



**COLLEGE OF MEDICINE AND HEALTH SCIENCES**  
**SCHOOL OF HEALTH SCIENCE**

**LOW COMPLETINESS OF SURGICAL CONSENT FORM IN GAHINI DISTRICT  
HOSPITAL**

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS  
FOR MASTER OF HOSPITAL AND HEALTHCARE ADMINISTRATION (MHA)

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## **DECLARATION**

This capstone dissertation is submitted in partial fulfillment of the requirements for college of medicine and health sciences, University of Rwanda, Degree of Master in Hospital and Healthcare Administration.

### **Supervisor's Declaration:**

I confirm that, to the best of my knowledge:

- The study was carried out and the dissertation was prepared under my direct supervision;
- The study was conducted in accordance with the degree regulations;
- The capstone dissertation represents the original work of the candidate;
- The contribution made to the study by me, by other members of the supervisory team, by other members of staff of the university and by others was consistent with normal supervisory practice;
- External contributions to the research are acknowledged.

Supervisor \_\_\_\_\_ Date \_\_\_\_\_

### **Candidate's Declaration**

I confirm that:

- This capstone dissertation represents my own work;
- The contribution of any supervisors and others to the research and to the capstone dissertation was consistent with normal supervisory practice;
- External contributions to the research are acknowledged.

Candidate \_\_\_\_\_ Date \_\_\_\_\_

## **DEDICATION**

I dedicate my dissertation work to my family and many friends. I also dedicate this dissertation to many friends, Gahini team and church family who have supported me throughout the process. I will always appreciate all they have done, especially for helping me in my writing skills and for the many hours of proofreading. I dedicate this work and give special thanks to my wife for being there for me throughout the entire program. Both of you have been my best cheerleaders.

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May the almighty God bless you all abundantly.

## **ABSTRACT**

### **Background**

Gahini hospital is a district hospital which offers preventive, promotional and curative services, with special attention to people with disabilities.

The incompleteness of surgical consent form has been discovered by accreditation evaluation done by central level and during the baseline assessment; it was found that 12.2% of surgical consent form were complete.

### **Methods**

We conducted pre-post intervention study to observe the result of the implementation of surgical consent form completeness before surgery.

In pre-intervention 187 files were audited as sample size selected randomly from January to April 2016. In post intervention 106 files were used as sample size selected randomly to analyze the root causes and select the intervention of surgical consent form completeness from December 2016 to March 2017.

### **Results**

The surgical consent form completeness increased significantly from 12.2% to 57.5% with  $P < 0.001$ .

### **Conclusion and recommendations**

The findings indicate that staffs training on informed consent policy and regular follow up improve the completeness of surgical consent form at Gahini Hospital. The hospital should apply strategic problem-solving methodology to establish more quality improvement projects in the future.

## TABLE OF CONTENTS

<b>DECLARATION</b> .....	<b>i</b>
<b>ACKNOWLEDGEMENTS</b> .....	<b>iii</b>
<b>ABSTRACT</b> .....	<b>ivii</b>
<b>TABLE OF CONTENTS</b> .....	<b>iv</b>
<b>LIST OF TABLES</b> .....	<b>vii</b>
<b>LIST OF FIGURES</b> .....	<b>vviii</b>
<b>LIST OF ACRONYMS AND ABBREVIATIONS</b> .....	<b>vii</b>
<b>CHAPTER ONE: INTRODUCTION</b> .....	<b>1</b>
1.1. Background .....	1
1.2. Problem formulation .....	2
1.3. Objective .....	2
1.4. Hypothesis .....	2
1.5. Justification of the project .....	3
1.6. Organization of the dissertation .....	3
<b>CHAPTER TWO: LITERATURE REVIEW</b> .....	<b>4</b>
2.1. Informed consent.....	4
2.2. Importance of consent form .....	5
2.3. Level of consent form .....	5
2.4. Interventions and efforts to improve consent form completion .....	7
2.5. Surgical consent form completeness in Gahini hospital . <b>Error! Bookmark not defined.</b>	
<b>CHAPTER THREE: METHODOLOGY</b> .....	<b>8</b>
3.1. Design of the study.....	8
3.2. Magnitude of the problem .....	8
3.3. Sample size calculation .....	9
3.4. Root cause analysis .....	10

3.4.1. Verification of root causes .....	11
3.3.2. Results of Root Cause Analysis.....	16
3.5. Intervention .....	17
3.5. Measures.....	18
3.6. Data analysis .....	18
3.7. Ethical consideration .....	19
<b>CHAPTER FOUR: RESULTS .....</b>	<b>20</b>
<b>CHAPTER FIVE: DISCUSSION.....</b>	<b>21</b>
<b>CONCLUSION AND RECOMMENDATIONS.....</b>	<b>24</b>
Conclusion.....	24
Recommendations .....	24
<b>REFERENCES.....</b>	<b>25</b>

## LIST OF TABLES

Table 1: Shortage of staff.....	<b>Error! Bookmark not defined.</b>
Table 2: Knowledge assessment on the importance of consent form.....	13
Table 3: staff training on informed consent policy.....	<b>Error! Bookmark not defined.</b> 5
Table 4: Availability of consent form.....	145
Table 5: Condition of patient .....	<b>Error! Bookmark not defined.</b>
Table 6: Comparative analysis.....	147
Table 7: a table summarizes the results of level of completion after the implementation.....	20

## **LIST OF FIGURES**

Figure 1: Fishbone for all possible root causes on incompleteness of surgical consent form before surgery .....	11
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## **LIST OF ACRONYMS AND ABBREVIATIONS**

CRF:	Centre de Réadaptation Fonctionnelle
HIV:	Human Immunodeficiency Virus
Dr:	Doctor
Prof:	Professor
UR:	University of Rwanda
CMHS:	College of Medicine and Health Sciences
PLWDs:	People Living With Disabilities
SPSS:	Statistical Package for the Social Sciences
ART:	Anti Retrovirus Treatment
NCDs:	None Communicable Diseases
MD:	Medical Doctor
LEP:	Limited English Proficiency

## **CHAPTER ONE: INTRODUCTION**

### **1.1. Background**

Promotion of patients' participation in care through their involvement in decision making is an integral component of quality improvement in health systems. This is currently recommended by many quality organizations <sup>(4)</sup>. With the ultimate goal of providing patient centered health care to clients, Gahini hospital has adopted the use of informed consent form.

