RELEVANCE OF ROUTINE PREOPERATIVE TESTING IN ASA GRADE 1 AND 2 PATIENTS UNDERGOING MINOR TO MODERATE ELECTIVE SURGERIES AT KENYATTA NATIONAL HOSPITAL

# RELEVANCE OF ROUTINE PREOPERATIVE TESTING IN ASA GRADE 1 AND 2 PATIENTS UNDERGOING MINOR TO MODERATE ELECTIVE SURGERIES AT KENYATTA NATIONAL HOSPITAL

A research dissertation as part fulfilment of the requirements, for the award of Master of Medicine (General Surgery) at University Of Nairobi

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## DECLARATION

I hereby declare that this dissertation is my original work and has not yet been presented at any other university.

Signed: ..... Date: .....

Dr. Hassan Bharmal MBChB (UON) H58 / 76488 / 2009

## SUPERVISOR

This dissertation has been submitted for examination with my approval as a university supervisor.

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## ABBREVIATIONS

- 1. ASA American Society of Anaesthesiologists
- 2. UON University Of Nairobi
- 3. KNH Kenyatta National Hospital
- 4. KCE Belgian Health Care Knowledge Centre
- 5. NICE National Institute for Health and Clinical Excellence
- 6. CVD Cardiovascular Disease
- 7. GTN Glyceryl Trinitrate
- 8. COAD Chronic Obstructive Airway Disease
- 9. COPD Chronic Obstructive Pulmonary Disease
- 10. PCV Packed cell volume
- 11. MCV Mean corpuscular volume
- 12. MCH Mean corpuscular haemoglobin
- 13. MCHC Mean corpuscular haemoglobin concentration
- 14. WHO World Health Organization
- 15. SPSS Statistical Product and Service Solutions
- 16.SD Standard deviation
- 17. U/E/Cr Urea, electrolytes and creatinine

## ABSTRACT

## BACKGROUND

Several studies and guidelines have recommended avoiding routine preoperative testing in American Society of Anaesthesiologists (ASA) grade 1 and 2 patients undergoing minor to moderate elective surgeries. However, most of these studies were conducted in developed countries. At Kenyatta National Hospital, routine preoperative tests are done on all patients undergoing elective surgery at the main theatre regardless of grade of surgery or ASA grade. This study was done to find out if routine testing does actually reveal any additional information other than findings on history and physical examination in our setup. This data was used to determine if we can develop local guidelines similar to those in the developed countries.

## OBJECTIVE

To evaluate the usefulness of routine preoperative testing in ASA grade 1 and 2 patients undergoing minor to moderate elective surgeries at the main theatre at Kenyatta National Hospital.

## METHODOLOGY

A cross sectional study of 166 consenting ASA grade 1 and 2 patients undergoing minor to moderate surgeries at the Kenyatta National Hospital main theatre was conducted after approval from the University of Nairobi (UON) / Kenyatta National Hospital (KNH) Ethics and Research Committee. The study was conducted over three and a half months. Data was gathered using pre tested questionnaires on abnormal results, consequences of abnormal results on immediate perioperative management and number of times preoperative tests are conducted. Discrete variables were analyzed using percentages and frequencies while continuous variables were analyzed using measures of central tendency. Results were then compared to previous studies from developed countries using chi square, and p values obtained.

## RESULTS

The study reviewed preoperative tests of 166 patients. The mean age of the sample was 40 years (SD 13), of which 55.4 % were male. 58.4 % were classified as ASA grade 1 while 93.4 % underwent a grade 2 surgery. Anaemia was prevalent in 6.6 % (p value 0.363) of the patients, 6.6 % (p value 0.00001) had a leukocytosis, 3 % (p value 0.0092) had thrombocytopenia, 4.8 % (p value 0.056) had an abnormal urea, 6.6 % (p value 0.00066) had an abnormal creatinine and around 4 % (p value 0.0032) had an abnormal electrolyte level. 25 patients had a repeat test done, although all their tests were within normal range. Out of the 55 % patients who had an abnormality on their preoperative test only 4.2 % (p value 0.2615) had their surgery postponed while 3 % had additional investigations.

## CONCLUSION

The incidence of abnormal routine preoperative tests in our population is higher than that in developed countries, however, the rate at which it impacts perioperative management is not different. This study alludes to the possibility of developing local guidelines similar to those from developed countries.

## INTRODUCTION

Routine preoperative testing is defined by the American Society Of Anaesthesiologists (ASA) as those done without any precise clinical indication <sup>(1)</sup>; they include <sup>(2)</sup>

- 1. Full Blood Count
- 2. Blood Grouping
- 3. Renal function test
- 4. Coagulation profile
- 5. Blood glucose
- 6. Urinalysis
- 7. Pregnancy test
- 8. Arterial Blood Analysis
- 9. Chest X ray
- 10. Resting electrocardiography
- 11. Pulmonary function test

They are usually done prior to elective surgery to unravel discrete information about a patient's health not revealed from history and physical examination<sup>(2)</sup>. In addition they determine a patient's fitness for surgery. Other reasons surgeons, anaesthetists and physicians have given include<sup>(2)</sup>

- 1. To confirm or refute current diagnosis
- 2. To use the test results for the benefit of the patient and modify management
- 3. To better understand postoperative complications
- 4. To form as a baseline for use postoperatively
- 5. As a means of screening for other conditions

Many institutions and hospitals have a battery of tests they routinely perform before elective surgery in the hope of reducing the risk of adverse outcomes<sup>(3)</sup>. Is this scientific or out of fear of legal consequences? Approximately 30 years ago researchers began questioning this routine behaviour<sup>(3)</sup>. Another controversial issue is about timing of the tests, that is, are tests done 4 months ago acceptable before surgery or need more recent tests. Do the results in healthy adult patients change significantly over time? After several studies showing no benefit from these routine tests, several authoritative bodies devised guidelines on use of routine preoperative testing. Almost all guidelines conclude more or less that, routine preoperative testing for healthy patients undergoing minor to moderate elective surgeries are of no benefit.

At Kenyatta National Hospital routine preoperative tests performed are full blood count and

renal function test, as per the preoperative checklist (Appendix 3) to be filled before all surgeries conducted at the main theatre. Patients incur cost for the tests, use up their time during the testing and on follow up of the results. Kenya, being a developing nation with the majority of its population of low socio-economic status, reduction in unnecessary tests would be beneficial. In terms of timing, an arbitrary 2 weeks expiry period is set beyond which routine preoperative tests are repeated. Several patients have repeat preoperative tests done as a result of deferment of elective surgery beyond two weeks.

