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Digital labelling feature integration with OpenMRS design to mitigate Human Papilloma Virus specimen identification errors. Case of Ruhengeri Referral Hospital.

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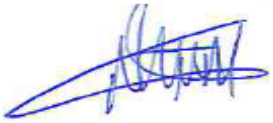
DECLARATION

I, NIYITANGA TUYIZERE Marcellin, declare that this research thesis titled "**Digital labelling feature integration with OpenMRS design to mitigate HPV specimen identification errors. Case of Ruhengeri Referral Hospital."** submitted in fulfillment of University of Rwanda academic rules and regulations for the Master's degree in Health Informatics; is my original work and it has never been presented elsewhere (in any universities or institution of higher learning) for any purpose. And we do declare that all cited information is shown in the provided list of references as indicators of the sources. Publication is granted to the University of Rwanda/College of Medicine and Health Sciences for academic interest.

NIYITANGA TUYIZERE Marcellin



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DEDICATION

This work is warmly dedicated to the Almighty God for the gift of life and love, my families especially my lovely parents, my sisters, brothers and my friends for their extraordinary support and care. What is more, I am dedicating this work to my charming classmates with whom I have been together with in my studies all along. Finally, I would like to dedicate this task to my lecturers, supervisors and career guiders I met across during studies for the knowledge, skills and attitude that they have shared.

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ABSTRACT

INTRODUCTION: It is a well-known fact that humans are prone to making mistakes. In the medical field, patient specimen and laboratory testing identification errors have consistently stood out as the primary contributors to laboratory errors with approximately one in every 300 and the adverse events can be traced back to one out of every 18 specimens due to patient identification errors. The adoption of a specimen barcode tracking system emerges as a highly effective solution which offers numerous advantages, including improved access to universal healthcare services, increased effectiveness and efficiency in healthcare processes. The main objective of this study is to analyze and design the digital labelling feature integration as tool to mitigate HPV specimens mislabeling and patient identification errors.

Methods: This study was carried out using both quantitative and qualitative approach. Structured questionnaires were used to collect data from 110 health professionals on need of integration of digital labelling feature; In-depth interviews of 16 software engineers were purposively carried out for technical requirements elicitation. The tools for analysis included SPSS and Excel, and thematic analysis while the iterative model was used for prototype design for the integration of digital labelling feature with OpenMRS at Ruhengeri Referral Hospital.

Results: The study found that, with quantitative approach, manual labelling was 100%; 70% of healthcare professional are not comfortable with the existing system and the system is rated to be prone to errors at 94.5%. Health professionals needs the digital alternative at 83.4% however highlighted infrastructures, financial resources and unskilled workforce as key barriers at 36.4%, 21.5%, 21.5% respectively. Qualitatively, the main requirements identified by software engineers were the use of barcode, enhancing compatibility of devices and systems and user adoption.

Conclusion: The findings of this study shows that the system is exhaustive, inefficient, full of duplication of work, time consuming, and prone to errors. Also, the study investigated what it may take improve the current scenario and proposed a design. This may overcome the work overloadness of the clinicians and laboratory technicians through quick responses to the clients concerns, and consequently slowing down the burden of cervical cancer.

Key words: Barcode, OpenMRS, Human Papilloma Virus.

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LIST OF ABBREVIATIONS

HPV: Human papilloma Virus

EMR: Electronic Medical Records

OpenMRS: Open Medical Record System

QR Code: Quick Response Code

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CHAPTER ONE: INTRODUCTION

1.1. Background

Handwritten labels can pose significant challenges, primarily due to issues related to legibility. Statistics indicate that approximately one out of every 300 handwritten characters contains an error (1). When dealing with the task of writing labels extensively throughout the day, especially involving thousands of characters, the potential for numerous mistakes becomes quite high.

Laboratory examinations play an indispensable role in medical treatment decisions (2). Notably, the Center for Disease Control and Prevention (CDC) has reported that more than 7 billion tests are conducted annually in the United States, and the results from these tests are relied upon to inform 70% of medical decisions (3). This highlights the critical need for a reliable laboratory testing framework. Patient specimen and laboratory testing identification errors have emerged as the primary cause of errors in laboratory settings (4). Errors related to incorrect patient identification and subsequent inaccuracies in specimen labeling can pose substantial hazards to patients. It is crucial to emphasize that no one desires to compromise patient safety. However, it is alarming that adverse events arise from one out of every 18 specimens due to patient identification errors alone (5). In a comprehensive study that examined the risk associated with various aspects of the phlebotomy process, it was identified that specimen labeling and patient identification carry the highest risk. These two steps are absolutely critical to ensure the correct results are consistently associated with the appropriate patients.

Electronic barcoding has emerged as a highly efficient method for creating a strong system of identification and connection between patients, specimens, and laboratory testing throughout the entire testing process. This process includes test ordering, specimen collection, analysis, and reporting of test results. Guaranteeing the precise identification of patients, their specimens, and the associated laboratory test results is crucial in any healthcare environment. This precision is fundamental for providing healthcare that is effective, safe, punctual, efficient, fair, and centered on the needs of the patient. The integration of digital technologies in healthcare holds the potential to enhance access to cervical cancer services, improve overall effectiveness and efficiency, and promote accountability within the healthcare system. Conclusively, adopting a digital labeling and tracking system represents a strategic and effective approach to reduce error rates when collecting sample specimens at the collection site and transmitting them to the laboratory (6).

1.2. Problem statement

The focus on reducing medical errors has been a significant national objective ever since the influential report "To Err is Human" was published. Within healthcare, one critical area of concern is identification errors (ID errors), which have the potential to harm patients and are entirely avoidable. Ensuring precise patient identification is not solely a local issue but a priority for patient safety at the national level. This priority has the support of accrediting organizations, patient safety groups, professional associations, industry players, and regulatory bodies. These errors, which are entirely avoidable, have the potential to lead to severe negative consequences for patients (7).

Nonetheless, efforts to mitigate these errors present a considerable challenge for both clinical and laboratory staff. Failing to accurately identify patients can have far-reaching implications. In the most severe cases, it can lead to diagnostic errors, misdiagnosis, unnecessary and potentially harmful treatments, or delays in necessary treatments. On the less severe but still significant end, it may necessitate repeating a test.

Identifying effective strategies for reducing these errors has been recognized as a research priority. However, in Rwanda, there are currently no available studies that have investigated the efficacy of using digitalized tools for specimen labeling and patient identification. Therefore, the aim of this study is to assess and design the integration of a barcode module to mitigate mislabeling of HPV specimens and patient identification errors, focusing on the case of Ruhengeri referral hospital.

1.3. Study significance

This study has play a vital role to the healthcare system mainly in mitigating the HPV specimens mislabeling and patient identification errors. It has allowed the assessment and evidence based designing a digitalized tool that has make easy healthcare workload and improve the care delivered to women seeking cervical cancer screening services.

What’s more, it has been the opportunity to get knowledge and skills in conducting health informatics related quantitative versus research project proposal.

1.4. Research objectives

1.4.1. Main objective.

The main objective of this study is to analyse and design the digital labelling feature integration requirement as tool to mitigate HPV specimens mislabeling and patient identification errors.

1.4.2. Specific objectives

I. To assess healthcare providers need on integration of the digital labelling feature in OpenMRS.

II. To analyse the technical requirements for integration of the digital labelling feature in OpenMRS.

III. To design the prototype of the product for integration of the digital labelling feature in OpenMRS.

CHAPTER TWO: LITERATURE REVIEW

2.1. Introduction to cervical cancer

Cervical cancer is a global health concern, with one woman losing her life to this disease every two minutes (8). It ranks among the leading causes of mortality among women worldwide (9). In the year 2020 alone, approximately 604,000 women received a diagnosis of cervical cancer, and sadly, about 342,000 women succumbed to this disease (10). Notably, in Rwanda, cervical cancer stands as the most frequently diagnosed cancer among women(11). However, it is crucial to recognize that these deaths are preventable.

Screening plays a pivotal role in this prevention effort, particularly with the advent of new HPV DNA-based tests. Thanks to these advancements in screening, cervical cancer can either be prevented altogether or detected in its early stages when it is highly treatable(12). The primary cause of precancerous and cancerous cervical lesions is infection with high-risk or oncogenic Human Papilloma Virus (HPV) types, making HPV the most common sexually transmitted infection (13).

2.2.Electronic labelling

Electronic labeling stands as a highly efficient method for establishing identification and linking patients, specimens, and laboratory testing throughout the entire testing process, which includes test ordering, specimen collection, analysis, and the reporting of test results (14). Ensuring precise identification of patients, their specimens, and the corresponding laboratory test results holds paramount importance in all healthcare settings. This precision is a fundamental requirement for delivering healthcare that is effective, safe, punctual, efficient, fair, and patient-centric (14).

Leveraging digital technologies in healthcare can significantly improve access to cervical cancer services, enhance overall effectiveness and efficiency, and foster accountability within the healthcare system. An effective approach to reducing errors in healthcare involves adopting a barcode tracking system, especially during the collection of sample specimens at the collection site and their transmission to the laboratory (6). Errors in patient and sample identification can have severe consequences for patients, particularly when incorrect data is used for various healthcare activities (4). It is evident that the foundation of efficient and high-quality care begins

with accurate patient identification. Healthcare and laboratory medicine sectors are susceptible to various opportunities for misidentification, including homonymy, registration errors, reliance on incorrect patient data, order entry mistakes, collection of biological specimens from the wrong patients, improper sample labeling, and inaccurate entry or erroneous transmission of test results through the laboratory information system (6). To address this significant challenge in healthcare, various ongoing initiatives are being pursued. These efforts involve the development of streamlined strategies for patient identification across the healthcare industry, encompassing both traditional and innovative identification methods. Additionally, there is an exploration of technological tools to enhance the quality and efficiency of blood tube labeling (4).

2.3.Review of existing digital labelling features integration

2.3.1. Barcodes history

Barcodes, which are now an integral part of our modern lives, made their first appearance approximately 80 years ago. The earliest documented reference to barcoding can be traced back to US patent 1985035A, published on December 18, 1934, by John Kermode, Douglass Young, and Harry Sparkes (15). This patent described the use of sorting machines equipped with photo-electric cells or similar light-responsive devices to sort cards, records, or similar items based on codes or marks on them. It also detailed how these machines could be used for tabulation, recording, and control based on these marks. In October 1949, Norman Woodland and Silver Bernard filed another patent (US patent 2612994A), outlining the first barcode system, titled "Classifying apparatus and method." Woodland and Bernard were working on a method to automatically scan products in grocery stores to expedite the checkout process. Norman Woodland continued his work on barcodes at IBM.

