



UNIVERSITY of  
RWANDA

COLLEGE OF SCIENCE  
AND TECHNOLOGY

---

**Regional Centre of Excellence in Biomedical Engineering and e-Health (CEBE)**

**[Development of Health Technology Assessment (HTA) Framework for Rwanda]**

By:

[Denyse TUYIZERE]

Reference Number: [216090873]

A Dissertation Submitted to the Regional Centre of Excellence in Biomedical Engineering and e-Health (CEBE), University of Rwanda as partial fulfilment of the requirements for the Master's Degree in Biomedical Engineering.

**Supervised by:**

Eng. Jean Ngoie

Prof. Celestin TWIZERE

January 2023

## **Declaration**

I, Denyse TUYIZERE, hereby declare that the thesis project entitled “**DEVELOPMENT OF HEALTH TECHNOLOGY ASSESSMENT (HTA) FRAMEWORK FOR RWANDA**” submitted for the degree of Master in Biomedical Engineering realized to the best of my knowledge. I also declare that the information from other work presented here has been cited and referenced according to the academic rules and ethics. This thesis is my original work and it has never been submitted to any institution of high learning for any academic reward or qualification.

Student Name:

[Denyse TUYIZERE]

Student Reference Number: [216090873]

Student Signature:



Date: 16<sup>th</sup> January 2023



UNIVERSITY of  
RWANDA

COLLEGE OF SCIENCE  
AND TECHNOLOGY

---

**Regional Centre of Excellence in Biomedical Engineering and e-Health (CEBE)**

**Certification**

This is to certify that the project entitled “**DEVELOPMENT OF HEALTH TECHNOLOGY ASSESSMENT (HTA) FRAMEWORK FOR RWANDA**” is a record of original work done by Denyse TUYIZERE (Reference number: 216090873) a MSc. Degree student in Biomedical Engineering.

This work has been submitted under the guidance of Eng. Jean Ngoie and Prof. Celestin Twizere

**Main Supervisor:**

A handwritten signature in black ink, appearing to read 'J. Ngoie'.

Eng. Jean Ngoie

**Co-Supervisor:**

Prof. Celestin Twizere

**Biomedical Engineering Master’s Program Coordinator**

Dr. Gerard Rushingabigwi

## **Acknowledgment**

I am very thankful to the Almighty God for all he has done for me and for protecting me through my studies.

I extend my sincere appreciation to my supervisor **Eng. Jean Ngoie** and **Prof. Celestin Twizere** for their inspiration, collaboration, support, and advice kindly provided to me for the accomplishment of my MSc thesis.

I would like to express my gratitude to the Center of Excellence in Biomedical Engineering and e-Health at the University of Rwanda (UR) for allowing me to continue my study in the MSc program of Biomedical Engineering. On the other hand, I would like to appreciate the lecturers and staff of CEBE for providing me with all the necessary knowledge and skills in the Biomedical Engineering field. I also thank **Dr. Gerard RUSHINGABIGWI**, the coordinator of the MSc program in Biomedical Engineering for his continuous support, orientation, and follow-up on what might be done.

I also thank the respondents who provided me with the data that I needed for this study. I would like to thank a lot my family, friends, and classmates of the 1<sup>st</sup> cohort in Biomedical Engineering for their friendship and support during our studies. May Our Almighty God who never fails, rewards you all accordingly.

## **Abstract**

This study deals with the Health Technology Assessment (HTA) in Rwanda especially for medical devices by developing a framework as well as a policy to be followed while carrying out decision-making on the incorporation of new technology or replacement of the existing technology. The developed framework shows how HTA could be used in decision-making when an institution or a hospital is planning to incorporate new technology, especially medical devices. The term Health Technology Assessment (HTA) refers to the systematic process of evaluating the properties, effects, and impacts of health technology. As a multidisciplinary process, it helps in the evaluation of the social, economic, organizational, and ethical aspects of health technology. This assessment looks at the benefits, efficacy, effectiveness, safety, appropriateness, and cost-effective analysis of the technology. It has the aim of developing the HTA framework for Rwanda through the establishment of national HTA policies including healthcare technology properties, economic attributes, and risk management in order to enhance the best health technology assessment in Rwanda. The specific objectives of this project were to identify challenges and gaps regarding the assessment of the health technology system in Rwanda using SWOT analysis. It proposes feasible solutions through the development of the HTA framework for Rwanda and develops the Health Technology Assessment policies in terms of healthcare technology properties, economic attributes, and risk management. As part of this thesis, a literature review was conducted to obtain more information related to the Health Technology Assessment. Furthermore, a questionnaire was used as the methodology to collect data that were needed for better performance of the thesis. The collected data were analyzed using SPSS version 21 and MS Excel. The chi-square test and Binary logistic regression analysis were used to test the correlation and significance between the variables (both dependent and independent) respectively. The alpha ( $\alpha$ ) level of 0.05 was used to determine the statistical significance of the data. More generally, the result showed that there is a significant, and correlation or relationship between the dependent and the independent variables. The result showed that there is a need to adopt the use of HTA in decision-making while incorporating new technology or replacing the existing one, especially for medical devices and this should be done based on the framework. For future research, the developed framework needs to be validated through consultation with experts and policy-makers.

**Keywords:** Health technology, Health Technology Assessment, framework, medical devices.

## **List of Acronyms**

BME: Biomedical Engineer

BMET: Biomedical Technicians

CADTH: Canadian Agency for Drugs and Technologies in Health

CCOHTA: Canadian Coordinating Office for Health Technology Assessment

CEBE: Center of Excellence in Biomedical Engineering and e-Health

CL: Confidence Level

CT: Computer tomography

Df: degree of freedom

HRQoL: health-related quality of life

HTA: Health Technology Assessment

MDs: Medical devices

MENA: Middle East and North Africa

NHS: National Health Service

NICE: National Institute for Health and Care Excellence

OTA: Office of Technology Assessment

PDSA: Plan-Do-Study-and Act

QI: Quality Improvement

QoL: Quality of life

RBC: Rwanda Biomedical Center

SDGs: Sustainable Development Goals

SDSN: Sustainable Development Solutions Network

SMART: Specific Measurable, Affordable, Realistic and Time-bound

SPSS: Statistical Package for Social Sciences

SWOT: Strength, weakness, opportunity, and threats

UHC: Universal Health Coverage

UR: University of Rwanda

WHO: World Health Organisation

## List of Figures

Figure 2.1. Historical background of HTA [9] .....	5
Figure 3.2. Research design .....	17
Figure 4.3. Professional background of respondents .....	22
Figure4.4. Respondent's Area of work.....	23
Figure 4.5. The systematic formal process by which information is gathered to support healthcare decision-making in institution/hospital.....	24
Figure 4.6. Availability of formal process to assess health technology for medical devices .....	24
Figure4.7. Presences of standard methodology or process guideline for conducting HTA or decision-making processes.....	25
Figure4.8. Presence of policy on Health Technology Assessment.....	26
Figure4.9. The willingness of using HTA in decision-making in institution/hospital especially on medical devices.....	27
Figure4.10. Number of professional staff who are involved in the HTA committee .....	30
Figure4.11. Number of assessments performed related to medical devices .....	31
Figure4.12. Health Technology Assessment framework.....	39

## List of Tables

Table 2.1. Description of the plan–do–study–act (PDSA) cycle method .....	8
Table 4.2. Professional background of respondents .....	22
Table 4.3. Respondent's Area of work .....	23
Table 4.4. Availability of prioritization criteria.....	25
Table 4.5. Respondents' views on whether the process is referred as the Health Technology Assessment (HTA).....	25
Table4.6. Collaboration between organisation on HTA .....	26
Table 4.7. Information on whether the policy cover medical devices .....	26
Table4.9. Criteria used by their institution/hospital to assess the impact of HTA .....	27
Table4.10. Committee or group that help to review the Health Technology Assessment.....	28
Table4.11. Members of the team for HTA of medical devices .....	29
Table 4.12. strategic tool in which their institution/hospital use in planning for replacement of technology .....	29
Table4.13. Time of assessment process takes on average for any given case of medical devices	30
Table 4.14. Number of assessments performed related to medical devices .....	30
Table 4.15. Suggestions of respondents.....	31
Table 4.16. correlation of variables (selected factors) to the willingness of using HTA in decision making especially on medical devices .....	34
Table 4.17. Model Summary .....	35
Table4.18. Classification Table .....	36
Table 4.19. Shows the significance of variables.....	37
Table 4.20. Z-distribution table [72].....	XI
Table 4. 21. Chi-Square distribution table [72] .....	XII

## Table of Contents

Declaration.....	i
Certification.....	ii
Abstract.....	iv
List of Acronyms.....	v
List of Figures.....	vi
List of Tables.....	vii
<b>Chapter1. General introduction .....</b>	<b>1</b>
<b>1.1. Introduction.....</b>	<b>1</b>
<b>1.2. Problem Statement.....</b>	<b>2</b>
<b>1.3. Research questions.....</b>	<b>2</b>
<b>1.4. Objectives of the Study.....</b>	<b>3</b>
<b>1.4.1. General Objective .....</b>	<b>3</b>
<b>1.4.2. Specific Objectives .....</b>	<b>3</b>
<b>1.5. Scope of Study .....</b>	<b>3</b>
<b>1.6. Significance of the Study .....</b>	<b>3</b>
<b>1.7. Organization of the study .....</b>	<b>4</b>
<b>Chapter 2. Literature Review .....</b>	<b>5</b>
<b>2.1. Background of Health Technology Assessment .....</b>	<b>5</b>
<b>2.2. Definition of Key terms.....</b>	<b>8</b>
<b>2.3. Health Technology Assessment Status .....</b>	<b>9</b>
<b>2.4. Why HTA of Medical devices should be done.....</b>	<b>11</b>
<b>2.5. Ways in HTA contribute towards the incorporation of new technology (medical devices) or the replacement of existing technology in health facilities. ....</b>	<b>12</b>
<b>2.6. Challenges hindering the use of HTA in Health facilities .....</b>	<b>13</b>
<b>2.7. Strategies for sustainable use of HTA in health care system .....</b>	<b>15</b>
<b>2.7. Summary.....</b>	<b>15</b>
<b>Chapter 3. Research Methodology .....</b>	<b>16</b>
<b>3.1. Introduction.....</b>	<b>16</b>
<b>3.2. Research Process.....</b>	<b>16</b>
<b>3.3. Research Design .....</b>	<b>16</b>

3.4. Study Area .....	17
3.5. 3.6. Sample size determination and Selection .....	17
3.7. Source of Data .....	19
3.8. Data Collection Methods .....	19
3.9. Methods of data analysis .....	19
3.9. Limitation of the study .....	20
3.10. Summary .....	20
4.1. Results .....	21
4.1.1. Qualitative results .....	21
4.1.2. Test of Correlation and Significance of Variables .....	32
4.1.3. HTA Framework and Policy .....	37
4.1.4. Discussion.....	41
4.2. Summary.....	43
Chapter 5. Conclusion, Recommendation and Future Study .....	44
5.1. Conclusion .....	44
5.2. Recommendation.....	45
5.3. Future Study.....	45
References:.....	46
APPENDICES .....	I
Appendix 1: Questionnaire used in data collection.....	I
Appendix 2. HTA Policy on medical devices .....	VIII
Appendix 3. Areas of a standard normal distribution.....	XI
Appendix 4. Chi-Square table.....	XII

## **Chapter1. General introduction**

The study explored the Development of Health Technology Assessment (HTA) Framework for Rwanda. This chapter contains the introduction to HTA, problem statement, research questions, Study objectives, the scope of the study, hypotheses questions, scope of study, significance of the study, and organization of the study.

### **1.1.Introduction**

New medical technology, as well as its efficiency, safety, and costs, are on the rise in medical facilities during a time when healthcare resources are under increasing pressure [1]. It is crucial to make sure that the greater prices of the new technology are well worth it in terms of improved health [2]. Health Technology Assessment (HTA) is a multidisciplinary study area to assist in the usage, introduction, and financial support of health technologies in clinical practice and policy decisions. The primary goal of HTA is to inform the policy decision-maker in health care to improve the uptake of cost-effective new technologies and prevent the uptake of technologies that are of doubtful value for the health system.

HTA helps to ensure that the new technology is not added until it is proven to be effective and to make sure that the outdated technology is kept and used in health facilities until it is found to be ineffective or not cost-effective before its replacement. It employs certain techniques to analyse the health and social value, financial considerations, and ethical concerns associated with the use of health technology in a systematic, transparent, objective, and thorough manner to guide decision-making [3].

The term "health technology" describes the use of structured knowledge and skills in the form of tools (medical devices), medications, vaccines, processes, and systems created to address health issues and enhance the quality of life (QoL) [4]. Both new and dated health technologies are used in healthcare systems, yet there aren't enough resources to support them both. To overcome this, "opportunity cost" should be used to describe the worth of the benefits that might be attained by sponsoring one technology at the expense of another [5].

As a result, the HTA framework is useful in choosing the best health technologies to sponsor. Due to limitations and gaps in local capacities, overseas specialists currently carry out HTA in Rwanda, By creating an HTA framework in Rwanda, it will take the lead on capacity development investments for national actors through the establishment of HTA policies that will strengthen

policymakers', local researchers, and buyers' capacities to create health benefits packages to support an "equitable, effective, and high-quality healthcare system in Rwanda".

HTA primarily serves as a source of information for the creation of clinical guidelines based on evidence. Any action or product used to promote health in any form is often referred to as "health technology" when the term is used in its broadest definition for instance, by enhancing long-term care, rehabilitation, and disease prevention or treatment [1]. This part of the study was motivated by the conviction that decision-making concerns regarding the adoption of new health technology can only be effectively addressed and carried out within the confines of a procedurally structured and controlled HTA framework.

### **1.2.Problem Statement**

HTA in Rwanda is undertaken by international experts due to the lack of local expert knowledge and gaps in local capacities. Decision makers in healthcare systems are faced with challenges of how best to allocate the healthcare resources while incorporating new technology or during the time of replacing the existing technology. Another issue is that most of the sub-Saharan Africa countries including Rwanda are faced with the HTA challenges of inadequate use of evidence in policy-making, limited technical expertise [6]. Therefore, there is a need to develop an HTA framework for the evaluation of innovative technology in different institutions to solve those problems.

### **1.3.Research questions**

The area of research for this project is focusing on the development of the HTA framework for Rwanda. Especially on medical devices. This project attempts to answer the following questions:

- Is there any policy related to HTA of medical devices in Rwanda?
- Why HTA is undertaken by international experts who may not be aware of the local context and perspective?
- How the HTA stakeholders in Rwanda understand the HTA concept, functions and practices?
- Is there any group, agency, or organization with responsibility of establishing HTA policies in Rwanda?

- How HTA framework can contribute to the advancement of clinical interventions and practices, through the use of medical technology?

#### **1.4.Objectives of the Study**

##### **1.4.1. General Objective**

- To develop the HTA framework for Rwanda through the establishment of national HTA policies including healthcare technology properties, economic attributes and risk management in order to enhance the best Health Technology Assessment in Rwanda.

##### **1.4.2. Specific Objectives**

- To identify challenges and gaps regarding the assessment of health technology system in Rwanda using SWOT analysis
- To propose a feasible solution through the development of the HTA framework for Rwanda and develop Health Technology Assessment policies in terms of healthcare technology properties, economic attributes, and risk management

#### **1.5. Scope of Study**

The study was limited to the development of Health Technology Assessment framework for Rwanda. This consisted of the proposal writing and which included Chapter one (introduction), two (problem statement), three (Hypothesis questions), four (Objectives of study), five (Literature Review), six (Methodology), seven (Anticipated outcomes) and eight (Potential Impact) and conclusion. The proposal of the whole thesis was presented to the supervisors and lectures to confirm the feasibility of the project. After presentation, the thesis project was confirmed to be feasible. The conclusion and recommendation of this study has to be drawn based on the objectives of the study in the same order with results of the study after data collection, analysis and interpretation of the obtained data. The study was carried out in MOH, RBC, and ten hospitals including five District hospitals, two referral hospitals, two provincial hospitals and one Teaching hospital.

