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FEASIBILITY OF TELEPHONE CALL VERSUS IN-CLINIC FOLLOW-UP FOR SHORT-TERM OUTCOMES AFTER ADULT AND PEDIATRIC ELECTIVE INGUINAL HERNIA REPAIR IN CHUK

Dissertation submitted in partial fulfilment of the requirements for the award of the Degree of Master of Medicine in General Surgery, University of Rwanda

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Kigali June, 2020

DECLARATION

The researcher

I hereby declare that this dissertation **"Feasibility of telephone call versus in-clinic follow-up for short-term outcomes after pediatric and adult inguinal hernia surgery in CHUK."** except where specifically acknowledged, and it has been passed through the anti-plagiarism system and found to be compliant and this is the approved final version of the Thesis.

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Date:10/07/2020

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Date: 10 /07/2020

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Christian NIYONZIMA, MD

ABSTRACT

Background: Post-operative follow-up is being done to know the outcome following inguinal hernia surgeries. The aim of the study was to increase the follow-up rate with telephone follow-up in hernia surgeries in CHUK.

Methods: This was a quasi-experimental prospective intervention study with comparison to a historical control group (charts for 6-month period prior to intervention) and was conducted in CHUK in a 5-month period (from December 2019 to April 2020). Data was collected using a pre-established questionnaire. Analysis done using SPSS 16.0 and STATA 13 using descriptive statistics, chi-square test, and Mann-Whitney's test.

Results: Retrospectively in six month-period, 35.2 % of patients (45/128) who underwent elective adult and pediatric inguinal hernia surgery were seen in the outpatient clinic postoperatively, and 87.3% (48/55) had a successful postoperative telephone call follow-up. Five months during our study, telephone call follow-up decreased patient's loss to follow-up (Odds ratio [OR]:12.64; 95% confidence interval[CI]:5.06-35.39; P=0.000). Overall, post-operative complication rate was not significant between two groups with p=0.520 for potential complication, and p=0.140 for true complication (as the complication was ruled out after the patient presented himself in-clinic post telephone call). In the study (telephone) group, all patients felt free to describe their clinical status, 98% were happy with telephone call and could recommend a telephone call to a friend. Regardless the district of origin, almost all patients strongly agree that telephone call follow-up was effective for them.

Conclusion: Telephone call follow-up can be an alternative to in-clinic following inguinal hernia surgery in adult and pediatric patient during post-operative period. It is effective and safe while also increasing the follow-up rate in hernia surgeries in CHUK.

Keywords: inguinal hernia; follow-up; post-operative; feasibility.

LIST OF ABBREVIATIONS

CHUK: Centre Hospitalier Universitaire de Kigali (University Teaching Hospital of Kigali)

E.N.T.: Ear, nose and throat surgery

U.S.:United States

PI: principal investigator

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I.INTRODUCTION

I.1.Background

Previous follow-up studies have shown that in-clinic exam is the gold standard to detect complications following inguinal hernia repair [1]. Those complications are either long-term or short-term and include seroma/ hematoma, chronic pain, and wound (or mesh, where applicable) infection [2].

However, post-operative telephone call follow-up has been used successfully different surgical subspecialties [1], [3]–[7]. Nowadays, telephone follow-up is proven in some settings to be efficient for low-risk procedures including hernia repair, using a structured protocol [8], [9]. In an elective setting, this is feasible as complications are less compared to emergency hernia repair [10]–[12].

Additionally, some studies have demonstrated that telephone call can be used to reduce patient's loss to follow-up without compromising clinical outcomes and serve more new patients [13], [14].

I.2 Problem statement

The burden of patients who consult in the outpatient general surgical clinic is increasing, and post-operative follow-up visits compromise the regular schedule with unnecessary consultations as the surgical staff is limited; this may further delay new patient consultations[15], [16].

In countries with limited resources, the number of surgeons is low compared to the surgical workload [17]. Post-operative complications are rarely identified at a routine post-operative visit for elective hernia surgery procedures[8]. Therefore, finding ways to decrease the burden to patients and providers is important in improving and advancing care overall.

Patients scheduled for elective inguinal hernia repair at University Teaching Hospital of Kigali are contacted by telephone to notify them of their scheduled surgery. They present the day prior to the operation and are discharged on the first post-operative day. They receive an appointment for a return to clinic visit at one month postoperatively.

A similar protocol exists for patients operated in surgical camps, whose follow-up appointment is also given for a clinic visit at CHUK.

Preliminary retrospective evaluation of elective hernia patients during a 6 month-period at CHUK showed that 35% of postoperative patients returned for follow-up. Only 2 out of the 45 patients who consulted presented with minor complications. It led to disturbance in scheduling outpatients' list as 65% of patients who received a post-operative clinic appointment did not consult, effectively blocking this clinic time from scheduling other patients or new consultations.

With only 35% of patients presenting for follow-up, the true burden of complications post elective inguinal hernia surgery at CHUK is unknown.

Given the shortage of surgeons in CHUK, consultation lists are often long and face-to-face consultations that are not clinically needed may negatively affect the surgical care delivery and utilize resources and appointment space that could potentially be better managed to be beneficial to other needy surgical patients.

This study is intended to demonstrate the suitability of telephone call follow-up of patients operated for inguinal hernia in CHUK and compare our result with that reported in the literature. The objectives are two-fold. First, the study aims to show that phone call is a safe replacement for in-person consultation for elective hernia repair. Second, with only 35% of patients presenting for in-person follow-up, the study aims to improve the follow-up and provide a better understanding of complications.

I.3 Study justification

In United States, it has been shown that in selected surgeries with low-risk of post operative complications like hernia surgeries, telephone call can be a substitute to in-clinic follow-up. This practice has been proven to be associated with high patient satisfaction[4].

We reviewed patients' charts over a 6-month-period, and found only 2/45 had complications (one case of drained hematoma, another with a hematoma which was managed conservatively) at the post-operative visit, and 83/128 were lost to follow-up.

No new consult is done if not scheduled for that day; and that leads to long outpatient pending list. Another way of postoperative follow-up is needed in order to balance the consultation of new patients and postoperative patients, while minimizing loss to follow-up.

To our knowledge, after consulting local journals, there is no study done concerning telephone follow-up post hernia surgery in Rwanda. We conducted a study to assess if telephone call-based postoperative follow-up in hernia patients could be the best alternative to the physical one in order to contribute to hernia surgical care.

I.4 Research question

Can telephone call follow-up safely be used to decrease in-person post-operative follow-up for adult and pediatric hernia repairs at CHUK?

Hypothesis

Telephone call follow-up can increase successful follow-up by 50% without increasing the need for in-person follow-up and improve patient satisfaction.

I.5 Research objectives

I.5.a General objective

To increase the follow-up rate with phone follow-up in hernia surgeries in CHUK.