## LITERATURE REVIEW

Around 50 to 60 years ago routine preoperative tests were done if there existed a clinical indication following history and physical examination or if the type of surgery detected it<sup>(4)</sup>. After the introduction of automated machines which could perform larger volumes of tests faster; surgeons, anaesthetists and physicians requested for multiple tests since it was cheaper and theoretically it increased the chance of detecting subtle preoperative conditions which might influence surgical outcome<sup>(5),(6)</sup>. This practice became ingrained and was passed on, without any scientific basis and extra cost to patients<sup>(3),(4),(9),(10)</sup>. With the advent of increased likelihood of litigation, this practice became more common<sup>(13)</sup>. An interview of 23 physicians demonstrated variety of reasons for routine preoperative testing. Some interviewees felt routine tests were necessary, others were not certain, while most found them useless. 5 main reasons were revealed;

- i. Practice tradition
- ii. Feeling that anaesthetists will demand these tests
- iii. Medico-legal fears
- iv. Fear of postponement or cancellation of surgery
- v. Unawareness of current guidelines and evidence based practice

Most interviewees however, suggested that guidelines formed by collaboration between different cadres of medical staff would avoid unnecessary tests and reduce costs. Surgeons and gynaecologists were 60% more likely to order unnecessary tests than anaesthetists<sup>(14)</sup>. Anaesthetists were more likely to order unnecessary tests if they completed their training before 1980, emphasizing the ingrained practice that has been passed on<sup>(14)</sup>.

Around 30 years ago a study was done to challenge this dogma<sup>(15)</sup>. The study<sup>(15)</sup> reviewed charts of 2000 patients undergoing elective surgery. Results of this study showed abnormal test findings in 96 (22%), 10 were not clinically indicated and only 4 influenced perioperative management. Over the years several retrospective and prospective studies recommended that routine preoperative testing should only be done if there exists a clinical indication. Patients undergoing surgery are not homogeneous, multiple variations do exist, hence one needs to look into the diagnosis, type of surgery, estimated blood loss, co-morbidities, physiological and chronological age, type of anaesthesia and other patient factors. Few tests could be done on patients undergoing surgery where major blood loss is anticipated. The ASA classification and grade of surgery were better predictors of surgical or anaesthetic complications rather then chronological age<sup>(2)</sup>.

From previous studies prevalence of abnormal results in routine preoperative tests range from 5% - 60% in patients with ASA grade 1 to  $5^{(17),(18),(19),(20)}$ . Studies which have focussed on ASA grade 1 and 2 patients, report very low prevalence (0.8%) of abnormalities<sup>(21)</sup>. Studies and reviews done in

similar population have reported a prevalence of

1.	Anaemia	5% - 19% <sup>(19),(20),(23).</sup>
2.	Abnormal white cell count	< 1% <sup>(23)</sup>
3.	Abnormal platelet count	< 1% <sup>(23)</sup>
4.	Abnormal urea	0.2% - 2.5% <sup>(22),(23).</sup>
5.	Abnormal creatinine	0.4% - 2.5% <sup>(22),(23).</sup>
6.	Abnormal electrolytes	0% - 1.4% <sup>(22),(23).</sup>

Local studies on prevalence of abnormalities in routine preoperative tests of patients undergoing elective surgery is unavailable. The predictive value of preoperative tests reduces significantly with very low prevalence of abnormalities as reported by studies done on ASA grade 1 and 2 patients. Such abnormal laboratory values with very low predictive values may result in further unnecessary workup and delays in surgery. Hence the value of routine preoperative tests as a screening tool to detect abnormalities in ASA grade 1 and 2 patients after history and physical examination is questionable.

Perioperative management is thought to be influenced by results of routine preoperative test. Studies have shown that anaesthetists may not even review the test results and would go on with the surgery / anaesthesia<sup>(24)</sup>. A study done on patients undergoing elective herniorrhaphy, recorded 1% of abnormal results, out of which only 4 changed management<sup>(25)</sup>. Another study found a prevalence of preoperative anaemia of 18.6% out of the 116 sample population, however only 2 patients were transfused preoperatively<sup>(19)</sup>. So the small number of ASA grade 1 and 2 patients who have abnormal results have again a small chance that their results will actually influence decision making in the perioperative period.

Routine preoperative tests are expected to predict postoperative complications, especially if they are abnormal however this has been challenged. In a study which recorded 61% prevalence of abnormal results only 0.3% developed complications<sup>(17)</sup>. Another study looking at records of 9584 patients, 4 patients received postoperative transfusion and none had preoperative anaemia<sup>(21)</sup>. Similarly in 116 patients undergoing surgery 14 patients developed postoperative complications however none could be predicted from preoperative tests<sup>(19)</sup>.

Preoperative tests conducted on patients that had an indication after history and physical examination had a higher chance of influencing management rather than routine preoperative tests. A meagre 0.9% of the test results changed management amongst patients undergoing routine tests while 3.3% influenced the nature of perioperative management if the tests were clinically indicated<sup>(26)</sup>.

Repeating routine laboratory tests within 2 weeks for otherwise healthy patients is too soon for any changes to occur. Test results done up to 4 months earlier could be used as demonstrated by a study done on 7549 laboratory results of 1109 patients, 47% of the test results from this study were the same as those obtained within 1 year<sup>(27)</sup>. Out of 3096 normal test results, only 13 (0.4%) repeated values were abnormal, and most could have been predicted on the basis of patient history and physical findings<sup>(27)</sup>.

Although most guidelines recommend use of routine preoperative testing in elderly patients, studies have not conclusively determined their effectiveness on basis of age alone; a study evaluating the prevalence and predictive value of abnormal tests in elderly patients undergoing elective surgery found low rates<sup>(28)</sup>. It emphasizes that chronological age is not a good predictor of perioperative complications. As alluded earlier, ASA classification and grade of surgery are better predictors.

After most studies revealing almost similar results, the National Institute for health and Clinical Excellence (NICE) issued guidelines on use of preoperative testing<sup>(2)</sup> whose conclusions were similar to the studies above. A review<sup>(29)</sup> suggested that the guidelines are based more on professional opinion and risk assessment is based on invalidated methods. The Canadian guidelines are also similar to the NICE guidelines, however they indicate routine testing for underprivileged populations who would seek medical help only when they are severely unwell.

Complication rates after implementation of the Belgian Health Care Knowledge Centre (KCE) guidelines on routine preoperative testing, were not observed to show any rise in perioperative complications<sup>(30)</sup>. Review of data before and after implementation of preoperative testing guidelines, found no increment in complications<sup>(31)</sup>. Studies have found that 97% of patients who did not have routine preoperative testing safely underwent anaesthesia and surgery<sup>(32)</sup>; this finding is in keeping with the current guidelines.

Preoperative testing costs the United States Of America approximately \$18 billion dollars annually. Routine preoperative testing results in false positive results which necessitate additional testing, leading to more financial and psychological stress and postponement of surgery. A study sought to find out the economic impact of routine preoperative testing in 1363 elective surgery patients. Out of the 5879 tests conducted, 81.7% were against current guidelines; 226 tests were duplicated due to multiple preoperative visits or review by different cadres of doctors. Its analysis postulated possible savings per 1000 patients as 26 287 Euros if guidelines were to be followed and 1076 Euros if duplicate tests were to be avoided<sup>(33)</sup>. Other studies reported 90% savings in laboratory costs after implementation of current guidelines in Canada<sup>(34)</sup>. Johnson RK et al reported a saving of 50000 pound per year if guidelines were to be implemented<sup>(35)</sup>. Vogt AW et al<sup>(36)</sup> in his evaluation of 312 patients found 72.5% of tests unnecessary and would lead to annual savings of approximately \$80000.