#### **1.6. Significance of the Study**

A copy of the thesis will be submitted in the University library to help scholars, academicians and other researcher in need of searching information on Health Technology Assessment framework and its application in health facility. In achieving to the universal health coverage in Rwanda, HTA framework to be developed will help to increase the transparency in decision making and to

negotiate the price of technology before being introduced in health facility. In terms of economic evaluation, HTA framework will be helpful for health facilities to make decisions on how best to allocate the resources or limited healthcare funds to different technologies especially on medical equipment. Due to the challenges of insufficient resources to fund both new and old technologies in health care system, 'opportunity cost' will be applied in order to check which technology that comes at the expense of another as HTA application in health facility will help to decide which technology is best to fund depending on its need, cost and benefits. Using HTA, Hospitals will be helped in decision making while selecting medical technology to be used in health care delivery based on the local will by looking at different aspects such as usability and quality of care that will lead to the significant reduction of external consultant, obtain high return on investment and low cost of technology.

### **1.7. Organization of the study**

This thesis is organized into five chapters as follow:

**Chapter 1** that covers the introduction information including background and motivation, problem statement, study objectives (both general objective and specific objectives), hypothesis questions, scope of study, significance of study, and organization of the thesis. **Chapter 2** presents the Literature Review about the HTA status, ways in which HTA contribute towards the introduction of new or replacement of technology in health facility, Challenges hindering the use HTA in health facility, strategies for sustainable use of HTA in health care system, finally the gap was identified. **Chapter three** explains the methodology followed in the whole study. **Chapter four** describes the results and Discussion. Finally, conclusion, recommendations, and future study are provided in chapter five.

## Chapter 2. Literature Review

### 2.1. Background of Health Technology Assessment

According to WHO, HTA started in the early 1970s, when the rising demand for computer-assisted tomography (CT scans) became a policy concern because of the extremely expensive cost per unit, which was frequently more than US\$ 300,000 [7]. The recently established Office of Technology Assessment was invited by the US Senate Committee on Labor and Public Welfare (on behalf of its Subcommittee on Health) carry out a study of the arguments required before the deployment of expensive new medical technologies and procedures in February 1975 [7].

The first study on the Health Technology Assessment was published by the United States Office of Technology Assessment (OTA) in 1976 [8]. With the founding of the Swedish Council on Technology Assessment in Health Care in the late 1980s, HTA began to expand to the rest of the world. In 1989, the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) was renamed the Canadian Agency for Drugs and Technologies in Health (CADTH). In the early 1990s, Australia became the first nation in the world to include a cost factor in HTA judgments [9].

To reduce variation in the accessibility and quality of treatments and care provided by the UK's National Health Service (NHS), the National Institute for Health and Care Excellence (NICE) was established later in 1999. HTA is used to support a variety of health decisions by decision-making bodies, such as the implementation of extensive public health programs, priority setting by identifying interventions that produce the greatest health gain at the lowest cost to improve resource allocation, decisions to publicly subsidize medical services and medications, and the creation of clinical guidelines [10].

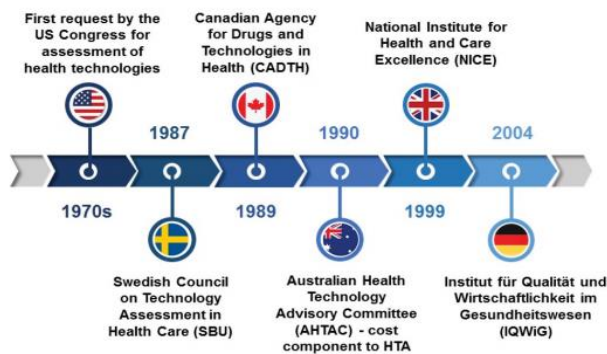


Figure 2.1. Historical background of HTA

HTA has expanded to practically all European countries in the two decades since, then to some of the wealthier countries in Central Europe, Latin America, and Asia. International agencies such as the World Bank and, to a lesser extent, the WHO have aided in its spread [8].

In Europe, there has been an increase in the use of HTA to strengthen the scientific basis for health policy decisions. HTA is primarily used to support public coverage decisions of new medications in almost every country where it has been implemented, in part because there is a lot more scientific data available for medicines than for other technologies. Despite these difficulties, HTA has also been utilized more frequently to support the coverage decisions of MDs, necessitating the need for particular methodological standards for MDs [11].

Health Technology Assessment (HTA) has developed into a common policy instrument for educating decision-makers who must control the entry and use of medicines, medical devices, and other complicated interventions inside health systems, for instance through reimbursement and pricing [12]. HTA is used as a tool for decision-making in the development of health policies [13]. In particular on the path to reaching UHC, HTA is a useful tool to help priority setting and produce evidence for decision making. The development of trustworthy evidence, insights, and comparisons to supplement current knowledge advancement as well as for further innovating global and regional best practices of HTA have been theorized to play a vital role in enhancing healthcare delivery and UHC [14].

Solving the issue of evaluating the useful component of instrumentation is the main challenge in every technology review. Although instrumentation may not have a direct impact on the parameters linked to quality of life, it does have an impact on the effectiveness of therapeutic and diagnostic procedures, the attending physician's workflow, and, last but not least, the patient's comfort. Data like technical specifications of individual devices, knowledge of their control, failure rate, quality of outcomes, etc. are heavily analyzed when assessing the quality of medical devices [15].

Health care decision-makers are now increasingly frequently requesting quicker responses to help them make emergency decisions. In order to provide decision makers with high-level responses, "rapid HTAs," which are more concentrated, less comprehensive evaluations, have been devised [16]. An effective HTA must first identify the assessment topics, define the assessment issue or issues, determine the organizational locus or responsibility for the assessment, retrieve the pertinent evidence that is already available, produce or gather new evidence, assess or interpret the

quality of the evidence, integrate or synthesize the evidence, and then formulate conclusion and recommendations. final step is to track impact after distributing findings and recommendations [17].

It has been proposed that the results and interpretation of economic evaluations help to explain the variety in coverage recommendations and decision-making across Europe because the economics of healthcare supply was a local challenge. Indeed, there is ongoing discussion on the appropriate ways to describe, measure, and assess the value of various health interventions. However, the value of health-economic analysis in HTA is undeniable and increasing [18]. HTA's goal is to supply evidence to policymakers so they may make informed decisions and to create guidelines for the administration and payment of new medical technology in a system of national healthcare [1].

HTA aids in determining whether a certain health technology offers the local healthcare system good value for money or is cost-effective [19]. The literature now in existence concentrates on the clinical elements of mHealth (mobile health) but still there is a gap of not having an integrated assessment framework of health technology to enhance the sustainability of health system [20]. A "medical and public health practice supported by mobile technology, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices" is what is referred to as "mobile health" (mHealth) (p. 14) [21]. Information and communication technology is necessary for mobile health. Apps, smart watches, glasses, and activity trackers are all wearable, wireless electronic devices that use a set of sensors to collect and measure body data and signals for health monitoring and diagnosis; these sensors are also used to send messages to medical professionals when emergency situations are detected [20,21].

According to the definition given by the Sustainable Development Solutions Network (SDSN), a sustainable health system is one "that improves, maintains, or restores health, while minimizing negative impacts on the environment and leveraging opportunities to restore and improve it, to the benefit of the health and well-being of current and future generations [20]. A sustainable building is one that can "easily be maintained and that can be effective from an environmental, social, and economic point of view, in order to comply with the different interests and needs of all the stakeholders [24].

The establishment of HTA in Health facility and its uses in decision making should be applied using Plan-Do-Study-and Act (PDSA) [25]. Plan-do-study-act (PDSA) cycles offer a

framework for iteratively testing modifications to raise system quality. Delivering enhancements in healthcare quality and safety continues to be a global problem. Plan-Do-Study-Act (PDSA) cycles and other quality improvement (QI) techniques have been employed recently in an effort to promote these changes [26]. The following table describes all about PDSA.

*Table 2.1. Description of the plan–do–study–act (PDSA) cycle method*

	<b>Deming (1986) Original description of the method related to manufacturing</b>	<b>Langley (1996) how the PDSA method may be adapted for use in healthcare contexts</b>	<b>Speroff and O’Connor (2004) how the PDSA method is analogous to scientific methodology</b>
<b>Plan</b>	Plan a change or test aimed at improvement	<ul style="list-style-type: none"> <li>➤ Identify objective</li> <li>➤ Identify questions and predictions</li> <li>➤ Plan to carry out the cycle (who, when, where, when)</li> </ul>	Formation of a hypothesis for improvement
<b>Do</b>	Carry out the change or test (preferably on a small scale)	<ul style="list-style-type: none"> <li>➤ Execute the plan</li> <li>➤ Document problems and unexpected observations</li> <li>➤ Begin analysis of data</li> </ul>	Conduct study protocol with data collection
<b>Study</b>	Examine the results. What did we learn? What went wrong?	<ul style="list-style-type: none"> <li>➤ Complete the data analysis</li> <li>➤ Compare data to predictions</li> <li>➤ Summarise what was learnt</li> </ul>	Analysis and interpretation of the results
<b>Act</b>	Adopt the change, abandon it or run through cycle again	<ul style="list-style-type: none"> <li>➤ What changes are to be made?</li> <li>➤ What will the next cycle entail?</li> </ul>	Iteration for what to do next

## 2.2. Definition of Key terms

**Health Technology Assessment (HTA):** According to O’Rourke et al., 2020 “**HTA**” is a multidisciplinary procedure that employs explicit methodologies to assess a health technology’s worth at various stages of its lifecycle. Making informed decisions using HTA helps to advance an equitable, effective, and high-quality healthcare system [27].

**Health technology** is defined by WHO as the organization of knowledge and skills in form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve the quality of life [28].

**Medical devices** is a device created and manufactured for use in healthcare, not just for nutritional or medicinal purposes [29].

**Priority setting** is the process of making sure that the few health budgets are directed to the purposes that are most valuable.

**Framework** is a content or process structure that acts as a general overview, skeleton, or outline of interconnected objects that supports a particular approach to a certain purpose.

### **2.3. Health Technology Assessment Status**

According to WHO, only 64% of high-income nations, 85% of middle-income countries, and all low-income countries adopted HTA for planning and budgeting [30]. According to WHO, different nations have different levels of development for HTA. A number of factors have been identified as HTA facilitators, including political will, networks, organized health systems, legal frameworks, and pertinent instances of gain. Political unrest, tiny economies, and a lack of human resources are all obstacles. Future action is advised, including mapping needs and possibilities, bolstering collaborative projects, incorporating stakeholders, and developing roadmaps toward open and long-lasting HTA frameworks [31].

According to WHO, HTA is expanding quickly in industrialized nations. Canada and Switzerland are two of the top nations in this sector. HTA is especially crucial in low- and middle-income countries. HTA or HTA-like activities are carried out and used in 52% of Middle Eastern nations, leaving 48% of them without such activities. HTA has gained significant popularity and is now regarded as a development approach. World Health Organization (WHO) claims that solving global concerns, enhancing health systems, and reaching the Sustainable Development Goals (SDGs) all need the use of HTA [14].

In response to World Health Assembly Resolution WHA67.23 on "Health intervention and technology assessment in support of universal health coverage," which urged the WHO Secretariat to evaluate the state of HTA internationally, the WHO 2015 Global Survey on HTA was launched. A systematic mechanism for making decisions about investments in health technology exists in half of the Middle East and North Africa (MENA) region's countries, according to the research. However, just 3% of nations have clear regulations, and practically all of them lacked enough competent personnel, data, and knowledge to conduct HTA and use the results in decision-making.

This suggests that the MENA countries have a technological and policy deficit that needs to be filled [32].

It has been found that there is a lack of a unified interpretative framework of Health Technology Assessment in healthcare [33]. This master's thesis aims to fill in this gap by developing an HTA framework to support decision making in health technology. As political leaders of various nations pledge to implement universal health coverage (UHC) in the middle of the epidemiological and demographic shifts that have been extensively studied as well as the transition away from aid [34],[27].

Sustainable financing strategies are essential for the UHC ambition to become a reality as financial challenges continue to increase. Public resources are still insufficient in the poorest countries of sub-Saharan Africa (SSA), despite the fact that economic growth is now the primary driver of budgetary space for health [27]. Even the most basic service packages cannot be covered. As a result, decisions regarding priorities must be made; decisions that frequently include challenging trade-offs. Since demands (whether needs or demands) on healthcare resources are always larger than the resources available, priority setting-the process of choosing the priority to be assigned to a service or individual patient at a given point in time is inevitable. The systematic evaluation of the properties and effects of a health technology, which can include any intervention that may be used to promote health, prevent, diagnose, or treat acute or chronic disease, or for rehabilitation, is the focus of Health Technology Assessment (HTA), a tool that is employed globally to support explicit, evidence-informed priority setting [4].

The WHO endorses HTA (WHO assembly HTA in 2014) [5]. Using context-sensitive evidence to make trade-offs explicit and a consultative procedure to allow for thought and participation in the decision-making process, to inform priority-setting decisions in the context of UHC [4]. Currently, HTA in Rwanda is undertaken by international experts due to the lack of local expert knowledge and gaps in local capacities [35]. there is a need to develop the HTA framework that will include the policies that are very crucial for investing in capacity development for local actors as well as strengthening policymakers and purchasers' capacities to develop health benefits packages that consider population needs in terms of disease burden, national priorities, equity, and cost-effectiveness using an evidence-based approach [35].

## **2.4. Why HTA of Medical devices should be done**

Nowadays, medical devices are viewed as the foundation of advances in modern medicine. medical devices (MDs) include a wide range of items such as syringes medical imaging devices, and implanted devices like pacemakers. MDs are divided into four groups based on the level of risk to which the patient is exposed (I, IIa, IIb, and III) [28].

Compared to other technologies, HTA of medical devices is essential because MDs differ from other health technologies in several ways, including: (i) they frequently change quickly; (ii) clinical outcomes frequently depend on the end-training, user's competence, and experience; and (iii) pricing is typically more dynamic than other health technologies. Expenses frequently include both running costs (including maintenance and consumables) and procurement costs (including the accompanying infrastructure)." Concerns about the ability of existing HTA approaches to address the difficulties created by the unique characteristics of MDs have grown over time [36].The ongoing increase in the rates of introduction of the new technologies in the healthcare industry is a reflection of the scientific research's increasing advances in the creation of technologies integrated into medical devices. These cutting-edge medical devices must be assessed using a decision-making process that can take into account a wide range of factors, including clinical value, safety, potential and operational effectiveness, economic and organizational impact, as well as the burdens the end user bears. Health Technology Assessment (HTA) enables to effectively tackle such considerations [37].

In order to assist local decision-makers in choosing potentially very different medical devices, a significant amount of research has been conducted in the field of micro-assessment [37]. Also known as local/hospital-based HTA [38]. HTA of medical devices has mostly been established with the evaluation of drugs/pharmaceuticals in mind [39].

Forgetting significant distinctions between drugs/pharmaceuticals and devices, and failing to take into account critical elements of medical devices. Because decision-makers must identify new criteria each time a new device needs to be evaluated, propose appropriate measurement scales for them, and then validate them, the practical application of HTA tools has been significantly threatened. Therefore, there is a need of establishing the use of HTA as well as its framework in decision making as a supporting tool for to assist in decisions making based on the best available evidence on the introduction and use of technologies in the healthcare system in a way that is both safe and effective.

## **2.5. Ways in HTA contribute towards the incorporation of new technology (medical devices) or the replacement of existing technology in health facilities.**

HTA is useful while evaluating the value for money, it is usually used to measure the differential in costs required to achieve an extra health benefit of a new therapy through the application of the HTA framework. Frameworks provide the ability to measure and compare health system functions in different countries in order to make better and more meaningful decision to make comparisons within and between countries, identifying gaps, and sharing information [40].

