COLLEGE OF MEDICINE AND HEALTH SCIENCES

Department of Anesthesiology, Critical Care and Emergency Medicine

VALIDATION OF APFEL SCORE POSTOPERATIVE NAUSEA AND VOMITING (PONV) RISK-BASED PREVENTION IN ADULT PATIENTS UNDERGOING ELECTIVE ABDOMINAL SURGERY AT KIGALI UNIVERSITY TEACHING HOSPITAL, RWANDA.

Dissertation submitted in partial fulfillment of the requirements of the degree of Masters of Medicine in Anesthesiology, Critical Care and Emergency Medicine of the College of Medicine and Health Sciences, University of Rwanda.

By

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Kigali, October 2020

DECLARATION

I, TUYISHIME Habyarimana Jean de Dieu, declare that this dissertation is the result of my work and has not been submitted for any other degree in the University of Rwanda or any other institution.

Jean de Dieu TUYISHIME Habyarimana, M.D

Approval for submission by the supervisor

I hereby declare that this dissertation has been submitted with my approval as the supervisor.

Date: 08 / 12 / 2020

Prof. Theogene TWAGIRUMUGABE

DEDICATION

I dedicate this dissertation to Almighty God without whose blessings and gifts of life and strength this study would not have been started.

This study is also dedicated to my family, friends, and colleagues.

Special dedication to my wife Claudine UWERA for her resilience and support

With the deepest gratitude and love that I dedicate this dissertation also to my brother and sisters for all that they have sacrificed for me. I am hoping that with this completed dissertation, I have proven to you that there is no mountain higher as long as God is on our side.

Jean de Dieu

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ABSTRACT

Background: The efficacy of postoperative nausea and vomiting (PONV) prevention protocols in low and middle-income settings is not well known, and differences in surgical procedures, available medications, and co-existing diseases imply that existing protocols may need to be validated in those settings. The purpose of this study was to determine the impact of a risk-directed PONV prevention protocol on the incidence of PONV and short-term surgical outcomes in various resource settings.

Methods: We compared the incidence of PONV during the first 48 hours postoperatively in the period with routine practice versus after implementation of an Apfel score-based PONV prevention strategy among 116 adult patients undergoing elective open abdominal surgery at Kigali University Teaching Hospital (58 patients for each period) between April 2019 and September 2019. Time to first oral intake, hospital length of stay, and rates of wound dehiscence were compared between the two periods by using the chi-square and Mann-Whitney U tests accordingly.

Results: The overall pre-intervention incidence of PONV during the first 48 hours postoperatively was 84.5% for nausea and 74.1% for vomiting. This incidence was reduced in the post-intervention period to 31.0% for nausea ($p< 0.001$) and 13.8% for vomiting ($p< 0.001$). The intervention was also associated with a significant reduction in the time to first oral intake, from 24[24-36] to 17.5[12-24] hours ($p< 0.001$). The hospital length of stay was also significantly lower in the post-intervention period compared with the pre-intervention one (5[3-7] days versus 4[2-6] days; $p<0.020$). Signs of wound dehiscence tended to be more observed in the pre than in the post-intervention period (10.3% versus 3.5%; $p<0.271$) without a significant difference

Conclusion: This study has demonstrated the potential value to implement PONV prevention protocol in resource-limited settings. Risk-directed PONV prophylaxis is possible and effective in a low-income country and improves postoperative outcomes.

Keywords: Apfel score, PONV risk assessment, and prevention of open abdominal surgery, oral intake, wound healing, and hospital length of stay.

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LIST OF ABBREVIATIONS

ACOR: Acute Care Operational Research

CASIEF: Canadian Anesthesiologists' society on International Education Foundation

CMHS: College of Medicine and Health Sciences

CHUK: Centre Hospitalier Universitaire de Kigali

Dr: Doctor

FCCM: Fellowship of Critical Care Medicine

GA: General Anesthesia

HRH: Human Resource for Health

ID: Identity

IRB: Institutional Review Board

IQR: Interquartile

KUTH: Kigali university teaching hospital

LOS: Length of stay

MD: Medical Doctor

MMed: Masters of Medicine

NPA: Non-Physician Anesthetist

PONV: Post-operative Nausea and Vomiting

PACU: Post Anesthesia Care Unit

SD: Standard Deviation

UR: University of Rwanda

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CHAPTER I. INTRODUCTION

I.1 Background of the study

Postoperative nausea and vomiting/retching (PONV) is an unpleasant and potentially harmful complication of surgical procedures and remain poorly addressed[1-5]. PONV typically occurs within 24 to 48 hours after surgery, with 70-80% of events, in general, occurring during the first 24 hours after surgery[6-8]. According to the 2014 American Society for Ambulatory Anesthesiology guidelines, the incidence is about 30% for vomiting, and 50% for nausea among patients who undergo surgery under general anesthesia[9-11]. Unresolved PONV may result in a long period in the post-anesthesia care unit (PACU) and unanticipated prolonged hospital admission, which results in a significant increase in overall healthcare costs[9, 12-17].

PONV scoring systems and guideline-driven prophylaxis are well established in high-income countries. Well established risk factors include female gender post pubescence, non-smoking status, history of PONV or motion sickness, childhood and young adulthood, prolonged surgery duration, and the use of volatile anesthetics, nitrous oxide, large-dose neostigmine, and intraoperative or postoperative opioid use[2-3, 16, 19]. The existing preventive measures are guided by these well-established risk factors, typically through the use of a preoperative simplified risk assessment developed by Apfel et al.[15-16]. However, little is known about the effectiveness of PONV prevention strategies in resource-limited settings[13, 18].

In many low and middle-income countries, routine PONV prophylaxis is not well structured. Anti-emetic prophylactic medications are not consistently available, drug choices are made without protocol guidance, and risk stratification is not used in many settings. Differences in co-existing diseases, surgical procedures, anesthetic and analgesic drugs used, and other factors, imply that existing models from high-income countries may not be automatically applied, and need to be validated in low-resource settings.

To address this issue, we studied the effectiveness of risk score-driven prophylaxis in Rwanda.

We used the Apfel score, which is a simplified tool consisting of 4 predictors for PONV: gender, history of motion sickness or PONV, non-smoking status, and the use of opioids in the postoperative period[15-16]. Prophylactic medications for PONV were given based on predicted risk as stratified by Apfel score. The implementation of the Apfel score allows anesthesia providers to more accurately prevent postoperative nausea and vomiting and to reduce associated complications. The identification of patients at risk for PONV through preoperative risk assessment by Apfel score is an effective means to reduce the incidence of PONV[5, 17, 20-22]. However, this approach has never been evaluated in resource-limited settings.

