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An Assessment of the Accuracy of Decision Criteria Used to Determine the Need for Relook Laparotomy in Intensive Care Unit Patients Post Emergency Laparotomy.

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Medicine in the branch of Surgery.

Johannesburg 2009

Declaration

I, Dean Laurence Lutrin declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the branch of Surgery in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University

_____ 1 August 2009

Dedication

To Josie, for teaching me how to live and to Tamar and Liora for showing me why.

Abstract

Background

Persistent intraabdominal sepsis is a condition that may be difficult to diagnose and treat. Planned relaparotomies and relaparotomies on demand are two surgical approaches to this problem. A planned relaparotomy is when a surgeon makes a decision to schedule a repeat operation in 24 to 48 hours for further therapy. An on-demand repeat laparotomy (relook) is when the surgeon completes an operation with the intent to reoperate only if it is felt to be clinically indicated. There are multiple methods of identifying which patients need an on-demand relaparotomy. There is good evidence available showing that relooks should be performed primarily on demand and that unnecessary relooks carry significant morbidity. In the absence of clear clinical evidence demonstrating the need for a relook, organ dysfunction and imaging are the best indicators of ongoing pathology.

Aim

The aim of this study was to look at how the decision was made to reoperate on patients and determine the accuracy of those decisions.

Patients and Methods

All emergency surgical admissions to the multidisciplinary intensive care unit at Johannesburg Hospital over a one year period were evaluated. Thirty patients admitted to ICU after an emergency laparotomy fell within the criteria for inclusion in this study, sixteen of whom died whilst in hospital. Twenty two patients qualified as cases and eight as controls, who did not need

further operation. Particular attention was paid to whether the patient had further operations whilst in ICU, how the decision to reoperate was made and what were the eventual outcomes.

Results

Eighty relooks were performed on the 22 cases, 46 (57%) of which were positive. There were equal numbers of positive and negative relooks in the planned relaparotomy group. Within the relook on-demand group, a significant proportion of the relooks were positive (23 vs. 10). Traditional inflammatory markers were not helpful predicting positive relooks. Organ dysfunction, as measured by the Sequential Organ Failure Assessment (SOFA) score ($p<0.00$), proved to be useful to predict a positive relook. Imaging was not used to a significant degree in this study.

Conclusion

There is sound evidence to support a policy of relooks on-demand. The daily measurement of organ dysfunction and use of CT scanning will assist in determining those patients who would benefit from a relook laparotomy.

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List of abbreviations

ACS	Abdominal Compartment Syndrome
AIDS	Acquired Immune Deficiency Sydrome
ARDS	Acute Respiratory Distress Syndrome
CRP	C Reactive Protein
HIV	Human Immunodeficiency Virus
ICU	Intensive Care Unit
IL-6	Interleukin-6
MODS	Multiple Organ Dysfunction Score
ROC	Receiver Operating Curve
SOFA	Sepsis-related/Sequential Organ Failure Assessment

1 Introduction

1.1 Scope and objective

A key challenge in caring for critically ill surgical patients is to identify those patients with ongoing abdominal sepsis. Although these patients need to return to theatre for source control, taking a patient back to theatre unnecessarily can have multiple deleterious consequences.

The treatment of patients with an intra-abdominal septic catastrophe has progressed from being a relatively futile endeavour to one that offers the sickest patients the opportunity of a full recovery. Whilst there are many aspects of the treatment of these patients that are clearly defined[1] there is still uncertainty in many spheres.

This study aims to examine the treatment of intraabdominal sepsis in surgical patients in an intensive care unit (ICU) setting.

A central question that faces critical care staff daily is deciding which patients are recovering satisfactorily, and which have ongoing infection in their peritoneal cavity that would benefit from further intervention.

The objective of the study is to examine intra-abdominal sepsis, decision making regarding its treatment and outcomes of interventions carried out by clinicians.

The results of this study clearly demonstrate that a policy of 'on-demand' relook is superior to that of a planned relook. The difficulty lies in the definition of 'demand'.

1.2 History

The primary objective of the treatment of intra-abdominal sepsis has always been "source control" - removal or control of the source of the sepsis. The treatment of peritonitis was facilitated by the introduction of anaesthesia in 1846. Mikulicz first proposed the basic principles of management of peritonitis involving early operation, source control and lavage.[2] These principles have withstood the test of time and over the last 150 years the techniques used in the management of peritonitis have been augmented, refined and developed. The 1970s and 1980s saw an increase in publications concerning the management of peritonitis (See section 2.4).

1.3 Context

This study included patients admitted to the multi-disciplinary ICU at Johannesburg Hospital following an emergency laparotomy. This ICU serves the greater Johannesburg area and is one of the major tertiary referral centres in Gauteng province.

1.4 Significance

Whilst there are many similarities between ICU populations around the world, each centre has issues that make it unique. A South African ICU is an interface between first and third world medicine and both the patient population and disease processes need to be understood in context. It is hoped that this study will contribute towards the body of knowledge regarding the treatment of critically ill surgical patients.

2 Literature Review

2.1 Introduction

The basic principles of the management of intraabdominal sepsis are well established and simple. The surgeon must control the source of sepsis, clean the peritoneum and support the sick host. Despite these simple rules, intraabdominal sepsis remains a cause of significant mortality. An improved understanding of the patients, the host response and the utility of interventions will help improve outcomes. The primary objective of this study is to better define those patients who require further surgical therapy.

Many patients admitted to ICU after an emergency operation will need more than one visit to the operating theatre. At times the decision making is simple: a patient who has swabs intentionally left in the abdomen to aid haemostasis clearly needs another procedure to remove the swabs. However, the decision to reoperate becomes more complicated when, for example, the patient is three days into an ICU stay, and has signs and symptoms of systemic inflammatory response syndrome or sepsis. There are many plausible explanations for these findings, from the relatively benign to the life threatening. It can be very difficult to decide which patients need further operative intervention and which need to be carefully observed.

The idea of a relook laparotomy was established decades ago with the understanding that the adequate treatment of patients with peritonitis may occasionally demand more than one

operation. Many issues regarding this topic have been addressed in the literature and some of these controversies have been elaborated further in this dissertation. This aids in the understanding of the primary aim of this study – defining which patients need further surgical therapy.

This literature review has dealt with some of the following issues in some detail:

- The basic science and physiology of reoperative surgery
- The definitions and types of peritonitis
- The history and context of the treatment of intraabdominal sepsis including a discussion on planned versus on-demand relaparotomy
- The surgical techniques of reoperative surgery

2.2 Basic Science

The physiological insult of a relaparotomy is felt by the patient on many different levels. Firstly, a relaparotomy is known to activate inflammatory cytokines such as interleukin-6 (IL-6) leading to hypotension and increased inotrope requirements.[3] Multiple operations have a cumulative effect, resulting in an increased systemic inflammatory response from the patient, thus adding 'wood to the inflammatory fire'.[4] Additionally, analysis of the fluid used to wash out the abdomen shows greatly increased levels of inflammatory mediators, endotoxin and other particles (TNF-alpha, elastate, neopterin)[5], which correlate with severity of peritonitis. Multiple relaparotomies increase the inflammatory insult resulting in a worse clinical course for the patient as a consequence of the inflammation.[6] In a study from Germany looking at the effect of relaparotomy in secondary peritonitis, the authors suggest that the deleterious effect of

relaparotomy leads to a more lengthy ICU stay. They propose more narrow indications for relaparotomy to minimise this insult.[6] This is one reason to avoid unnecessary relaparotomies.

IL-6 has been shown to correlate with mortality in sepsis.[7,8,9] It has been observed clinically that the IL-6 rises significantly in a patient population undergoing relaparotomy as compared with a fairly well matched group who had only one operation.[10] This cytokine response precedes a predictable episode of post-operative hypotension. Although the exact nature of the morbidity associated with these post-operative hypotensive episodes is not clear, they are likely to be harmful to the patient.

Additionally, there is good experimental evidence to show that multiple relaparotomies have a deleterious effect on multiple organ systems. These effects include the coagulation, immune, and renal systems as well as the liver.[11,12,13] Coagulation factors are lost by proteolytic destruction, haemorrhage and dilutional effects related to the relook laparotomy. The systemic inflammatory response is also exacerbated by relaparotomy and may contribute to further organ dysfunction.[12]

2.3 Peritonitis

There are multiple forms of peritonitis and an understanding of the various types will facilitate a better appreciation of the problems associated with the treatment of peritonitis.