HTA has a strong foundation in research on the health effects and broader implications of the use of technology in health care [41]. For many low- and middle-income countries, HTA offers a powerful modernizing vision for their health system [42]. Conducting HTA studies is important for efficiently and effectively use of healthcare services resources to safeguard the public health systems and financial resources [43]. The outcomes of HTA are useful at various levels of effects on decision making, to plan capacities and reorganize the service provision [44]. Health Technology Assessment is a method of maximizing health gain while also making resource allocation decisions more clear and explicit [45].

HTA plays a great role for supporting the decision making about procurement and incorporation of medical devices. In order to develop an egalitarian, efficient, and high-quality healthcare system, HTA attempts to provide evidence for health policy decision-making [39]. In order to ensure that limited resources are used effectively, Health Technology Assessment (HTA) is used as a tool to support evidence-based decision-making. Pharmaceuticals are where Health Technology Assessment has been used most frequently. However, over the past ten years, there has been an increase in interest in using HTA for other health technologies, such as medical devices [46]. The term "health technology" is frequently used to refer to a variety of aspects of health, including therapy, diagnosis, and prevention.

It comprises all equipment, methods, and systems used in the provision of healthcare services [47]. Health Technology Assessment (HTA) as a systematic process helps to evaluate of properties, effects, ethical, and economic aspects of the technology in order to better inform health policymakers and improve the decision-making process in the area [48].

The use of HTA has grown throughout the world, enabling evidence-based coverage decisions and enhancing resource allocation effectiveness. The evaluation considers a number of factors, including effectiveness, safety, efficiency, social and legal issues, and ethical

considerations [49]. Technology evaluation can be done at any stage of the product's life cycle and has a variety of uses. These include supporting coverage decisions, counseling clinicians and patients on how to utilize health technology properly, advising a regulatory agency about the authorization and use of technology, and directing disinvestment decisions [50].

Decisions about HTA are important because of the effects they may have on patients, healthcare professionals, funding organizations, technology producers, and health policy makers. In order to successfully implement HTA, a multidisciplinary analysis of the spectrum of social, economic, clinical, and organizational ramifications resulting from the introduction of a new technology compared to the current standards of care is required [51].

## **2.6. Challenges hindering the use of HTA in Health facilities**

Although there is a general tendency in health care toward a stronger role for HTA, improved HTA processes, greater openness of HTA, and higher stakeholder involvement in HTA, there are still a number of forces that work against HTA. Health Technology Assessment is still having different challenges as they are described below: insufficient personnel to carry out HTA This includes a lack of ability and inadequacy in the recruitment and retention of human resources [52]. Especially in fields like meta-analysis, health economics, and budget impact analysis, the need for specialized training for employees in an era of rapid technology innovation was noted as a major concern. Studies demonstrate the value of training investments, but they can be costly [53].

**Process Design for Stakeholder Participation** The creation of an effective procedure for the involved stakeholders, first and foremost the patient, is one of the most significant issues[53]. Another issue is that certain parties are unaware of the HTA's objectives [54]. How to successfully involve stakeholders from the healthcare sector, businesses policymakers, and philanthropic organizations that provide technology to hospitals is another topic of discussion [53].

**Applying findings from research to conclusion in HTA reports Making Decisions Based on Evidence** The inadequacy of HTA reports, its policies with other departments, and stakeholders' ignorance of HTA knowledge and implementation are only a few of the obstacles to adopting HTA results. High-quality data is available, but there isn't enough assurance to support the use of Health Technology Assessment in decision-making. Even in locations where assessments by national authorities have been performed, gathered evidence is typically ignored or not used [53]. Only half of Health Technology Assessment reports have an impact on decision-making, according to several studies on the influence of HTA on health policy. However, the goal of HTA has been to

enhance health managers' and policymakers' judgment in order to promote quality, effectiveness, and justice[55].

The validity of data and evidence has been cited as a major issue in numerous research on HTA difficulties. The institutions providing public health care do not share a single database. For economic evaluation, there is not enough information. Reports indicate a decrease in the standard of the evidence [53]. Shifting Political Context Issues with administration, funding, and operations of health systems organizations can result from tension between the federal government and states or provinces within a nation. Conducting HTA is also being hampered by political unrest, a quick change in the composition of the government, and political change[53]. The same set of items apply to the macro-level inadequacy of health policy caused by many decision-making processes [54]. There is no established HTA methodology. Even if they frequently employ the same technique, there may be a difference depending on the available resources. differences in evaluation methods, comparison group choices, and the assessment of the degree of uncertainty in the evidence currently available [56].

Demand for HTA is rising, and there is pressure for quick assessments. Agencies reported that, frequently without more resources, they were unable to meet the growing demand for HTA in their jurisdictions. They observed that this demand frequently exceeded the capacity of the agencies to provide the HTA. Agencies claimed that this demand frequently stems from the government and may be related to the introduction of more expensive medical technologies [53].

Putting HTA Into Practice and Policy and the key problem is putting an HTA's recommendations into practice. How can HTA recommendations be effectively translated into policy and practice [53]. And those challenges are really caused by inadequate quality of evidence, a lack of communication and trust between policymakers and researchers, and financial conflict [57]. Other significant difficulties include a lack of money, poor financial planning, and inadequate financial resources. Most sub-Saharan Africa countries meet with the problem of limited healthcare budgets, strive for achieving to prioritize the needs of health care and invest in health technologies [58].

According to **Babigumira et al. (2016)**, it has been found that Rwanda and South Africa sought to use HTA for a range of regulatory, coverage or formulary decisions, and reimbursement activities [59]. Decision makers face many challenges in how best to allocate health care resources.

## **2.7. Strategies for sustainable use of HTA in health care system**

Since the lack of resources is a major obstacle when choosing new technology or when there is a need to replace the existing technology especially for medical devices, hence HTA framework developed, will help the stakeholders in HTA process health management, the healthcare professions, industry, and government in health-care for planning , budgeting, resource allocation, policy and decision-making in health institutions [60].

The role of healthcare technology, which are constantly evolving, is becoming more and more important as emphasis is paid to the treatment and care of patients [21]. In fact, technology offers a great opportunity to improve patient care and the efficiency and effectiveness of all healthcare stakeholders, including policymakers, regulatory bodies, payers, and physicians [2]. Technology has the potential to improve efficiency and effectiveness in a number of areas of healthcare. A successful implementation necessitates a thorough "a priori" understanding of the technology's capabilities and its use because technology cannot alone change the entire healthcare system [61].

For economic sustainability, the gold standard for allocating healthcare resources is the cost-effectiveness study. A long-standing and well-respected approach called a Health Technology Assessment (HTA) assesses the effects, advantages, and implications of cutting-edge medical technologies or therapies, as well as their costs and effects on the healthcare budget [20]. This will be achieved through the use of HTA on whether to introduce new technology (medical devices) or replace the existing one in health facility as HTA could be used to support decision maker to ensure the best technology to be provided to the patients within healthcare system in order to enhance the safety of both patients and the end users of the technology (medical devices).

## **2.7. Summary**

In this chapter of literature review, the study has mainly focused on the background of Health Technology Assessment, definition of key terms, the ways in HTA contribute towards the incorporation of new of technology (medical devices) or the replacement of existing technology in health facilities, challenges hindering the use of HTA in Health facilities, strategies for sustainable use of HTA in health care system.

## **Chapter 3. Research Methodology**

### **3.1. Introduction**

This chapter discusses the research design, research procedure, study area, study population, sample size and selection, data source, data collection methods, methods of data analysis, limitations encountered during the period of data collection, and summary of all contents of this chapter.

### **3.2. Research Process**

During the study different literatures were reviewed in order to get information on the HTA globally and local context. To obtain the data which were needed for this thesis, the coordinator of MSc program in Biomedical Engineering provided the introduction letter to be presented to the institutions in order to get the permission for collecting data. During the period of data collection at the field, questionnaires link was distributed to the selected respondents who were able to answer the questions which were asked in the given questionnaire. The obtained data were analysed using IBM SPSS version 21. Chi-square and logistic linear regression analysis were used for testing the correlation and significance between dependent and independent variables. Therefore, the conclusion, recommendation and future study were designed based on the analysed data.

### **3.3. Research Design**

The study involved qualitative data collected using the questionnaire tool in order to get the primary data. The secondary data was obtained through internet search for the literature of books, articles, journals and other reports which contained information related to the Health Technology Assessment. Data that were collected enabled to draw the conclusion, recommendations and future study.

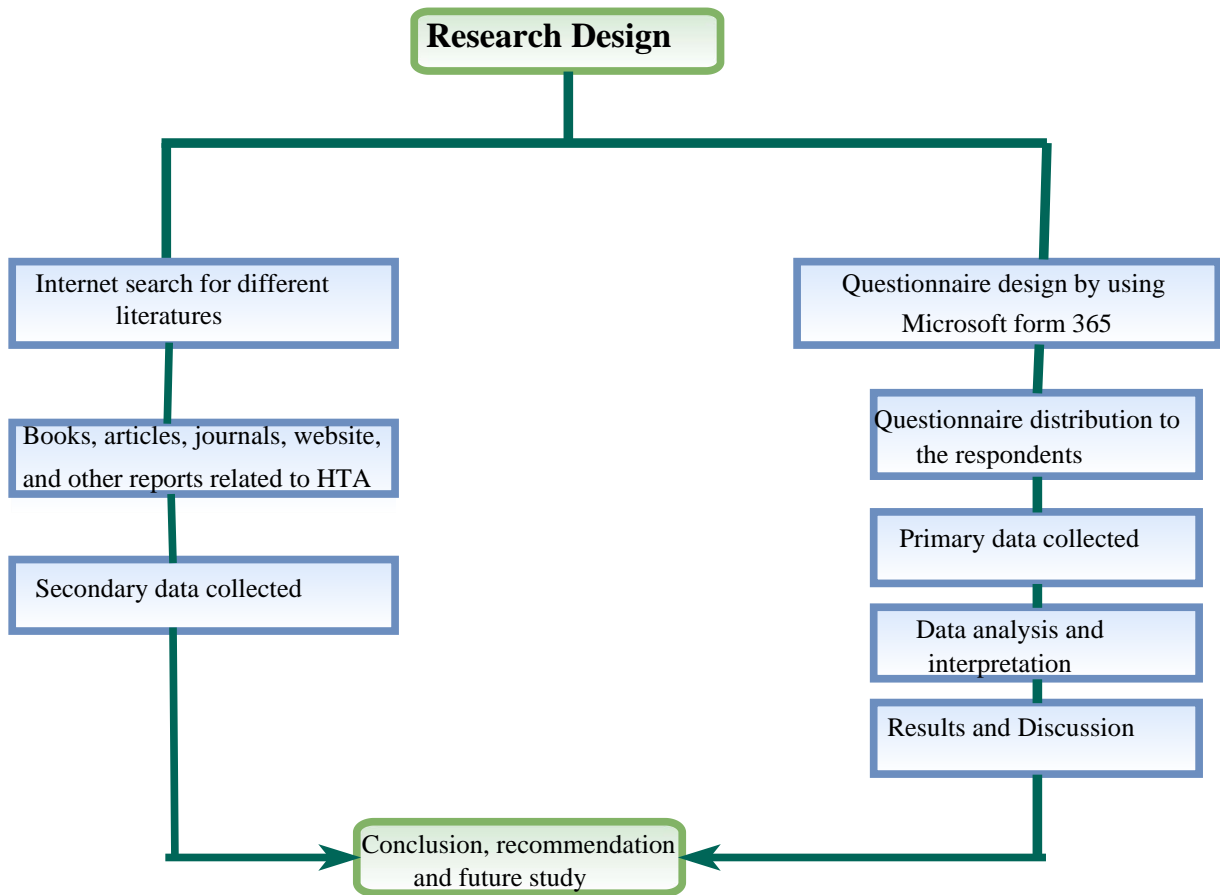


Figure 3.2. Research design

### 3.4. Study Area

The study was carried out in MOH, RBC and ten hospitals including five District Hospitals (DH), two referral hospitals, two provincial hospitals, and one Teaching Hospital.

### 3.5. 3.6. Sample size determination and Selection

#### ➤ Sample size determination

In this study the sample size was determined using the z value of 1.32 which is found on the area of distribution table in the book wrote by C.R. Kothari in 2004 [62] . This value of z was found using alpha( $\alpha$ ) of 0.02, and the p-value of 0.70 was used.

The sample size is usually influenced by a number of factors, including the purpose of the study, the risk of selecting a bad sample, and the allowable sampling error. In addition, three criteria need to be specified to determine the appropriate sample size, namely, (1) the level of precision, (2) the level of confidence, and (3) the degree of variability in the attributes.

1. **The Level of precision:** The level of precision, sometimes called sampling error, is the range in which the true value of the population is estimated to be. This is often expressed in percentage; in this study the preferred high precision of results was 9%.
2. **The confidence level:** In the present study, the population size implies that the assumption of normal populations is straight forward for both strata and therefore, value of **confidence level** equal to 81.32%
3. **Degree of variability:** It refers to the variation of the distribution of attributes of interest in the population. The more heterogeneous a population is, the larger the sample size is required to obtain a given level of precision. A proportion of 50 % indicate a greater level of variability than either 20% or 80%. This is because 20% and 80% indicate that a large majority do not or do, respectively, have the attributes of interest. The previous studies indicator values will allow the present study to choose an appropriate degree of variability. Therefore, the degree of variability provisionally adopted for this study is 70%.

Based on the above factors, the sample size that is statistically accepted for the study was calculated using the following formula:  $n = \frac{z^2 pq}{e^2}$  and  $q = 1 - p$

Where:

$p$  : is proportion of people satisfied with the desired characteristics

$q$ : is the proportion of people not satisfied with the desired characteristic

$e$ : is the acceptable margin of error or the level of precision required

$$n = \frac{1.32^2(0.7)(0.3)}{(0.09)^2} = 45$$

Therefore, the size used in this study was made of 45 respondents.

### ➤ **Sample size selection**

The study population of thesis was made of respondents from different institutions including MOH, RBC and Hospitals (District Hospitals, Referral Hospital, Provincial Hospital and Teaching Hospital). The respondents of the study included Allied Health professionals (Radiologist, Lab Technicians, Lab Scientists, etc.), Doctors, Nurses, Biomedical Technician, Biomedical Engineers and others. This study involved a total number of 45 respondents who were selected using

systematic sampling method in order to get the key information required. This method was used for the purpose of choosing the participants who are believed to be more knowledgeable and informed about the Health Technology Assessment and its use in health facility especially when it comes to the process of decision making related to the inclusion of Technology in health institutions.

### **3.7. Source of Data**

The collection of data and information was done by using both primary and secondary sources with the aim of getting the meaningful interpretation of the findings. The primary data was collected from the respondents who were approached at the field during the study. In order to effectively gather those primary data, questionnaire tool was used. The secondary data was collected through an extensive literature review to get more information on Health Technology Assessment and its application in health facility especially for decision making and this was done framework by using internet to search for literature and other websites.

### **3.8. Data Collection Methods**

Data is defined as the information collected during the study and that information can be used to draw conclusions [63]. Data collection is the process of acquiring and analyzing information on relevant variables in a predetermined, methodical way so that one can respond to specified research questions, test hypotheses, and assess results [64]. In this study, the questionnaire tool was constructed by using Microsoft form 365 and then, used for data collection process. The simple, clear, and straight forward questionnaire was prepared for easy understanding and interpretation to the respondents. The questionnaire was specific, measurable, affordable, realistic and time bound (SMART). The questionnaire consisted of twenty questions including both open and closed questions that was structured based on objectives of the study.