I.5.b.Specific objectives

- To evaluate/identify short-term complication rate among patients operated for inguinal hernia surgery in CHUK.
- To increase the number of patients contacted for post-operative evaluation compared to in-person consultation.
- To demonstrate patient's level of satisfaction (regarding the telephone call).
- To demonstrate this is safe (patients who had complications were identified and did not present later)
- To decrease the clinic volume burden of routine post-operative visits for the pediatric and general surgical clinic.

II.LITERATURE REVIEW

II.1. Definition

A hernia is the protrusion of an organ through the defect in the wall of the cavity in which it is contained [18]. It includes internal hernias which pass through the mesenteric defect [19], external hernia which pass through a defect in abdominal wall [20], and diaphragmatic hernias which pass through the diaphragm [21].

Among the external hernias, we distinguish incisional hernia which is post surgery, groin (inguinal and femoral), and others (umbilical, para-umbilical, and epigastric) [22].

II.2Inguinal hernia

Inguinal hernia results from the protrusion of abdominal organs; which are contained in a peritoneal sac; ; through a defect within the groin area [23]. Inguinal hernias constitute 3/4 of abdominal wall hernias, with a lifetime risk of 27% in men and 3% in women [11]. It can be direct or indirect.

II.2.1 Direct inguinal hernia

It arises from an acquired weakness through the fascia transversalis in the Hesselbach's triangle [24].

II.2.2 Indirect inguinal hernia

Indirect inguinal hernia results from non obliteration of processus vaginalis, leading to peritoneal contents to pass through the deep inguinal ring [25]. This is the most common inguinal hernia in children [26].

II.3.Pathophysiology and risk factors

Hernias may be classified either congenital or acquired. The first appear prenatally or in infants and are caused by a persistent patent processus vaginalis. The risk factors for the second are obesity, coughing, and straining [20].

II.4 Diagnosis of inguinal hernia

The gold standard diagnosis of inguinal hernia is by clinical exam (where the patient reports inguinal swelling, with its neck superomedial to the pubic tubercle on physical exam [27], [28].

II.5 Treatment modalities

Inguinal hernia is managed surgically [23].

II.5.1 In children

The approach is herniotomy consisting of high ligation of the processus vaginalis with or without external oblique aponeurosis incision [29].

II.5.2 In adult:

As the mechanism is the weakness of posterior abdominal wall, mainly transversalis fascia, surgery is intended to reinforce the posterior abdominal wall [30].

II.5.2.1 History of inguinal hernia surgery

From the last decades, there is evolution in groin hernia surgery, from open tension tissue repair, open tension-free repair to laparoscopic approach [31]. In adult, different surgical approaches are open non mesh, mesh and laparoscopic techniques [32].

II.5.2. 2 Open non mesh

Modified Bassini technique involves high ligation of the sac with floor reconstruction by interrupted non-absorbable sutures by approximating the conjoined tendon with the inguinal ligament, and the first bite to the pubic tubercle, without incising the fascia transversalis [33].

II.5.2. 3 Lichtenstein tension-free mesh repair

It is used either in direct or indirect hernia.

In indirect hernia, after sac dissection from cord structures and high ligation, the non absorbable mesh is placed between the layers of abdominal wall, and interrupted non-absorbable sutures are used to fix it [34].

In direct hernias, imbrication of its contents is the first step and for the indirect one, high sac ligation is done prior to put a mesh.

II.5.2. 4 Laparoscopic repair

It includes 2 approaches:

Total extraperitoneal approach (TEP)

Considering the anatomical landmarks with exposure of "triangle of pain" and "triangle of doom" without breaching the peritoneum, a mesh is placed in the extra peritoneal space to cover the hernia site [35].

Transabdominal preperitoneal approach (TAPP)

Passing transabdominally and taking into account the anatomical landmarks (Epigastric Vessels, Spermatic vessels, vas deferens or round ligament, urachus, iliac vessels and bladder), the preperitoneal space is opened incising the peritoneum transversely from the region of the umbilical artery laterally to the hernia defect, prior to mesh placement [35].

Co-morbidities may complicate hernia repair, but the holistic review of the clinical picture of the patient is the main determinant for surgical care [36].

II.6 Discharge plan

The follow-up is done in 2-4weeks after discharge over several days to detect complications [8], [37], [38].

II.7.Post-operative follow-up

The post-operative follow-up is either in-clinic or through telehealth [39], [40] .

Telemedicine is a remote delivery of healthcare services such as teleconferencing, mobile phone and tablet applications (for example, Skype), digital images, text messaging, and has been used to provide post-operative consultation, monitoring and surgical education [41].

Telephone follow-up (TFU) consists of providing education and advice, recognizing complications early, giving reassurance to patients [42].

Several studies have shown that patients appreciate telephone follow-up by discussing with non physician providers (nurses) and are highly satisfied with it as the patient must travel long distance, which represent a waste of time and travel cost, for post operative clinic which is quite brief, also saving time for the surgeon [4].

Several studies done in U.S. showed that post-operative telephone follow-up has been used as a triage tool to select patients who need in-person care as it is used to care for majority of low-risk general surgical procedures such as inguinal hernia surgery, and may be feasible for patients who undergo select abdominal operations and no direct physical contact with operative team, using a bundled care [43]–[45].

The doctor-patient discussion must be well documented in the patient's chart [45].

II.7. Post operative complications and their management

II.7.1.Complications

The short-term complications after inguinal hernia surgery include scrotal swelling (seroma, hematoma) and wound infection [2], [46]. Recurrence of hernia, stitch abscesses/sinuses, faecal/urine fistulae, keloid and hypertrophic scars/neuromas, neurological pain are long-term complications [47], [48].

According to the Swedish hernia register, hematoma is bleeding causing significant tissue distension [38]. Risk factors are warfarin and recurrent hernia [49].

The same register considers infection as local signs of inflammation, pus discharge with/without positive wound culture within 30 days post-operatively [38]. Risk factors are Diabetes, morbid obesity, and smoking [50].

Seroma presents within 3-4 days, and its peaks at the seventh day postoperatively. Patients with seroma formation usually worry that their hernia has recurred [51]. Risk factors are old age, a large inguinoscrotal hernia, as well as the presence of a residual indirect sac [52].

Early postoperative complications(seroma/hematoma and SSI) rate vary between 1% and 7% [11].

Postoperative complications in the pediatric population are very low [53]. Koulack and collegues found complications following inguinal hernia repair was 0.7% [54]. In the study by Yeung et al. on 262 outpatients who underwent inguinal herniotomy, 0.8% presented with wound hematoma ,while 0.8% had wound infection [55].

In adult patients, different studies, it has been shown that complication rate differs depending on the approach used: G. Bouras and collegues found that more complications were in open hernia surgery than laparoscopic cohort (3.5% versus 1.8%,) [56].