Primary peritonitis (spontaneous bacterial peritonitis) is rare and is typically caused by a single organism in certain at-risk patient groups, such as those with cirrhosis complicated by portal hypertension with ascites.[14]

Secondary peritonitis is usually a result of a breach in the gastrointestinal tract, such as a perforated peptic ulcer. The majority of cases dealt with in this study fall within this category. Secondary peritonitis has a myriad causes and its treatment always involves source control. Secondary peritonitis includes patients who develop post-operative intra-abdominal infection despite a relatively clean initial operation, such as a penetrating trauma case with bowel injury.

Tertiary peritonitis is the most difficult form of peritonitis both to understand and to treat. It is a clinical syndrome characterised by recurrent or persistent intra-abdominal infection in the context of critical illness and organ dysfunction.[15] The normal peritoneal response to infection is impaired and instead of forming discrete abscesses, the abdomen contains poorly localised fluid collections containing organisms of relatively low intrinsic virulence.

Most of the general surgical cases included in this study were admitted with secondary peritonitis. Whilst the trauma cases did not have peritonitis on admission, some developed peritonitis as a result of either the disease itself or post-operative complications. Many of both the trauma and general surgery cases appeared to develop tertiary peritonitis. This report did not look specifically for tertiary peritonitis, but in case series of both trauma and general surgical patient populations, it is not uncommon. In one published series, 74% of patients with intraabdominal sepsis admitted to an ICU developed tertiary peritonitis.[16]

2.4 History of Treatment of Intraabdominal Sepsis

In the early 1980s critically ill ICU patients who did not have relooks had a mortality rate approaching 80%.[17] One of the earliest studies looking at organ dysfunction and relaparotomy was published by Polk in 1977. In this study six patients who developed post-operative organ failure were taken for relaparotomy and five of them had an occult intra-abdominal abscess.[18]

In 1984 a larger series took cognisance of the development of critical care as a unique discipline.[19] This study analysed all patients who were re-explored for sepsis with reference to indications and outcomes and showed a high mortality (43%). However, those patients with organ failure and positive physical examination or imaging demonstrating intra-abdominal sepsis benefitted from reoperation. In multiple studies[20,21,22] the death rate from persistent intra-abdominal sepsis had been consistently high, with mortalities averaging between 40% and 60%. Planned relaparotomy evolved in the 1980s as a response to the realisation that once multiple organ failure has developed, relaparotomy is probably futile.[23] The cornerstone of the planned relook approach is the prevention of infectious collections. Therefore, a policy of planned relaparotomies in patients with abdominal sepsis became more commonplace[24,25] during this period.

Despite the development of antibiotics and the improvement in intensive care over the last few decades, there has not been a significant improvement in the mortality of secondary peritonitis.[26] A long term follow up study of this group of patients treated between 1983 and 1995 showed a 28% in-hospital mortality.[27] A group of 125 patients treated between 1990 and 1993 had a 63%

mortality.[28] In a patient population of 136 patients with secondary peritonitis treated between 1996 and 1999 there was a 46% mortality for secondary peritonitis.[29] In another group of 65 patients studied between 1997 and 2002, 43% died from secondary peritonitis requiring reoperation.[30] Data supporting a policy of *planned* relook are limited. Opponents of this approach argue that reoperations do not improve outcome, and may perhaps increase complications[31] such as bowel fistulae, anastomotic leaks[32] and abdominal wall defects.

However, as mortality remained high and many unnecessary relooks were being performed, the value of planned relooks came under scrutiny in the form of trials comparing planned to on-demand relook. The aim of these studies[11,21,32] was to see whether some patients could be spared the morbidity and expense of further surgery.

2.5 Planned versus On-Demand Relook Laparotomy

Much research has been devoted to the debate whether to plan a second look operation at the time of the first procedure.[11,21,32] This would be done on the basis of a subjective assessment of the severity of findings at the initial operation. The surgeon may be concerned that adequate source control has not yet been obtained and may want to proceed with a relook in 24 to 48 hours to ascertain whether any further intervention is necessary. The result of a planned relook may be negative, where no ongoing pathology is found and the relook was, in retrospect, unnecessary. The relook may be positive where pathology was found that required intervention. This relook may be definitive or further interventions may be planned thereafter.

The notion of an on-demand relook differs as it approaches each patient with an individualised treatment plan. After an initial operation, the clinical team would observe the patient progress and use a variety of signs, symptoms and special investigations to determine the patient's improvement. Should the patient not recover adequately, a relook may be scheduled to address a potentially ongoing problem in the abdomen.

The data on patient outcomes of planned relaparotomy versus on-demand relaparotomy favour relook on demand as the preferred approach to the critically ill patient with secondary peritonitis.[11] The Dutch Peritonitis Study Group randomised 232 patients with peritonitis (with a full spectrum of causes) into a relook on-demand arm and a planned relook arm. They demonstrated similar rates of death and morbidity in both groups and concluded in favour of relooks on demand.[11] This study matched patients for severity and it appears that no selection bias existed. Their argument for a policy of relook on demand hinged on the fact that these patients did not have a higher morbidity or mortality than the planned relook group and also that the overall costs and length of stay were decreased in the on-demand group.

2.6 What is 'On-Demand'?

Each published study has a unique definition of what constitutes an 'on-demand' relook laparotomy. The main categories used to define 'on-demand' are clinical, sepsis related, organ dysfunction and imaging. These broad categories are not used in isolation, but rather complement each other to give a complete picture of what is happening to the patient.

A scoring system, the Abdominal Reoperation Predictive Index (ARPI), was developed to account for multiple factors that assist in predicting the presence of postoperative intra-abdominal sepsis. The ARPI includes clinical, physiological and organ function parameters and brings them together to form a predictive tool[33] to help identify those patients who would benefit from a relook. While this index is not in general clinical use, its principles remain important to this discussion. It has eight variables that contribute to a score to aid decision making regarding investigation and reintervention:

Variable	Score
Emergency surgery	3
Respiratory failure	2
Renal failure	2
Ileus	2
Abdominal pain	5
Wound infection	8
Consciousness alterations	2
Symptoms from 4th day post-op	6

A cumulative score of greater that ten significantly increases the probability of a positive relook laparotomy.

Each of the 'on-demand' categories will be further elucidated:

2.6.1 Clinical

Simple clinical criteria that have been used indicate the need for a relaparotomy are listed below:

Acute abdomen/ abdominal tenderness
Wound infection

Enteric contents leaking from a drain or through the wound
Prolonged ileus
Abdominal pain
Abdominal distension
Failure to progress

Daily clinical examination with specific attention to abdominal signs and symptoms should reveal obvious pathology.

2.6.2 Sepsis

Sepsis related criteria include:

Pyrexia (temperature <36°C or >38°C)
Tachycardia (heart rate >90 beats per minute)
High or low white cell count (<4000 cells/mm^3 or >12000 cells/mm^3)
Falling platelet count
Rising C-reactive protein
Increased insulin requirements to maintain normoglycaemia
Elevated procalcitonin
Metabolic acidosis

These criteria are discussed fully in the 'Surviving Sepsis' guidelines.[1] These guidelines are the product of a consensus conference devoted to the diagnosis and treatment of sepsis. Many of these septic markers are well established and have a track record of high sensitivity and specificity with good positive and negative predictive values.[34]

Procalcitonin has been studied extensively and there is evidence both for[35] and against[36] it being used routinely as a marker of sepsis. In this study procalcitonin was not measured often. In the Johannesburg Hospital ICU, procalcitonin is measured only where there is significant doubt as

to whether the patient has bacterial infection and where the clinical findings and the biochemical data are discordant.

2.6.3 Organ dysfunction

Organ dysfunction[1] as a marker of intraabdominal sepsis may manifest as:

Renal dysfunction (<0.5ml urine/hour or 1.5x rise in creatinine)
Coagulopathy (INR >1.5 or aPTT >60 seconds)
Confusion
Hypotension and new inotrope requirements (systolic blood pressure <90mmHg despite appropriate resuscitation)
ARDS/Respiratory distress ($Pa0_2/Fi0_2$ <300)

Multiple techniques have been developed to quantify the degree of organ dysfunction. The Sepsis-related Organ Failure Assessment (SOFA) score is a useful indicator of multisystem organ failure[37] as it is relatively easy to calculate on a daily basis and uses data that are routinely available in the ICU. The SOFA score takes into account five parameters: the cardiovascular, respiratory, renal, haematological and nervous systems are scored on a daily basis. The minimum score obtainable is 0 and the maximum is 20. The scoring system is attached in appendix B.

Another familiar scoring system is the Multiple Organ Dysfunction Score (MODS)[36], but it is quite cumbersome to calculate.