### **3.9. Methods of data analysis**

The term "data analysis" covers a wide range of distinct processes and techniques. It entails working with the data itself as well as goals, relationships, decisions, and ideas. The data used in this study include qualitative data. The data that was collected during the research was saved as Excel sheet. The excel sheet containing the collected data imported into IBM SPSS software version 21 for descriptive analysis. Ch-square test and Binary logistic regression model were used to test the relationship and significance between independent and dependent variables. The

statistically significant of a p-value less than 0.05 was considered. The results were later presented in form of tables, pie chart, graphs for easy interpretations.

### **3.9. Limitation of the study**

- Some hospitals refused to provide the data due the reason of not getting the ethical clearance on time.
- Some respondents did not have information about what HTA is dealing with and this required me the time to explain all about HTA and its functions in health facility especially for decision maker

### **3.10. Summary**

In this study the questionnaire was as method for data collection. This questionnaire tool was constructed by using Microsoft form 365 and then, used for data collection process. The simple, clear, and straight forward questionnaire was prepared for easy understanding and interpretation to the respondents. The questionnaire was specific, measurable, affordable, realistic and time bound (SMART). The questionnaire consisted of twenty questions including both open and closed questions that was structured based on objectives of the study. The collected data was analyzed using IBM SPSS software version 21 for descriptive analysis. Ch-square test and Binary logistic regression model were used to test the relationship and significance between independent and dependent variables.

## **Chapter 4. Result and Discussion**

### **4.1. Results**

This chapter gives the detailed presentation of the analyzed data, their interpretation and discussion depending on the objectives of the study such as: to identify challenges or gaps regarding assessment of health technology system in Rwanda using SWOT analysis and to propose feasible solution through the development of HTA framework for Rwanda and develop Health Technology Assessment policies in terms of healthcare technology properties, economic attributes and risk management. The collected data were analyzed based on the objectives of the study and SPSS software was used during that process of data analysis.

#### **4.1.1. Qualitative results**

The total number of 45 respondents participated in this study. The questions asked to the respondent during the data collection were focusing on the professional background of the respondents, the institutions of the respondents (where do they work), whether their institutions have a systematic formal process by which information is gathered to support healthcare decision-making and other questions related to health technology in order to know their perspectives on HTA. All qualitative results provided by the respondents are described below:

##### **➤ Professional background of the respondents**

Regarding the professional background of the respondents, the study showed a large number of participants were made of Biomedical Technicians(BMET) and Biomedical Engineer (BME). The number of respondents and their corresponding percentages are the following: Hospital administrator (n=1, 2.2%), Management including quality manager (n =2, 4.4% ), Doctor (n=2, 4.4%), Nurse (n=4, 8.9%), Allied health professional including Radiologist, Lab scientist, Lab technician, etc. (n=9, 20%), Biomedical Engineer (n=13, 31.1%) and Biomedical Technician (n=14, 28.9%). The chart below describes the percentage of participants based on their professional background.

Table 4.2. Professional background of respondents

S/N		Frequency	Percent	Valid Percent	Cumulative Percent
1	Hospital administrator	1	2.2	2.2	2.2
2	Management (quality manager, etc.)	2	4.4	4.4	6.7
3	Doctor	2	4.4	4.4	11.1
4	Nurse	4	8.9	8.9	20
5	Allied health professional (Radiologist, Lab scientist, Lab technician, etc.)	9	20	20	40
6	Biomedical Engineer	14	31.1	31.1	71.1
7	Biomedical Technician	13	28.9	28.9	100
<b>Total</b>		45	100	100	

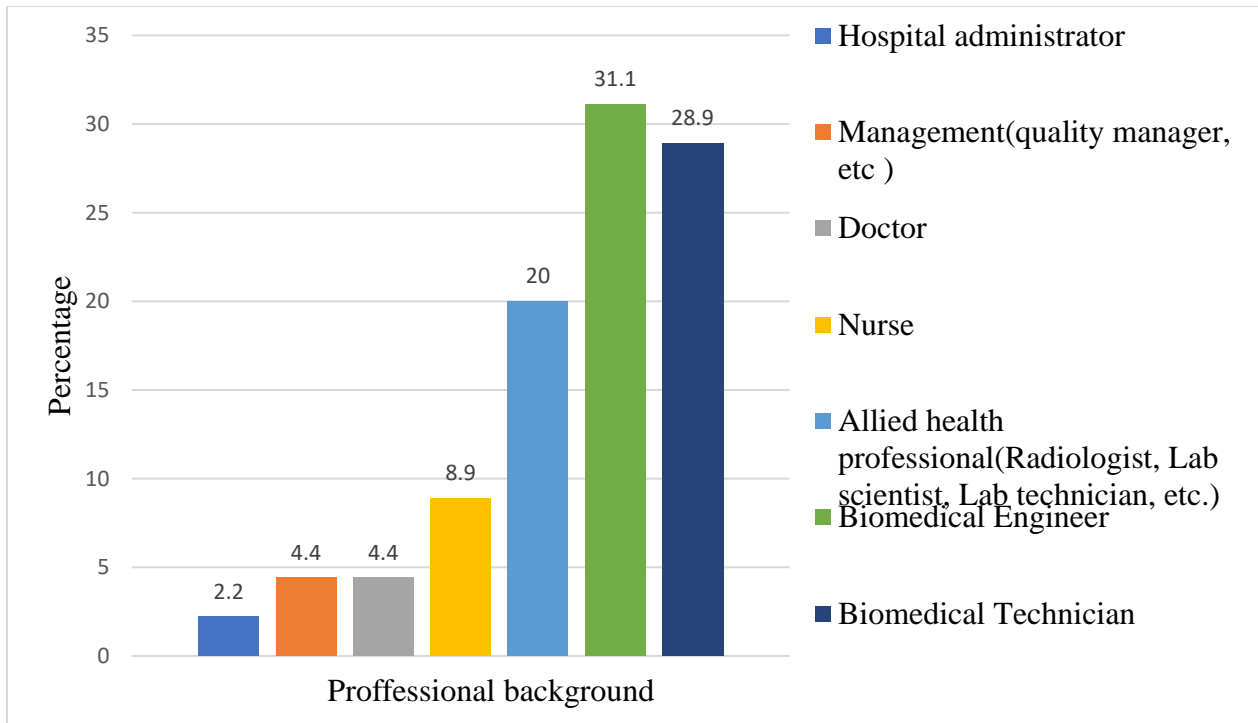


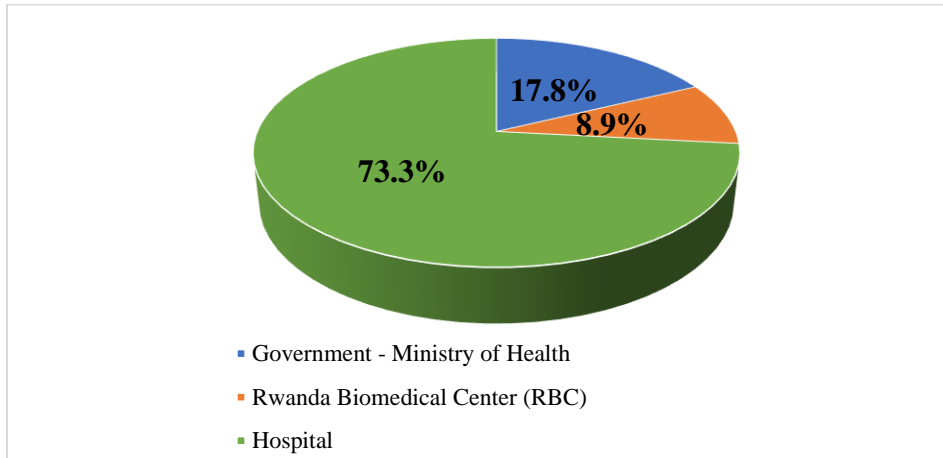
Figure 4.3. Professional background of respondents

➤ **Primary organization/ institution of the respondents (Where do they work?)**

*Table 4.3. Respondent's Area of work*

S/N		Frequency	Percent	Valid Percent	Cumulative Percent
1	Government - Ministry of Health	8	17.8	17.8	17.8
2	Rwanda Biomedical Center (RBC)	4	8.9	8.9	26.7
3	Hospital	33	73.3	73.3	100
Total		45	100	100	

The diagram below shows the primary institution in which the respondents work. The most respondents were from hospital as it occupied 73.3%.



*Figure 4.4. Respondent's Area of work*

- Respondents' views on whether the Institution/ Hospital have a systematic formal process by which information is gathered to support healthcare decision-making

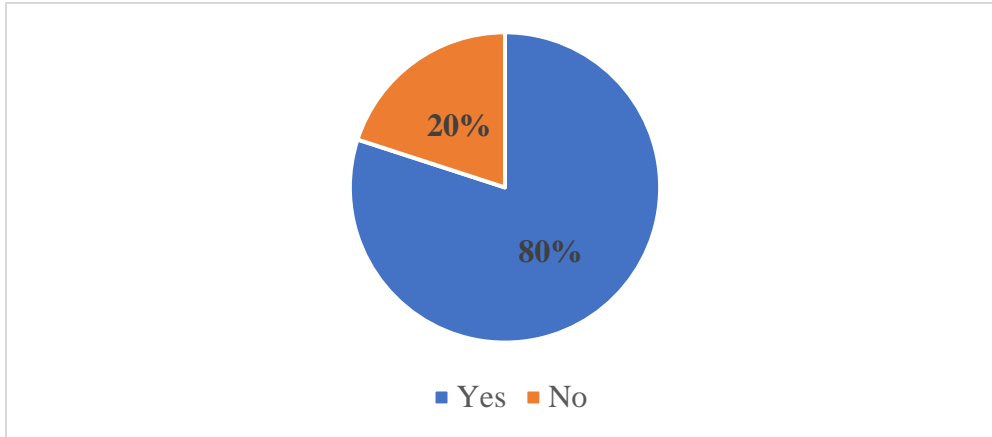


Figure 4.5. The systematic formal process by which information is gathered to support healthcare decision-making in institution/hospital

- Existing of formal process to assess health technology for medical devices

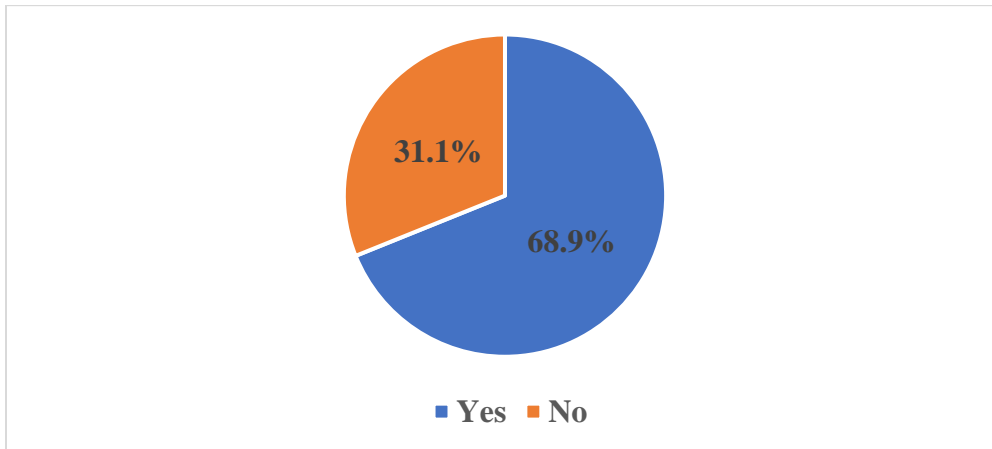


Figure 4.6. Availability of formal process to assess health technology for medical devices

- **Respondents view on availability of prioritization criteria used to determine health technologies to be considered in institution /hospital**

*Table 4.4. Availability of prioritization criteria*

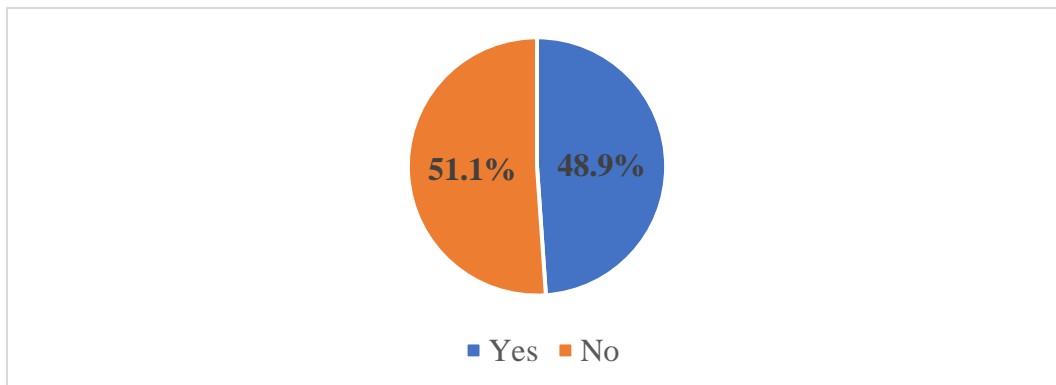
	Percent	Frequency	Valid Percent	Cumulative Percent
Yes	75.6	34	75.6	75.6
No	24.4	11	24.4	100
Total	100	45	100	

- **Respondents view on whether the process is referred as the Health Technology Assessment (HTA)**

*Table 4.5. Respondents' views on whether the process is referred as the Health Technology Assessment (HTA)*

	Percent	Frequency	Valid Percent	Cumulative Percent
Yes	64.4	29	64.4	64.4
No	35.6	16	35.6	100
Total	100	45	100	

- **Respondents view on whether their institution has a standard methodology or process guideline for conducting HTA or decision-making processes**



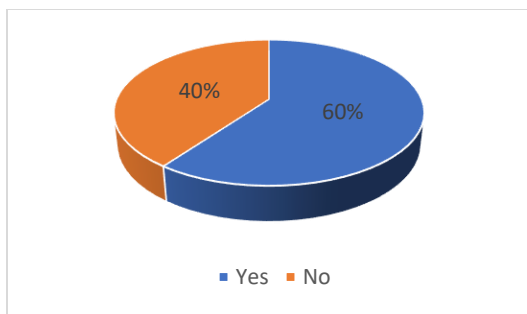
*Figure 4.7. Presences of standard methodology or process guideline for conducting HTA or decision-making processes*

- **Respondents view on whether their organization (institution or hospital) formally collaborated with other organizations locally or outside the country for the HTA or decision-making process**

*Table4.6. Collaboration between organisation on HTA*

	Percent	Frequency	Valid Percent	Cumulative Percent
A. Yes, with organizations within our country	51.1	23	51.1	51.1
B. Yes, with organizations from other countries	4.4	2	4.4	55.6
C. Both A&B	22.2	10	22.2	77.8
D. No	22.2	10	22.2	100
Total	100	45	100	

- **Respondents view on whether their institution/hospital have a policy on Health Technology Assessment**



*Figure4.8. Presence of policy on Health Technology Assessment*

- **Gathering information on whether the policy cover medical devices**

*Table 4.7. Information on whether the policy cover medical devices*

		Percent	Frequency	Valid Percent	Cumulative Percent
Valid	Yes	44.4	20	44.4	44.4
	No	55.6	25	55.6	100
	Total	100	45	100	

- Respondents view on whether institution or hospital have any HTA framework

Table 4.8. Availability of HTA framework in Institution/hospital

		Percent	Frequency	Valid Percent	Cumulative Percent
Valid	Yes	37.8	17	37.8	37.8
	No	62.2	28	62.2	100
	Total	100	45	100	

- Respondents view on the willingness of using HTA in decision-making in institution/hospital especially on medical devices

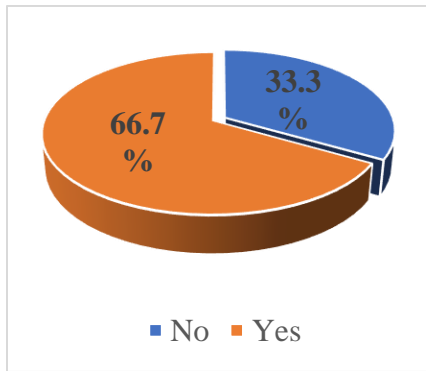


Figure 4.9. The willingness of using HTA in decision-making in institution/hospital especially on medical devices