II.7.2 Management of complications

Minor wound infections, characterized by mild erythema, tenderness and fever, are well managed with warm, moist compresses and antibiotics. Wound margins should be opened down to the fascia to allow drainage if discharging pus [57]. Seroma is managed conservatively and generally resolves within 4–6 weeks, or carefully aspirated under strict asepsis if big [57], [58]. Hematoma is managed non operatively in most cases [49].

Hwa K and colleagues found that complications in the telehealth patients were 4.8% for herniorrhaphy, and 2 out of those patients were having minor complications(superficial skin separation which required no further treatment, and a local wound infection to which oral antibiotics were prescribed at the clinic visit) While one remaining had a significant complication of an incisional hematoma with the risk factor was coagulation disorder which required anticoagulation, and almost all patients were greatly satisfactied with this method of follow-up [4]. Responses to patients' feedback were recorded using a Likert scale [1].

Dan Eisenberg and colleagues found that in all 62 patients; who underwent laparoscopic inguinal hernia repair; were consulted on telephone. 88.7% successfully completed planned telephone follow-up. 4.8% were lost to either type of follow-up. Of those who were reached by telephone, 90.9% of them were satisfied enough by phone call, whereas 9.1% had issues during the telephone call discussion. Of these, 1 was found to have an early hernia recurrence and 1 had a seroma found in-clinic [37].

III.METHODOLOGY

III.1. Study design

This is a quasi-experimental prospective intervention study with comparison to a historical control group. This study was conducted in CHUK in a 5-month period (from December 2019 to April 2020).

III.2. Setting

It took place in General and Pediatric Surgery departments of CHUK.

CHUK is a tertiary level hospital located in Kigali, the capital city of Rwanda and it has 519 beds. It covers 53% of referrals from district hospitals. The hospital has 6 general surgeons, 2 neurosurgeons, 1 plastic surgeon, 1 pediatric surgeon, 5 orthopedic surgeons and a varying number of visiting surgeons.

As a teaching hospital, CHUK bears also a varying number of surgical trainees and medical/nursing students.

III.3. Study population

III.3.1 Inclusion criteria

- Patients of any age operated for inguinal hernia
- Patients who can be reached on phone

III.3.2 Exclusion criteria

- Patients operated for emergency hernia (incarcerated, needing bowel resection)

III.3.3 Primary outcomes and measures

Efficacy of each type of follow-up.

Secondary outcomes: patient's satisfaction in the call group, rate of post-operative complications within 30 days.

III.3.4 Sample size

Previous 6 months showed that 35% of operated patients in historical control group presented themselves in outpatient department, calculating the phone follow up to get contact in 65% in study group (increase to 65%, which was the rate of patients missed in historical group).

Using Stata 13.0, Power analysis for a two-sample proportions chi-squared test, we concluded:

```
. power twoproportions 0.35 0.65, test(chi2)

Performing iteration ...

Estimated sample sizes for a two-sample proportions test
Pearson's chi-squared test
Ho: p2 = p1  versus  Ha: p2 != p1

Study parameters:

        alpha =    0.0500
        power =    0.8000
        delta =    0.3000  (difference)
           p1 =    0.3500
           p2 =    0.6500

Estimated sample sizes:

            N =        86
  N per group =        43
```

III.4. Data Collection and analysis

- Patients were recruited at the time of discharge after consensus with the treating surgeon.

- There was historical control group (retrospective review for 6 months prior to start date to see how many were given a rendez-vous, where patients lived, how many actually came for their follow-up, and how many complications were identified.

- Phone call follow-up was done on Day28-D30 post-operative to detect whether the patient had a complication. Three attempts during daytime were made to reach the patient.

- Those who reported a significant complication were called in face-to-face to confirm it if the patient expressed concerns on phone. The patient without a concern on phone was out of the study after completion of phone call, and the one who reported complication on phone was discharged from the study after being physically reviewed in-clinic.

- The phone call was made by the principal investigator.

- The electronic outpatient registry was used to calculate the rate of complications and respect of follow-up appointment in the retrospective group.
- All data were captured using a pre-established data collection sheet including demographic characteristics, clinical aspects of hernias and post-operative complications.
- These questionnaires were kept by the PI under discretion to be used only for research purpose

Data analysis:

Data were recorded using Microsoft excel and analysed using both SPSS 16.0 and STATA 13.0 using descriptive statistics. Categorical variables (sex, side of hernia) were analysed using a x2 test, and continuous variables (age, satisfaction score) evaluated by Mann-Whitney's test.

III.5. Ethical considerations and dissemination.

- To be enrolled in the study, the consent was obtained from the adult patient or from the caretaker for incompetent and debilitated patient; an assent was obtained for the pediatric patient where applicable.
- Before conducting the study, the approval was obtained from IRBs of University of Rwanda and CHUK research ethical committee.
- The patient's was insured for confidentiality of delivered information, and was reserved with the right to leave the study any time he/she no longer wants to be part of it.
- Data were collected on questionnaire, secured in a locker then entered in a password-protected excel database.
- Results were disseminated to CHUK, Rwanda Surgical Society, Rwanda ministry of health, through conferences and peer-reviewed publications.

