User requirements for an electronic medical records system for a cancer hospital in Uganda

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Affirmation

I hereby affirm that this Master thesis was composed by myself, that the work contained herein is my own except where explicitly stated otherwise in the text. This work has not been submitted for any other degree or professional qualification except as specified; nor has it been published.

Stockholm, June 2016

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Johnblack Kabaalu Kabukye
Title:

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Abstract:

Background: The context of oncology in a low and middle income (LMIC) poses a unique context of use for an electronic medical records (EMR) system, and therefore the user requirements for the EMR for this context are expected to be unique. There is plenty of literature and reference documents describing EMR features and functionalities or user requirements, for generic EMRs and for specific applications such as oncology or for LMIC but there has been none found specifically describing user requirements for an EMR for oncology in a LMIC.

Objective: This study aimed at describing user requirements for an EMR for a cancer hospital in Uganda, and to compare these requirements with those for cancer hospitals in the United States.

Methods: A qualitative study with focus group discussion and interviews was conducted. Nine clinicians at the Uganda Cancer Institute (UCI) were purposively selected as participants since they are the target end users of an EMR software developed by Clinic Master International Ltd. which the UCI is in the process of implementing. Audio recordings of the sessions were transcribed verbatim and qualitative content analysis done with a deductive approach, referencing to the Clinical Oncology Requirements for the EHR (CORE) Whitepaper.

Results: User requirements for the EMR for the UCI include generic EMR functionalities such as capturing patient information (demographics, clinic information, etc) but also oncology specific documentation (e.g. detailed cancer diagnosis recording including stage, tumor measurements and graphical representation of it, chemotherapy recording, recording of special investigations done in cancer care, etc) and oncology specific functionalities such as clinical decision support to ensure correct, standard and safe chemo prescription and administration, patient scheduling, among others. There are significant differences in requirements for the UCI and those in the CORE Whitepaper, such as clinical trials support and billing features being irrelevant for the UCI plus other differences e.g. in investigations, treatment, etc that arise from the details of the workflow and the setting of LMIC.

Conclusion: The UCI as a cancer hospital in a LMIC has unique user requirements that need to be carefully considered when developing or selecting an EMR.

Keywords: Requirements Engineering, Electronic medical records, User centered design, Context of Use, Low and middle income country, Oncology
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### Acronyms

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<th>Full Form</th>
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<tr>
<td>AIDS</td>
<td>Acquired Immunodeficiency syndrome</td>
</tr>
<tr>
<td>CDSS</td>
<td>Computerized clinical decision support</td>
</tr>
<tr>
<td>CMS</td>
<td>Centers for Medicare and Medicaid services (US)</td>
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<tr>
<td>CORE Whitepaper</td>
<td>The Clinical Oncology Requirements for the EMR, a whitepaper by the US National Cancer Institute and the American Society of Clinical Oncology</td>
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<tr>
<td>CoU</td>
<td>Context of Use</td>
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<tr>
<td>EMR</td>
<td>Electronic Health Record/Electronic medical record</td>
</tr>
<tr>
<td>UCD</td>
<td>User centered design</td>
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<tr>
<td>FGD</td>
<td>Focus group discussion</td>
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<tr>
<td>Health IT</td>
<td>Health(care) information technology/eHealth</td>
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<tr>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<tr>
<td>ICT</td>
<td>Information and communication technology</td>
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<tr>
<td>IT</td>
<td>Information technology</td>
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<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
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<tr>
<td>LMIC</td>
<td>Low and middle income country</td>
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<tr>
<td>TB</td>
<td>Tuberculosis</td>
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<tr>
<td>UCI</td>
<td>Uganda Cancer Institute</td>
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<tr>
<td>US</td>
<td>United States of America, USA</td>
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<td>WHO</td>
<td>World Health Organization</td>
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1. Introduction

Information and communication technology (ICT) has greatly impacted many aspects of our lives and has revolutionized many sectors such as commerce, engineering, aviation, education etc with an increasing use of computers - which are exponentially getting more powerful and cheaper.

For a while now ICT has also been considered key for the improvement of the healthcare industry. The Institute of Medicine in its reports "To err is human: Building a safer health system" (1) and " Crossing the quality chasm: A new health system for the 21st century" (2) of 1999 and 2001 respectively advocate for use of ICT in healthcare as a way of improving the industry that was found to be "at odds with itself" causing harm to patients through medical errors yet on the contrary it should be healing and helping to prevent harm - the ethical promise of "first do no harm". The reports pointed that the healthcare industry was "a decade or more behind many other high-risk industries in its attention to ensuring basic safety" and had "fallen far short in its ability to translate knowledge into practice and to apply new technology safely and appropriately". Use of information technology in healthcare was proposed as a tool for improving healthcare by making healthcare safe, efficient, equitable, effective, timely and patient centered (STEEEP).

Since then there has been an increase in the fervor by major stakeholders to adopt Health IT including governments and ministries of health, health insurance companies, the private sector as well as international health bodies (3). The World Health Organization (WHO) during its 58th world health assembly (4) took the resolution to adopt e-health and urged its member states to get onto the same agenda.

In the United States, the Centers for Medicare & Medicaid Services (CMS) established the Meaningful use incentive program to reimburse healthcare practices that use Electronic medical record systems (EMR) (5,6).

Despite the enthusiasm and attempts to embrace Health IT, its overall adoption and effective use remain challenging and over 75% of cases of implementation of health IT fail (7–11). Among the challenges are the following:

- the high initial capital required: couple with the fact that the benefits of such health IT projects are long term, making healthcare professionals and managers skeptical of the worthiness of the investment.
- there is also limited experience and research evidence in the field of health IT because it is a relatively young field, and the challenges of evaluation of health IT system and tendency to cover up, ignore or rationalize failures thus no lessons learned
- resistance by healthcare professionals to embrace health IT tools such as computerized clinical decision support (CDSS) because they threaten the clinician's autonomy or they are considered an inconvenience or irrelevant due to the high risk and complex nature of healthcare e.g. when a clinician has to override the system because there is need to make a decision specific to an individual patient that goes against the evidence on which the CDSS is based.
- Moreover, there are differences between health IT systems and other IT systems in terms of the expectations, with Health IT systems being required to have well defined standards for interoperability and terminologies, conform to strict legal regulations (e.g. Personal data protection), and to be flexible to support a variety of healthcare settings/environments, as well as assisting in
improving workflow, reduce cost and improve quality of patient care, all the while allowing seamless communication and collaboration.

Therefore, for success of a health IT system/project, several key factors need to be in place. The excerpt below summarizes these factors (10)

<table>
<thead>
<tr>
<th>Type of criteria</th>
<th>Examples</th>
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| **Functional**   | - Functionality: Comprehensive functionality, Supports various ways of system use, Balance between new functionality and stability, User-tailored ICT  
                  - Usability: High usability”, Good fit between use and system, Intuitive user interface, Not too many different screens |
| **Organizational** | - Historical Context: Earlier positive experience with new way of working. Previous experiences of users with ICT  
                       - Fit of perceived cost and benefit: ICT answers perceived, continuous need”, Positive cost-benefit perceptions of users”, Positive influence on patient care, Patients feels benefit, too”, Balance between expectations and ICT outcome  
                       - Support of workflow: ICT supports care process of patient care, ICT embedded in clinical workflow, ICT supports concrete clinical tasks, Activities made easier through ICT”, Reduction of routine documentation activities, Not too many changes on work organization and workload |
| **Technical**    | - Development process: Development in small teams, Continuous user involvement and user participation”, Sufficiently modeling health care processes, Use of open standards  
                   - System Architecture: Flexible system concept”, Modular and scalable system concept”, Good interoperability and integration with other ICT systems”, Low complexity of the overall system”  
                   - Technology: Stable, not too innovative technologies”, Affordable technologies, Easy-to-use devices |
| **Managerial**   | - Sufficient funding available  
                   - Good and flexible project management: Strong motivation of project team, Good public relation of project team, No interpersonal tension in project team, Use of tools for project management  
                   - ICT introduction: Availability of skilled IT staff, Sufficient user training and user education”, Extensive user support” |
| **Cultural**     | - Availability of promoters with a vision: Active marketing of new system, Forming a support based for change, Support through various user groups, Conviction of project idea”  
                   - Openness to change and innovation: Acceptance of new way of care delivery. Acceptance of standardized way of care delivery, Not too independent professional status of users, Alignment of individual goals with institutional goals |
| **Legal**        | - Appropriate legislation, Willingness for health care reformers, Willingness to change legislation, Involvement of ICT expert in legislation committees, Health authorities promote innovation |

Figure 1.1: Success factors for health IT. Adapted from: J. Brender, E. Ammenwerth, P. Nykänen JT. Factors Influencing Success and Failure of Health Informatics Systems. Methods Inf Med 2006;1:125–36

1.1 Health IT in Low and Middle Income Countries (LMICs)
The challenges to adoption and implementation of health IT are particularly more pronounced in LMICs compared to the high income counterparts, as are the challenges to other aspects of healthcare or other sectors (12–17). LMICs face greater challenges in the terms of financial limitation, lack of cutting edge infrastructure and technological advancement, limited research and education in health informatics, socio-cultural barriers to health IT adoption such as negative attitude toward use IT tools in healthcare, low computer literacy, etc as well as lack of support from healthcare managers (e.g. lack of effective and secure national health IT policies)
among others. The result is that LMICs, which are most stricken by a myriad of healthcare challenges and thus probably needing the benefits of health IT the most, are the ones that least leverage/harness it. There is a scarcity of large sustainable implementation of health IT projects in LMICs, and most implementations being only pilot and isolated programs and involving basic technologies and tools, mostly mobile phones (m-Health, mostly for simple data collection and reporting or communication such as patient reminders) and simple, mostly open-source electronic medical record systems that are specific for particular diseases (especially HIV) (12,18,19). A study by Millard et al (18,20) on EMRs used in resource limited settings concluded that none of them had the minimum requirements for a fully functional EMR suitable for such a setting. In general however, health IT is increasingly being employed in LMICs and with promising results especially in areas of telemedicine, clinical decision support (such as drug safety and monitoring in HIV and TB care) as well as collection and reporting of healthcare management information, among other uses. This is, at least in part, due the ubiquitousness of mobile phone technology and the rapid increase in the presence of personal computers and internet access, albeit the mismatch such as evidence by limited development of phone apps in LMICs (12,19,20).

1.2 The EMR
As S. Julien (3) elaborates, the electronic medical record has evolved over time as medicine and technology converged, from simple billing and accountability systems to complex, interactive, fully-fledged systems of today in an effort to adequately represent the wills of the medical community, public health and governments. Today, an EMR is described as a digital version of the patient’s paper chart, that provide instant, real-time and secure access to a longitudinal record of patient health information generated by one or more encounters in any care delivery setting (21,22). Beyond just being a database of clinical information about the patient such as patient demographics, progress notes, problems, medications, vital signs, past medical history, allergies, immunizations, laboratory results and radiology reports, as well as billing information, among others, the EMR also serves other functions including clinical decision support, research and education, support for patient self management, reporting and population health management, work process and policy support, etc. (3,23). The EMR can have varying extent of implementation of these functions however and thus used to varying scopes, or designed to interface with other systems that extend its functionality such as lab information systems, imaging information systems etc (24). It is thus a proxy for health information technology.

1.3 Requirements
Requirements refer to the services that a product such as a software system is expected to offer and the constraint under which it must operate (25–28). They are the attributes, capabilities, characteristics or qualities that a system must have for it to be of value to the customer/user, organization or other stakeholders, and are influenced by users’ likes, dislikes and prejudices, and by political and organizational issues. Elicitation and understanding the user requirements is very key for the success of projects especially computer software development as it enables development of
products that are acceptable and satisfactory to the customers/users or meet their needs.