- Respondents view on the criteria used by their institution/hospital to assess the impact of HTA

Table 4.9. Criteria used by their institution/hospital to assess the impact of HTA

SN	Variables (choice)	Responses		Percent of Cases
		N	Percent	
1	Changes within the organization or facilities (training staff, buying materials, etc.)	27	34.2%	60.0%
2	Variation between current practice and recommended practice over time	12	15.2%	26.7%
3	Change in health outcomes over time (clinical changes)	11	13.9%	24.4%

4	Level of technology diffusion over time	5	6.3%	11.1%
5	Changes in health from the point of view of the patients (perceived health, satisfaction, others)	7	8.9%	15.6%
6	Changes in the cost of the medical practice over time	11	13.9%	24.4%
7	None of the above	4	5.1%	8.9%
8	Other	2	2.5%	4.4%
<b>Total</b>		79	100.0%	175.6%

➤ **Respondents view on committee or group that help to review the Health Technology Assessment appraisal**

*Table4.10. Committee or group that help to review the Health Technology Assessment*

SN	Variables (choice)	Responses		Percent of Cases
		N	Percent	
1	Scientific Committee of the HTA or decision-making body	5	9.4%	11.1%
2	Executive Board of the HTA or decision-making body	12	22.6%	26.7%
3	Director of the HTA or decision-making body	3	5.7%	6.7%
4	Department/Ministry of Health	13	24.5%	28.9%
5	National Health Service	6	11.3%	13.3%
6	Patient Organizations	1	1.9%	2.2%
7	None	6	11.3%	13.3%
8	Other	7	13.2%	15.6%
<b>Total</b>		53	100.0%	117.8%

- **Members of the team for HTA of medical devices (It was allowed to select more than one choice)**

*Table 4.11. Members of the team for HTA of medical devices*

SN	Variables (choices)	Responses		Percent of Cases
		N	Percent	
1	Biomedical Engineer	39	30.2%	86.7%
2	Nurse	16	12.4%	35.6%
3	Finance	24	18.6%	53.3%
4	Facilities Engineering	20	15.5%	44.4%
5	Materials Management/Purchasing	27	20.9%	60.0%
6	Other	3	2.3%	6.7%
<b>Total</b>		129	100.0%	286.7%

- **Respondents view on strategic tool in which their institution/hospital use in planning for replacement of technology, especially on medical devices**

*Table 4.12. strategic tool in which their institution/hospital use in planning for replacement of technology*

	Percent	Frequency	Valid Percent	Cumulative Percent
Assessment of Need	31.1	14	31.1	31.1
Assessment of Impact	8.9	4	8.9	40
Assessment of Cost	4.4	2	4.4	44.4
Assessment of Benefit	2.2	1	2.2	46.7
All above	53.3	24	53.3	100
Total	100	45	100	

- **Respondents results on the estimation of the number of professional staff who are involved in the HTA committee (in full-time equivalent)**

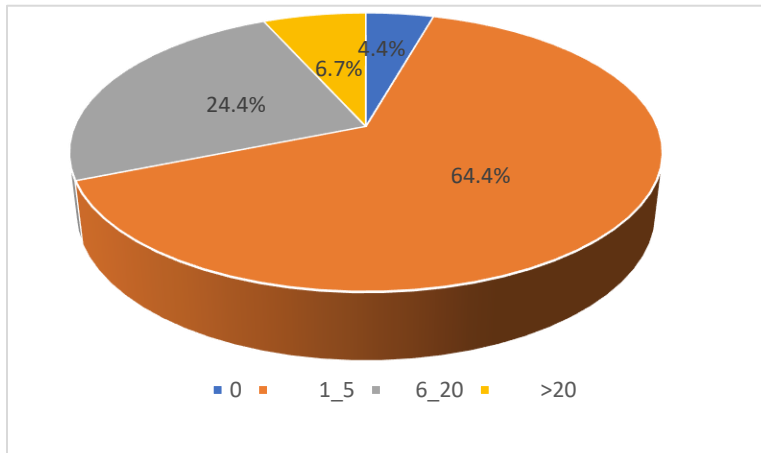


Figure 4.10. Number of professional staff who are involved in the HTA committee

- **Respondents view on how long does the assessment process takes on average for any given case of medical devices**

Table 4.13. Time of assessment process takes on average for any given case of medical devices

	Percent	Frequency	Valid Percent	Cumulative Percent
1-3 months	62.2	28	62.2	62.2
4-6 month	22.2	10	22.2	84.4
7-12 months	11.1	5	11.1	95.6
>1 year	4.4	2	4.4	100
Total	100	45	100	

- **Respondents' views on the number of assessments performed related to medical devices in the last 12 months**

Table 4.14. Number of assessments performed related to medical devices

S. N		Percent	Frequency	Valid Percent	Cumulative Percent
1	1 Assessment	15.6	7	15.6	15.6
2	2 Assessments	28.9	13	28.9	44.4
3	3 Assessments	26.7	12	26.7	71.1

4	4 Assessments	6.7	3	6.7	77.8
5	5 Assessments	2.2	1	2.2	80
6	10 Assessments	2.2	1	2.2	82.2
7	12 Assessments	4.4	2	4.4	86.7
8	20 Assessments	13.3	6	13.3	100
Total		100	45	100	

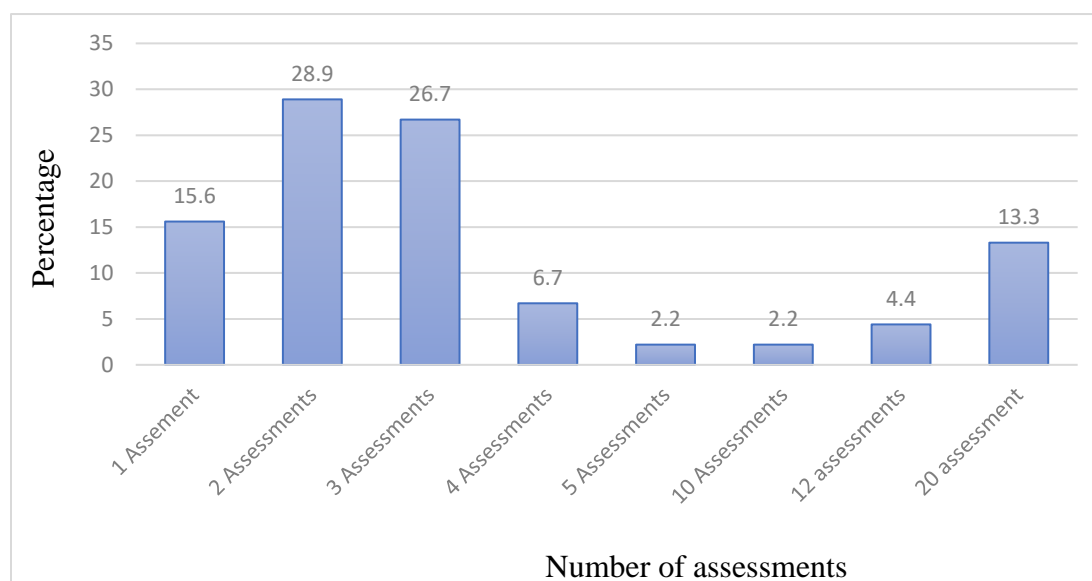


Figure 4.11. Number of assessments performed related to medical devices

➤ **Suggested ideas of respondents on the improvement of HTA in health facility**

The data collection of this study was concluded by requesting the respondents to suggest the ideas or strategies that can be used in improvement of using Health Technology Assessment (HTA) of medical in health facility and the results are presented in the following table:

Table 4.15. Suggestions of respondents

Suggested ideas	Frequency	Percentage
Ensure the availability of Health data which can guide people on the capacity of medical equipment to be procured	6	13.33
Ensure availability of after sell services is very important to be considered in deciding the technology to be employed	4	8.88

Need of developing the HTA policies on medical devices and its framework	10	22.22
Health facility should have Health Technology Assessment committee to participate in decision making	1	2.22
Extend the involved personnel so that decision can be made from a wide range of people who are actually end users of medical devices	5	11.11
The assessment (HTA) is so good just to help the improvement of health facilities	4	8.88
Enough budget should be planned for good HTA of any technology to be introduced in health facility	2	4.44
Increase the staff training on HTA	6	13.33
Use HTA in decision making to allocate the resources	3	6.66
Lack of spare parts due to issue of not performing well HTA	1	2.22
Not having enough information on HTA	3	6.66
Total	45	100

Based on the results of study, 22.22% of the respondents suggested there is a need to develop the policy of HTA of medical devices together with the roadmap showing how HTA should be applied in decision making during the time of incorporating the new technology or its replacement in health facility. While 2.22% is the least number of the respondents who suggested that health facility should have Health Technology Assessment committee to participate in decision making and another 2.22% is for the respondent who mentioned that there a lack of spare parts due to issue of not performing well HTA.

#### **4.1.2. Test of Correlation and Significance of Variables**

In this study SPSS software were used especially chi square test and binary logistic regression analysis were used in order to test the relationship between variables (independent and dependent variables) and their significance respectively. The term correlation refers to the measure of bivariate that shows the association or the strength of relationship between two variable at the same time [65]. The statistical test of significance aims to identify whether an observed difference

implies that the specified features of two or more groups are the same or different; or whether a relationship exists between two or more variables.

➤ **Chi-Square Test Results**

Chi square test is useful while testing the hypothesis. Hypothesis-testing results in either accepting the hypothesis or in rejecting it [66] . This test is a statistical measure used in sampling analysis to assess the relationship between two attributes (variables). Chi square test is used for the following purposes : (i) testing the null hypothesis that there is no association between two or more groups, populations, or criteria (which means, determining the independence between two variables); and (ii) determining the likelihood that the observed data distribution matches the expected distribution (which means the determining the goodness-of-fit) [67]. Chi square is symbolized by  $\chi^2$ . In this study, the significance of the chi-square value [ $\chi^2$  (calculated)] was determined by using the suitable degree of freedom [ $df = (r - 1) (c - 1)$ ] and the degree of significance ( $\alpha = 0.05$ ) in comparison with the chi-square value from a table showing Critical Values of  $\chi^2$ . The expected value is determined as follow:  $E_i = \frac{\text{Row total} * \text{Column total}}{n}$  which is obtained using the cross table and the formula to get chi square is  $\chi^2 = \sum \frac{(O_i - E_i)^2}{E_i}$ , where  $\chi^2$  = chi-square,  $O_i$ = Observed value,  $E_i$ = Expected value.

The table indicates the chi-square test results to find relationships between variables (selected factors including professional background of respondents, Area of work, general process of assessing HTA, formal or systematic process of HTA, priority settings, process consideration, The standard methodology of HTA, collaboration with other organizations, HTA policy on medical devices, HTA framework, strategic tool used for planning, staff number who participate in HTA and assessment performed in the last 12 months) and the willingness of using HTA in decision making (HTA adoption in decision making) especially on medical devices.

Table 4.16. correlation of variables (selected factors) to the willingness of using HTA in decision making especially on medical devices

S.N	Variables (selected factors)	df=(r-1) (c-1)	$\chi^2$ (Calculated)	$\chi^2$ (Critical)	p-value	$\chi^2$ test (Ho)*
1	Professional of respondents	6	15.753	12.592	0.0151	SC
2	Area of work	3	8.366	7.815	0.0390	SC
3	General process of assessing HTA	1	6.1875	3.841	0.0129	SC
4	Formal or systematic process of HTA	1	4.500	3.841	0.0339	SC
5	Priority settings	1	4.717	3.841	0.0298	SC
6	Process consideration	1	9.3879	3.841	0.0021	SC
7	The standard methodology of HTA	1	12.6405	3.841	0.00034	SC
8	Collaboration with other organizations	3	13.7366	7.815	0.00329	SC
9	HTA policy on medical devices	1	4.37702	3.841	0.03643	SC
10	HTA framework	1	11.81723	3.841	0.0005	SC
11	Strategic tool used for planning	4	15.02679	9.488	0.00465	SC
12	Staff number who participate in HTA	3	12.68159	7.815	0.00538	SC
13	Assessment performed in the last 12 months	7	15.28071	14.067	0.03257	SC

\*Ho: means there is no relationship between the selected independent variable (selected factors) and the dependent variable (willingness to use HTA on medical devices). SC= the selected factors

is statistically correlated to the willingness of the use of HTA on medical devices.  $r$  = number of rows.  $c$  = number of columns.

Since the chi-square calculated is greater than critical values (values obtained by considering values of degree of freedom at the level of  $\alpha=0.05$  found in  $\chi^2$  table, hence there is stronger evidence of rejecting null hypothesis ( $H_0$ ) means that there is a correlation between variables and the willingness of using HTA on medical devise.

Another evidence of confirmation the correlation between the variables is that the p-values must be less than to the level of significance ( $\alpha=0.05$ ). Final in this study of selected variables it has found that there is a relationship.

➤ **Binary logistic regression model**

*Table 4.17. Model Summary*

Step	-2 Log likelihood		Cox & Snell R Square	Nagelkerke R Square
1	29.329 <sup>a</sup>		.518	.692
		a. Estimation terminated at iteration number 8 because parameter estimates changed by less than .001.		

The model summary table **reports the strength of the relationship between the model and the dependent variable**.  $R$ , the multiple correlation coefficient, is the linear correlation between the observed and model-predicted values of the dependent variable. Its large value indicates a strong relationship. According to Cox & Snell R Square Nagelkerke R Square, the R square value for binary logistic regression model range between 0-1, the more the R square-value tends to 1, this indicates the stronger significance between independent and dependent variables [68]. Based on the analysis, the results for Cox & Snell R Square and Nagelkerke R Square are 0.518 and 0.692 respectively, therefore there is a strong significance between independent and dependent variables.

Table 4.18. Classification Table

	Observed		Predicted		
			The willing of using HTA in decision-making in especially on medical devices		Percentage Correct
			Yes	No	
Step 1	The willingness of using HTA in decision-making especially on medical devices	Yes	17	4	81.0
		No	4	20	83.3
	Overall Percentage				82.2
a. The cut value is .500					

➤ **Classification table (accuracy assessment)**

The classification table is another method to evaluate the predictive accuracy of the logistic regression model. In this table the observed values for the dependent outcome and the predicted values (at a user-defined cut-off value, for example,  $p=0.50$ ) are cross-classified. In our example, the model correctly predicts **82.2%** of the cases. The predictive percentage must be above 50% which shows the significance between variables.

➤ **Binary logistic results**

This study also uses the Binary Logistic Regression Model to investigate if there is a statistical significance between selected variables (independent variables) and the willingness of using HTA in decision making especially on medical devices. The nine variables commonly associated with that willingness are listed in Table below:

Table 4.19. Shows the significance of variables

SN	Variable (Selected factor)	B	S.E.	Wald	df	Sig.	Exp(B)
1	Professional background	-1.689	0.693	5.946	1	0.015	0.185
2	Area of work	-4.084	1.642	6.185	1	0.013	0.017
3	Systematic method or process	8.151	3.635	5.028	1	0.025	3466.767
4	Priority setting	14.622	5.608	6.799	1	0.009	0
5	HTA Process consideration	6.036	2.379	6.438	1	0.011	418.207
6	Standard methodology	-3.944	1.927	4.189	1	0.041	0.019
7	Collaboration with other institution	-0.371	0.537	0.478	1	0.489	0.69
8	HTA policy on medical devices	-11.7	4.417	7.018	1	0.008	0
9	HTA framework	6.843	2.993	5.226	1	0.022	937.136
	Constant	33.568	13.122	6.544	1	0.011	3.79E+14

While assessing the contribution of the nine variables (selected factors) on the willingness of using HTA in decision making especially in medical devices. According to the study carried out by Park, Hyeoun Ae, in 2013, The following notations and meanings were used: B: Regression coefficient in the binary logistic regression model. S.E: Standard error. Exp (B): Odds ratio. Sig.: p-values (in the column of Sig.). Wald: A Wald chi-square test was used to determine whether the coefficients within the model are statistically significant. df: Degree of freedom (for the Wald chi-square test) [69]. Factor is said to be significance if p is less than 0.05 and if wald is greater than critical value at 1 degree of freedom also indicates the significant between variable. In this study, it was found that Sig (p-value) is less than the alpha ( $\alpha$ ) which is equal to 0.05, Therefore, there is a significance between variables (independent and dependent variables).