The facility is a District Hospital founded in 1927 by the Anglican Church missionary society as one of the many developments to improve the health of the population in the region. Since then it has been serving people from the country and from other countries across the borders. It is one of the two hospitals in Kayonza district. The vision of Gahini Hospital is to promote health of the population throughout different health services in Kayonza District. The main mission of Gahini District Hospital is to offer preventive services, promotional and curative high quality in general, with special attention to people with disabilities.

It has a catchment area of 196,424 and covers 7 Health centers, 3 health posts, 2 private dispensaries in the Kayonza District. It also receives patients with disability from the entire Rwanda and abroad. This hospital has capacity of 216 beds with 7 medical doctors, 56 nurses, 7 midwives and 40 supporting staff. The later provides different services including orthopedic and hernioraphy surgeries. It is mainly done in conjunction with "Centre de Réadaptation Fonctionnelle de Gahini (CRF)" dealing with disability.

The main departments of hospital are internal medicine, pediatric, maternity, surgery, dentistry, ophthalmology, out patients' consultation, NCDs, physiotherapy, mental health, psycho-social counseling, ART unit, nutrition services, social services, Para medical services laboratory,

pharmacy stock, medical imaging, Centre de Réadaptation Fonctionnelle de Gahini (CRF), medical consultations, occupational therapy department, ergonomic work shop, orthopedic workshop, cerebral palsy care, incontinence care, HIV/AIDS in PLWDs care, outreach activities and psycho-social department.

## **1.2. Problem formulation**

There is a low completion rate of surgical consent form in Gahini District Hospital. This was confirmed by external evaluators from Ministry of Health in quarterly peer evaluation of established standards for quality of health care including consent form as one of the standards in accreditation program. The World Health Organization defines external quality assessment as any process in which an external organization assesses health facility compliance with pre determined quality standards<sup>(1)</sup>. The use of informed consent form is one of the key issues identified among patients whom underwent surgical operations in different departments mainly in surgery and maternity departments.

The magnitude of this problem was measured by a retrospective review of 187 patient's files of January to end of April 2016 has been selected randomly from 350 operated during that period. At this level, the completion rate of surgical consent form in Gahini hospital was found to be 12.2%.

## **1.3. Objective**

To increase completeness of surgical consent form, from 12.2% to 50% from December 2016 to March 2017.

## **1.4.Hypothesis**

H<sub>0</sub>: staff training will not improve the completeness of surgical consent in Gahini hospital

H<sub>a</sub>: staff training will improve the completeness of surgical consent form in Gahini hospital

### **1.5. Justification of the project**

Health care accreditation is often adopted, in widely differing settings, as a system for service improvement or as a vehicle for health reform<sup>(2)</sup>. Informed consent has been identified among standards to be improved in health care settings. To get informed consent is considered as an essential element of modern clinical practice. It works as a safeguard of patient's rights and minimize the chances of legal action against the physician in case of any complication arising from the proposed therapy<sup>(2,3)</sup>. It serve also as a participatory approach aiming at involving patient in taking decisions regarding his or her own life and treatment<sup>(4)</sup>.

### **1.6. Organization of the dissertation**

This thesis is divided into six main chapters. Chapter one introduces the setting and background. Chapter two contains the literature review on the related matters. Chapter three is concentrated on the methodology used during the process of producing this report including methods and techniques used in collecting and analyzing data. Chapter four was focused on the results presentation. Chapter five was limited to discussion while last chapter was centered conclusion and recommendations.

## **CHAPTER TWO: LITERATURE REVIEW**

### **2.1. Informed consent**

#### **Definition and historical background of consent form**

The word ‘informed consent’ was first used in 1957 in California legal and is defined as the process whereby health care providers provide the patient with the information necessary to make an informed decision about their care<sup>(5)</sup> or it is a voluntary and continuing permission of the patient to receive treatment based on their understanding of the procedure and inherent risks in addition to its likely success and any alternatives<sup>(3,4)</sup>. It is a principle born of outrage at the atrocities committed by German physicians and scientists under the Hitler regime. As is well known, thousands of concentration camp prisoners were used as human guinea pigs against their will in experiments that were typically excruciatingly painful and generally led to death or permanent disfigurement. As a part of its written decision, the war crimes tribunal that convicted several of the notorious “Nazi Doctors” produced what has since become known as the Nuremberg Code widely regarded as the first global code of human experimentation ethics<sup>(6)</sup>.

A minimum required information that patients should receive regarding (1) nature of the procedure, including whether it is diagnostic or therapeutic; (2) risks involved, especially those that are severe and likely to occur; (3) benefits of the procedure; and (4) alternatives to the procedure, along with their risks and benefits<sup>(8)</sup>. However, consent should be validated when patient is competent to take the particular decision, have received sufficient information to make a decision and not be acting under coercion<sup>(9)</sup>, the none use of consent form for performed procedure for patient is considered as health care malpractice<sup>(10)</sup>.

## **2.2. Importance of consent form**

To obtain informed consent is considered as an integral part of modern clinical practice. It works as a safeguard of patient's rights and minimizes the chances of legal action against the physician in case of any complication arising from the proposed therapy, the education of patient is a key part of providing health care(11). The benefits of informed patient consent for surgical procedure including education of patient about benefit of surgery and related risks, this should increase patient collaboration during procedure and minimize related complications for the surgeon or institution; a proper documentation of surgical consent form may increase the chances of the highest defense against potential litigation<sup>(5)</sup>.

## **2.3. Level of consent form**

Many researches have been done in different developed countries as well as developing countries as follows, a survey conducted at surgical departments of a university hospital in Pakistan from December 2007 to March 2008. This survey dealt with patients over the age of 18 years, who had undergone elective or emergency surgery. The result is as follows; among 106 patients selected for this study. 38% of the surveyed patients acknowledged that they actually understood the information imparted to them. 66% patients were informed about the type of anesthesia proposed but none was given any hint about complications of anesthesia. 11% patients actually signed the consent forms themselves(11).

