

**Master Thesis**

**An Investigation into Quality Management Risks and its Impact  
on Biobank Operations of the National Health Laboratory Service  
(NHLS)**

**Biobank Risk Management**

**Bonginkosi Duma**

For the academic degree of

**Master of Science in Biobanking  
(MSc)**

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Under the supervision of

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*Statutory Declaration*

*I declare on my honor that I have written this dissertation independently and without assistance, that no sources other than those cited were used and that the sources used verbatim or in substance have been marked as such.*

*Graz, 21.12.2022...B Duma...*

## Foreword

As I came to understand the importance of biobanking, the quality of its processes and what motivates the biobank staff is the quality of its processes. The biobank objectives must ensure its constant existence and sustainability by managing its risks.

## **Acknowledgement**

I'm grateful to my lecturers at MUG for this wonderful course. I'm thankful to my mother, brother and kids for the support. I'm enormously grateful to my supervisor Prof Berthold Huppertz.

## **Abstract (German)**

Die als Biobank bekannte Zweigstelle der National Health Laboratory Services (NHLS) ist für das Sammeln und Aufbewahren von Biomaterialien für den kurz- und langfristigen Gebrauch durch Forscher zuständig. Ein Qualitätsmanagementsystem und mehrere Forschungsprogramme sind beide Teil der Biobank als Ganzes. Die Initiativen beinhalten Risiken, die Einfluss auf den Betrieb der Biobank, das Qualitätsmanagementsystem und den organisatorischen Betrieb haben können. Die Leistung des Unternehmens wird durch das Qualitätsmanagement (QM) des Biomaterials in der Forschung und das Vertrauen in die gelieferten Ergebnisse beeinflusst. Die Biobank kann in Bezug auf die Speicherung von Biomaterial und Daten effizienter arbeiten, indem sie das Risikomanagement in die Praxis umsetzt. Die Effektivität der Organisation wird regelmäßig evaluiert und verfolgt. Es ist unklar, wie sich der Einsatz der risikobasierten Analysen auf den Betrieb der Biobank auswirken wird.

Die Auswirkungen auf die Risikominderung umfassen eine Erhöhung der Anzahl der Forscher, die die Biobank nutzen, eine Erhöhung der Mitarbeiterschulung, laufende Qualitätsaudits des QM-Systems, die Entwicklung neuer Verfahren und die Sicherheit von Biomaterial und den damit verbundenen Daten. Die in der Biobank implementierten Verfahren dienen als Nachweis des identifizierten Risikos sowie der Minderung und des Managements, die nach der Implementierung des QM im Kontext dieser Studie stattgefunden haben. Auch die Mitarbeiter der Biobanken werden betroffen sein, da sich ihre Arbeitsweisen ändern müssen. Schulungen sind auch erforderlich, um die Mitarbeiter mit den neuen Arbeitspraktiken vertraut zu machen und ihre Fähigkeiten in ihren derzeitigen Rollen zu verbessern.

Die Implementierung des Risikomanagements bietet die Möglichkeit, die Bereitstellung von Biobankdienstleistungen, das Biomaterialmanagement und die Datensicherheit zu verbessern.

## **Abstract (English)**

The National Health Laboratory Services (NHLS) branch known as the Biobank is in charge of gathering and preserving biomaterials for both short- and long-term use by researchers. A quality management system and several research programs are both part of the Biobank facility as a whole. The initiatives involve risks that may have an influence on the biobank's operations, the quality management system, and organizational operations. The performance of the company is impacted by the quality management (QM) of the biomaterial in research and confidence in the outcomes delivered. The biobank can work more efficiently in terms of storing biomaterial and data by putting risk management into practice. The effectiveness of the organization will be regularly evaluated and tracked. It is unclear how the risk-based analyses' deployment will affect the biobank's operations.

The impact on risk reduction includes an increase in the number of researchers using the biobank, an increase in staff training, ongoing quality audits of the QM system, the development of new procedures, and the safety of biomaterial and the data it is connected with. The procedures implemented in the biobank will serve as a demonstration of the risk identified as well as the mitigation and management that took place following the implementation of the QM in the context of this study. The biobank employees will also be impacted because their working practices will need to change. Training will also be required to acquaint staff with the new working practices and to enhance their abilities in their current roles.

Implementing risk management offers the chance to enhance the biobanking service delivery, biomaterial management, and data safety.

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## **Glossary and Abbreviations**

NIOH	National Institute for Occupational Health
NCR	National Cancer Registry
NB	National Biobank
QM	Quality Management
NICD	National Institute for Communicable Diseases
QMR	Quality Management Risks

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# 1 Introduction

## 1.1 Quality Management Systems

At the National Health Laboratory Service (NHLS), a biobank is a part of the service that gathers biomaterials, which are samples taken from both live and demised people and are capable of revealing any clinical information. An integrated organizational effort called quality management (QM) aims to raise the quality of everything. Poor quality is made worse when corporate employees lack the authority to address flaws in the quality of their work or do not appear to be motivated to do so (Dale 2015). Such an attitude results in lost clients, and in the case of a biobank, it results in lost researcher and donor communities as well as missed possibilities for competitors to profit from the demands of researchers. Research into biomedicine is the goal of biobanks, which may be public, non-profit organizations that maintain one or more collections of biological samples of human origin for scientific studies. These collections are arranged according to technical criteria that include quality, order, and purpose (Cortes et al. 2014). The current industry standard for general quality is ISO9001:2015, which is utilized with quality management systems (QMS).

Documenting methods, procedures, and accountability for achieving quality is done through quality management systems. According to Swanepoel et al. (2008), many firms employ a quality management system (QMS) to make sure that all facets of controlling the organization's quality are covered. The whole collection of organizational policies and procedures are contained in the QMS, which also specifies the documentation and tools to be used in their implementation.

This organization's quality management system establishes rules for every department that could potentially have an impact on the sample or data resource. Implementing this standard has been utilized to carry out prevention-related quality assurance and quality control activities. According to Swanepoel et al. (2008), it makes little difference how a company conducts business. The evolving paradigm of quality, along with how it is measured, applied, or observed, and ultimately embraced as an approach to the company as a whole, are significant issues to take note of, according to Swanepoel et al. (2008). Additionally, inspection is becoming less common, which is almost like how quality control and quality assurance were policed. The goal of quality assurance is to find areas for improvement that the

organization is able to assess itself and consistently recommend improvements on their own volition, as opposed to inspection, which involves an external person or body comparing performance to standards. This indicates that businesses do not raise quality standards because they must be prepared for an inspection; rather, they do so because they value providing customers with high-quality goods and services. According to Betsou et al. (2008), a successful biobank has various design components that ensure the material is maintained safely, support the equipment used, and offer a secure and productive working environment for the biobank operators, and understanding the materials being stored and the ideal storage environment. A successful biobank design depends on the anticipated retention times and material uses.

According to Steenkamp (2013), the method used to attain overall quality is what sets it apart from conventional business practices. Total quality is characterized by its obsession with quality, focus on both internal and external customers, long-term commitment, teamwork, continuous process improvement, bottom-up education and training, freedom through control, unity of purpose, employee involvement, and employee empowerment - all of which are specifically intended to support organizational development. According to Gustafsson (2016), the creation of a quality management system is a constant process of improvement. When a corporation gains experience or the business environment is disturbed by a worldwide, unforeseen event, plans and demands may change. The commitment from the top to define priorities in optimal resource allocation during the design and implementations of an ISO 9001 quality system is a crucial component of this endeavor. Those elements are crucial if a company wants to keep getting better and gain long-term advantages from having a quality management system in place.

Gustafsson (2016) claims that developing a quality management system is a never-ending process of improvement. Plans and expectations may alter as a company matures or if a big, unanticipated incident disturbs the commercial environment. A key element of this endeavor is the commitment from the top to identify priorities in the best resource allocation during the design and implementations of an ISO 9001 quality system. According to Kaziliunas (2010), sustained efforts are crucial in the post-certification era. If a business wants to maintain improving and get the benefits of having a quality management system in place, those components are essential.

## **1.2 Biobank Risks**

The process of discovering, evaluating, and controlling dangers to the organization is known as risk management. You must take into account each case, project, and exposure that the biobank project faces when managing risk. According to Kendrick (2003), while it is impossible to anticipate an individual project's exact outcome in advance, it is possible to estimate the range and frequency of possible outcomes. In order to address causes, risk avoidance is necessary, either by eliminating risk or by reducing its likelihood or potential impact (mitigation). The projected effects of the event and the likelihood that the event will occur combine to create risk.

Lack of staff training and knowledge, resolving quality-related non-conformances, equipment failure, customer satisfaction, health and safety risks, and psychosocial risk, which includes employee behavior and attitude, are the recognized quality-related biobank risks. According to Kendrick (2003), risk can either be described as an overall measure for a vast population of events (macro hazards), or it can be evaluated event by event (micro risks). Risk perception, according to Rohrman (2008), is the way in which individuals assess the dangers to which they (or their facilities, or environments) may be exposed. Such perceptions guide choices regarding the acceptability of risks and are a major factor in actions taken before, during, and following a disaster. People's risk assessments are a complicated outcome of hazard characteristics and individual mindsets. People's intents to assess a risk scenario favorably or unfavorably and respond accordingly are known as risk attitudes. Risk inclination and risk aversion, or caution, are the fundamental characteristics. Hazards can result from high risk propensity, yet risk management efforts may call for some risk propensity. Risk attitudes are not uniform or always constant across different hazard kinds, though.

### **Possible consequences of the risk in the biobank are:**

- Loss of samples and data
- Loss of money and time
- No new projects or third party money of funding
- Injury to biobank staff
- No space for samples and thus resulting in not being able to take new projects and collections of samples
- Cessation of biobank operations

The formulation of a strategic quality plan that is compatible with the overall organizational goals is facilitated by understanding and quantifying the cost of subpar quality and risk controls, as well as the other evaluation components. The primary factors that make up the cost of poor quality - which apply to both manufacturing and service organizations - reflect not only the cost of nonconformities but also the impact of processes on sales income and process inefficiencies. According to Gyra et al. (2007), expressing the magnitude of the quality problem in monetary terms enhances communication between middle managers and higher managers.

In some businesses, starting a study of the consequences of poor quality and inadequate risk management has made improving communication on quality and risk-related concerns a primary goal. This cost can be measured as a way to assess the success of quality improvement initiatives and highlight roadblocks to advancements. Because the biobank works on a variety of projects, project planning is crucial to minimizing scheduling risks. The project team must review the biobank's plans and discuss potential concerns. Resources in the biobank may be risky. According to Kendrick (2003), most resource hazards are related to bottlenecks and restrictions. A biobank has to conduct a sufficient resource analysis to balance its skill requirements and project budget with the staff that is on hand.

Auditing based on processes is more efficient. The auditor identifies the outcomes that the organization hopes to achieve, confirms that these outcomes take into consideration the demands of the clients and other interested parties, and then looks at how the processes are run to bring about these outcomes and enhance performance. There will not be a solid foundation for reporting non-conformities if evidence shows that a company is satisfying customers and other interested parties and using quality management concepts in how it conducts business (Kaziliunas, 2010). It is possible to identify ways to lessen consumer unhappiness and the associated risks to the capacity to sell products. Failures of products after a sale lead to some costs associated with poor quality. However, whether or not the manufacturer bears the costs, the failures increase consumer costs because of downtime and other types of disruption.

### **1.3 Biobank Operations**

The collecting of human biospecimens, processing of the specimens and related data, and storage of biospecimens are all regular procedures at a biobank depending on the many programs. Because NHLS is a sizable biobank, it has organizational structures. Staff members who have specific functions and committees with roles and responsibilities for quality and health and safety make up the operational structures of the biobank. Procedures for sample access, equipment maintenance, supply, and resource acquisition are all part of the biobank's operations. Planning and resource management are required.

Operation in the biobank needs to guarantee accurate, dependable, and reliable biospecimen processes and data that satisfy the objectives of researchers or clients. The operation of a biobank makes sure that there are enough supplies of high-quality inputs created specifically for the biobank and produce high-quality outputs that clients are prepared to litigate for. The labor, employees, raw materials, and component parts that go into biobank operations make up the input. Ultra-freezers, computers, and other devices are used in the conversion stage, and the product is high-quality work. Collection of specimens, receipt into the biobank, processing, and storage are all included in biobank operations.

The biospecimen and its related data can be tracked using the biobank's information technology system. When collecting and identifying specimens and data, tracking of those items takes place. Each study's data components are taken into account. Data protection and security are crucial as a result. According to Stair and Reynolds (2009), the majority of users desire to get access to as much of the database's data as they can. Policies must be created to outline what data users may access because data may be confidential. Additionally, it is necessary to write down the details of what data can be read, uploaded, downloaded, and modified.

To comprehend the costs associated with running a biobank, normal business processes must be used due to the significant resource costs of gathering, processing, and storing huge collections of biospecimen. These expenses cover labor, tech support, quality control, and informatics.

Equipment upkeep, staff training, record keeping, data management plans, development and control of stand-by procedures, health and safety management,

customer focus, process and handling of biospecimens, document control system, internal auditing, and staff training are all required by the biobank quality management system. A rigorous review procedure must be used to identify and resolve any systemic flaws, and the flaws or non-conformances must then be adjusted or corrected (Vaught and Lockhart, 2012).