Scoring systems are generally used as research tools rather than as aids to clinical decision making. This is because the scores have been difficult to obtain and use. There is increasing evidence that daily scoring has authentic clinical utility and it is becoming a part of routine

practice in many ICUs.[38] The challenge of determining those patients with ongoing or new pathology whilst in ICU is being simplified by the organ dysfunction scoring systems. This has particular relevance since the utility and accuracy of traditional markers of sepsis (white cell count, CRP and temperature) are being challenged.[39]

The Mannheim Peritonitis Index[40] takes into account factors that are associated with the severity of peritonitis. The higher the score, the greater the predicted mortality for the patient.[41] In this study the index was measured in patients who presented with peritonitis. It was not used for trauma patients as these patients do not present with peritonitis. The components of the index are listed in appendix C.

2.6.4 Imaging

Imaging plays an important role in the identification, localisation and treatment of intra-abdominal sepsis. Whilst ultrasound is useful to detect collections and can be performed at the bedside, it generally provides inadequate information. Ultrasound is hampered by bulky dressings and the presence of standard ICU equipment. Deep subphrenic, pelvic and retroperitoneal pathology is also easily missed on ultrasound.

Contrast enhanced CT scanning has a pivotal role in the management of patients with suspected intraabdominal sepsis[42] as a large amount of information can be gathered from a CT scan. The presence, size and location of rim-enhancing collections may be clearly identified. Sites of potential anastomotic complications can also be seen, especially if oral/rectal contrast is given.

Additionally, lesions amenable to percutaneous drainage can be identified. CT has good negative predictive value in patients with equivocal signs, and a good quality CT scan may aid the prevention of negative relook laparotomies. A study performed by the University of Southern California[43] analysed a population of trauma patients with sepsis of unknown origin. It found abdominal CT scanning to be useful, with a change in management in 69% of the studied cohort. In one study, the post-test probability of a positive imaging study was 0.57 for ultrasound and 0.71 for CT scanning.[39] As with all imaging modalities, one needs to be aware of the danger of false negative studies, although these are generally less than 15%.

2.7 How strong does the "demand" need to be?

The decision to reoperate 'on-demand' may be simple. A patient with clinical signs that strongly suggest an intra-abdominal catastrophe such as septic shock, a distended abdomen and faeces leaking through the wound clearly needs another operation. Yet frequently, the decision to reoperate is difficult. A patient may have ileus and mild abdominal tenderness along with a pneumonia and renal failure. The abdominal signs may be the indication that there is intra-abdominal sepsis or they may be a 'red herring'. For these patients a CT scan may be helpful to ascertain whether abdominal pathology is responsible for the clinical picture. That being said, imaging does have a false negative rate and there is a group of patients (probably less than 15%) who will have florid intra-abdominal sepsis and an unhelpful CT scan.[44]

The major point of this study is that while the literature is clear that 'on-demand' relooks are superior, we do not know how to define 'demand'.

2.8 Surgical Techniques

Coupled with the decision to reoperate is the need to understand the unique operative strategies that are used for relaparotomies. Many options and alternatives are available and it is necessary to understand the indication for each specific technique. The predominant doctrine of each operation is to do as little harm as possible whilst maximising benefit. It is also accepted that certain interventions which are considered safe in a healthy abdomen are not appropriate in a septic abdomen.

The following strategies have been used in patients requiring relaparotomy:

Open abdomen and temporary abdominal closure
High volume lavage and continuous post-operative lavage
Controlled fistulae and diversion

There is no consensus regarding:

The place of reanastomosis in the face of leaks
Duration of antibiotics
The role of laparoscopic relook laparotomy

2.8.1 The open abdomen and temporary abdominal closure

The first descriptions of the management of intraabdominal sepsis with a temporary closure (the so-called Opsite sandwich) emerged in the 1980s. Until then it had not been considered feasible or safe to leave a patient's abdomen open. Many ways have been described to manage the patient with a temporary laparostomy, all of them aiming to provide an egress point for the abdominal

fluid or pus. Additionally, these methods aim to prevent enterocutaneous fistulae, control fluid loss and maintain abdominal domain.[45] Temporary abdominal closure also provides the benefit of lowering abdominal compartment pressure, aiding the prevention and treatment of abdominal compartment syndrome. Vacuum dressings have become more popular as a method of managing the open abdomen but there is still scant evidence demonstrating their superiority over conventional and possibly cheaper methods.[46]

2.8.2 Abdominal Lavage

Washout of the abdomen has long been considered a cornerstone of the management of intraabdominal sepsis. Trials have been conducted exploring how much lavage is necessary and whether continuous postoperative lavage has any benefit.[47]

In the past there was a trend to use very large volumes of washout fluid (up to 60 litres) and to continue with post-operative lavage due to its supposed clinical benefit.[48] However this fell out of favour for technical reasons and as evidence emerged that it was not beneficial.[49] Current practice is to wash out obvious purulent material and not persist with post-operative continuous lavage. The exact amount of fluid used varies from centre to centre.

2.8.3 Methods for dealing with enteric leakage

The decision-making process with respect to enteric leakage at the initial laparotomy has been clearly defined and there are guidelines as to which lesions should be diverted and which can be

safely anastomosed or repaired. In the face of ongoing sepsis with enteric leakage at relook laparotomy, it is generally considered prudent to divert whenever possible. Leaks in the proximal GIT may be considered for repair[50] but distal leaks should be diverted, although this distinction may be debated. Diversion may take the form of loop or end stomas or the formation of controlled fistulae. Reanastomosis of enteric leaks in critically ill patients with secondary peritonitis is generally considered unsafe.[51]

2.8.4 Enterocutaneous Fistulae

There is clear evidence how enterocutaneous fistulae should be managed.[52] This involves aggressive treatment of the sepsis, adequate nutrition and control of the effluent. These fistulae can be more complicated to manage in patients having multiple relook laparotomies due the presence of an open abdomen. Additionally, these patients often have persistent intra-abdominal sepsis that needs to be addressed surgically, thus potentially injuring the bowel even more. Occasionally, a controlled fistula would need to be created. This is usually due to an inability to exteriorise the leaking segment of bowel.

2.8.5 Duration of Postoperative Antibiotics

The initial enthusiasm for prolonged culture directed antibiotic therapy in peritonitis[53] did not persist as evidence showed that the intraabdominal pathogens in patients with tertiary peritonitis seemed to be a consequence of multisystem organ failure as opposed to the cause of it.[54] Thus it is not necessary to give antibiotics until the peritoneal fluid is sterile on culture. Generally a 5-7 day

course of antibiotics is given for the more severe intra-abdominal infections, although there is some evidence that even a shorter (2-3 days) course may be appropriate.[55]

2.8.6 The role of laparoscopic relook laparotomy

In cases where there is doubt as to the necessity for reoperative surgery, laparoscopy offers a potentially less traumatic method of re-exploration. As discussed, relook laparotomy is associated with many complications including pain, ileus, wound infection and incisional hernia, as well as the so called 'second hit' of an increased inflammatory response,[56] all of which may be minimised with laparoscopy. Furthermore laparoscopy is particularly useful in relooks for mesenteric ischaemia where visual information is of paramount importance. Laparoscopy has a useful role in determining the presence of anastomotic leaks and definitive exteriorisation may be accomplished laparoscopically without having to reopen the midline wound.

Laparoscopy is not yet a standard of care with respect to relook laparotomy and demands a high level of laparoscopic skill. Nevertheless, it is likely that laparoscopic relook laparotomy will become the preferred method of re-exploration in the future.

2.9 Summary

Intra-abdominal sepsis is a complicated disease process. A relook laparotomy is a "double-edged sword" that harms as it helps. There is a critical need to understand the clinical course of patients with peritonitis in order to treat persisting sepsis. The indications for a relook on demand should

be clearly understood in order to minimise the morbidity of unnecessary relooks. For patients who have repeat visits to theatre, the principles of careful operative surgery and thorough perioperative care should be meticulously applied. On the basis of this review of the literature, organ dysfunction and positive imaging are the best indicators of the need for a demand relook. The practice of planned relaparotomy is defunct for most clinical scenarios except that of damage control laparotomy.

3 Methods

All patients admitted to the Johannesburg Hospital General ICU after an emergency laparotomy were considered eligible for the study. The ICU was visited daily to determine the presence of new patients who fulfilled entry criteria into the study. If a suitable patient was identified, consent was obtained and baseline data were collected (Appendix A,C,D,F,G,H). If necessary information was not available, the treating clinician was contacted to provide further detail. The patient was visited daily and the daily follow up form (Appendix B) was completed until discharge from ICU or death (Appendix E). Each relook laparotomy was considered to be a unique event and was analysed independently. Some patients who had relooks on demand had subsequent planned relooks. Similarly, there were patients who initially had a planned relook that later had on-demand relooks. The relaparotomy was classified as 'planned' or 'on-demand' by direct questioning of the ICU clinicians. The Johannesburg hospital patient database was accessed to determine the outcome of patients once they had been transferred to the wards. All data was initially captured on paper and then later transferred to a Microsoft Excel spreadsheet.