The earliest application of barcoding was seen in the railroad sector, known as the KarTrak automatic car identification system. This system utilized a color barcode system that bore many resemblances to the barcodes we use today. It featured 13 horizontal labels with different widths and spacing, as well as start and stop lines and a line checker. However, due to the high error rates associated with human reading, this system was discontinued in the 1970s. In the mid-1960s, the supermarket industry started experimenting with various barcode formats for automated checkout systems. Following numerous committee meetings, the National Association of Food Chains

designated the uniform product code (UPC) as the national standard for identifying grocery products in 1973 (16). The International Organization for Standardization (ISO) introduced the ISO 9000 quality-management standards in 1987, which played a crucial role in ensuring companies' adherence to barcode systems (1). These developments have paved the way for the widespread global adoption of barcodes. Consequently, the healthcare industry has also embraced barcode technology to a significant extent (17).

Table 1: Historical events of barcodes

Date	Event
December 18, 1934	US patent 1985035A marks the initial mention of barcode technology
October 20, 1949	US Patent 2612994A is filed, outlining the first barcode process
1961	Colour barcodes are first employed on railroad cars
June 23, 1973	The first UPC point of sale system is announced
June 26, 1974	The first product barcode is scanned in a supermarket, featuring Wrigley gum
September 21, 1981	The US Department of Defense adopts the Code 39 barcode
September 1982	The US Postal Service adopts the POSTNET barcode to represent zip codes
1987	Quality management standards are initially established
February 2004	The US Food and Drug Administration mandates the use of barcodes for medications
October 12, 2005	AABB mandates the use of ISBT 128 barcodes for accreditation

AABB stands for the American Association of Blood Banks, while POSTNET is an acronym for Postal Numeric Encoding Technique. These are examples of the evolution of suggested symbols for product identification. You can find more details about this history in the ID History Museum, as documented in 2013 and accessible at the following website: http://www.idhistory.com/.

Barcodes, as defined in the Britannica Dictionary, are printed sequences of parallel bars or lines with varying width, used for inputting data into a computer system. Typically, these bars are black against a white background, and their width and number can vary depending on the application (18). These bars serve to represent binary digits 0 and 1, and sequences of these binary digits, in turn, can represent numbers from 0 to 9, which can be processed by a digital computer. To understand how barcodes work in a simple way, you can think of them as a technologically advanced means of transferring strings of characters. They function somewhat like a license plate

that is linked to data files. These strings of characters can represent various types of information. Instead of manually writing and copying this information, it is encoded in barcode languages or symbologies for quick transfer through a scanner to a computer (6) Each symbology adheres to a specific algorithm for standardizing the encoding and storage of these characters.

In essence, barcode symbologies possess varying qualities such as capacity and linearity, making some more advantageous for specific uses and industries than others. Barcode technology is constantly evolving. For instance, the recent rise of 2D barcoding has gained popularity, allowing you to scan directly from your smartphone to access a wealth of data.

2.3.2. Types of barcodes

A barcode is a machine-readable symbol that represents a collection of data. Barcodes function by using light reflection on bars or dots of various sizes and colors, encoding a binary data string, typically consisting of 1s and 0s (2). There are many types of barcodes, with most falling into two categories: linear (1-D) and 2-D barcodes (6). 1-D barcodes encode data along the horizontal axis and are made up of differently spaced and sized line bars. While 2-D barcodes, which use black and white dots to encode data along both the vertical and horizontal axes, have become more popular, 1-D symbologies are still commonly used in laboratories. These symbologies usually require more label space, offer better error detection, but have lower data density capabilities. One of the most commonly used 1-D symbologies in laboratories is Code 128 (19).

During the 1990s, the mass production of charge-coupled devices (CCDs) led to the widespread adoption of 2-D scanning. These scanners employ advanced image analysis algorithms to decode 2-D symbologies, resulting in improved detection rates. In recent times, 2-D barcodes have become more prevalent in laboratories due to their scalability, reduced label space requirements, ability to encode higher character densities, and significantly reduced error detection rates. For instance, depending on the matrix size and coding schema, Data Matrix can encode varying amounts of data, such as up to 3116 numeric characters, 2335 alphanumeric characters, or 1555 bytes of binary data (19).

Here are a few examples of commonly used barcode symbologies:

Code 39: A versatile alphanumeric 1-D barcode commonly used in electronics, healthcare, and government applications. It can include the entire 128 ASCII character set and is extendable to various lengths.

Code 128: Derived from the ASCII 128 character set, it is widely used in packaging and shipping applications globally. It features an automatic switching setting for optimizing barcode length.

Interleaved 2 of 5: Typically used in warehouse, distribution, and manufacturing settings, this numeric-only barcode pairs two digits to create one symbol. It requires an even number of digits.

Universal Product Codes (UPC): Found on most retail products, originally designed for grocery stores to facilitate receipt printing and inventory tracking.

International Article Number (EAN): A superset of UPC used by booksellers, libraries, universities, and wholesalers for book traceability, created from International Standard Book Numbers (ISBN).

PDF417: A stacked linear 2D barcode used in various identification forms, known for its advanced capabilities and the ability to encode links to multiple data files.

Data Matrix: A square-shaped 2D barcode capable of encoding large amounts of information in a compact space, widely used in electronics manufacturing and healthcare.

Quick Response (QR) Codes: Gaining popularity as marketing tools to link to web-based information, often used on advertising materials and storefronts for promotions or product details.

Figure 1: Linear (1-D) and 2-D bar code symbology examples.

2.3.3. Barcode applications

Barcodes are standardized tools used for identification and asset tracking, finding wide-ranging applications in point-of-sale purchases, delivery services, the automotive industry, and healthcare. Technological advancements in recent decades have significantly improved both barcode and scanner performance. The primary objectives of implementing a barcode and tracking system are error reduction and increased efficiency. Instead of relying on manual data entry, barcoding automates identification and tracking processes, thereby reducing human errors (17). Automatic identification systems, such as barcodes and RFID, offer a broad spectrum of applications. These include point-of-care scanning to match product data with patient data, verifying patient identity through wristbands, enabling the use of robotic dispensing systems, recording implant serial numbers in patient records and central registries, tracking individual instruments through decontamination processes, managing stock control and supplies, and tracking assets across a network of facilities (16).

Barcode technology plays a crucial role in preventing medical errors by providing detailed and reliable information at the point of patient care. Barcodes typically contain reference numbers that computers use to retrieve records containing descriptive data and other essential information (6).

However, like all technologies, challenges can arise during the implementation or enhancement of a barcode system. These obstacles can be overcome with careful planning and comprehensive training (20).

One common issue in medical labs is determining where to place labels on hardware. Tubes, vials, microwell plates, and slides all have limited space for labels. Therefore, it is essential to determine early on how much information needs to be encoded (19). It is important to resist the temptation to encode excessive information. Shorter messages are easier to decode, and smaller labels are more cost-effective.

Symbol contrast also plays a crucial role as barcode scanners must easily distinguish between bars and spaces, making black and white the preferred color scheme (21). Pre-printed labels from experienced vendors offer the best assurance of barcode image quality. If possible, outsourcing barcode label production should be considered. In label production, thermal transfer is the most suitable print technology for on-site label printing. However, not all thermal transfer printers are the same.

Factors like dpi resolution and print tolerances should be considered, and matching the label stock with the right ribbon is crucial for successful scanning. A vendor with expertise in laboratory settings can help determine the best equipment to avoid common pitfalls.

Selecting the appropriate scanners is another critical aspect. While the array of available scanners can be overwhelming, it is important to consider how scanning will occur in your lab under real-life scenarios. Factors such as the types of barcodes used and the need for image readers should guide your scanner selection. In situations where human-based scanning is required, hands-free scanner holders can be valuable. Testing scanners with the same labels used in your application is essential to ensure compatibility. The primary objective of implementing barcode and tracking systems is to eliminate preventable misidentification errors. This leads to reduced collection costs, increased staff productivity, elimination of specimen labeling errors, improved turnaround times, higher STAT order response rates, ensured compliance with standard operating procedures, and enhanced specimen collection processes.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1. Introduction

This chapter describes the research methodology which was used. It includes Study area, study design, study population, study sample and sampling strategy, data collection methods and procedures, data analysis, problems and limitations of the study, instruments used including the ethical issues which were taken into account, and the validity and reliability of the research tool.

3.2. Study setting

The research study case is Ruhengeri Referral Hospital in its laboratory department and the served health centers regarding HPV samples processing. This hospital serves health centers and its internal clinic in collecting samples and processing them in its high standard Laboratory. The laboratory which processes HPV samples is based at this hospital.

3.3. Study design

The study was carried out using both quantitative and qualitative approach to understand the existing business process from the point of specimen sampling up to the feedback of the results. Then after, data has been collected to assess healthcare providers' needs regarding the integration of digital labelling feature in the sampling methodologies. Finally, the elicitation of system requirements whether functional and non-functional has been carried out accordingly and the proposed prototype for the integration of digital labelling feature in current electronic medical records (EMR).

3.4. Study population

On one side of the study population for quantitative approach was the healthcare professionals in the area of interest which are 120 clinicians and Lab technicians in Ruhengeri Referral Hospital, Rwanda Biomedical Center's Mentors and Trainers in HPV DNA samples collection and testing were contacted to assess the need for digital labeling integration and to elicitate what can be the functional requirement.

On the other side, for qualitative approach, the researcher has investigated the insight of the information technologists support working on the electronic systems used in the process, this is the team of IT support composed of the Hospital IT officers and the developer of OpenMRS from Ministry of Health and Partners in Health Study sample

The researcher has used different methods to get the study sample. Regarding quantitative approach, the population as whole was in capabilities of the study to be reached. To achieve the objectives of this study, health professional whether clinicians or laboratory technicians from all health centers, district hospital, Rwanda Biomedical Center (RBC) trainers and mentors were targeted to assess the need of digital labelling feature on the point of sample collection to the laboratory.