However some researchers consider language as a threat of poor documentation of consent form as shown in a designed study to compare informed consent documentation for common invasive medical procedures between LEP and English-speaking patients at big public teaching hospital as United States population is increasing linguistically many diverse each year, almost 11 million

people identified they speak English not well or not at all this is from 2000U.S.census the outcome show that language barriers have been found to make more difficult many aspect of patient care, including receipt of medical services, patient satisfaction, informed consent documentation(12).

Another study was conduct in tertiary hospital in Karachi with objective of how preoperative informed consent practice and result is as follow, 200 randomly chosen patients (121 males and 79 females) were interviewed postoperatively. 184 (92%) say that consent was not taken by the surgeon who will be performing the procedure. 143 (71.5%) patients were informed of their existing medical condition while 90 (45%) of patients were informed about the nature of proposed surgery while 89 (44.5%) was informed about risks and complications only 41 (21.5%) informed about alternate treatment, 143 (71.5%) were aware of the type of anesthesia given, 30 (15%) know the complications and risks of proposed anesthesia, 40 (20%) said they were allowed to ask questions during the consent and 156 (78%) of patients were satisfied from the information provided, all the patients signed the consent form.

This study suggests that the current preoperative informed consent practice in a large tertiary teaching hospital of Karachi is below standard to international and ethical acceptability. The quality of informed consent may be improved by increasing awareness of the ethical issues surrounding consent. More work will be require to educate doctors and health care providers to respect the patients right to know, even if they are satisfied by the very little information provided as part of preoperative informed consent process(13).

## **2.4. Interventions and efforts to improve consent form completion**

The Ministry of Health of Rwanda has implemented many strategies to reinforce the country's health systems and to improve quality of care by establishing standards through introduction of accreditation program<sup>(1)</sup>. Documentation record facilitates diagnosis and treatment, communicates the information to other caregivers to ensure patient safety and reduce medical errors, and serves an important medical-legal function in risk management(14). by utilization of education as a model of clinical documentation improvement has shown to improve the quality and accuracy of clinical records and to increase the clinicians' awareness of the importance of good documentation<sup>(5)</sup>.

## **CHAPTER THREE: METHODOLOGY**

### **3.1.Design of the study**

A pre and post interventional study design was conducted in this project to evaluate the effect of the intervention. During pre-intervention phase from March to December 2016, a multidisciplinary team was formed to perform data collection on surgical consent form completeness in Gahini Hospital. An evaluation to determine the magnitude of the problem, which served as a baseline data, and root cause analysis were conducted by the project team. Based on the root cause, an intervention was designed and implemented. The implementation of the intervention began in December 2016 and continues to become part of the hospital daily routine. Post intervention evaluation was conducted in April 2017.

### **3.2. Magnitude of the problem**

The magnitude of this problem was measured by files review conducted on 187 patient's files as sample size from January to end of april2016 selected randomly from 350 files of operated patient during this period.

The tool used to assess the level of completeness of surgical consent (Appendix4)has been developed by head nurse, head of maternity unity, head of surgery unity and one medical doctor, surgical consent form (Appendix5). Around here, nine items in the surgical consent form will be audited. They are (1) patient name, (2) patient age, (3) patient signature, (4) physician name, (5) physician signature, (6) witness name (7) witness signature, (8) nature of procedure and (9) information about possible risks. The consent form is considered as completed only if all components are documented otherwise the consent form is considered incomplete.

A baseline assessment show that completion rate of surgical consent form is 12.2%

The tool used to assess the level of completeness of surgical consent in pre intervention has been applied in post intervention. A post intervention sample size is defferent of the pre intervention due to the different number of surgeries performed in the post intervention periode equal to 144 surgeries. Post intervention sample size is 106 files selected randomly from 144 files for all performed surgeries in the post intervention period.the outcome of post intervention is 57.3%

### **3.3. Sample size calculation**

The sample will be 187 delivered from the population of 350 patient files in pre and 106 delivered from the population of 144 patient files in post intervention were audited using the Solver's formula 2012(15).

#### **Formula for Determining Sample Size**

$$n = \frac{N}{1 + N(e)^2}$$

n= Sample size,

N= Population size,

e= Margin of error.

