within this framework it measures certain attributes, which further help in comparing the application‘s progress over time as well as the comparison of competitor applications.

A UCD process does take time; however, the time is usually made up in the development phase. UCD executed well produces high quality user interface specifications that actually reduce time and reduce rework because 'bugs' have been worked out before user interface development begins.

The expectations from UCD should not be to produce incredible breakthroughs in human performance but significant improvement can be observed psychologically in the minds of clinicians that the product has been made keeping them in mind. However, often what is needed is solid incremental improvement, and this is where the UCD process is very beneficial.

Therefore the UCD process should be imbibed by every organization so that they can embark upon the usability concept for their clinical applications.

LIMITATIONS:

- The less number of respondents is a limitation.
- The questionnaire exercise was done for gathering user information, usability requirements etc. henceforth no SPSS tools were applied, once the test plans are designed and executed the performance measurements are done to know the means and variances between the operational time recorded.

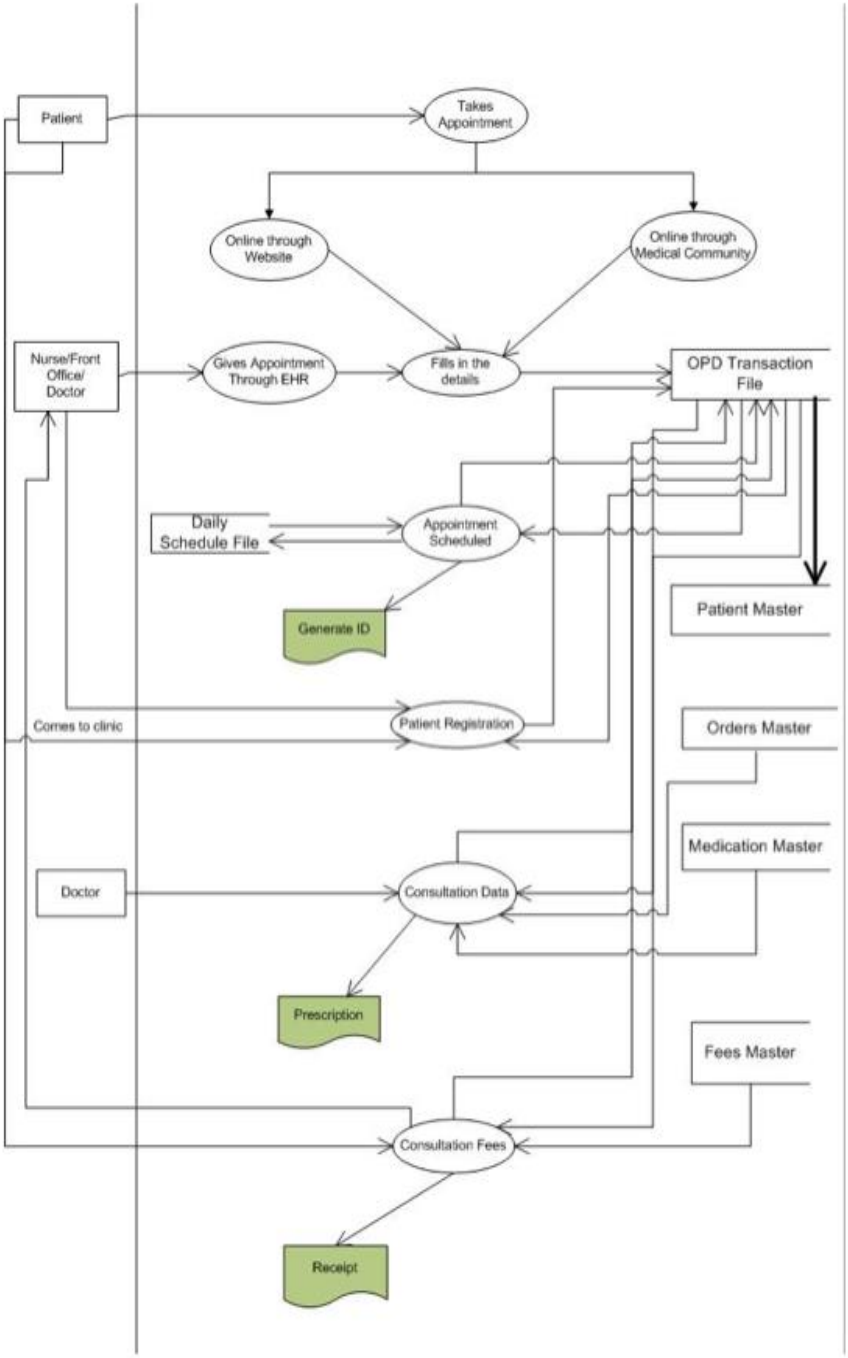
Appendix

Software Requirements Specification Snapshots:
Clinical Workflow
Data Flow Diagram