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## AMERICAN SOCIETY OF ANESTHESIOLOGISTS PHYSICAL STATUS CLASSIFICATION

ASA grading is a scale used to grade fitness for surgery<sup>(1)</sup>. ASA grade 1 and 2 patients are considered low risk patients for surgery. Most guidelines recommend either avoiding or probably consider doing routine preoperative tests<sup>(2)</sup>. ASA grade 3 and beyond limits a patient's activity and most guidelines recommend routine preoperative testing due to the high risk and presence of severe systemic disease. Hence this study is limited to ASA grade 1 and 2 patients where controversy lies on the decision to perform routine preoperative tests or not. At KNH all grades of patients are subjected to the same routine preoperative tests.

ASA Physical Status 1 -	A normal healthy patient
ASA Physical Status 2 -	A patient with mild systemic disease
ASA Physical Status 3 -	A patient with severe systemic disease
ASA Physical Status 4 -	A patient with severe systemic disease that is a constant threat to life
ASA Physical Status 5 -	A moribund patient who is not expected to survive without the operation
ASA Physical Status 6 -	A declared brain-dead patient whose organs are being removed for
	donor purposes

Classifying patients with mild systemic disease into ASA grade 2 or 3 is sometimes difficult. The following table was used in doing so.

Table 1:

Characterisation of 'mild' and 'severe' co-morbidity, corresponding to ASA

grades 2 and 3,	for cardiovascular,	respiratory and	d renal co-morbidities <sup>(2</sup>
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	ASA GRADE 2	ASA GRADE 3	
ASA definition	'A patient with mild systemic disease'	'A patient with severe systemic disease'	
Cardiovascular (CVD):			
Current angina	occasional use of glyceryl trinitrate (GTN) spray (two to three times per month). Does not include patients with unstable angina who would be ASA grade 3.	regular use of GTN spray (two to three times per week) or unstable angina	
Exercise tolerance	not limiting activity	limiting activity	
Hypertension	well controlled using a single antihypertensive medication	not well controlled, requiring multiple antihypertensive medications	
Diabetes	well controlled, no obvious diabetic complications	not well controlled, diabetic complications, eg claudication, impaired renal function	
Previous coronary revascularisation	not directly relevant – depends on current signs and symptoms		
Respiratory:			
Chronic obstructive airway/pulmonary disease COAD/COPD	productive cough, wheeze well controlled by inhalers, occasional episodes of acute chest infection	breathlessness on minimal exertion, eg stair climbing, carrying shopping, distressingly wheezy much of the time, several episodes per year of acute chest infection	
Asthma	well controlled by medications/inhalers, not limiting lifestyle	poorly controlled, limiting lifestyle – on high dose of inhaler/oral steroids, frequent hospital admission on account of asthma exacerbation	
Renal disease:	elevated creatinine (creatinine > 100 μmol/L and < 200 μmol/L), some dietary restrictions	documented poor renal function (creatinine > 200 µmol/L), regular dialysis programme (peritoneal or haemodialysis)	

## **GRADING OF SURGERY**<sup>(2)</sup>

Routine preoperative testing may be avoided in grade 1 and 2 elective surgeries<sup>(2)</sup>. However at KNH all patients are routinely tested regardless of grade of surgery. The following classification was used as a guide to classify the surgeries into grades.

Grade 1 (minor):	Excision of lesion of skin, lipomas, breast lumps, diagnostic cystoscopy
Grade 2 (intermediate):	Primary repair of hernias; haemorrhoidopexy / haemorrhoidectomy, anal
	internal sphincterotomy, anal fistulectomy, excision of varicose vein(s) of
	leg; knee arthroscopy
Grade 3 (major):	Total abdominal hysterectomy; endoscopic resection of prostate; lumbar
	discectomy; thyroidectomy
Grade 4 (major+):	Total joint replacement; lung operations; colonic resection; radical neck
	dissection; neurosurgery; cardiac surgery

## NORMAL REFERENCE RANGE OF LABORATORY VALUES TO BE USED

The following table was used during the study as the normal reference range for the routine

preoperative tests conducted.

Table 2: Normal reference ranges

TEST	NORMAL RANGE
Haemoglobin	11 – 18 g/dl
Red Blood Cells	4 - 6×10 <sup>12</sup> /l
White Blood Cells	4 - 10×10 <sup>9</sup> /l
Neutrophils	2.0–7.0×10 <sup>9</sup> /l (40 – 75%)
Lymphocytes	1.0-3.0×10 <sup>9</sup> /l (20 - 44%)
Monocytes	0.2–1.0×10 <sup>9</sup> /l (0 – 6%)
Eosinophils	0.02–0.5×10 <sup>9</sup> /l (0 – 6%)
Basophils	0.02–0.1×10 <sup>9</sup> /l (0 – 2%)
Platelets	150 – 450×10 <sup>9</sup> /l
PCV (packed cell volume)	36 – 54 %
MCV (mean corpuscular volume)	77 – 99 FL
MCH (mean corpuscular hemoglobin)	25 – 36 Pg
MCHC (mean corpuscular hemoglobin concentration)	32 – 40 g/dl
Urea	2.5 - 6.7 mmol/L
Creatinine	70 – 150 micromol/L
Sodium	135 – 145 mmol/L
Chloride	98 – 106 meq/L
Potassium	3.5 – 5.0 mmol/L

## **STUDY JUSTIFICATION**

Several studies have been done over the past 30 years showing limited benefit of performing routine preoperative testing in otherwise healthy patients undergoing non major surgery. Slowly hospitals are adopting selective testing which reduces cost, time and burden on laboratories. No studies have been conducted locally or regionally to justify our need to adopt these guidelines. Varied prevalence of abnormalities in physiological parameters and chronic illnesses in our population and different health seeking behaviours make it prudent to get local figures before forming local guidelines or implementing foreign guidelines. World Health Organization (WHO) in their 1993 to 2005 report on anaemia<sup>(36)</sup> confirms varied prevalence of anaemia in different continents and countries, with one of the highest prevalence being in Africa. This study was conducted to find out if we can adopt these preoperative testing guidelines or continue with our trend of practice. Answers to questions like, how many routine preoperative results turn out to be abnormal? Do they influence change in management plan? Need to be answered. We can greatly reduce the economic burden on our patients, and move a step closer to evidence based surgical practice.

Preoperative testing guidelines are obviously difficult to implement, as it will definitely be met with some resistance due to long term practice of routine testing. However, providing local data strengthens faith in such guidelines.

## **OBJECTIVES**

## **BROAD OBJECTIVE**

To evaluate the usefulness of routine preoperative testing in ASA grade 1 and 2 patients planned to undergo minor to moderate grade elective surgeries at Kenyatta National Hospital.