According to Gustafsson (2016), the creation of a quality management system is a constant process of improvement. When a corporation gains experience or the business environment is disturbed by a worldwide, unforeseen event, plans and needs change course. The management of the organization must adhere to and frequently assess the quality management system, for example through external audits. The findings of an audit are not always bad, and the provided "improvement recommendations" should not be viewed as criticism when appropriately implemented; they could even lead to new ideas. The process descriptions are a crucial instrument for implementing such advice and they should be updated.

The customer is the main factor when it comes to entire quality. This statement is true for both internal and external clients. The caliber of the service or product provided is determined by external customers. Internal consumers contribute to defining the standards for the settings, systems, and people involved in the production of the goods or services. A thorough quality management strategy must be in place, and resources must be given, for all quality-related processes to be carried out.

Due to their ability to continuously develop people, education and training are essential to quality and risk management. People are taught how to work hard and learn how to work smart through education and training.

Risks associated with quality can reveal conformance, increasing the worth of quality management systems. The fact that these judgements are based on current performance and frequently all the audit shows is current conformance. Current performance means that they invariably do not give data for managerial decisions concerning staff development, technology, growth, product, and procedure. The organization's strategy plan for implementing quality management systems is intended to offer it a long-lasting competitive advantage at work.

#### **1.4 The quality management system at the NHLS biobank**

The adoption of the NHLS biobank quality management system has increased the risk associated with biobank operations. The risk impact of quality management on organizational performance has not been studied. The storage and processing of biomaterials become more effective and efficient as a result of organizational performance. The control and mitigation of hazards enhance the quality of the specimens, which in turn enhances the output of clinical research. Because of the risks inherent with the quality management system's installation, the performance of the biobank has been affected. To ensure that these risks have little to no impact on the functioning of the biobank and the effectiveness of the organization, they must be recognized, assessed, and controlled.

#### **1.5 Aim of the study**

The objective is to look into, examine, and evaluate quality management issues, as well as determine how they affect biobank operations. To reduce the risk to the biobank and enhance operations, the goal is to come to a conclusion about the impact and improvements made in the operations. This thesis intends to demonstrate how the impact of quality management risk can be lessened and how to develop strategies for reducing risk and maintaining the sustainability of the biobank. Recommendations will be made on how the risk found in the biobank operations can be controlled and what improvements are needed.

#### **1.6 Focus of the study**

The following questions were addressed as part of this thesis:

1. What are the current biobank quality risks?
2. How does implementation of quality management risks affect biobank operations?
3. What recommendations can be given after implementation and the impact of the risks of a QMS on biobank operations?

## **1.7 Hypothesis**

The hypothesis of this study is as follows:

- The current quality management system and its shortfalls in the biobank are affected by the risk plan within the NHLS biobank.
- Researchers anticipate gaps in the implementation of biobank risk identification, analysis, mitigation and monitoring that impact the operations and quality management.

## 2 Methodology

### 2.1 Overview

50 individuals with 31 females and 19 males from various levels of employment inside the biobank and researchers were asked to participate in this study. The poll used a Likert scale to ask specific questions. The questionnaire had 12 questions that were divided into 10 sections to address the following:

- Understanding of biobank risks
- Management involvement
- Training of biobank staff
- Allocation of resources within the biobank
- Customer satisfaction
- Biobank quality-related risk audit
- Risks identified
- Employee involvement
- Benefits
- Attitude of staff

Because some of the participants' experiences with the biobank operation and quality management may vary in terms of hazards, there was a mix of male and female participants. The study focused on the biobank's employees, management laborers, and medical researchers and scientists that utilize the facility. Both men and women worked as biobank staff. Biobank employees, technicians, medical scientists, and researchers are among the participants.

Interviews were used to get data on the risk of using biobanks. The biobank is subject to a variety of operational hazards, including those connected to quality management systems, the environment, macroeconomics, and microeconomics. Following the gathering of responses, interviews with participants were conducted to elicit further information and clarification on their responses, particularly with regard to benefits and attitudes. NHLS employees who do not work at the biobank and scientists and researchers who are not affiliated with the biobank were among the exclusion criteria and researchers that do not use the biobank. Anonymity was maintained during the whole analysis of the study's data. Some individuals had

employment histories spanning two years or more. A letter inviting them to participate in the study was sent to them as part of the recruitment process via email.

## **2.2 Pilot Study**

A pilot study is a scaled-down version of a larger study or a test run conducted in advance of the full investigation. This second research is often known as a "feasibility" study. It could also be a particular pre-testing of questionnaires or interview schedules as part of a research study. In the paragraphs that followed, the researcher first described the importance of a pilot study as stated by several authors before discussing how it applied to the current investigation. After outlining the importance of such a study, the researcher put together a pilot study's objectives for the ongoing investigation (Arain et al. 2010). Ten biobank employees first participated in a pilot study before 40 individuals were added for the main investigation.

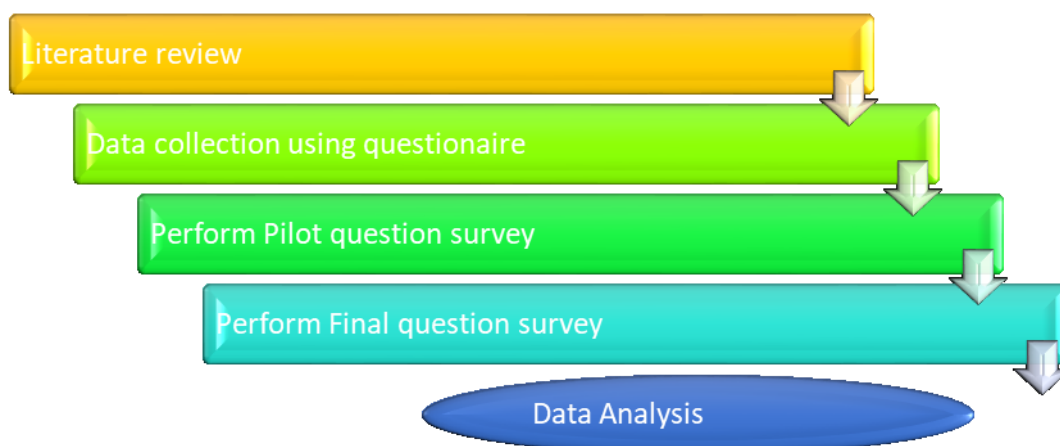
## **2.3 Data Collection**

To answer specified research questions, test hypotheses, and assess results, data collection is the act of acquiring and measuring information on variables of interest in a systematic and defined manner. A questionnaire with a Likert scale was employed for the research objectives. Through the creation of numerical data that may be converted into useful statistics, the study used the Likert scale to quantify the issue. Face-to-face interviews offer the researcher the unique advantage of allowing them to get to know potential subjects personally and win their cooperation (De Bruin, 2010). The purpose of the reflective data collection was to allow the participants the chance to communicate their experience, knowledge, and understanding. Face-to-face interviews and questionnaires are tools used in data collection. In light of the hazards discovered in the biobank over the previous years, I questioned the respondents about their quality management systems. In order to increase response rate and response accuracy, I made a pledge of secrecy and did not ask for the respondents' identities. In survey research, these interviews produced the highest response rates. They also let the researcher to clarify unclear responses and, where necessary, request additional data. A disadvantage is that it is time-consuming, expensive, and impractical when dealing with big samples. After performing a pilot research and soliciting feedback from the respondents, I further

improved the questionnaire to make it more user-friendly, clear, intelligible, and straightforward.

The figure 2.1 below shows the process on how the data was collected. The study included literature review on previous research on quality management systems and risks. The literature review process involved review of guidance and published studies. Published studies were identified through search on Pubmed, Researchnet, and Google Scholar using the keywords “quality management” or “risk management” or “quality management risk” and “biobank”. Journals from Biorepository and Biopreservation were also searched for information such as Implementation of a quality management and accreditation and accreditation by Mouttham et.al (2021). Guidance documents used included project risk books e.g. Identifying and Managing Project Risk by Tom Kendrick. The other search journals were used as referenced article and are stated in the reference list. Data was reviewed and analyzed to identify agreement and areas of uniqueness between guidance documents. This gave this study a theoretical base for the research questionnaire and to phrase them in line with the focus of the study. Methodology stages were identified and defined. This was followed by collection of data using questionnaires and the performance of a pilot study. The data was collected from participants who were willing to participate and also eligible participants. Interviews were performed to gather opinion, perception, attitude and expect knowledge. The final survey was followed by data analysis after collecting all the data set by the study requirements.

**Figure 2.1 Data Collection Process**



## **2.4 Interviews**

In this study, information was acquired by using the questionnaire to interview the participants in a peaceful, disturbance-free environment where they felt at ease. Individual interviews lasted 30 to 40 minutes each. The personal interview approach was chosen for this study because it gave the information required to understand the goal of the investigation and was relevant to the choice made. The purpose of the study's interview guide was to provide answers to the study's research questions. The interview tool was created to use clear language whenever possible. The approach most frequently employed for this study is one-on-one interviews, during which participants are explicitly asked questions. To minimize jargon, the questions were also straightforward. The questionnaire was forwarded to the medical scientist and management, who then responded and returned it back as they could not sit for interviews. The exercise's goal was to create questions that responders, not the researcher, would find simple to answer.

## **2.5 Cohort**

This study provides a quantitative breakdown of the risks associated with quality management that have an effect on biobank operations. The impact of the quality-related risk that was experienced at the biobank was predicted using the quantitative description approach. The method is used to describe the risks that have been identified and how to manage them to eliminate or lessen their impact on the operations of the biobank. 62% of the participants in the study were female, whereas 38% were male. The age range of the participants was 18 to 49 years. Based on the kind of study questions employed, the researcher was able to classify the results and statistically display them on the table. The people who work in other departments besides the biobank were not included in this study. The biobank medical scientist, biobank administrators and biobank researchers were included.

## **2.6 Limitations of the Research**

The study's restriction was based on the fact that there are not many biobanks in the country and that not many people in organizations have a thorough understanding of biobanks yet. The investigation was carried out at NHLS with the

assistance of other local researchers. In South Africa, there are not many biobanks available. Other researchers do not fully understand how biobanks work because they do research that does not result in sample biobanking.

## **2.7 Data Analysis**

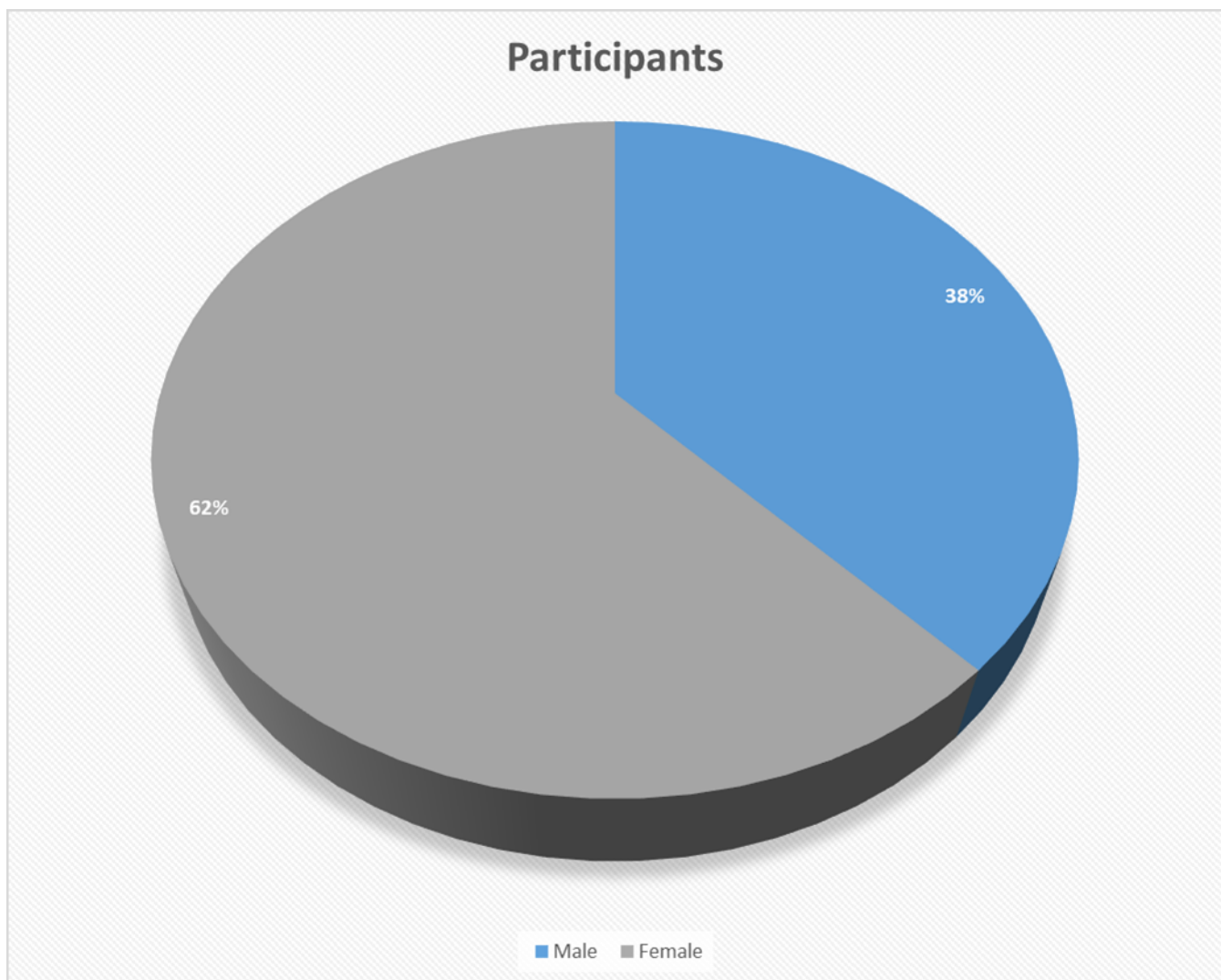
Based on the participant's responses, the data was evaluated using graph statistics. This was done using calculation of the percentage of responses by male and female using percentages. The science of gathering, arranging, analyzing, and interpreting data in order to make decisions is known as statistics (Asadoorian and Kantarelis, 2005). The statistical calculation was done using the t -test. The t- test is used to assess the difference between groups to see whether their mean values show a significant difference. The p value is used to identify the sample distribution of the test sample data and to test the null hypothesis. The Math portal software was used for the calculation of the t- test and p- values. The information is based on how the risk is affecting the participants and how it affects the biobank's operations. The t- test was used to determine the critical value and if T is smaller than the critical value then there is no significant difference. The critical value defines regions in the sampling distribution of the test statistic. This value plays a role in both hypothesis testing and confidence intervals. The p value on the results tells us the likelihood that the data occurred under the null hypotheses. The lower the p value the greater the statistical significance of the observed difference. The results demonstrate how quality management risk is perceived and how that influences whether a biobank can operate successfully or not depending on how some of the identified risks are handled.