#### 4.1.3. HTA Framework and Policy

As one of the specific objectives of the project is to propose a feasible solution through the development of the HTA framework for Rwanda and develop Health Technology Assessment policies in terms of healthcare technology properties, economic attributes, and risk management. The proposed HTA policy is found the appendix.

### ❖ HTA framework

This framework is intended to guide healthcare decision maker especially those who are in charge of performing the evaluation of needed health technology (medical devices) in health facility or institution and deciding whether technology should be introduced in the institution. The HTA framework is also crucial to provide the knowledge and skills that are necessary required for a better decision making related to health technology. The developed framework is made of four main components including technology itself, institutional capacity, economic evaluation and patient and staff related. And this framework was sketched using draw.io software. The figure below shows the procedure structure of the HTA framework developed:

**HTA Framework**

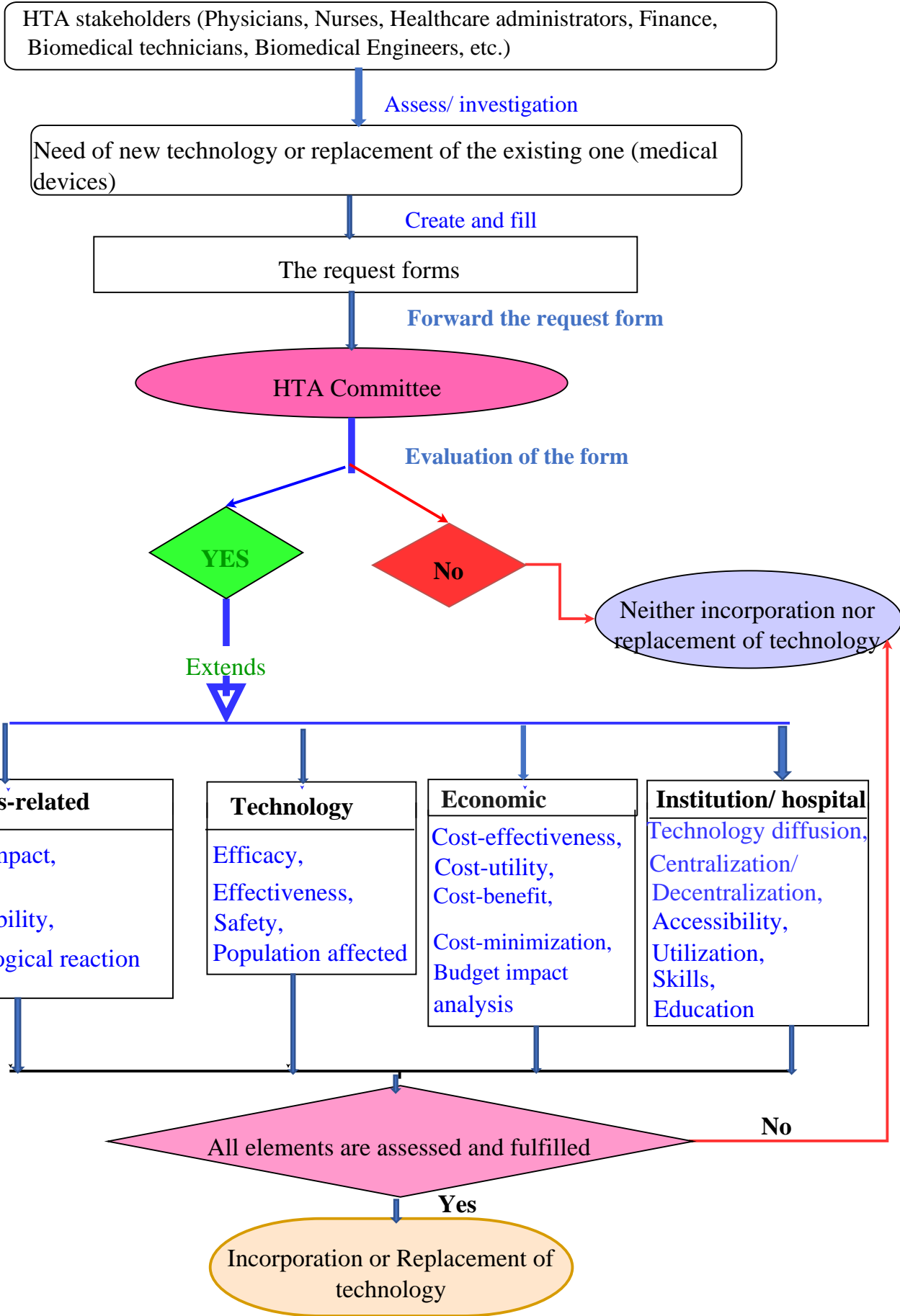


Figure 4.12. Health Technology Assessment framework

The overview of each component in this HTA framework is described below:

➤ **Institutional capacity**

The institution or health facility should ensure that the following resources are necessary in performing Health Technology Assessment before a new technology is being incorporated in health facility or replacing the existing technology. Such resources include a person with a strong educational background and experience in Health Technology Assessment, sufficient financial resources and time for conducting the HTA of new technology or the existing one especially medical device, the capacity for training the end user of medical devices. This component is made of technology diffusion, centralization/decentralization, utilization, accessibility, skills, education like training and other organizations parameters such facilities or infrastructure.

➤ **Technology**

This component consists of different dimensions such as efficacy, safety, population affected and outcomes. At this stage decision makers have to assess if the efficacy and effectiveness of the technology by evaluating whether the technology is right and it is performing well what it was designed for and the size of the population that would receive it.

➤ **Economic evaluation**

At level of economic, HTA can assist a health system in choosing how to distribute the frequently constrained healthcare funding to various health technologies. Decision makers should assess the cost-effectiveness, cost utility and cost benefit. For the cost-effectiveness analysis, HTA committee or healthcare decision maker should determine if a new medical technology is beneficial in comparison to current medical technologies already in use. The second factor to assess in economic evaluation is cost-utility analyses which are essentially cost-effectiveness evaluations that take into account and evaluate improvements in health-related quality of life (HRQoL). And the last step is cost-benefit studies, which quantify the financial impact of both costs and consequences.

➤ **Patient-related**

At this stage, healthcare decision makers have to assess the effect of the technology to the human life by taking into account the following factors: social impact, ethics, acceptability, psychological reactions and other patient parameters. The decision-maker should consider whether the new technology (medical equipment) has values that can alter the way of life and attitudes of the current society. During the process of decision making using HTA, ethics have to be considered as an

integral part of HTA in order to enhance the quality of human life. And this is confirmed by study done by Hafizah Besar Sa'aid. e tal (2015), which stated that Improved healthcare and higher quality of life, or the "good life," are morally good things that are being promoted through health technology. Ethics therefore has a natural position in HTA since it is the logos of the good life [13].

#### **4.1.4. Discussion**

This thesis intended to develop the Health Technology Assessment framework for Rwanda especially for medical devices. The hypothesis of this research was mainly focusing on the adoption or the willing of HTA use in decision making process during the introduction of new technology or replacement of existing technology in institution/hospital. This section deals with the discussion of the results in relation to the research questions.

##### **➤ Is there any policy related to HTA of medical devices in Rwanda?**

According to the survey conducted by WHO on medical devices in global atlas of medical 2022, it was found that healthy healthcare system depends on health technology. In particular, medical devices are essential for patient monitoring, illness prevention, diagnosis, and treatment. The World Health Assembly adopted resolution WHA60.29 in May 2007 after acknowledging the crucial role that health technologies play in society [70]. This survey showed in some high income countries like China, Belgium, Russia, etc. have Health technology (medical device) national policy while most African country including Rwanda do not have a designated unit/department for Health Technology Assessment (HTA) [70]. HTA unit/department includes the assessment of medical devices while There are identified HTA activities which are specifically done in pharmaceuticals for pricing and reimbursements as well as health economics; however, there is no national unit [70]. The research findings of this study revealed that there is HTA policy in general but does not cover medical devices as it was confirmed by 55.6% of respondents as it is discussed in the results, therefore this research question was answered by proposing the HTA policy that covers medical devices especially for three main key points such as healthcare technology properties assessment, technology economic attributes assessment and technology risk assessment.

➤ **Why HTA is undertaken by international expert who may not be aware of the local context and perspective?**

Rwanda's health sector has made great achievements toward improving the population's health Over the past 20 years. HTA in Rwanda is undertaken by international experts due to shortages and gaps in local capacities. There is a need to invest in capacity development for local actors to develop the required technical capacities in benefit package revisions and HTA, as well as strengthen policymakers', local researchers', and purchasers' capacities to develop health benefits packages that consider population needs in terms of disease burden, national priorities, equity, and cost-effectiveness using an evidence-based approach[35]. And this confirmed by the findings of this study as large number of respondents showed that they don't have enough information on how HTA should be performed.

➤ **How HTA stakeholders in Rwanda understand the HTA concepts, functions and practices?**

The study showed that stakeholders such as physician, nurses, allied health professional, Biomedical technician (BMET and Biomedical Engineer (BME) have limited knowledge on the use and understanding of HTA. The stakeholders believe that HTA should be promoted as a tool for evidence informed policymaking. And they suggest that HTA programs should be applied in decision making before introducing a new technology or replacing the existing one in the institution or hospital.

➤ **Is there any group, agency or organization with the responsibility of establishing HTA of medical devices policies in Rwanda?**

The Agency which is responsible for establishing the HTA policy play a great role in assessing the safety, efficacy, cost and benefit of new technology. Their decisions can have reflective effect on the length and quality of patients' lives. This task demands the greatest care; not just to evaluate the technical and financial dimensions of a new technology but to carefully assess the full impact the new technology on patients. New technology not only have impact on health status of patients, it can also have effect on quality of life. HTA agencies are responsible for discussions, or deliberations on the value of a technology [71]. Results obtained from field showed that most respondents said that there is no agency responsible for formulating HTA of medical devices. And those participants suggested that there should be organization or unit of HTA for providing HTA

policy especially on medical devices in order to enhance the better decision making on health technology.

➤ **How HTA framework will contribute to the advancement of clinical interventions and practices, though the use of medical technology?**

The HTA framework developed will show the road map of all processes required to incorporate new technology in health facility based on the priority, by giving guidance on step by step on how HTA can help to maximize the chance of the newly developed technology being accepted and used in order to enhance the quality of healthcare system. Based on the study findings some respondents showed that there is an issue of budget while planning to introduce new technology (medical device) in health facility, therefore the use of HTA framework in decision making will help to overcome the issue of limited budget as it will help for better resources allocation. Also, the study carried out by Wang et al 2021, indicated that the widespread of HTA adoption is due to quick development of new health technology and limited health budget [72].

#### **4.2. Summary**

The responses that have been given by the respondents during the time of data collection were qualitative and showed well their perspectives on Health Technology Assessment. The results of analyzed data through the use of Chi-square and binary logistic regression analysis tests showed the correlation and significance between the dependent and independent variables.

## **Chapter 5. Conclusion, Recommendation and Future Study**

### **5.1. Conclusion**

The use of Health Technology Assessment has been expanding globally, and it has a well-recognized potential to enhance healthcare decision-making. HTA is crucial to inform the policy decision-maker in health care to improve the uptake of cost-effective for new technologies and prevent the uptake of technologies that are of doubtful value for the health system. This study highlights the potential use of HTA in decision making while the health facility plans to adopt a new technology especially for medical devices. The research was initiated to identify challenges or gaps regarding assessment of health technology system in Rwanda using SWOT analysis and to propose feasible solution through the development of HTA framework for Rwanda and develop Health Technology Assessment policies in terms of healthcare technology properties, economic attributes and risk management.

A well-structured questionnaire was used for data collection and a total number of 45 respondents participated in the study. Various factors were used to test the correlation and significance between variables including independent variables like professional background of respondents, Area of work, general process of assessing HTA, formal or systematic process of HTA, priority settings, process consideration, The standard methodology of HTA, collaboration with other organizations, HTA policy on medical devices, HTA framework, strategic tool used for planning, staff number who participate in HTA and assessment performed in the last 12 months) and dependent variable (the willingness of using HTA in decision making (HTA adoption in decision making) before introduction of new technology especially on medical devices in health facility. The chi-square test indicated that the independent variables were associated ( $p < 0.05$ ) with the willingness of using HTA in decision making (HTA adoption in decision making) especially on medical devices. Moreover, the binary logistic regression model revealed that both independent and dependent variables access positively correlated significantly.

After data collection and analysis, the research questions were all successfully answered and the objectives of the study were achieved. To the end of the study, HTA framework and policy were proposed and can be used to support and promote good practice through the integration of HTA usage in decision making for the purpose of enhancing better incorporation or replacement of technology (medical devices) in health facility.

## **5.2. Recommendation**

Finally, this study recommends the following: (i) the Ministry of Health (MoH) to implement the developed framework and encourage the health facilities to use it in decision making; (ii) the Government of Rwanda to establish the HTA agency which should be in charge of Health Technology Assessment of each medical device in health facility. This agency should join the global health initiative on HTA so they can share information on how HTA should be done in order to enhance better decision making; (iii) the Government of Rwanda to develop the local technical capacity for HTA through partnership and increase awareness among stakeholders in order to promote the institutionalized Health Technology Assessment systems; (iv) Health facilities to provide the staff training on HTA and its function; (v) individuals who participate in decision making have to consider the HTA framework during time of deciding on health technology to be introduced in health facility in order to improve the patients safety.

## **5.3. Future Study**

For better improvement of quality of life for public health, the HTA framework developed need to be validated through consultation with experts and policy makers. Therefore, a wider use of HTA should be applied in decision making of health technology in health facilities.