e=0.05

Calculation of sample size in pre-intervention

$$n = \frac{350}{1 + 350(0.05)^2} = 187$$

Calculation of sample size in post-intervention

$$n = \frac{144}{1+144(0.05)^2} = 106$$

### **3.4. Root cause analysis**

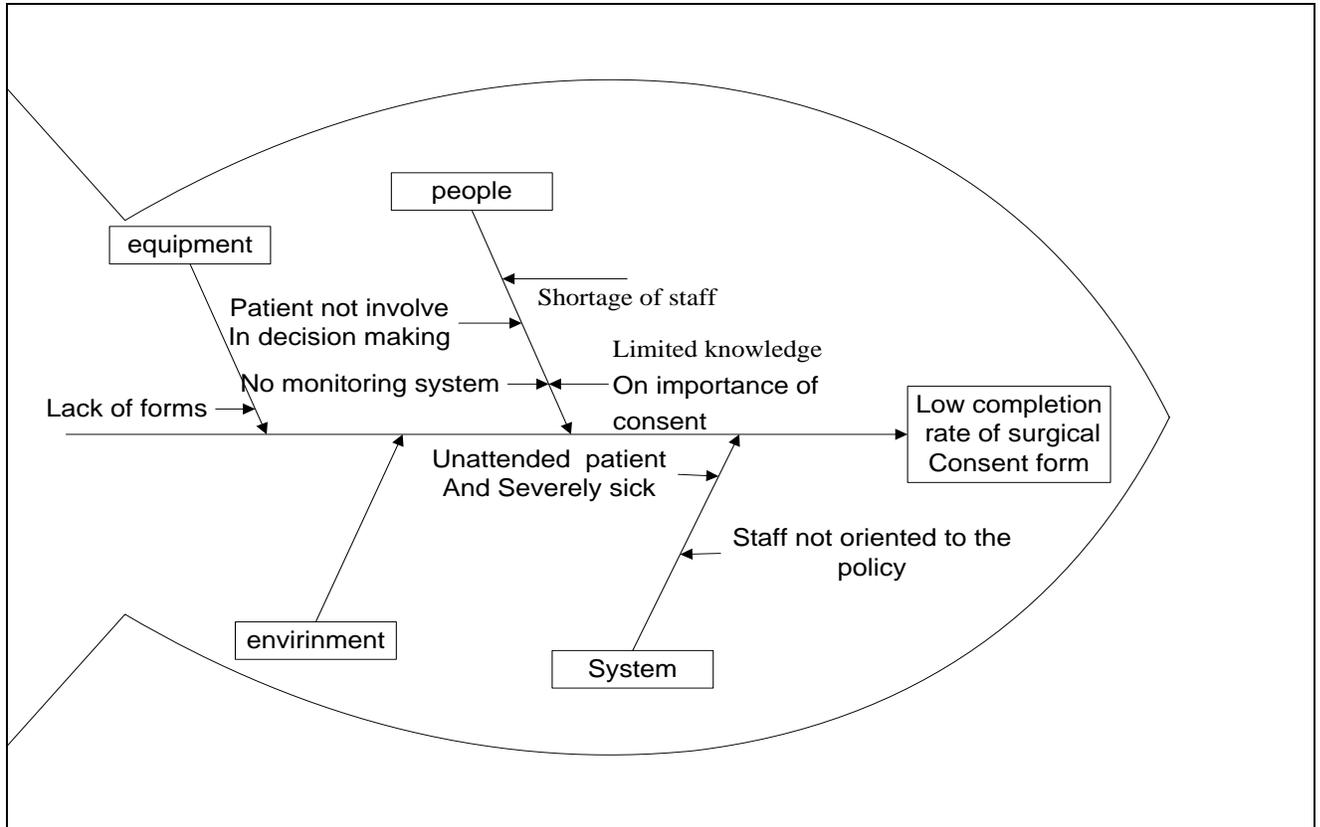
A literature review was conducted to identify published possible causes of incompleteness of consent form. The literature considers a language as a barrier of less documentation of consent form before an invasive procedure. Two group of people were involved in their study one group was English speakers while other was limited English proficiency. They found that patients who spoke English were almost twice likely as patient with limited English Proficiency to have documentation of consent form (12). In Gahini hospital context there is no language barrier because we have the surgical consent form in two languages including Kinyarwanda and English.

A multidisciplinary team from maternity unity, surgery unity and operating theatre organized a brainstorming session in July 2016 there was one physician,10 nurses and 4 midwives from the mentioned department, to discuss all possible causes for incompleteness of surgical consent form.

The identified root causes of the low completeness of surgical consent form are:

1. Shortage of staff/ work overload;
2. Staff have limited knowledge on the importance of consent form;
3. Forms inaccessible during admission/ Lack of forms;
4. No guidance and close supervision by in charges;
5. Nature of patients: severely sick & unattended patients;
6. Patient not involved in decision making;
7. Staff not oriented to the policy.

Seven possible root causes that were suggested by staff through brainstorming as a barrier of incompleteness of surgical consent form were summarized in the fish bone diagram (Figure1)



**Figure 1: Fishbone for all possible root causes on incompleteness of surgical consent form before surgery**

### 3.4.1. Verification of root causes

Data collection was done in order to verify the seven possible root causes and recognize the final root cause.

### 3.4.1.1.Shortage of the staff

To verify this cause, we conducted an assessment for clinical staff workload for patient ratio table1. The nurse ratio in Gahini Hospital is one nurse to eight (1/8) patients while physician is one medical doctor per twenty three (1/23) patients in medical/surgery department. In the developed countries, nurse to patient ratio in surgical and post-partum department is one nurse to four patients (1:4), while in labor and delivery is one nurse to one patient(16). In Rwanda in Surgical services: day1:7, night 1:10, obstetrics and Gynecology: Antenatal1:15, post natal care day 1:5, night 1:8, delivery room 1:1 and labor ward 1:3(17). Based on the result of the study, the shortage of staff is rejected to be a cause of low completeness of surgical consent form as detailed in Table 1.

**Table1.**

Date	Day/Night	Number of nurses	Number of patients	Nurse to patient ratio	Number of Physicians	Physician to patient ratio
29/07/2016	Day	3	27	1:9	1	1:27
	Night	3	23	1:7	1	1:23
30/07/2016	Day	2	22	1:11	1	1:22
	Night	3	27	1:9	1	1:27
31/07/2016	Day	2	25	1:12	1	1:25
	Night	2	27	1:14	1	1:27
01/08/2016	Day	2	20	1;10	1	1:20
	Night	3	23	1:7	1	1:23
2/08/2016	Day	4	20	1:5	1	1:20
	Night	3	24	1:8	1	1:24

3/08/2016	Day	4	19	1:5	1	1:19	
	Night	3	21	1:7	1	1:21	
4/08/2016	Day	4	20	1:5	1	1:20	
	Night	3	22	1:7	1	1:22	
Average nurse to patient ratio		1:8					
Average physician to patient ratio					1:22		

### 3.4.1.2.Limited knowledge on the importance of consent form

A questionnaire tool has been developed (appendix6) and tested. The table2 indicates that the level of knowledge of the importance of informed consent is high but patient are not involved in decision making regarding the planed procedures to him. The following is a result from 15 responded among 19 staff of maternity and surgery department.

**Table 2: Knowledge assessment on the importance of consent form**

N <sup>0</sup>	Question	Yes	No
1	Do you know the importance of informed consent form?	14(93.3%)	1(6.7%)
2	Do you know minimum required information; patients should receive before him to consent?	12(80%)	3(20%)
3	Have you been educated and trained about the existing informed consent form in your health facility?	12(80%)	3(20%)

4	Is the consent form used for all patients before surgery?	7(46.7%)	7(53.3%)
5	Did health care providers explain reason of intervention to the patient?	3(20%)	12(80%)
6	Did patient involved in decision making for operation?	3(20%)	12(80%)

Pursuant to the results from responded 93.3% have knowledge on informed consent while 6.7% says no, 80% knows minimum information that patient should receive before surgery including nature of the procedure whether it is diagnostic or therapeutic, risks involved especially those that are severe and likely to occur, benefits of the procedure and alternatives to the procedure along with their risks and benefits while 20% do not.