Consultation Screen Functionality Showing:
Mode of Inputs,
Patient Clinical Summary Screen,
Clinical Vitals Charting (Usability Aspects asked from the Doctors)

2. General Workflow of the Clinic

3. Data Flow Diagram



	FR11.Consultation Screen[1]	**11. This screen is displayed:** **a. If the patient is already registered either online or by the nurse or front office and the doctor clicks on the patient name on FR4.** **b. If the doctor himself is registering the patient then this screen is displayed as the doctor clicks DONE on the registration screen.**
	FR11.1Consultation Progress Bar	**11.1 A progress bar on the left of the consultation screen will denote the completeness of the consultation.**
	FR11.2 Chief Complaint	**11.2 This segment of the Consultation is displayed when the doctor clicks anywhere on the area just below the clinic credentials (the screen headers). The doctor can enter his observations as a free text.**

[1] The consultation screen is virtually divided into 4 segments the screen resembles a blank prescription, designed in the same flow and format as the doctor writes. Once the doctor finishes writing one segment a color bar is displayed on the left of the segment (FR10.1) as a progress mark, the segment left unfilled wont show on the consultation progress bar.

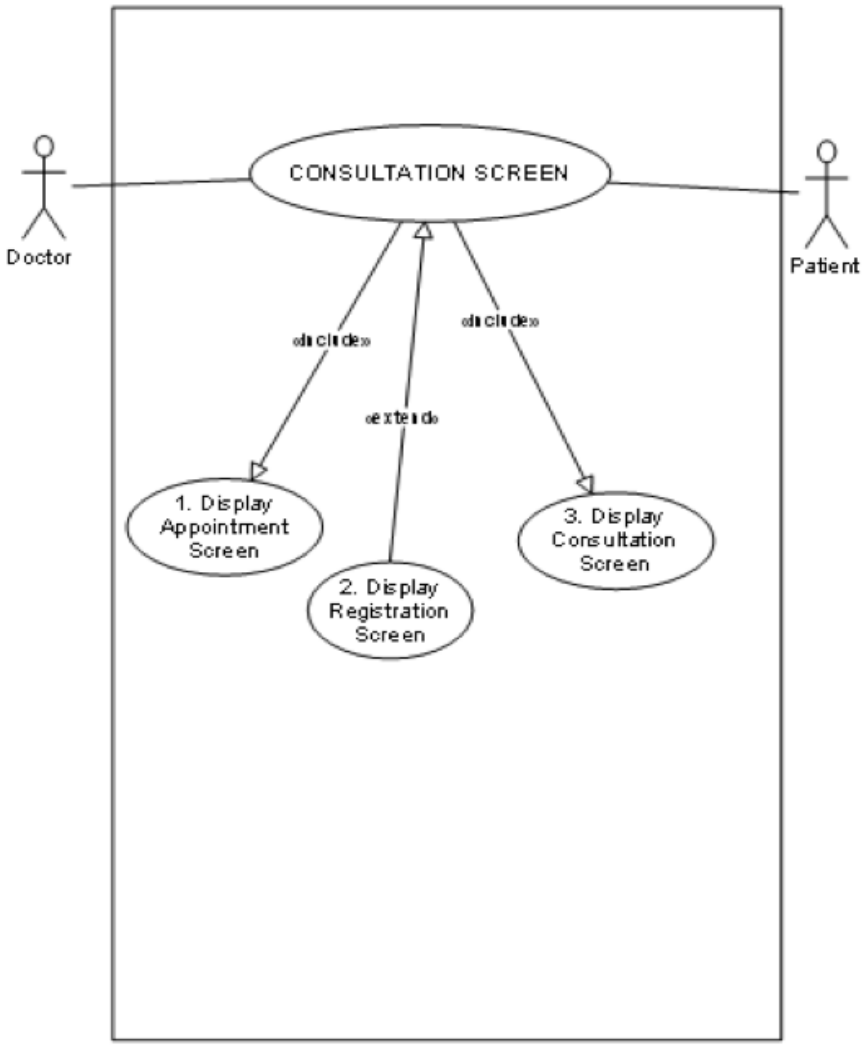
	FR11.2.1 Allergies Table	**11.2.1 This table is displayed as add on FR11.2 when the doctor clicks on the Allergies tab present within the FR11.2 segment in the bottom right corner. This table comprises of certain fields and dropdowns for the doctor to select.**
	FR11.2.2 Vitals Table	**11.2.2. This table is displayed as add on FR11.2 when the doctor clicks on the Vitals tab present within the FR11.2 segment in the bottom right corner. This table comprises of certain fields and dropdowns for the doctor to select.**
	FR11.2.2.1 Clinical Charting (Graphical Representation)	**11.2.2.1 The Clinical Charting will generate graph charts for the values entered for a specific vital or any screening parameter such as weight, blood pressure, blood sugar etc. with the normal values as standards for matching the progress.**
	FR11.2.3 Past History	**11.2.3 This table is displayed as add on FR11.2 when the doctor clicks on the Past History**