## References:

- [1] M. Joore, S. Grimm, A. Boonen, M. De Wit, F. Guillemin, and B. Fautrel, “Health technology assessment: A framework,” *RMD Open*, vol. 6, no. 3, pp. 6–8, 2020, doi: 10.1136/rmdopen-2020-001289.
- [2] J. Pereira *et al.*, “HTA Reshaping: Rethinking the Health Technology Assessment Framework in Portugal,” *Port. J. Public Heal.*, vol. 39, no. 1, pp. 36–47, 2021, doi: 10.1159/000516501.
- [3] R. Millar *et al.*, “Assessing the performance of health technology assessment (HTA) agencies: developing a multi-country, multi-stakeholder, and multi-dimensional framework to explore mechanisms of impact,” *Cost Eff. Resour. Alloc.*, vol. 19, no. 1, pp. 1–14, 2021, doi: 10.1186/s12962-021-00290-8.
- [4] World Health Organization (WHO), *Human Resources for Medical Devices: The role of biomedical engineers*. 2017.
- [5] C. Sorenson, M. Drummond, F. Boerlum Kristensen, and R. Busse, “World Health Organization Policy Brief: How can the impact of health technology assessments be enhanced?,” *Eur. Obs. Heal. Syst.*, p. 35, 2008.
- [6] S. Hollingworth, A. P. Fenny, S. Y. Yu, F. Ruiz, and K. Chalkidou, “Health technology assessment in sub - Saharan Africa : a descriptive analysis and narrative synthesis,” *Cost Eff. Resour. Alloc.*, pp. 1–13, 2021, doi: 10.1186/s12962-021-00293-5.
- [7] World Health Organization, “Health technology assessment of medical devices WHO Medical device technical series WHO MEDICAL DEVICE TECHNICAL SERIES : TO ENSURE IMPROVED ACCESS , QUALITY AND USE OF MEDICAL DEVICES DEVELOPMENT OF MEDICAL DEVICE POLICIES WHO MEDICAL DEVICE TECHNICAL SE,” 2011.
- [8] D. Banta and E. Jonsson, “History of HTA : Introduction,” vol. 1, pp. 1–6, 2009, doi: 10.1017/S0266462309090321.
- [9] B. J. Salisbury N, Castro H, “The Emergence of Health Technology Assessment Organizations Lessons from five countries New Health Technologies for TB, Malaria and

- NTDs From the People of Japan,” 2017.
- [10] A. Falkowski *et al.*, “How Least Developed to Lower-Middle Income Countries Use Health Technology Assessment: A Scoping Review,” *Pathog. Glob. Health*, vol. 00, no. 00, pp. 1–16, 2022, doi: 10.1080/20477724.2022.2106108.
- [11] R. Daubner-bendes, S. Kovács, M. Niewada, and M. Huic, “Quo Vadis HTA for Medical Devices in Central and Eastern Europe ? Recommendations to Address Methodological Challenges,” vol. 8, no. January, pp. 1–10, 2021, doi: 10.3389/fpubh.2020.612410.
- [12] F. B. Kristensen *et al.*, “Identifying the Need for Good Practices in Health Technology Assessment: Summary of the ISPOR HTA Council Working Group Report on Good Practices in HTA,” *Value Heal.*, vol. 22, no. 1, pp. 13–20, 2019, doi: 10.1016/j.jval.2018.08.010.
- [13] H. Besar, A. B. Zakaria, P. Bizpoint, and J. P. P. P, “Islamic Bioethics as an Extended New Element in Health Technology Assessment ( HTA ) Framework,” no. September 2012, pp. 1–12, 2015.
- [14] M. Alkhalidi, A. Al Basuoni, M. Tanner, and S. Ahmed, “Health Technology Assessment in High , Middle , and Low-income Countries : New Systematic and Interdisciplinary Approach For Sound Informed- policy Making : Research Protocole,” pp. 2757–2770, 2021.
- [15] Ā. Āūzd’ and P. Kneppo, “HEALTH TECHNOLOGY ASSESSMENT FOR MEDICAL DEVICES,” no. March 2018, 2014, doi: 10.14311/CTJ.2014.3.
- [16] R. C. Carlos and R. Goeree, “Introduction: Health Technology Assessment in Diagnostic Imaging,” *J. Am. Coll. Radiol.*, vol. 6, no. 5, pp. 297–298, 2009, doi: 10.1016/j.jacr.2009.01.025.
- [17] S. Diamond, *Health Technology Assessment Toolkit*. .
- [18] M. Blüher, S. J. Saunders, V. Mittard, R. Torrejon Torres, J. A. Davis, and R. Saunders, “Critical Review of European Health-Economic Guidelines for the Health Technology Assessment of Medical Devices,” *Front. Med.*, vol. 6, no. November, pp. 1–12, 2019, doi: 10.3389/fmed.2019.00278.

- [19] S. Ludwig, *Health technology assessment.*, vol. 97, no. 5. 2001.
- [20] F. Degavre *et al.*, “Searching for Sustainability in Health Systems : Toward a Multidisciplinary Evaluation of Mobile Health Innovations,” pp. 1–17, 2022.
- [21] World Health Organization (WHO), “New horizons for health through mobile technologies,” vol. 3, 2011.
- [22] O. Gurova, T. R. Merritt, and E. Papachristos, “Sustainable Solutions for Wearable Technologies : Mapping the Product Development Life Cycle,” vol. 64, pp. 1–26, 2020.
- [23] Lancet Global Health, “Comment Opportunities and challenges for telehealth within , and beyond , a pandemic,” vol. 2667, no. 20, pp. 20–21, 2020, doi: 10.1016/S2214-109X(20)30362-4.
- [24] M. Buffoli, S. Capolongo, and M. Bottero, “Sustainable Healthcare : how to assess and improve healthcare structures ’ sustainability,” no. October, 2013, doi: 10.7416/ai.2013.1942.
- [25] Y. Xiao, Y. Qiu, L. Shi, and I. Viguera-guerra, “OP165 Health Technology Assessment And Public Health Priority Setting In China OP169 Implementation Of A Quality Management System In The Spanish Network Of Health Technology Assessment OP168 The EUnetHTA Quality Management System : Development And Evalua,” p. 1017, 2019.
- [26] M. J. Taylor, C. McNicholas, C. Nicolay, A. Darzi, D. Bell, and J. E. Reed, “Systematic review of the application of the plan – do – study – act method to improve quality in healthcare,” pp. 290–298, 2014, doi: 10.1136/bmjqs-2013-001862.
- [27] B. O’Rourke, W. Oortwijn, and T. Schuller, “Announcing the New Definition of Health Technology Assessment,” *Value Heal.*, vol. 23, no. 6, pp. 824–825, 2020, doi: 10.1016/j.jval.2020.05.001.
- [28] Alexandropoulos Christos, “MSc program ‘ Health Technology Assessment Tools and Methods for Medical Devices ; Case study of Mobile Health Applications ,” 2020.
- [29] J. K. Aronson, C. Heneghan, and R. E. Ferner, “Medical Devices : Definition , Classification , and Regulatory Implications,” *Drug Saf.*, no. 0123456789, 2019, doi:

10.1007/s40264-019-00878-3.

- [30] World Health Organization (WHO), “2015 Global Survey on Health Technology Assessment by National Authorities Main findings,” 2015.
- [31] World Health Organization (WHO), “Current status of health intervention and technology assessment in the balkan region,” vol. 2020-1303-, 2020.
- [32] Dr Nabil Kronfol, “Health Technology Assessment for Universal Health Coverage,” 2019.
- [33] F. Iandolo, P. Vito, I. Fulco, and F. Loia, “From Health Technology Assessment to Health Technology Sustainability,” 2018, doi: 10.3390/su10124748.
- [34] A. Luz, B. Santatiwongcha, J. Pattanaphesaj, and Y. Teerawattananon, “Identifying Priority Methodological Issues in Economic Evaluation in Low- and Middle-Income Countries: Finding the Holy Grail,” p. 58, 2016.
- [35] A. N. and P. U. Stella Matutina UMUHOZA, Sabine F. MUSANGE, “Establishing Health Technology Assessment in Rwanda – Lessons for Other Countries,” *Blog, SPARCing SPARC Oct. 10, 2021CBHI, Rwanda, Strateg. Heal. Purch. Strateg. Purch. Univers. Heal. Cover.*, 2021.
- [36] R. Tarricone *et al.*, “Health policy Establishing a national HTA program for medical devices in Italy : Overhauling a fragmented system to ensure value and equal access to new medical technologies,” *Health Policy (New. York)*., vol. 125, no. 5, pp. 602–608, 2021, doi: 10.1016/j.healthpol.2021.03.003.
- [37] S. Tallarico, D. Aloini, R. Dulmin, S. Lazzini, V. Mininno, and L. Pellegrini, “Health Technology Assessment of medical devices. Overcoming the critical issues of current assessment,” *J. Multi-Criteria Decis. Anal.*, vol. 29, no. 1–2, pp. 150–172, 2022, doi: 10.1002/mcda.1764.
- [38] M. Gagnon, M. Desmartis, T. Poder, and W. Witteman, “Effects and repercussions of local / hospital-based health technology assessment ( HTA ): a systematic review,” vol. 3, no. 1, pp. 1–14, 2014, doi: 10.1186/2046-4053-3-129.
- [39] J. Ming *et al.*, “Health technology assessment of medical devices : current landscape ,

- challenges , and a way forward,” *Cost Eff. Resour. Alloc.*, pp. 1–9, 2022, doi: 10.1186/s12962-022-00389-6.
- [40] E. Nazari, M. H. Shahriari, and H. Tabesh, “Applications of Framework In Health Care: A Survey,” *Front. Heal. Informatics*, vol. 8, no. 1, p. 16, 2019, doi: 10.30699/fhi.v8i1.186.
- [41] M. V. Garrido, F. B. Kristensen, C. P. Nielsen, and R. Busse, “HEALTH TECHNOLOGY POLICY-MAKING IN EUROPE Current status , challenges and potential,” *World Heal. Organ.*, p. 197, 2008.
- [42] O. Löblová, “What has health technology assessment ever done for us?,” *J. Heal. Serv. Res. Policy*, vol. 23, no. 2, pp. 134–136, 2018, doi: 10.1177/1355819617725545.
- [43] B. Yazdizadeh, F. Mohtasham, and A. Velayati, “Impact assessment of Iran’s health technology assessment programme,” *Heal. Res. Policy Syst.*, vol. 16, no. 1, pp. 1–20, 2018, doi: 10.1186/s12961-018-0286-0.
- [44] K. Williams, S. Sassler, A. Frech, F. Addo, and E. Cooksey, “Health technology assessment. An introduction to objectives, role of evidence, and structure in Europe.,” *J. Health Soc. Behav.*, vol. 54, p. 277, 2013, [Online]. Available: <http://www.ncbi.nlm.nih.gov/pubmed/24055071>.
- [45] M. Gad, T. A.-H. Economics, and G. Health, “Setting Priorities Fairly : Sustainable policies for effective resource allocation in Africa Introduction to HTA,” no. September, 2018.
- [46] P. Klein, H. Blommestein, M. Al, and B. Pongiglione, “Real-world evidence in health technology assessment of high-risk medical devices : Fit for purpose ?,” vol. 31, no. June, pp. 10–24, 2022, doi: 10.1002/hec.4575.
- [47] World Health Organization (WHO), “USING HEALTH TECHNOLOGY ASSESSMENT FOR UNIVERSAL HEALTH COVERAGE AND REIMBURSEMENT SYSTEMS,” no. November, 2015.
- [48] D. Banta, “The development of health technology assessment in Brazil,” vol. 1, pp. 255–259, 2009, doi: 10.1017/S0266462309090722.

- [49] M. B. Ferraz, P. Coelho, D. S. Ii, and P. Z. Iii, “Health technology assessment in Brazil : What do healthcare system players think about it ? Avaliação de tecnologias em saúde no Brasil : O que os atores do sistema de saúde pensam a respeito ?,” vol. 129, no. 4, pp. 198–205, 2011.
- [50] C. S. Goodman, D. Ph, and F. Church, “INTRODUCTION TO HEALTH TECHNOLOGY ASSESSMENT,” no. January, 2004.
- [51] K. H. Cerri, M. Knapp, J. Fernandez, and A. Published, “Decision making by NICE : examining the influences of evidence , process and context,” 2014, doi: 10.1017/S1744133113000030.
- [52] M. Moharra *et al.*, “Systems to support health technology assessment ( HTA ) in Member States of the European Union with limited institutionalization of HTA,” vol. 2, pp. 75–83, 2009, doi: 10.1017/S0266462309990717.
- [53] B. O. Rourke, S. S. Werkö, T. Merlin, L. Y. Huang, and T. Schuller, “The ‘ Top 10 ’ Challenges for Health Technology Assessment : INAHTA Viewpoint,” no. November 2017, pp. 2017–2020, 2019.
- [54] T. Kim *et al.*, “Addressing Challenges in Health Technology Assessment Institutionalization for Furtherance of Universal Health Coverage Through South-South Knowledge Exchange: Lessons From Bhutan, Kenya, Thailand, and Zambia,” *Value Heal. Reg. Issues*, vol. 24, pp. 187–192, 2021, doi: 10.1016/j.vhri.2020.12.011.
- [55] Andrew Dillon, “RESPONSIVENESS , LANGUAGE , AND ALIGNMENT : REFLECTIONS ON SOME CHALLENGES FOR HEALTH TECHNOLOGY ASSESSMENT,” vol. 4, pp. 223–225, 2015, doi: 10.1017/S0266462315000458.
- [56] J. Simões, C. Galendi, C. A. Caramori, C. Lemmen, D. Müller, and S. Stock, “Expectations for the Development of Health Technology Assessment in Brazil,” pp. 1–12, 2021.
- [57] A. Rajan and M. Moharra, “Addressing issues in health technology assessment promotion : Motives , enablers , COUNTRIES,” vol. 1, pp. 55–63, 2011, doi: 10.1017/S0266462310001352.

- [58] S. Hollingworth, A. P. Fenny, S. Y. Yu, F. Ruiz, and K. Chalkidou, “Health technology assessment in sub-Saharan Africa: a descriptive analysis and narrative synthesis,” *Cost Eff. Resour. Alloc.*, vol. 19, no. 1, pp. 1–13, 2021, doi: 10.1186/s12962-021-00293-5.
- [59] J. B. Babigumira, A. M. Jenny, R. Bartlein, A. Stergachis, and L. P. Garrison, “Health technology assessment in low- and middle-income countries: A landscape assessment,” *J. Pharm. Heal. Serv. Res.*, vol. 7, no. 1, pp. 37–42, 2016, doi: 10.1111/jphs.12120.
- [60] A. Pichon-Riviere, N. Soto, F. Augustovski, S. Garcia-Marti, and L. Sampietro-Colom, “Involvement of relevant stakeholders in health technology assessment development,” *Second Lat. Am. Forum Heal. Technol. Assess. Policies*, pp. 1–13, 2017.
- [61] A. P. Oliveira and I. Patterson, *MINISTRY OF HEALTH Brasília – DF*. 2012.
- [62] C.R.Kothari, *Research methodology (Methods and Techniques)*, vol. 4, no. 1. 2004.
- [63] V. O. Ajayi, “Course Title : Course Code : Advance Statistical Methods in Education Course of Study : PhD Science Education Presentation Title : Distinguish between primary sources of data and secondary sources of data Candidate Names : Oluwatosin Victor Ajayi Lecturers in Charge : Professor Emmanuel Ije nkeli O ’ kwu & Benjamin Iortwam Imoko , PhD,” no. September, 2017, doi: 10.13140/RG.2.2.24292.68481.
- [64] S. Muhammad and S. Kabir, “Methods of data collection,” no. July 2016, 2018.
- [65] Nduka WONU and Uyodhu Amekauma VICTOR-EDEMA, “1-2 1 2,” vol. 9, no. 2, pp. 53–68, 2021.
- [66] N. Chukhrova and A. Johannssen, “Fuzzy hypothesis testing : Systematic review and bibliography,” *Appl. Soft Comput.*, vol. 106, p. 107331, 2021, doi: 10.1016/j.asoc.2021.107331.
- [67] R. Rana and R. Singhal, “Chi - square Test and its Application in Hypothesis Testing,” no. January, 2015, doi: 10.4103/2395-5414.157577.
- [68] E. R. Ugba and J. Gertheiss, “A Modification of McFadden’s  $R^2$  for Binary and Ordinal Response Models,” pp. 1–18, 2022.
- [69] H. A. Park, “An introduction to logistic regression: From basic concepts to interpretation

with particular attention to nursing domain,” *J. Korean Acad. Nurs.*, vol. 43, no. 2, pp. 154–164, 2013, doi: 10.4040/jkan.2013.43.2.154.

- [70] W. H. Organization, *Global atlas of medical devices*. 2022.
- [71] J. L. Wale, S. Thomas, D. Hamerlijnek, and R. Hollander, “Patients and public are important stakeholders in health technology assessment but the level of involvement is low – a call to action,” vol. 9, pp. 1–11, 2021.
- [72] Y. Wang, W. Rattavipapong, and Y. Teerawattananon, “Technological Forecasting & Social Change Using health technology assessment to set priority , inform target product profiles , and design clinical study for health innovation,” *Technol. Forecast. Soc. Chang.*, vol. 172, no. July, p. 121000, 2021, doi: 10.1016/j.techfore.2021.121000.