We hypothesized that using PONV prophylaxis based on the Apfel score would result in a lower incidence of PONV. Besides, we expected earlier oral feeding and better wound healing, and hence a shorter length of stay in comparison with the pre-existing routine practice.

I.2. Review of literature

Nausea is defined as an unpleasant sensation with an awareness of the urge to vomit and vomiting is defined as successful or unsuccessful (retching) expulsion of gastric contents[15]. Therefore, postoperative nausea and vomiting (PONV) describe any nausea, vomiting, or retching occurring during the first 24–48h after surgery in inpatients[7, 20]. PONV is one of the most frequent sources of patient dissatisfaction after anesthesia, with reported incidences of 30% in all post-surgical patients and up to 80% in high-risk patients[7, 16].

The event of PONV is multifactorial[33]. The 2 main causes are humoral and/or neuronal stimuli, through different afferent and efferent pathways. Principle components of these pathways are **area postrema** located in the floor of the fourth ventricle which contains a "chemoreceptor trigger zone" that is sensitive to many humoral factors, including neurotransmitters, drugs, and toxins; and another area in the medulla known as the **nucleus tractus solitarius** serving as a central pattern generator for vomiting; for information from humoral factors via the area postrema and visceral afferents via the vagus nerve[32].

Also, different neurotransmitter receptors including M1 (muscarinic), D2 (dopamine), H1 (histamine), 5-hydroxytryptamine (HT)-3-serotonin, and NK1 (neurokinin) or substance P, mediate physiology of nausea and vomiting reflex[34].

Due to the complexity and significance of PONV, different risk scoring systems were developed to predict patients who are at risk of having PONV. The simplified Apfel score is based on four predictors: female, history of PONV and/or motion sickness, nonsmoking status, and use of postoperative opioids[33]. The prevalence of PONV with the existence of 0, 1, 2, 3 and 4 risk factors is around 10%, 20%, 40%, 60% and 80% respectively[33]. Therefore, there are three categories of risk as stratified by gravity; 0-1 (low), 2 (medium), and 3-4 (high) [33].

Thus, pharmacological and non-pharmacological preventive measures of PONV are guided by its possibility according to the risk.

Post-operative nausea and vomiting (PONV) have been recognized as one of the complications of surgical procedures for many decades[4, 5, 13]. Besides, PONV is the regular anesthesia outcome the patient would most like to avoid. Consequently, patients across Europe and North America reveal a high readiness to pay an extra cost of about $50–100, to avoid PONV. Even if significant complications associated with PONV such as suture dehiscence, pulmonary aspiration of stomach contents, esophageal tear among others are infrequent, nausea and vomiting is still an unpleasant and most common postoperative morbidity that can delay patients from being discharged out of the post-anesthesia care unit and increase unanticipated hospital admissions in outpatients[7].

The onset of nausea or vomiting within the first 24 hours after surgical anesthesia, collectively termed postoperative nausea and vomiting (PONV) [17], adversely impacts patient experience during the postoperative period and increases health care costs[15].

Despite the publication and dissemination of PONV prevention guidelines and algorithms in Europe and the United States, PONV is still a major concern in low-middle income settings. A recent study showed that the incidence of PONV is about 30% in the first 24 hours following anesthesia and it can reach about 70%-80% among some high-risk groups, such as being female, having a previous history of PONV, and being a non-smoker[4, 16, 32].

A study done in Uganda revealed that the prevalence of PONV was 40.7% within 24 hours after surgery[36].

Another study done in Tanzania revealed that the incidence of PONV among surgical patients at Bugando Medical Centre was unacceptably high and the predictors of postoperative nausea and vomiting within 24 hours included being a young adult, female, having a history of PONV, been under general anesthesia and intraoperative pethidine[13].

Another study done in Eritrea revealed that the incidence of PONV is about 47%[37].

In South Africa, a study was conducted to test the Apfel PONV predictive scoring system and its utility to reduce the incidence of postoperative nausea and vomiting among black South Africans. The incidence of PONV between Africans and Non-Africans was 27% and 45% respectively[23].

In Rwanda, could the use of risk-directed PONV prevention strategies based on pre-operative high-risk assessment reduce the incidence of postoperative nausea and vomiting?

To do this, we conducted a pre and post-implementation cross-section study on 116 patients at Kigali university teaching hospital (KUTH).

I.3 Justification of the study

CHUK is one of the main public hospitals that deliver major surgical procedures in Rwanda. General anesthesia (GA) is commonly used for laparotomy among gynecological and gastrointestinal surgeries. Currently, no protocols or tools are guiding PONV prevention. Also, there is no previous study or publication done to identify the occurrence of PONV as well as the impact of risk-driven PONV prevention. Therefore, this study was done to raise awareness and the impact of risk-based PONV prevention protocol (Apfel score).

I.4 Aim and Objectives

I.4.1 Aim

To determine the impact of risk-directed PONV prevention on the incidence of PONV and short term surgical outcomes.

I.4.2 Specific objectives

- To assess the routine practice of PONV prevention
- To determine the incidence of PONV in patients undergoing elective open abdominal surgery
- To evaluate the impact of a standardized approach based on Apfel score to PONV prevention in patients undergoing elective abdominal surgery at CHUK (incidence of PONV, time to first oral intake, hospital LOS)

I.5 Research question

- Is a risk-directed PONV prevention based on Apfel score more efficient than the usual care in resource-limited settings?

I.6 Hypothesis

We hypothesize that using a standardized and consistent approach to address PONV using the Apfel score will result in a lower incidence of PONV, an earlier oral feeding, better wound healing, and shorter hospital length of stay in comparison to routine practice.

CHAPTER II. METHODOLOGY

II. 1 Study design

This was a single-blinded prospective pre and post-interventional study. The principal investigator and research assistant (s) knew well PONV risks and medications to be administered based on the risk assessment while the participants were blind.

The pre-intervention consisted of a period where there was no systematized approach to PONV prevention. The intervention was an initiation of PONV preventive measures based on the simplified Apfel score as presented in table 1.

Retching was defined as any unsuccessful expulsion of gastric contents[15]. Besides, motion sickness was defined in our context as a history of nausea and vomiting, hypersalivation, malaise during travel in a bus, boat, or airplane and trains for those who traveled abroad[25]. Experience of nausea and vomiting after a previous surgery was included in this category. Then, we assessed postoperative nausea and vomiting (PONV) and short term surgical outcomes in the period before and after implementation of a score-based PONV prevention.