1.3.1 Classification of requirements
Requirements can be categorized in different ways into different types (27–29) but broadly fall into Functional requirements and Non-functional requirements. Functional requirements describe the what the system should be able to perform: they are explicit features and functionalities that the users want for the system to work. Functional requirements directly relate to (and are derived from) goals or tasks that the user needs to accomplish such as in the case of EMR the capture, storage and retrieval of patient clinical history and findings, clinical decision support with prescriptions, diagnosis, reminders for appointments, etc. Non-functional requirements describe what the system should be or specify the criteria for judging the system: they are quality attributes of the system such as usability, stability, security, scalability, maintainability, etc (27,30). They tend to be more generic for the whole system and are traceable to the functional requirements. They are what the system needs to be in order to achieve the functional requirements. For instance, for proper and safe storage and retrieval of clinical records, the system might need to have backups of the databases, have a high speed connection with a database server and security mechanisms to ensure integrity of the database is maintained.

**User Requirement Definition**

1. The MHC-PMS shall generate monthly management reports showing the cost of drugs prescribed by each clinic during that month.

**System Requirements Specification**

1.1 On the last working day of each month, a summary of the drugs prescribed, their cost, and the prescribing clinics shall be generated.
1.2 The system shall automatically generate the report for printing after 17.30 on the last working day of the month.
1.3 A report shall be created for each clinic and shall list the individual drug names, the total number of prescriptions, the number of doses prescribed, and the total cost of the prescribed drugs.
1.4 If drugs are available in different dose units (e.g., 10 mg, 20 mg) separate reports shall be created for each dose unit.
1.5 Access to all cost reports shall be restricted to authorized users listed on a management access control list.

Figure 1.2 Requirements definition. Source: Ian Sommerville, Software engineering, 9th Edition, Boston: Addison-Wesley; 2010 Figure 4.1, User and System requirements, p.84

Another way of categorizing requirements as used by Ian Sommerville (28) is into User requirements and System requirements. This categorization is on the basis of abstraction where **user requirements** are high level, abstract statements of what
services the system is expected to provide to the users and the constraints under which it must operate, whereas system requirements are more detailed, low level descriptions of the system’s functions, services, and operational constraints and defining exactly what is to be implemented. The example in the figure 1.2 above illustrates this difference. In this thesis, this categorization by Sommerville is used.

1.3.2 Context of use and user requirements

Even for a relatively similar system (e.g. an EMR) or a similar overall goal (such as patient care), the requirements vary greatly. This is because of there is always differences in the exact tasks or work processes the user undertake (e.g. differences in the protocols for management of a particular disease), differences in constraints on the system such as policies, regulations, resources or the physical environment in which the system is to be deployed, or differences in the users such as their attitudes, experiences or preferences, among other factors. This concept of variation in usage of a system or user requirements is referred to as Context of Use. Context of use encompasses the users, tasks and equipment (hardware, software and materials), and the physical and social environments in which a product or system is used, and it directly impacts on system usability and user satisfaction (31,32). An understanding of the context of use is very key to understanding the user requirements.

1.3.3 Requirements engineering

Requirements engineering(30,33–36) is the process of the eliciting, analyzing and documenting of user requirements. It is the initial and most important step in the system development life cycle. Poor requirements engineering is the greatest contributor to system failure, accounting for 70 - 90% of the cases. Also the cost of fixing problems due to requirements engineering is higher than other sources of error (33). There are many different approaches to requirements engineering, broadly divided into two: 1) artifact driven such as reviewing documents (policies, standard operating procedures, etc), brainstorming, prototyping, surveys, process modeling, etc and 2) Stakeholder driven where people who are to be affected by the system (such as the end users) are involved through interviews, observations, focus group discussions, etc.

Whatever the approach, requirements engineering requires a thorough understanding of the stakeholders (particularly the target end users) including their needs, wants, wishes, dislikes, prejudices and limitations (such as skills and knowledge), as well as the context of use of the system.

Involving stakeholders, i.e. stakeholder driven is considered better than artifact driven approach as it is more likely to be more informative and lead to more accurate requirements, and allows for end user buy-in if the users are involved throughout the software development process as it gives them a sense of ownership and a chance to learn about the product even before it is rolled out. User centered design (UCD) is the name given to this paradigm of system development in which aims to produce "usable" systems by involving the target end users in the development process and putting much emphasis on their needs, wants and limitations (31,37–44). UCD is an iterative and collaborative process. The figure below represents the steps in UCD according to ISO
User centered design is probably more important in healthcare IT systems development, as human factors have been shown to be a major influencer of failure or success of a system (9,10,45–47). Moreover requirements engineering and in particular UCD faces in health IT development faces such issues as users (the healthcare professionals) being reluctant to participate because they are busy with clinical work or finding it difficult to communicate their requirements in technical (medical) language to system developers (and vice versa). Other challenges to requirements engineering include: costly and time consuming, requirements changing as the project proceeds, ambiguity when clients communicate requirements or asking for requirements that are not necessary for (or even contradictory to) the business goals (30,33).

1.3.4 The Context of Use of an EMR in Oncology vs other medical specialties

Different medical practice contexts pose different contexts of EMR use and this can call for variations in the EMR features to suit them for the context. The practice of oncology differs from other medical specialties in several ways (48,49).

- the patients are chronically ill thus requiring long term care, many cancers are incurable and many are characterized by severe and life threatening complications, either from the disease or the treatment, and occasionally requiring intensive treatment.
- treatment involves several modalities such as complex medication/chemotherapy protocols, coupled with radiotherapy, surgery, biological therapy, etc
- cancer care is (therefore) multi-disciplinary, and commonly experiments with many patients being recruited into clinical trials.
Even basic information capture and routine clinical care processes are different for oncology for example clinical notes requiring doctors to record cancer stages and tumor size, location, etc; there are several investigations done specifically and/or more frequently for cancer patients due to the nature of the disease e.g. bone marrow and other cytopathology studies for diagnosis, extensive imaging studies for staging or frequent full blood counts to monitor toxicity of chemotherapy.

These and other differences mean that an EMR to be used specifically in oncology has different requirements than EMRs designed for other specialties. For instance, the storage of pictures is key in a dermatology EMR since dermatology is a very visual practice (50) but this might not be necessary in oncology where simple sketches or caricatures for representing physical details of the tumor might be sufficient. Similarly, in pediatrics EMRs need to have pediatric specific features such as immunization and growth monitoring with special measurements like percentiles of head circumference, weight, height, etc and allowing for graphical representation of these for instance by graphs, medication dosing according to age and weight, special patient identification such as of newborns without names or including a next of kin since children always need a caretaker, as well complying to constraints such as privacy for adolescents, precision of data (e.g. not rounding off figures such as weight for small children as this can affect the doses of drugs and hence safety), among other constraints (51,52). Some of these features might be relevant for oncology, in particular pediatric oncology, for example the biometric measurements height and weight, etc but others used for growth monitoring such as head circumference might not be given much priority in oncology practice since such services as not routinely done in oncology centers.

1.3.4.1 The CORE Whitepaper

In light of the uniqueness of oncology practice, and the resulting specific requirements for the EMR, the American College of Clinical Oncology (ASCO), the U.S. National Cancer Institute (NCI) and the National Community Cancer Center Program (NCCCP) in 2009 developed the Clinical Oncology Requirements for the EMR (CORE) Whitepaper (48) to describe functional requirements, data element specifications and interoperability requirements for an EMR that will support oncologists providing patient centered care in the US. The Whitepaper is a comprehensive reference document that was developed through a collaborative process that involved clinicians, informaticians and volunteers from US NCI, ASCO and NCCCP taking part in several meetings and getting feedback from stakeholders. The motivation for this is uniqueness of oncology, which as mentioned in the paper involves complex care processes such as documenting cancer type and stage, oncology specific flow sheets, chemotherapy administration and documentation, multi disciplinary care and there is need for lab and imaging integration, drug safety checks and generation of standardized treatment plans and summaries and reports. It was noted that existing EMR solutions provided varying functional capabilities and there was no reference source that listed a detailed, consensus driven set of core requirements for oncology. The main functional requirements according to the CORE Whitepaper are:

- generating and transmitting a cancer treatment plan including proper demographics recording, diagnosis information such as diagnosis, pathological
User Requirements for an Oncology EMR for LMICs

1.3.5 The Context of Use of an EMR LMICs vs High income countries

As there are differences between the different medical specialties and thus posing different user requirements on the EMR, there are differences in the practice of medicine in LMICs as opposed to high income countries. This difference in the context of use also puts different needs and constraints on the EMR suitable for the setting of LMIC, even if in similar medical specialty. Some of the unique characteristics for medicine in LMICs are the following:

- LMICs are faced with challenges such as limited healthcare budget, low healthcare professionals-to-patient ratio and a huge burden of illnesses that are more common or even unique to these areas (e.g. malaria, HIV/AIDS, Tuberculosis, etc) in addition to other diseases such as diabetes and cancer which are also common in high income countries.
- Moreover, these illnesses tend to have poorer outcomes due to the poor health seeking behaviors such as late presentation, less preventive efforts and (or due to) illiteracy. For example 70% of all cancer deaths are now occurring in LMICs. All these factors cascade to make each other even worse.
- Healthcare workers in oncology hospitals in LMICs thus usually have to deal with many other non-oncologic illness that co-exist in cancer patients since there is a low doctor patient ratio and lack specialists to refer the patients to, let alone the big patient load.
- There are also variations and deviations in treatment practices for instance chemotherapy protocols are commonly modified due to unavailability of certain drugs or to lack of capacity to deal with the toxicity, or due to co-morbidities such as HIV/AIDS, malnutrition, etc which make the toxicity worse.

Combining the uniqueness of the oncology practice, and the context of LMIC then results into even more differences in the tasks, constraints and different user needs, wants and attitudes. The user requirements for an EMR for use in an oncology hospital in a LMIC are thus different than for other medical specialties or for other contexts.
1.4 Problem statement
The CORE Whitepaper describes the user requirements for an EMR to be used in the US oncology practice, and functions as a reference for EMR developers and purchasers. This document can be used as a reference by other high income countries where the context of use is similar to the US. There are also documents and guidelines intended to guide generic EMR development and implementation in LMICs, for example by the WHO (57) or by the Kenyan health body (58) and these can also be extrapolated to other LMICs, albeit with some context specific modifications on low level details. There is however no such document found that describes requirements for an oncology EMR for LMICs. Yet with the challenges of user requirements engineering, particularly the cost, together with the limited health informatics advancement and research in LMICs many systems implemented in these settings are procured off the shelf after they have been developed for other settings, commonly high income countries. In addition, such systems are developed generically and not specifically for the unique context of oncology. This means that these health IT tools are not designed to particularly fit the context in which they get deployed. Moreover, with lack of a reference guide for developers to customize the products to fit the context of oncology in LMICs or for purchasers to select off the shelf products that might be transferrable to this context, there is a risk of failure of such EMR implementations because they are likely to not meet the target users' requirements (9,11,12,59).

Currently, the Uganda Cancer Institute (UCI)\(^1\), a public tertiary hospital in Uganda, is in the process of implementing an EMR software system called Clinic Master, which was developed by a Ugandan software company, Clinic Master International Ltd\(^2\) as a generic EMR and currently in use in about 50 private clinics and hospitals in Uganda. Before this EMR can be rolled out at the UCI, it needs to be modified to customize it to the UCI's needs. This study was aimed at eliciting user requirements to be used by the developers of the EMR in this modification process. The findings can also be used by other developers targeting similar contexts of use, or by purchasers selecting EMRs for similar contexts. In addition, a comparison was made between the user requirements for EMR at the UCI and those for oncology practices in a high income country to find out if there are differences or similarities which might affect transferability of EMRs between these two contexts.