Likewise with the qualitative approach, the Information Technology (IT) support team has been targeted for the interview to analyses their suggestions, nonfunctional requirements elicitation as far as digital labelling feature is integrated in the HPV screening daily activity. Sampling strategy

A stratified sampling strategy has been used whereby among trained clinicians from different strata, whether Health Center, District hospital in Musanze District; RBC mentor or trainer were contacted. And inside each stratum a simple random sampling has been used to get respondents depending on the availability. The number were unlimited for the fact that the trained personnel as the study population were manageable by the researcher, estimated to be 125. The same strategy applied to the Information Technology (IT) team, where the respondents were selected randomly for interview. The interviewers had to keep interviewing until there is no new knowledge got.

3.4.1. Inclusion criteria

The trained clinicians or laboratory technicians on HPV sampling catchment area and RBC trainers and mentors. The team of IT support composed of the Hospital IT officer and the developer of OpenMRS from Ministry of Health and Partners in Health.

3.4.2. Exclusion criteria

The clinicians or laboratory technician working in service of women cancers early detection but not trained on HPV sampling or testing respectively. The IT support team not working on OpenMRS cancer instance.

3.5. Data collection

The author has designed tools the data collection. These tools were a questionnaire and an interview guide. The questionnaire was designed taking into consideration objective one regarding to assess the need and it was comprised of the closed ended questions to health professionals were built and tested through pre-collection of some data. The test and validation was done through

collection of preliminary data on 10 participants which were analyzed to see if they provide the desired outcome. The author reached the targeted population through the WhatsApp group "Musanze WECD Trainees" whereby a google form link incorporating the questions was shared and filled. Then after the data were collected for analysis.

Regarding qualitative approach an interview guide has been formulated and get integrated into google forms too. The tool was tested and validated. The respondents and the author met physically and get briefed on the research objectives and get interviewed one by one, the answers being recorded and transcribed in google forms. Hence get conserved for next analytical procedures.

3.6. Data management and analysis

Regarding the assessment of digital labelling feature Integration need, the data were collected for the targeted participants of 125, the Statistical Package for the Social Sciences, SPSS version 25 and excel sheet were used for data coding and processing, whereas frequency and mean summary statistics were performed to describe the study population characteristics. Data were analyzed, presented and grouped. Tables were used to present the results for easy interpretation.

While the exploration of insights regarding non function requirements, qualitative data has been gathered from the target of 20 Information technologists, the records was done through online google forms and been downloaded to be checked for completeness and accuracy before being cleaned and analyzed. Then after, a thematic analysis has be designed to construct themes from the recorded perceptions and insights.

3.7. Design of the digital labelling feature

In the system development process, the researcher focused on the activities directly related to the production of a system which is iterative model in this case. The iterative model is an approach to software development that focuses on breaking down the development process into small, manageable steps (11). This method operates in iterations, where significant tasks are divided into smaller steps, and each step is developed iteratively to ultimately reach a final solution.

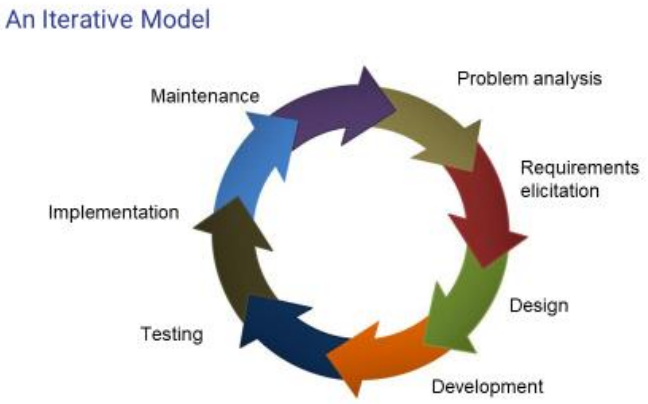


Figure 2. An Iterative Model for system design (22)

A requirement is a characteristic, feature, attribute, quality, or capacity that a system should possess. Requirement specification is a document that outlines and defines the requirements of a system. At the heart of the requirement specification are two key types of requirements: functional and non-functional requirements. Non-functional requirements pertain to how a system should perform its functions. These requirements encompass aspects such as performance, reliability, usability, security, platform constraints, and more.

On the other hand, functional requirements are specific functions that a system should execute. In essence, they describe "what" the system is expected to do. For instance, an example of a functional requirement would be: "The system should have the capability to register an order."

3.8.Ethical consideration

The study protocol has be submitted to the University of Rwanda, College of Medicine and Health Sciences Institution Review Board (IRB) for review and ethical clearance approval. Afterwards, the clearance has presented at Ruhengeri Referral Hospital in research department and Muhoza Health Center to seek the permission for data collection. The respondents has be explained about the research and sign the consent form before data gathering. What's more, their information has be kept confidential, no respondents' names has be recorded and has only be used research purposes. The participation in this research has be entirely voluntary and there has be no punishments for those who has choose not to participate in the study. The authors mentioned in this study has be acknowledged within the references.

3.9.Anticipated outcomes

At the end of this study, the researcher has been in position of understanding the extent of challenges resulting in the absence of an integrated digital labelling feature in the current workflow on HPV specimens from the point of sampling to the testing stations. What's more, the system requirements has be identified to facilitate the design the blueprint which has serves the development activities later on.

3.10. Potential impact

The work has a paramount role in harmonizing the activities of samples collection, testing and results provision in such way that mislabeling and unlabeling at all are avoided and therefore fasten, optimize the screening and early treatment activities of cervical cancer to achieve the universal health coverage easily.

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter is holds the analysis of collected data, their interpretation and the information drawn from the data. It is comprised of results collected on two first objectives of the study, and each being presented separately below. The analysis tools involved Excel for cleaning, coding, and formatting purpose; SPSS version 25 for descriptive tables' generation purpose and hence being incorporated word document with some edits. It also used the thematic content analysis on qualitative data gathered.

4.2 Objective One: Digital sample labelling need assessment

To assess healthcare providers needs on integration of the digital labelling feature in OpenMRS. The data gathered on this objective were cleared and imported in excel worksheet, and exported in SPPS for analysis, however, in this thesis, tables were edited for esthetical purpose. The below presented results are for the sample of 110 respondents with diverse gender, health facilities, occupations but above all being trained on the particular area of interest was the inclusion criteria.

Table 2: Socio-Demographic information

Variables		**Frequency(n)**	**Percentage (%)**
Gender	Male	86	78.2
	Female	24	21.8
Health Facility	RBC Mentor	72	65.5
	Health Center	31	28.2
	District Hospital	7	6.4
Occupation	Clinician	74	67.3
	Laboratory Technician	36	32.7
Attended HPV Sampling	Yes	110	100
	No	0	0

As summary table one shows statistical repartition of respondents and the diversity in participants' profiles. RBC mentors is the team of clinicians working with Rwanda Biomedical Center, RBC to

support Ruhengeri Referral Hospital in mass screening and they were part of our respondents too and they are either clinicians or laboratory technicians.

In addition, health centers and Hospital also were represented and participated in the study. Among the participants, Males count 78.2%, Female 21.8%; RBC Mentor (65.5%), Health Center (28.2%), District Hospital (6.4%); Clinician (67.3%), Laboratory Technician (32.7%); Being attended the training is (100%). Males are presented in big number on influence of RBC Mentors which are mostly males probably as they are mobile field team which is exhausting and the filed activities lifestyle is not so friendly. Also the clinicians are presented in big number 67.3% for the fact that there is one laboratory serving the rest of the catchment area. The whole respondents' team were trained 100% as it was among the inclusion criteria. Regarding the deep understanding of the existing manual process the following table below summarizes activity at workplace.

Table 3: Current labelling technique during HPV sample collection

Variables		**Frequency(n)**	**Percentage (%)**
Existing labelling method	Manual	110	100
	Digital	0	0
Called for identified errors	Yes	107	97.3
	No	3	2.7
Errors frequency in general	Very frequent	11	10
	Frequent	90	81.8
	Neutral	7	6.4
	Uncommon	1	0.9
	Very uncommon	1	0.9
Comfortness with existing method	Extremely comfortable	0	0
	Comfortable	11	10
	Neutral	21	19.1
	Uncomfortable	77	70
	Extremely uncomfortable	1	0.9
Rating existing method with proneness to errors	Not prone (0-4)	3	2.7
	Neutral (5)	3	2.7
	Prone (6-10)	104	94.5

As summarized in table 3 above, it holds the information regarding the current method, it is manual at 100%, the ever being called between clinician and laboratory technicians for clarification related to manual labeling is prevalent at 97.3%; it is Very frequent at 10%, Frequent at 81.8%, Neutral at 6.4%; The 70% of healthcare professional are not comfortable with the existing system while 19.1% are neutral and 10% being comfort with the tradition way. At the level of 94.5% the system is rated to prone to errors.

The labelling by manual means present in every facility, and the calls for clarification regarding is highly rated resulting in frequent ask for some further explanation related to the manual labelling. This makes the team involved fatigued and uncomfortable with the process.

The figure below details the reasons why the need for clarification raises and to which extent they are observed. The errors related to labelling are listed and explained as follow: Mislabeling which is to label (specimen) incorrectly or falsely; Incompleteness or skipping some information on sample or the label itself; Non-matching labels vs Lab request; Illegible whereby the hand writing is difficultly read; Unlabelled where there is no labels at all and Delayed results in which the there is a call for absent or delayed results due to some errors met during sample processing.

Figure 3 Detailed Percentages of every errors in relation to the existing method.

The figure 3 shows the frequency of every errors mentioned in relation to the existing process and as conclusion, the most recurrent error is sample mislabelling with 27% followed by non-matching

labels and lab request with 19.4%, then after skipping of information on sample tube or lab request at 16.7%, delayed results due to clarifications made at 15%, 11.9% illegible labels and the minority being unlabelled samples at 9.7%.

Mislabelling being explained as to attach the wrong label to something a piece of paper, a bottle, etc. that gives you information by Cambridge Online Dictionary accessed June 2023 is the most frequent error which clinicians and laboratory technician come across, this might be as a result of work overload included in the process. The unlabelled sample at all also was reported which may be associated with extensive workload reading to some mistakes. It was also found that the clinician call due to delay of examination results which can be the source of other errors in the process.