II. 2 Study setting

i. **General setting:** Rwanda – Kigali

ii. **Specific setting:** *Centre Hospitalier Universitaire de Kigali* (CHUK, University Teaching Hospital of Kigali), one of the major referral hospitals in Kigali; in the main operating rooms as well as gynecology theatre.

II. 3. Methods

The PONV risk factors were determined at the pre-operative period during the anesthesia visit (either the day before surgery or on the day of surgery) by the Principal Investigator (PI) or a trained research assistant anesthesia resident. Patients were informed in advance about the study purpose and were given both their verbal and written consent.

During the pre-implementation period (from April, 1st; May to June, 30th 2019), routine care was observed and Apfel was assigned to each patient at the discretion of the PI. PONV occurrence was assessed by the PI immediately after surgery in the recovery room, 12 hours, 24 hours, and 48 hours postoperatively.

In the post-implementation period (from July, 1st; August to September, 30th 2019), PONV prophylactic medications were administered according to the level of the risk of PONV based on the Apfel score[23]. Practically, a patient scored one point for each of the four criteria ('female', 'non-smoking', 'PONV history and/or motion sickness' and 'anticipated need for opioids') and zero in the absence of them. The Apfel score was deduced from the presence or absence of any of the four constituents. Patients with 0 or 1 risk factor did not receive prophylactic medication, table 1. In the presence of two risk factors, 4 mg of ondansetron IV was given to the patient 30 minutes before the end of the procedure, table 1. If three risk factors were present, 8 mg of dexamethasone IV was added to the ondansetron regimen. In the presence of four risk factors, haloperidol 0.5 mg IV was added to this regimen.

If any of the above medications were not available, substitutions could be made as follows: ondansetron by metoclopramide 10 mg and haloperidol by induction of anesthesia with propofol instead of the usual induction agents, thiopental or ketamine. Therapeutic ondansetron 4 mg IV was given up to four times daily when PONV occurred during the 48 hours of follow up.

Table 1: Implemented PONV prevention protocol about Apfel Scoring system

Apfel Score[18] **(Total PONV Risk Factors)**	**Anti-emetics**
0-1/4	No prophylaxis[23]
2/4	Ondansetron 4mg IV, 30 min before the end of anesthesia • **Alternative: Metoclopramide (10 mg IV**)[24]
3/4	Ondansetron 4mg IV, 30 min before the end of anesthesia • **Alternative: Metoclopramide 10 mg IV** + Dexamethasone 8 mg IV during induction of anesthesia
4/4	Ondansetron 4mg IV, 30 min before the end of anesthesia • **Alternative: Metoclopramide 10 mg IV** + Dexamethasone 8 mg IV during induction of anesthesia + Haloperidol / Domperidol 0.5 mg • **Alternative: Propofol induction**[4, 27]

II.4. Study Population

All patients consulted in CHUK and were scheduled for elective abdominal surgery.

II.5. Inclusion criteria

All adult patients over 18 years old, both male and female planned for elective open abdominal surgery under GA between April, 1st, 2019 and September, 30th, 2019

II.6. Exclusion criteria

- ✓ Diabetic patients (if dexamethasone is planned to be used)
- ✓ Patients admitted in ICU under mechanical ventilation or unable to communicate effectively after surgery
- ✓ Those undergoing relook laparotomy within 48 hours
- ✓ Patients having an allergic reaction to any of the preventive medications used

II.7. Data variables, sources of data, and data collection

i. Outcome variables

The primary outcome was to assess the impact of the protocol-guided by Apfel score on the incidence of PONV during the first 48 hours postoperatively. The occurrence of PONV was reported by the patients to the PI or the research assistant through an interview in the above set schedules postoperatively. Ward nurses were instructed to call the attending surgeon for a prescription of therapeutic ondansetron 4 mg IV when vomiting occurred and it was planned to be given up to four times in 24 hours. Other variables collected from study participants were age, sex, history of active (first hand) smoking, and any history of motion sickness or previously experienced PONV in the past surgical history. Participants were also asked about the exact time they were able to take the first meal or drink postoperatively. Finally, at the discharge from the hospital, the length of hospital stay was recorded and so was the appearance of the surgical incisions to identify any potential signs of wound dehiscence (swelling, fluid discharge from the wound, open wound, or incisional hernia)

ii. Source of Data

The data was obtained from Patients' pre-operative and post-operative interviews as well as files and anesthesia charts.

iii. Data Validation

Patients' post-surgical follow up interview in words enhanced data validation.

iv. Data collection instrument

Form data collection sheets/questionnaires

II.8. Sample size

The sample size was calculated by using Open Epi Version 3.01 (Kelsey et al., Methods in Observational Epidemiology 2nd Edition) updated in April 2013. Assuming that the incidence of PONV with routine care at CHUK with almost no prophylaxis is 50%, we expected that if Apfel score-based prophylaxis is implemented, this incidence will be decreased by 50%. With a power of 80%, a two-sided type 1 error of 5%, and a case/control ratio of 1:1. Using Kelsey:

Two-sided confidence level (1-alpha)	95
Power (% chance of detecting)	80
Ratio of Controls to Cases	1
The hypothetical proportion of controls with exposure	of 50
The hypothetical proportion of cases with exposure	of 25
Least extreme Odds Ratio to be detected	0.33
	Kelsey
Sample Size-Cases	58
Sample Size-Controls	58
Total sample size	116

We found that we needed a sample size of at least 58 patients in the pre-intervention group and 58 patients in the post-implementation to detect such a large difference with a chi-square test.

II.9. Data analysis and statistics

Statistical analyses were performed as chi-square test to compare proportions for categorical data between the two periods whereas a non-parametric test (Mann-Whitney U test) was used to compare median and interquartile (IQR) from continuous numerical variables (age, time to first oral intake and hospital length of stay).

In all analyses, a $p<0.05$ was considered as statistically significant.