The information related to the staff training on consent form indicated that 80% of respondent have been educated and oriented on current hospital consent form and 20% do not. Patient involved in decision making regarding surgical procedure, it clearly indicate that 80% from responded says that patient are not involved in decision making regarding their care while 20% from responded agree that patient are involved in decision making on their care. It is patient's right to know about his diagnosis and the reason of intervention.

A consent form is not used for all patients who underwent surgical procedure in Gahini Hospital as evidenced by result from survey, 53.3% do not use consent form always while 46.7% says consent form are used every time before surgeries.

#### **3.4.1.3. Staff orientation to the policy**

To analyze that root cause, staff interviews were conducted for 23 clinical staff and the response is in table below. This aims at knowing the level of awareness of staff regarding consent policy. Based on result from the staff survey, it is realized that 87% have not been oriented and

communicated by the hospital regarding consent. After a deep analysis, it is clearly indicated that this is one of the key reasons of not fulfilling the informed consent form as majority of the staff confirmed not being informed on the policy of completing informed consent form as indicated by Table 3.

**Table 3: Staff training on informed consent policy**

N <sup>o</sup>	Question	Yes	No
1	Were staff trained on informed consent policy	3(13%)	20(87%)

#### **3.4.1.4. Availability of informed consent forms**

To analyze this cause, the assessment was conducted to the patient files in order to find out if there is patient file without consent form. The findings from data collection show that the consent form is including in patient file and all of the time patient files are available in each department. Meaning that availability of informed consent is not a reason of low completion rate of surgical consent form as it is indicated in Table 4.

**Table 4: Availability of consent form**

N <sup>o</sup>	Availability	Yes	No
1	Is consent form available	187(100%)	0(0%)

#### **3.4.1.5. Patient who is severely sick and unattended**

Based on different causes outlined by staff, the status of patient was among them, especially those who are severely sick and unattended is expected to be one of the reasons of low rate of informed

consent form completion. Same staff confirmed that status of patient may lead to no fulfilling surgical consent form. However, this was quickly rejected as a real root cause as indicated in the table be low. From 187 files of patients, 10 of them were severely sick and all have next of kin motherless the level of fulfilling consent form was still low only one has consent form well completed as indicated in Table 5.

**Table5: Condition of patient**

condition of the patient	Frequency	Level of completeness	Percentage
Severely sick and unattended	0	0	0
Severely sick and attended	10	1	10
Not severely sick(conscientious)	177	15	8.4

#### **3.4.1.6.Insufficient follow up system**

The informed consent is a serious issue in Gahini hospital. This is due to the absence of mechanism aiming at increasing the rate of consent form in the Hospital. The results from the assessment revealed that no existing mechanism targeting to increase this level in the Hospital and may be considered as one of root causes of low completion rate of surgical consent form.

#### **3.3.2. Results of Root Cause Analysis**

After root cause, analysis for each possible root causes, we realize that three root causes have been identified. This root causes including, patient not involved in decision making; staffs are not oriented to the policy and lack of supervision.

### 3.5. Intervention

Based on the identified root causes, the project team generated strategies to address the root cause. A detail comparative analysis was conducted as indicated in decision matrix.

#### COMPARATIVE ANALYSIS

**Table 6. Decision Matrix**

	Impact	Time to effect	Feasibility	Cost	Total
To avail reminder posted in theater	2	4	3	1	10
Conduct monthly monitoring and evaluation	4	3	3	2	12
Communicate hospital policy to the staff	4	5	5	1	15
Conduct sessions to explain the importance of patient participation in decision making on planed procedure for him	4	5	5	1	15

Based on the comparative analysis, the project team decided to conduct staff training on hospital policy, to avail reminder posted in theatre room, maternity and surgery unity, organize session to explain the importance of patient participation in decision making on planed procedure by using current consent form and provide supportive supervision to ensure clinical staff are complying to the strategies.

The intervention includes the following:

- a. Training on hospital informed consent policy: After development and validation of policy, the training was prepared and conducted to the clinical staff including physician, nurses and midwives.
- b. Availability of reminder posted in service: After approval of surgical consent reminder (appendix3), by clinical Director, it was directly posted in mentioned services.
- c. Organize session to explain the importance of patient participation in decision making on planed procedure by using current consent form.
- d. Monitoring: the implementation of these strategies required strong monitoring and evaluation by heads of department and quality improvement officer this should produce monthly report on completion of surgical consent form.

Staff training have been selected as the best intervention

### **3.6. Measures**

The number of surgical consent form completeness (outcome indicator) was measured to evaluate the outcome of the intervention and the completeness of each of the nine components of surgical consent form was also measured. Number of staff training has been measured as process indicator and his impact on expected outcome of the intervention (appendix4).

### **3.7. Data analysis**

The pre and post intervention of surgical consent form completion rate as well as each of the consent form component completion rates were compared using Chi Square tests. All statistical tests were conducted using SPSS software v.20, with P-value set at 0.05.

### **3.8. Ethical consideration**

The study did not involve patient contact, treatment were not affected, we did files audit where we got approval from hospital Director for conducting the files audit and allow to collect all data we needed (appendix). Nurses have given a verbal consent.

## CHAPTER FOUR: RESULTS

Patient files audit, a total of 292 surgical consent forms were audited, among them, 187 in pre intervention and 105 in post intervention. The rate of surgical consent form completeness increased significantly from 12.2% to 57.5% with  $P < 0.001$ . The results of each of the nine components of consent form shown patient name increased from 41.1% to 91.5% ( $P < 0.001$ ), patient age from 37.9% to 95.2% ( $P < 0.001$ ), patient signature from 52.4% to 96.2% ( $P < 0.001$ ), physician name from 27.2% to 97.1% ( $P < 0.001$ ), physician signature from 25.1% to 95.2% ( $P < 0.001$ ), witness name from 31.5% to 90.5% ( $P < 0.001$ ), witness signature from 41.1% up to 90.5% ( $P < 0.001$ ), nature of procedure from 19.2% to 64.1% ( $P < 0.001$ ) and information about procedure from 21.9% to 63.2% ( $P < 0.001$ ).