		tab present within the FR11.2 segment in the bottom left corner. This table comprises of certain fields and dropdowns for the doctor to select.
	FR11.2.4 Family History	**11.2.4 This table is displayed as add on FR11.2 when the doctor clicks on the Family History tab present within the FR11.2 segment in the bottom left corner. This table comprises of certain fields and dropdowns for the doctor to select.**
	FR11.3 Diagnosis	**11.3 This segment of the Consultation is displayed when the doctor clicks anywhere on the area just below the FR11.2. This segment contains intelligent search of diagnosis for the doctor to select which is based upon the International Classification of Diseases version 10 nomenclature standards.**
	FR11.4 Investigation Orders	**11.4 This segment of the Consultation is displayed when the doctor clicks anywhere on the area just below the FR11.3. This segment contains certain fields and**

		dropdowns for the doctor to select and order the necessary investigations
	FR11.5 Medication Orders	**11.5 This segment of the Consultation is displayed when the doctor clicks anywhere on the area just below the FR11.4. This segment contains certain fields and dropdowns for the doctor to select and order the necessary medications.**
	FR11.5.1 General Instructions Text box	**11.5.1 This text box is displayed as add on FR11.5 when the doctor clicks on the Instructions tab present within the FR11.5 segment in the bottom right corner. The doctor can mention the instructions as free text.**
	FR11.5.2. ACTION menu	11.5.2 This menu button will contain 3 tabs as a drop down, which mark the end of the consultation cycle or an encounter.
	FR 11.5.2.1 Follow Up tab	11.5.2.1 The FOLLOW UP tab will facilitate the user to schedule the next appointment for the patient.
	FR 11.5.2.2 Referral Tab	11.5.2.2 The REFERRAL tab will facilitate the user to refer the patient to another