## SPECIFIC OBJECTIVES

- 1. To determine prevalence of abnormal results
- 2. To determine if the abnormal tests influenced anaesthetic plan or immediate perioperative management.

## SECONDARY OBJECTIVES

- 1. To determine the number of times routine tests are conducted preoperative.
- 2. To determine the difference in prevalence of abnormal results before and within 2 weeks preoperative.

## METHODOLOGY

## STUDY AREA

The study was conducted at the Kenyatta National Hospital (a teaching and tertiary referral hospital).

## **STUDY POPULATION**

All adult ASA grade 1 and 2 patients preoperatively investigated to undergo elective minor to moderate surgeries at the main theatre of Kenyatta National Hospital. Examples of surgeries which were selected for the study include:

- 1. Herniorrhaphy
- 2. Haemorrhoidopexy / haemoirrhoidectomy
- 3. Anal Internal Sphincterotomy
- 4. Anal Fistulectomy
- 5. Excision of lipomas
- 6. Excision of breast lumps
- 7. Excision of skin or subcutaneous lesions without expected major blood loss.
- 8. Diagnostic cystoscopy

## **STUDY DESIGN**

Cross sectional study.

## STUDY DURATION

The study commenced on 10<sup>th</sup> July 2014 after obtaining ethical approval. Although estimated to be complete in three months, the study took three and a half months since the required sample size was not obtained.

## SAMPLE SIZE

The following formula was used to calculate the sample size for each of the variables being studied, that is, abnormalities in

- Haemoglobin
- White cell count
- Platelet count
- Urea
- Creatinine
- Electrolytes

$$\mathbf{n} = \frac{Z^2 \alpha \times P(1-P)}{e^2}$$

 $Z^2a = 1.645$  area under the standard normal curve representing 90% confidence interval.

e = 5% margin of error

P = the prevalence of each of the variables was used to calculate the sample size required for each. The prevalence used for each variable (reference point being studies quoted in the literature review) and its corresponding sample size calculated are as follows.

		PREVALENCE	SAMPLE SIZE
•	Prevalence of abnormal haemoglobin	19%	166
•	Prevalence of abnormal white cell count	1%	11
•	Prevalence of abnormal platelet count	1%	11
•	Prevalence of abnormal Urea	2.5%	26
•	Prevalence of abnormal Creatinine	2.5%	26
•	Prevalence of abnormal Electrolytes	1.4%	15

Hence the highest number of sample size, that is, **166** was used for this study.

## SAMPLING PROCEDURE

Consecutive non random progressive recruitment of patients who met the inclusion criteria was done until sample size was obtained. That is, everyday from the start of the study, every patient scheduled for a minor to moderate elective surgery at the main theatre and fell under ASA grade 1 and 2 was cumulatively recruited into the study until the sample size was obtained.

## **INCLUSION CRITERIA**

- 1. Patients preoperatively investigated and planned to undergo minor to moderate elective surgeries (as mentioned above).
- 2. Patients above 12 years of age.
- 3. Patients classified as ASA grade 1 or 2.

## **EXCLUSION CRITERIA**

1. Patients who do not provide consent to participate in the study

## MATERIALS AND METHODS

The study setting was the wards of Kenyatta National Hospital, where patients who met the inclusion criteria were recruited and consent obtained.

The study commenced after ethical approval from the Ethics and Research Committee of Kenyatta National Hospital.

Data was collected using pre tested questionnaires.

In the wards all patients who had been planned to undergo any of the stated surgeries above were interviewed and consent obtained. The researcher went through the patient file to record

- 1. Demographic data,
- 2. The type of investigations ordered,
- 3. Test results.

The patient was asked questions regarding number of times these tests were performed before finally being scheduled for surgery. If investigations had been done more than once, than records of previous results were sought. Those with abnormal test results were followed up to record consequences of abnormality, such as;

- 1. Postponement of surgery
- 2. Additional investigations
- 3. Preoperative transfusion
- 4. Change in management plan
- 5. Change in anaesthetic plan (one of the members from anaesthetic team was interviewed)

## DATA COLLECTION AND ANALYSIS

Data was collected using pretested questionnaires. Consecutive, non random progressive sampling of eligible patients were done in the wards. Data was entered into Microsoft Database, errors were identified and missing data filled and followed up. Statistical Product and Service Solutions (SPSS) version 16 (a Windows based program that can be used to perform data entry and analysis and to create tables and graphs) was used to analyze data. Discrete variables were analyzed using percentages and frequencies, while continuous variables were analyzed using measures of central tendency.

Data obtained after analyzing the questionnaires revealed

- Number and percentage of abnormal results after routine preoperative testing of all ASA grade
   1 and 2 patients undergoing minor to moderate elective surgeries at KNH.
- 2. Number and percentage of abnormal results that actually changed immediate perioperative management of patients, that is, change in diagnosis, change in management, additional investigations, cancellation or postponement of surgery, change in anaesthetic plan.
- 3. Comparison of percentage of abnormal results done within two weeks and those done two weeks before surgery to determine if results in the subset of population under study do change within this period.

## STUDY LIMITATION

- 1. Results were from different laboratories, which had different reference ranges and quality control standards. Hence only laboratories which were certified by the International Organization of Standardization were used for the purpose of the study.
- 2. Tracing of tests done previously, and recall by patients.
- 3. Reagents being out of stock at the KNH laboratory

## **ETHICAL CONSIDERATION**

Only upon approval by the Department of Surgery of The University of Nairobi and Ethical and Research committee of Kenyatta National Hospital, did the study begin.

Informed consent was sought from each and every patient included in the study, by the principal researcher. Confidentiality was maintained at all times, with detailed information revealed to researcher and those involved in the study. Raw data was scanned by an Epson scanner and original hard copies destroyed by shredding and disposal. The electronic versions of the raw data has been stored in an external hard drive kept under lock and key and protected by a password, accessible to the researcher only.

## RESULTS

### Age And Sex Distribution

The study managed to reach its sample size of 166 patients. The mean age of the sample was 40 years (SD - standard deviation 13), with the youngest being 13 years, while the eldest being 71 years with a median of 40 years.

The following table shows the sex distribution within the sample.

Table 3: Sex distribution

Sex	Frequency	Percentage
Male	92	55.4 %
Female	74	44.6 %





Figure 2:



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## Grade Of Surgery And ASA Grade

Over 93.4 % of the patients underwent a grade 2 surgery, the most common being herniorraphy at 26 % followed by excisions at 14 %. Around 60 % of the patients were classified as ASA grade 1.

Table 4: Distribution of grade of surgery and ASA grade.

	Grade of Surgery	ASA Grade
Grade 1	11 (6.6 %)	97 (58.4 %)
Grade 2	155 (93.4 %)	69 (41.6 %)

Figure 3:



## Prevalence Of Anaemia and Red Blood Cell Abnormality

11 (6.6 %) patients had preoperative anaemia. Its association with other parameters of red blood cells are represented on the graph below.