**Table 7: The results of level of completion before and after the implementation**

	Before intervention		After intervention		Chang	P value
	N	%	N	%	%	
<b>Sample</b>	<b>187</b>		<b>106</b>			
Patient name	77	41.1	97	91.5	50.4	<0.001
Patient age	71	37.9	101	95.2	57.3	<0.001
Patient signature	98	52.4	102	96.2	43.8	<0.001
Physician name	51	27.2	103	97.1	69.9	<0.001
Physician signature	47	25.1	101	95.2	70.1	<0.001
Witness name	59	31.5	96	90.5	59	<0.001
Witness signature	77	41.1	96	90.5	49.4	<0.001
Nature of procedure	36	19.2	68	64.1	45	<0.001
Information about risks	41	21.9	67	63.2	41.3	<0.001
<b>Consent completeness</b>	<b>23</b>	<b>12.2</b>	<b>61</b>	<b>57.5</b>	<b>45.3</b>	<b>&lt;0.001</b>

## **CHAPTER FIVE: DISCUSSION**

### **5.1. Association of staff training with surgical consent form completeness**

This study aimed at increasing the completeness of surgical consent form in preoperative care. As literature said the completeness of informed consent may be improved by increasing awareness of consent especially clinical staff training or education, this also protect patients right (13) An informed consent is a process whereby patient receives all necessary information to make decision related to the planed procedure<sup>(5)</sup>. The use of informed consent in clinical setting is an essential part of modern clinical medicine and it works as a safeguard of patient's right<sup>(12)</sup>. However other researchers found that limitation due to language is also a barrier for informed consent form completeness(12).

After getting a baseline data we realize that level of surgical consent form completeness in Gahini hospital was low compared to the standards. During data collection, nine component of surgical consent form has been audit to assess level of completeness before surgery or any related procedure. The level of surgical consent form completeness was 12.2% in pre-intervention at Gahini Hospital. Throughout data analysis we found that staffs were not oriented to the existing policy related to the informed consent and this leads the causes of incompleteness of surgical consent form. However the benefits of informed consent for surgical procedure including education of patient about benefit of surgery and related risks, this also should increase patient collaboration during procedure and minimize related complications for the surgeon or institution<sup>(5)</sup>.

## **5.2. Interpretation of result**

The increasing rate of completeness of surgical consent form in Gahini hospital before surgical procedure was due to training session regarding hospital informed consent policy. This hospital policy included the procedures for the informed consent process, right of patient, the protocol in filling out the consent and responsibilities of everyone during that process. This intervention strategy increased significantly the level of completeness from 12.2% to 57.5% with  $P < 0.001$  in pre-intervention to post-intervention and this was gone beyond the target of 50%. Also we realize that the completeness of the nine components of surgical consent form was increased.

Moreover the success of this project relied on a few key factors including team work which is crucial to the success of the project because the completeness of the surgical consent requires more than one staff to participate and to generate the expected outcome. From beginning of the project the team composed by chief nursing, maternity unity in charge, surgical unity in charge, midwives, nurses and doctors were involved in different steps of strategic problem solving to the pre-post intervention such as data collection for measuring magnitude of the problem, root cause analysis, selection of intervention, implementation of intervention, monitoring and evaluation.

Conducting proper root causes analysis is fundamental in the success of an implementation: Acquiring evidence and data to understand the situation facilitated the generation of appropriate and effective intervention.

The implementation of hospital consent requires holding the staff accountable for their actions and performance. Applying proper leadership and governance principles in managing internal workforce was essential by monitoring the compliance of the validated and implemented hospital

consent policy. By applying the strategic problem solving approach in our respective institutions helped to resolve easily the hospital issues and develop the system by introducing useful solutions. The project did not come as burden and was not additional cost to the hospital. The project used available resources. Monitoring and evaluation to show progress is important and can also be used to motivate staff to continue to sustain their achievements.

However, this project was not without limitations. The post intervention period of this project was short. The sustainability of the project request to be assessed in long term; the project did not assess the quality of data in the surgical consent form.

## **CONCLUSION AND RECOMMENDATIONS**

### **Conclusion**

Surgical consent form is a medical legal essential tool used before any medical procedure or related activity without permission of the patient; it help to minimize medical legal issues and promote patient's rights. The completion rate of surgical consent form in Gahini hospital was 12.2%, this because staff were not oriented to hospital policy regarding informed consent. Clinical staffs were not accountable on any malpractice by not using consent form and not involving patient in decision making according on planed procedure.

The intervention included staff training or presentation on existing informed consent policy which was not yet presented to the Gahini hospital staff and has been identified among the aiming of low completeness of surgical consent form. The impact of the project showed the strategies effectively improved the completeness level of surgical consent form before surgery from 12.2% to 57.5%. The project did not cost the hospital financial investment.

### **Recommendations**

Pursuant to the results of the study, considering the identified root causes of low completeness of surgical consent form, it is recommended that Gahini hospital should continue the monitoring in order to evaluate whether the achievement of this quality improvement project can be sustained over time. This should be recommended that strategic problem solving applied in other quality improvement project should be considerably supported in hospital. Surgical consent form completion should be applied in other medical procedures.(2)

## REFERENCES

1. Lane J, Barnhart S, Luboga S, Arudo J, Urassa D. The Emergence of Hospital Accreditation Programs in East Africa : Glob J Med PUBLIC Heal. 2014;
2. Shaw CD, Braithwaite J, Moldovan MAX, Nicklin W, Grgic I, Fortune T, et al. Profiling health-care accreditation organizations : an international survey. Int J Qual Heal Care. 2013;25:222–31 Advance Access Publication: 13 February 20.
3. WHO. Surgical Care at the District Hospital. Surg care Dist Hosp. 2003;
4. Brabbins C, Richardbentall JB. Consent to Neuroleptic Medication for Schizophrenia : Clinical , Ethical and Legal Issues. Clin Ethical Leg Issues. 1996;
5. CLINICAL DC and SS. The consent and counselling of patients for cataract surgery : a prospective audit. Surg often have an overoptimistic view Cataract surgery Eye. 2005;(April):963–71.
6. MG BERRY<sup>1</sup>, JENNIFER UNWIN<sup>2</sup>, GL ROSS, ELIZABETH PEACOCK AJ. A comparison of the views of patients and medical staff in relation to the process of informed consent. 2007 p. 368–73.
7. Shahnazarian D, Mentor MSWCS. Informed Consent in Human Subjects Research. (University of southern CALIFORNIA).
8. Melissa M. Bottrell, MPH; Hillel Alpert, MPM, BSc; Ruth L. Fischbach, PhD, MPE; Linda L. Emanuel, MD P. Hospital Informed Consent for Procedure Forms. Facil Qual Patient-Physician Interact Meliss. 2000;135.
9. Anderson OA. Informed consent for elective surgery. J R OYAL Soc O F M EDICINE. 2007;
10. Thomas CMF and B. CADIAN MEDICAL MALPRACTICE LAW IN 2011:MISSING