In reference to following table, the respondents showed how electronic labelling is thought to be the best alternative and may solve the problem and the degrees on which this may happen.

Table 4: The need for Digital alternative integration in sample processing.

Variables		**Frequency(n)**	**Percentage (%)**
Agreeing with Digital labelling method use	Extremely agree	65	54.8
	Agree	34	28.6
	Neutral	11	9.2
	Disagree	0	0
	Extremely disagree	0	0

Table 4 is showing in short, the need for alternative digital labelling feature integration in the current process where 54.8% strongly support the use of it, 28.6% just agree with replacement of it, 9.2 being neutral but none of the participants disagreed with the adoption of digital method.

It was found that the majority believe in electronic labeling as the best solution. Some participants were neutral. This may be related to the digital skills needed to adopt the alternative digital, the resource shortage and sustainability of the integrated digital feature. However, none of the respondents denied the role of implementing digital way.

Health professions as they use other electronic tool like OpenMRS itself were in position to presume some challenges in the implementation process as some literatures has shown too.

This might be the financial capabilities of different health institutions, leading to inability of putting in place some infrastructures like portable printers and others. The health workforce itself might have digital literacy required to implement successful electronic processes and their willing and acceptability have a word in the implementation.

The figure 4 highlights the provisioned constraints that will raise while the digital labelling is in place. Financial resource constraints refer to the expenses accompanying the integration of digital labelling feature and the continuous implementation cost; infrastructures barrier are lack of printers, electricity, and computers. Unskilled workforce refers to the health professional digital literacy capacity regarding the process; Unwillingness is the lack of one's interest in the digital labelling integration while the unacceptability is the denial of shifting from current process.

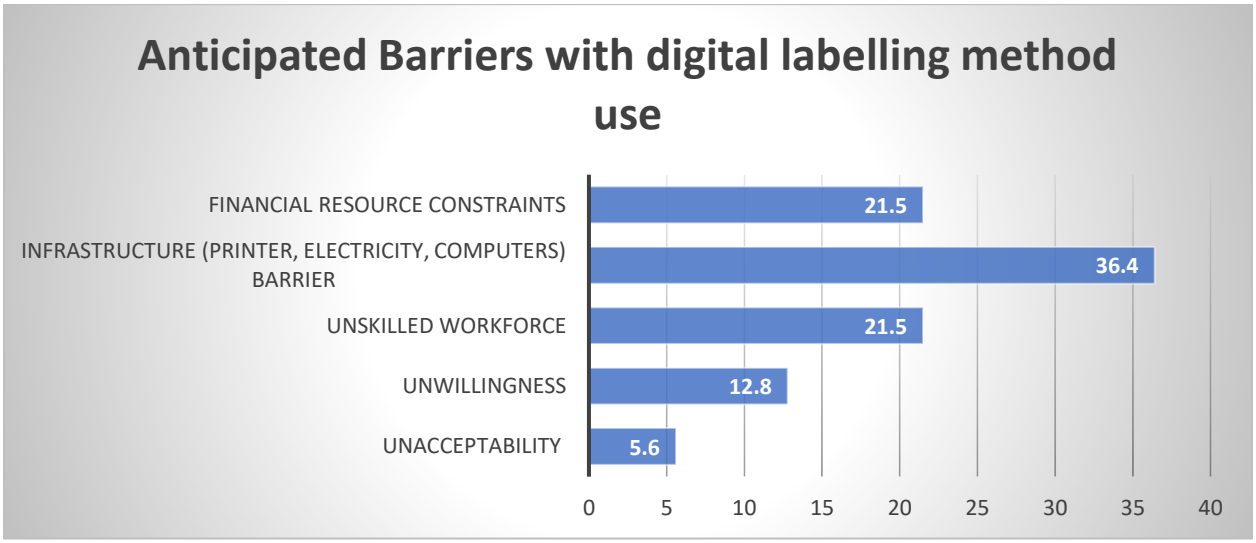


Figure 4: Anticipated barriers while the digital alternative is integrated

It clearly shown that infrastructures is the most challenge at 36.4%, financial resources and unskilled workforce with 21.5% each, unwillingness of some conservative health professionals at 12.8% and unacceptability by 5.6%. Financial constraints, lack of infrastructures and digital illiteracy are major challenges is common in Rwandan health settings which are new in digital world. However, the willingness and unacceptability is represented with some percentages probably due to some discomforts, unfamiliarity in use of electronic tools.

4.3 Objective two: Exploring of technical requirements for integration of the digital labelling feature in OpenMRS

This study has taken into account the irreplaceable role of stakeholders. It was in that regards that OpenMRS ITs were contacted to appreciate their contribution. Cervical Cancer screening through Human Papilloma virus DNA test is electronically recorded through mUzima registration and data being synced to the OpenMRS however samples labelling is done manually. The discussion focused how sample labelling activity may be digitalized with efficacy, efficiency, effectiveness, elegancy and scalability, and ethically. Then after, an interview guide was elaborated and the records analyzed to draw conclusions in different collected ideas through thematic analysis.

Table 5: Socio-Demographics information of the respondents

Variables		**Frequency(n)**	**Percentage (%)**
Gender	Male	14	87.5
	Female	2	12.5
Health Facility	RBC	8	50.0
	Partners In health	8	50.0
Occupation	Software Engineer	13	81.3
	Information Technologists	3	18.8
Educational Background	Computer science	12	75.0
	Information and technology	2	12.5
	Data Science	2	12.5

Table 5 summarizes the demographics of respondents where Male (87.5%), Female (12.5%) of whom a half works in RBC and the other half in Partners in Health (PIH). Software engineers are 81.3% while information technologists count 18.8%.

The table below summarizes the themes and subthemes drawn in the insights of respondents.

Table 6: Themes and subthemes for digital labelling feature integration.

Themes	Subthemes
Integration of the digital labeling in OpenMRS	- QR code - Barcode
Challenges hindering the successful integration	- Incompatibility with other devices - User Adoption

Integration of the digital labeling in OpenMRS

Subthemes emerging from participants‟ responses to the question to their understanding of the integration of digital labeling are summarized in the following sections:

Quick Response (QR) code

Digital labeling serves as a vital component within OpenMRS, enabling healthcare professionals to efficiently organize and identify patient data(19). By assigning digital labels to specific medical records, healthcare providers can quickly locate and access relevant information, streamlining clinical decision-making processes(6). Traditional paper-based labeling is prone to errors, loss, and inefficiencies, making digital labeling a superior alternative (16).

The integration of digital labeling with QR code technology in OpenMRS presents a promising approach to enhance patient care and optimize clinical workflows. By leveraging the advantages of QR codes, healthcare providers can benefit from improved data accuracy, increased efficiency, and enhanced.

One of the participants stated "*OpenMRS should have a built in module which can work with an external device (Code scanner) and of course in the metadata there should be the characteristics for those Data scanned*" (Participants 001)

Barcode

Barcodes provide a standardized method for encoding information in a visual format that can be easily scanned by barcode readers. When applied to digital labeling, barcodes become powerful tools for efficient data capture and retrieval. By encoding patient-specific identifiers or medication details into barcodes, healthcare providers can quickly access and update patient records.

Barcodes enhance accuracy, minimize transcription errors, and enable seamless integration with other healthcare systems.

The integration of digital labeling, particularly through barcode integration, has the potential to greatly enhance the efficiency, accuracy, and patient safety within OpenMRS. By leveraging barcode technology, healthcare providers can streamline medication administration, improve patient identification, optimize inventory management, and facilitate laboratory workflows. One of the participant mentioned:" *Code generator function (system), connection between bar code printer and the application, ways of saving generated code in the system, sync the code to central server*." (Participants 006)

Incompatibility with laboratory machines.

One of the primary challenges is ensuring compatibility between the digital labeling system and the OpenMRS platform. Differences in data models, schemas, or technical architectures may require extensive customization or development efforts to establish a seamless integration. There should creation of features in OpenMRS that interoperate with external devices. Among the other respondents one reported: "*Connection to printer, unique and short generation of barcode proper use of the code at the lab. App compatibility with printer*." (Participants 013)

This will be achieved by conducting a thorough analysis of the digital labeling system and OpenMRS to identify any incompatibilities; customization of the digital labeling system or OpenMRS data model as needed to ensure compatibility; developing adapters or middleware to facilitate data exchange and integration between the two systems.

User Adoption

User Adoption: Introducing a new feature to the OpenMRS system requires user acceptance and adoption. Clinicians, healthcare providers, and administrative staff may require training and support to effectively use the digital labeling functionality. Resistance to change and lack of user engagement can hinder successful integration. One of the respondents said: *"the research needs should involve end-users early in the design and development process to gather their input and requirements, provision of comprehensive training and documentation to educate users about the digital labeling functionality, offering ongoing support and assistance to address user questions or concerns."* (Respondents 009)

CHAPTER FIVE: DESIGN OF THE PRODUCT FOR INTEGRATION OF THE DIGITAL LABELLING FEATURE IN OPENMRS.

5.0 Current HPV sample labelling systems scenario at Ruhengeri Referral Hospital

Currently the pathway of HPV sample collection happens between the health centers and District hospitals. At health centers mainly women came for HPV sample collection thereafter be transported to the Hospital for testing and results entry in OpenMRS. Briefly, the figure below outline the process modeling of the scenario.