1.5 Research questions
In order to elicit user requirements, an understanding of the workflow is needed, including the task that the target users of the EMR need to accomplish, their communication needs, the information or data that they collect or exchange, as well as the challenges or limitations. Knowledge and understanding of these allows for accurate interpretation and translation into system features, functionalities and constraints. Besides the above which mainly answer the "what" of system, exploration

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\(^1\) http://uci.or.ug/
\(^2\) http://clinicmaster.net/
of the "why" is also important in order to consider alternatives to the requirements (60). In this case, the "why" questions to explore thoughts on reasons for the requirements and the constraints serve to shade more light on the differences between the context of oncology in a LMIC versus the high income countries. The following research questions were therefore addressed by the study:

- What are the user requirements for an EMR for an oncology hospital in a LMIC?
- What are the reasons for these requirements (the "why")?
- How do these user requirements compare with those for an oncology EMR for a high income country?

1.6 Objectives

The objective of this study were:

- to analyze and map the workflow and work processes at the Uganda Cancer Institute.
- to elicit and describe the user requirements for the EMR intended for use at the Uganda Cancer Institute
- to compare these user requirements with those described in the CORE Whitepaper
2. Methodology

2.1 Approach

A qualitative study was carried out, with a focus group discussion and follow-up one-on-one interviews with the participants. The focus group discussion followed a semi-structured format where probes seeking collect information to understand the workflow and elicit user requirements were posed for participants to discuss. These probes were developed prior to the study by the investigator basing on literature review, and they were discussed and agreed upon with the supervisor who is a senior researcher in health informatics. The follow-up interviews were unstructured but followed up on issues that had been raised during the focus group discussion. The table below shows the topics and probes.

Table 2.1: Probes/Topics for focus group discussion and interviews

<table>
<thead>
<tr>
<th>Topic</th>
<th>Probes</th>
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| tasks/activities such as scheduling, clerking, prescriptions, referrals, etc | • what are the routine tasks involved in patient care? (Processes and flow, people involved and time spent)  
• are there any inefficiencies/problems? Please elaborate (such as unnecessary repetitions, chances of making errors/forgetting/distractions or information loss e.g. loss of patient charts)?  
• do the participants feel these can be improved using computers?  
• what functionalities would they want to have in such a system to be able to carry out the tasks or improve them? |
| information/data e.g. patient history, lab reports etc | • what information is normally collected?  
• which format is the information (text, pictures, caricatures)? is it standardized and structured (e.g. standard patient clerking form, lab/imaging reports or standard questions to ask the patients)?  
• are there chances of errors when collecting this information (including it being illegible, miscommunication or missing the information)?  
• do the participants feel standardizing would be feasible? would they prefer this as opposed to free |
| communications and information exchange | • what communications are routinely performed and between which parties?  
• what information is exchanged?  
• can it be done electronically? |
| challenges, workarounds and clinical decision support | • what challenges do the participants face in execution of their work?  
• what support do they need? do they feel use of computers would be helpful e.g. in error catching and clinical decision support? |
| o Any other ideas, opinions, issues? |

Qualitative methods were chosen because in this research it was important to understand the context from the perspective of the participants. Qualitative research allows for detailed exploration into the "how" and "why" to as to understand reasons behind certain phenomena rather than just measuring them.(61–63). For user requirements elicitation, it is important to explore the various opinions and ideas of the different stakeholders but also to take business analysis approach to understand
reasons for certain requirements so as to come up with several different or alternative solutions (30,33,39). It is also common that the target end users don't have a clear idea of the requirements, especially since the users are likely to not be familiar with the technical details or available options e.g. in health IT where the clinicians might not fully understand the technical aspects of the solutions. In this case, the requirements engineer must try to understand fully the context and the needs of the user so as to come up with the solutions.

Considering that the UCI is just in the process of implementing an EMR currently and also the limited use of healthcare IT in Uganda in general (64), it was assumed that the participants did not have much exposure or experience with EMRs or other health IT tools and thus might have been less opinionated (65), so a workshop was first arranged which potential participants attended, before the focus group discussion. In the workshop, the investigator presented and discussed about health IT and EMRs in general, as well as context of and requirements engineering process. The attendees of the workshop also took part in a short mockup of a requirements elicitation process for (as suggested by the participants) a software tool to help with chemotherapy management, with a focus of the business analysis. In addition, during the workshop a representative of the vendors/developers gave a short demonstration of the main modules and pages (windows) of the Clinic Master EMR software which the UCI is intending to roll out.

2.2 Study site
The study was conducted at the Uganda Cancer Institute in Kampala, Uganda. The UCI is a public 80 bed tertiary hospital specializing in cancer care. It was established in 1967 (then Under the Mulago National Referral Hospital) by the Uganda Ministry of Health and Makerere University in collaboration with the US National Cancer Institute (NCI). The site was a center for important research and advancement of cancer treatment especially for combination chemotherapy and treatment of Burkitt's lymphoma, Kaposi's sarcoma and other cancers common in this area.
Today, the UCI is an independent hospital but still in close collaboration with Mulago Hospital as teaching centers for Makerere University and other local and international institutions. It is also collaborating with the US based Fred Hutchinson Cancer Research Center to carry out research especially in the area of infection related cancers.
The UCI has a total of 240 staff, with about half being clinicians while the other half being administrative and support staff. Of the clinicians, there are 29 doctors (6 consultants/oncologists, 10 medical officer special grade (Internists, general surgeons, pediatricians, gynecologists, etc) and 13 junior medical officers), 58 nurses (8 senior nursing officers, 50 nursing officers including community nurses, pediatric nurses, etc), 7 lab staff and 5 pharmacy staff, among others.
The UCI was selected for this study because of several reasons. First, it represents typical oncology practice in LMICs with characteristics and challenges/limitations

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3 http://health.go.ug/
4 http://chs.mak.ac.ug/
common in such a setting such as limited funds, under-staffing, limited Health IT experience as well as a typical oncology practice characterized with lots co-morbidities especially due to infectious diseases, malnutrition, among other features that are unique to LMICs. There are also opportunities such as the collaboration with organizations from high income countries which also give a special perspective in terms of health IT, such as the possibility of information sharing, transferring of technology and health IT tools from the collaborating organization, etc. Another reason is that the investigator is an employee of the UCI and has worked there for over two and a half years as a medical officer and understands the hospital's dynamics, making it easier to understand and interpret the study findings. Lastly, the UCI is currently in the process of rolling out an EMR system and is embracing other Health IT technologies such as telemedicine so it is quite appropriate for the study since the findings shall have an immediate practical application.

2.3 Participants
The participants were identified strategically to represent the main target end users of the EMR at the UCI i.e. doctors, nurses, pharmacists, medical records officers, lab technicians, etc. These groups interact directly with patients so understand the work processes and system dynamics of patient care at the institute including its challenges, and will also be the ones most likely to directly interface with the EMR once it is implemented. Nine clinicians were able to find time and consented to participate in the study since many others were too busy to take part in the focus group discussion on that particular day. All the nine took part in the FGD but only five took part in the follow up interviews because of time constraints, but generally all the target user groups (e.g. nurses, junior doctors, senior doctors, pharmacist, medical records officer) were represented. Moreover, most clinicians are normally aware of the processes/tasks that other colleagues carry out even if they are in a different department or user group. (See table 3.1).

2.4 Data collection
Data was collected as audio recordings of the focus group discussion and follow-up interviews that were later transcribed verbatim. To ensure that the participants were available for the study activities, the investigator traveled to the study site the week before and discussed with potential study participants as well as clinical managers of the UCI to agree on the day when participants would have time, considering that they are clinicians and need to be relieved of their duties. The most convenient which was chosen was one where there is already existing meetings and no ward rounds or busy clinics for the doctors. The nurses that attended also had day offs following night/evening duties and the other clinicians had other people covering their duties.

The focus group discussion was moderated by an independent moderator who is experienced in qualitative research and with a medical background (a nurse and a secretary to an Institutional review board) but not a clinician at the UCI. This moderator was first trained by the investigator in advance to make sure the moderator fully understood the probes to be followed in the focus group discussion. The moderator also attended the workshop prior to the focus group discussion. The
investigator was present in the focus group discussion as a note taker, and he also conducted the follow-up interviews which followed the notes taken during the focus group discussion or listening to the audio recordings - to clarify on issues that were not fully explored in the focus group discussion. The follow-up interviews took place during the two week following the focus group discussion, the scheduling dependant on when the participants had time. Only 5 clinicians who participated in the focus group discussion were available for follow up interviews.

**Preparation for the study**
- Literature review and consultation with supervisor: creation of FGD/Interview guide
- Seeking approval by Research and Ethics Committee
- Participant identification
- Training FGD moderator

**Workshop**
- The morning before the FGD
- All UCI employees welcome to attend including would-be participants
- Overview of Health informatics and EMRs discussed by investigator in an interactive way
- A brief mockup of requirements engineering task done interactively with attendees for a system to accomplish a task/process suggested by attendees (chemo management)

**Follow up interviews**
- Within 2 weeks after the FGD
- Only 5 follow up interviews done
- Semi-structured with questions/probes arising from the FGD notes or listening to the recording

**Focus group discussion**
- Nine clinicians as participants, with a moderator and the Investigator taking notes
- Audio recorded
- Workflow analysis done, challenges/inefficencies identified, solutions suggested in relation to EMR features, functionalities and constraints

**Analysis**
- Transcription (Verbatim) by Investigator
- Qualitative content analysis with a deductive approach

Figure 2.1: Overview of the methodology
2.5 Analysis
The focus group discussion and follow-up interview recordings were transcribed verbatim by the author and printed out for content manual analysis. Throughout the process of transcription as well as the fact that the author attended the focus group discussion and personally did the follow up interview, he gained insight into the contents of the transcripts by the time they were printed. The author then read all the transcripts carefully and thoroughly, highlighting/underlining meaningful units and noting codes in the margins of the pages.

A deductive approach (61,66) was used where, basing on literature, in particular the CORE Whitepaper (48) and other material on user requirements and functionalities of EMR software (3,23), preconceived codes and categories were applied onto the transcripts. As the aim of this study was to analyze the workflow and then elicit and analyze user requirements for the EMR suitable for use at a cancer hospital in a LMIC, as well as to explore how these differ from the high income country counterparts, the meaningful units were words/phrases/statements which related to these concepts or those that could be translated into requirements or had some implications on the design of the EMR. These included words/phrases/statements about the work tasks or goals, data and communication elements and needs, challenges, inefficiencies and constraints, wishes, opinions and suggestions for improvement. A mind map was made and constant comparison and aggregation done for the codes, moving them to different branches or different levels of the branch that was most appropriate. A free online tool called Coggle\(^6\) was used for making the mind map.

A logical workflow map was then developed using an online BPMN modeler called Gliffy\(^7\) by summarizing and ordering the codes relating to tasks or processes. Finally, translation of the results from the workflow analysis into user requirements was done (66), and these were eventually compared and contrasted with the requirements in the CORE Whitepaper to identify key differences or similarities.

\(^6\) https://coggle.it/
\(^7\) https://www.gliffy.com/
Figure 2.2: A picture showing some of the transcripts with the underlined/circled meaningful units and codes in the margins, and in the lower area the initial summaries and workflow map draft.