II.10. Ethical considerations

i. Ethical clearance

The study protocol was approved by the University of Rwanda College of Medicine and Health Sciences, Institutional Review Board (UR/CMHS-IRB; No211/CMHS-IRB/2019), and the University Teaching Hospital of Kigali ethics committee (Ref: EC/CHUK/100/2019).

ii. Data confidentiality

Form data sheets were kept in a closed room in the Anesthesia department. Also, a soft copy was encrypted to ensure full privacy.

iii. Patient benefits

Adequate PONV prophylactic medications based on a standardized approach to PONV.
Enhanced recovery after surgery and short term hospital stay

iv. Community participation and benefits:

Ability to work as soon as possible after surgery

v. Feedback and dissemination of results

- Done in Anesthesia staff meetings
- Conferences
- Residents' academic days

vi. Implications for policy and practice

Recommendations to use Standardized approach for PONV prevention

vii. Collaborative partnerships

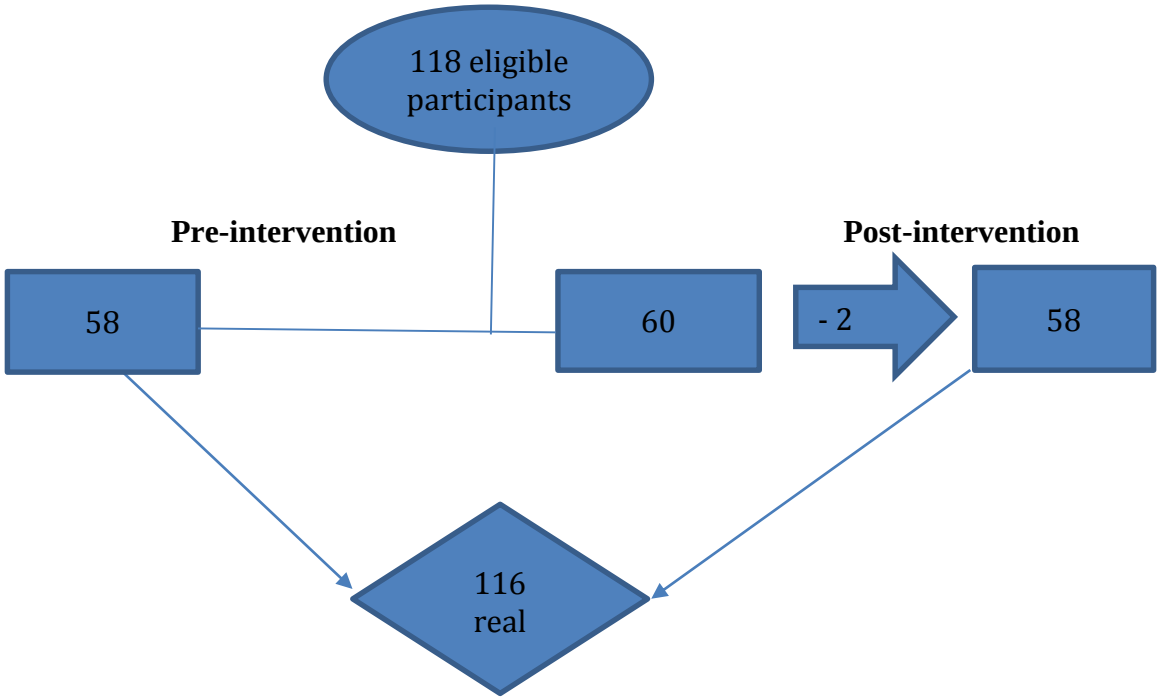
All anesthesia providers including Anesthesiologists, Anesthesia residents, and Non-physician anesthetists; all Surgeons and gynecologists; pharmacists and nurses

CHAPTER III. DATA PRESENTATION, ANALYSIS, AND INTERPRETATION

III.1. Description of sample

In total, we studied 116 patients, 58 in the pre-intervention period and 58 in the post-intervention period who underwent elective open abdominal surgeries under general anesthesia. Those in the post-intervention cohort, have met the PONV prophylaxis protocol. Two patients have lost follow up, hence they were excluded from the study. Data were analyzed from April 1st, 2019 to September 30th, 2019 which consisted of 3 months for the pre-intervention cohort and 3 months for a post-intervention cohort. The STROBE diagram, shown in Figure 1, details patients' recruitment process.

Figure 1. Total number of participants who have met inclusion criteria



This is a strobe diagram displaying the number of patients that met inclusion criteria and ultimately how many were excluded before reaching the final number for analysis. Two participants have lost the follow-up in the post-intervention arm. Therefore, the total participants have remained 116 participants.

High-risk patients were identified based on Apfel score and PONV Prevention Prophylaxis was driven by the protocol illustrated in Table 1. Both male and female patients were recruited for the study.

However, there was a predominance of females in the pre-intervention cohort as well as in the post-intervention cohort at a ratio of 2:1 and 3:1 respectively, table 2.

III.2. Social demographic data and Apfel score

Table 2: Social demographic data and Apfel score

	Pre-intervention N=58	Post-intervention N=58	
Demography/PONV risk factors n (%) / Median [IQR]		n (%)/ Median [IQR]	p-value
Age	46[37-58.2]	46.5[35-61.5]	0.953
Gender			0.160
Male	22 (38%)	14 (24%)	
Female	36 (62%)	44 (76%)	
Smoking Status			< 0.001
Yes	24 (41.4%)	4 (6.9%)	
No	34 (58.6%)	54 (93.1%)	
History of motion sickness			0.432
Yes	22 (37.9%)	17 (29.3%)	
No	36 (62.1%)	41 (70.7%	
History of PONV (if operated before)			0.420
Yes	10 (17.2%)	6 (10.3%)	
No	48 (82.8%)	52 (89.7%)	
Perioperative and or anticipated postoperative use of opioids			0.743
Yes	52 (89.7%)	54 (93.1%)	
No	6 (10.3%)	4 (6.9%)	
Apfel score			0.001
1	10 (17.2%)	1 (1.7%)	
2	17 (29.3%)	12 (20.7%)	
3	26 (44.8%)	27 (46.6%)	
4	5 (8.6%)	18 (31.0%)	

Table 2 is showing that the majority of patients were female in the pre-intervention as well as post-intervention period. There was 62% of females in the first group versus 76%, p; 0.160 in the second group. This increased number of female gender has influenced the high-risk group as described by the Apfel score. This risk assessment has revealed that Apfel scores 3 was the predominant number in both the pre and post-intervention period at a rate of 44.8% and 46.6%, p: 0.001 respectively.

Despite this high-risk group after intervention than in before intervention group, there was a reduced PONV incidence after implementing the prevention protocol. Therefore, the PONV prevention protocol has contributed to reducing the incidence of PONV.

Furthermore, the study has revealed a lack of an organized systematic way to prevent PONV. Besides, there was a high percentage of use of Dexamethasone alone as a single prophylactic medication in the pre-implementation period, table 3.