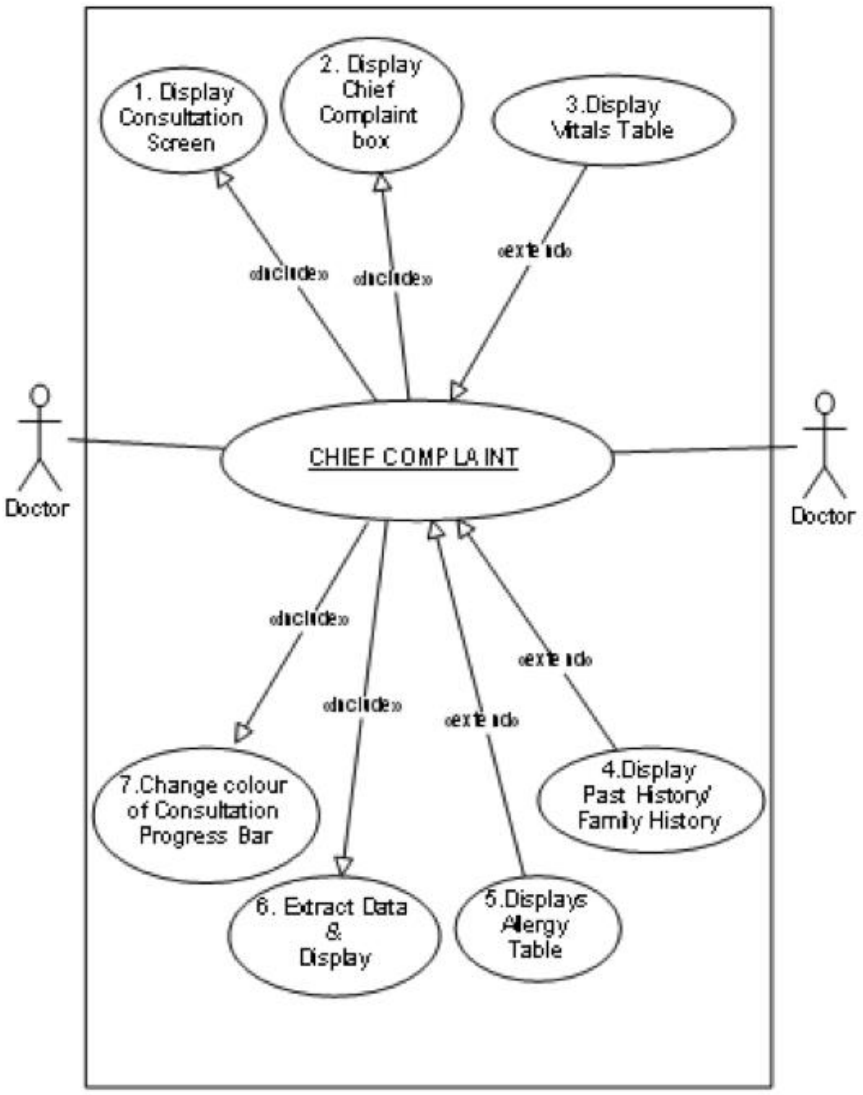
		consultant. For this the user will use the list of consultants present in the Doctor Dashboard, as the details will be pulled in once user selects the consultant.
	FR11.5.2.3 Print Prescription	11.5.2.3 The **Print tab** will print the prescription. The prescription will contain all the details filled in by the doctor in the consultation screen including the follow up appointment, the referral details if given.
	FR11.6 Prescription overview	**11.6 The Prescription Overview for the follow up patients will be present as a "gesture" as top to bottom swipe on the new consultation screen when the patient comes for follow-up visit.**
	FR11.7 Patient Dashboard	**11.7 The Patient Clinical Summary will be displayed when Clinical Summary tab is clicked.**