For ease of reference and standardisation, certain terms listed below, were defined upon initiation of this study.

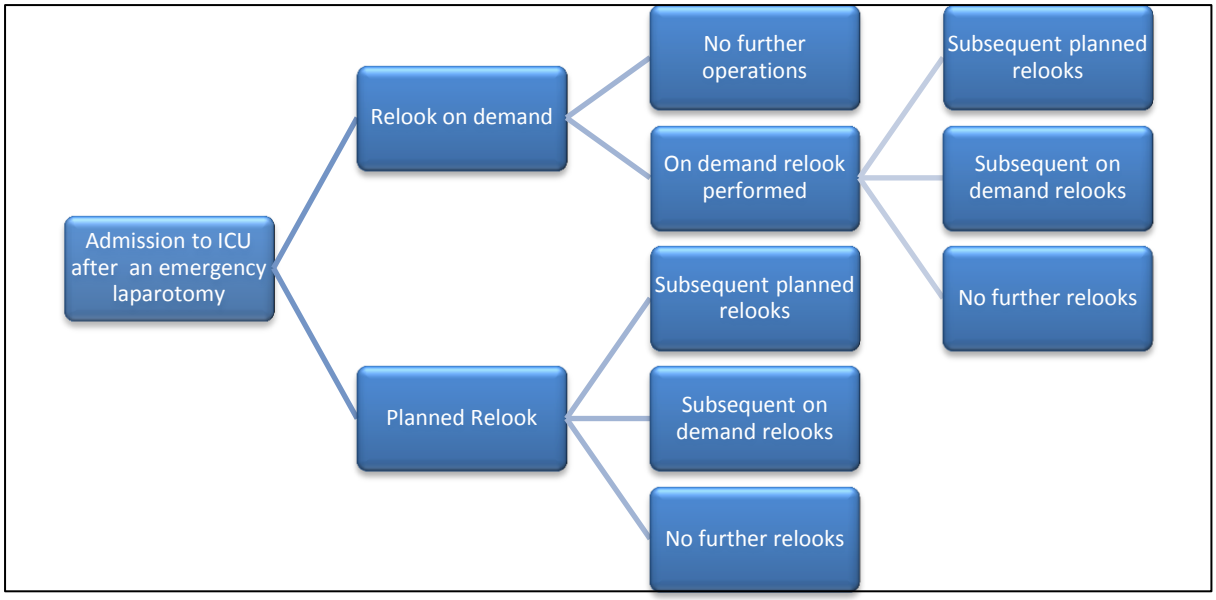
The abdominal compartment syndrome was defined using standardised criteria.[57] These include the development of organ dysfunction in the presence of raised intra-abdominal pressure.

An ‘on-demand’ relook laparotomy based on clinical findings included criteria such as signs of wound infection, evidence of anastomotic dehiscence, persistent ileus, abdominal distension and an acute abdomen. Appendix D contains a full list of the observed clinical parameters.

Imaging was used selectively in patients with equivocal clinical and laboratory findings where further evidence of intra-abdominal sepsis was needed to justify a relook laparotomy. Generally the investigation of choice was a contrast enhanced CT abdomen, although, on occasion an ultrasound was used.

Persistent organ dysfunction was one of the indications for relook laparotomy. Ongoing haemodynamic instability or worsening renal function despite optimal medical therapy, were amongst the parameters used to define multiple organ dysfunction. These criteria have been described elsewhere[58] and are listed in Appendix A and B.

A ‘planned’ relook laparotomy was a reoperation that was planned at the previous operation. Within this study, some of the planned relooks were undertaken as a completion of a damage control laparotomy. If, for example, haemostatic packs had been placed into the abdomen at the initial operation, the aim was to remove these at the planned relook. This was one component of the planned relook group in this study. A planned relook was also done if the surgeon at the index operation felt that there was inadequate source control. The relook may have been done to wash out the abdomen or further debride necrotic tissue. There were many instances where a patient was planned for on-demand relooks yet, after a positive on-demand relook, further planned relooks were undertaken. This is illustrated in the flow chart below.



A positive relook was defined by:

- The presence of a drainable intraabdominal collection
- The presence of diffuse infected intraperitoneal fluid
- Anastomotic complications requiring intervention
- The need for control of surgical haemorrhage
- Release of abdominal compartment syndrome
- The need for an intraperitoneal debridement
- Planned relook performed to complete an operation
- The need to address missed or iatrogenic pathology

There is anecdotal evidence that patients who appear to deteriorate in ICU and have a relook on clinical grounds where no obvious pathology is found improve after the reoperation. However given what we know about the harm of non-therapeutic laparotomies, it would be ethically unacceptable to design a study to evaluate non-therapeutic relaparotomy. Those patients whose clinical condition improved despite a negative relook laparotomy were not included as 'positive relooks' for the purpose of this study.

3.1 Aim

The aim of this study was to understand how the decision was made to reoperate on patients and whether these relook laparotomies were beneficial to the patient. The relook laparotomies were performed for one of six potential indications as decided upon by the treating clinicians:

- Planned relaparotomy
- Sepsis criteria
- Abdominal compartment syndrome
- Clinical findings
- Imaging
- Organ dysfunction

The usefulness of each of these indications was analysed in light of what was found at the reoperation.

3.2 Subjects

All patients admitted to the General ICU (576) at Johannesburg Hospital after emergency operations were considered eligible for inclusion in the study. Patient data were collected between June 2005 and July 2006. A single ICU was chosen as a source of patients to ease data collection. Both general surgical and trauma patients (including those who had damage control surgery) were included. Patients with pancreatitis, vascular surgical patients as well as gynaecological patients were excluded on the basis that the natural history and treatment of these

patients is different from the studied population. Only patients older than 18 years were included.

Cases were defined as patients who had further laparotomies whilst in ICU.

Controls were defined as patients who were admitted to the ICU after an emergency laparotomy and were discharged from ICU without any further operations.

Consent was obtained from the patients' families and from the patients themselves once they had recovered sufficiently to be able to give informed consent.

This study was approved by the Human Research Ethics Committee of the University of the Witwatersrand (Appendix I).

3.3 Data Collection

The data was collected on standard data entry sheets (see Appendix A). Extensive baseline information was obtained when the patient was initially admitted to the ICU. The patients were seen every day and daily progress sheets were completed documenting the patients' course over the previous 24 hours. Furthermore, the data regarding reoperations was collected.

3.4 Statistical Analysis

The data was initially entered into a Microsoft Excel datasheet. This was subsequently imported into SPSS v16.2 statistical software. Chi squared and Mann-Whitney tests were used to analyse the non-parametric data. Simple descriptive statistics were used for percentages and proportions and means with standard deviations were discussed where appropriate. Univariate and multivariate logistical regression were used to define the relationship between certain measured variables and clinical findings.

4 Results

4.1 Introduction

The data generated for this cohort of patients was broken down into the following categories:

Patient demographic statistics

Length of stay statistics

Relook laparotomy statistics

Analysis of indications for relooks

Interpretation of clinical data

Analysis of predictive value of various measurements

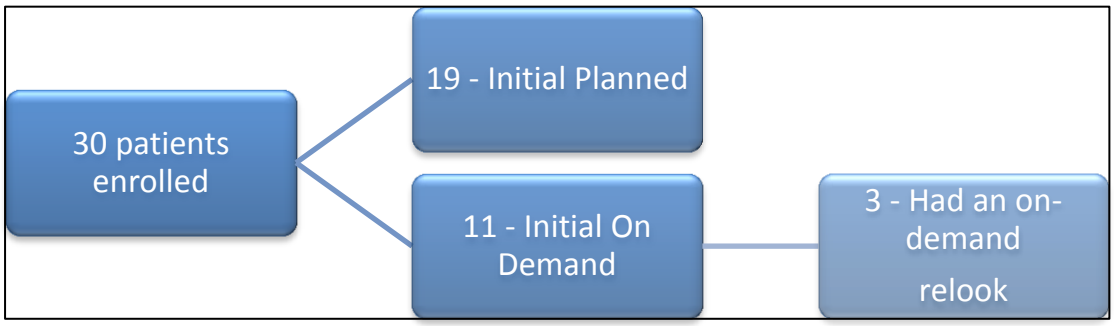
4.2 Patient Demographics

A total of 30 patients (cases and controls) were enrolled in the study over a one year period from July 2005 until August 2006. All patients' data were collected sequentially. Four additional patients were not included in the study due to lack of sufficient data as a result of file loss. Twenty one of the patients were male and nine were female. Twenty of the patients were general surgical patients and ten were trauma patients. The ages of the patients ranged from 19 years to 80 years with a median age of 40 years.