III.3. PONV Prophylactic medications

Table 3: Rate of PONV Prophylactic medications among two groups

	Pre-intervention N=58		Post intervention N=58	
PONV Prophylaxis received	Frequency	Percentage	Frequency	Percentage
None	10	17%	1	2%
Dexamethasone alone	27	46%	0	0%
Ondansetron alone	1	2%	0	0%
Propofol alone	5	9%	0	0%
Dexamethasone+Metoclopramide	0	0%	28	48%
Dexamethasone+Propofol	15	26%	12	21%
Dexamethasone+Propofol+ Ondansetron	0	0%	6	10%
Dexamethasone+Propofol+Metoclopramide	0	0%	11	19%

Table 3 is showing the distributional use of available anti-emetics in two periods. Dexamethasone alone was commonly used at a rate of 46%, in the pre-implementation period. This high number of dexamethasone consumption was explained by a lack of guidance to PONV prevention.

To overcome this challenge, the PONV prevention protocol was established based on the Apfel scoring system (table 1). Therefore, in the post-implementation group, there was a well-structured use of anti-emetics as stratified by Apfel, hence a reduction of PONV incidence. The overall pre-intervention incidence of PONV was estimated at 84.5% for nausea and 74.1% for vomiting, whereas there was a significant decrease in the post-intervention incidence of PONV estimated at 31.0% for nausea and 13.8% for vomiting, table 4. Although segmented regression analysis did not show any statistical significance among coefficients considering the small number of time points and with estimated coefficients having large standard errors (figure 2 and 3). Dexamethasone alone was the most common medication administered in our routine practice to prevent PONV (46% of patients, table 3). However, in protocol guided drug administration (table 1), the anti-emetic combination was given: 48% received metoclopramide + dexamethasone and 21 % received dexamethasone + propofol induction.

The intervention was also associated with a reduction in time to first oral intake, from 24[24-36] to 17.5[12-24] hours; p< 0.001(table 4).

Although we observed signs of wound dehiscence in 10.3% of non-intervention patients compared with 3.5% in the post-intervention group, our study was not powered to determine statistical differences between these groups.

Finally, the hospital length of stay was significantly longer in the pre-intervention period compared with the post-intervention period, 5[3-7] days versus 4[2-6] days; p<0.020, Mann-Whitney test (table 4).

III.4. PONV Incidence and Outcomes

Table 4: Results of PONV incidence and outcomes

Outcomes	Pre-intervention N=58 n (%)	Post-intervention N=58 n (%)	p-value
Nausea within 48 hours			< 0.001
Yes	49 (84.5%)	18 (31.0%)	
No	9 (15.5%)	40 (68.9%)	
Vomiting within 48 hours			< 0.001
Yes	43 (74.1%)	8 (13.8%)	
No	15 (25.9%)	50 (86.2%)	
Status of wound healing			0.271
Closed	52 (89.7%)	56 (96.5%)	
Dehiscent	6 (10.3%)	2 (3.5%)	
Time (hours) to first oral intake			< 0.001
Median[IQR]	24[24-36]	17.5[12-24]	
Hospital Length of Stay			0.020
Median[IQR]	5 [3-7]	4 [2-6]	

Table 4 is showing the incidence and outcomes of PONV among the two groups. The incidence of nausea and vomiting was 84.5% and 74.1% respectively before intervention compared to 31.0% of nausea and 13.8% of vomiting after the intervention. This reduction was explained by the PONV prevention implementation protocol. Also, the time to first oral intake (in hours) and hospital length of stay (in days) were reduced in two groups; 24[24-36] to 17.5[12-24]; p<0.001and 5[3-7] to 4[2-6]; p< 0.020 respectively. However, the status of wound healing has shown 10.3% signs of wound dehiscence pre-intervention versus 3.5%, p<0.271 post-intervention.

III.5. Apfel scores versus the incidence of PONV

Table 5. Apfel score versus the incidence of PONV

	Pre-implementation		Post- implementation	
		PONV present		PONV present
	N	n (%)	N	n (%)
Apfel score				
1	10	9 (90%)	1	1 (0%)
2	17	17 (100%)	12	4 (33.3%)
3	26	24 (92.3%)	27	6 (22.2%)
4	5	4 (80%)	18	8 (44.4%)

Table 5 above is showing the distribution of Apfel scores versus the incidence of PONV. 10 patients in the pre-intervention cohort had an Apfel score of 1 and 9 of them (90%) experienced at least one symptom of PONV within 48 hours of their surgery. Then, 17 patients who had an Apfel score of 2, all of them (100%) had at least one symptom of PONV in the first 48 hours after their operation. Also, 24 (92.3%) among 26 patients in Apfel score 3, had experienced PONV while 4 (80%) out of 5 patients of Apfel score 4 have had at least one episode of symptom.

On the other hand, in the post-intervention cohort, there was a significant reduction in PONV incidence. There were zero symptoms of PONV in 1 patient of Apfel score 1 and 4 (33.3%) out of 12 patients in Apfel score 2, had a least one episode of PONV. Also, 6 (22.2%) out of 27 patients of Apfel score 3 had PONV symptoms and 8 (44.4%) out of 18 patients of Apfel score 4 had at least one episode of PONV.

III.6. Medication used versus the incidence of PONV

Table 6. Medications used versus the incidence of PONV

		PONV present	
	Medications used	N	n (%)
Pre-implementation			
	None	10	9 (90%)
	Dexamethasone alone	27	25 (92.5%)
	Ondansetron alone	1	1 (100%)
	Propofol alone	5	5 (100%)
	Dexamethasone+Propofol	15	14 (93.3%)
Post-implementation			
	None	1	0 (0%)
	Dexamethasone+Propofol	12	4 (33.3%)
	Metoclopramide+Dexamethasone	28	7 (25%)
	Metoclopramide+Dexamethasone+Propofol	11	6 (54.5%)
	Ondansetron+Dexamethasone+Propofol	6	1 (16.67%)

Table 6 is showing PONV prevention prophylaxis used versus the incidence of PONV. In the pre-intervention, there were 9 (90%) out of 10 patients who had PONV and did not receive any prophylaxis. Also, Dexamethasone alone was commonly used in routine practice. However, 25 (92.5%) out of 27 patients who received dexamethasone, had developed at least one symptom of PONV. Again, the Dexamethasone+Propofol combination was commonly used, but 14 (93.3%) out of 15 patients who received this combination had developed at least one episode of PONV. Contrary, the use of Apfel score risk-based prophylaxis had influenced the incidence of PONV the post-intervention. The most common combination was Dexamethasone +Metoclopramide. The 7 (25%) out of 28 patients who received this cocktail had PONV.