USE CASE 11: CONSULTATION SCREEN



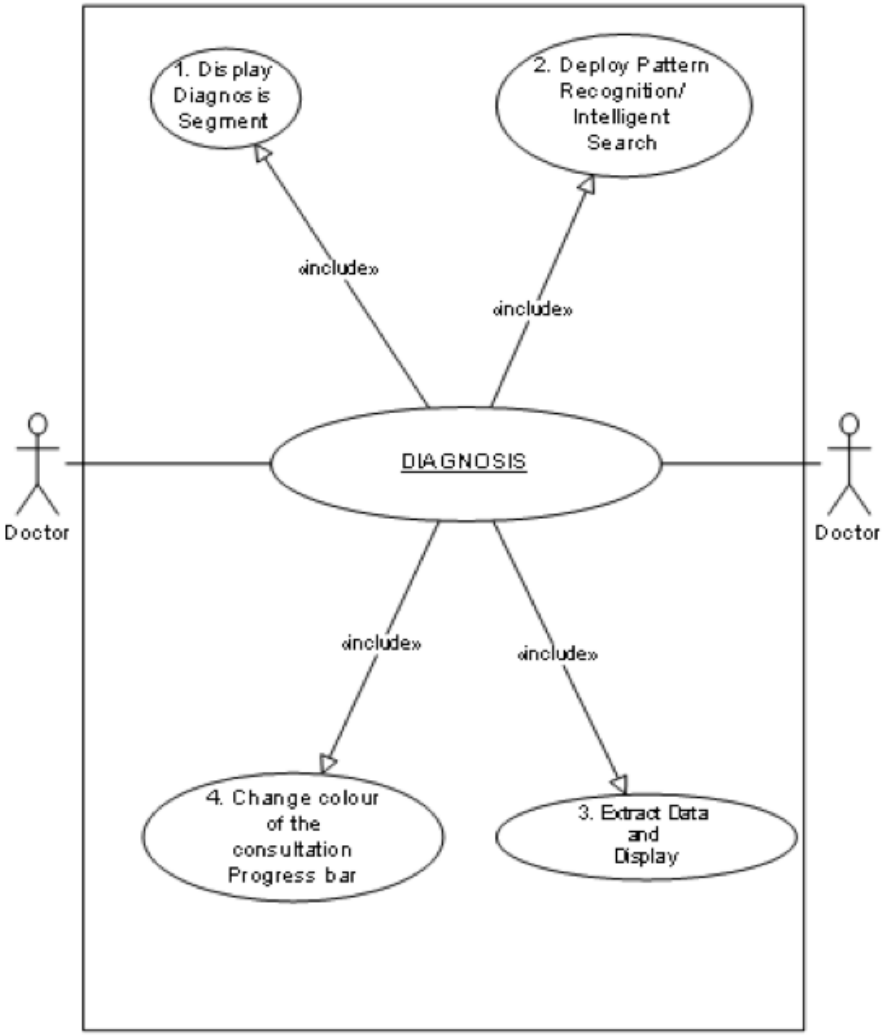
Use Case ID	UC11
Use Case	Consultation Screen.
Elaboration	Base use case
Actors	Doctor
Description	The doctor starts the clinical consultation by taking the details from the patient and prescribing investigations and medications.
Trigger	a. If the patient is already registered either online or by the nurse or front office and the doctor clicks on the patient name on FR4. OR b. If the doctor himself is registering the patient then this screen is displayed as the doctor clicks DONE on the registration screen.
Pre-conditions	The patient has been registered.
Flow of Events	1. The doctor clicks on the Patient Name on the FR4. OR The doctor clicks on DONE on the registration screen after filling in the details on FR6. 2. The system displays the CONSULTATION SCREEN. 3. The use case ends.
Post-conditions	The doctor has entered the patient's consultation screen.
Priority	High

USE CASE 12: CHIEF COMPLAINT and HISTORY.