- THE MARK ON PATIENT SAFETY COLLEEN. 2014.
11. Siddiqui FG, Shaikh JM, Memon MM. AN AUDIT OF INFORMED CONSENT IN SURGICAL PATIENTS AT A UNIVERSITY HOSPITAL PAKISTAN. *J Ayub Med Coll Abbottabad*. 2010;22(December).
  12. Schenker Y, Wang F, Selig SJ, Ng R, Fernandez A. The Impact of Language Barriers on Documentation of Informed Consent at a Hospital with On-Site Interpreter Services. *J Ayub Med Coll Abbottabad*. 2007;294–9.
  13. Amin MF, Jawaid M. AN AUDIT OF INFORMATION PROVIDED DURING PREOPERATIVE INFORMED CONSENT. *Inf Consent Pract*. 2005;22(General surgery unit of Civil Hospital Karachi):2.
  14. Soto CM, Kleinman KP, Simon SR. Quality and correlates of medical record documentation in the ambulatory care setting. *BMC Health Serv Res*. 2002;7:1–7.
  15. Tejada JJ, Punzalan JRB. On the Misuse of Slovin ' s Formula. *Philipp Stat*. 2012;
  16. Statement P. MANDATED NURSE-PATIENT RATIO. BCNU Position Statement MANDATED NURSE-PATIENT RATIOS. 2015;(March).
  17. MOH. SERVICE PACKAGES FOR HEALTH FACILITIES AT DIFFERENT LEVELS. KIGALI; 2011.



## Appendix1. INFORMED CONSENT POLICY

<p><b>REPUBLIC OF RWANDA</b></p>  <p><b>EASTERN PROVINCE</b></p> <p><b>KAYONZA DISTRICT</b></p> <p><b>GAHINI HOSPITAL</b></p> <p><b>PO.BOX:75 RWAMAGANA</b></p> <p><b>Tel : +255112289</b></p> <p>Email:<a href="mailto:Gahinih@yahoo.com">Gahinih@yahoo.com</a>, <a href="mailto:hopitagah@gmail.com">hopitagah@gmail.com</a>,</p>	<b>TITLE: INFORMED CONSENT</b>		
	Policy code: <b>GH-CL-002</b>	<b>Effective Date:</b> <b>26<sup>th</sup> November, 2016</b>	<b>Revision date:</b> <b>26<sup>th</sup> November, 2018</b>
	<b>Department:</b> clinical	<b>Applies to:</b> All departments(maternity and surgical ward)	
	<b>Responsible Person:</b> Clinical director	Approvals: Titles Administrator  Hospital Director	<b>Signatures/dates</b>

### 1. Purpose:

To consider that all patients required for any diagnostic, therapeutic and surgical procedures sign informed consent before intervention with aim to take responsibility in the risks that may occur while performing the procedure.

### 2. Policy Statement

All Gahini hospital health care providers (those in concern) must know that informed consent is based on the moral and legal premise of patient autonomy, whereby a decision of client is taken to participate in medical examination, evaluation, diagnosis, interventions and treatment.

It is freely given by a client who has received the necessary information (Risks and benefits), adequately understood the information and after considering the information has arrived at a decision without having been subjected to coercion, undue influence, inducement or intimidation.

### **3. Definitions:**

#### **Informed consent:**

It is a process by which a fully informed client/patient can participate in choices about her health care for getting permission before conducting health care intervention on a person

#### **Signed Informed Consent:**

Is a written decision from individual who want to participate in assessment, treatment after receiving the necessary information.

#### **Equipment/Forms:**

- Informed consent form.
- Patient file.
- Pen.

### **4. Procedure**

1. Explain to the patient diagnosis and indication of the medical or surgical procedure and the identity of the person who performs the procedure or treatment.
2. Explaining the intervention, the condition, potential benefits and drawbacks (disadvantages) to the proposed procedure related to recovery.
3. Explaining the approved protocols and guidelines available to the proposed procedure
4. Explain possible alternatives of treatment and possible results of non treatment major and minor characteristic risks, any other procedures that may become necessary during the treatment.
5. The physician or other practitioner responsible for the care identifies him or herself.
6. Explain the risks and benefits of not receiving or undergoing a treatment or procedure.

7. Explain the likely hood of successful treatment.
8. Explain alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance).
9. A consent form will be signed by the client/patient himself or next of kin( if is child, unconscious patient, blind or dumb), the treating practitioner (doctor) and at least two witnesses ,one from the hospital and another from client .
10. Patient should consent for any photographs to be taken during treatment or intervention.
11. In case the client refuses to sign the consent form, a second health professional is required to explain in further detail to the patients or family, if the patients continue to refuse the proposed treatment must sign the informed refusal form.
12. Document the information and explanations given to the patient for the procedure in the patient progress notes.
13. A signed informed consent will be kept in patient file.

## 5. References

1. World Confederation for physical therapy (2011) Policy statement: Informed consent. [Online] . Available: <http://www.wcpt.org/policy/ps-consent> [05 September 2013].
2. John Hopkins Medicine (2012) Informed Consent Guidance [Online] . Available: [http://www.hopkinsmedicine.org/institutional\\_review\\_board/guidelines\\_policies/guidelines/informed\\_consent\\_i.html](http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/informed_consent_i.html) [05 September 2013].