Lickert scale data are analysed at the interval measurement scale. Lickert scale items are created by calculating a composite score (sum or mean) from four or more types. Descriptive statistics recommended for internal scale items include the mean for central tendency and standard deviation for variability (Boone and Boone, 2012). In this study, the results calculated in percentages are multiplied by scale number and then divided by 100 to get the mean.

### 3. Results

#### 3.1 Characteristics of participants

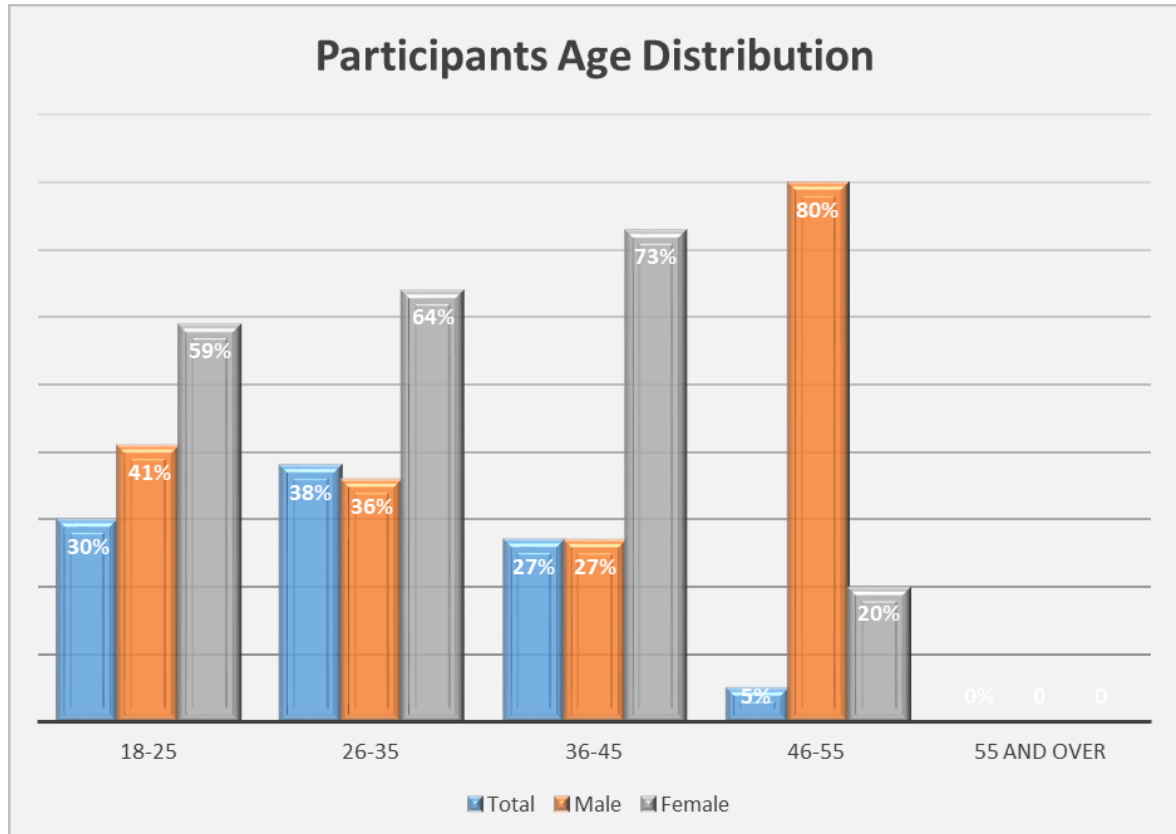
Figure 3.1 below shows the proportion of participants in the survey according to gender. 62% of the responding participants were female and 38% responders were male. The 62 percent of the 50 participants that were part of the study and the 38% of the 50 participants. The female participants are in grey color and the male participants are in blue color, Figure 3.1 Participants' Gender



## Participants Age Distribution

Figure 3.2 below show the participants' age range across the different levels of employment within the biobank. The blue graph represents the percentage of the total participants age distribution. Within the age distribution there is a breakdown of the female and male representative in percentages. The age distribution of 18-25 is 30 % of the overall participants and within that 30 % there is 59% female representative and 41% male representatives. The age range 26-35 (38%) has the highest number of participants. The 38% is made up of 64% female participants and 36% male participants and this is followed by the younger staff of age between 18 and 25 (30%). The middle-aged staff (35-45) constituted 27% of the participants. The age distribution of 46-55 years constitutes 5% of all the age distribution. Within the 5 % there is 80% percentage male participants and 20% female participants. The participants were also distributed according to male participants and female participants with the age range. There were no participants that were 55 and over.

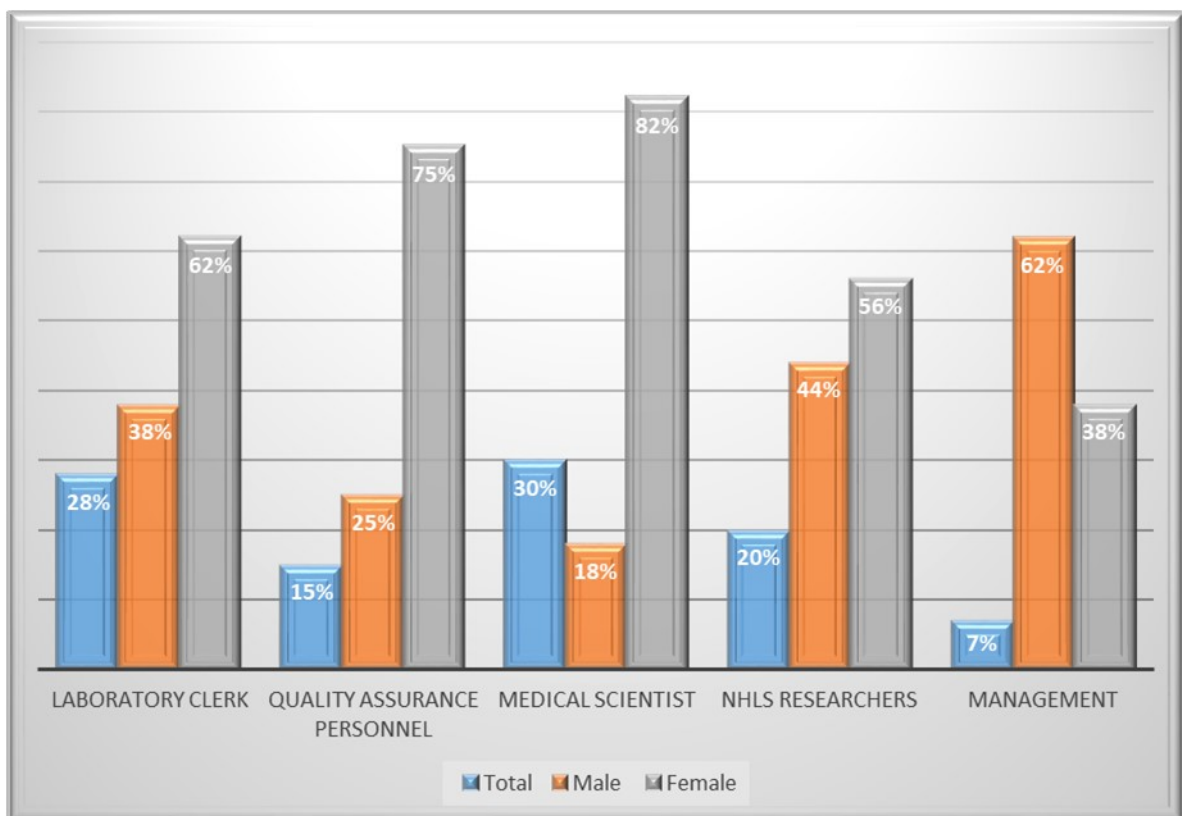
Figure 3.2 Participants Age Distribution



## Participants' Work Positions

Figure 3.3 below shows the working position of participants. The blue graph percentage represent the total of participant's work positions. The work position was also broken down to male and female respondents within the different working positions. The laboratory clerks have 28% of the total work position and within the 28% the total number of female participants constitute 62% and the male participants are 38%. Quality assurance personnel are 15 % of the overall participants and within the quality assurance personnel there is 75% of participants and 25% male participants The medical scientists have the highest proportion of 30% overall participants within 82% female participants and 18% male participants while the NHLS researchers made up 20% overall participants with 56% female participants and 44% male participants and the management of the organization made up 7% of all participants with 38% female participants and 62 % male participants..

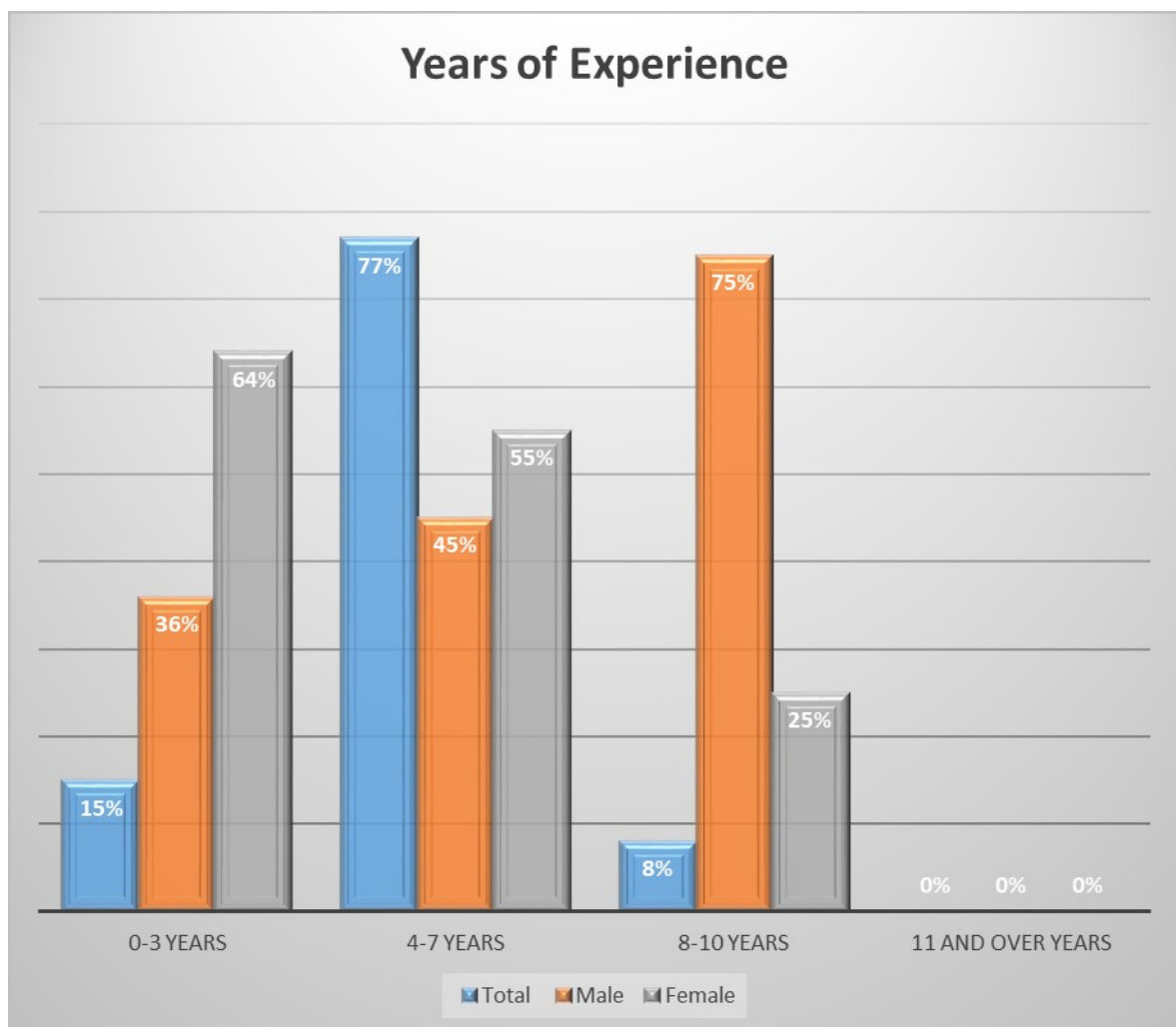
Figure 3.3 Participants' Work Positions



## Years of Experience

Figure 3.4 below shows the number of years of experience from the staff and the highest proportion with 77% is found in 4-7 years of experience. The biobank existed only from 2012 and the biobank projects increased from 2016 resulting in the increase of staff recruitment drive. The participants' years of experience were also broken down to male and female participants. The blue graph percentage represent the total of participant's work positions. The 0-3 years has 15% of the total participants with 64% female representative and 36% male participants. The 4-7 years has 55% female participants and 45% male participants. The 8-10 years has 8% of the total number of participants 25% female and 75% male. There are no participants that have 11 years and over experience.