## Figure 4:



## Distribution of Hemoglobin and Red Blood Cell Levels

Table 5: Prevalence	of red	blood	cell	abnormality
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	Normal Frequency (%)	Abnormal Frequency (%)	P value
Haemoglobin	155 (93.4 %)	11 (6.6 %)	0.363
Red Blood Cells	162 (97.6 %)	4 (2.4 %)	0.126
PCV	106 (63.86 %)	60 (36.14 %)	0.00001
MCV	159 (95.8 %)	7 (4.2 %)	0.644
МСН	160 (96.4 %)	6 (3.6 %)	0.413
МСНС	160 (96.4 %)	6 (3.6 %)	0.413

## Prevalence Of White Blood Cell Abnormality

The table below elaborates the prevalence of abnormalities in total and differential counts of white blood cells.

	Normal Frequency (%)	Abnormal Frequency (%)	P value
Total White Cell Count	155 (93.4 %)	11 (6.6 %)	0.00001
Neutrophils %	161 (97 %)	5 (3 %)	0.0092
Lymphocytes %	160 (96.4 %)	6 (3.6 %)	0.00071
Monocytes %	156 (94 %)	10 (6 %)	0.00001
Eosinophils %	159 (95.8 %)	7 (4.2 %)	0.00001
Basophils %	163 (98.2 %)	3 (1.8 %)	0.30

Table 6: Prevalence of white blood cell abnormality

Figure 5:



Distribution of White Cell Count Levels

Percentage

## Prevalence Of Urea, Electrolyte And Creatinine (U/E/Cr) Abnormality

All the 166 patients had preoperative urea, creatinine and electrolytes requested preoperative; however only 138 patients had serum electrolyte actually done due to reagents being out of stock at the KNH laboratory.

	Normal Frequency (%)	Abnormal Frequency (%)	P value
Urea	158 (95.2 %)	8 (4.8 %)	0.056
Creatinine	155 (93.4 %)	11 (6.6 %)	0.00066
Sodium	132 (95.7 %)	6 (4.3 %)	0.0032
Chloride	131 (94.9 %)	7 (5.1 %)	0.000241
Potassium	133 (96.4 %)	5 (3.6 %)	0.026

Table 7: Prevalence of Urea, Creatinine and Electrolyte abnormality

Figure 6:



Distribution of U/E/Cr Levels

Preoperative Test

Only 5 patients ( 3 % ) had an abnormal platelet count.

 Table 8: Prevalence of Platelet Abnormality

	Normal Frequency (%)	Abnormal Frequency (%)	P Value
Platelets	161 (97 %)	5 (3 %)	0.0092

## **Double Testing**

25 patients had their preoperative tests repeated after their elective surgery was postponed due to non medical reasons. The tests had to be repeated because they had passed the 2 week expiry period set at KNH. All their tests were within the normal range.

## **Consequence of Abnormal Preoperative Test Results**

Table 9: Consequence of abnormal preoperative test results

	Abnormal Frequency	Surgery Postponed Frequency	Additional Investigations
Haemoglobin	11	7	2
Red Blood Cell	4	3	
PCV	60	7	2
MCV	7	5	
МСН	6	5	
МСНС	6	5	
White Blood Cell	11		
Neutrophils	5		
Lymphocytes	6		
Monocytes	10		
Eosinophils	7		
Basophils	3		
Platelet	5		
Urea	8	2	2
Creatinine	11	2	2
Sodium	6	1	1
Chloride	7	1	1
Potassium	5		3

Out of the total 91 (55 %) patients who had an abnormality on their preoperative test, only 7 (4.2 %) had their surgeries postponed and an additional 5 (3 %) had additional investigations done.

#### DISCUSSION

This study reviewed 191 preoperative tests, 13 % had repeat routine preoperative test as they had missed elective surgery due to a none medical reason. Although all patients had a full blood count and U/E/Cr request, only 138 had electrolyte levels done preoperatively due to reagents running out of stock at the KNH laboratory. A full blood count has 13 different components tested within it, while U/E/Cr has 5; hence a total of 3279 different components were reviewed.

The prevalence of anaemia within this study was 6.6 %; comparable to studies done in developed countries (p value 0.363) which reported prevalence of 5 % <sup>(23)</sup>. Out of the 11 patients who had anaemia, 8 had microcytic hypochromic anaemia, of which 7 were female. 3 patients had incidental chronic kidney disease causing anaemia, all of whom had controlled hypertension (ASA grade 2). 7 patients had their surgeries postponed due to anaemia, the 3 patients with incidental chronic kidney disease had additional investigations, and a physician review requested. Anaemia had the highest influence on the decision to postpone surgery; 64 % of patients with anaemia having their surgery postponed.

The only component of red blood cell indices that was statistically different from prior studies <sup>(23)</sup> was PCV (p value 0.00001). It was abnormal in 36 % of the patients; however, its influence on perioperative decision making was minimal. Only 12 % of the patients with an abnormal PCV had their surgery postponed, all of whom had an associated abnormal haemoglobin level, which was the major influence. The high PCV abnormality could be explained due to the inclusion of trauma patients who had their tests done on the day of the injury, however, operated electively within two weeks.

The prevalence of white blood cell abnormality was significantly different from studies done elsewhere  $^{(23)}$  (p value 0.00001). 6.6 % had a leukocytosis, while the differential count was elevated in about 2 – 6 % of the patients. Majority of the patients who had a leukocytosis where either trauma patients or had a wound before surgery. However, none of the abnormal white cell counts had any impact on the surgeon or anaesthetist. All the patients underwent their scheduled elective surgery and it did not influence the anaesthetic plan.

Despite only 5 patients (3 %) having an abnormal platelet count, it was significantly different from previous studies <sup>(23)</sup> which have reported percentage abnormal platelets of less than 1 % (p value 0.0092). All had either borderline low or borderline high platelet counts and did not deter the theatre team to continue with the surgery.

All the components of the preoperative test – U/E/Cr, had p value less than 0.1. Percentage abnormality ranged from 6 – 4 %, compared to Ishaq's study <sup>(22)</sup> which reported ranges between 1 – 2.5 %. However, on analyzing this group of patients it seems only 3 patients were identified

incidentally as having chronic kidney disease, out of which, 2 had their surgery postponed and additional investigations requested thereafter. The rest had isolated borderline low or high levels which were probably regarded as laboratory error and surgery went on as planned.

55 % of the patients had an abnormality in their preoperative test, however, only 4.2 % (p value 0.2615) had their surgery postponed due to the abnormality and 3 % had additional investigations to further understand or confirm the abnormality. The results are comparable to a study done by Mantha S <sup>(26)</sup>, who reported 3.3 % of preoperative tests changing management. Overall, despite several components of routine preoperative tests recording significantly different prevalence of abnormal results from studies done in developed countries, their impact on influencing any change in perioperative decision making was statistically not significant.

Only 25 patients had their preoperative test done more than once before they eventually underwent the surgery. All the 25 patients had their elective surgery cancelled more than 2 weeks earlier due to non medical reasons (for example, time constraints on the day of surgery or delay in starting the elective list). All the tests remained within normal range. Due to only a small number of patients being double tested, no appropriate conclusion can be made on the changes which occur on repeating the tests after 2 weeks.