### Appendix2. Gantt chart for implementation plan

TASK	RESP PERSON	Time line					
		NOV	DEC	JAN	FEB	MAR	April
Invitation(nurses, midwives and doctors)	Head of nursing	14-18					

Acquire (projector, flipchart, makers...)	Head of nursing	21-25					
Staff presentation on informed consent policy	Head of nursing doctor in charge of maternity	28- 30					
Implementation starting	Staff from maternity, surgery and theatre						
Plan session of supervision to check if the system is followed	Head of nursing						
Collect data for evaluation of surgical consent form completion rate	Head of nursing					30-31	
Provide feedback	Head of nursing						3-4

### APPENDIX3. EVALUATION PLAN

#### OUT COME INDICATOR:

<b>INDICATOR</b>	<b>DEFINITION</b>	<b>Responsible</b>	<b>Source of information</b>	<b>Time line</b>
% of consent form fully completed	# of surgical consent form well completed compared to # of all surgical consent forms	Chief Nursing	Patient files	In two weeks after starting implementation.

#### PROCESS INDICATORS

<b>INDICATOR</b>	<b>DEFINITION</b>	<b>Responsible</b>	<b>Source of information</b>	<b>Time line</b>
# of staff to be trained	# of staff trained compared to # of staff invited	Chief Nursing	Attendance lists	At the end of the training sessions

**Appendix4. Informed consent form data collection tool**

Consent	UNIT	Patient			Physician			Witness			Info about possibl e risks	Nature of proced ure	Compl ete
		Nome	Date	Signat ure	Nome	Date	Signat ure	Nome	Dat e	Signat ure			
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
12													
13													

**Appendix 5: Consent form for surgical / medical procedures**

You have been given necessary information (risks and benefit) about your condition and the recommended surgical, medical or diagnostic and therapeutic procedure(s) to be performed.

I, \_\_\_\_\_, age \_\_\_\_\_ sex..... after discussion with doctor, hereby consent following surgical/medical procedure, to be performed on:

.....

I understand and agree that the doctors and other members of the Medical Staff of the hospital, may perform, or assist with the surgery/medical procedure.

.

I understand also the risks of not receiving or undergoing this treatment or procedure(s).

The reasons for the surgery/medical procedure, as well as the anticipated effects, its nature and associated risks, have been explained to me by Dr.

\_\_\_\_\_

I also consent to such additional or alternative diagnostic, operative or treatment procedures as are immediately necessary on the opinion of the physician performing the procedure

The expected time of procedure is: .....hours/days

Dr..... I certify that I am fully aware and understand the contents of this consent.

Patient Signature:.....

.....  
Names and Signature of Witness  
.....

Date:...../...../..... time .....

Name and Signature of the Dr

**APPENDIX 6: QUESTIONNAIRE TO BE ADDRESSED TO THE HEALTH CARE PROVIDERS**

1.	Names (Optional)	
2.	Telephone number (Optional)	
3.	Gender	a. Male b. Female
4.	What is your occupation?	a. Physician b. nurse c. midwife d. allied
5.	Is there a quality improvement program in the health facility?	a. Yes b. No

6.	Is there a quality improvement focal person in the health facility?	a. Yes b. No
7.	Is the surgical intervention done at your health facility?	a. Yes b. No
8.	Did health care providers (HP) explain the diagnosis and reason of intervention to the patient?	a. Yes b. No
9.	Did the patient take decision for operation himself	a. Yes c. No
10.	Is it necessary to sign consent before surgery?	a. Yes b. No
11.	Is this health facility having the consent form?	a. Yes b. No
12.	If yes; is it available	a. Yes b. No
13.	Is the consent form used systematically for all patients who underwent operation?	a. Yes b. No

15	Do you know the role of informed consent form?	a. Yes  b. No
17.	Have you been educated and trained about the existing informed consent in your health facility?	a. Yes  b. No
18.	Do you know minimum required information; patients should receive before him to consent?	a. Yes  b. No

REPUBLIC OF RWANDA  
ESTERN PROVINCE



KAYONZA DISTRICT  
GAHINI HOSPITAL  
B.P:75RW AMAGANA  
E-mail : gahinih@yahoo.fr

April 8<sup>th</sup> 2016

To Charles R.GAFITA

University of Rwanda

Kigali

Dear Charles

**Re: Request for Permission to conduct a Quality Improvement Project**

Referring to the above subject requesting the permission to conduct a quality improvement project on improving completeness of surgical consent form GAHINI Hospital.

I am pleased to inform you that you are allowed to conduct your research in Gahini Hospital Maternity and Surgery Department; we are ready to support in case is necessary.

We kindly request you to share with us your findings

We wish you all the best.

Dr. MUVUNYI Alphonse

Director of Gahini Hospital

CC:

Matron of Maternity Department

Matron of surgery unity



GAHINI HOSPITAL

[gahinih@yahoo.fr](mailto:gahinih@yahoo.fr)

Date: 26/12/2016

NOTICE:

PLEASE REMEMBER TO SIGN CONSENT

BEFORE SURGERY.

CLINICAL DIRECTOR

A blue rectangular stamp is partially visible, with some illegible text. Overlaid on the stamp is a handwritten signature in blue ink, consisting of a large, stylized loop and a horizontal line extending to the right.

REPUBLIC OF RWANDA  
EASTERN PROVINCE



KAYONZA DISTRICT  
GAHINI HOSPITAL  
B.P:75RWAMAGANA.  
E- mai : gahinih@yahoo.fr

Maternity and surgery department

Dear Midwife, Nurses and medical Doctors

I'm with pleasure to invite you to attend a training session (presentation) on surgical consent form completeness held at Gahini Hospital in staff room meeting on Wednesday 28 December 2016 at 7:30 am

Best regard

Done at Gahini 20 Dec 2016

Approved by

Dr MUSABYIMANA Joseph

Hospital Director

Charles R. GAFFTA

Chief of Nursing

A handwritten signature in blue ink, appearing to read 'C. GAFFTA'.

A handwritten signature in blue ink, appearing to read 'Dr. Musabyimana Joseph'.



GAFITA R.Charles  
Tel 0788358434  
Email:gafitcha@gmail.com  
MHA Student at UR  
April 6<sup>th</sup> 2016



To Hospital Director

Gahini Hospital

**Re: Request for Permission to conduct a Quality Improvement Project**

Dear Sir

I'm with pleasure to request permission of conducting a Quality Improvement Project on completeness of surgical consent form in Gahini Hospital. I will need data from surgery and maternity department

Best regards

GAFITA R. Charles

Chef nursing of Gahini Hospital