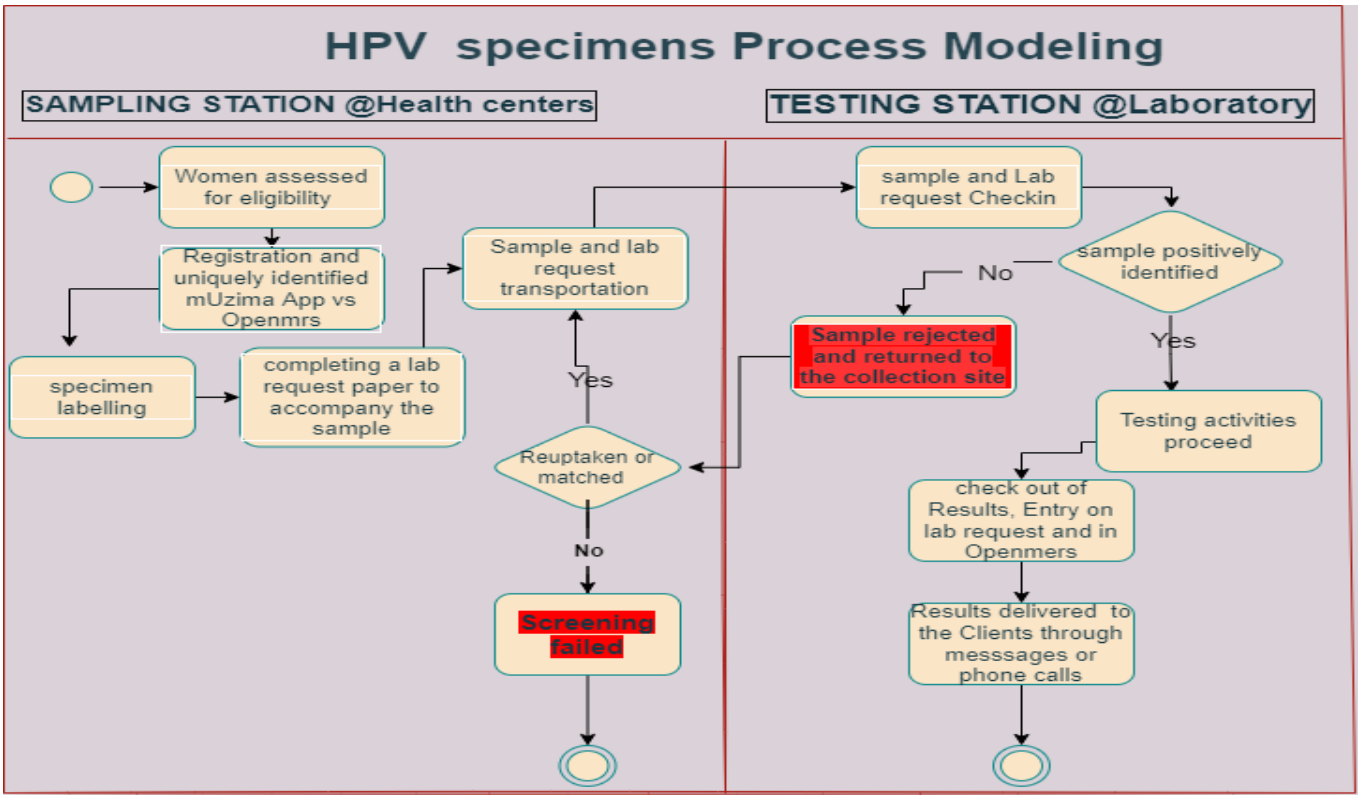


Figure 5 Process modelling, existing flow for HPV sampling and testing.

As per the figure above, the process start when an eligible clients is consulting for HPV screening test, the clinician registers the client in the android mUzima application or else in OpenMRS, followed by labelling the sample and filling the accompanying lab request then after being sent to the laboratory for testing. At arrival the laboratory technician do check-ins of the sample label and request form and if it meets the requirements being processed for results. However, if it does not meets the requirements, He calls for clarification or it is retuned back to the collection site for correction and positive patient identification. The author focused on the gaps in the process to improve the process and avoid the recurrent errors hindering efficient and prompt results provision.

This is to reduce or else eliminate the reasons for sample rejections at laboratory which may even lead to the total failure of consideration. As consequence, this slows down Cervical Cancer elimination mission with as one of the objectives of testing women with HPV DNA test.

In the system development process, the researcher focused on the activities directly related to the production of a system which is iterative model in this case.

The iterative model is a way of software development that works in small steps for the development of the software. The researcher adopted the model for the design of the prototype of digital labelling feature integration.

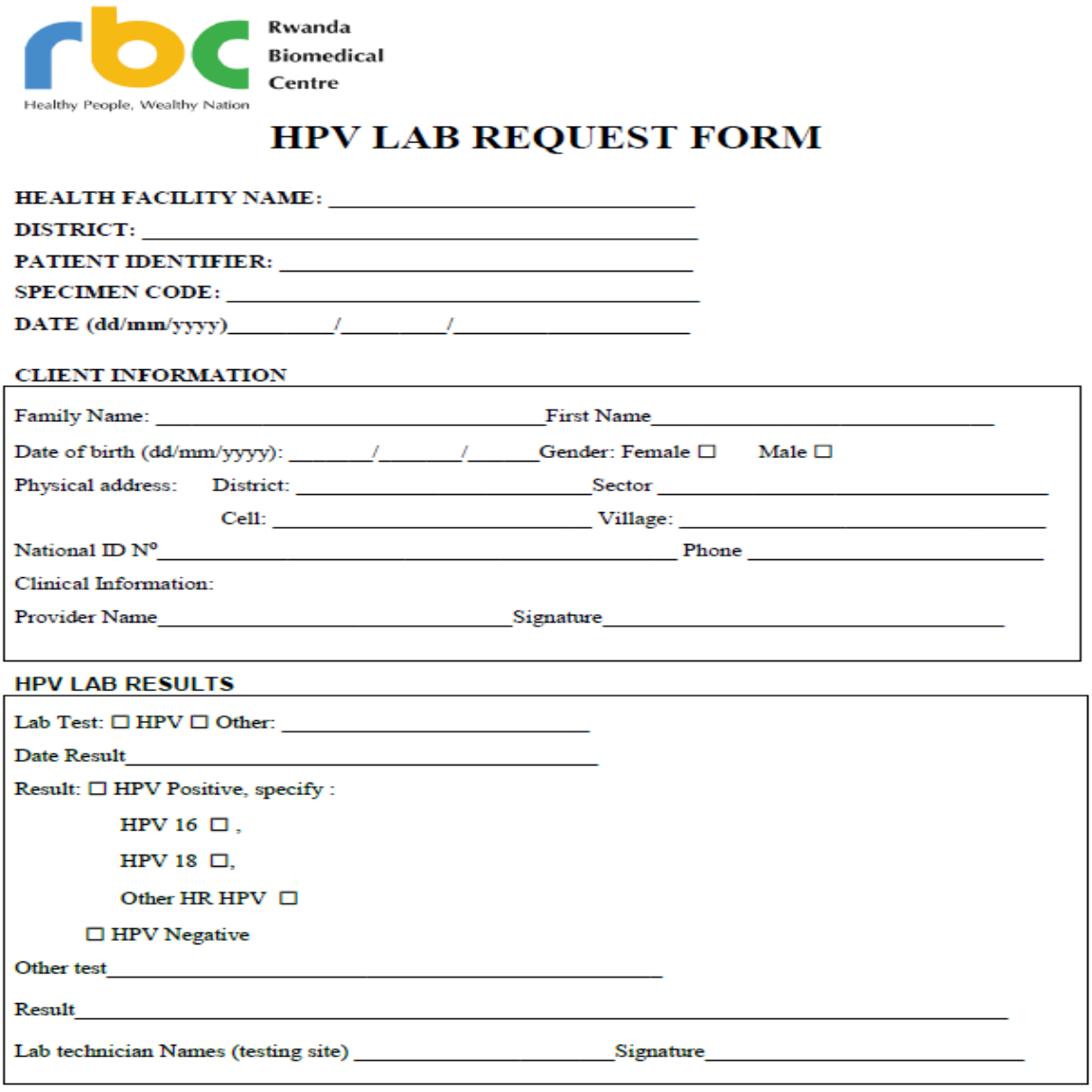
5.1 Functional requirement elicitation with reference to the request form.

The following functional requirements are of paramount role for the successful integration of the digital labelling feature in OpenMRS. The figure below shows the current laboratory form used to collect the information sent to the lab for testing. In reference to the below figure 6 the following are drawn functional requirements for the digital labelling feature integration in the process. In general the OpenMRS should generate the barcode or the QR code with theses label composition in place.

1. **Health facility Name**: The label should show from which health facility is the sample from so that the positive patients is protected at laboratory for smooth testing and results provision.
2. **Address on the request form:** a little bit on address should be mentioned.
3. **Date and time of request:** The label must show the date and time on which the sample is being taken.
4. **Specimen code:** This is the order number of sample collected and normally it describe sample with the yearly order number, the facility code and the year. This is simplified in the table below:

Yearly order number	Facility code	Year label
0001	**0045**	**2023**

5. **Unique identifier:** This is the unique identifier generated from the system as the client is registered.
6. **The type of exam requested:** This should be the orientation for the laboratory technicians to know what to do.
7. **Hiding the name, Age, Sex, and Address**: The name of the client should be hidden for the sake of privacy and confidentiality.
8. **Image/File Storage:** Set up a mechanism to store and manage the digital labels associated with patient records. This may involve integrating with a file storage system or using a dedicated image storage solution.
9. **Integration with Imaging/Labeling Tools:** Integrate OpenMRS with appropriate imaging or labeling tools that support the desired labeling functionality. This could involve leveraging existing open-source labeling tools or developing custom solutions.
10. **Workflow Integration:** Consider how the labeling process fits into the overall workflow of OpenMRS. Ensure that the labeling functionality seamlessly integrates with other modules and workflows within the system.
11. **API Development:** Develop appropriate APIs (Application Programming Interfaces) to facilitate the exchange of data between OpenMRS and external labeling systems or tools. This enables interoperability and integration with other systems.
12. **Data Synchronization**: Implement mechanisms to synchronize label-related data between different instances of OpenMRS or other systems, if necessary. This ensures that labels are accessible across multiple environments or applications.



Rwanda Biomedical Centre

Healthy People, Wealthy Nation

HPV LAB REQUEST FORM

HEALTH FACILITY NAME: _____

DISTRICT: _____

PATIENT IDENTIFIER: _____

SPECIMEN CODE: _____

DATE (dd/mm/yyyy)_____/_____/_____

CLIENT INFORMATION

Family Name: _____First Name_____

Date of birth (dd/mm/yyyy): _____/_____/_____Gender: Female ☐ Male ☐

Physical address: District: _____Sector _____

Cell: _____ Village: _____

National ID N°_____ Phone _____

Clinical Information:

Provider Name_____Signature_____

HPV LAB RESULTS

Lab Test: ☐ HPV ☐ Other: _____

Date Result_____

Result: ☐ HPV Positive, specify :

HPV 16 ☐ ,

HPV 18 ☐,

Other HR HPV ☐

☐ HPV Negative

Other test_____

Result_____

Lab technician Names (testing site) _____Signature_____

Figure 6: Human Papilloma Virus laboratory request form at Ruhengeri Referral Hospital.