2.6 Ethics
The study was approved by the Uganda Cancer Institute Research and Ethics Committee (UCIREC). Informed consent was sought from participants and all the participants signed the informed consent forms prior to taking part in the study. The study did not involve any medical or invasive interventions or procedures and no patients, but rather as mentioned above participants (clinicians) took part in focus group discussions and interviews, so they were not exposed to harm. Participants were reimbursed for their time. Participant's identification information (such as names) was treated confidentially (See Appendix for copy of UCIREC approval letter and informed consent form).
3. Results

3.1 Participants
Nine clinicians took part in the study, 4 males and 5 females, with age range between 27 and 51 years (Mean 34.5 years). All had worked at the UCI for at least 2 years each and familiar with the work processes. All the participants had computer literacy at least to the level of comfortable day-to-day use such as internet and email, office suite and have had exposure to tasks such as data entry for clinical research. Some, had in fact, used an EMR system before (in particular, the Clinic Master software) but not in the setting of the UCI, rather in other private hospitals or clinics.

The table 3.1 below shows the professions/job of the participants and whether they had used an EMR software before.

Table 3.1 Participants

<table>
<thead>
<tr>
<th>Number</th>
<th>Title/Job</th>
<th>Prior exposure to an EMR</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Junior medical officer</td>
<td>No</td>
</tr>
<tr>
<td>02</td>
<td>Doctor/Internist</td>
<td>Yes</td>
</tr>
<tr>
<td>03</td>
<td>Doctor/Surgeon</td>
<td>No</td>
</tr>
<tr>
<td>04</td>
<td>Senior Nursing officer</td>
<td>No</td>
</tr>
<tr>
<td>05</td>
<td>Pharmacist</td>
<td>Yes</td>
</tr>
<tr>
<td>06</td>
<td>Nursing officer - Pediatrics</td>
<td>No</td>
</tr>
<tr>
<td>07</td>
<td>Doctor/Pediatrician</td>
<td>Yes</td>
</tr>
<tr>
<td>08</td>
<td>Medical records officer</td>
<td>Yes</td>
</tr>
<tr>
<td>09</td>
<td>Nursing officer</td>
<td>No</td>
</tr>
</tbody>
</table>

3.2 Data:
One focus group discussion lasting 2 hours was conducted and this was followed up by 5 one-on-one follow up interviews with participants 01, 02, 05, 06, and 08. The follow up interviews lasted averagely 25 minutes each. A mind map (Figure 3.1) was made from the analysis of the transcripts and it had the following main branches (i.e. the main themes):

- tasks/processes
- challenges/constraints/inefficiencies that the clinicians face in the execution of their work
- wishes/needs that the participants suggested for improvement of the workflow
- people that do the different tasks such as doctors, nurses, etc as well as the patients who receive the services
- documents that are handled during execution of task including those that are received from outside and those that are generated from the UCI
- places: the different locations where tasks are accomplished
Fig 3.1: Mind map of the analysis
Figure 3.2: shows typical flow of patients and overview of activities/work processes that take place at the UCI
3.3 Description of work flow and work processes/tasks:

The Uganda Cancer Institute is a tertiary hospital specializing in cancer care. It carries out cancer treatment, research and prevention.

"... generally UCI... has ah 3 arms, prevention, treatment as well as research." -- Participant 02

Central of the three arms is the treatment, and it is this that was explored and described in details by the participants during the focus group discussion and follow up interviews. The prevention and research arms relate to the treatment arm in that the some clients who show up for the screening clinics end up as patients that need treatment when found with cancers, and data from the treatment arm feeds into the research. Moreover, mostly the same clinicians who treat the patients are the ones who carry out the research and are involved in screening, patient education and follow up as part of the complete cancer patient management.

"Now for research, we see the Fred Hutch and other people conducting research and again some participants who are cancer patients are interfaced at that area" -- Participant 02

"...cancer is unique compared to other diseases often with cancer diagnosis goes with cancer registry. Again this may not apply a lot to me as a clinician but to me as a researcher..." -- Participant 02

"CCCP as in cancer screening program... the staff ... belong in different departments but we serve the purpose when the activity is available " -- Participant 09

The figure 3.2 above shows a summary of the work processes that take place in the treatment arm.

**Registration**

When patients arrive, their first contact with the hospital is the Records office. Here, they are dealt with differently depending on whether they are new patients or returning, and whether they are stable or critically ill. New patients present their referral documents and have a paper file opened up and they are sent for clerking, those for screening are directed to the screening clinic whereas the returning patients present the discharge note they received on the previous visit and have their files retrieved and are sent for review and to receive chemo. Before opening a file for a new patient however, the patient has to be accepted into the UCI and endorsed by a doctor, on the basis that he/she has a cancer diagnosis. The patient thus must have a histological result report confirming the diagnosis, or should have clinical features that are consistent with a cancer diagnosis.
"...when they step on UCI soil, they come with their papers to Records department where they are registered into the system ... a file is opened for them, and then they are sent to the different clerkship points." -- Participant 01

"... in the medical records department ... we take note of the documentation that they have come with, and we refer them to doctors for endorsement, and after we open files depending on the specific wards. And then for reviews, we retrieve files then forward to OPD... those who want to be screened, we forward them to the screening side." -- Participant 08

"... when they give us a document we go through them if they have the biopsies, we go ahead to forward the documents to medical personnel who will endorse and if they don't we still.. and they are suspecting, we still forward to the medical personnel to a device better how on we can go about it but I have seen some patients being admitted without confirmed histology. So, but there are these ones whom we see that these are obvious cases they can't be with us ... those cases we refer to assessment center first." -- Participant 08

If the patient presents in an unstable state (i.e. critically ill for instance due to advanced cancer or cancer complications, or complications of chemo in returning patients among other reasons), they are triaged with the help of different clinicians and they get admitted to the wards for stabilization first before they can proceed to receive chemo or do the baseline workup.

"... and if they are critically ill we forward the files to the specific wards." -- Participant 08

"... those who are very sick, we admit them, work them, rehabilitate them accordingly. Those who come with severe anemias, we take off blood and transfuse them. Those who are severely sick for like with infections they're admitted..." -- Participant 04

**Clerking**

Clerking, which is usually done by the junior doctors initially, involves taking a complete as well as cancer diagnosis specific medical history and physical examination, and identification of issues that are key in cancer management. Out of all the information that can be gathered when clerking a patient, the following are some of the data elements or information that was reported as key to be picked up at the UCI.

- Demographics including name, age, address, telephone number, next of kin, and so on for patient identification and for general management such as when there is need to contact the patient when he/she is not in hospital or in the event the patient is incapacitated or dead, or in case of children who require a parent or legal guardian.
"...patient has come in... identification, complaints, past medical history, previous treatment, diagnosis..." -- Participant 07

"... basically patient’s bio data... it is very key... that each time the patient comes at least you are able to identify who this is..." --Participant 06

"... when a patient dies, the death certificate is given to the next of kin... so when the child dies and it’s not the next of kin, they don’t give the death certificate to the mother. They give to the person whose names are in the file." -- Participant 04

"... if the information is missing for example if you want to get the next of kin of this patient and they exchanged huh? for example if the aunt came yesterday and tomorrow it's the mother.. now maybe... you want to get clarity of the history of disease and someone is saying me I've been with the patient for only 2 days.. now there is even no phone number for you to go back and contact, so for goodness' sake you cannot get a clear background information of the disease or the history of disease." -- Participant 06

- medical history especially cancer specific clinical history (such as complications of cancer and features of cancer spread/advancement, history of cancer treatment e.g. prior chemo or radiotherapy) but also other illness and co morbidities

"...besides the usual cancer diagnosis for example breast cancer, prostate cancer, colon cancer... the inpatient has an extra disease. Either they have severe malaria severe lower respiratory tract infection maybe pneumonia they have a gastroenteritis, mucositis, febrile neutropenia." -- Participant 02

"We also admit children who have come in with intercurrent illnesses." -- Participant 07

"Nutritional issues may vary,... immune status may vary... especially when I deal with children.... So, if I get the protocol developed in the UK or the US to be used here, definitely I must factor in how I'm going to cater for nutrition gap that is there. So all the protocols we use are not our protocols, we must modify them based on some small criteria like nutrition status of the patient." -- Participant 07

- key medical facts such as allergies and sensitivities, blood group
Staging workup
After clerking, patients proceed to do baseline and staging investigations to compliment the information obtained from the clerking in staging the cancer and determine the treatment plan (to determine how fit the patient is for chemo). Common investigations include lab tests (Complete blood count, Renal and Liver function tests, Lactate dehydrogenase, bone marrow aspirates, etc), imaging studies such as Computes tomography, Ultrasound scans, X-rays), heart function studies (ECG and echocardiogram), etc. Depending on the type and/or stage of cancer (and hence the choices available for treatment), condition of the patient (e.g. critical and admitted on the ward vs outpatients) and other factors, a selection of these investigations is done, and lasts varying duration.

"They are asked to do investigations and after a diagnosis has been made, staging workup and stuff like that then the patient is started on treatment..." -- Participant 02

"Usually we have very ill patients and you don't want to prescribe when the patient has end stage renal disease, hyperkalemia. This is common in advance cancel the cervix..." -- Participant 02

Review by Oncologist
When the patient has completed the baseline workup, he/she gets reviewed by an oncologist who ensures that all the necessary medical information about the patient was obtained, summaries the clinical and investigation findings, makes a final diagnosis and staging of the cancer and chooses a treatment protocol for the patient.

For patients who came very unwell and were admitted for stabilization, the investigations are done from the ward and the review by the oncologist is done as soon as the investigations are completed and chemo initiated. For stable patients who workup as outpatients, the oncology review is given as an appointment about 2 weeks from the time of initial clerking, depending on the patient numbers and other factors.

"But when they come on the ward, our target is to have them there for only 3 days because of the rapid turnover of patients so first day we'll have the patient clerked, a list of investigations issued, ... once they are worked up, probably by the second review, they're starting chemo and then on the 3rd day we're monitoring response, attending to a few complications, and then the 4th they're off to either home and then followed up as outpatients.." -- Participant 02

Treatment
Treatment is mainly with chemotherapy but some patients also receive radiotherapy or undergo surgery and get palliative care. Chemo is generally given as repeated phases or cycles of a combination of drugs. The duration of a cycle and intervals between them is largely standardized in a protocol. When a patient comes for a cycle of chemo, after registration he/she gets some routine tests done to assess if he/she is
fit for chemo, gets reviewed by a doctor who prescribes the chemo. Cycles that last a short duration (e.g. one day) are given in OPD whereas those receiving cycles that last longer get admitted on the wards.

"I typically run the ... outpatient clinics ... we do outpatient prescriptions to be delivered to the pharmacy. We also do prescription for admissions especially children who are going to have more than 2 days of chemotherapy that particular visit.... Typically our clinics are scheduled 3 weeks, however we also receive children who are of unscheduled visits because of intercurrent illnesses" -- Participant 07

**Follow up**
After completion of the chemotherapy, patients are started on long term follow up in order to deal with relapses, long term side effects of chemo or any other issues that may arise.

"we know that once a patient has completed treatment we shall see them monthly for the first 3 months then every 3 months for half a year every 6 months for one or two years and then annually okay?" -- Participant 02

During follow up, some of the investigations done during the initial staging workup are repeated.

".. some things are done mandatory for particular follow up for example cancer of the breast, as you follow up this room to do an annual mammogram to look into the other breast... and then a things like lymphoma, at one point you need to do ah ahh re evaluation of the entire patient probably after the after one year. Repeating a chest CT, abdomen CT, LDH along with other parameter some patients who need a ECHO..." Participant 02

**3.4 Identified challenges**
The following challenges were mentioned by the participants

1. **Documentation**
   a. lack of a standardized structure or template for capturing medical history, clinical examination findings or other clinical documentation such as lab orders and consultation notes. This leads to inconsistence, information being left out, and unnecessary repetitions such repetition of instructions to every patient since information cannot be reused.