A case was defined as a patient who had a relook whilst in ICU and a control was a patient who did not have any further relooks after admission to ICU. In total 22 of the patients were classified as cases and there were 8 control patients. A patient admitted to ICU after an emergency laparotomy had a high likelihood of at least one relook (p=0.01).

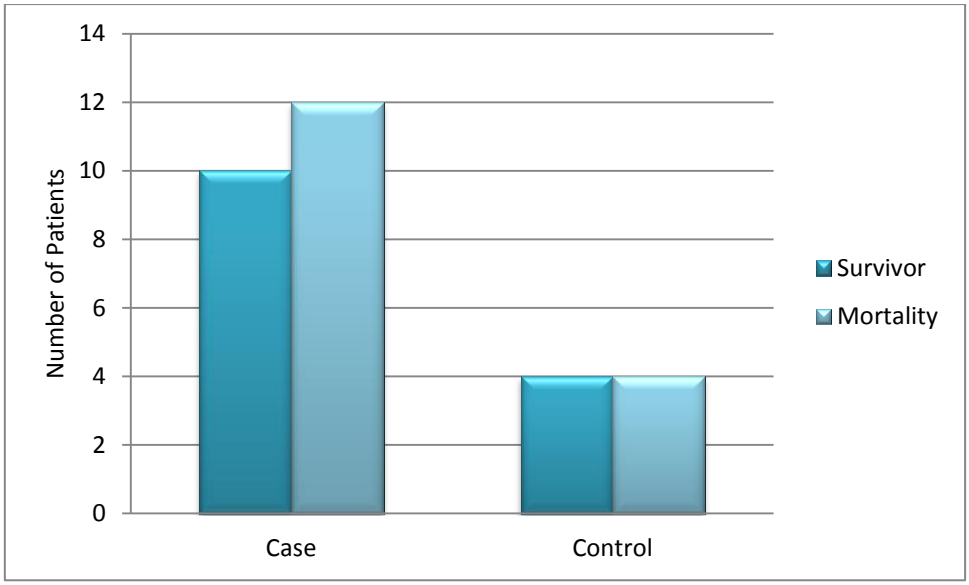
In the entire group of 30 patients, 19 had relook laparotomies planned from the outset and 11 did not. An additional three patients had a first relook on demand, resulting in a total of 22 patients who were considered as cases for the purpose of this study (Flow Chart 1).

Flow Chart 1: Number of planned or on-demand laparotomies and control patients



In total 16 of the 30 subjects died during their hospital stay (53%). Fourteen patients were discharged from hospital.

There was no significant difference in overall mortality in this study. This implies that in the study cohort (both cases and controls) an equal number of patients died in both groups (Cases 12 of 22 (55%); Controls 4 of 8 (50%); p=0.715).



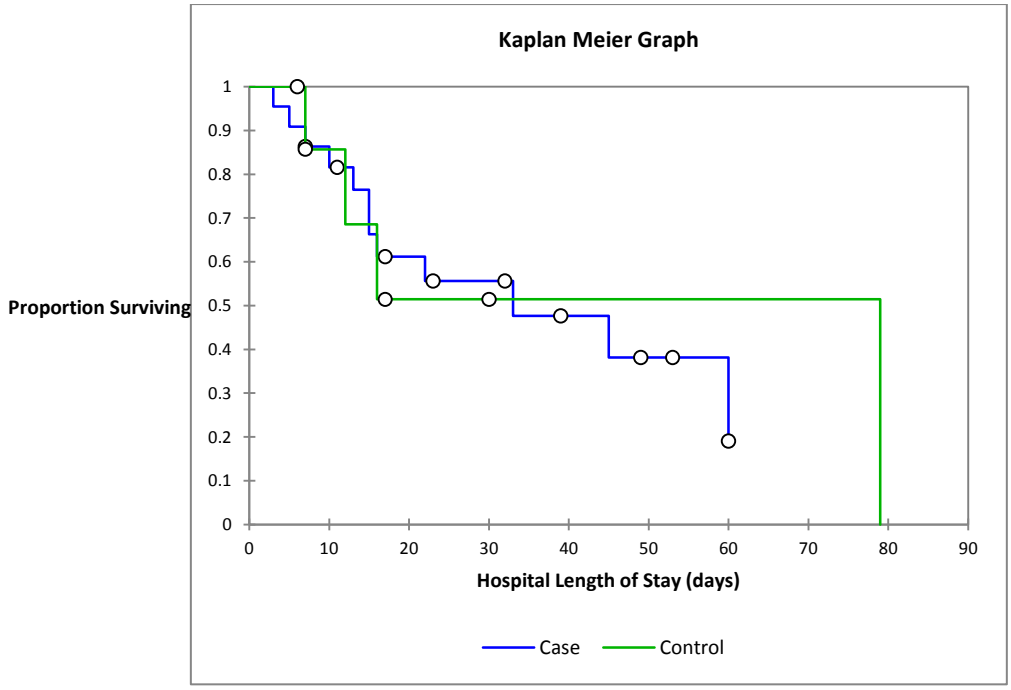
Graph 2: In hospital mortality - Case vs control

As can be seen (Graph 2), the mortality rates of cases and controls were similar (p=0.76 for cases and p=1.00 for controls). These data are interpreted more extensively in the discussion.

The Mann-Whitney U test was used to determine whether there was a statistically significant difference between baseline data of the case and control groups. There was no significant differences in any of the following variables between the two groups (Table 3).

Table 3: Baseline information

Demographic	All Mean +- SD	Control Mean +-SD	Relook Mean +-SD	P value
Age	45.66±18.97	54.75±16.65	42.19±19	0.103
Admission APACHE II score	13.4±5.7	15.4±5.18	12.90±5.85	0.371
Admission MPI	22.83±10.24	28.33±10.97	21±9.95	0.282



Graph 3: Survival curve

As shown in the above graph (Graph 3), the survival curves were similar for both cases and control with no significant difference in survival (p=0.808).

These data show that a patient admitted to ICU after an emergency laparotomy was as likely to die if they did not have a relook laparotomy as if they did. The admission APACHE II score did not have an impact on whether the patient was a case or a control.

A consultant was present at the first operation in 16/30 of the cases and the operation was performed by a registrar only in 14/30 of the cases. There was no correlation between mortality and the presence of a consultant at the initial procedure (p=0.298).

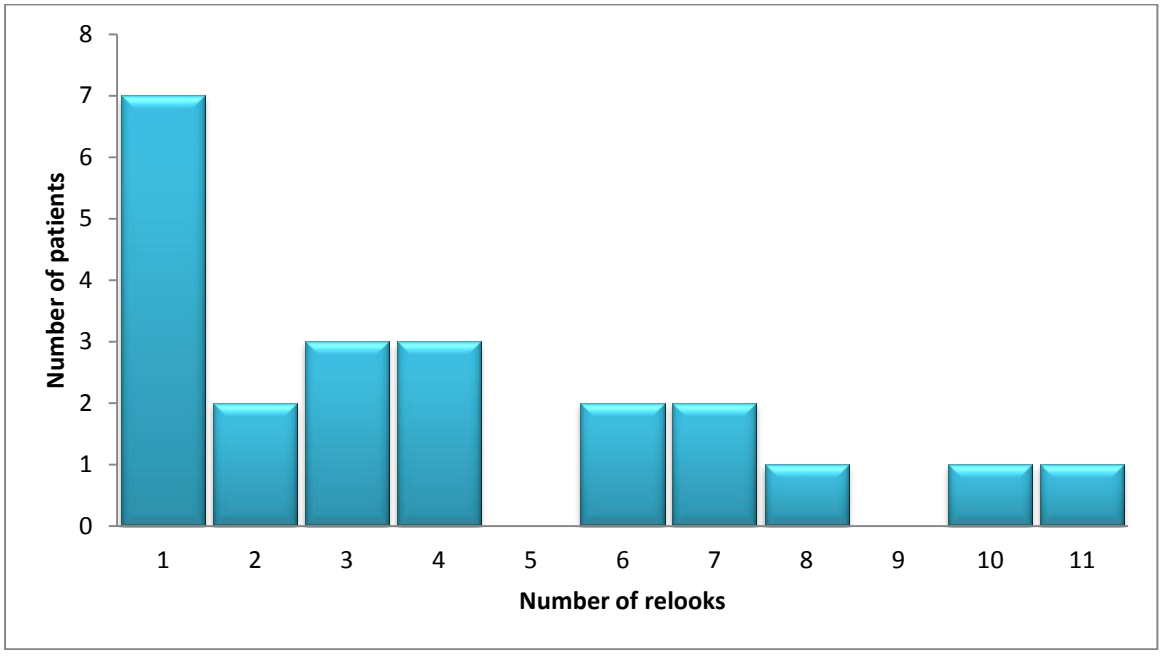
4.3 Length of Stay Statistics

Amongst those patients who died (16/30, both cases and controls) the median ICU and hospital stays were 15 days. Amongst survivors, the median hospital stay was 26.5 days with a median ICU stay of 3.5 days. There was no significant difference in length of stay between those patients who had relooks and those who did not (p=0.435).