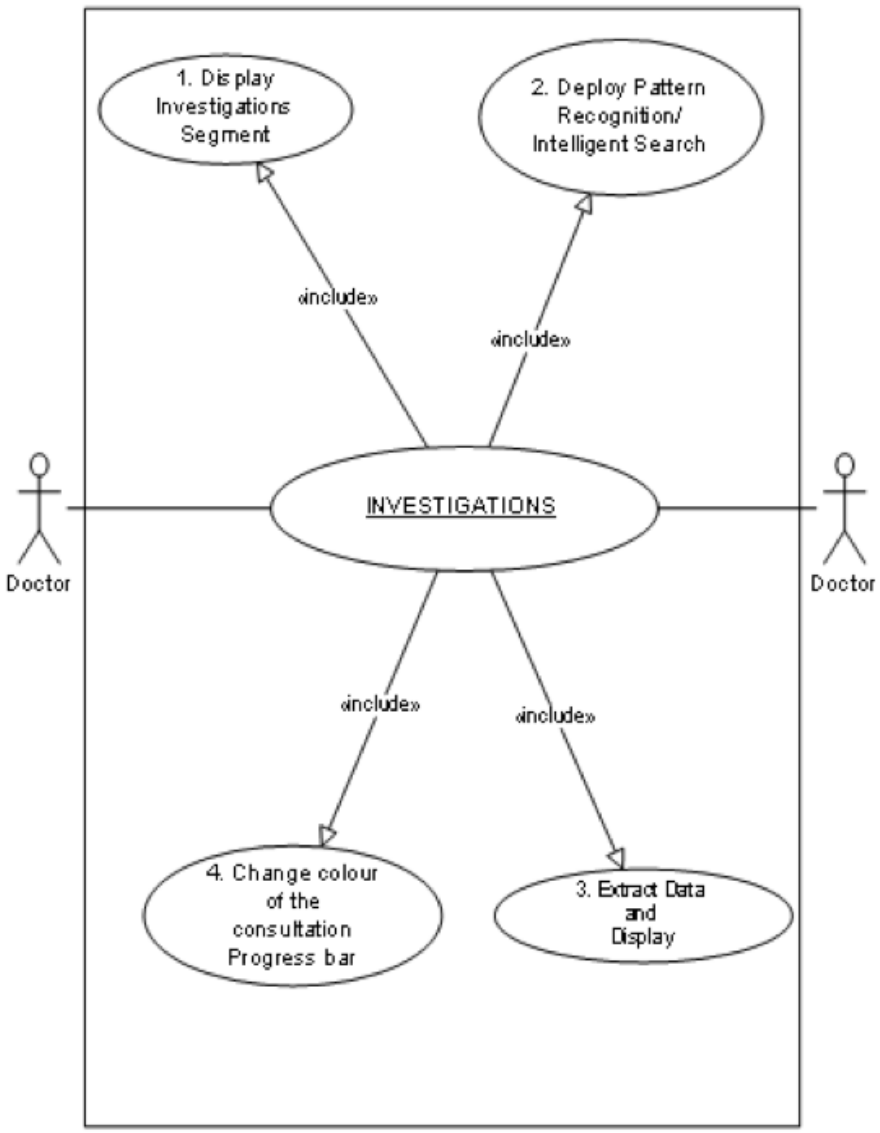
Use Case ID	UC12
Use Case	Chief Complaint and History box
Elaboration	Base use case
Actors	Doctor
Description	The doctor starts the clinical consultation by taking the details from the patient and side by side filling in the consultation screen.
Trigger	When the doctor clicks anywhere on the area just below the clinic credentials (the screen headers).
Pre-conditions	The patient has been registered.
Flow of Events	1. The system displays the CONSULTATION SCREEN. 2. The doctor clicks anywhere on the area just below the clinic credentials (the screen headers). 3. The system displays the Chief Complaint and History box. (FR11.2) 4. The doctor writes the chief complaint for which the patient has come for consultation. 5. IF <the doctor clicks on the Vitals Tab> THEN <display the Vitals table>. 5.1 The doctor selects the Vital for which charting is to be done. 5.2 The system plots a chart with TIME on x-axis and vital readings on y-axis with the normal range already plotted for reference on y-axis. 6. IF <the doctor clicks on the Allergies Tab> THEN <display the Allergy table>. 7. IF<the doctor clicks on the Past History/Family History Tab> THEN<display the Past History/Family History box> 8. The system extracts the data from the table and displays the data on the consultation screen. 9. The system changes the colour of the progress bar (FR 10.1) only after extraction of data 10. The use case ends.
Post-conditions	The doctor has entered the patient's chief complaint.
Priority	High