Figure 3.4 Participants' Years of Experience



### 3.2 Presentation of Interview Results

This study analyzed the results that were collected during the interviews of participants. Participants were asked to rank their response on the questionnaire from strongly disagree to strongly agree. The responses based on the interviews were analyzed in this chapter.

#### Response Assessment Matrix and Mean Range

- 1 Strongly disagree – absolutely not agreeing
2. Disagree – not agree with some reservations
3. Undecided – not sure whether to agree or disagree
4. Agree – agree but with some reservations
5. Strongly agree – absolutely agree with the statement

Response assessment matrices below show the response from different genders and the extent to which they perceive the implementation of quality management systems and risk and its impact.

#### Understanding biobank risks (strongly disagree = 1 to strongly agree = 5)

Section	Gender	1	2	3	4	5
Understanding of biobank risks	Male	0%	1%	5%	43%	51%
	Female	0%	2%	7%	47%	44%

**Mean:** Male = 3.94 Female = 4.33

**Variance:** Male = 81.6 Female = 93.4

**Standard Deviation:** Male = 0.90 Female = 0.97 t = -0.132

P value <0.05, Critical value = 2.31 T < critical value = no significant difference

The male respondents mean is lower than the mean of the female respondents. Male and female participants have low standard deviation and this means they are both closer to the respective average mean of data. The female participants strongly agree to the understanding of risks than the male respondents who agree. The variance of both male and female participants differ and the female has higher variance than the male and this means that the data points of female respondent are less similar than the data points of the male participants. The t value of -0.132

is lower than the critical value of 2.31 this means the results has no statistical significant difference between the male and the female respondents. However, the low P value of <0.05 shows that the observed difference between male and female is significant. Their female and male responded understanding of risk may differ in the terms of means but they still agree in terms of understanding of the Biobanking risks. Less than 10% statistically separates the male and female participants in terms of agreement. This demonstrates that, despite certain variances, the perspectives of the two sexes on risk are essentially comparable.

**Management involvement (strongly disagree = 1 to strongly agree = 5)**

Section	Gender	1	2	3	4	5
Management involvement	Male	0%	0%	2%	58%	40%
	Female	0%	0%	4%	51%	45%

**Mean:** Male = 4.38 Female = 4.41

**Variance:** Male = 110.9 Female = 106.9

**Standard Deviation:** Male = 10.5 Female = 10.3 t = - 0.009

P value <0.05 , Critical value = 2.31 T < critical value = no significant difference

When comparing the male participant mean and female participants mean, the female mean is higher than the male mean, that means more female participants were in agreement about the management involvement in the quality management risk. Both male and female agree on the involvement of management as data suggest. The standard deviation for both genders is similar and this means they are both not have similar results. The results show that for both genders the dispersion towards the mean is at 10. T test has shown that the t is at -0.009 and this means that T test is lower than the critical value of 2.31. The means of male and female participants are not statistically significantly different in the way they view the management involvement in quality management risks. However, the P value of <0.05 shows that the observed difference between male and female is significant. Data shows that the management's involvement in the quality management risks in the biobank, both male and female participants in the biobank expressed strong agreement.

**Training (strongly disagree = 1 to strongly agree = 5)**

Section	Gender	1	2	3	4	5
Training	Male	2%	10%	12%	52%	24%
	Female	5%	7%	10%	60%	18%

**Mean:** Male = 3.86 Female = 3.79

**Variance:** Male = 59.1, Female = 76.2

**Standard Deviation:** Male = 0.77. Female = 0.87 t = 0.027

P value <0.05 , Critical value = 2.31 T < critical value = no significant difference

Training responses have shown that male participants are in agreement with mean of 3.86 higher than the female participants mean of 3.79. Both gender data sets show agreement on the training done in the biobank.

There were a variety of responses to training, including workers who vehemently disagreed with the biobank's training objectives. Data shows that they are male participants and female participants who strongly disagreed to the training done. The responses may differ but the standard deviation data suggest that both genders are close to their respective means. The majority of the responses from both male and female participants were in agreement, but not strongly agree. The T test is 0.027 that is below the critical value of 2.31. This suggest that there is no statistically significant difference in the responses for both genders. The P value of <0.05 shows that the observed difference between male and female is significant. Training of staff is a component of the management goals when creating a risk objective. Several participants, including scientists and office workers, expressed their satisfaction with the education they had received so far.

*"I'm fine with the training and I received from the quality department; it included document control risk management, writing of non-confirming work, and health and safety", an administrative staff member said. When creating a quality management system, management objectives include training. The participants, which included administrative workers and scientists, acknowledged their pleasure with the instruction they had received so far. The means of both data sets are equal so we can conclude that there is no significant difference between them.*

**Allocation of resources (strongly disagree = 1 to strongly agree = 5)**

Section	Gender	1	2	3	4	5
Allocation of resources within the biobank	Male	8%	12%	25%	33%	22%
	Female	15%	18%	30%	27%	10%

**Mean:** Male = 3.49 Female = 2.99

**Variance:** Male = 22.9 Female = 11.8

**Standard Deviation:** Male = 0.48 Female = 0.34.  $t = 0.378$

P value <0.05, Critical value = 2.31  $T < \text{critical value} = \text{no significant difference}$

When comparing the male participant mean and female participants mean, the female participants mean is lower than the male participants mean, that means less female participants were in agreement about the allocation of resources within the biobank. Data shows that the T test results at 0.378 is lower than the critical value of 2.31 and this suggest that means of male and female participants are not statistically significantly different. However, the P value of <0.05 shows that the observed difference between male and female is significant. The female mean at 2.99 suggest that more female participants are on neutral side than the male participants.

The allocation of resources to biobank operations and risk has demonstrated that diverse perspectives exist inside the biobank based on one's position within the organization. Data shows that some male respondents agreed with the allocation of resources, compared to some of female respondents, and that female participants have the highest level of dissatisfaction. The administrative and scientific employees at the biobank disagree with the allocation of resources in general. Some participants concurred that overall resource allocation in all biobank processes had been satisfactorily done. Other people disagreed with this, though. The first member to disagree claimed that *"under the processes for health and safety, N95 face masks are running low"*.

**Customer satisfaction (strongly disagree = 1 to strongly agree = 5)**

Section	Gender	1	2	3	4	5
Customer satisfaction	Male	0%	2%	3%	51%	44%
	Female	0%	3%	8%	59%	30%

**Mean:** Male = 4.37 Female = 4.16

**Variance:** Male = 1.04 Female = 0.88

**Standard Deviation:** Male = 1.02 Female = 0.94.  $t = 0.068$

P value < 0.05, Critical value = 2.31  $T < \text{critical value} = \text{no significant difference}$

Customer satisfaction data shows that male participants have a higher mean of 4.37 than the female participants mean of 4.16. Data suggests that there was consistency in the response between male and female participants on the topic of customer satisfaction. T test results are 0.068 and that is below the critical value of 2.31. This means that there is no statistical difference between the respondents on this topic. However, the P value of < 0.05 shows that the observed difference between male and female is significant. The standard deviation between the two genders where male is 1.02 and female is 0.94 respectively suggest that both genders responses are close to the mean. The results of the study have demonstrated that the biobank's customer-focused approach to adopting the QM has improved customer service. Processes used by biobanks to gather and store samples were becoming more effective. Additionally, this has strengthened the expertise and self-assurance of the workforce. The means of both data sets are equal so we can conclude that there is no significant difference between them.

#### **Biobank quality related risks audits (strongly disagree = 1 to strongly agree = 5)**

Section	Gender	1	2	3	4	5
Biobank quality –related risk audits	Male	7%	13%	21%	35%	24%
	Female	9%	7%	17%	40%	23%

**Mean:** Male = 2.56 Female = 3.49

**Variance:** Male = 26.7 Female = 34.7

**Standard Deviation:** Male = 0.52 Female = 0.59  $t = 0.04$

P value < 0.05, Critical value = 2.31  $T < \text{critical value} = \text{no significant difference}$

The Biobank quality related risk data and means for both male participants and female participants have shown that the male participants are lower at 2.56 than the female participants at 3.49. The male participants suggest that there is a disagreement with the biobank risk related audits. The female participants mean

suggest that they are neutral in the way that the risks are conducted. The t test score of 0.04 is lower than the critical value of 2.31 that means both data sets have no statistical significant difference between them. However the P value of <0.05 shows that the observed difference between male and female is significant. The standard deviation for both genders is low at 0.52 for male and 0.59 for female. This suggest that the participants data is close to the mean value. The male participant's disagreements will have to be investigated further as all biobank participation in the quality management risk audits are important.

Although it is obvious that an audit will reveal whether or not processes are being followed, the premise guiding them is not one of establishing conformity.

**Risks identified (strongly disagree = 1 to strongly agree = 5)**

Section	Gender	1	2	3	4	5
Risks identified	Male	10%	12%	7%	36%	35%
	Female	13%	16%	6%	45%	20%

**Mean:** Male = 3.74 Female = 3.43

**Variance:** Male = 0.49. Female = 0.40

**Standard Deviation:** Male = 0.70 Female =0.64 t = 0.15

P value <0.05, Critical value = 2.31 T < critical value = no significant difference

The risks identified data has suggested that the female response is lower than the male respondents in understanding of the risks identified. The mean for female participants is at 3.43 and for male participants is 3.74. The male participants are more agreeing with the biobank risks identified than the female participant. The standard deviation is low that suggests that the females and males participants data is close to the mean. The majority of female and male respondents may be similar to each other. The T test value is 0.15 and the critical value is 2.31. The test value is lower than the critical suggesting that there is no statistical significance between the male and female participants. However, the P value of <0.05 shows that the observed difference between male and female is significant.

Although there is no statistically significant difference in agreement, there is over 5% discrepancy in what the participants believe the identified hazards to be. The

participants acknowledged that the hazards were documented. Some participants disagreed, claiming that while they were aware of the risks through quality meetings, they had not seen all of the stated dangers.

**Employee Involvement (strongly disagree = 1 to strongly agree = 5)**

Section	Gender	1	2	3	4	5
Employee involvement	Male	7%	10%	12%	45%	26%
	Female	11%	16%	18%	30%	25%

**Mean:** Male = 3.01 Female = 3.46

**Variance:** Male = 24.4 Female = 21.4

**Standard Deviation:** Male = 0.49 Female = 0.46  $t = -0.27$

P value <0.05, Critical value = 2.31  $T < \text{critical value} = \text{no significant difference}$

The means of both male and female participants at 3.01 and 3.46 suggest that the participants are mostly neutral to the idea of the employee involvements in the biobank quality management risk and its outcomes. The female and male participants view are supported by the standard deviation that is low at 0.49 male and 0.46 female, respectively. This suggests that the participants had similar views and the data is close to the means. The T test result is -0.27 lower than the critical value result of 2.31. However the P value of <0.05 shows that the observed difference between male and female is significant. This means there is no statistical significance difference in the results of the respondents. With relation to their involvement in quality management and risks, the participants' comments differed.

There is some staff that strongly disagrees, with some male as well as female participants felt that they are not completely participating. When asked whether staff members should be involved in implementing the QMS within the biobank and aiding in risk management, the majority of participants strongly agreed.

The other participants in other biobank positions, such as laboratory clerks, believe that staff involvement and participation might be improved. Currently, staff members participate in risk audits, staff meetings, and processes that directly include them.

Another participant felt that they are usually involved when non-conformances need to be closed out and remedied following the audits. This participant's response illustrated how employees are only involved when management requires them.

**Benefits to staff (strongly disagree = 1 to strongly agree = 5)**

Section	Gender	1	2	3	4	5
Benefits for biobank staff	Male	10%	23%	22%	35%	15%
	Female	5%	18%	14%	43%	20%

**Mean:** Male = 3.37 Female = 3.55

**Variance:** Male = 18.1 Female = 34.9

**Standard Deviation:** Male = 0.43 Female = 0,59 t = -0.11

P value <0.05, Critical value = 2.31 T < critical value = no significant difference

Benefits of implementing the quality management risk data are seen similar between male and female responses, with means of 3.37 and 3.55, respectively. The results suggest that the male participants are neutral and the female are in agreement with the benefits to the staff. The female participant's agreement is not strong. This means that some improvements will still need to be made to increase the perception of staff. The standard deviation of both the male and female is low. This suggest that their answers were close to the mean.