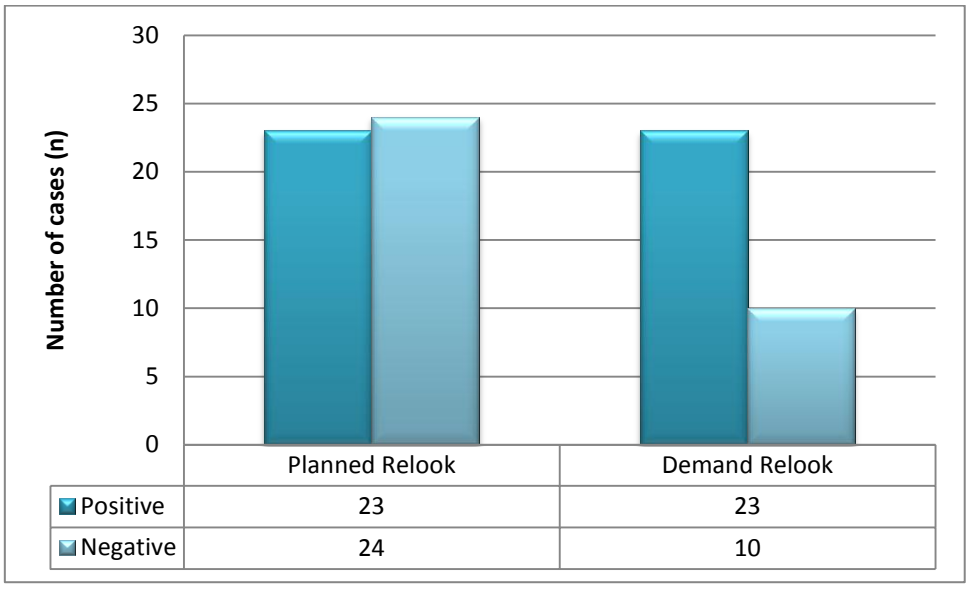
4.4 Relook laparotomy statistics

A total of 80 relook laparotomies were performed during the study period. As can be seen (Table 4), seven patients had only one relook and one patient had eleven relooks.

Table 4: Breakdown of number of relooks amongst cases



Of the 80 relooks that were performed, 46 were positive and 34 were negative. A total of 47 planned relooks were performed and 23 of these were positive (49%). Thirty three on-demand relooks were performed and 23 of these were positive (69.7%).



Graph 5: Relook results breakdown

Amongst the planned relooks there were a similar number (p=0.884) of positive and negative relooks (Graph 5). For the subset of patients who had a relook on demand there was a statistically significant difference between the positive and negative relooks (p=0.024) in favour of positive relooks. Of particular interest in this group is that there was no correlation between mortality and the number of relooks performed.

4.5 Analysis of indications

The main indications for the relooks were:

Abdominal compartment syndrome (ACS)

Clinical grounds (e.g. obvious leak or acute abdomen)

Evidence of collections on imaging

Multiple organ dysfunction (MODS)

Planned relook laparotomy

Sepsis criteria (e.g. raised white cell count or CRP)

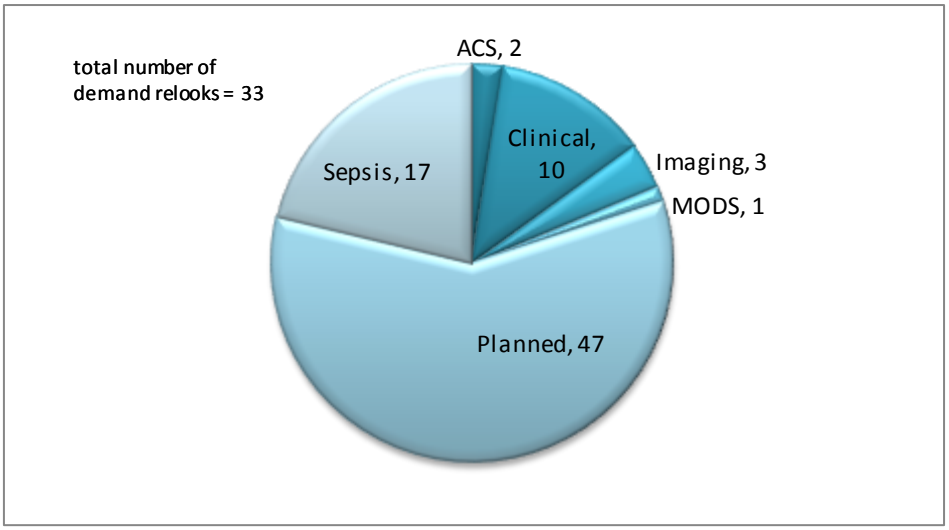


Figure 6: Indications for relook laparotomy (n=80)

As demonstrated in figure 6 most of the demand relooks were done for sepsis criteria (17/33). The majority of relooks in this series were planned (47/ 80). Suspected sepsis or clinical reasons accounted for 27 out of 80.

Table 5: Relook indications and results

Relook Indication	Positive	Negative	P value
ACS	2	0	Not applicable
Clinical	8	2	0.058
Imaging	2	1	0.564
MODS	1	0	N/A
Planned	23	24	0.884
Sepsis	10	7	0.467

Table 5 shows the breakdown of the relook findings for each of the major indications for a relook. Chi squared analysis was used to see whether any of these six categories was useful to predict the need for a relook laparotomy. There were no significant differences in the numbers of patients with positive or negative relooks amongst all six major groups. Relooks performed on clinical grounds were the most likely to be positive and it is possible that if a larger cohort of patients were to be studied, this would be statistically and clinically significant.

The intraoperative findings for those patients who had a relook were broken down into the following categories:

1 No pathology found
2 Abscess
3 Diffuse infected intraperitoneal fluid (positive fluid culture)
4 Diffuse fluid, not infected (negative fluid culture)
5 Anastomotic leak
6 Organ necrosis
7 Missed pathology
8 Pack removal
9 Bleeding
10 ACS
11 Bile leak

Figure 7 demonstrates these findings amongst all patients who had a relook laparotomy (planned and on-demand). Anastomotic complications and localised septic collections formed the majority of cases of positive relooks, but note that nearly half of the relooks were negative.

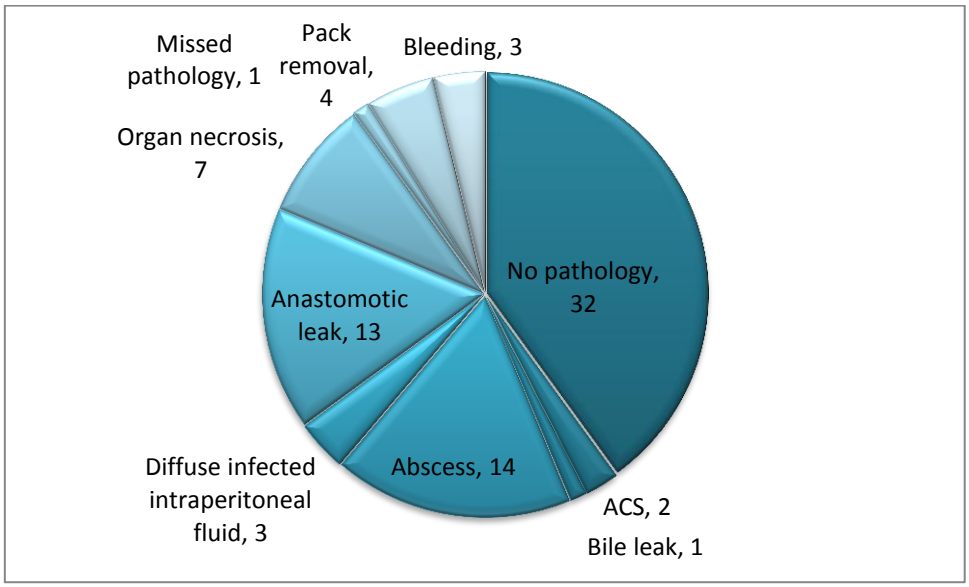


Figure 7: Relook findings (n=80)

4.6 Interpretation of clinical findings and special investigations

Multiple variables were measured in each patient in an attempt to understand the contribution and predictive value of these variables.