   "..we have no unified documentation system. Every oncologist reviews the patient the way he wants. you can write 2 lines, I can write 4 lines, another can write 8 lines. 4, no standardized protocols of working. You find the same tumor, 2 different oncologists write 2 different treatments" -- Participant 07
".. I feel that if you have a standard template of what we want, every clinician to ask a patient of a class of disease, then such issues of omissions will be minimized... you'll have a consistent standard information." -- Participant 07

"there is a lot of repetition of things for example commonly we do feeding gastrostomies and there's a feeding protocol after, which is actually similar in all the patients, at least most of them. So ... you write for this patient Day 1 you give this and this and this day 2... then you if you've done 3 patients, maybe 5 patients on that day, you do that for each of the patients that you've done" -- Participant 03

b. challenges of using paper based patient files such as not having access to the file when Records office is closed, or when another clinician is using it and/or the challenge of tracking who has the file at a particular time, risk of files getting lost or torn, the need for stationary, the time and workload of retrieval and storage and the inefficiency of extracting data from paper documents compared to electronic ones

"..[the records office] tend to misplace our files. Sometimes the patient for 2 days is moving around because we don't know where the hard copy file is. The Records people can't trace it, the research doctors can't trace it.. " -- Participant 07

"..we have a challenge of files getting lost.. and that usually comes for example a file will go to OPD and then somebody picks it for example for research ... fine we have the tracing system in place [for tracking where the files are] but we don't effect it as such because other people are overwhelmed with work, they find themselves not tracking." -- Participant 08

"We write on papers these are just papers that you just punch and fix in the files, so many times they can pluck out... So many times you find that you look for a chemotherapy recording paper, you cannot find it.. this patient has been on treatment for like 3 months so that means there should be some recording and you can't find it." -- Participant 06

"...[in]an emergency, [with the current paper files]you cannot easily enter in the patient's name... and it gives you everything... patient was last seen on this date, patient was given this... what
can I do? In case a patient is maybe reacting to some drug you can easily know [if it is computerized]. But now you can give your emergency drug which may even be very bad for the patient because you don't have data there…” -- Participant 06

"... stationary, sometimes we don't have enough paper to write on” -- Participant 02

"... right now we don't have enough space in records [office]…” -- Participant 08

2. Communication and information exchange challenges: There is inefficiency and delays in transferring or exchanging documents (such result of investigations) between the different service/care points which are not co-located, as well as exchange of messages such as ordering for supplies or consulting other clinicians. Sometimes results get lost and investigations are re-ordered.

"... the other thing also[is]delays, we are up the other side, some wards are up in the new building but most of the investigations happen down this way” --Participant 01

"... communication between departments. If I order for hemogram or chemistry, how quickly do I get results? That's a problem ... you want to treat the patient you need the renal function but you find it was ordered yesterday you don't have it yet you order it again, it is lost somewhere either is in the machine not printed yet because no paper or it is printed and kept in the file or printed and lost on the ward or printed and somebody's pocketed it. So some information that has been ordered for doesn't affectively get to the patient chart, which delays care and leads to misuse of resources…” --Participant 02

"You have to call store or even leave the building, you go down yourself…” -- Participant 06

3. Organization/workflow issues:
   a. Weaknesses or faults in organization of the workflow for example the records office which is where patients report first when they come to the UCI does not have a medical officer or clinician yet one is need to endorse that a patient be registered into the UCI or sometimes for triaging and attending to patients who come in critical conditions. In addition, the location of the different departments or units of the UCI leads to inefficiency or challenges
"The record officer who is not a medic is the first person to contact with the patient" -- Participant 07

"...there's no medical personnel to endorse these documents on time, patients have to wait till they are endorsed... " -- Participant 08

".. many patients are sometimes lost up within the system because as you know this place UCI has more than three campuses ... and some patients tend to cut across all these areas. For instance a patient is seen by a surgeon, the surgeon does mastectomy ... sends the patient for radiation at the lower campus ... now.. the radiation oncologist .. attends to the radiation part of it and if the patient is not well informed that you need further chemotherapy, that patient may be lost to follow-up" -- Participant 02

4. Resource limitation: this includes understaffing (and lack of expertise or specialist training) and the resulting workload on the hospital staff as well as limitation in facilities/resources needed for clinical operations such as investigative facilities, materials and drugs.

"... we have limited staffing.. so you find usual situation 1 - 2 nurses attending to 40 patients ... so you find that the typical schedule, the nurses are not able to even detect that this patient is critically ill... sometimes even we don't even have adequate medical cover on the side of doctors."-- Participant 02
"the low staffing, the work load becomes so so big on us" -- Participant 03

"...first of all, in Uganda we lack that specialty in our surgery. We do not have, you know, a specialist like a surgical oncologist." --Participant 03

"...lack of specialized knowledge or specialty in the different units... we are in a cancer setting but I think we all need specialized or specific knowledge in managing our patients for better." -- Participant 06

"...here at the UCI, we don't have a comprehensive system to diagnose every patient.." -- Participant 01

5. Prescriptions and drug/supplies stock management: The current system for management of stock of drugs and other supplies, which is not computerized, is inefficient. There is also no integration of stores and the pharmacist to map the dispensed drugs with the stocks so as to track the stock levels in real-time. As mentioned by the pharmacist, sometimes drugs run out without the stores manager or the pharmacist realizing it to order for more in time. In addition, it leads to inefficiencies for the clinicians when they prescribe drugs that are out of stock and have to change the prescriptions later. There is also no support for reviewing prescriptions to mitigate errors such as drug interactions, allergies or fitness for chemo prior to dispensing. The pharmacist have to do this manually.

"...to manage stock and supplies both at the supply side and at even at our own store level. But also even within the pharmacy. That makes it very challenging...to monitor drugs in my store rather than going there in the last minute and am putting in a request in the store and it tells me it's out of stock, it got finished, I gave you the last stock last week...

... very important for cancer institute is to know their stock levels... then you can be able to prioritize. That is very important in terms of ordering but also when a prescription comes, in order of processing. Then the other thing would be the cost attached to that because in most cases we don't know these costs. It may not be that patients are going to pay but it is important to know how much the government is spending on the patients. Then the other thing that I would have loved is having a prescription coming to me electronically with lab results ... that is very important because before I go ahead to prepare chemo I must know that the patient is suitable for chemo..." -- Participant 05

"Sometime we have to leave your clinic room and walk to the pharmacy to ask, do you have Cefuroxime by the way?" -- Participant 07
3.5 Suggested solutions and wishes for improvement

The participants gave their thoughts and ideas on how the challenges mentioned could be solved or mitigated, particularly with the use of computerized tools such as an EMR. The following were the main suggestions/ideas and wishes:

a) Computerized documentation and communication: besides having electronic versions of the patient clinical notes with perceived advantages such as being always accessible even simultaneously from multiple locations and improved coordination, participants also wished for other flow sheets and clinical documents such as discharge notes, referral or consultation letters, etc to be electronic. They also suggested computerization/automation of such processes as compilation of ward/clinical summaries and real time statistics such as mortality and morbidity audits, real time patient numbers and vitals, reports to cancer registry, and transmission of orders for lab or imagining, reports, and other messages. Incorporation of ontologies and other knowledge bases (such the national ID database for patient registration, the NCCN chemotherapy guidelines database or the Adjuvant! Online tool for treatment decision) as well as translation features into the computerized system were also suggested.

"So if the system is in place there's no business of saying the file disappeared, the file was not there you'll just always enter the things directly there and then" -- Participant 06

"...a computer system that helps us to track both the ward and outpatient numbers... For instance on the ward the new discharges by their diagnoses, age groups and stuff like that, and then like weekly reports.. our M&M meetings, we come ah, how many patients are on the ward? 10 females, 5 males and that but that we have to extract that every other Friday. Ok? But if we had a computer system, that you know? it is automated. You just go punch in and then you see number of discharges, number of admissions and stuff like that and over time, it would help us to track how many people are we treating? what is our overall survival after all? or we're just killing everyone in the first 6 months." -- Participant 01

"..interlinkages within departments are really very helpful... because I know that for example if I have a request from the lab... I don't have bother a patient our patients very sick moving here to there I just have to say information reached there... the lab tells me oh, we have seen your request but we don't have blood give us two hours instead of making somebody manually go and look for whether there's is blood.. so I think that will really exchange of information between the various team members.." -- Participant 07

"...once we have a particular agreed protocol say we all agree UCI to use the NCCN national Comprehensive Cancer network..."
protocols, then we'll just get those protocols, incorporate into this database that once you say diagnosis is cancer of esophagus stage 4 then the options come: chemo-radi[ation] and you task is just click and modify the doses." -- Participant 02

".. is it possible to your registration system to the national ah ID database." Participant 02

"..a multilingual system... whereby by click of a mouse somebody can easily communicate with somebody because you find.. a patient comes in knows only Swahili... there is no one around to translate for you... no way you can start opening up a file without this bio data which is key."-- Participant 08

b) Computerized clinical decision support: Processes/Tasks such as scheduling of patients who need to return for chemo or follow up, assistance when clerking, triaging or making a diagnosis and suggestion of correct treatment, correct dosing and drug safety checks including allergies, sensitivities and other contraindications as well as stock management were some of the areas in which participants suggested application of CDSS.

"...the computer system would be important in helping with patients' scheduling dates like when they're supposed to come back. [Be]cause we are up in the new building the children's clinic happens down here most of the OPD clinics are down this way yet the wards are up. So, sometimes it's hard to correlate...even when we open up a diary... sometimes it doesn't work." -- Participant 01

"you know a calendar on the wall you may miss... you may just have a small error between week 1 and week two instead of recording week 2 on somebody's file which may be 8th... if week 1 is supposed to be 8th of next month for example and week 2 is supposed to be 15th.. you know you have a human error where you can just interchange the days which may be a problem but once you enter them in the system, the system will always highlight." - Participant 07

"... different chemos are for different cancers. There are automatically tests that have to be done every time a patient has a visit. Like in our screening there are tumor markers that you must do if a person came maybe for ovarian carcinoma screening which must be highlighted so that the doctor has a few things to add." -- Participant 09
"If the patient was treated with doxorubicin the program give an alert echo at six months, echo at 1 year, echo every year after treatment." -- Participant 02

"..probably they can give a warning that you know this temperature you need to act this BP you need to act.." -- Participant 02

"if there's a way I can [get] an alert on allergies.." -- Participant 05

"..the key information about him should be popped up, including he is sensitive to this, his blood group is this, his allergy status are that.." -- Participant 07

"...an alert on dosages in relation to maybe body surface area maybe related to weight I think those ones should be very important." -- Participant 07

c) Structuring and standardizing templates for documentation: It was suggested that having a predefined template where the clinician checks off clinical findings or order sets instead of actively typing them in would be preferred as a quicker option for entering information, in addition to ensuring consistence.