#### CONCLUSION

The prevalence of abnormality in routine preoperative tests conducted on ASA grade 1 and 2 patients undergoing grade 1 and 2 elective surgeries is higher in our population compared to studies done in developed countries. However its impact on perioperative management is not significantly different from other studies.

From this study development of local guidelines on routine preoperative testing could be similar to guidelines in developed countries, however, further studies may be required to ascertain this.

#### RECOMMENDATIONS

Further interventional studies on the use of routine preoperative tests need to be conducted, for example, comparing the postoperative complication rates in patients who underwent routine preoperative testing vis a vis those who did not have any preoperative testing.

## STUDY TIME FRAME

## Figure 7: Study time frame

	APR 2014	MAY 2014	JUN 2014	JUL 2014	AUG 2014	SEP 2014	OCT 2014	NOV 2014
Ethical approval								
Data collection & analysis								
Dissertation Writing								

## BUDGET

Table 10: Budget

ITEM	AMOUNT (Kshs)
Transport	5000
Communication	5000
Food	5000
Statistician	20000
Stationery	10000
Contingencies	8000
Research Fee	2000
Printing / Binding	20000
TOTAL	75000

Funding was provided by the researcher.

## REFERENCES

- 1. American Society of Anaesthesiologists Task Force on Preanesthesia Evaluation. Anaesthesiology. 2012 Mar;116(3):522-38.
- 2. Preoperative tests; The use of routine preoperative tests for elective surgery, National Institute for Clinical Evidence. <u>http://www.nice.org.uk/nicemedia/pdf/preop\_fullguideline.pdf</u>
- 3. Kumar A, Srivastava U. Role of routine laboratory investigations in preoperative evaluation. J Anaesthesiol Clin Pharmacol. 2011 Apr;27(2):174-9. PMID: 21772675.
- Roizen MF. More preoperative assessment by physicians and less by laboratory tests. N Eng J Med 2000;342:204-5
- 5. MacPherson RD, Reeve SA, Stewart TV, Cunningham AE, Craven ML, Fox G, *et al.* Effective strategy to guide pathology test ordering in surgical patient. ANZ J Surg 2005;75:138-43.
- Roizen MF, Lichtor JL, Preoperative assessment and premedication for adults. In: Healy TEJ, Knight PR, editors. Wylie and Churchill Davidson's A practice of Anesthesia, 7 th ed, 2003. p. 415-25.
- 7. Allison JG, Bromley HR. Unnecessary preoperative investigations evaluation and cost analysis. Am Surg 1996;62:686-9
- 8. Fischer S. Cost effective preoperative evaluation and testing. Chest 1999;115;965-1005.
- 9. Badar AM. Pre-operative testing. Curr Anesth Reports 2001;1:67-9.
- Schein OD, Katz J, Bass EB, Tielsch JM, Lubomski LH, Feldman MA, *et al.* The value of routine preoperative medical testing before cataract surgery. Study of medical testing for cataract surgery. N Engl J Med 2000;342:168-75
- 11. Patey AM, Islam R, Francis JJ, Bryson GL, Grimshaw JM, et al. Anesthiologists' and surgeons' perception about routine preoperative testing in low risk patients: application of Theoretical Domains Framework (TDF) to identify factors that influence physicians' decisions to order preoperative tests. Implement Sci 2012;52.
- Yuan H, Chung F, Wong D, Edward R. Current preoperative testing practices in ambulatory surgery are widely disparate: a survey of CAS members. Can J Anaesth 2005 Aug-Sep;52(7):675-9.
- 13. Brown SR, Brown J. Why do physicians order unnecessary preoperative tests? A qualitative study. Fam Med 2011 May; 43(5):338-43.
- 14. Katz RI, Dexter F, Resenfeld K, Wolfe L, Redmond V, Agarwal D, et al. Survey study of anesthiologists' and surgeons' ordering of unnecessary preoperative laboratory tests. Anesth Analg 2011 Jan; 112(1):207-12.

- 15. Kumar A, Srivastava U. Role of routine laboratory investigations in preoperative evaluation. J Anaesthesiol Clin Pharmacol 2011;27:174-9.
- van Gelder FE, de Graaff JC, van Wolfswinkel, van Klei WA. Preoperative testing in non cardiac surgery patients: a survey amongst European anesthesiologists. Eur J Anaesthesiol 2012 Oct; 29(10):465-70.
- Benaroch-Gampel J, Sheffield KM, Duncan CB, Brown KM, Han Y, Townsend CM, et al. Preoperative laboratory testing in patients undergoing elective, low risk ambulatory surgery. Ann Surg 2012 Sep; 256(3):518-28.
- 18. Turnbull JM, Buck C. The value of preoperative screening investigations in otherwise healthy individuals. Arch Intern Med. Jun 1987;147(6):1101-5.
- 19. Adenekan AT, Faponie AF, Oginni OF. Preoperative hematological investigations in pediatric orofacial cleft repair: any relevance to management outcome? Afr J Paediatr Surg 2012 Jan-Apr; 9(1):52-6.
- 20. Pal KM, Khan IA, Safdar B. Preoperative work up: are the requirements different in a developing country? J Pak Med Assoc 1998 Nov; 48(11):339-41.
- 21. Olson RP, Stone A, Lubarsky D. The prevalence and significance of low preoperative haemoglobin in ASA 1 or 2 outpatient surgery candidates. Anesth Analg 2005 Nov; 101(5):1337-40.
- 22. Ishaq M, Khan BH, Masud S, Kamal SR, Malik MA. Role of Routine Preoperative Biochemistry in Anaesthesia. Annals Jul Sept 2011; 17(3):229-233.
- Munro J, Booth A, Nicholl J. Routine preoperative testing: a systematic review of the evidence. School of Health and Related Research, University of Sheffield. Health Technology Assessment. (Impact Factor: 4.03). 02/1997; 1(12):i-iv; 1-62.
- 24. Narr BJ, Hansen TR, Warner MA. Preoperative laboratory screening in healthy Mayo patients: cost-effective elimination of tests and unchanged outcomes. *Mayo Clin Proc*. Feb 1991;66(2):155-9.
- 25. Adams JG, Weigelt JA, Poulos E. Usefulness of preoperative laboratory assessment of patients undergoing herniorrhaphy. Arch Surg 1992 Jul; 127(7):801-4.
- 26. Mantha S, Roizen MF, Madduri J, Rajender Y, Shanti NK, Gayatri K. Usefulness of routine preoperative testing: a prospective single-observer study. J Clin Anesth 2005 Feb; 17(1):51-7.
- 27. Macpherson DS, Snow R, Lofgren RP. Preoperative screening: value of previous tests. *Ann Intern Med.* Dec 15 1990;113(12):969-73.
- 28. Dzankic S, Pastor D, Gonzalez C, Leung JM. The Prevalence and predictive value of abnormal preoperative laboratory tests in elderly surgical patients. Anesth Analg 2001 Aug; 93(2):301-8.