Males and females had different levels of familiarity with the advantages of implementing QM and risk management, with females agreeing on these benefits and males more neutral. It is interesting to note that several participants disagreed on the benefits, believing the organization to have benefited more than they had. Furthermore, it should be mentioned that the majority of participants concurred that, based on their responses, the QMR's deployment had a good influence. Participants believe that putting the QMR into practice under ISO 9001 has benefited them since their work is being recognized by clients, which is bringing in more business. Participants also learned how to spot weaknesses in the biobank's QMS and how to fix them. The participant's comments illustrate the goal of having a quality management system, which is to have efficient operations. Some participants firmly agreed that keeping tabs on their performance had advantages. Turnaround times are quicker, there are less mistakes made at work than before, and the procedures are more effective. Their level of assurance in their actions has increased. The comments make it clear that the adoption of the QMR has benefited participants in

various ways, generally had a good effect, and helped to create a culture that is customer-focused.

**Attitude of staff (strongly disagree = 1 to strongly agree = 5)**

Section	Gender	1	2	3	4	5
Attitude of staff	Male	9%	25%	18%	28%	24%
	Female	11%	11%	20%	18%	12%

**Mean:** Male = 3.45 Female = 2.25

**Variance:** Male = 17.3, Female = 5.7

**Standard Deviation:** Male = 0.42 Female = 0.24 t = 1.12

P value <0.05, Critical value = 2.45 T < critical value = no significant difference

The relationship between the attitude of staff impacts on service delivery and impact on customers. In this study, the attitude of staff in quality management risk may impact on the respond to the implementation. The hypothesis suggests that there may be a gap on the implementation of the QMR and it may impact on the biobank services. The mean of the female participant's attitude towards the risk implementation is low with a value of 2.25 that is lower than the male participants' mean at 3.45.

Female participants disagree with a bit of reservation. The female standard deviation is lower at 0.24 than the male participants at 0.42. This means the data of female participants are closer to the mean and they also have similar views. The T test data is lower than the critical value that means there is still no statistical significant difference between the values but this t test result is highest than all the collected data T test value. This means there is a shift in statistical difference will other collected data points. However the P value of <0.05 shows that the observed difference between male and female is significant. Corrective action can be done to correct the difference.

## Participants age range

Participants Age	Age Range	1	2	3	4	5	Mean	Variance	Standard Deviation(SD)
Understanding of Biobank Risks	18-25	10%	23%	22%	30%	15%	3.17	12.99	0.36
	26-35	5%	18%	14%	43%	20%	3.55	34.92	0.59
	36-45	7%	9%	11%	35%	38%	3.88	54.10	0.74
	46-55	0%	2%	8%	48%	42%	4.30	89.15	0.94
Management involvement	18-25	7%	3%	8%	43%	39%	4.04	71.25	0.84
	26-35	1%	13%	10%	36%	40%	3.92	62.38	0.79
	36-45	4%	2%	11%	48%	35%	4.86	97.14	0.99
	46-55	0%	1%	6%	45%	48%	4.77	121.56	1.10
Training	18-25	8%	26%	11%	35%	20%	2.99	26.34	0.51
	26-35	8%	4%	10%	38%	40%	4.61	65.20	0.81
	36-45	4%	1%	13%	41%	41%	4.16	70.33	0.84
	46-55	1%	1%	20%	34%	44%	4.48	89.69	0.95
Allocation of resources	18-25	25%	9%	18%	30%	18%	3.25	12.36	0.35
	26-35	17%	10%	44%	20%	9%	3.04	17.10	0.41
	36-45	14%	32%	16%	28%	10%	2.50	10.69	0.33
	46-55	5%	4%	11%	46%	34%	4.59	78.33	0.89
Customer satisfaction	18-25	3%	1%	14%	51%	30%	4.64	79.66	0.89
	26-35	7%	3%	17%	27%	46%	4.78	84.54	0.91
	36-45	0%	10%	18%	40%	32%	4.79	81.59	0.90
	46-55	0%	2%	10%	48%	40%	4.85	87.56	0.94
Quality Risk Audits	18-25	1%	30%	11%	32%	26%	2.70	21.00	0.46
	26-35	10%	24%	15%	28%	38%	4.62	79.54	0.89
	36-45	6%	3%	17%	50%	24%	3.94	52.55	0.73
	46-55	0%	10%	10%	41%	39%	3.96	70.18	0.84
Risks identified	18-25	1%	25%	7%	49%	18%	3.27	51.86	0.72
	26-35	9%	8%	13%	40%	30%	4.10	61.14	0.78
	36-45	4%	6%	14%	35%	41%	4.22	56.73	0.75
	46-55	6%	2%	18%	40%	34%	3.97	70.95	0.84
Employee involvement	18-25	2%	0%	11%	43%	44%	4.45	80.91	0.90
	26-35	6%	32%	14%	27%	21%	3.25	26.97	0.52
	36-45	9%	12%	19%	34%	26%	3.38	20.63	0.45
	46-55	8%	24%	25%	23%	20%	4.23	45.79	0.67
Benefits to staff	18-25	14%	7%	37%	40%	12%	2.94	14.21	0.38
	26-35	3%	10%	29%	38%	20%	4.08	24.85	0.50
	36-45	22%	24%	22%	36%	16%	3.81	37.67	0.61
	46-55	2%	1%	30%	35%	32%	4.10	42.03	0.65
Attitude of staff	18-25	10%	4%	40%	30%	16%	3.94	20.99	0.46
	26-35	13%	12%	21%	32%	22%	3.92	13.10	0.36
	36-45	17%	13%	22%	40%	8%	4.47	49.74	0.71
	46-55	10%	5%	53%	20%	12%	3.30	28.64	0.54

With the exception of the age range of 18 to 25, where there is no difference in response, participants' comprehension of biobank risks has been consistent across all age groups. Ages 46 to 55 strongly concur with recognizing biobank risks. Except for the age range of 26–35, which just agreed, all age groups that were asked about managerial engagement gave similar replies of strong agreement. The age range of 18 to 35 differs from other age ranges regarding training since they disagree with the institution's training policies. Similar answers of agreement are found for other age groups.

The replies differ depending on how resources are allocated. While other age groups are neutral, neither agreeing nor disagreeing on the subject, there is disagreement with the age range 36-45 with some reservations. It is interesting to see that the management team, who range in age from 46 to 55, generally agrees on resource distribution. Despite the disparity in age groups, participants' responses to questions about customer satisfaction were consistent. Regarding the topic of client happiness, they all firmly concur. According to the quality risk audits data, those between the ages of 18 and 25 had a neutral opinion of risk audit responses, while those between the ages of 26 and 35 strongly agreed.

The youthful employees, aged 18 to 25, felt the need to be more involved in the quality management risk processes. The comments demonstrate resounding support for employee participation. The age groups of 26 to 35 and 36 to 45 have comparable responses that are neutral, but the age groups of 46 to 55 agree to participate in QMR. With regard to staff perks, reactions have varied, although those between the ages of 18 and 25 appear unconvinced. Other age groups give similar answers, and they all concur that the risk associated with the deployment of quality management systems is advantageous.

There is a similar agreement in the change of attitude to most ranges except the age range of 46-55 that is neutral in their responses on the attitude changes.

## Work positions

Topic	Work position	1	2	3	4	5	Mean	Variance	SD
Understanding of Biobank risks	Laboratory clerks	2%	7%	20%	26%	28%	2.92	27.2720.21	0.45
	QA personnel	0%	16%	17%	24%	31%	3.34	29.10	0.54
	Medical Scientists	0%	20%	12%	41%	14%	3.10	30.94	0.56
	NHLS Researchers	0%	17%	15%	55%	20%	3.99	59.48	0.77
	Management	0%	0%	18%	35%	34%	3.64	49.83	0.71
Management involvement	Laboratory clerks	4%	11%	33%	33%	19%	3.52	23.93	0.49
	QA personnel	0%	6%	35%	35%	24%	3.15	32.68	0.57
	Medical Scientists	2%	11%	22%	52%	13%	3.28	56.27	0.75
	NHLS Researchers	2%	9%	37%	42%	10%	2.81	35.14	0.59
	Management	0%	0%	13%	46%	41%	3.98	86.49	0.93
Training	Laboratory clerks	4%	13%	51%	23%	9%	2.28	80.89	0.30
	QA personnel	1%	18%	39%	35%	7%	2.61	21.85	0.47
	Medical Scientists	2%	14%	42%	32%	10%	2.81	18.41	0.43
	NHLS Researchers	1%	19%	28%	36%	16%	3.22	22.73	0.48
	Management	0%	9%	27%	44%	20%	3.41	39.99	0.63
Allocation of resources	Laboratory clerks	6%	19%	52%	15%	8%	2.79	18.67	0.43
	QA personnel	7%	23%	39%	25%	6%	2.50	10.10	0.32
	Medical Scientists	4%	29%	19%	30%	18%	3.51	15.04	0.39
	NHLS Researchers	8%	27%	7%	44%	14%	3.54	16.36	0.40
	Management	0%	0%	15%	53%	32%	3.79	82.10	0.91
Customer satisfaction	Laboratory clerks	2%	27%	27%	26%	18%	3.21	12.59	0.35
	QA personnel	1%	8%	22%	55%	14%	4.17	61.75	0.78
	Medical Scientists	3%	20%	4%	60%	13%	3.87	70.00	0.84
	NHLS Researchers	0%	23%	18%	40%	19%	3.32	31.25	0.56
	Management	0%	3%	15%	60%	22%	3.86	81.67	0.90
Quality risk audits	Laboratory clerks	8%	22%	27%	35%	8%	3.40	23.48	0.48

	QA personnel	4%	9%	15%	59%	13%	4.38	69.68	0.83
	Medical Scientists	3%	18%	25%	39%	15%	4.00	32.61	0.57
	NHLS Researchers	6%	20%	8%	49%	17%	4.29	41.74	0.65
	Management	2%	4%	29%	47%	18%	3.18	47.12	0.69
Risks identified	Laboratory clerks	0%	13%	47%	26%	14%	3.29	19.11	0.44
	QA personnel	4%	23%	23%	34%	16%	3.07	19.74	0.44
	Medical Scientists	6%	21%	23%	28%	22%	3.62	17.29	0.42
	NHLS Researchers	2%	23%	2%	49%	24%	4.65	40.92	0.64
	Management	3%	8%	5%	50%	34%	4.44	66.10	0.81
Employee involvement	Laboratory clerks	10%	29%	2%	48%	11%	4.85	59.24	0.77
	QA personnel	7%	17%	26%	37%	13%	3.29	22.78	0.48
	Medical Scientists	18%	9%	28%	38%	7%	3.13	26.68	0.52
	NHLS Researchers	4%	18%	1%	62%	15%	4.27	73.63	0.86
	Management	0%	7%	10%	39%	44%	4.11	78.64	0.89
Benefits to staff	Laboratory clerks	13%	50%	8%	23%	6%	3.89	23.60	0.48
	QA personnel	7%	49%	7%	24%	13%	3.67	12.89	0.36
	Medical Scientists	19%	30%	5%	30%	16%	4.00	2.0.49	0.45
	NHLS Researchers	4%	33%	6%	45%	12%	4.15	32.44	0.57
	Management	1%	22%	20%	33%	24%	3.56	23.85	0.49
Attitude of staff	Laboratory clerks	19%	56%	2%	15%	8%	4.14	29.81	0.55
	QA personnel	16%	40%	14%	19%	11%	3.43	10.93	0.33
	Medical Scientists	7%	20%	26%	22%	25%	3.89	22.47	0.47
	NHLS Researchers	16%	33%	3%	22%	26%	4.17	20.14	0.45
	Management	2%	20%	18%	38%	22%	3.04	27.24	0.52

According to the statistics, comprehension of biobanks varies little depending on a person's job. This demonstrates the neutrality of laboratory workers, quality assurance staff, and medical professionals in their awareness of biobank risks. The management concur that they are aware of the biobank concerns. Similar replies on a neutral approach toward management engagement are indicated by the

distribution of data on management involvement. The data information demonstrating that management approves of their participation in the implementation of the biobank risks is the management responses.

There is a need to increase training in the biobank throughout the various work positions, according to training data, which indicates an equitable distribution of replies across all work positions. Data on resource allocation has indicated that different employment levels may have varied perspectives on resource allocation. The QA staff look neutral, but the laboratory clerks disagree with how the resources are being distributed. The management has come to a unanimous decision regarding resource allocation. They may be managing the resources, based on this.

All levels of employment, with the exception of lab clerks, have an equal distribution of agreement on customer satisfaction. The risk audits reveal that management and laboratory clerks are neutral, that is, they neither agree nor disagree, about the risk highlighted. Data indicates that other job positions concur with risk audits. Data on employee benefits hints at widespread agreement across all positions about the application of quality management risk and employee benefit. The results on employee attitudes indicate that all other positions relating staff changes in attitude following the implementation of quality management risks are in agreement with each other.