"...the computer.. should be able to give us all the detailed headlines of what we are supposed to do... such that we have consistence of information." -- Participant 07

"...another thing are the multiple requests... request CBC, request LFTS, request RFTs, request X-ray... if there was a check-check-check...that would be very easy.." -- Participant 02

d) Organizational changes

• having and enforcing SOPs for different clinical processes such as how to allocate wards to patients or how to clerk/review patients or which treatment to give for a particular illness

".. if we have a standardized protocols. Standardized protocols give standardized infusions, give standardized care. But you find that for the same diagnosis different prescribers have got different prescriptions. That even becomes hard to plan for. You find this drug runs more than the other. And sometimes because of that prescribers have a certain season of prescribing certain drugs more than the other, and if you ask, he says ah I found that one appropriate. But it what is the standard? There's no standard protocol for that particular diagnosis." -- Participant 05
• revision of the current organization of work to eliminate faults e.g. by having a clinician at the records office to help with the triage and endorsement of patients when they arrive

e) Constraints: There were some constraints to some of the above solutions as follows

• computers should be mobile/portable (computer on wheels) so that they are accessible in the very mobile environment such as on ward rounds

".in wards where you have to do a ward round, I am suggesting that we have smaller, portable computers so that do not have to duplicate things. You just write there and then, as you see the patient, you're writing.. you're either writing or clicking." -- Participant 03

• need for flexibility of the decision support (the system should not take over the clinician's power)

".automatic things are dangerous. They're not flexible therefore they may not address routine issues that emerge. But here we are talking about the system which we think should have standard protocols, should have standard clerkship criteria... I definitely think that we might have some challenges as we go on... some issues may not be clearly foreseen today as we're trying to embrace such a system but in our operations tomorrow we may see that there's a challenge." -- Participant 07

• Security: access control to track who has done what on the system or limiting certain clinicians from doing task beyond their jurisdiction.

".there should be room for clinicians to have control over system... and I think that also still need to be restricted, not every clinician should have... because if that is the case, a nurse can sit somewhere and modify a protocol... a pharmacist can sit somewhere and single handedly modify a protocol... I think... the lead clinicians who are authorized by the Institute to actually prescribe.. should be given the administrator access administrator password to modify some protocols." -- Participant 07

"... if we had a system that allows logging in, and registering what you've done, it helps someone to be accountable. You know? different clinicians or nurses would have their.. their log in passwords to access the information." -- Participant 01
- Electricity: there is unreliable and unstable electricity supply

"In 24 hours, there are 10 blackouts in Uganda... Even when you talk about a backup generator, with fuel, this fuel must come from ministry of energy" -- Participant 07

3.6 Translation and summary of user requirements for the EMR for the UCI

The findings from the workflow analysis above (tasks, challenges, constraints, wishes/needs, documents, input and output, etc) were translated into user requirements in the table 3.2 below by enriching the plain, high level statements or concepts as made by the participants to turn them into implicit low level, relatively more detailed requirements with implications on the design of the EMR. This translation process (36,67) leveraged the author's experience and knowledge of the requirements engineering process as well as literature (including the CORE Whitepaper) and experience as a doctor at the Uganda Cancer Institute, which was essential for understanding and interpreting the raw findings. For example, the blanket concept of "patient registration" was translated into the different data elements that are captured during this process as they appear on the paper based face sheet that is used at the UCI (which the author is familiar with). The same applies to concepts such as "clerking" which, according to routine clinical practice and from the author's experience, involves taking clinical history and physical examination and investigation of the patient as elaborated. Certain elements/concepts such as Next of kin, Patient number, Contact information and other low level details of the functionalities (e.g drug safety checks and other clinical decision support features), etc which were explicitly highlight during the focus group discussions or interviews (mostly because they were sources of challenges or considered very important by the participants) have been noted and bolded in the table below. A column on the table that maps the requirements to the workflow analysis concepts above or to an explanation of the detail basing on the author's understanding and experience such as the routine clinical practice at the UCI (even though not explicitly mentioned in the focus group discussion or interviews) is also included. The requirements in the table have been grouped to approximate a sequential order as per the workflow and how they normally appear in the paper based file.
### 3.7.1 Table 3.2 summarizing the user requirements

<table>
<thead>
<tr>
<th>Element/Functionality/Feature</th>
<th>Concepts or themes in workflow analysis (description, challenges or suggestion) from which requirement is derived</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Registration</strong>&lt;br&gt;<strong>Capture patient registration information:</strong></td>
<td></td>
</tr>
<tr>
<td>Demographics: Name, Sex, Age/Date of birth, Religion, Tribe/Language, Occupation</td>
<td>Patient Identification (Section 3.3)</td>
</tr>
<tr>
<td>Contact information: Address, <strong>Telephone numbers</strong>, <strong>Next of kin and relationship</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Provision to register using (integration of) national ID</strong></td>
<td>Important for prescription and drug/blood transfusion safety (CDSS, Section 3.5 b)</td>
</tr>
<tr>
<td><strong>Height, Weight and Body surface area</strong>&lt;br&gt;<strong>Allergies and sensitivities, Blood group</strong></td>
<td></td>
</tr>
<tr>
<td>Referring hospital and doctor</td>
<td></td>
</tr>
<tr>
<td>Admission information: <strong>patient number</strong>, ward, Diagnosis at admission, <strong>Histology results</strong>, laboratory</td>
<td>Endorsement for admission and ward allocation</td>
</tr>
<tr>
<td>Element/Functionality/Feature</td>
<td>Concepts or themes in workflow analysis (description, challenges or suggestion) from which requirement is derived</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Clerking</strong></td>
<td></td>
</tr>
<tr>
<td>Standardized templates with fields for capturing (and where possible probes or reminders to capture or ask about)</td>
<td>(Section 3.3)</td>
</tr>
<tr>
<td>Vital signs and warning on critically ill patients as well as sorting them according to priority</td>
<td>Triage (CDSS, Section 3.5 b)</td>
</tr>
<tr>
<td><strong>Clinical history</strong></td>
<td></td>
</tr>
<tr>
<td>including presenting diagnosis/Histological diagnosis, details of presenting complaints</td>
<td>Routine patient information captured for assessment (Section 3.3), Standardized documentation (Section 3.5 c)</td>
</tr>
<tr>
<td>Review of systems and capturing or assessment for disease progression/metastasis</td>
<td></td>
</tr>
<tr>
<td><strong>Past medical history</strong></td>
<td></td>
</tr>
<tr>
<td>including previous admissions and investigations, previous treatment (chemo or other), surgical operations or radiotherapy including date, doses, sites, adverse events/effects, response, etc</td>
<td></td>
</tr>
<tr>
<td><strong>Blood transfusions</strong></td>
<td></td>
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<tr>
<td><strong>Co-morbidities</strong> such as HIV</td>
<td></td>
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<tr>
<td><strong>Risk factors for cancer</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Physical examination</strong></td>
<td></td>
</tr>
<tr>
<td>findings, with provision for graphical representation such as caricatures, photos, etc</td>
<td></td>
</tr>
<tr>
<td><strong>Ability to make consultations electronically such as when surgical or other specialist medical care is needed</strong> (infectious diseases specialists, cardiologists, nephrologists, etc)</td>
<td>Electronic communication (Section 3.5 a)</td>
</tr>
<tr>
<td><strong>Investigations: order sets and ability to electronically make requests and receive/import results (interoperability)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Assessment and treatment</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Pathology</strong></td>
<td></td>
</tr>
<tr>
<td>metastatic workup (e.g. X-rays, Ultrasound scans, CT scans, Bone marrow biopsy, etc as appropriate for each malignancy or co-morbidity), and suitability for chemo (e.g. ECHO and EKG for anthracyclines, CD4+ count for HIV positive, Hemoglobin and White cell counts, RFTS, LFTS, etc)</td>
<td>Staging workup results and routine follow up (Section 3.3)</td>
</tr>
<tr>
<td>Problem list</td>
<td></td>
</tr>
<tr>
<td>Performance status (ECOG/Karnofsky)</td>
<td></td>
</tr>
<tr>
<td><strong>Element/Functionality/Feature</strong></td>
<td><strong>Concepts or themes in workflow analysis (description, challenges or suggestion) from which requirement is derived)</strong></td>
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<tr>
<td>----------------------------------</td>
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</tr>
<tr>
<td>Intent and plan (e.g. Palliation or Curative)</td>
<td></td>
</tr>
<tr>
<td>Supportive care for <strong>intercurrent illnesses</strong> and management of oncologic emergencies or complications such as <strong>anemia, neutropenia</strong></td>
<td><strong>CDSS (Section 3.5 b)</strong></td>
</tr>
<tr>
<td><strong>Suggestions of diagnosis, treatment plan, investigation orders</strong></td>
<td><strong>Standardization/Ontology (Section 3.5 a)</strong></td>
</tr>
<tr>
<td><strong>Cancer diagnosis</strong> with ontology e.g. ICD 10 or SNOMED CT and <strong>staging</strong></td>
<td><strong>CDSS</strong></td>
</tr>
<tr>
<td>System should assist in assigning a stage</td>
<td></td>
</tr>
<tr>
<td><strong>Treatment/Chemo</strong></td>
<td></td>
</tr>
<tr>
<td>Chosen protocol, number of cycles, duration and schedule/intervals</td>
<td><strong>Standardization/CDSS (Sections 3.5 a,b,c)</strong></td>
</tr>
<tr>
<td>Link to protocol databases such as NCCN</td>
<td><strong>Flexibility to modify protocols (Section 3.5 e)</strong></td>
</tr>
<tr>
<td>UCI’s protocols to be incorporated into the system to select from.</td>
<td><strong>Security/access control (Section 3.5 e)</strong></td>
</tr>
<tr>
<td>Ability to modify protocols or orders sets but with reasons captured when a protocol is modified and only authorized clinicians can modify protocols</td>
<td></td>
</tr>
<tr>
<td><strong>Parameters to monitor toxicity</strong> (anemia, neutropenia, mucositis, etc) and response (number, location and size of lesions or tumor size or LDH, cell counts, etc, and when to interrupt or which actions to take in face of unwanted effects.</td>
<td></td>
</tr>
<tr>
<td>Other modalities e.g. surgery, radiotherapy planned and when (adjuvant, neo adjuvant)</td>
<td></td>
</tr>
<tr>
<td><strong>Ability of system to suggest protocol according to diagnosis or clinical findings, calculate doses according to weight and height (BSA) with adjustments basing on clinical/lab findings e.g. dose reduction in severe immune suppression (low CD4+) or renal impairment (low GFR)</strong></td>
<td><strong>CDSS for chemo management/safety (Section 3.5 b)</strong></td>
</tr>
<tr>
<td><strong>alert on allergies or contraindications, ceiling doses of drugs</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Ability of system to generate prescriptions and transmit them electronically to pharmacy, with automatic filling in of multiday regimens</strong></td>
<td><strong>Electronic communication (Section 3.5 a)</strong></td>
</tr>
<tr>
<td><strong>Ability to reuse previous prescriptions</strong></td>
<td></td>
</tr>
<tr>
<td>Link to protocol from e-prescription</td>
<td></td>
</tr>
<tr>
<td><strong>Element/Functionality/Feature</strong></td>
<td><strong>Concepts or themes in workflow analysis (description, challenges or suggestion) from which requirement is derived)</strong></td>
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<td>---------------------------------</td>
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</tr>
<tr>
<td>Ability for nurses to enter chemo administration information and sign off including dose, date, patient condition at end of administration, any immediate reactions</td>
<td></td>
</tr>
<tr>
<td><strong>Ability of system to schedule patients (return dates) according to protocol</strong>, and to generate discharge forms.</td>
<td>Scheduling (CDSS, Section 3.5 b)</td>
</tr>
<tr>
<td><strong>Follow up</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Schedule of follow up appointments</strong> and plan (e.g. whether for chemo or investigation or review and what to review/monitor) Orders for investigations to be done on follow up <strong>System should assist by suggesting dates and tasks e.g. to do ECG at 6 months or colonoscopy at 1 year.</strong></td>
<td>Electronic communication/CDSS</td>
</tr>
<tr>
<td><strong>System should be able to send reminders to patients on when to return and what is required</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Other features</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Linking clinicians to appropriately filtered literature sources</strong></td>
<td>Specialist training/EMR as a learning tool (Section 3.4-4) electronic documentation and communication (Section 3.5 a)</td>
</tr>
<tr>
<td><strong>Generation of reports and summaries</strong> e.g. Mortality and Morbidity report, Real time patient numbers, Drug stocks and prompts to order or restock when stocks are running below a critical minimum</td>
<td></td>
</tr>
<tr>
<td><strong>System should give an overview/summary of patients in each ward/clinic and summary of their condition</strong> (vitals, plan such as “for chemo”, “on work up”, “to have repeat vitals taken at XX time”, etc)</td>
<td></td>
</tr>
<tr>
<td><strong>ability to exchange messages between the different users</strong> of the system and transmit the patient records.</td>
<td></td>
</tr>
<tr>
<td><strong>Reuse:</strong> ability to re-order from previous cycles or <strong>reuse previous instructions</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Electronic signatures</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Translation of face sheets into various languages that are encountered at the records office</strong> System should be fast and available whenever needed.</td>
<td></td>
</tr>
<tr>
<td><strong>Backup for electricity and of data should be available</strong> System should be available on mobile/portable computers</td>
<td>Constraint for information security/Availability (Section 3.5 e)</td>
</tr>
</tbody>
</table>
3.8 Comparison of the user requirements for the EMR for the UCI with those in the CORE Whitepaper?