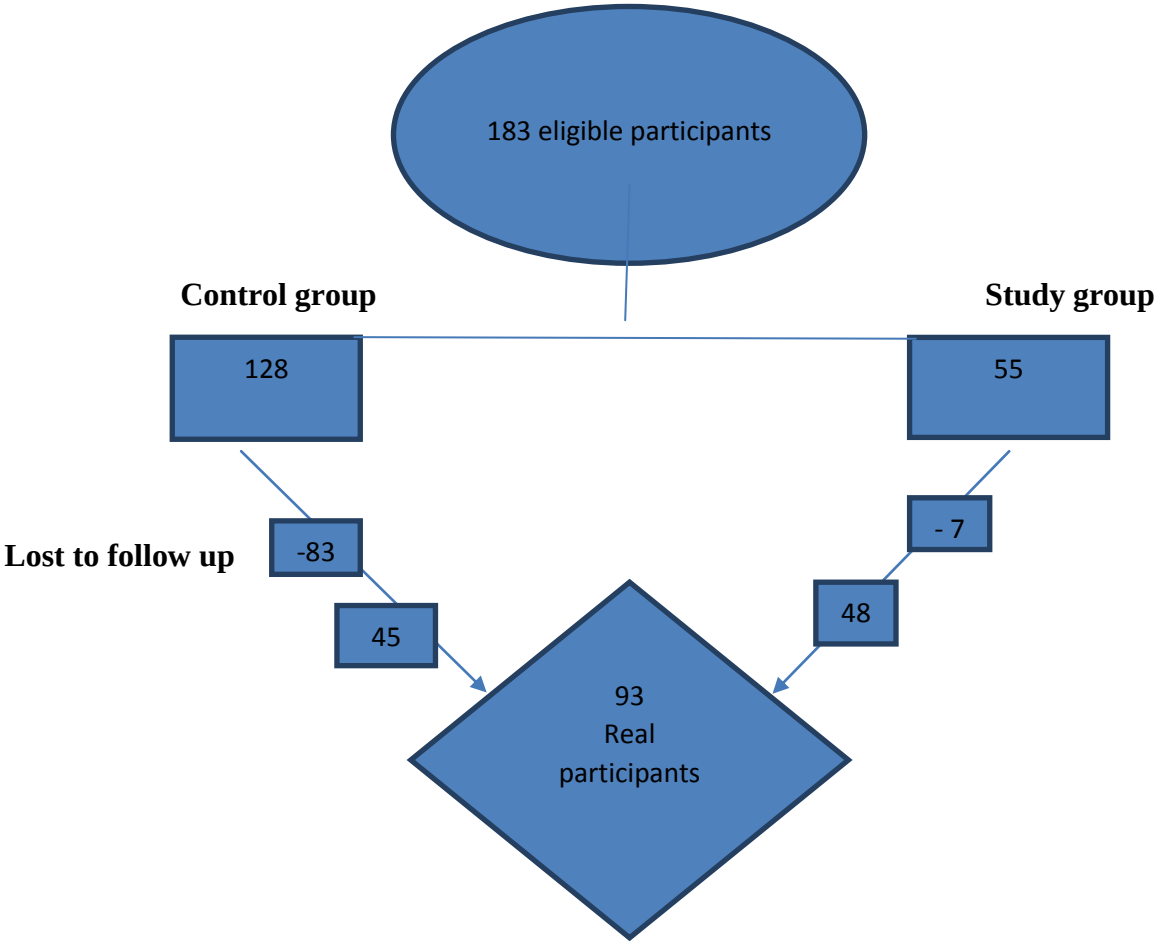
III.6 Study limitations

Several limitations of this study must be considered to put the conclusions in proper context. First, the randomization was not possible, and no time to follow 2 groups (routine and call group) in parallel and compare results later and the loss of patients to follow-up which didn't permit us to know the true rate of early short-term complications in both arms.

IV. RESULTS

Part I. Presentation of patients follow-up among control and study group (a month-period post-operative)

Strobe diagram showing the 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. Eighty-three participants were lost to the follow up in routine practice (control group) versus seven who were lost to the follow in the study group (prospective follow up group). Therefore, the total real participants remained 93 participants.

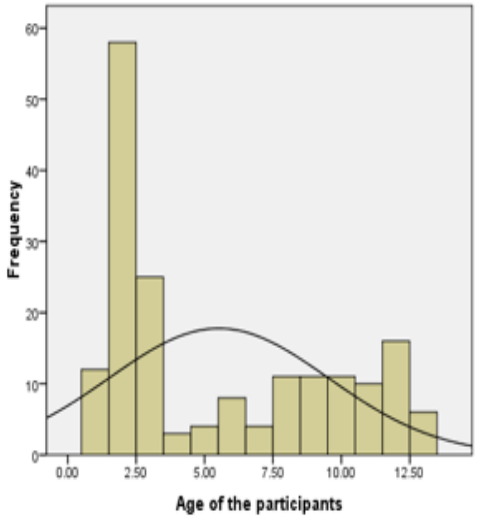


Figure 1: Demonstration of participants' demographics, surgical procedures and complications

Figure 1 above shows that ages of the participants were not normally distributed. Hence, non-parametric test (Mann Whitney test) was used to compare medians and interquartile of age.

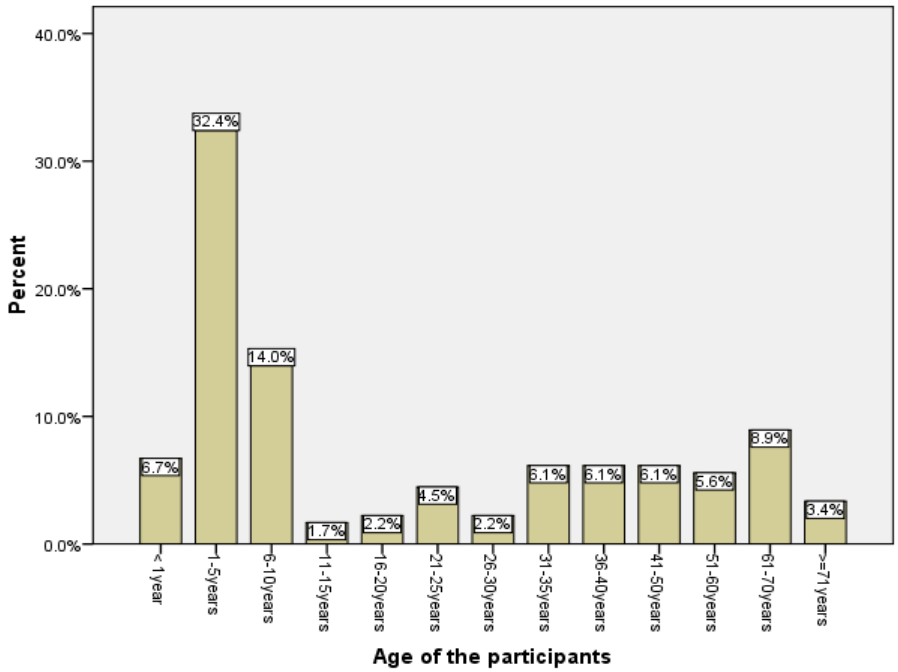


Figure 2: Distribution of participants' age

Table 1: Demonstration of participants' demography, surgical procedures and availability to follow-up

Demography and procedure	**control group**	**study group**			
	N=128	**N=55**			
	n (%)/Median [IQR]	**n (%)/Median [IQR]**	**difference between two group**	**Odds ratio (95%CI)**	**p-value**
Age	3[3; 37]	6[23; 47]			0.003
Gender					0.204
Male	120 (93.8%)	54 (98.2%)			
Female	8 (6.3%)	1 (1.8%)			
Procedure					0.022
Herniotomy (pediatric high ligation)	78 (60.9 %)	24 (43.6%)			
Open hernia repair (with mesh)	38 (29.6 %)	28 (50.9)			
Adult lap hernia repair (with mesh)	12 (9.5%)	3 (5.5%)			
Laterality					0.271
Right side	79 (61.7%)	30 (54.5%)			
Left side	43 (33.6%)	19 (34.5%)			
Bilateral	6 (4.7%)	6 (10.9%)			
Availability to follow-up			**12.64**	**5.06to35.39**	0.000
Presented for follow-up	45 (35.2 %)	48 (87.3%)			
Lost to follow-up	83 (64.8%)	7(12.7%)			

The table 1 above illustrates that ages of the two groups were statistically comparable. However, the majority of patients were male in both two groups; 93.8% of males in the control group and 98.2% of males in the study group. Hence, male to female ratio was 15:1 in retrospective group and 54:1 in prospective group respectively without statistical significance. The most common performed procedure was herniotomy at about 60.9% in the control group versus 43.6% in the study group. Open hernioplasty was mostly done in the interventional group at about 50.9% compared with 29.6% in the routine practice statistically comparable. The commonest affected side was right for both of two groups at 62% versus 54%

respectively. There was a loss to follow-up of about 64.84% in the routine practice that may be explained by a lack of follow-up compared with 12.7% in the study group. Therefore the "call follow-up" intervention was contributive in regular patients' follow up compared to routine practice (Odds ratio [OR]:12.64; 95% confidence interval[CI]:5.06-35.39; P=0.000).