Another combination that was commonly used was Dexamethasone+Propofol +Metoclopramide. The 6 (54.5%) of 11 patients who received this combination, had at least one symptom of PONV. The overall incidence of PONV was influenced by a standardized approach to prevent PONV.

Figure 2. Distribution of pre and post-intervention rates of nausea within 48 hours

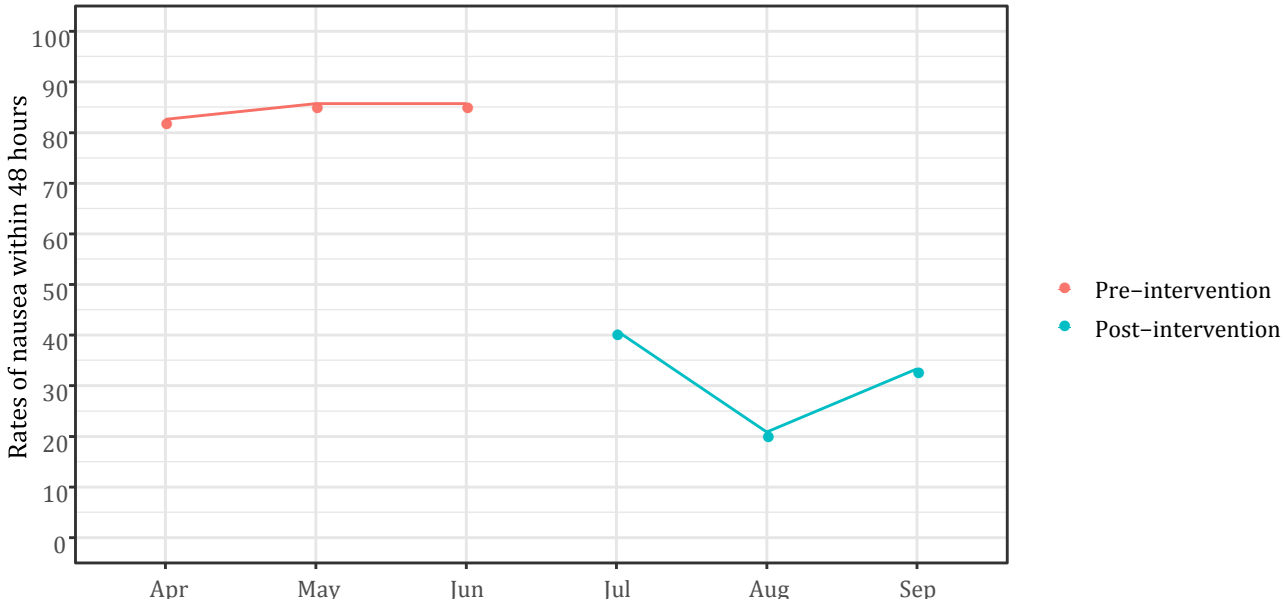
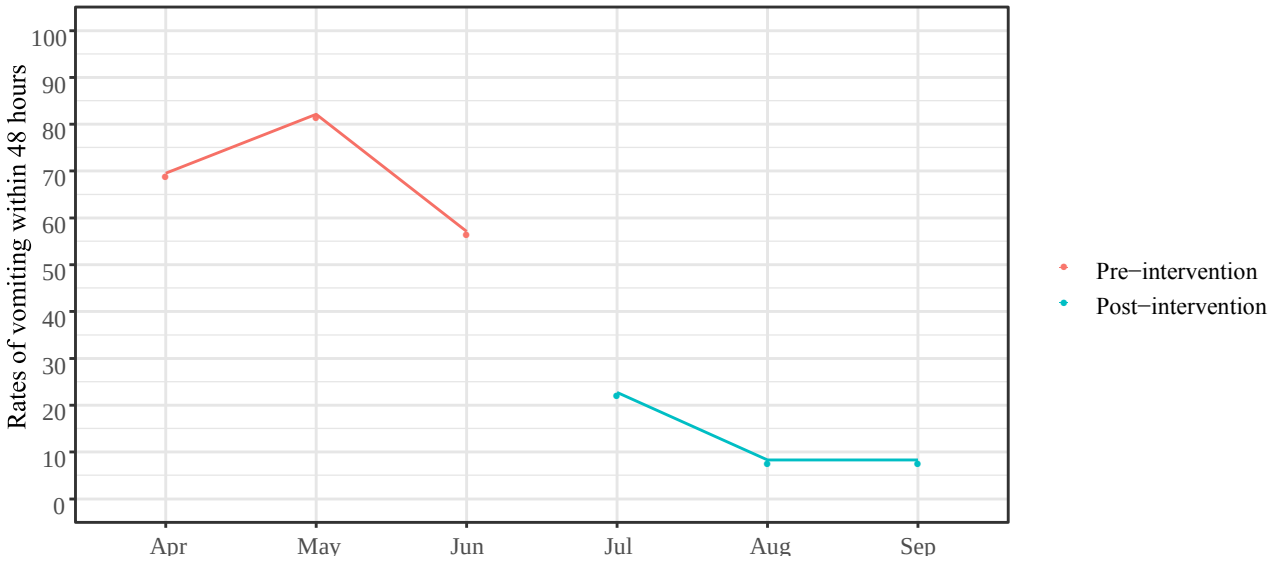


Figure 3. Distribution of pre and post-intervention rates of vomiting within 48 hours



Graphs 2 and 3 represent the segmented regression distribution of pre and post-intervention rates of nausea and vomiting within 48 hours.

The red lines show high rates of nausea and vomiting before intervention whereas the blue lines represent those of nausea and vomiting after PONV prevention protocol implementation. The intervention showed a significant reduction in the incidence of PONV.

CHAPTER IV. DISCUSSION

This study demonstrates that in a low-income country like Rwanda pre-operative risk factor screening based on Apfel score and the use of a structured PONV prevention protocol is associated with a substantially decreased incidence of PONV in patients undergoing open abdominal surgeries. Managing PONV prophylaxis based on these risk factors allowed a significant reduction in the incidence of PONV occurring over the first 48 hours postoperatively, as well as earlier oral intake and earlier hospital discharge. Before implementing this management approach the overall incidence of PONV was 84.5% for nausea and 74.1% for vomiting. This incidence is consistent with Apfel-score prediction, as the observational phase of our study showed that more than 80% of patients had two or more risk factors. PONV prophylaxis was underutilized in our settings and often combined therapy is not instituted due to availability or cost, explaining this high incidence of PONV. Demonstrating the effectiveness of this approach is critical, as the low-resourced setting is very different from the settings where the risk score was developed and treatment approaches validated.