- 29. Reynolds TM, National Institute for Health and Clinical Excellence, Clinical Scince Reviews Commitee of the Association for Clinical Biochemistry. National Institute for Health and Clinical Excellence guidelines on preoperative tests: the use of routine preoperative test for elective surgery. Ann Clin Biochem 2006 Jan; 43(Pt 1):13-6.
- 30. Georges P, Kremer Y, Ledent M, Lechat JP, De Kock M. Does the KCE restrictive policy for preoperative testing lead to increased postoperative complications rate? Acta Anaesthiol Belg 2010; 61(1):5-11.
- 31. Mancuso CA. Impact of new guidelines on physicians' ordering of preoperative tests. J Gen Inetern Med 1999 Mar; 14(3):166-72.
- Narr BJ, Warner ME, Schroeder DR, Warner MA. Outcomes of patients with no laboratory assessment before anaesthesia and a surgical procedure. Mayo Clinic Proc 1997 Jun; 72(6):505-9.
- 33. Flamm M, Fritsch G, SeerJ, Panisch S, Sonnichsen AC. Non-adherence to guidelines for preoperative testing in a secondary care hospital in Austria: the economic impact of unnecessary and double testing. Eur J Anaesthesiol 2011 Dec; 28(12): 867-73.
- 34. Imasogie N, Wong DT, Luk K, Chung F. Elimination of routine testing in patients undergoing cataract surgery allows substantial savings in laboratory costs. A brief report. Can J Anaesth 2003 Mar; 50(3):246-8.
- 35. Johnson RK, Mortimer AJ. Routine preoperative blood testing: is it necessary? Anaesthesia 2002 Sep; 57(9):914-7.
- 36. Vogt AW, Henson LC. Unindicated preoperative testing: ASA physical status and financial implications. J Clin Anesth 1997 Sep; 9(6):437-41.
- 37. http://whqlibdoc.who.int/publications/2008/9789241596657\_eng.pdf

## **CONSENT FORM**

## USE OF ROUTINE PREOPERATIVE TESTING AT KENYATTA NATIONAL HOSPITAL

### ENGLISH VERSION

This informed consent is for patients planned to undergo minor to moderate elective surgeries at the main theatre of Kenyatta National Hospital. The title of the study is 'RELEVANCE OF ROUTINE PREOPERATIVE TESTING IN ASA GRADE 1 AND 2 PATIENTS UNDERGOING MINOR TO MODERATE ELECTIVE SURGERIES AT KENYATTA NATIONAL HOSPITAL.'

#### PRINCIPAL RESEARCHER: Dr HASSAN BHARMAL

### INSTITUTION: SCHOOL OF MEDICINE, DEPARTMENT OF SURGERY, UNIVERSITY OF NAIROBI

This informed consent has three parts

- 1. Information about the research
- 2. Certificate of consent
- 3. Statement by the researcher

You will be given a copy of the full informed consent.

#### PART 1

#### INTRODUCTION

I am Dr. Hassan Bharmal, a postgraduate student at the University of Nairobi's School Of Medicine. I am undertaking a study to evaluate the use of routine preoperative testing at Kenyatta National Hospital. The study will run for an estimated period of three months from when ethical approval is obtained (exact dates will be filled in once confirmed).

#### STUDY PURPOSE

Several guidelines and research has proved that routine preoperative testing for patients undergoing minor to moderate surgeries is not necessary. This study seeks to determine if we can adopt those guidelines or not, by evaluating the use of routine preoperative testing at Kenyatta National Hospital.

I will give you information regarding this study and request your participation in this study. You may ask any questions if you do not understand any terminology or need clarification at any point during this conversation.

#### **VOLUNTARY PARTICIPATION / RIGHT TO REFUSE**

You must be willing to participate in this study, hence you have a right to refuse to participate or withdraw from this study at any point. If you choose not to participate in this study, it will in no way interfere with the treatment you were to receive at Kenyatta National Hospital.

#### CONFIDENTIALITY

All the information in this study will treated with the confidentiality it deserves. Detailed information will only be available to the researcher and the study team. Your identity will be concealed during the study; you will be identified by a number assigned to you.

#### SHARING THE RESULTS

Information gathered from this study will be shared with other doctors and policy makers through publications and conferences. However, confidential information will not be revealed.

### **RISKS AND DISCOMFORT**

You will not be exposed to any harm during this study, as your participation will be through interviews with the research team and allowing us to evaluate your test results. This study has been approved by the Department of Surgery of The University of Nairobi and the Ethics and Research Committee of Kenyatta National Hospital, whose duty is to protect the participants from any harm.

#### **COST AND COMPENSATION**

You will not incur any extra cost during the course of this study nor will you receive any compensation.

### CONTACTS

In case you have any queries later on, please feel free to contact any of the following team members.

- Principal Researcher
   Dr. Hassan Bharmal
   Department of Surgery, University of Nairobi
   P.O Box 19676 KNH, Nairobi 00202
   Tel: 0722891326
- University of Nairobi supervisor

   Dr. Wambugu Mwangi
   Department of Surgery, University of Nairobi
   P.O Box 19676 KNH, Nairobi 00202
   Tel: 0722 530687

   For ethical concerns contact:

   Secretary KNH/UON ERC
   P.O Box 20723 KNH, Nairobi 00202
   Tel +254-020-2726300-9 Ext 44355
   Email: <u>KNHplan@Ken.Healthnet.org</u>

## PART 2

## CERTIFICATE OF CONSENT

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant\_\_\_\_\_

Date \_\_\_\_\_

If Non -literate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness\_\_\_\_\_

Thumb print of participant

Signature of witness \_\_\_\_\_

Date \_\_\_\_\_

## PART 3

## STATEMENT BY THE RESEARCHER

I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the participant understands that the following will be done:

- 1. Refusal to participate or withdrawal from the study will not in any way compromise the care of treatment.
- 2. All information given will be treated with confidentiality.
- 3. The results of this study might be published to facilitate management and use of targeted therapies in gastric cancer patients.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Name of researcher taking consent.....

Signature of researcher taking consent.....

Date..... Day/Month/Year

### FOMU YA MAKUBALIANO YA KUJIUNGA NA UTAFITI

## RELEVANCE OF ROUTINE PREOPERATIVE TESTING IN ASA GRADE 1 AND 2 PATIENTS UNDERGOING MINOR TO MODERATE ELECTIVE SURGERIES AT KENYATTA NATIONAL HOSPITAL

MTAFITI: DKT HASSAN BHARMAL

KITUO: SHULE YA AFYA, KITENGO YA UPASUAJI. CHUO KIKUU CHA NAIROBI

Fomu hii ya makubaliano Ina sehemu tatu

- 1. Habari itayokusaidia kukata kauli
- 2. Fomu ya makubaliano(utakapo weka sahihi)
- 3. Ujumbe kutoka kwa mtafiti

Utapewa nakala ya fomu hii.