### Years experience

Topic	Years range	1	2	3	4	5	Mean	Variance	SD
Understanding of Biobank risks	0-3	10%	20%	28%	30%	12%	3.14	14.07	0.38
	4-7	8%	11%	6%	41%	34%	3.82	54.96	0.74
	8-10	0%	0%	16%	52%	32%	4.18	72.45	0.85
Management involvement	0-3	30%	26%	7%	25%	12%	2.63	7.62	0.28
	4-7	0%	13%	9%	46%	32%	3.97	73.40	0.86
	8-10	0%	0%	3%	53%	44%	4.41	109.10	1.04
Training	0-3	10%	23%	17%	35%	15%	3.31	22.70	0.48
	4-7	30%	26%	13%	23%	8%	3.90	30.16	0.55
	8-10	0%	5%	28%	47%	20%	3.00	21.20	0.46
Allocation of Resources	0-3	40%	35%	6%	13%	6%	3.60	16.16	0.40
	4-7	4%	18%	15%	43%	20%	3.55	43.70	0.66
	8-10	0%	12%	10%	50%	28%	4.13	56.83	0.75
Customer satisfaction	0-3	10%	15%	20%	25%	30%	3.90	18.16	0.43

	4 -7	25%	32%	1%	30%	12%	3.85	12.86	0.36
	8 -10	10%	27%	6%	45%	22%	3.84	37.84	0.61
Quality Risk Audits	0-3	18%	35%	4%	35%	8%	3.58	17.78	0.42
	4 -7	30%	45%	12%	10%	4%	3.10	17.36	0.42
	8 -10	2%	9%	22%	35%	32%	3.30	27.69	0.53
Risks identified	0-3	30%	23%	26%	15%	6%	2.85	11.16	0.33
	4 -7	5%	22%	6%	43%	24%	3.83	36.74	0.61
	8 -10	0%	18%	41%	25%	16%	2.75	12.20	0.35
Employee involvement	0-3	10%	28%	13%	35%	14%	3.13	23.70	0.49
	4 -7	25%	30%	14%	25%	6%	2.95	8.24	0.29
	8 -10	10%	5%	7%	58%	20%	4.35	63.56	0.80
Benefits to staff	0- 3	20%	60%	3%	13%	4%	3.60	28.56	0.53
	4 -7	25%	40%	5%	20%	10%	3.50	6.80	0.26
	8 -10	10%	25%	18%	27%	20%	4.70	42.64	0.65
Attitude of staff	0-3	14%	30%	26%	20%	10%	3.24	12.84	0.36
	4 -7	30%	36%	7%	19%	8%	3.65	12.96	0.36
	8 -10	20%	20%	8%	32%	20%	3.70	15.84	0.40

The biobank participants' years of experience were used to separate the years of experience data into three categories, the experience years of 0–3; 4–7; and 8–10 years. The information on biobank understanding has showed that employees with 8 to 10 years of experience are neutral about it, while all other participants with 0 to 3 and 4 to 7 years of experience believe that they understand the implementation of the QMR.

According to the research, all employees with varying levels of expertise agree on management involvement, and those with 8 to 10 years of experience strongly concur. According to the research, freshly hired employees with 0–3 years of experience are neutral about training, while other experienced employees with 4 years or more of experience are in agreement with the training provided to workers.

Regardless of their level of experience, all participants agreed that training is necessary and a crucial component of implementing quality management risks. The statistics indicate that additional resources should be devoted to biobank activities in terms of resource allocation, regardless of the age of the participants. In all of the years of customer satisfaction experience, there has been comparable consensus. The importance of risk audits is supported by data from participants aged 0 to 3 years old. The more than three years of experience staff have recommended neutrality, neither agreeing nor disagreeing.

The participants, who have 4–7 years of experience, concur on the identified risk, whereas other participants, who have varied years of experience, are unconcerned about the hazards. Employee involvement on the agreement from participants with 8 to 10 years of experience and other staff members with 0 to 3 and 4 to 7 years of experience suggest neutrality.

Benefits to staff data show that all participants concur, and those with 8 to 10 years' experience highly concur. The data on employee attitudes reveals that experienced participants concur that staff attitudes changed with the implementation of quality management risks, while newly experienced workers remain neutral.

## **4. Discussion**

The purpose of the study was to examine and evaluate quality management risks and determine how they affect the biobank operations. The areas of focus were on current biobank quality risks and how the implementation of quality management affects biobank operations. The hypothesis was that the current quality management system and its shortfall in the biobank are affected by the risk plan within the biobank. There will be anticipated gaps in the implementation of risk plan and this will impact on the biobank operations.

The data analysis from the results show some key finding that support the hypothesis that there are gaps in the implementation of quality management risks within the biobank. These gaps are observed in the results analysis of the identified risks for allocation of resources, training and staff benefits. The data also shows that there are no gaps in some identified quality management risks between male and female staff. Hence, this data shows that the understanding of biobank risks is opposed to the theory that there are gaps. Gaps in the implementation of the quality management risk depends on the type of the risks identified in the biobank.

The discussion in this chapter focusses on the findings of the study with the literature data and draws comparison to analyse and assess implementation of the quality management risk impact on biobank operations. The evaluation criteria used in this study involve a range of activities in quality management systems related risks and biobank operations.

## 4.1 Understanding of Biobank Risks

The predicted hypothesis gap demonstrates that there are gaps in understanding of the quality management related risks, but is no statistically significant gap on this specific identified risk. Participants understood risks better expressed as natural frequencies (that range from 15 to 100), according to Carrasco-Labra et al. (2015), than risks expressed as probabilities. The data responses from male and female participants show a difference of male mean at 3.94 and female at 4.33. Since some of them already possess knowledge, the T value attest to the suggestion that has demonstrated that there is no discernible difference in the way they use and comprehend QMR.

The adoption of the QMS benefits from the expertise obtained through prior employment, which has boosted the rate of risk control implementation with less change resistance. The majority of participants' data strongly concur that they are aware of some risks.

The implementation of QM in the biobank system is for biobank staff to gain more knowledge and be competent in what they do. The participants, especially biobank medical scientists and biobank researchers demonstrated understanding to what QMR entailed and the knowledge of setting up a quality management system and some risks in the organization. The biobank established the management requirements portion of ISO 9001, which is connected to other laboratories that have other different ISO standards.

Healthcare professionals use different formats for presenting risk information including absolute risk, relative risk, and number needed to treat. These formats have shown to affect how risk information is interpreted and providers of information need to be aware of this (Llyod, 2001) According to the data this suggest that some participants had prior knowledge and did not appear to be completely ignorant regarding their understanding of QM. Implementing a QMS requires knowledge from prior employment, and doing so may speed up the deployment of risk controls with less opposition to change. The majority of participants strongly concur that they are aware of some risks.

The male and female participants understanding of the quality management risk help with the reduction of the impact on biobank operations. This also helps them to

address the focus of the how this affects the biobank. This reduces the rate in implementation of risk plans, as the staff understands the quality management risks. This is due to the fact that biobank is a new division of NHLS, and the biobank personnel was still picking up new procedures.

## **4.2 Management involvement**

Data on the management involvement demonstrates the impact of the management involvement in the quality management risk. Participants, both male and female, agree on about their acknowledgement of the management involvement. This agreement is slightly different. The male and female comparison differs based on their involvement with management. The results showed that participants believed that management participation in the process was essential to advancing the adoption of QM risks. Young and Jordan (2008) state that top management support is the most important critical success factor for project success and is not only simply one of the many factors. The beginning of management engagement in the biobank was the development of the quality manual and risk policy for the biobank, which provide guidance on the procedures that should be followed and set deadlines for when they should be finished.

Leadership is one of the enabling factors for the implementation of QMS. In terms of quality, leadership involves efforts by senior leadership and management leading by example to integrating quality improvement into the strategic planning process and throughout the entire organization and to promote quality values and quality indicator techniques in work practices (Claver and Molina, 2003). This statement compares with the findings that show increased percentage of agreement and strong agreements respectively by both male and female staff that do see the management involvement.

As part of the founding personnel that started the biobank from its beginning phase, management made up 8% of the staff with more than 7 years of experience in the biobank operation. They are involved in developing quality policies and risk management procedures for the biobank. Management must establish policies and procedures to manage QMS. Programs, processes, and training are provided to the biobank staff, who must become familiar with them. Because biobank processes are less prevalent within the NHLS organization as a whole, it is more difficult to develop them quickly because research is also necessary to guarantee that all necessary

processes are carried out and documented. All departments, including those supporting the biobank, are involved in these activities. These include infrastructure, purchasing, marketing, and financing. Collection, storage, distribution, people, quality, and operations are the processes that are most closely related.

### **4.3 Training of staff**

The training of staff is consistent with the hypothesis as the results show that the training of biobank staff shows a gap as anticipated by the hypothesis. Female involvement in training has shown that females do not get as much training as their male counterparts. As expressed by most participants, training forms part of the management strategy to implement the QMS. The training of staff forms part of the resource planning because some training happens internally within the organization, while other training is outsourced externally.

Wardhani et al. (2009) state that a quality promotion strategy prior to education and training for quality management technical skills is needed for diffusion organization awareness on quality, the new paradigm and culture. The efforts of top level management must start quality activity; the day to day quality activity relies on the operational core. Hence education and training on quality improvement should be conducted for all staff.

During the study, it was discovered that not all of the staff members were acquiring the biobank's software at the same rate. This is due to the complexity level and level of employee comprehension. All participants concur that management is allocating funds for QMS through the current training plan. The allocation of training matches the resource strategy. Patient data input errors may occur with untrained workers. Biobank scientists expressed their agreement with the quality and sufficiency of the training they receive there. Other employees, particularly those in administration, believe they should receive biobank training abroad like biobank scientists.

The operations training the scientists acquired while working abroad led to this error. This training is specific and not just for QMS. The administrative personnel believed they must travel abroad for training as well. The organizational administration believed it fell outside of the purview of each participant. This is true even though everyone acknowledges that the training plan for the QMS covers the majority of the processes they use. Document control, registration, shipping, equipment upkeep,

quality audits, safety, non-conformances, and corrective action are all included in this strategy.

#### **4.4 Allocation of Resources**

The resource allocation is consistent with the literature review. Results carried out in this study agree with the review statement that there must be sufficient resources and budget for skills. The budget and facilities promote different influencing factors for achievement and implementation of QMS (Wardhani et al. 2009). The need for resources and training can be absorbed by management to a great extent. According to internal budget allocation, the resources are ranked in order of importance. The experience between male and female in resource allocation show a gap in mean where the male mean is more agreeing to the allocation of resources and female are neutral neither agreeing or disagreeing. This is also consistent with the hypothesis of the study that there is gap. The business must make plans for its resources, and in every organization that implements a new system or changes management program, some of the participants were already familiar with the concept of quality management. Implementing a QMS requires knowledge from prior employment, and doing so may speed up the deployment of risk controls with less opposition to change. The majority of participants strongly concur that they are aware of some risks.

There is a clear trade-off between funding management of a greater number of cost efficient and least risky projects and funding fewer projects to manage the outcomes of higher value (Joseph et al. 2009). The resources are also determined by the investment's return in terms of money. The objectives and deliverables serve as the foundation for resource prioritization. Since it is a component of the ongoing cycle of audit and risk assessment, management spent the majority of its time producing the biobank quality manual, which is a significant undertaking. It is necessary to have sufficiently trained people and respective resources.

The organization's resources must also be carefully considered, as well as what is needed in the short and long terms to create and maintain the quality management system and where those resources will come from. The administration of the biobank needs to balance the resources and priorities for the implementation of the QMS and risk management to the appropriate level for the budget and time frames allotted.

## 4.5 Customer satisfaction

Results data shows that male and female experience in customer satisfaction had the similar experience with means that are closer to each other. Risk management has improved customer products, such as specimen integrity and services, having a favorable impact on the customer focus. Additionally, it strengthens the commitment to evaluating quality and resolving disputes between the client and the biobank. Customers' perceptions of their real service experiences are arbitrary judgments. Customers are now receiving questionnaires from the biobank to provide feedback on the company's services. The consumer feedback, including some of the customer suggestions, needs to be increased to more customers. Perception, according to Rohrman (2008), is how people assess the dangers to which they (or their facilities, or environments) are currently or may be exposed. Such perceptions guide choices regarding the acceptability of risks and are a major factor in actions taken before to, during, and following a disaster. In order to improve consumer impression of the biobank operation, it is crucial to assess the customers' understanding of the service. According to Ali et al. (2013), customers in both the public and private sectors want businesses with an effective quality management system to give them confidence. One of the reasons for satisfying these expectations is doing so. The enhancement of productivity and company performance is another cause.