Each site will be different, but in general, in low-resourced settings, one can expect to see different indications for operation (a high percentage of cases will be for major intra-abdominal infection such as typhoid), different demographics (many patients will be young), different co-existing diseases and nutrition status, and different anesthetic and surgical management (in many locations induction with thiopental and maintenance with halothane and ketamine will be standard). It can therefore not be expected that risk stratification and prevention strategies developed in high-income settings will necessarily apply, and re-validation is required.

The hospital in Rwanda where we performed our study is fairly typical for low- and middle-income settings so that our results will be of interest to many other sites. The main weakness of the study is that the sample size was relatively small, and we, therefore, we're unable to assess the impact of the protocol on secondary outcomes. The study was also single-blinded. This is an appropriate approach for operational research studies but increases the likelihood of bias in our findings.

The prophylaxis regimens in our protocol were established from studies suggesting their efficacy in patients at risk of PONV[24-27].

We chose to provide no prophylaxis in low-risk patients while one or two medications were administered to medium-risk patients and at least three medications were required for high-risk patients. By using a similar protocol in another "before-after" study, Sigaut et al, demonstrated that similar educational strategies aiming at improving medical care by a systematic recording of simplified items were efficient[5]. Patients in the routine practice group (pre-intervention) had a higher incidence of PONV. This was explained by a lack of systematic use of anti-emetic medications. For instance, there were 9 (90%) out of 10 patients who had PONV and did not receive any prophylaxis. Also, Dexamethasone alone was commonly used in routine practice and 25 (92.5%) out of 27 patients who received dexamethasone, had developed at least one symptom of PONV. Contrary, the use of Apfel score-based PONV prevention protocol had influenced PONV incidence in the post-intervention. The most common combination was Dexamethasone +Metoclopramide. The 7 (25%) out of 28 patients who received this cocktail had PONV. Another combination that was commonly used was Dexamethasone+Propofol+Metoclopramide. The 6 (54.5%) of 11 patients who received this combination, had at least one symptom of PONV. Hence, the overall incidence of PONV was influenced by the use of standardized strategies to prevent PONV.

It was observed that the administration rate of anti-emetic prophylactic was significantly increased in high-risk patients for PONV as defined by Apfel's simplified score greater than or equal to 2. According to Ofelia Loani Elvir-Lazo et al, pharmacologic management of PONV should be tailored to the patient's risk level using the validated PONV risk-scoring system and a combination of prophylactic antiemetic drugs with different mechanisms of action should be administered to patients with moderate to high risk of developing PONV[39].

In our prospective study, we also confirmed the effectiveness of implementing both a preoperative risk score assessment and score–based prophylaxis protocol in patients at risk for PONV. Patients in a pre-intervention group especially the ones in the high-risk category of Apfel score (3 and 4) had a higher proportion of PONV incidence. So, we were able to demonstrate the need for an escalation of intervention with higher-risk patients. Contrary, the risk group in the post-intervention period who underwent a systematized approach, showed a low number of PONV.

Therefore, it demonstrates a potential value to implement PONV prevention protocol based on the pre-operative risk assessment.

PONV may increase the time admitted in PACU as well as hospital length of stay. Our study resulted in a significant reduction of LOS in our intervention group. Health costs have a significant impact on LIC. There are few beds available, staff are often few and overworked due to the volume of patients and the daily cost of admission is challenging to patients themselves. Therefore, procedures or techniques that lead to a reduction in admission times are an important finding. In this study, we found a median length of hospital stay of 5[3-7] days in the pre-intervention period compared with 4[2-6] days in the post-intervention group[30]. Serious complications may arise from untreated PONV and influence hospital stay after surgery. Apfel et al. demonstrated that PONV may delay recovery, induce wound dehiscence, and cause pulmonary aspiration of gastric contents leading to aspiration pneumonia [25, 28, 29].

In our study, we observed signs of wound dehiscence in about 10.3% within the group of pre-existing routine practice compared with 3.5% in the post-intervention group; our study was not powered to determine statistical differences between these groups.

We also observed a decreased time interval to first oral intake: approximately 24[24-36] hours in the pre-intervention group compared with 17.5[12-24] hours in the post-intervention group. Bisgaard et al. have demonstrated that tolerance to early oral nutrition is enhanced by a multimodal PONV prevention strategy[11]. Oral intake will reduce catabolism and the usual post-surgical loss of lean body mass.
Our study did not address the financial implications of our PONV protocol. However, Hirsch has shown that post-operative nausea and vomiting can result in additional cost-related consequences not only to the patient but also to the hospital[31].

In conclusion, even in a low-resource setting, where patients undergo surgery for different diseases presentation, have different co-morbidities, and different anesthetic and surgical management a risk stratification of PONV and its management shows benefit. Implementing multimodal prevention of PONV based on a simple pre-operative risk-stratification by Apfel score allows a significant reduction of PONV during the first 48 hours after abdominal surgery.

Analysis of long-term compliance with the protocol and PONV incidence will be important to demonstrate the sustained effectiveness of introducing this approach. This study was designed as a pragmatic operational research trial, with associated strengths and limitations. The results have direct and practical implications for clinical management and can be immediately applied to practice.

CHAPTER V. CONCLUSION AND RECOMMENDATIONS

V. 1. CONCLUSION

This study has demonstrated the potential value to implement PONV prevention protocol with minimal available resources at CHUK, in Kigali Rwanda. It resulted in a reduction of the incidence of PONV after its implementation and complications associated with PONV. We did not specifically address the cost-saving resulting from this protocol and patients' satisfaction but these could be addressed in future studies.

V. 2. RECOMMENDATIONS

1. **To Anesthesia department**

We would like to recommend a preoperative systematic screening of PONV risks based on the Apfel score, which is simple and feasible, and plan PONV prevention based on the protocol.

Also, we would like to recommend further research on the compliance and sustainability of this risk-driven PONV prevention protocol as well as its impact among pediatric and obstetric patients.

2. **To the hospital and pharmacy**

We would like to recommend hospitals to avail essential anti-emetics medications. This would avoid frequent stock out and improve the quality of care to our patients

3. **To the Ministry of health**

In collaboration with the anesthesia department to develop and validate perioperative guidelines including PONV prevention guidelines and disseminate them to different health facilities.

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Appendix 1. FORM DATA COLLECTION

Date (DD/MM/YYYY)……..

Patient hospital ID number…….