The figure 6 shows the details which are completed normally on the laboratory request form accompanying the collected specimens. It served as the backbone of descriptive information to be coded with barcodes. However, not all the information should be coded, it will rather serve as the link to further description in the systems and as result reduce the work overload and the time spent during form completing.

5.2 Non-functional Requirements elicitation drawn from interviewees.

In reference to the summary of interviewees' insight and suggestions, to integrate digital labeling into OpenMRS, there are several technical requirements that should be considered. Here are some important aspects to consider:

1. Data Model and Schema: Ensure that the OpenMRS data model and schema are flexible enough to accommodate the digital labeling requirements. This may involve defining new data structures or modifying existing ones to store label-related information.
2. User Interface (UI) Customization: Implement a user-friendly interface within OpenMRS to capture and display digital labels. This could involve creating new screens or modifying existing ones to incorporate label-related functionalities.
3. Security and Privacy: Ensure that the labeling system adheres to appropriate security and privacy standards. Implement access controls, encryption mechanisms, and audit trails to protect patient data and comply with relevant regulations.
4. Performance and Scalability: Consider the performance and scalability aspects of the labeling system. Ensure that it can handle the expected load and storage requirements, especially if there are plans for large-scale deployment.
5. Testing and Quality Assurance: Conduct thorough testing and quality assurance activities to ensure the robustness, reliability, and usability of the labeling integration. Perform both functional and non-functional testing to validate the system.

It is important to note that the specific technical requirements may vary depending on the unique needs of the digital labeling solution and the OpenMRS implementation. Therefore, a detailed analysis of the specific use case and consultation with technical experts would be beneficial during the implementation process.

5.3 Challenges presumed and the mitigation factors by respondents.

"Several challenges can hinder the successful integration of digital labeling into OpenMRS. These challenges can vary depending on the specific context and requirements of the integration. Here are some common challenges to consider:

1. Compatibility: One of the primary challenges is ensuring compatibility between the digital labeling system and the OpenMRS platform. Differences in data models, schemas, or technical architectures may require extensive customization or development efforts to establish a seamless integration.

2. System Complexity: OpenMRS is a complex health information system with various modules and functionalities. Integrating a new feature like digital labeling may require understanding and working with existing codebases, which can be challenging and time-consuming.

3. User Adoption: Introducing a new feature to the OpenMRS system requires user acceptance and adoption. Clinicians, healthcare providers, and administrative staff may require training and support to effectively use the digital labeling functionality. Resistance to change and lack of user engagement can hinder successful integration.

4. Workflow Alignment: Aligning the digital labeling process with existing workflows and clinical practices can be challenging. It requires understanding the current workflow patterns, identifying points of integration, and ensuring that the labeling system fits seamlessly into the clinical workflow without causing disruption or inefficiencies.

5. Data Quality and Standardization: Digital labeling relies on accurate and standardized data. Challenges may arise if the data within OpenMRS is incomplete, inconsistent, or of poor quality. Data cleansing and standardization efforts may be necessary to ensure reliable labeling results.

6. Interoperability: OpenMRS may need to exchange data with external systems or tools for labeling purposes. Challenges can arise in terms of interoperability standards, data exchange formats, and integrating with external labeling solutions. Aligning different systems and ensuring smooth data flow between them can be complex.

7. Performance and Scalability: The integration of a new feature like digital labeling can impact the performance and scalability of the OpenMRS system. Increased data storage requirements, processing demands, or network traffic due to labeling functionalities may need to be addressed to maintain system performance and scalability.

8. Security and Privacy: Incorporating digital labeling introduces additional considerations for data security and privacy. Ensuring that patient information is adequately protected, access controls are in place, and compliance with privacy regulations is maintained can be challenging.

9. Resource Constraints: Integration projects may face resource constraints, including time, budget, and skilled personnel. Limited resources can impact the development, testing, deployment, and ongoing maintenance of the digital labeling integration, potentially leading to delays or compromised functionality.

10. Long-Term Maintenance and Upgrades: OpenMRS is a continuously evolving platform, with regular updates, bug fixes, and feature enhancements. Maintaining the digital labeling integration in the long term requires ongoing support, updates, and compatibility checks to ensure it remains compatible with the evolving OpenMRS ecosystem.

Addressing these challenges requires careful planning, stakeholder engagement, technical expertise, and effective project management. Conducting thorough assessments, involving end-users in the design process, and collaborating with experienced developers can help mitigate these challenges and increase the chances of successful integration."

5.4 Prototype of the product for integration of the digital labelling feature in OpenMRS.

The alternative digital labelling feature is prototyped as by figure 7. The iterative model was used whereby the first objective assessed the need and problem analysis and identified the gap in all its forms. The second objective has analysed the technical requirement to design flow processes and their successful technical implementation. Therefore, the figure below shows the prototype of digital labelling feature to be integrated with OpenMRS. This feature was later integrated with OpenMRS engineer for testing and output assessment.

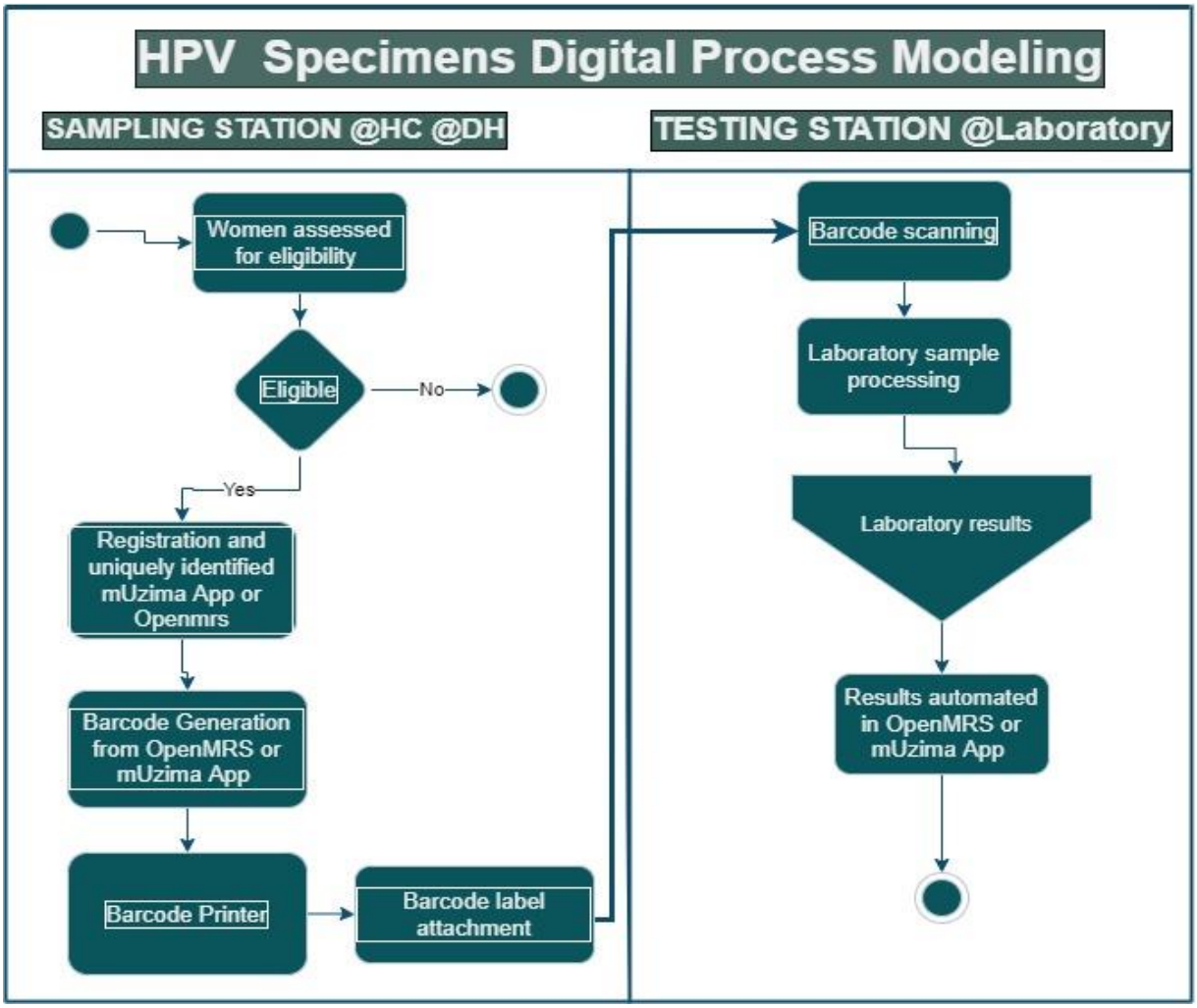


Figure 7: Design of HPV specimens' digital labelling prototype.