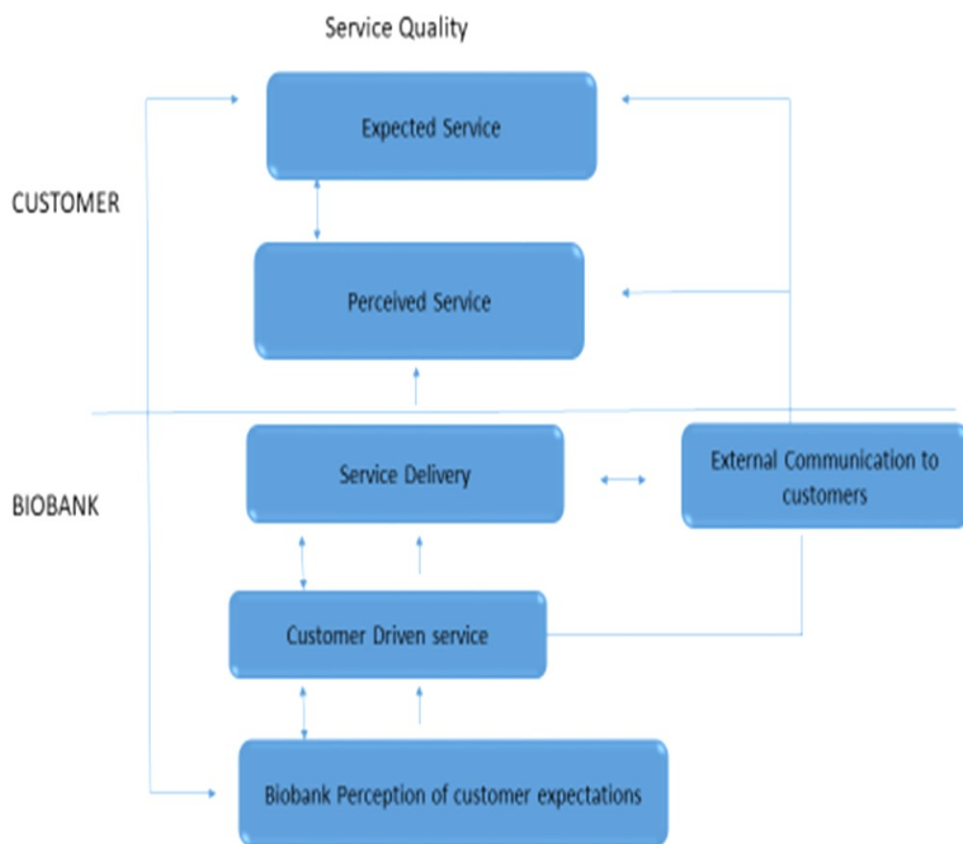
Increased customer satisfaction assures that the desired quality is being maintained and achieved and this gives proof of the organization's abilities to meet clients' needs and attract potential clients. While a quality management system can assist in fulfilling these expectations, it is not an end in and of itself; rather, it is a tool for achieving the goals specified for the organization.

The participants all expressed a strong agreement with the customer-centered approach and the difference the biobank has made for them. Based on the participants' reactions, it appears that most consumers are usually satisfied, and another explanation could be that because the biobank is new to South Africa and some of the processes are unfamiliar to them, they are unsure of what they would complain about right now.

The figure 4.1 below shows the relationship of customer service and perceived service by the customer and how it affects the relationship between the customer

and biobank service delivery. This shows that communication to the customers can change between perceived service by the biobank and expected service. This will reduce the anticipated gaps that may impact the biobank operations and this anticipated gap is in line with the hypothesis.

**Figure 4.1 Service Quality**



Customer needs to be given the expected service rather than perceive service. This would reduce the risk of perceived expectations.

Participants have the impression that customers are satisfied with the service based on the rise in customer utilization of the biobank and the rise in the quantity of biomaterials kept there. Twelve thousand biomaterials were there when the biobank first opened; today, there are over one and a half million specimens there and utilized almost daily for research purposes.

## **4.6 Biobank Quality-Related Risk Audits**

Additionally, evaluation is a component, asking why there is a non-conformance and determining whether the procedures benefit the populace or are a nuisance (Dale, 2015). The male participants responses means were lower than female participants demonstrate the impact and gap in understanding the QMS risk audits and this data support the hypotheses. They are also informed of the audit date. Participants also concurred that they are aware of several audit-related non-conformances. The participants remarked that the dates provided by the auditors as well as the risks found during the audits are disclosed.

Staff from the biobank participates in the risk audits from the quality assurance department and respond to client inquiries about the system and procedures. The biobank's staff must also justify its internal procedures.

Zou et al. (2021) state that conducting a risk assessment requires a high volume of manual work and mobilizes quality assurance resources. This is a reactive process in that audits are executed based on risk assessed from past data. Employees from the biobank take part in the risk audits by answering questions about the policies and processes. The personnel of the biobank must also defend its internal practices. The issue facing the biobank employees is timely risk nonconformance closing. This is because some risks of nonconformance call for financial support, which the finance department must allocate for that specific financial budget. If more funding is required, it will be provided in the next fiscal year. There are several issues with paying clients' customers who perform maintenance on schedule. The danger is that some equipment could raise nonconformances during the audit if maintenance is not performed as required on time. The in-transit thermometers in the biobank that are used for sample collection are part of this equipment. This impacts on biobank operations because they need to use calibrated equipment. This is in line with the aims of this study.

## **4.7 Risks Identified**

Identifying the risks to be treated or mitigated and understanding the consequences play a vital part in the biobank operations. These risks must be under continuous monitoring for future evaluation (Diabat et al. 2012). The risk register contains the

identified risks. They are recognized by the risk description, the risk owner, the impact of the risk, the risk responses mitigation, and the risk management. The study's risk identification included physical, process, equipment, and psychosocial risks related to staff attitudes, as well as risks related to data gathering, potentially dangerous biological agents, customer satisfaction data, and IT risk. This study has demonstrated that, aside from the psychosocial risk, other dangers are found in previous investigations. The beliefs and attitudes of the biobank workers are part of the psychological risk. Because the biobank personnel serve as both a doorway and a reflection for the biobank's consumers, the psychosocial components of the risks must be identified. The data suggest that there is a gap in understanding some of the identified risk. The biobank staff converse with clients as well. Their understanding of the risk may impact the biobank operations. Their knowledge of the biobanking process and attitude there are crucial. They must be aware that they are integral to the procedures. An analysis of the psychological risk is always required.

#### **4.8 Employee Involvement**

The study demonstrated that there are still gaps in the involvement of staff in the biobank QMS and lower level biobank employees, such as administrators, are distinct because they believe they still have much to learn and because they are excluded from other processes due to their places of employment and job descriptions. Mouttham et al. (2021) state that competency gained by biobank personnel increased the ability to develop and implement new procedure in more efficient manner thereby minimizing the impact of challenges.

Since the theory does not consider all staff levels inside the organization, this is inconsistent with it. Participants have acknowledged that their participation in biobank systems includes everything from receiving specimens at the biobank to maintaining health and safety. The demands of the personnel can be divided into several categories, including functional, psychological, and social. The involvement of biobank employees demonstrates better sensitivity towards the customer expectations because of the various consumer needs and expectations.

## **4.9 Benefits to staff**

According to Biazzo and Garengo (2013), in order to raise the value of certificates and boost the potential to uncover conformity, there must be an evolution toward the so-called performance and management audit model. Not all employees have experienced the advantages of quality management systems and risk plans. Due to differences in training and updates on risk adjustments, not all workers have benefited. The variance difference between male and female participants has supported the hypothesis that there is a gap in the way staff benefits from the implementation of quality management systems risks. The data suggest that there is a difference in how the staff benefits and this may impact the biobank operations when there is a perceived unfairness. Wardhani et al. (2009) state that QMS requires a change in organizational culture, standards, values and belief systems about the organization's function. QMS requires a change in the organization's political systems, decision making processes and power bases. The study has demonstrated that in order for benefits to be realized, all staff members who work at the biobank must experience them, but this is not the case at the moment.

## **4.10 Attitude of staff**

A person's attitude appears to be based on how they feel, and those feelings are based on how much they stand to gain from the system's risky adoption. The data suggestion of female participant's disagreement with reservation on the attitude of staff and the male participant's neutrality, supports the hypothesis that there is a gap in the attitude of staff towards the implementation of quality management risks. This supports the focus of the study that demonstrate the impact in the biobank operations. It is interesting to note that a participant thought that their perspective on QMR had improved and their attitude had changed. It is important to note that both male and female participants' attitudes may have an unfavorable effect if not addressed. Saunders et al. (2009) state that attitude of staff toward clients are often negative, mirroring the experience of service users. Interventions can have a positive impact improve the quality of operations. Although most staff members are more assured in the method they are using at the biobank and have clear instructions on what to accomplish there, there is still room for improvement on the part of the organization.

The favorable opinions will be due to enhanced processes and increased confidence in them. As a result, they now recognize the value of implementing a QMS. Some participants claimed that the system implementation they started when they did was the beginning of their optimistic perspective. Because the biobank is their first line of work and they had no other system to compare it to when starting with the system's implementation at the beginning of their employment, the other participants have not noticed any changes in their viewpoints or attitudes. Additionally, there is now more paperwork. The evolving paradigm of quality, along with how it is measured, applied, or observed, and ultimately embraced as an approach to the company as a whole, are significant issues to be aware of, according to Swanepoel et al. (2008). The four steps of the risk management agenda - risk identification, risk analysis, risk evaluation, and risk treatment - bear relevance. The findings above show that management's risk analysis can take into account people's knowledge, attitudes, and behaviors in relation to hazards. They now recognize the significance of risk control QMS adoption and have favorable opinions as a result of better processes and confidence in them. Some participants claimed their optimistic perspective did not begin until they started the system's risk detection process.

#### **4.11 Participants age**

According to the study, the age of the participants varies across all different biobank operations, and research has demonstrated that while participant ages may vary, their comprehension of quality management risks is consistent across all ages. The difference in age whether the participants was 18-25, 26-35, 36-45 and 46-55 the study showed that they are exposed to the same quality management systems and their risk experience remained the same whether they are male or female. There are gaps and preferences in different workforce age. The similarities occur in reea of customer satisfaction but differences are in areas of allocation of resources and attitude of staff. Boumans et al. (2011) states that older employees are more in need of intrinsic challenges and fulfilling jobs. Younger worker's motivation increases as they are offered more opportunities in the workplace.

## **4.12 Work positions**

In this study to ascertain the degree of participant agreement with respect to the work position-based ranking has demonstrated the difference in level of understanding of quality management risk based on positions within the biobank. It was crucial to determine whether there were any notable disparities between participants because they were from various fields. The study showed that the work position has difference in the allocation of resources. The work position also similar agreement in areas of management involvement and risk audits. The participants in the lower positions disagreed with the allocation of the resources and the management agreed with the allocated resources for the biobank operations.

## **4.13 Experience in years**

Difference in responses regarding work experience has demonstrated that understanding risks within biobank and its operation is largely learned, and it continues to develop. People go through day to day experience of biobank operations and their competence in it keeps growing. The study shows that through work experience there is more understanding of quality management risks than people with less working experience in biobank. Work experience is described as consisting of qualitative and quantitative components that interact and accrue over time (Tesluk and Jacobs, 2006).

## **4.14 Impact of QM risk on organizational performance**

The study has demonstrated that the biobank's operations are impacted by the quality management risks that are put into place there. The information in Table 4.1 demonstrates how important it is for personnel to understand and be aware of the dangers associated with the biobank in order to prevent costly mistakes. Since management is involved in drafting the biobank quality policy and risk policy, which provide guidance for how the business runs, their involvement has a significant impact. Management allocates funds for staff training, equipment purchases, and maintenance from the budget. They manage the risk associated with biobanks as well.

**Table 4.1 Risk Impact Analysis**

	Very Low	Low	Moderate	High	Very High
Understanding of Risk				X	
Management involvement					X
Training				X	
Allocation of resources					X
Customer satisfaction					X
Biobank Quality related risk audits					X
Risks Identified				X	
Employee Involvement				X	
Benefits			X		
Attitude of Staff			X		

Very low – no impact on biobank operations

Low – small impact on biobank operations

Moderate – impact but no significant changes to biobank operations

High – impact with effects on biobank operations

Very High – impact with severe impact on biobank operations

Focusing on the needs of the customer has a significant influence since it determines how the NHLS biobank is used. Because they identify risk gaps in the biobank activities, risk audits have a significant impact on operations. The risk that has been discovered has a significant impact, but that impact varies based on the type of risk. Some of the risks that were identified may be expensive, but others may be less so. The advantages to the personnel and the attitude depend on how the biobank operations are handled and how they directly influence the staff; as a result, the impact is modest as the amount of comprehension of the dangers affects the attitude. The influence of risk on biobank operations demonstrates that a clearly defined methodology has been a focus of risk assessment.

#### **4.15 Research Question 1: What are the current biobank quality risks?**

The data from the results compares with the existing research that implementing quality management systems creates additional risks for the biobank operation that are not just financial or related to day-to-day activities like collecting, processing, and storing specimens, but also have an impact on those operations. Handling reagents, dangerous chemicals, and heavy machinery poses risks to one's health and safety. The existence of procedures that must be followed in the biobank and the need for data to be preserved as evidence of those procedures must be documented as control risks. Internal audits are not conducted as a self-evaluation tool to determine whether the biobank complies with quality management system standards and risk policies, such as the National Health Act and other risk-related laws regarding specimen handling and patients' rights to consent when collecting samples.

The non-conformances that were discovered during the audit present difficulties for timely non-conformance closure and risk elimination if not completed within the allotted period. Mouttham et al. (2021) states that a corrective action report is created to document non-conforming output and other events that could adversely affect the quality of services. Resources are at danger as a result of reduced budgets or no financial budget being allocated for employee training and biobank operation. A good understanding of the underlying risk must be the foundation of any risk communication program, and it is essential for effective risk management to align biobank operations with risk communication procedures. Risk perception and risk attitude influence people's risk behaviour.