Age in years ……

Sex: Male □ Female □

Smoking within the previous 6 months: No □ Yes □

History of motion sickness: No □ Yes □

History of PONV: No □ Yes □ N/A □

Opioids us (pre or postop): No □ Yes □

Apfel score: 1 □ 2 □ 3 □ 4 □

PONV Prophylaxis received: No □ Yes □

`If Yes, which one (more than one applies):

Ondansetron □

Dexamethasone □

Haloperidol □

Other……..…

PONV occurrence:

A. Nausea:

Immediate after recovery: Yes □ No □ N/A

12 hours after recovery: Yes □ No □ N/A

24 hours after recovery: Yes □ No □ N/A

48 hours after recovery: Yes □ No □ N/A

B. Vomiting/ Retching

Immediate after recovery: Yes □ No □ N/A

12 hours after recovery: Yes □ No □ N/A

24 hours after recovery: Yes □ No □ N/A

48 hours after recovery: Yes □ No □ N/A

The number of episodes of vomiting within the 48 hours postoperatively……

Time to first oral feeding……...…hours postoperatively

Status of wound healing at day 3 postoperatively: closed □ dehiscent □

Hospital length of stay after the operation…….days

Appendix 2. INFORMATION TO THE PARTICIPANT and CONSENT FORM

"Amakuru agenewe umurwayi''

Researcher Identification/ *Umwirondoro w' umushakashatsi*

1. **Dr. Jean de Dieu TUYISHIME, MD, Resident in Anesthesia, Critical care and Emergency Medicine, University of Rwanda**

Yohani w' Imana TUYISHIME, umuganga uri kwiga gutanga ikinya no kuvura indembe

2. **Prof. Théogène TWAGIRUMUGABE, MD, MMed, FCCM (Fr),PhD**

Tewojeni TWAGIRUMUGABE, umuganga w' inzobere mu kuvura indembe no gutanga ikinya kumbagwa

A. **What is the purpose of this research*// Impamvu y' ubu bushakashatsi***

1. The primary objective of this study is to assess the routine practice of PONV prevention and to evaluate the incidence of PONV in patients undergoing elective abdominal surgery.
2. The secondary objective is to evaluate the impact of the standardized approach based on the Apfel scale to PONV prevention in patients undergoing elective abdominal surgery at CHUK (incidence of PONV, time to oral feeding, hospital LOS).

1. Icyambere n' ukureba muri rusange uko hirindwa iseseme, kwihaga cyangwa kuruka nyuma yo kubagwa, no kureba ingano y' abarwayi baruka cyangwa bakagira isesemi nyuma yo kubagwa mu nda.

2. Icyakabiri, kureba ingaruka nziza zaterwa n' ishyirwamubikorwa ry' uburyo rusange mu kwirinda isesemi, kuruka cyangwa kwihaga nyuma yo kubagwa mu nda muri CHUK

B. How long will I take part in this research/ ***Igihe ubushakashatsi buzamara***

3. The study will take 6 months from April 2019 to September 2019. During this period, we will conduct a **pre and post-implementation study on** risk directed post-operative nausea and vomiting (PONV) prevention in adult patients undergoing elective abdominal surgery at CHUK

3.

Ubushakashatsi buzamara amezi 8 guhera muri Mutarama 2019 kugeza muri Kanama 2019. Muricyo gihe, tuzareba ishyirwamubikorwa hamwe n' ingaruka nziza by' uburyo rusange bwo kwirinda iseseme, kuruka cyangwa kwihaga mu barwayi bakuru babazwe mu nda.

C. What are the risks and benefits of taking part in this research?
Ibyago n' inyungu zo kuba muri ubu bushakashatsi

4. If you choose to participate, there is no risk anticipated, instead, you may benefit by having data, based on them, we shall elaborate on an appropriate policy to lower and prevent PONV at CHUK. There is no compensation for you when you participate

4. Ntabyago duteganya igihe waba uri muri ubu bushakashatsi. Ahubwo ushobora kunguka ubona amakuru, ari nayo azagenderwaho mu gushyiraho ingamba zizafasha kugabanya no kwirinda iseseme, kuruka no kwihaga nyuma yo kubagwa mu nda muri CHUK. Nta kiguzi cyangwa andi mafaranga uzahabwa igihe uzaba uri muri ubu bushakashatsi.

D. Being part of this research project how will be my privacy protected. What happens to the information you collect? / Ni gute amabanga bwite azabungwabungwa? Ese amakuru muzafata yo azakoreshwa iki?

5. The information will not have your full name on it, but a code to identify you. It will be analyzed by the researcher (s) and may be reviewed by the research team. Then, the results of the study will be disseminated to stakeholders to make the policy.

5. Tuzakoresha umubare mu kubika amakuru, nta zina tuzakoresha. Ikipe y' ubushakashatsi yonyine niyo izakoresha amakuru tuzafata. Inshamake y' ibyavuye mu bushakashatsi izashyikirizwa abafata ibyemezo kugira ngo hafatwe ingamba.

E. If I have any questions, concerns, or complaints about this research study, who can I talk to? Ni nde nabaza ngize ikibazo kuri ubu bushakashatsi?

6. The researcher for this study is **Dr. Jean de Dieu TUYISHIME, MD** who can be reached at phone: **(+250)783142030** and **Email: shimejean1986@gmail.com,** the supervisor is **Dr. Théogène TWAGIRUMUGABE, MD, MMed, FCCM (Fr), Ph.D.,** who can be reached at phone number: **(+250)788539904** and Email**: twagirumugabe@gmail.com**

***6. Umushakashatsi ni Yohani w' Imana TUYISHIME wamubona kuri numero: (+250)783142030 na Email: shimejean1986@gmail.com, uhagarariye ubushakashatsi Tewojeni TWAGIRUMUGABE, wamubona kuri numero (+250)*788539904 *hamwe na Email:* twagirumugabe@gmail.com**

F. Participation is voluntary/ Kwitabira ni kubushake

7. Participation is your choice whether or not to participate in this research. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stop your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

7. Kwitabira ni kubushake, kandi ushobora guhagarika uruhare rwawe igihe cyose. Kutitabira ubu bushakashatsi, ntibyagutera guhabwa igihano cyangwa kubuzwa uburenganzira bwawe.

G. Statement of Consent/ Kwemera kugira uruhare mu bushakashatsi

8. Your signature below indicates your permission to take part in this research. You will be provided with a copy of this consent form.
8. Umukono wawe werekana uruhushya rwawe rwo kuba muri ubu bushakashatsi. Urahabwa kopi y' uru rwandiko.

……..
……
……..
…….....

Full name and signature **Date and location**
Amazina n' umukono **Italiki n' ahantu**