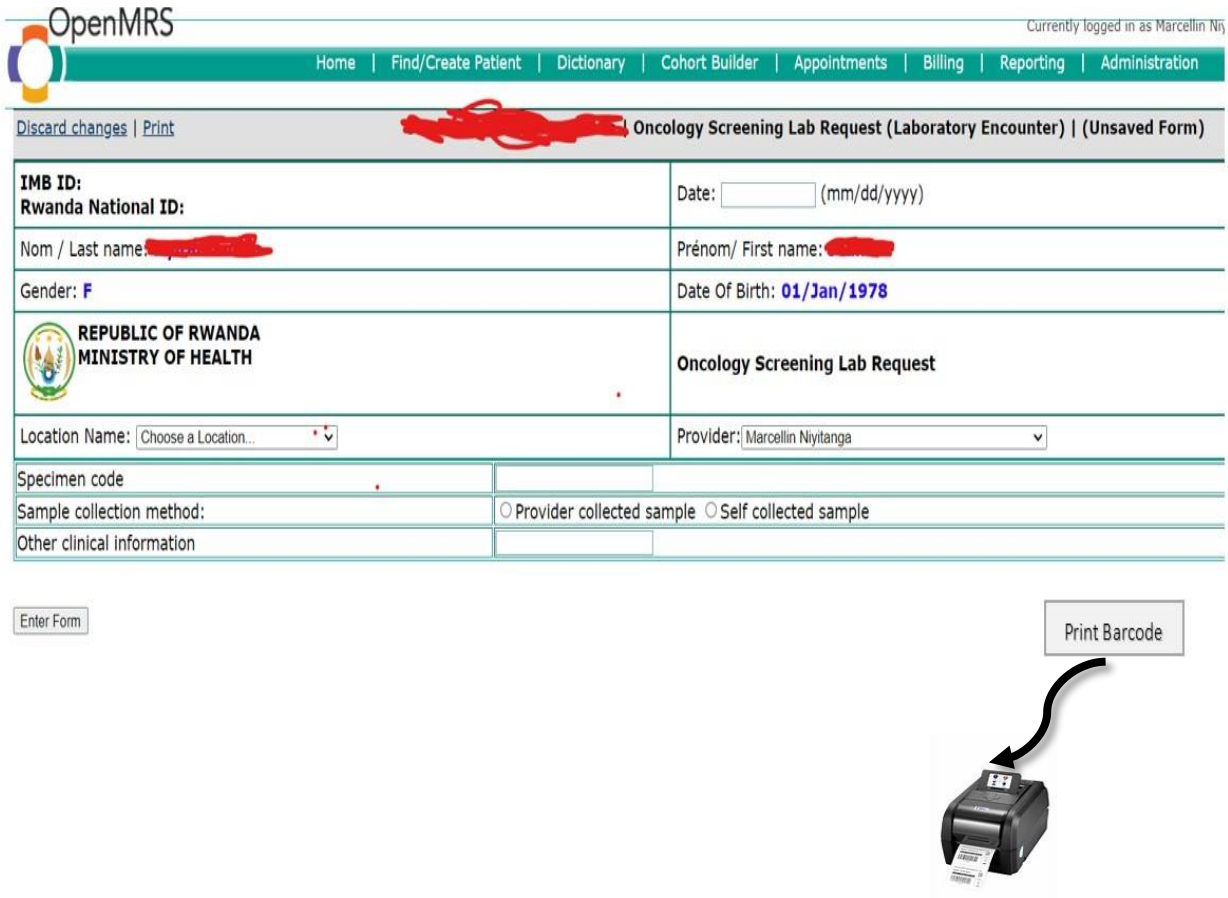


Figure 8: Digital labelling feature development and integration, OpenMRS Interface after the integration of Barcode feature.

The figure above shows the OpenMRS web page with integrated digital labelling feature. As the result, there is an option to print a barcode after recording the laboratory request form in OpenMRS. Once the administration avails the resources the digital label may get used in HPV samples point of collection and laboratory processes.

CHAPTER SIX: DISCUSSION

6.1 Introduction

This chapter provides an overview of the research findings, accomplishments, and a review of how the research goals were achieved, including a discussion of the limitations of the study. It details the deep understanding and integrate the findings in the context of other researches. It is composed of three section in reference to three objectives covered in the study. Therefore it gives broad image and the implication of the results found.

6.2 Review of research objectives

This research presents various discoveries, which are categorized into three sections.

1. The first part covers the need assessment of a digital labelling feature integration in OpenMRS.
2. The Second part covers the insights, perceptions of the IT team who works routinely on the development and customization of OpenMRS.
3. The third part covers the prototype designing of web-based models.

As by section 1.4.1 the first objective of the study was to assess healthcare providers' needs on integration of the digital labelling feature in OpenMRS, we used a one shot quantitative approach with sample size of 110, which represents the population. The study area was Ruhengeri Referral Hospital based in Musanze District as one of the pioneer Hospital testing HPV samples. Regarding this objective the study has described the participants where Male counts 78.2% and Female 21.8%; RBC Mentor were represented at 65.5%, Health Center 28.2%, and District Hospital at 6.4%; 67.3% Clinician while 32.7% Laboratory Technician; the whole team of respondents were trained on the procedure of Human papilloma Virus sampling.

Even though OpenMRS is an electronic way introduced in Ruhengeri Referral Hospital to facilitate the easy and sustainable way of records keeping, the procedure of sample labelling is still manual 100%, raising frequent calls for clarification of most manually labelled specimens as shown in table 2. In this study, paper based labelling was found to be prone to errors at 94.5% and healthcare professionals are overwhelmed with this approach at the rate of 70% (23). Automation, bar-coding, and interfaces with electronic medical records (EMR) helps in reducing specimen collection labelling errors (24). The most recurrent error are sample mislabelling with 27% , non-matching

labels and lab request with 19.4%, skipping of information on sample tube or lab request at 16.7%, delayed results due to clarifications made at 15%, 11.9% illegible labels and unlabelled samples at 9.7%. Tabatabaee et al in the study done in Northeast Iran, found that the top three examples of errors were unlabelled specimens (18.7%), wrongly labelled specimens (16.3%), and improper collection (13.2%) (2).

The need for alternative digital labelling feature integration in the current process is highly supported at 83.4%. Guadagni et al. in the study done in Rome, Italy said: "if the information related to the nature of a biological sample is paired with the exact location, this come with a remarkable saving of time otherwise spent for manual sample searching, and there is a significant increase of availability in terms of numbers and quality of samples as well as data related to them" (25).

To reference with the second objective being to analyse the technical requirements for integration of the digital labelling feature in OpenMRS, the interviewees admired this new way of processing the sample with the integration of digital labelling with QR code or barcode technology in OpenMRS is the reliable and efficient way to optimize the care delivered to the clients and strengthen clinical workflows. Barcodes are synonymous with specimen labelling accuracy. Barcoding systems are four times less likely to produce errors than manual entry methods. "*Error mitigation and time savings over the long term are hard to quantify, though these goals are given the highest priority within our lab"*(26).

By appreciating the advantages of QR codes or barcode, healthcare providers can benefit from improved data accuracy, increased efficiency, and prompt care. One of the respondents says: *"I think digitalazing this way of sample labelling may reduce almost all errors we often make while labelling and even it may be easy to track any error that may arise during the process."* Ley et al. in the study done in Australia found that the electronic data collection (EDC) has become a well-accepted alternative to paper-based data collection (PBDC), reducing the risk of errors and allowing real time checks for completeness and logical consistency(27). By leveraging this technology, healthcare providers can streamline medication administration, improve patient identification, optimize inventory management, and facilitate laboratory workflows.

To make the integration of this digital labelling in OpenMRS, Some technical requirement should be in place. From the collected data, some of them are data model and schema, user interface customization, image/file storage, integration with imaging/labeling tools, onsite printer, code scanner, security and privacy, API development, data synchronization, performance and scalability, testing and quality assurance. One of participants mentions there should be: "*Connection to printer, unique and short generation of barcode, proper use of the code at the lab and App compatibility with printer*."

However the need to consult end users also needs much attention. One of the respondents said: *"the research needs should involve end-users early in the design and development process to gather their input and requirements, provision of comprehensive training and documentation to educate users about the digital labeling functionality, offering ongoing support and assistance to address user questions or concerns."* (Respondents 009)

In the third part of creating a web-based model prototype, we employed the waterfall model methodology to complete each stage necessary to develop the prototype. These stages include defining the system requirements and specifications, designing the system, and creating the prototype. The functional requirements were delivered from the quantitative data as provided by health professionals in this particular area of interest. What's more, the study considered the laboratory request form to make sure that nothing is left behind regarding the functionalities of current paper based system. The digital label should have the ability to hold the information like unique identifier number, health facility name, date and time of exam, specimen code, and type of exam requested. Mehrdad Farzandipour et Al., study done in Iran shown that the ability to specify the information including sample number, status, date, time are essential requirement in laboratory information system (28).

Nonfunctional requirements were drawn from the Information Technologist, ITs and computer scientist working on daily basis on continuous OpenMRS development, customization, and maintenance. These are set of specifications that describe the system's operation capabilities and constraints and attempt to improve its functionality. The electronic medical record should generate barcode or else QR code, the compatibility with external devices like printer should be enhanced. This may guide and assist in development and testing of the digital labelling feature to breach the gap resulting in the usage of manual labelling.

6.3 Advantages of the digital labelling feature.

Integration of digital specimen labelling in the current system is expected to improve the situation, minimizing errors associated with manual specimen labelling and it should be a sustainable solution because the man power we have are differently skilled hence this strategy will help to minimize errors reported during HPV sample labelling, also reduce sample rejections due to incomplete information on tube and lab request and also it will reduce time taken to label sample and lab request hence the time will be managed. It will facilitate during each patient identification during results.

CHAPTER SEVEN: CONCLUSION AND RECOMMENDATION

7.1 Conclusion

As conclusion the present study has assessed the need, investigated the requirement of the digital labelling feature integration with OpenMRS. Hence proposed the design of the skeleton that can facilitate in the development and test of feature. It was conducted in Ruhengeri Referral Hospital catchment area, in Musanze District. However the data, the findings are generalizable to the other setting carrying out the same procedures. The overall results show that there is a need of integrating this feature for services optimization of the process. To reference to the findings the study quantitatively assessed the need for digital labelling feature in current process shows that the system is exhaustive, inefficient, full of duplication of work, time consuming, and prone to errors jeopardizing the outcome of the activity of the other side. Also, the study investigated what it requires to break the ice and improve the current scenario. They resulted in elicitation of functional and non-functional requirements to integrate a health providers-centered, customized digital labelling feature responding to the identified gap. Finally, the study proposed a design reflecting to the findings to enhance optimal and successful implementation of the electronic instance in OpenMRS. In return, this may overcome the work overloadness of the clinicians and laboratory technicians and improve prompt services through quick responses to the clients concerns, and consequently slowing down the burden of cervical cancer over local and global population in general the population.

7.2 Recommendation

The present study has pointed out that there is a will and support in the integration of the digital labelling feature in OpenMRS, to improve the current processes undergone in HPV sample collection and testing. Testing. The following recommendations are allocated to the different decision making institutions concerned with this particular area for proper and reinforced implementation:

7.2.1 Rwandan Ministry of Health

The mission of the Rwandan Ministry of Health is to offer and consistently enhance accessible healthcare services, including promotion, prevention, treatment, and rehabilitation, all while upholding the highest standards of quality. This commitment aims to contribute to poverty reduction and enhance the overall well-being of the population.