#### **SEHEMU 1: UKURASA WA HABARI**

#### **KITAMBULIZI**

Jina langu ni Dkt Hassan Bharmal ambaye nasomea Upasuaji. Punde hivi sasa nafanya utafiti kwa anwani ya "Relevance of routine preoperative testing in ASA grade 1 and 2 patients undergoing minor to moderate elective surgeries at Kenyatta National Hospital".

#### NIA YA UTAFITI HUU

Miongozo kadhaa na utafiti imethibitisha kuwa vipimo vinavyofanyiwa kabla ya upasuaji kwa wagonjwa wanavyochukuliwa kwa ajili ya upasuaji sio muhimu. Utafiti huu itaamua kama vipimo hivyo vinastahili kuandaliwa au la.

Nitakupatia taarifa kuhusu utafiti huu na kuomba ushiriki wako. Unaweza kuuliza maswali yoyote kama huelewi istilahi yoyote au unahitaji ufafanuzi katika hatua yoyote wakati wa mazungumzo hii.

#### HAKI YA KUKATAA UTAFITI

Unaweza ukachagua kutoshiriki katika utafiti huu, Na huduma zote utapewa pasi na pingamizi. Uhusiano baina yako na wafanyikazi wa hospitali hautatiwa mashakani iwapo utakosa kujihusisha na utafiti huu. Ni uamuzi wako kuendelea ama kutoendelea na utafiti huu.

### TANDHIMA YA SIRI

Ujumbe kuhusu majibu yako yatahifadhiwa. Ujumbe kuhusu ushiriki wako katika utafiti huu utawezekana kupatikana na wewe na wanaoandaa utafiti na wala si yeyote mwingine. Jina lako halitatumika bali ujumbe wowote kukuhusu itapewa nambari badili ya jina yako.

### ANWANI ZA WAHUSIKA

- Dkt. Hassan Bharmal Department of Surgery, University of Nairobi P.O Box 19676 KNH, Nairobi 00202 Tel: 0722891326
- Dkt. Wambugu Mwangi
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   P.O Box 19676 KNH, Nairobi 00202
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   Wahusika wa maslahi yako katika Utafiti:
   Secretary KNH/UON ERC
   P.O Box 20723 KNH, Nairobi 00202
   Tel +254-020-2726300-9 Ext 44355
   Email: KNHplan@Ken.Healthnet.org

## SEHEMU YA PILI: FOMU YA MAKUBALIANO

Nimeelezwa utafiti huu kwa kina. Nakubali kushiriki kwa utafiti huu kwa hiari yangu. Nimepata wakati wa kuuliza maswali na nimeelewa kuwa iwapo nina maswali zaidi, ninaweza kumwuliza mtafiti mkuu au watafiti waliotajwa hapo mbeleni.

Jina la Mshiriki	
_	

Sahihi ya	mshiriki	
	-	

Tarehe\_\_\_\_\_

Kwa wasioweza kusoma na kuandika

Nimeshuhudia usomaji na maelezo ya utafiti huu kwa mshiriki, na mshiriki alipewa nafasi ya kuuliza maswali. nakuthibitisha kuwa mshiriki alipeana ruhusa ya kushiriki bila ya kulazimishwa.

Jina la shahidi\_\_\_\_\_

Alama ya kidole cha mshiriki.

Sahihi la shahidi\_\_\_\_\_

Tarehe \_\_\_\_\_

## SEHEMU YA TATU

## UJUMBE KUTOKA KWA MTAFITI/MWENYE KUHUSIKA

Nimemsomea mshiriki ujumbe kiwango ninavyoweza kuhakikisha kuwa amefahamu yote yanayohusika katika utafiti huu. Aidha, ninahakikisha kuwa mshiriki alipewa nafasi ya kuuliza maswali na akajibiwa vilivyo kiasi mno na vilevile, kutoa ruhusa bila ya kulazimishwa.

Jina la mtafiti: \_\_\_\_\_

Sahihi ya Mtafiti /Anaechukua ruhusa\_\_\_\_\_

## **APPENDIX 2 : KNH PREOPERATIVE CHECK LIST**



#### KENYATTA NATIONAL HOSPITAL

KNH 309

PREOPERATIVE CHECK LIST

Name of Patient (in full).....

	Ward Check	Ward Check	Theatre Check
	(INDISC S)	(Docior s)	(Anacsuletist s)
(a)	Gowns and socks	Hydration NormalYes/No	HbGm <sup>9</sup>
	Wigs	Hb	PCV
	Jewellery, etc	Electrolytes Normal	Electrolytes Normal
	Dentures	Temp°C	Temp
	Preparation	Chest Normal	Urinalysis:
b)	I.V. (Drips)	BP SystolicmmHg	Albumin
	Urinalysis:	DiastolicmmHg	Sugar
	Sugar	Pulse/min.	Blood Pressure:
	Albumin	Relevant medical preoperative	Systolicmml-
		preparation completed	
	Bladder check		DiastolicmmF
	and urinary	Yes/No	
	catheter		Pulse/min
		Is patient fit for operation?	
''			Dentures
	Gastric tube	Yes/No	
	•		Is Patient fit for operation?
	***************************************		
			Yes/M
	X-rays		
	Blood available litres	Blood available litres	Blood availableLitre
	Has Consent been given?	Has Consent been given?	Has Consent been given?
		Ves/No	Yes/
	Premedication given		Promodigation given
	Vec/No	and the second	Vac/N
	165/140		
	Certified by:	Certified by:	Certified by:
		Ward Doctor's Signature	
	Ward Nurse's Signature		Anaesthetist's Signature
		Date	
	Date	Time a m /n m	Date
	Time a m /n m		Time a m/s
	p.111	Patient seen by Anaesthetist	
		Vas/No	
		Signatus of Angesthatist	
		Dete	
		Date	

## QUESTIONNAIRE

## RELEVANCE OF ROUTINE PREOPERATIVE TESTING IN ASA GRADE 1 AND 2 PATIENTS UNDERGOING MINOR TO MODERATE ELECTIVE SURGERIES AT KENYATTA NATIONAL HOSPITAL

STUDY NUMBER	
AGE	
SEX	
DATE OF SURGERY	
SURGERY	
GRADE OF SURGERY	
ASA GRADE	

TEST	DATE	DATE	DATE	DATE	DATE	DATE
Haemoglobin						
Red Blood Cells						
White Blood Cells						
Neutrophils						
Lymphocytes						
Monocytes						
Eosinophils						
Basophils						
Platelets						
PCV						
MCV						
МСН						
МСНС						
Urea						
Creatinine						
Sodium						
Chloride						
Potassium						

FOR THOSE WITH ABNORMAL TEST RESULTS RECORD IMMEDIATE PERIOPERATIVE

## CONSEQUENCE

CONSEQUENCE	TICK FOR YES / ELABORATE IF NECCESSARY
Postponement of surgery	
Additional investigations	
Preoperative transfusion	
Change in management plan / diagnosis	
Change in anesthetic plan	
Other	