Table 2: Representation of one month period post-operative follow-up between two groups (those who consulted post-operatively)

	Control group	**study group**			
	N=45	**N=48**			
Outcomes	**n (%)/Median [IQR]**	**n (%)/Median [IQR]**	**difference between two group**	**Odds ratio (95%CI)**	**p-value**
Potential complications					**0.520**
Yes	2(4.4%)	1(2.1%)			
No	43(95.6%)	47(97.9%)	2.3%		
True complications					**0.140**
Yes	2(4.4%)	0			
No	43(95.6%)	48(100.0%)	4.4%		
Surgical site Swelling					**0.520**
Yes	2(4.4%)	1(2.1%)			
No	43(95.6%)	47(97.9%)	2.3%		
Concern(s) on Follow up					**0.520**
Yes	2(4.4%)	1(2.1%)			
No	43(95.6%)	47(97.9%)	2.3%		
Scrotal Swelling/pain					**…...**
Yes	-	-			
No	45(100.0%)	48(100.0%)	0%		

Table 2 above shows the outcome of patients who consulted post-operatively. Comparing those who consulted in both arms, both groups report swelling of surgical site with 4.4% (2 out of 45 patients) in control group and 2.1% (1 out of 48 patients) in study group.

Finally in those who presented post-operatively, there was a potential post-operative complication rate of 2.1% was in the study group compared to 4.4% (2 out of 45 patients) in the control group not statistically significant. There is no real complication (the in-clinic physical examination was normal for the patient who had a concern during telephone call), but not clinically conclusive as there was a selection bias (assuming that those who failed to consult did not have complications, the true complication rate is 1.6% in control group).

Part II. Evaluation of patient's satisfaction (Study group)

Table 3: Evaluation of patient's satisfaction in the telephone call group

	Frequency	Percent
Are you satisfied of your surgery and the post-operative follow-up?		
Strongly agree	48	100.0%
Agree	0	0%
No opinion	0	0%
Disagree	0	0%
Strongly disagree	0	0%
Was telephone call follow up sufficient?		
Strongly agree	45	93.9%
Agree	2	4.1%
No opinion	0	0%
Disagree	1	2.0%
Strongly disagree	0	0%
Were you happy with telephone follow up?		

Strongly agree	47	98.0%
Agree	1	2.0%
No opinion	0	0%
Disagree	0	0%
Strongly disagree	0	0%
Could you easily describe your problems on telephone?		
Strongly agree	48	100.0%
Agree	0	0%
No opinion	0	0%
Disagree	0	0%
Strongly disagree	0	0%
Would you recommend a telephone follow up to a friend?		
Strongly agree	47	98.0%
Agree	1	2.0%
No opinion	0	0%
Disagree	0	0%
Strongly disagree	0	0%
Total	48	100.0

Table 3: 93.9% of the participants strongly agreed that telephone follow-up was sufficient, 100% of the participants were happy with telephone follow up, and confirmed also easy description of their problems on phone, and also it is a safe intervention as 98% of the participants strongly agree that they would recommend the new intervention; telephone follow-up to a friend.

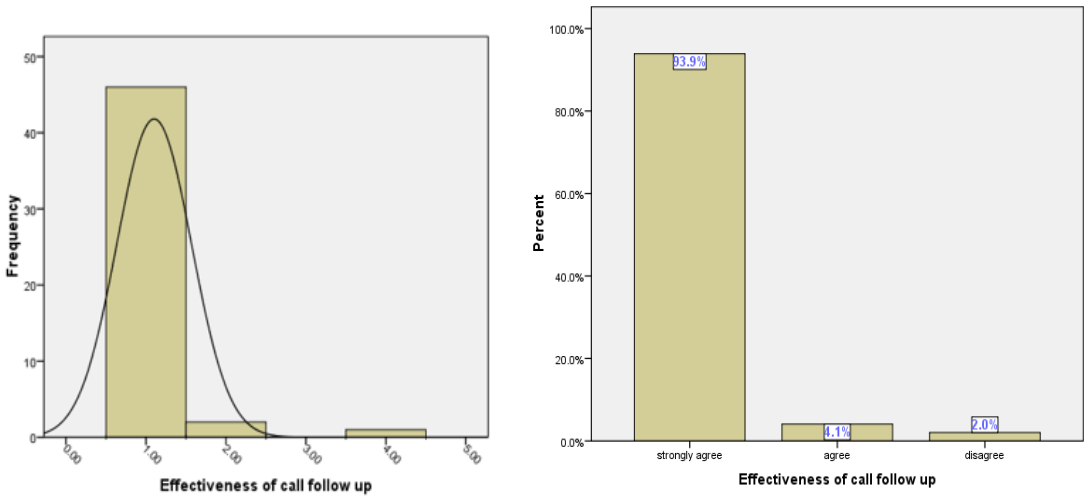


Figure 3: Positive distribution of call follow-up effectiveness

The study has evaluated the adequacy of telephone follow up. 93.9% of the participants strongly agreed that telephone follow up was sufficient. In addition, the figure 3 shows a positive distribution of the curve that explains the effectiveness of the intervention.