There are several similarities as well as differences that have design implications when the user requirements elicited for the UCI's EMR are compared with the CORE Whitepaper. On a high level, the users have many similar tasks and processes as in both cases the overall goal is care for the cancer patient, so the requirements are much similar on the high level. However, on a lower level, there are differences in the requirements that arise due to differences in the context of use such as available resources and technology, socio-cultural differences in execution of tasks (even when the tasks are relatively similar) as well as differences in limitations, etc.

3.8.1 Similarities

The following is a summary of the major similarities:

- Many documentation requirements, data elements and/or task are similar for example capturing patient identification and contact information, clinical findings including details of the cancer (e.g. staging) and treatment especially chemotherapy and other cancer specific clinical data.
- Some constraints such as need for flexibility in the clinical decision support tools/features with the ability for modification and incorporation of local or institute specific protocols, need for disaster recovery measures
- Similar requirements for clinical decision support features and functionality particularly oncology specific decision support including chemotherapy management (dosing, scheduling, electronic prescription and safety checks such as alerts and reminders on allergies, ceiling doses or contraindications, etc), access to standard guidelines and protocols
- Communication requirements and needs such as electronic exchange of messages and documents (referral letters, consultations, importing results and other reports from other systems i.e. interoperability) and generation and transmission of reports, summaries, order sets, etc.

3.8.2 Differences

1. Requirements concepts in the CORE Whitepaper that are not relevant (as apparent from the focus group discussion or interviews)
   a. Clinical trials support: The CORE Whitepaper reiterates the requirement for the EMR to assist in enrolling patients into clinical trials: having fields for clinical trial number and links to pertinent clinical trial protocol documents, as well as clinical decision support features for assessing the eligibility of patients for clinical trials. This was however not a requirement for the EMR for the UCI, because the UCI does not carry out clinical trials.

   "... unfortunately we don't have the capacity to do our own clinical trials to develop our own protocols that suit our interests"
hundred percent. We still rely a lot on the work done in the developed world..." -- Participant 07

b. Billing: The CORE Whitepaper highlights the need for the EMR to have functionalities relating to billing and reimbursement by insurance companies (Oncology specific billing) such as interfacing with existing billing management systems, J-codes for billing, communication with the billing office and insurance pre-authorization. These are however not relevant for the UCI since it is a public facility and in general healthcare is not paid for by the patients but rather by the government.

"...the cost attached to that... because in most cases we don't know these costs.. it may not be that patients are going to pay but it is important to know how much the government is spending on the patients." -- Participant 05

c. Order sets for certain investigations which are not available at the UCI such as imaging (CT scan), Lab investigations (biomarkers, chromosome markers), etc

"...a list of investigations issued some of which are available within UCI, and others, they may seek for services out of UCI, for example a CT scan, audiogram, an Echo, ECG those are services sought elsewhere not within UCI." -- Participant 02

d. Requirement for the EMR to be a learning tool for the clinician without specialist training by linking to knowledge bases

"..once a stage of the cancer is prescribed then we need more guidance with the specific treatment. Now, this can be done and I think is possible because they are several online forums whereby cancer stage is linked to particular treatment for example this breast cancer which is the second commonest cancer in Uganda.. Now, one of the applications online is Adjuvant online. So, Adjuvant online, the way it works is that you get all this information, you feed in into the website and then the website helps to inform the clinician the appropriate therapy for that patient. So, it would be very nice and smart if this special clinic master for UCI is linked to this in addition to other existing databases... then it'll improve utilization of knowledge, it would promote evidence and it'll improve accuracy and consistency of our treatment options" -- Participant 02

2. Requirements for the EMR system at the UCI that are not listed in the CORE Whitepaper
   a. Certain demographics information such as tribe, religion and integration into the national ID database
   b. emphasis on need for standardization and requirement for the EMR to assist in ensuring uniform care protocols by having templates for
consistence when capturing history and other clinical notes as well as predefined treatment protocols and CDSS tools to enforce them

c. Need for language translation functionality
d. Need for backup electricity supply

3. Requirements or elements/concepts in the CORE Whitepaper that were not explicitly discussed as requirements for the UCI EMR.
   a. Consent
   b. Certain demographics and contact information types such as race/ethnicity, language of preference, email contacts
   c. Pain score and management
   d. Patient education materials and a patient portal
   e. Graphical representation of data such as caricatures/sketches to indicate diseases sites
   f. Radio Frequency ID (RFID) for patient identification
4. Discussion

4.1 Discussion of the results

From this study a workflow mapping and analysis for the Uganda Cancer Institute was done from which user requirements for the EMR were elicited/translated, and a comparison of these with those in the CORE Whitepaper (48) was done.

Most of the work processes and tasks at the UCI are about treatment of the cancer patients, and include reception and registration of patients, clerking, staging work up and diagnosis, treatment especially with chemotherapy and subsequent follow up. The institute also carries out research and cancer prevention services, however these seem secondary although interlinked to treatment with patients and clinicians cutting across these three different core functions. The elicited user requirements thus relate to the system's ability to support or facilitate these tasks/processes (49), including among others the ability to create a digital version of the patient medical record with provision to capture the data in an oncology specific manner (such as details about the cancer diagnosis staging, sketches for illustration, treatment details e.g. protocols for chemo, response assessment, toxicities, etc); automation of common tasks or provision of computerized clinical decision support functionality to assist with diagnosis and medication management (including suggestion of the right chemo for a particular diagnosis, dose calculation, allergies and contraindication checks, proper scheduling, etc); electronic communication such as order entry and transmission and importing of results from other systems, as well as need for standardized templates to enable uniformity and consistence. In comparison with the CORE Whitepaper which describes the user requirements for an oncology EMR for the US, the above requirements which relate to the tasks/processes are much similar because of the overall similarity in the tasks/processes involved in care for the cancer patient and the needs for the users involved in these processes.

There are however several differences in the user requirements on the lower level especially due to differences in the context of use, and it is these that are likely to have significant design implications and subsequent differences in the features and functionalities of the EMR the suits the UCI as a cancer hospital in a LMIC as opposed to oncology hospitals in high income counties for which the CORE Whitepaper is intended. These differences imply that the EMR designed for use in a US cancer hospital is likely to be significantly different from one that suits the UCI and thus transferring such an EMR to the UCI is like to fail. These differences also call for purposively paying attention to the unique user requirements for the UCI and perhaps for such a hospital to design its own EMR in-house (68,69), as finding one off the shelf that perfectly suits this context is quite unlike and hence such off the shelf EMRs would require some modification prior to being implemented in this context. Some examples of such contextual differences that put unique requirements for the UCI's EMR or render some requirements in the CORE Whitepaper irrelevant for the UCI include the UCI being a public facility so no need for billing features since the government funds the healthcare rather than patients paying or reimbursement by insurance, resource limitations and absence of certain services e.g. clinical trials which are not done at the UCI making the need to support this in the EMR irrelevant as well as the inclusion of certain investigation order sets which are not done at the UCI. In addition, the relatively less developed technologies such as the
fact that use of internet and email in Uganda and in LMICs in general (64) could explain why such methods of communication as email or use of patient web portals were not mentioned as requirements for the EMR at the UCI or use of RFID for patient identification since this technology is not widely available. Conversely, due to understaffing the participants suggested having data entry done by checking off items from a predefined list in the forms in the UCI's EMR since this would be quicker, even though they appreciate the disadvantage of lack of flexibility and potential for frustration, let alone the difficulty and cost of implementing such functionality.

4.2 Discussion of the methods: Strength and limitations
This study took a user centered approach to requirements engineering by involving the very target end users of the EMR at the UCI - the clinicians, as the participants in the FGD and interviews (41,44,70). This stakeholder driven requirements elicitation process, as opposed to the artifact driven where for example old systems or documents are reviewed/analyzed to derive requirements, is advantageous and superior as it is allows for better understanding of the context of use and the human factors contributing to user requirements - details of the challenges and work-arounds, wishes, prejudices, etc. The requirements engineer is able to ask for clarification on concepts that are not clear or probe further to understand reasoning behind the requirements as well as negotiating with the target user for alternative solutions to challenges. There is also the advantage of early involvement of the target end users in the system development life cycle which gives them more information and understanding of the system as well as a sense of ownership and thus eases acceptance.

Moreover, in this study two different qualitative methods were used: focus group discussion and follow-up interviews. FGDs have the advantage of allowing participants to negotiate among themselves and reach a consensus about controversial issues, to learn from each other as well as to explore a wide range of ideas and issues from different perspectives. Particularly in this study where the requirements were being elicited for an EMR that is to be used by different clinicians (nurses, doctors, pharmacists, etc) efforts were made to have a representative of each of these groups so as to attempt to exhaust all the varying views and opinions, and thus to get a complete list of requirements since each clinician (or their work processes) might differ to some degree from another's. The follow up interviews then gave the investigator an opportunity to dig dipper so as to understand the "why" or the reasoning behind certain issues or ideas that were raised in the focus group in case any were not clear or were controversial.

A disadvantage with FGDs is that they are time consuming and difficult to organize i.e. having all the participants free to attend especially in this case clinicians who are always busy with patients. In fact, in this study about 12 clinicians had been contacted to participate but only 9 could be available on the day of the FGD. This was however a sufficient number for an FGD aimed at eliciting requirements since more participants was unlikely to have resulted into discovery of more system features (65,71).

Relying on discussions and/or interviews with target users alone however runs the risk of not exhausting the user requirements particularly if the participants, as in the case of this study, are not familiar with the process or the field/topic in question (65,72). The user's prior experience with the system allows him/her to be imaginative and
opinionate on what is possible with technology. This was also evident from this study in that participants who had had prior exposure to some health IT technologies such as the Clinic Master EMR software had more to contribute in the FGDs and interviews, while those with no prior exposure we less imaginative, especially in regards to computerized clinical decision support and other potentially automated functionalities of the EMR. Participants without prior exposure also often seemed less confident when giving their opinions, often saying "I don't know if that is possible" while those who had had prior exposure and thus had seen certain functionalities before sounded more confident, often making clear statements of requirements with phrasing such as "the system should have" this feature or that. This suggests that if the participants aren't familiar with the concepts, there is also a likelihood that some requirements might not be mentioned. In an attempt to minimize this in this study, a workshop was conducted prior to the FGD and interviews which the potential participants attended, and the process of requirements engineering as well as details about EMRs and their common functionalities were discussed so as to orient the UCI clinicians with no prior exposure to health IT tools or EMRs about these systems.