USE CASE 13: DIAGNOSIS



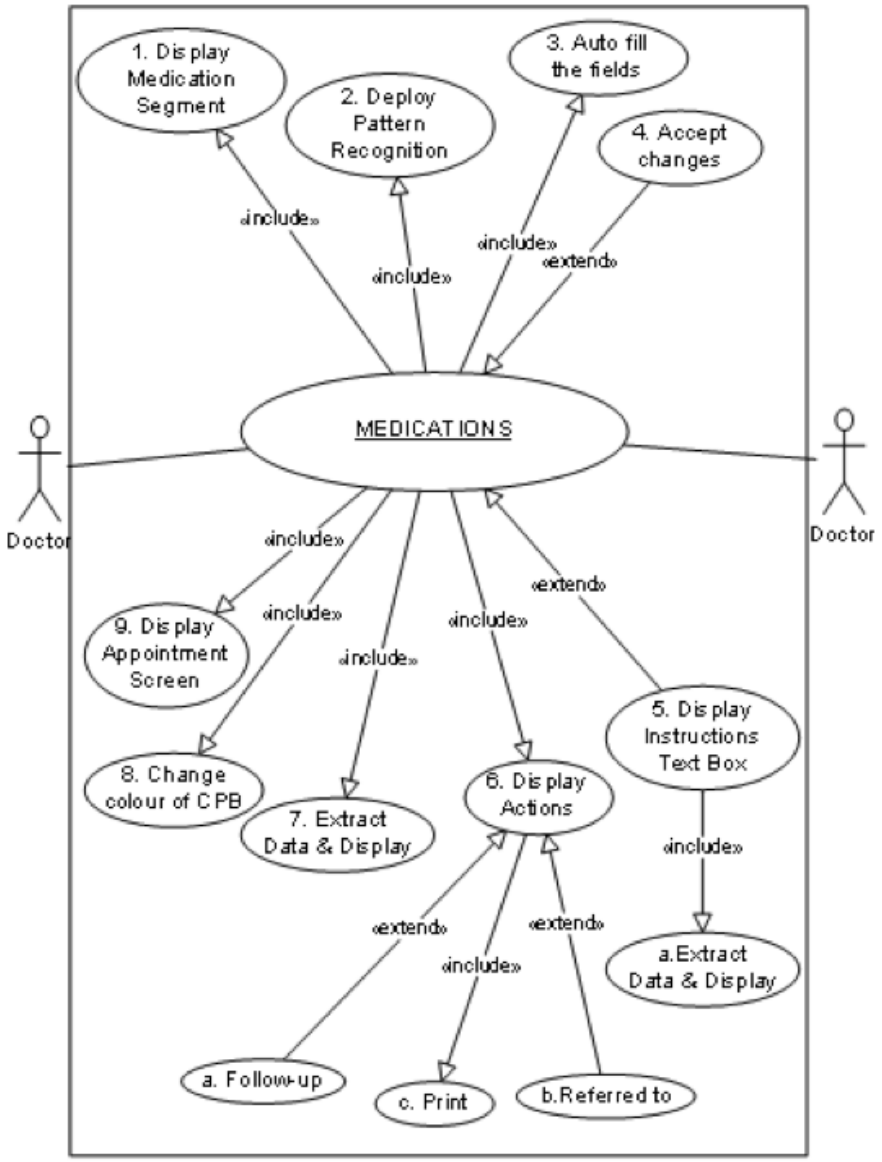
Use Case ID	UC13
Use Case	Diagnosis box
Elaboration	Base use case
Actors	Doctor
Description	The doctor fills the final diagnosis based upon the details taken earlier.
Trigger	When the doctor clicks anywhere on the area just below the FR11.2.
Pre-conditions	The patient has been registered.
Flow of Events	1. The doctor clicks on the area just below the FR11.2 (or the chief complaint box). 2. The doctor fills in first few letters of the disease the doctor has diagnosed the patient is suffering from. 3. The system deploys the intelligent search and shows matching results from the ICD10 database. 4. The doctor selects the appropriate match. 5. The system extracts the data from the table and displays the data on the consultation screen. 6. The system changes the color of the progress bar (FR 10.1) after extraction of data 7. The use case ends.
Post-conditions	The doctor has reached the final diagnosis and filled in the details.
Priority	High

USE CASE 14: INVESTIGATIONS



Use Case ID	UC14
Use Case	Investigations box
Elaboration	Base use case
Actors	Doctor
Description	The doctor advices the various investigations required for further analysis of the case.
Trigger	When the doctor clicks anywhere on the area just below the FR11.3.
Pre-conditions	The patient has been registered.
Flow of Events	1. The doctor clicks on the area just below the FR11.3 (or the diagnosis box). 2. The doctor scribbles first few letters of the investigation he or she wants to order. 3. The system deploys intelligent search and displays the best possible matches. 4. The doctor selects from the displayed matches. 5. The system extracts the data from the table and displays the data on the consultation screen. 6. The system changes the colour of the progress bar (FR 10.1) only after extraction of data 7. The use case ends.
Post-conditions	The doctor has advised a set of investigations which the patient is supposed to undergo.
Priority	High

USE CASE 15: MEDICATIONS



Use Case ID	UC15
Use Case	Medications box
Elaboration	Base use case
Actors	Doctor
Description	The doctor prescribes medications for the patient.
Trigger	When the doctor clicks anywhere on the area just below the FR11.4.
Pre-conditions	The patient has been registered.
Flow of Events	1. The doctor clicks on the area just below the FR11.4 (or the investigations box). 2. The doctor types the first few letters of the medicine name in the given field. 3. The system deploys intelligent search and shows the best matches. 4. The doctor selects the drug. 5. The system fills in the rest fields depending on the drug selected. 6. The doctor can overwrite the auto-filled fields if required. 7. IF <the doctor clicks on Instructions tab> THEN < the system displays a text box for the doctor to write instructions. > 8. The doctor clicks on ACTION menu. 8.1 IF< the doctor clicks on FOLLOW UP tab> THEN< the system displays the calendar for scheduling the next appointment> 8.2 IF<the doctor clicks on the REFERRAL tab> THEN < the system displays a search box where the doctor can search for consultants from his or her list either by name or specialty. 8.3 The next appointment or referral is pulled on the prescription. 8.4 The doctor clicks on the PRINT tab, and the prescription gets printed. 9. The system extracts the data and displays on consultation screen. 10. The system changes the colour of the progress bar (FR 10.1) only after extraction of data. 11. The system displays the Appointment Screen. (FR4) 12. The use case ends.
Post-conditions	The doctor has prescribed a set of medications that the patient is supposed to take.
Priority	High