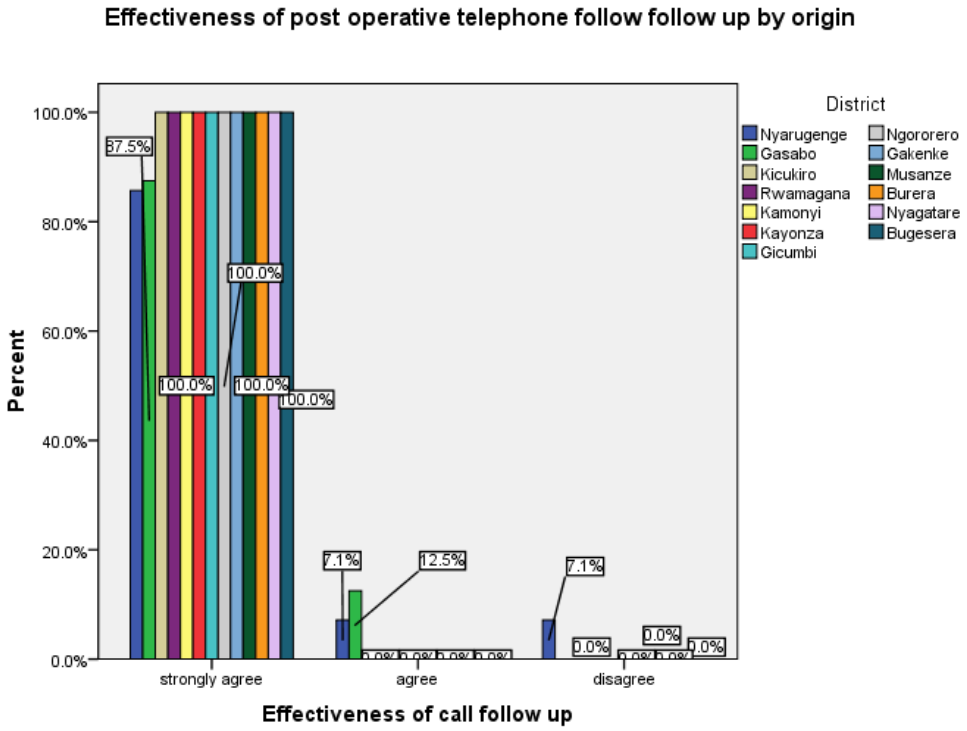


Figure 4: Patient opinion on effectiveness of telephone call follow-up regarding the district of origin.

The proximity to the health facility may influence face to face post-surgical patients visit based on easy and available means of transport. However, this study revealed that patients satisfaction and adequacy of telephone follow up was positively distributed everywhere in the country regardless the district of origin.

V. DISCUSSION

Loss to follow-up is a concern in post-operative follow-up following inguinal hernia surgery. In settings with limited resources, the number of patients who consult is low. Telephone call follow-up has been proposed to be a valuable alternative [59], [60]. This study aimed at increasing post-operative follow-up rate with telephone follow-up among patients who underwent hernia surgeries in CHUK.

Given the presented data, telephone call follow up was found to decrease the loss of follow-up as compared to face to face counterpart, these findings are similar to the ones found in the study done by Fischer and colleagues [8], where telehealth was found to improve post-operative follow-up by 63% as compared to 56% in clinic follow up . Some studies have shown that telephone call is an alternative to in-clinic follow-up during special times, especially during the corona virus disease 2019 pandemic. It is shown to be efficient while also enhancing social distancing [61]–[63]. Protocols for hernia surgery follow-up have been elaborated, without compromising the outcome [64]. It was the same in our setting as the telephone call follow-up was done during lockdown. As we did in this study, it is always important to remind patients and physicians alike that if there is ever a concern for a patient's condition, an in-office visit will always be allowed and available.

Hwa and colleagues [4] reported 4.8% of complications in telehealth group versus no complication in routine follow-up that came out of the substitution of telehealth for a gold standard clinic visit, with high patient satisfaction. Eisenberg and colleagues also had a complication rate of 3.6%. In contrast to them, the complication rate in our study was 4.4% in routine group with a potential complication rate in the call group of 2.1% in our study, but without any true complication.

Regarding our study, patients in telephone cohort were highly satisfied with this mode of patient-physician communication. It is also a safe intervention as almost all participants strongly agree that they would recommend the new intervention; telephone follow-up to a friend. Eisenberg and colleagues [37] found that in 55 out of 62 patients who successfully completed planned telephone follow-up, 90.9% who were reached by telephone were satisfied enough by phone call.

9.1% returned in-clinic based on concerns raised during the telephone call discussion. Of these, 1 was found to have an early hernia recurrence and 1 had a seroma. In our study, 1 patient (1.8%) had concern raised on telephone follow-up (surgical site swelling) and returned in-clinic; the patient had a normal exam in clinic and was given reassurance thereafter.

Concerning economic savings, Gunter and colleagues [39] reported patients gain of time and less money expenditure with telehealth approach. Regardless the district of origin (far or near our setting; CHUK), this study showed that patients were satisfied by this mean of follow-up, the telephone call, which was a means of time and money saving.

VI. CONCLUSION AND RECOMMENDATION

VI.1 Conclusion

Our study shows that telephone call is effective for post-operative follow-up outcomes after pediatric and adult inguinal hernia surgeries. There is no difference in short-term complications between 2 groups but with less patient loss to postoperative follow-up in telephone call group compared to routine follow-up group.

Elective hernia surgery patients are scheduled from the list of patients by calling them on telephone. This method could be beneficial to elective hernia patients during post-operative follow-up. However, this should depend on the treating surgeon judgment whether the patient's condition might require advanced in-clinic physical examination

VI.2. Recommendations

In the light of these results:

We recommend to surgical personnel to extend the post-operative telephone call; after evaluation of its effectiveness not only in inguinal hernia surgeries; to other low-risk procedures in order to maximize the post-operative follow-up.

Further randomized controlled trial studies might evaluate the use of video-based telehealth for surgery follow-up and consultations, taking into consideration the hospital and patient's cost of care.

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VIII. APPENDICES

Appendix 1: Questionnaire

Topic: "Feasibility of telephone call follow-up for short-term outcomes after pediatric and adult inguinal hernia surgery in CHUK"

I. At discharge: date:…….

Name: ID:……..

Age: …….Gender: M , F

Residence: Province: District: Tel number(for call cohort):

Hernia repair site: Right Left Bilateral

Hernia surgical approach: a.herniotomy. b. Open hernioplasty

c.Laparoscopic hernioplasty

II. At follow-up (POD#28):

Questions asked	Postop D28:
5. Is there increasing swelling at the incision site?	Yes No
6. Is there scrotal swelling or pain?	Yes No
8. Do you have any concerns?	No
If yes, which concerns?	Yes :
9. Would you like to have a face-to-face clinic visit?	Yes No

Patient's satisfaction questionnaire

Question	Strongly agree	Agree	No strong opinion	Disagree	Strongly disagree
Q1. The outcome of your surgery was satisfactory					
Q2. Telephone call follow-up is sufficient					
Q3. You were happy with the telephone follow-up					
Q4. You could easily describe your problems on the phone					
Q5. You would recommend a service to a friend					

Appendix 2: CONSENT FORM form children (English)

Informed consent to be enrolled in the study (less than 18years) Assent Form

Study title: "Short-term outcomes of post-operative telephone call follow-up for adult and pediatric elective inguinal hernia repair in CHUK."