Using other methods of requirements engineering such as prototyping, brainstorming as well as observation among others, in addition to discussion or interviews with the target users can greatly improve the results of a requirement engineering process, especially if more detailed, low level (system) requirements are needed, since certain issues are not easily described in interviews or discussions, but come to light when one observes the users or when the users are engaged in prototyping sessions where mock ups of the system, its functionality and appearance are made. In this study for instance, there were many details that the participants did not explain yet they are likely to significantly affect the requirements for the EMR. Examples include blanket statements about work processes such as "patient registration" or "opening up a [paper] file", "clerking", etc. These in fact involve many sub processes and tasks, different inputs and outputs (documents, communications/messages or orders sets) but due to time limitation in the FGD/Interview, assumption by the participants that the requirements engineer would understand or other reasons, these details were not given. The author thus relied on his prior experience as a clinician at the UCI to fill in the gaps and details to when translating the raw data from the FGD and interviews into user requirements (36,67). This is also why it is important that the requirements engineering process involves a domain expert so as to help interpret the findings. In this study, the author was also in a way a domain expert! There is undoubtedly a risk of bias in doing this as the author's opinion or what he fills might not exactly reflect the needs or views of all the target end users. Example in this study are the requirements from issues or concepts that were not explicitly discussed by the participants (See sections 3.8.2), and so it is not clear whether they forgot them, or whether they felt that these issues were not important or relevant, or because they did not know about them. Some of these, from the author's experience, seem relevant e.g. patient consent (which is usually done at the UCI and there is a section on the paper charts where a patient signs to consent to treatment), pain score and management and graphical representation which are also commonly done in the current work processes and thus it can be assumed that it is just because little emphasis was given to them, but for such requirements/concepts as use of RFID for patient identification or having patient web portals it could be because the participant did not know of them since
they aren't common, or that they were assumed unfeasible, among other reasons and thus they were not explicitly mentioned.

4.3 Future direction
From this study, only the first steps of the requirements engineering process were done, i.e. requirements elicitation and documentation. Since the software development life cycle in the user centered design is iterative and incremental, many more steps need to be made following this research in order to have a functional EMR suitable for the UCI in the future (43,72). The immediate next step is to validate and rank/prioritize the documented requirements, particularly those that the requirements engineer translated from the implicit statements, and to explicate those that are still on a high level so as to make clear and conscious low level (system) requirements which the system developers can start to implement. This can be done through prototyping (either lo-fi of hi-fi), brainstorming, observation or further iterations of discussions or interviews with the users and other stakeholders (or a combination of these methods). After that, incremental developments and formative evaluations of the EMR (or modification of the off the shelf Clinic Master software) should follow and then gradual implementation and evaluation of the whole system's impact.
5. Conclusion

The UCI as a cancer hospital poses a unique context of use for an EMR and as a result, the user requirements for an EMR that is designed to suit the UCI are unique in a way. The EMR needs to support oncology specific documentation and functionalities (e.g. detailed capture of information about the cancer diagnosis and cancer treatment, and computerized clinical decision support for processes involved in cancer care) in addition to other generic EMR functionalities and features. These requirements are relatively similar to those for the EMR for other cancer hospitals such as those in the CORE Whitepaper intended for the US, but there are other user requirements that are unique to or ones which are emphasized more at the UCI as compared to the CORE Whitepaper due to differences in the context of use arising from the UCI being a cancer hospital in a LMIC and thus having even more unique challenges and constraints or other differences in the work processes as compared to the high income counterpart (e.g. need for back up electricity supply or the EMR to have predefined data elements that are used for quicker data entry, etc). These differences also render some user requirements in the CORE Whitepaper irrelevant for the UCI, e.g. clinical trial support or use of certain technologies like RFID or electronic communication with patients, among others. The differences in the user requirements call for careful consideration when developing an EMR for the context such as the UCI, or when selecting an off the shelf EMR as this would most certainly need modification to suit the target users. Simply transplanting an EMR designed for another context, even if for an oncology practice, might end up in failure since such an EMR would not perfectly suit the user requirements for the UCI.
References


14. Hersh W, Margolis A, Quirós F, Otero P. Building a health informatics


www.ucc.ie/archive/hfrg/baseline/CoU20.rtf


Appendix

Copy of the ethical review board Approval letter

Date: 18th January 2016

Dr. Johnblack Kabuuya
Uganda Cancer Institute – Karolinska (Sweden)

Category of review
[X] Initial review
[ ] Continuation review
[ ] Amendment
[ ] Termination of study
[ ] SAI

Dear Johnblack,

Ref: Approval of Protocol # UCIREC REF: 01-2015

Title: “User Requirements for an Electronic Medical Records System for a Cancer Hospital in Developing Country”

Thank you for submitting the application for approval of the above referenced research protocol to the Uganda Cancer Institute Research and Ethics Committee (UCIREC). The committee reviewed it and granted approval for one (1) year, effective 18th January 2016. Approval is valid until 17th January 2017.

Continuing Review
In order to continue work on this study (including data analysis) beyond the expiration date, the Uganda Cancer Institute Research and Ethics Committee must reapprove the protocol after conducting a substantive, meaningful, continuing review. This means that you must submit a continuing report form as a request for continuing review. To avoid a lapse, you should submit the request eight (8) weeks before the lapse date. Please use the forms supplied by our office or download form from UCIREC website.
Amendments
During the approval period, if you propose any change to the protocol such as its funding source, recruiting materials, or consent documents, you must seek Uganda Cancer Institute Research and Ethics Committee approval before implementing it. Please summarize the proposed change and the rationale for it in a letter to the Uganda Cancer institute Research and Ethics Committee. In addition, submit two (2) copies of an updated version of your original protocol application- one showing all proposed changes in bold or ‘track changes,’ and the other without bold or track changes.

Reporting
Other events which must be reported promptly in writing to the Uganda Cancer Institute Research and Ethics Committee include:
- Suspension or termination of the protocol by you or the sponsor
- Unexpected problems involving risk to participants or others

Adverse events, including unanticipated or anticipated but severe physical harm to participants.

Please use the REC REF number listed above on any forms submitted which relate to this study/project.

Documents approved for use along with protocol include:
- English informed consent forms

Final approval is to be granted by Uganda National Council for Science and Technology.

Thank you for your cooperation and commitment to the protection of human subjects in research. Do not hesitate to contact us if you have any questions.

Good luck in your research. If we can be of further assistance, please contact us at +256- 0414-697618 or email ucirec@uci.or.ug

Yours sincerely,

[Signature]

David Kyaddondo (PhD)
Chairperson UCIREC

[Stamp with date 17 Jan 2017]
Copy of participant informed consent form

Informed Consent Form for clinical staff at the Uganda Cancer Institute who are invited in the research study titled "user requirements for oncology EMR for a developing country"

Name of Principle Investigator: Johnblack Kabukye

Name of Organization: Uganda Cancer Institute and Karolinska Institutet/Stockholms Universitet

Name of Sponsor: Uganda Cancer Institute

Name of Project: User requirements for an oncology EMR for a developing country

This Informed Consent Form has two parts:

• Information Sheet (to share information about the study with you)

• Certificate of Consent (for signatures if you choose to participate)

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Introduction

I am Johnblack Kabukye, a medical doctor at the Uganda Cancer Institute (UCI) and currently studying a Master's of Science in Health Informatics at Karolinska Institutet and Stockholms Universitet in Stockholm, Sweden. I am conducting a research concerning Electronic medical records (EMR) systems, such as the Clinic Master software which the UCI is in the process of implementing. I am going to give you information and invite you to be part of this research. Before you decide whether or not to participate, please read and understand the information or ask me to explain any terms or concepts that you may not understand. If you have questions later, you can ask them of me or of another researcher.

Purpose of the research

The UCI is in the process of implementing the EMR software Clinic Master and you as a clinician are expected to be one of the users of this system when it is rolled out. Research has shown that many projects to implement EMR systems and other health IT tools fail because such systems have not been developed to suit the target users'
specific needs or requirements i.e. what the users really want the system to do or to look like. This research thus is aimed at eliciting the user needs for an EMR for the UCI.

**Type of Research Intervention**

This research will involve your participation in a workshop and focus group discussion, as well as follow-up interview. During the workshop, you and other participants (clinicians at the UCI) shall first be given information about electronic medical records systems (EMR) as an e-health tool (what they can be used for or the common features, etc) and requirements engineering as the overall purpose of this study. A demonstration of the ClinicMaster software system shall also be done to this effect. This first part is expected to last about 2 hours. After that, you shall then take part in the focus group discussion where you will give opinion on the features and functionalities of the EMR, whether you feel they are appropriate for your work and context of the UCI. Follow-up interviews shall be done on later dates to validate and seek more clarification on the information gathered during the discussion.

**Participant identification**

You are being requested to participate in this study because you are a clinician at the UCI. Your knowledge of the work processes and the context of the UCI is vital in answering questions in this study. Your opinion in regard to the ClinicMaster system which is planned to be rolled out at the UCI is important since you are one of the target end users of the system.

**Voluntary Participation**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate, there are no negative consequences. You may also change your mind later and stop participating even if you agreed earlier.

**Procedures**

During the workshops demonstration of the Clinic Master system shall also be made basing on cancer patient scenario mock-ups and discussions on your impression, thoughts, preferences and suggestions on functionality of the software. Discussions of requirements suggested in a whitepaper by the US National Cancer Institute (NCI) and the American Society of Clinical Oncology (ASCO) shall also be done in order to stimulate the participants to comprehensively and imaginatively think about their own requirements.

**Risks**
There are no risks anticipated, physical, psychological or otherwise to you as a participant. No sensitive information about you shall be collected.

**Benefits**

We do not know if this research shall be of direct benefit to you now. However it shall help us know your opinions, needs, challenges, etc (called user requirements) as the users of the system so as to make changes/improvements aimed at making the system satisfactory to UCI staff when it is rolled out.

The findings if published can also be used by other developers of, or persons procuring EMR for similar contexts of oncology in a developing country setting. In addition, you shall receive training of how to use the system to prepare you for when it is rolled out.

**Reimbursements**

You will not be paid to participate in the study. However, you shall be provided with lunch on the day of the workshop, and you shall be compensated for your time with UgX 50,000/= for half day.

**Confidentiality**

You will participate in focus group discussions together with other participants and therefore they shall know of your participation and hear what you discuss. However, no personal information such as names or contact details shall be asked or discussed.

Audio recording of the discussions shall be made for the sole purpose of later transcription. They shall not be used outside of this research.

**Sharing the Results**

The findings shall be given to the UCI technical team to discuss with the Clinic Master developer team for making changes with the software. The research is also part of my master's studies and the results shall be included in the thesis to submit Karolinska Institutet for the award of the MSc Health Informatics. Findings could also be published or presented at conferences.

**Right to Refuse or Withdraw**

You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the discussions at any time that you wish without your job being affected.

**Who to Contact**
If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact me:

Dr Johnblack Kabukye

Uganda Cancer Institute, Upper Mulago Hill road

Tel: 0794069027

email: jkabukye@gmail.com or johnblack.kabukye@stud.ki.se

This proposal has been reviewed and approved by the UCI REC which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact

Research and Ethics office, Uganda Cancer Institute

Upper Mulago, P.O. Box 3935 Kampala, Uganda

Tel: +256-414-697618/336713 or +256-712-950776

email: ucirec@uci.or.ug or rmussoko@gmail.com

Part II: Certificate of Consent

Participant:

I have been invited to participate in research about user requirements for an EMR in oncology in a developing country. I have read the foregoing information. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study

Print Name of Participant________________________________________________________

Signature of Participant________________________________________________________

Date ___________________________ Day/month/year

Researcher:

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my
ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent____________________________

Signature of Researcher/person taking the consent___________________________________________

Date ___________________________  

          Day/month/year