The Mann-Whitney test was used to determine whether there was a statistically significant difference between a number of variables in patients who had a positive relook versus those who had a negative relook (Table 6).

Table 6: Utility of measured variables in predicting a positive relook

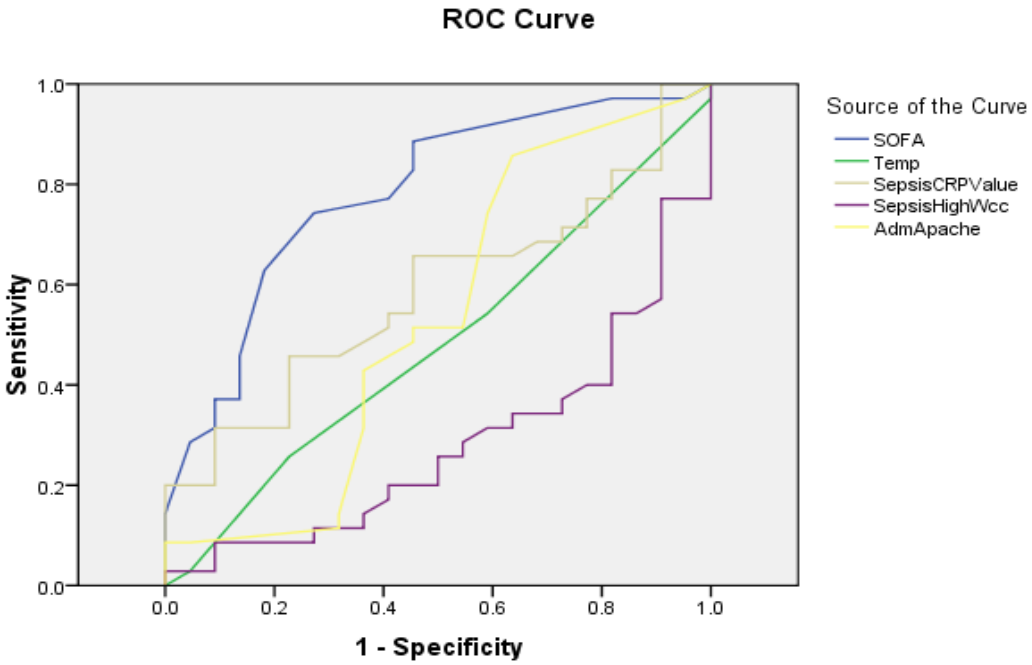
	Number of cases	Positive relook Mean±SD	Negative relook Mean±SD	p-value
CRP	70	233.7±107.1	200.9±91.0	0.155
White cell count	74	15.6±8.8	18.8±6.7	0.041
Insulin requirements	53	2.8±2.4	3.6±2.4	0.416
Temperature	68	37.7±0.9	37.8±0.9	0.820
SOFA score	77	7.9±4.6	4.4±3.2	<0.000

There was a statistically significant difference in the white cell count between patients who had a justified relook and those who did not. Interestingly, the negative relook patients had a higher average white cell count (mean of 18.8 versus mean of 15.6). This was a surprising result and is discussed below..

There was a significant difference in SOFA scores between those that had a positive relook and those that did not. The mean SOFA score amongst those patients who had a justified relook was 7.98 and 4.39 in those who had a negative relook.

4.7 Predictive Values

ROC curves were constructed to determine which measured values were useful in predicting a positive relook laparotomy.



Diagonal segments are produced by ties.

Variable(s)	Area
SOFA	.782
Temp	.482
CRP	.586
White cell count	.281
Admission Apache	.531

This study found that most of the measured values are not useful in predicting a positive relook laparotomy. Based on an area under curve of 0.782, the only one that had a fair accuracy was the SOFA score.

5 Discussion

The treatment of patients with severe intraabdominal sepsis has advanced significantly in the last three decades. A large body of evidence has been published which provides good guidance for current surgical therapy.

Prior to the mid 1970s, the standard approach to patients was to perform one operation only and 'hope for the best'. Subsequently it was noted that reoperating on patients who were not doing well yielded some benefits. As a result, the use of planned relooks gained a strong foothold.

However, it was noted that a large number of these planned relooks were non-therapeutic and a policy of relook on demand was subjected to peer review. Studies showed that reoperating on-demand was safe and effective,[18,25] where the outcome for this group of patients was similar to those who had planned relooks, however the exact definition of 'on-demand' was not clear. The opinions ranged from an aggressive relook policy to a very conservative one.

Currently the decision whether to reoperate on a critically ill patient in ICU remains a significant challenge. In some patients it is a simple decision. Those who have packs left in the abdomen to enhance haemostasis clearly need to have them removed. Patients who have an anastomotic breakdown with systemic sepsis also require further surgical intervention. The challenging cases are those patients without clear signs, symptoms or special investigations. Patients may also have

many other potential sites of sepsis - such as the lungs and the urinary tract - and these may complicate decision-making by either causing the abdominal signs or masking them.

Critically ill surgical patients generally have multiple problems. Each individual clinical or biochemical abnormality may be due to more than one cause and it is notoriously difficult to tease out the relevance of each abnormality. For many surgeons the standard of care is an approach that responds to each and every doubtful situation with a relook laparotomy. This approach has merit since it removes all doubt about what is happening in the abdomen. Advocates of this approach argue that a relook laparotomy is relatively safe in today's medical environment as the dangers of anaesthesia and surgical iatrogenesis can be significantly minimised.

An opposite position states that the abdomen is not a 'black box' (where it is impossible to see what is going on inside), but that abdominal imaging is possible and, in fact, vital.[59] Just as part of the management of respiratory distress involves a chest X-ray, so too with the management of abdominal sepsis. Proponents of this approach argue that as there are so many confounding factors, imaging of the abdomen is mandatory prior to reoperation to ensure that non-abdominal pathology is excluded. Both CT scanning and ultrasound have a role in the imaging of the potentially septic abdomen, but CT scanning is usually more sensitive and specific. The caveat of this approach are the false negatives that occur with imaging. The clinician must be prepared to reoperate on a patient in the face of negative imaging should the clinical picture demand it.

The decision to transport the patient either to theatre or to the CT scanner should not be taken lightly as intra-hospital movement of a critically ill patient can be harmful. The temporary disconnection of inotropes and ventilators can lead to rapid deterioration.[60]

The care of a cohort of patients such as that of this series is complicated by the fact that multiple disciplines are involved in their management. The surgeons operate on the patients but the intensivists (primarily pulmonologists) are responsible for the detailed care of the patients. Unfortunately, there is often suboptimal communication between clinicians involved in patient care leading to delays in decision-making. This is partly due to many people doing shift work as well as the absence of formalised multidisciplinary rounds.

The setting of this study is a major referral centre for the greater Johannesburg area. Many of the sickest patients come to this ICU, and as a result, a high mortality rate is not surprising. Whilst the ICU is particularly busy, the fact that only 30 patients were accrued in little over a year was unexpected. Four patients admitted to the ICU after an emergency laparotomy were not enrolled in this study due to lack of data. Unfortunately, due to bed limitations, many patients were denied ICU beds and managed in the wards. These patients were not followed and their exact number and outcome have not been studied. This is probably a fairly substantial group and should be studied in the future.

Sixteen of the thirty patients in this study died. This mortality is high, yet is consistent with the experience with these very ill patients in other centres[21] where mortality rates ranges between 40% and 60%. The majority of the deaths were from the group of patients who had relooks, yet

when the mortality within the cases and the controls was analysed independently, there was no significant difference between these two groups. In this study, a relook laparotomy was not an independent predictor of mortality as the probability of dying after an emergency laparotomy was similar whether or not a relook was performed. This study was limited by the small size and a different conclusion might have been reached if a larger number of patients were studied.

In those patients who had relooks, the ten of the twelve deaths occurred in ICU. These patients had severe multiple organ dysfunction and intra-abdominal pathology and it is not surprising that most of these patients died before they left the ICU. Of the control patients, only one patient died in ICU and a further three died in the ward. These three deaths were due to non abdominal pathology, one from pneumonia and two from in-hospital strokes.

A large number of relooks was performed. Whilst the majority of patients had three or fewer relooks there were patients who had significantly more. Traditionally, there has been an aggressive relook policy in the Johannesburg Hospital ICU and this is reflected by the number of relooks performed.

Forty seven planned relooks were performed and less than half of them were positive. Thus our criteria for planned relooks are clearly too broad. Of the demand relooks many more were positive relative to the negative relooks and this difference was statistically significant. This poses a real challenge to the clinician. One can criticise an aggressive planned relook policy as half of the planned relooks were negative. Still, half of the planned relooks were positive. Perhaps this number could have been reduced had a policy of on-demand relook been more rigorously

implemented. A relook is obligatory if swabs are left inside the abdomen to aid haemostasis or if a damage control laparotomy was performed, but some other relooks are not necessary. This study did not look specifically at the morbidity associated with negative reoperative surgery and its effect on the patient outcome. As discussed earlier on, the literature favours a policy of relook on demand, as opposed to planned relooks. It seems reasonable to suggest that Johannesburg Hospital ICU policy needs to shift more in line with the evidence to reduce the number of negative planned relooks.