World Health Organization

According to report of 2018, Health care systems should implement well studied interventions that demonstrate improvement, build resilience to enable prevention, detection and response to population needs(29). The Author calls upon Ministry of Health to the implementation of the design in existing practices to improve the quality of services delivered.

Ministry Of Health may ensure policy, monitoring, evaluation and continuous improvement. The framework of monitoring and evaluation should be established to monitor the effectiveness of the integration and identify areas for improvement. There should be regular feedback from end-users, and reply to make necessary updates and enhance sustainable efficiency and effectiveness of the solution.

7.2.2 Partners in Health

Partners In Health is an international nonprofit organization dedicated to assisting Rwanda in creating, constructing, and implementing a top-tier healthcare system. This system is designed to offer fair, accessible, and high-quality services to all individuals in need. We achieve this mission through innovative service delivery, enhancing the knowledge and capabilities of the healthcare workforce, and systematically applying evidence derived from research platforms rooted in the communities we serve. It has a Digital unit working on development of OpenMRS and as recommendation, the successful implementation of digital labelling feature implementation is in their good hands.

It may support for adequate training and ongoing technical support to healthcare providers before, during and after the implementation and this may result in successful integration and application of the digital labeling feature in OpenMRS.

7.3 Future works

Even though this study has assessed and analysed whatever it may take to integrate the digital labelling feature in OpenMRS for HPV sample labels production, there are some important limitations to take into consideration. Firstly, the study did not move on to develop and test the feature in real system due to the processes undertaken to arrive on that decision. The future research may work on its implementation and sustainability. Secondly, this work has not assessed the integration and automation of OpenMRS and laboratory information systems.

The integration of both systems may enhance the prompt results entry after analysis of results without taking long and additional workforce to enter the results.

Thirdly, due to the limited resources has considered one hospital catchment area. Even if the processes involved are the same, probably there should be some new insight regarding the use of digital labels in labelling HPV samples. Fourthly, future works may extend the work to the other kind of samples not only Human Papilloma Virus and may be look on stool, urine, however this may need the digitalization of whole journey for effectiveness and successful implementation. Last but not the least, Ruhengeri Referral Hospital in collaboration with Partners In Health may work on development of the feature, testing and implementation of the feature, ensure the maintenance and sustainability to impact positively the journey of easy sample collection, smooth testing and timely results provision for ideal service delivery. There should be human errors, reduced workload and super working environment.

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APPENDICES

APPENDIX I: STUDY TOOLS

APPENDIX I.1: QUESTIONNAIRE FOR CLINICIANS AND LABORATORY TECHNICIANS.

SECTION A: IDENTIFICATION

1) Study ID/CODE
2) Gender

   Female vs Male vs other.
3) Health Center/Hospital/RBC
4) Education background?

   Clinician vs Laboratory Technicians
5) Trained on HPV Sampling/ Testing?

   Yes vs no

SECTION B: QUESTIONS

6) How do you manage to **label** the sample of HPV during the screening of cervical cancer?

   Manually vs digitally
7) In the daily activity of sample collection and testing, have you ever called/ been called for clarification? Yes vs no
8) If yes, mention what the clarification was about:
   - ❖ Mislabeled samples.
   - ❖ Unlabeled at all samples.
   - ❖ Illegible labels
   - ❖ Non-matching of labels vice lab request
   - ❖ Skipped information on the labels and lab request
   - ❖ Delayed results
   - ❖ Other….
9) How frequent are you called/do you call due to unlabeled/mislabeled/other specimens?
   - ✓ Very frequent
   - ✓ Frequent

- ✓ Neutral
- ✓ Uncommon
- ✓ Very uncommon

10) To which extent are you comfortable with the existing process of labelling HPV specimen from the point of collection to the testing site?
    - ✓ Extremely comfortable
    - ✓ Comfortable
    - ✓ Neutral
    - ✓ Uncomfortable
    - ✓ Extremely uncomfortable
11) To which extent do you think manual specimen labeling is prone to identification errors and mislabeling?

    On the scale: 0 is not prone at all, 10 extremely prone to errors

12) Digital specimen labelling is an electronic way whereby a paper label may be printed out from the data entered through registration with the information normally being written by a pen on the sample tube. How do you agree this innovation may reduce the number of specimen identification errors and mislabeling?

    Extremely agree

    Agree

    Neutral

    Disagree

    Extremely disagree
13) What can you anticipate as barriers to the integration of digital specimen labelling in the process of sample labelling?

    Unacceptability

    Unwillingness

    Unskilled workforce

    Infrastructure (printer, electricity, computers) barrier

    Financial resource constraints

APPENDIX I.1.1: PARTICIPANT INSTITUTION INFORMATION FORM

Dear Sir/Madam,

My names are Marcellin NIYITANGA TUYIZERE, I am a candidate for Masters in Health informatics at University of Rwanda, Center of Excellence in Biomedical Engineering and Ehealth (CEBE). I am conducting a research study titled "Digital labelling feature integration with OpenMRS to mitigate HPV specimen identification errors. Case of Ruhengeri Referral Hospital. " This study will play a vital role to the healthcare system mainly in mitigating sample mislabeling and patient identification errors. It will allow the assessment and evidence based designing of a digitalized tool that will ease healthcare workload and improve the care delivered to women seeking cervical cancer screening services.

This questionnaire is designed to assess the healthcare providers need for the adoption of an integrated digital labelling system in the current OpenMRS system. You will not be punished or victimized for denying to participate in the study. It will take 10-15 mins to complete the questionnaire. You are free to make movements as you wish. Participation is free, no payment will be given to you for participating in this discussion.

If you have any questions regarding the research project as a whole, please feel free to ask. I can be reached through my cellular phone (0787856047) or my email: marcniytuy@gmail.com

Thank you in advance.

Kind regards,

Marcellin Niyitanga Tuyizere

Research Supervisor: Dr. Karara Gustave

Research Co-Supervisor: Dr. Masabo Emmanuel

APPENDIX I.2: INTERVIEW GUIDE FOR OpenMRS ITs

SECTION A: IDENTIFICATION

1) Study ID/CODE
2) Gender

   Female vs Male vs other.
3) Health Facility:

   Partners In health/RBC
4) Education background:

   Computer science/Information and technology/Data Science
5) Occupation:

   Software Engineer/ Information Technologists

SECTION B: QUESTIONS

6) To make the integration of this digital labelling in OpenMRS, Some technical requirement should be in place. What do you think should be those enablers?
7) How the enablers should correlate for optimal functionality of the integrated part
   - Probe for efficacy
   - Probe for efficiency
   - Probe for ethical
8) What can be challenges hindering the successful integration
9) What are the presumed measures for above mentioned concerns

APPENDIX I.2.1: PARTICIPANT INSTITUTION INFORMATION FORM

Dear Sir/Madam,

My names are Marcellin NIYITANGA TUYIZERE, I am a candidate for Masters in Health informatics at University of Rwanda, Center of Excellence in Biomedical Engineering and Ehealth (CEBE). I am conducting a research study titled "Digital labelling feature integration with OpenMRS to mitigate HPV specimen identification errors. Case of Ruhengeri Referral Hospital. " This study will play a vital role to the healthcare system mainly in mitigating sample mislabeling and patient identification errors. It will allow the assessment and evidence based designing of a digitalized tool that will ease healthcare workload and improve the care delivered to women seeking cervical cancer screening services.

This study has taken into account the irreplaceable role of stakeholders. It is in this regards that OpenMRS ITs were contacted to appreciate their contribution. Cervical Cancer screening through Human Papilloma virus DNA test is electronically recorded through mUzima registration and data being synced to the OpenMRS however samples labelling is done manually. Our discussion is going to investigate how sample labelling activity may be digitalized with efficacy, efficiency, effectiveness, elegancy and scalability, and ethically.

This interview guide was designed to analyze the perceptions regarding mislabeling and patient identification errors related to the existing HPV sampling process. Your thoughts and discussions will be recorded with your assistance where you will be given an online form to fill your insight. You will not be punished or victimized for sharing your thoughts in this discussion. The interview and recording will take 20-30 minutes. You are free to make movements as you wish. Participation is free, no payment will be given to you for participating in this discussion.

1. To make the integration of this digital labelling in OpenMRS, Some technical requirement should be in place. What do you think should be those enablers?
2. How the enablers should correlate for optimal functionality of the integrated part
   Probe for efficacy
   Probe for efficiency
   Probe for ethical
3. What can be challenges hindering the successful integration
4. What are the presumed measures for above mentioned concerns

APPENDIXI.3: CONSENT

I ……., voluntarily participate in this study. I understand that the project designed to gather information about "**Digital labelling feature integration with OpenMRS design to mitigate HPV specimen identification errors. Case of Ruhengeri Referral Hospital."** My participation in this study is voluntary. I understand that I will not be paid for my participation. I may withdraw and discontinue participation at any time without penalty. I understand that the researcher will not identify me by name in any reports using information obtained from this study, and that my confidentiality as a participant in this study will remain secure. I have read and understand the explanation provided to me. I have had all my questions answered to my satisfaction, and I voluntarily agree to participate in this study. I guarantee anonymity for the information collected and will be looked at by responsible individuals and will be used for the purpose of this study only.

My signature …… Date ……

7.4 APPENDIX II: ETHICAL CLEARANCE CERTIFICATE

UNIVERSITY OF RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 14/11/2022
Ref: CMHS/IRB/488/2022

NIYITANGA TUYIZERE Marcellin
Health Informatics Program,
Center of Excellence in Biomedical Engineering and E-Health (CEBE)
CMHS, UR

Dear NIYITANGA TUYIZERE Marcellin,

RE: ETHICAL CLEARANCE

Reference is made to your application for ethical clearance for the study entitled ***"Digital labelling feature integration with OpenMRS design to mitigate HPV specimen identification errors. Case of Rwinkwavu referral hospital".***

Having reviewed your application and been satisfied with your protocol, your study is hereby granted ethical clearance. The ethical clearance is valid for one year starting from the date it is issued and shall be renewed on request. You will be required to submit the progress report and any major changes made in the proposal during the implementation stage. In addition, at the end, the IRB shall need to be given the final report of your study.

We wish you success in the implementation stage.

Assoc. Prof. Stefan Jansen (PhD)
Acting Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:

- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate studies, UR

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