Investigator:Dr NIYONZIMA Christian

Telephone:0782429963

Our aim is to describe the effectiveness of post-operative telephone call follow-up post pediatric and adult inguinal hernia repair. After being recruited in the study, you will be called on day 21 post hernia repair asking you about general status and incision characteristics. Depending on discussion, you will be asked to come for in-physical consult or not (that's the time of being discharged from the study).

It is not a rule to be involved in the research. No one will be angry with you if you will not participate, we will ask your parents if they accept your participation in the study. Even if you can be enrolled, you are allowed to quit the study anytime you want.

When we will be done with the study, we will record information obtained but your nam will appear nowhere.

Consent: I accept to participate in the study

Child name: ……..Date: …….

I declare that I explained all the information to the study participant to the level he/she understands

Name and signature of the caretaker/parent:……..

Date and phone number …….

For further information,call: Dr Christian NIYONZIMA, University of Rwanda, Resident in the department of Surgery

Telephone: 0782429963 E-mail: nzimach@gmail.com

In case your right is not respected:

Professor Jean Bosco GAHUTU

Chairperson, Institutional Review Board ,Telephone: + 250783340040

Francois Xavier Sunday

Secretary, Institutional Review Board, Telefone: +250788563311

University of Rwanda, college of Medicine and health sciences

PO box 3286 Kigali, Rwanda

E-mail:researchcenter@ur.ac.rw

Website : http://cmhs.ur/ac/rw/

Appendix 3: Consent form for children (Kinyarwanda)

ICYEMEZO CY'UBURENGANZIRA BWO KWINJIRA MU BUSHAKASHATSI(munsi y'imyaka 18) Assent Form

UMUTWE W'IBYIGWA: "INKURIKIZI Z'IGIHE GITO ZA TELEFONE MU KWIKURIKIRANISHA NYUMA YO KUBAGWA UMUSIPA MU BANA NO MU BAKURU MU BITARO BYA CHUK"

Umushakashatsi:Dr NIYONZIMA Christian

Telefoni:0782429963

Turakora ubushakashatsi ku bijyanye n'ikoreshwa (effectiveness) rya telefone igendanwa mu gusuzuma umwana cyangwa umuntu mukuru uba warabazwe umusipa(herniaNiwinjira muri ubu bushakashatsi, uzahamagarwa ku munsi wa 21 nyuma y'ibagwa ubazwa uko umeze muri rusange n'uko aho wabazwe hameze. Bitewe n'ibizava mu kiganiro, ushobora gusabwa kuza ku bitaro cyangwa ntuze(ni cyo gihe uzahita usezererwa mu bushakashatsi)

Ntabwo ari itegeko kwitabira ubu bushakashatsi. Ntawe uzakurakarira nuba utabwitabiriye. Tuzabaza n'ababyeyi bawe niba bemera ko witabira ubu bushakashatsi. Ntawe uzakurakarira niba utabwitabiriye. Tuzabaza n'ababyeyi bawe niba bemera ko witabira ubu bushakashatsi. Nubwo wakwemera ubu, wemerewe kuva muri ubu bushakashatsi igihe ushakiye.

Niturangiza ubu bushakashatsi, tuzandika amakuru y'ibyo twabonye ariko izina ryawe ntaho rizagaragara.

Icyemezo:Nemeye kwitabira ubu bushakashatsi

Izina ry'umwana:

……

…….Itariki: …….

Ndemeza ko nsobanuriye uwitabiriye ubu bushakashatsi ku rwego abisobanukirwa bituma yemera kwitabira

Amazina n'umukono by'umubyeyi:……..It ariki na nimero ya telefone: …….

Ukenete ibindi bisobanuro, wabaza: Dr Christian NIYONZIMA

Kaminuza y'u Rwanda, Umunyeshuri mu ishami ryo kubaga

Telefone: 0782429963 E-mail: nzimach@gmail.com

Mu gihe uburenganzira bwawe butakubahirizwa wabaza:

Professor Jean Bosco GAHUTU

Chairperson, Institutional Review Board ,Telephone: + 250783340040

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Secretary General, Institutional Review Board, Telefone: +250788563311, Kaminuza y'u Rwanda, Ishuri ryigisha ubuzima n'ibijyanye n'ubuzima, PO box 3286 Kigali, Rwanda

E-mail:researchcenter@ur.ac.rw

Website : http://cmhs.ur/ac/rw/

Appendix 4: Consent form for adults (English)

INFORMED CONSENT OF PARTICIPATION IN THE STUDY (above 18yrs old)

Study title: "Short-term outcomes of post-operative telephone call follow-up for adult and pediatric elective inguinal hernia repair in CHUK."

Investigator:Dr NIYONZIMA Christian Telephone:0782429963

Read carefully before accepting your participation in the study

Study requirements: you are asked about your identification

Our aim is to describe the effectiveness of post-operative telephone call follow-up post pediatric and adult inguinal hernia repair. After being recruited in the study, you will be called on day 21 post hernia repair asking you about general status and incision characteristics. Depending on discussion, you will be asked to come for in-physical consult or not (that's the time of being discharged from the study).

Advantages This study will demonstrate thet telephone call can be an alternative to in-clinic follow-up post hernia repair.and to reduce long list of patients coming for consultation,and will be used as a triage tool for those who need more care than others

Confidentiality: the information which will be recorded will be kept confidentially. You will be given a code and the papers will be in a locker. And be burnt at the end of study.Nowhere in the study will be shown your names.

Right to withdraw from the study: You are allowed to withdraw from the study whenever you want,no other drawbacks in your medical care

For further information,call: Dr Christian NIYONZIMA. University of Rwanda, Resident in the department of Surgery

Telephone: 0782429963 E-mail: nzimach@gmail.com

In case your right is not respected:

Professor Jean Bosco GAHUTU

Chairperson, Institutional Review Board ,Telephone: + 250783340040

Francois Xavier Sunday, Secretary, Institutional Review Board. Telephone: +250788563311

University of Rwanda, college of Medicine and health sciences

PO box 3286 Kigali, Rwanda

E-mail:researchcenter@ur.ac.rw, Website : http://cmhs.ur/ac/rw

Consent: I accept to participate in the above study

Signature: ----------Date and phone number: ----------

Appendix 5: Consent form for adults(Kinyarwanda)

ICYEMEZO CY'UBURENGANZIRA BWO KWINJIRA MU BUSHAKASHATSI (hejuru y'imyaka 18)

UMUTWE W'IBYIGWA: "INKURIKIZI Z'IGIHE GITO ZA TELEFONE MU KWIKURIKIRANISHA NYUMA YO KUBAGWA UMUSIPA MU BANA NO MU BANTU BAKURU MU BITARO BYA CHUK"