Configuration Features:
(Usability Aspect asked in the Usability Requirements)

8. Configuration Profile

The following list will entail all details of the configuration changes, which the user can do at his end as per his/her requirements. The list can be configured in the admin settings, which is present in the doctor dashboard screen.

1. **Medication Tables and Investigation Tables**
2. **Vitals Sheet**
3. **Prescription Layout**
4. **Billing Details**
5. **My Consultants**
6. **Clinic Details**
7. **Setting Favorite Lists**

8.1 Medication Tables & Investigations

Doctor can configure the most frequently used medications from the pre-feeded list according to his/her requirements, and add set of medications and investigations as favorite.

8.2 Vitals Sheet

Doctor can add/delete the vitals according to his/her specialty from pre-feeded list provided.

8.3 Prescription Layout

This is applicable in cases where a doctor visits multiple clinics; the prescription layout in terms of header & footer can be changed according to the doctor's location.

8.4 Billing Details

The doctor will have to add his/her billing details as per their requirements for the first time. This will be provided as a template where the doctor can fill the visit types as per his choice and the related charges, which can be updated when needed.

8.5 My Consultants

The doctor configures this list for the first time; the name of the consultant, contact number & the address of the consultant are added. This is done, so that in cases of referral as the doctor selects the consultant; his/her information is extracted and printed in the prescription.

cases of referral as the doctor selects the consultant; his/her information is extracted and printed in the prescription.

8.6 Clinic Details

The doctor or the staff can configure the timings & days of the clinic, the duration of consultation and also can create the groups for classifying the appointment's (for e.g. VIP, Normal, etc.)

8.7 Font Size

The doctor or staff can increase or decrease the font size, and font type; by default Sans Serif fonts are used.

Questionnaire:

Name of the Clinic:

Doctor's Name:

Clinic's Address:

1.The total number of Users in your clinic?

- 1
- 2
- 2-5

2. How do you find yourself working with the computer and Internet?

- Easy
- Moderate
- Difficult

3. How do you find your staff working with the computer and Internet?

- Easy
- Moderate
- Difficult

4. Out of the following events, which are a part of workflow, followed in your clinic?

- Patient Appointment & Scheduling
- Registration
- Patient History
- Patient Examination (recording vitals)
- Investigation Orders
- Diagnosis
- Medication Orders
- Instructions
- Summary Notes
- All expect summary notes
- All

5. Please list the tasks performed by your staff based on the above selected workflow steps?

- Nurse:
- Front Office Staff:
- Doctor:

6. How many patients do you see on an average in 1 day?

7.On an average, how much time you spend on a patient?

8. Do you visit any other clinic apart from this?

- Yes
- No

9. Have you ever used an EMR/EHR or any practice management system before?

- Yes
- No

10. If given a chance of being a part of EHR development team Please answer the following questions as per your requirements in an EHR?

a.) The mode of data input you would prefer:

i. Typing
ii. Typing with Intelligent search
iii. Using dropdowns and menus for structure data entry
iv. Writing free text using a stylus
v. Voice Annotation

b.) The type of Documentation Pattern:

i. Subjective
ii. Objective

c.) Would you prefer the vitals data to be shown in form of graphs and charts?

- Yes
- No
-

d.) Would you prefer a Patient Dashboard showing the complete clinical summary of the patient?

- Yes
- No

e.) What design elements will you like to have in your configuration settings for edit purpose?

i. Font Size
ii. Prescription Layout
iii. View Options
iv. Creating Favourites List for Medications and Investigations.
v. All

f.) Would you like to have tips and tools for performing a task?

- Yes
- No

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