## APPENDICES

### Appendix 1: Questionnaire used in data collection

#### Development of Health Technology Assessment for Rwanda: Framework investigation questionnaire

Hello,

I, Denyse TUYIZERE a Master's student in Biomedical Engineering, Center of Excellence in Biomedical Engineering and e-Health from the University of Rwanda. I'm conducting research for my master's thesis with the title: "**Development of Health Technology Assessment (HTA) framework for Rwanda**" especially on medical equipment. This questionnaire is to fulfill the requirement of MSc project in Biomedical Engineering, and the data that I will get through this questionnaire will be only used for academic purposes in my thesis project. **it will take less than 5 min of your time to answer.** This questionnaire will allow me to collect data that will help me to gain an understanding of the current status of Health Technology Assessment (HTA) in our hospitals. Health Technology Assessment (HTA) is the systematic evaluation of properties, effects, and impacts of health care technology. this assessment looks at the benefits, efficacy, technical safety, appropriateness and cost-effectiveness of technology. The primary goal of HTA is to inform a policy decision making in health care to improve the uptake of cost-effective of new technologies and prevent the uptake of technologies that are of doubtful value for the health system. HTA is helpful to ensure that new technology is not added until it is proven to be effective. Additionally, it makes sure that outdated technology is kept in the health package until it can be proven to be ineffective or not cost-effective. Quality and the contribution of new technology to bettering health outcomes are other issues that HTA addresses. Microsoft forms is used to allow an automatic return of the questionnaire to me once completed. **This questionnaire will expire in 2 weeks' time.** Thank you in advance for your help. **Denyse TUYIZERE (MSc student).**

\* Required

1. What is your professional background? \*

- Hospital administrator
- Management (quality manager, etc.)
- Doctor
- Nurse
- Allied health professional (Radiologist, Lab scientist, Lab technician, etc.)
- Biomedical Engineer
- Biomedical Technician

2. What is your primary organization/ institution (Where do you work)? \*

- Government - Ministry of Health
- Rwanda Biomedical Center (RBC)
- Hospital

3. Does your Institution/ Hospital have a systematic formal process by which information is gathered to support healthcare decision-making? \*

- Yes
- No

4. Is there any formal process to assess health technology for medical devices? \*

- Yes
- No

5. Are any prioritization criteria used to determine which health technologies to be considered in your hospital? \*

Yes

No

6. Do you refer to this process as the Health Technology Assessment (HTA)? \*

Yes

No

7. Do you have a standard methodology or process guideline for conducting HTA or decision-making processes? \*

Yes

No

8. Has your organization formally collaborated with or is it currently collaborating with other organizations on the HTA or decision-making process? \*

A. Yes, with organizations within our country

B. Yes, with organizations from other countries

C. Both A&B

D. No

9. Does your organization/institution have a policy on Health Technology Assessment? \*

Yes

No

10. Does the policy cover medical devices? \*

Yes

No

11. Does your organization or institution have any HTA framework? \*

Yes

No

12. Does your institution/Hospital have the willing of using HTA in healthcare decision-making especially on medical devices? \*

Yes

No

13. Which of the following criteria are used by your organization to assess the impact of HTA: Please select all that apply. \*

Changes within the organization or facilities (training staff, buying materials, etc.)

Variation between current practice and recommended practice over time

Change in health outcomes over time (clinical changes)

Level of technology diffusion over time

Changes in health from the point of view of the patients (perceived health, satisfaction, others)

Changes in the cost of the medical practice over time

None of the above

Other (Specify): .....

14. Which committee or group that help to review the Health Technology Assessment appraisal?

\*

- Scientific Committee of the HTA or decision-making body
- Executive Board of the HTA or decision-making body
- Director of the HTA or decision-making body
- Department/Ministry of Health
- National Health Service
- Patient Organizations
- None
- Other (Specify): .....

15. Who are the members of the team for HTA of medical devices (Select more than from the list below)? \*

- Biomedical Engineer
- Nurse
- Finance
- Facilities Engineering
- Materials Management/Purchasing
- Other (Specify): .....

16. What strategic tool do you use in planning for replacement of technology, especially on medical devices? \*

- Assessment of Need
- Assessment of Impact
- Assessment of Cost
- Assessment of Benefit
- All above

17. Please estimate the number of professional staff who are involved in the HTA committee (in full-time equivalent). \*

- 0
- 1-5
- 6-20
- > 20

18. How long does the assessment process takes on average for any given case of medical devices? Please choose only one of the following: \*

- 1-3 months
- 4-6 month
- 7-12 months
- >1 year

19. In the last 12 months, approximately, how many assessments were performed related to medical devices? \*

20. Is there any other question or suggestion that will help me with, for the improvement of the Health Technology Assessment (HTA) framework for Rwanda?

## **Appendix 2. HTA Policy on medical devices**

### **i. Policy on healthcare technology properties assessment**

#### **RATIONALE**

Throughout the pre-market period, prioritize healthcare technology through quality, safety, performance, efficacy, and social-ethical impact assessment.

#### **POLICY STATEMENT**

- ✓ Involves different stakeholders in a real discourse, to reduce bias and improve the validity and applicability of the HTA in decision-making.
- ✓ Addresses the interaction between society and technology and emphasizes how to shape technology in the best ways to benefit people.
- ✓ Verify the infrastructure availability in terms of space, utilities, building, and other related factors such as interface and compatibility.
- ✓ List evidence and outcomes also link HTA findings and decision-making.
- ✓ Determine the timing of HTA according to the specific characteristics of the technology's life cycle. This decision must be based on product and context knowledge obtained by interacting with users, Suppliers, and manufacturers.
- ✓ Formulate a specific document that defines the scope and objectives of the HTA, taking into account the questions to be answered through the assessment and their alignment with the decisions to be made using the HTA.
- ✓ Never make single-point assessments instead go for an iterative process (at least two assessments) to ensure the technology's property.
- ✓ Measure the safety, efficacy, and effectiveness of healthcare technologies by using health outcome variables (Mortality, Morbidity, Adverse health events such as harmful side effects, Quality of life, Functional status, and Patient satisfaction).

## **ii. Policy on technology economic attributes assessment**

### **RATIONALE**

To strengthen the institutions or hospitals for sustainable financing and ensure accountability by using the available budget.

### **POLICY STATEMENT**

- ✓ Involves different stakeholders in a real discourse, to reduce bias and improve the validity and applicability of the HTA. The decision-makers are not involved.
- ✓ Estimate the overall technology life cycle cost including purchase price, training, spare parts, and personnel.
- ✓ Refer to legislation, highlight all requirements to make the findings of the evaluation available to the public, and fees that would be levied for each application (avoid any conflict of interest).
- ✓ For specific characteristics of the patient population, estimate the clinical trials cost.
- ✓ Incorporate appropriate methods for assessing costs and benefits.

## **iii. Policy on technology risk assessment**

### **RATIONALE**

To improve the safety, evaluate and eliminate the hazards caused by inappropriate formulation of the HTA question, preparation of the HTA outcomes, dissemination of the HTA product, and contractors management.

### **POLICY STATEMENT**

- ✓ Ensure that data extraction, analysis, and presentation of reports meet required standards and that processes used are transparent.
- ✓ Involves different stakeholders in a real discourse, to reduce bias and improve the validity and applicability of the HTA.
- ✓ Make HTA request acceptable, formulate and apply consistent criteria for refusal of the request. Make these available as appropriate. Where possible, provide some assistance to the requester even if the preparation of the assessment is not feasible or desirable.

- ✓ Make the scope of HTA, keep it under review, and where necessary, provide information to show HTA products are consistent with the program's mandate and address issues that are important to the healthcare system
- ✓ Minimize the delay, negotiate a realistic time frame and consider a partial assessment.
- ✓ Ensure that high quality is maintained in the preparation of HTA products, consistent with guidelines on HTA practice. Where necessary, undertake prompt correction of product and dissemination of any amendments. Dialogue with the client and think about provisional results where appropriate.
- ✓ Seek input and advice from stakeholders in problem definition. Balance transparency and accessibility of the HTA process, and benefits from the involvement of the public, with practicalities of meeting client's requests in a timely fashion.
- ✓ Follow up any inappropriate dissemination message with clarifying statement, ensuring that it is widely distributed.
- ✓ Make appropriate use of dissemination media and specialists by maintaining records of dissemination activities.
- ✓ Formulate documentation of action and responses such as risk registers and conduct clear communication with interested parties.
- ✓ Minimize the risks associated with contractors and collaborators by keeping contract procedures, and contractors, under ongoing review.

### Appendix 3. Areas of a standard normal distribution

Table 4.20. Z-distribution table

<i>z</i>	.0	0.01	.02	.03	.04	.05	.06	.07	.08	.09
.0	.0000	.0040	.0080	.0120	.0160	.0199	.0239	.0279	.0319	.0359
.1	.0398	.0438	.0478	.0517	.0557	.0596	.0636	.0675	.0714	.0753
.2	.0793	.0832	.0871	.0910	.0948	.0987	.1026	.1064	.1103	.1141
.3	.1179	.1217	.1255	.1293	.1331	.1368	.1406	.1443	.1480	.1517
.4	.1554	.1591	.1628	.1664	.1700	.1736	.1772	.1808	.1844	.1879
.5	.1915	.1950	.1985	.2019	.2054	.2088	.2123	.2157	.2190	.2224
.6	.2257	.2291	.2324	.2357	.2389	.2422	.2454	.2486	.2517	.2549
.7	.2580	.2611	.2642	.2673	.2903	.2734	.2764	.2794	.2823	.2852
.8	.2881	.2910	.2939	.2967	.2995	.3023	.3051	.3078	.3106	.3133
.9	.3159	.3186	.3212	.3238	.3264	.3289	.3315	.3340	.3365	.3389
1.0	.3413	.3438	.3461	.3485	.3508	.3531	.3554	.3577	.3599	.3621
1.1	.3643	.3665	.3686	.3708	.3729	.3749	.3770	.3790	.3810	.3830
1.2	.3849	.3869	.3888	.3907	.3925	.3944	.3962	.3980	.3997	.4015
1.3	.4032	.4049	.4066	.4082	.4099	.4115	.4131	.4147	.4162	.4177
1.4	.4192	.4207	.4222	.4236	.4251	.4265	.4279	.4292	.4306	.4319
1.5	.4332	.4345	.4357	.4370	.4382	.4394	.4406	.4418	.4429	.4441
1.6	.4452	.4463	.4474	.4484	.4495	.4505	.4515	.4525	.4535	.4545
1.7	.4554	.4564	.4573	.4582	.4591	.4599	.4608	.4616	.4625	.4633
1.8	.4641	.4649	.4656	.4664	.4671	.4678	.4686	.4693	.4699	.4706
1.9	.4713	.4719	.4726	.4732	.4738	.4744	.4750	.4756	.4761	.4767
2.0	.4772	.4778	.4783	.4788	.4793	.4798	.4803	.4808	.4812	.4817
2.1	.4821	.4826	.4830	.4834	.4838	.4842	.4846	.4850	.4854	.4857
2.2	.4861	.4864	.4868	.4871	.4875	.4878	.4881	.4884	.4887	.4890
2.3	.4893	.4896	.4898	.4901	.4904	.4906	.4909	.4911	.4913	.4916
2.4	.4918	.4920	.4922	.4925	.4927	.4929	.4931	.4932	.4934	.4936
2.5	.4938	.4940	.4941	.4943	.4945	.4946	.4948	.4949	.4951	.4952
2.6	.4953	.4955	.4956	.4957	.4959	.4960	.4961	.4962	.4963	.4964
2.7	.4965	.4966	.4967	.4968	.4969	.4970	.4971	.4972	.4973	.4974
2.8	.4974	.4975	.4976	.4977	.4977	.4978	.4979	.4979	.4980	.4981
2.9	.4981	.4982	.4982	.4983	.4984	.4984	.4985	.4985	.4986	.4986
3.0	.4987	.4987	.4987	.4988	.4988	.4989	.4989	.4989	.4990	.4990

## Appendix 4. Chi-Square table

Table 4. 21. Chi-Square distribution table

d.f.	.995	.99	.975	.95	.9	.1	.05	.025	.01
1	0.00	0.00	0.00	0.00	0.02	2.71	3.84	5.02	6.63
2	0.01	0.02	0.05	0.10	0.21	4.61	5.99	7.38	9.21
3	0.07	0.11	0.22	0.35	0.58	6.25	7.81	9.35	11.34
4	0.21	0.30	0.48	0.71	1.06	7.78	9.49	11.14	13.28
5	0.41	0.55	0.83	1.15	1.61	9.24	11.07	12.83	15.09
6	0.68	0.87	1.24	1.64	2.20	10.64	12.59	14.45	16.81
7	0.99	1.24	1.69	2.17	2.83	12.02	14.07	16.01	18.48
8	1.34	1.65	2.18	2.73	3.49	13.36	15.51	17.53	20.09
9	1.73	2.09	2.70	3.33	4.17	14.68	16.92	19.02	21.67
10	2.16	2.56	3.25	3.94	4.87	15.99	18.31	20.48	23.21
11	2.60	3.05	3.82	4.57	5.58	17.28	19.68	21.92	24.72
12	3.07	3.57	4.40	5.23	6.30	18.55	21.03	23.34	26.22
13	3.57	4.11	5.01	5.89	7.04	19.81	22.36	24.74	27.69
14	4.07	4.66	5.63	6.57	7.79	21.06	23.68	26.12	29.14
15	4.60	5.23	6.26	7.26	8.55	22.31	25.00	27.49	30.58
16	5.14	5.81	6.91	7.96	9.31	23.54	26.30	28.85	32.00
17	5.70	6.41	7.56	8.67	10.09	24.77	27.59	30.19	33.41
18	6.26	7.01	8.23	9.39	10.86	25.99	28.87	31.53	34.81
19	6.84	7.63	8.91	10.12	11.65	27.20	30.14	32.85	36.19
20	7.43	8.26	9.59	10.85	12.44	28.41	31.41	34.17	37.57
22	8.64	9.54	10.98	12.34	14.04	30.81	33.92	36.78	40.29
24	9.89	10.86	12.40	13.85	15.66	33.20	36.42	39.36	42.98
26	11.16	12.20	13.84	15.38	17.29	35.56	38.89	41.92	45.64
28	12.46	13.56	15.31	16.93	18.94	37.92	41.34	44.46	48.28
30	13.79	14.95	16.79	18.49	20.60	40.26	43.77	46.98	50.89
32	15.13	16.36	18.29	20.07	22.27	42.58	46.19	49.48	53.49
34	16.50	17.79	19.81	21.66	23.95	44.90	48.60	51.97	56.06
38	19.29	20.69	22.88	24.88	27.34	49.51	53.38	56.90	61.16
42	22.14	23.65	26.00	28.14	30.77	54.09	58.12	61.78	66.21
46	25.04	26.66	29.16	31.44	34.22	58.64	62.83	66.62	71.20
50	27.99	29.71	32.36	34.76	37.69	63.17	67.50	71.42	76.15
55	31.73	33.57	36.40	38.96	42.06	68.80	73.31	77.38	82.29
60	35.53	37.48	40.48	43.19	46.46	74.40	79.08	83.30	88.38
65	39.38	41.44	44.60	47.45	50.88	79.97	84.82	89.18	94.42
70	43.28	45.44	48.76	51.74	55.33	85.53	90.53	95.02	100.43
75	47.21	49.48	52.94	56.05	59.79	91.06	96.22	100.84	106.39
80	51.17	53.54	57.15	60.39	64.28	96.58	101.88	106.63	112.33
85	55.17	57.63	61.39	64.75	68.78	102.08	107.52	112.39	118.24
90	59.20	61.75	65.65	69.13	73.29	107.57	113.15	118.14	124.12
95	63.25	65.90	69.92	73.52	77.82	113.04	118.75	123.86	129.97
100	67.33	70.06	74.22	77.93	82.36	118.50	124.34	129.56	135.81