Umushakashatsi:Dr NIYONZIMA Christian Telefoni:0782429963

Soma neza mbere yo kwemeza niba ujya mu bushakashatsi

Icyo usabwa mu bushakashatsi: uzabazwa ibijyanye n'umwirondoro wawe

Turakora ubushakashatsi ku bijyanye n'ikoreshwa (effectiveness) rya telefone igendanwa mu gusuzuma umwana cyangwa umuntu mukuru uba warabazwe umusipa(hernia). Niwinjira muri ubu bushakashatsi, uzahamagarwa ku munsi wa 21 nyuma y'ibagwa ubazwa uko umeze muri rusange n'uko aho wabazwe hameze. Bitewe n'ibizava mu kiganiro, ushobora gusabwa kuza ku bitaro cyangwa ntuze(ni cyo gihe uzahita usezererwa mu bushakashatsi)

Ingaruka nziza: Ubu bushakashatsi buzagaragaza ko telefoni ishobora gukoreshwa nk'inyunganizi yo kuza kwisuzumisha mu bitaro nyuma yo kubagwa , bikagabanya imirongo abarwayi batonda baje kwivuza, bukazajya buba uburyo bwo gutoranya(triage) abantu bakenewe kwitabwaho kurusha abandi.

Kugirirwa ibanga:amakuru tuzabona azakoreshwa mu buryo bw'ibanga. Uzahabwa umubare w'ibanga kandi impapuro zihuza amazina n'umubare w'ibanga zizabikwa mu kabati gafungwa,zizanatwikwe ubushakashatsi burangiye. Nta hantu na hamwe havugwa ubu bushakashatsi hazagaragara amazina yawe.

Uburenganzira bwo kwikura mu bushakashatsi: wemerewe kwivana mu bushakashatsi igihe cyose wabishakira, nta zindi nkurikizi cg ingaruka mu kuvurwa kwawe

Ukeneye ibindi bisobanuro, wabaza Christian NIYONZIMA

Kaminuza y'u Rwanda, Umunyeshuri mu ishami ryo kubaga ,Telefone: 0782429963 E-mail: nzimach@gmail.com

Mu gihe uburenganzira bwawe butakubahirizwa wabaza: Professor Jean Bosco GAHUTU, Chairperson, Institutional Review Board ,Telephone: + 250783340040

Francois Xavier Sunday, Secretary, Institutional Review Board, Telefone: +250788563311

Kaminuza y'u Rwanda, Ishuri ryigisha ubuzima n'ibijyanye n'ubuzima, PO box 3286 Kigali, Rwanda

E-mail:researchcenter@ur.ac.rw Website : http://cmhs.ur/ac/rw/

Kwemera:Nemeye kujya mu bushakashatsi na sobanuriwe haruguru

Umukono: ----------Itariki na nimero ya telefone: ----------

Appendix 6: Department of surgery recommendation letter

UNIVERSITY of RWANDA

COLLEGE OF MEDICINE & HEALTH SCIENCES

SCHOOL OF MEDICINE & PHARMACY

OFFICE OF THE ACADEMIC HEAD

DEPARTMENT OF SURGERY

Kigali November 20, 2019

To CMHS IRB Committee

I am writing in support to Dr NIYONZIMA Christian application to CMHS IRB approval to conduct a research study entitled: "**Short-term outcomes of post-operative telephone call follow-up for adult and pediatric elective inguinal hernia repair in CHUK.**"

Dr NIYONZIMA Christian is a 4th year resident General Surgery MMed program in the department of Surgery. His research study aim is to describe the effectiveness of post-operative telephone call follow-up post elective pediatric and adult inguinal hernia repair in CHUK. Strategies will be proposed to improve the quality of post-operative follow-up.

He has presented his research proposal to the department of Surgery and has obtained the department clearance to carry on this study.

If any addition information is needed, please contact us on 0788732667 or on e-mail: fostino21@yahoo.com

With regards,

Dr NTIRENGANYA Faustin, MD, MMed/General & Plastic Surgeon

Academic head of Department

Department of Surgery/CHUK

Dr NTIRENGANYA Faustin CHIRURGIEN

Appendix 7: CMHS-IRB approval

UNIVERSITY OF RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 15th /October/2019

Dr. NIYONZIMA Christian
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 538/CMHS IRB/2019

Your Project Title ***"Short-term outcomes of post-operative telephone call follow-up for adult and pediatric elective inguinal hernia repair in CHUK"*** has been evaluated by CMHS Institutional Review Board.

Name of Members	Institute	Involved in the decision		
		Yes	No (Reason)	
			Absent	Withdrawn from the proceeding
Prof Kato J. Njunwa	UR-CMHS	X		
Prof Jean Bosco Gahutu	UR-CMHS	X		
Dr Brenda Asiimwe-Kateera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayonga N. Egide	UR-CMHS	X		
Mr Kanyoni Maurice	UR-CMHS		X	
Prof Munyanshongore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district		X	
Dr Gisbonia Darius	UR-CMHS	X		
Dr Donatilla Mukamana	UR-CMHS	X		
Prof Kyamanywa Patrick	UR-CMHS		X	
Prof Condo Umutesi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS	X		
Dr Nkeramihigo Emmanuel	UR-CMHS		X	
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social			X

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 5th December 2019. **Approval has been granted to your study.**
Please note that approval of the protocol and consent form is valid for **12 months**.

Email: researchcenter@ur.ac.rw P.O Box 3286 Kigali, Rwanda www.ur.ac.rw

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addendia to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval.
5. Failure to submit a continuing review application will result in termination of the study.
6. Notify the IRB committee once the study is finished.

Sincerely,

Date of Approval: The 5th December 2019

Expiration date: The 5th December 2020

Professor GAHUTU Jean Bosco
Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:
- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR

Appendix 8 : CHUK ethical committee approval

CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

Ethics Committee / Comité d'éthique

17,Jan,2020 Ref.:EC/CHUK/003/2020

Review Approval Notice

Dear Christian NIYONZIMA,

Your research project: ***"Short-term outcomes of post-operative telephone call follow-up for adult and pediatric elective inguinal hernia repair in CHUK "***

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 17,Jan,2020 to evaluate your request for ethical approval of the above mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your research project.

You are required to present the results of your study to CHUK Ethics Committee before publication by using this link:www.chuk.rw/research/fullreport/?appid=28&&chuk.

PS: Please note that the present approval is valid for 12 months.

Yours sincerely,

Dr Emmanuel Rusingiza Kamanzi
The Chairperson, Ethics Committee,
University Teaching Hospital of Kigali

ETHICS COMMITTEE
CHUK

Scan code to verify.

" University teaching hospital of Kigali Ethics committee operates according to standard operating procedures (Sops) which are updated on an annual basis and in compliance with GCP and Ethics guidelines and regulations "

B.P. :655 Kigali- RWANDA www.chuk.rw Tél. Fax : 00 (250) 576538 E-mail: chuk.hospital@chukigali.rw