The biobank staff's interactions with patients and other biobank clients while working on specimen collecting projects are related to psychosocial risk. When collecting samples from patients, biobank workers may be impatient, aggressive, and occasionally disgruntled, which leads to subpar service. Urbaniak et al. (2022) states that it is a truism that a good cooperation with clients affects the effectiveness and efficacy of business operations. Companies implement various management processes to improve client collaborations and minimize threats and risks.

Findings have demonstrated that QMS is effective and that the biobank process has improved. This supports the idea that organizations that practice Total Quality

Management (TQM) have a culture of ongoing improvement. According to the research, the deployment of a quality management system mostly provides internal, intangible benefits for a biobank's staff and operations.

#### 4.16 Research Question 2: How does implementation of quality management risks affect biobank operations?

The process shown in figure 4.2 illustrates how management develops quality policies, establishes quality objectives, conducts audits, analyzes audit data, applies corrective and preventative measures, and evaluates the entire system during management reviews.

Figure 4.2. Quality Related Process Approach



The quality process-based model in figure 4.2 helps in improving areas of the QM that need to be improved as quality forms part of the continual process of improvement. The result data from participants support the hypothesis that there is a gap in how the implementation is done at the biobank. The figure 4.2 above provide a suggested quality process based model that can reduce the gap in understanding of the risk implementations. While there is no single way to manage risk, there are best practices for a successful quality risk management program. A risk management approach includes the processes for prevention of potential issues with the aim of avoiding unwanted outcomes (Suprin et al. 2019).

The integration of the quality management system and risk assessment in the biobank is shown in Figure 4.3 below. This improves risk communication and also improves the risk management tools. The quality risk management process enables evaluation of the biobank's risks. The risk can be located, examined, and assessed in this way. Where dangers are there, they can be reduced and accepted as a part of life. The systems enable a risk assessment process to be repeated if the risk control is not found to be satisfactory following the evaluation. Review of risk output is done, and the biobank staff is informed.

**Figure 4.3 Quality Risk Management Process**

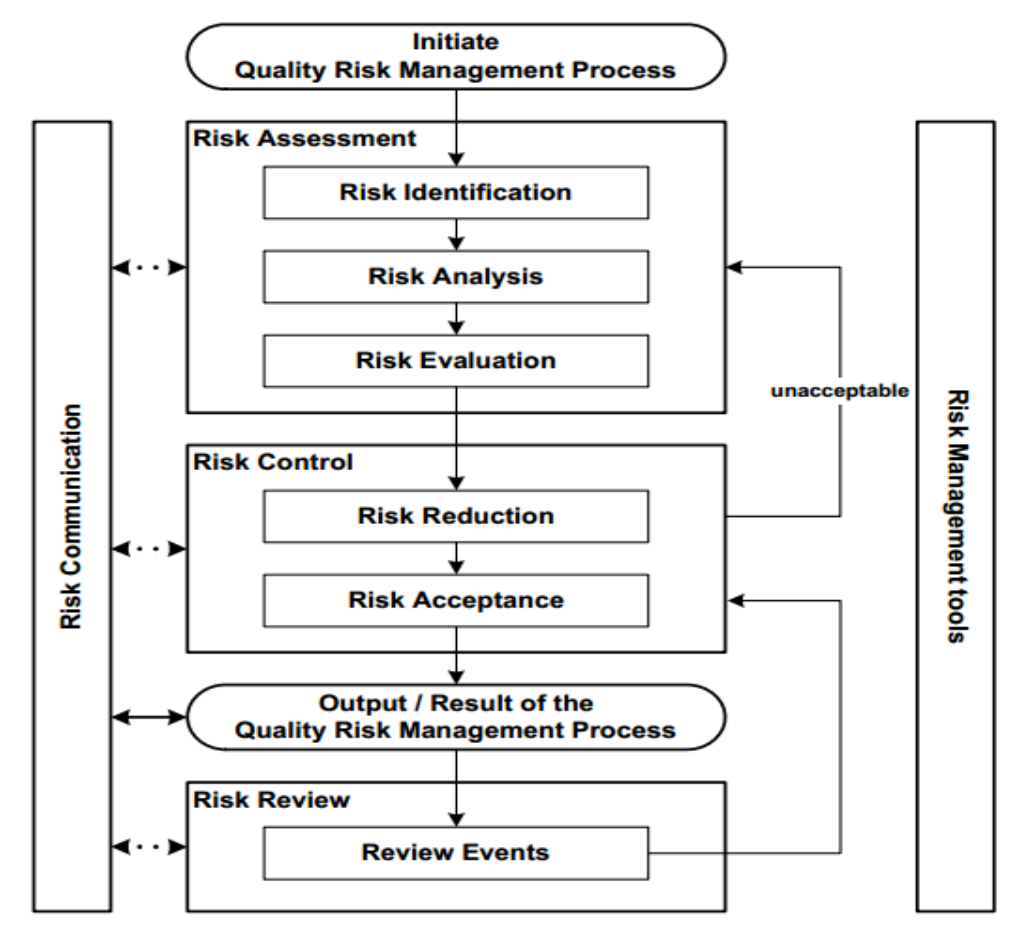


Figure 4.3 above also shows how easily the system may be turned around if risk control is ineffective or neglected. The biobank is able to review every step of its processes, from the pre-analytical stage through the storage of biomaterial, based on the outcomes of events or biobank processes.

#### 4.17 Research Question 3: What recommendations can be given after implementation and the impact of risks of a QMS on biobank operations?

The study question examined possible recommendations after evaluating the impact. It is advised that staff familiarize themselves with the biobank documents, quality management systems documentation, and risk policy.

The figure 4.4 below show how can staff at the biobank apply the quality risk management approach to familiarize themselves with risk that affect biobank operations.

Figure 4.4 Quality Risk Management Approach



Figure 4.4 demonstrates how the organization can approach quality related risk management. Every biobank employee, from the top down, will need to be educated in quality risk and the updates on the new risk that were detected. There must be evidence that the materials were read and that the contents were understood. Additionally, one must be aware of the many sorts of risk challenges present at the biobank. Suprin et al. (2019) states that it is important to identify interdependencies of the quality risk management program with the other aspects of the QMS. For

example, issue management, risk management and knowledge management are interconnected parts of the QMS that interact and work together to make it effective. Staff members must always have access to risk information so they may study it and familiarize themselves, including by looking over these risk documents. The program of education and retraining must be implemented by the company. The staff's challenges must be taken into account when planning training. These difficulties include risk occurrence probabilities, staff exposure to risk factors, staff physical vulnerability to risk, and psychosocial hazards from the assessment. This is possible by approaching problems methodically as demonstrated by figure 4.5.

**Figure 4.5 Process Approach to QMR challenges**



The study data suggest that as the quality management and risk are part of the system, the correction of the gaps in the system will require a systematic process approach. Urbaniak et al. (2022) suggest that management system risks are a component that consists of variables such as service, product innovation, employee qualification, financial standing and errors in documentation. These risks relate directly or indirectly to the quality management system.

## 5. Conclusion

The aim of the research was to look at the implementation of quality management systems risks and its impact on biobank operations. According to the study findings the male and female employees have varied perspectives on their experiences and exposure with regard to biobank risks, according to successful implementation of quality management systems and biobank hazards. Based on the findings, the management of the biobank has to close the gap or adopt a new strategy because there are still differences in experiences. The administration of the biobank must assess the situation at hand and determine what steps are still required to implement a successful quality control system. Determine quality-related implementation risks and put control measures in place are needed to lessen such risks. The advantage of a process-based approach is that it makes it possible to continuously control relevant single and combination processes as well as their interactions. The study findings suggest that strong internal motivation or willingness to improve a company's quality aids in the development of a quality management system that has both internal and external benefits, such as improving the position of the biobanks in the market.

The NHLS management must also eliminate concern over running out of money. Because they are hesitant to ask or make suggestions, biobank employees perform their duties continually and poorly. Fear has a significant impact on perception, economy, and quality. The organization needs to remove obstacles between management and employees. The key finding is that, despite the expectations of external benefits with customers being the primary drivers of the implementation of a quality system, the implementation primarily increases internal benefits, such as improvements in the biobank processes, the definition of roles and obligations for employees, a decline in non-conformism, improved employee communication, and increased productivity. Since there are not many biobanks in South Africa, new or different biobanks may investigate more dangers and improve the mechanisms that underpin biobank operations.

A significant shift in corporate culture may be necessary for the biobank to fully accept quality risks from patient recruiting, specimen collection, specimen

management, and data management to the biobank manager office. Even when everyone is willing to change the culture, it can be exceedingly challenging, and this is almost never the case. Some people view change as a threat to their personal position, the possibility of losing their position of authority or prestige, or even their job. Some people simply prefer things to remain the same and see no reason to alter them. Some people will not want to put in the necessary effort. Some find it hard to accept that risk and quality combined makes sense. Some people may be persuaded to disregard the QMR if the message coming from the top is not clear and the person in charge does not appear to be fully engaged. People's intents to assess a risk scenario favorably or unfavorably and respond accordingly are known as risk attitudes. Risk inclination and risk aversion, or caution, are the fundamental characteristics. Hazards can be created by biobank risk propensity, yet risk management operations may call for some risk propensity. Risk attitudes are not uniform or always constant across different hazard kinds, though.

People's risk assessments are a complicated outcome of hazard characteristics and individual philosophies. Risk communication is a social process that informs individuals about risks, influences them to change their behavior, and enables them to actively engage in risk-related decision-making. Almost all emergency management initiatives include such actions. A thorough understanding of risk perceptions and attitudes is essential for effective risk communication.

The transition to complete quality is a learning experience, thus top management must be involved. If the manager is not participating in it every day, he or she will never be informed enough to make decisions that will affect the change. On the most crucial matters, people anticipate their boss to put out their best efforts. The subliminal message is that total quality is not priority one if they fail to recognize that effort as being of the highest caliber. When accounting for company size and kind of biobank, quality management risks typically produce conflicting results. Varying sized businesses in the biobanking sectors have different relationships between QM risk and organizational performance, especially when it comes to the impact of detected risks, risk costs, and the development of new biospecimens or services. Depending on their years of experience and their position within the biobank, different staff members will experience the effect in different ways. Risk in quality

management has an effect that is compatible with theory. This study enables risk assessment process to be not only more holistic and integrated, as well as ensuring all eventualities, along with their respective significance, have been identified at the initial stages of the risk assessment. It would be interesting to develop more research that will look at the different biobank setup and larger population.

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### **Interview Tool (Questionnaire)**

The questionnaire below is the one used for conducting the study. It has information for the respondent to answer including ethical consideration and the signature of the participant.

### **TITLE OF STUDY**

An Investigation into Quality Management Risks and its Impact on Biobank Operations of the National Health Laboratory Service (NHLS)

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### **PURPOSE OF STUDY**

The aim of the research is to investigate into Quality Management Risks and its Impact on Biobank Operations of the National Health Laboratory Service (NHLS) investigate Total Quality Management and its impact on organizational performance in Biobank of the National Health Laboratory Service.

### **CONFIDENTIALITY**

Your responses to this survey will be anonymous. Please do not write any identifying information on this survey. Participant data will be kept confidential.

## VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. It is up to you to decide whether or not to take part in this study. If you decide to take part in this study, you will be asked to sign a consent form. After you sign the consent form, you are still free to withdraw at any time and without giving a reason. Withdrawing from this study will not affect the relationship you have, if any, with the researcher. If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed.

### Total Quality Management Risk Interview Tool

Questions	
1	Do you understand the operational risks of the biobank?
A.	Strongly Disagree    Disagree    Undecided    Agree    Strongly agree
2	Does Management prioritise risk management in all biobank processes?
A.	Strongly Disagree    Disagree    Undecided    Agree    Strongly agree
3	Are you satisfied with the biobank risk related training?
A.	Strongly Disagree    Disagree    Undecided    Agree    Strongly agree
4	Are resources allocated to the biobank to ensure elimination or mitigation of risk adequate?
A.	Strongly Disagree    Disagree    Undecided    Agree    Strongly agree
5	Are you satisfied with the impact the biobank is making to its research customers?
A.	Strongly Disagree    Disagree    Undecided    Agree    Strongly agree

6	Does the biobank follow any international published standard or best practices				
A.	Strongly Disagree	Disagree	Undecided	Agree	Strongly agree
7	Do biobank staff get involved in all quality related processes within the biobank?				
A	Strongly Disagree	Disagree	Undecided	Agree	Strongly agree
8.	Does the implementation of the QMS impacts the organisation workforce?				
A.	Strongly Disagree	Disagree	Undecided	Agree	Strongly agree
9.	Does the organisation engage with employees in terms of biobank quality related problem and quality improvements.				
A.	Strongly Disagree	Disagree	Undecided	Agree	Strongly agree
10.	Are identified risks or non-conformances or shortcomings identified during audits addressed?				
A.	Strongly Disagree	Disagree	Undecided	Agree	Strongly agree
11.	Do you benefit from the implementation of Quality Management System(QMS)?				
A.	Strongly Disagree	Disagree	Undecided	Agree	Strongly agree
12	Has your view or attitude change towards biobank after the risk management implementation in operations and QMS?				
A.	Strongly Disagree	Disagree	Undecided	Agree	Strongly agree



Comments

**CONSENT**

I have read and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Participants Age: \_\_\_\_\_

Gender: \_\_\_\_\_

Participant's agreement(Sign)\_\_\_\_\_

Date \_\_\_\_\_

Investigator's signature \_\_\_\_\_ Date \_\_\_\_\_