Interestingly, only three relooks were performed on the basis of imaging. As access to rapid CT scanning becomes more available, it should be used more frequently to guide surgical therapy, especially since interventional radiologists may be able to deal with many intra-abdominal complications via the percutaneous route.

The demand relooks done on clinical grounds were most likely to be positive (8/10), although this was not statistically significant. A relook is more likely to be positive if there are clear clinical signs that there is ongoing intraabdominal pathology. Unfortunately, the clinical signs are often quite gross, and cannot be used for the entire patient population where the clinical signs are often more subtle,[61] since patients in the ICU are often sedated and ventilated.

It would be most helpful if biochemical markers of sepsis could predict a positive relook laparotomy. As shown in Table 6 the C reactive protein and temperature were unhelpful in discriminating between those patients who had positive relooks and those who had negative relooks. Paradoxically, the white cell count in those who had negative relooks was higher. This is

probably not a true reflection of the value of the white cell count since it can also drop in the presence of severe sepsis and this confounds statistical analysis in this situation. Procalcitonin was very infrequently measured in this patient population, reflecting the global uncertainty of its utility.

As discussed in the literature review, organ dysfunction is a sensitive marker of ongoing sepsis. The SOFA scores in those patients who had positive relooks were statistically significantly higher than those who had negative relooks. This gives some direction as to how to predict those patients who would benefit from a relook laparotomy. Perhaps patients who have a SOFA score that is worsening, but white cell count and CRP that are normalising, should have a relook if there is concern about the abdomen. Conversely, patients elevated high inflammatory markers but resolving organ dysfunction scores should be carefully observed. The ROC curves constructed also suggest that the SOFA score has value in predicting a positive relook laparotomy. These findings are consistent with other studies.[62]

As with any scoring system in critical care, there is a need to follow a trend and to understand the status of the patient from day to day. An isolated value on a scoring system may easily be misconstrued. Current practice in most local ICUs is not to perform daily scoring of organ dysfunction. An opportunity exists to start doing this routinely to ascertain whether it aids decision making.

One of the limitations of this study is that patients were not tested for HIV as this was an observational study and no extra investigations were performed. Blood tests for HIV are not

routinely performed on our ICU patients and this data was not available for analysis. It would have been interesting to examine the relationship between relook findings, mortality and HIV positivity, as well as how the viral load influences outcome. Immune compromise may be a significant predictor of poor patient outcome.[63] The impact that AIDS has on intra-abdominal sepsis is not entirely clear.[64,65]

In this series there were no patients who died with intra-abdominal sepsis who did not have a relook. This is due to the aggressive relook policy that is currently in place within the studied ICU. Missed sepsis was not an issue in this study. In advocating a more conservative relook policy, the challenge will be to ensure that those patients with persisting sepsis receive the interventions that they require. It is also not clear whether any patients in this study died as a result of unnecessary reoperative surgery. This remains the challenge – to intervene on those patients that need therapy and not to operate unnecessarily on patients that just need time to heal.

6 Conclusion

The findings of this study are similar to the existing body of evidence. Most of the measured and observed parameters were not helpful in predicting those patients who would benefit from a relook laparotomy. The presence of more severe organ dysfunction stood out as a useful predictor of positive findings at relook laparotomy. Imaging and obvious clinical signs have a vital role in the decision making regarding these patients.

There was a large number of planned relooks in this study and more than half of them were negative. This is clearly an opportunity to refine surgical decision making as these negative operations carry both costs and the risk of harm. This study did not look specifically at morbidities associated with negative relooks such as reintubations, prolonged ICU stay, wound sepsis and immune compromise.

Consistent with the literature, the mortality in this study was very high (16 of 30 patients died). Emergency surgery that requires ICU admission carries with it a significant risk of death, independent of whether the patient has relooks or not. This continues to be a challenge for both surgeons and intensivists. Imaging was not used extensively in this study yet it remains a vital aid to decision making. The data obtained from this study suggest that fewer planned relooks should be performed. Additionally, greater emphasis should be placed on the use of trends in organ function to aid decision making.

7 Appendix

A Admission data entry form

B Daily follow up form

C Mannheim peritonitis index

D APACHE II score

E Discharge form

F Subject information sheet

G Consent – family

H Consent - patient

I Ethics Clearance

Appendix A

Relook Laparotomy Study
Admission Data Entry Form

Subject Number _____ Hospital Number _____
Age _____
Sex _____
Admission Date _____
ICU Admission Date _____

Trauma / General Surgery

Initial planned relook(s) Y / N (number_____)
Peritonitis at first operation Y / N

First operation primary source
Stomach / Duodenum / Gall Bladder / Small Bowel / Vascular / Colon / Rectum / Spleen / Liver / Abscess / Trauma(WC) / Trauma(NC) / Other
First operation aetiology
Infection / Perforation / Ischaemia / Abscess / Other_____
First operation contamination type
Turbulent / Faecal / Purulent / Clear / None / Trauma
First operation contamination extent
Diffuse / Focal / None

Admission APACHE _____
Admission SOFA _____
MPI _____

Consultant present at first operation Y / N

APACHE II on admission

Table 2 The Sequential Organ Failure Assessment (SOFA) [4]

	0	1	2	3	4
Respiratory: PaO_2/FIO_2 (mmHg)	>400	≤400	≤300	≤200[b]	≤100[b]
Renal: creatinine (mg/dl)or urine output	<1.2	1.2–1.9	2.0–3.4	3.5–4.9 or <500 ml/d	≥5.0 or <200 ml/d
Hepatic: bilirubin (mg/dl)	<1.2	1.2–1.9	2.0–5.9	6.0–11.9	≥12.0
Cardiovascular: hypotension	No hypotension	MAP <70 mmHg	Dopamine ≤5 or dobutamine (any dose)[a]	Dopamine >5 or epinephrine ≤0.1 or norepi-nephrine ≤0.1[a]	Dopamine >15 or epinephrine >0.1 or norepi nephrine >0.1[a]
Hematologic: platelet count ($\times 10^3/mm^3$)	>150	≤150	≤100	≤50	≤20
Neurologic: Glasgow Coma Score	15	13–14	10–12	6–9	<6

[a] Adrenergic agents administered for at least 1 h (doses given are in µg/kg/min)
[b] With ventilatory support

Appendix B

Relook Laparotomy Study

Patient Number _____

Hospital Number _____

Data Entry Form Day ___

Date_____

APACHE II score for last 24 hours _____
SOFA score for last 24 hours _____

Clinical Decision Criteria in last 24 hours

ClnTemp	Yes / No _____	**MODSOlig**	Yes / No _____
ClinAbdDis	Yes / No	**MODSCoag**	Yes / No _____
ClinAbdPain	Yes / No	**MODSCreat**	Yes / No _____
ClinBS	Yes / No	**MODSBili**	Yes / No _____
ClinFailure	Yes / No	**MODSLact**	Yes / No _____
ClinFistula	Yes / No	**MODSBP**	Yes / No _____
ClinIleus	Yes / No	**MODSLung**	Yes / No _____
ClinPus	Yes / No	**MODSIno**	Yes / No _____
ClinWoundInf	Yes / No	**MODSPlt**	Yes / No _____
InflamCRP	Yes / No _____	**ImgCT**	Yes / No
InflamPCT	Yes / No _____	**ImgUS**	Yes / No
InflamLowWCC	Yes / No _____	**ClnACS**	Yes / No
InflamHighWCC	Yes / No _____	**Bleed**	Yes / No
InflamGluc	Yes / No		

Relook today - Yes / No Planned / Demand
Source found at relook – Yes / No
Relook findings

Abscess / Bile leak/ Small bowel leak / Colorectal leak / Ischaemic bowel / Infected haematoma / Infected diffuse intraperitoneal fluid / serosanguinous fluid / Purulent peritonitis only / Tertiary peritonitis / No pathology found

Relook complications Yes / No _____

Apache II score 2 days post this relook_____
SOFA score 2 days post this relook_____

Table 2 The Sequential Organ Failure Assessment (SOFA) [4]

	0	1	2	3	4
Respiratory: PaO_2/FIO_2 (mmHg)	>400	≤400	≤300	≤200[b]	≤100[b]
Renal: creatinine (mg/dl)or urine output	<1.2	1.2–1.9	2.0–3.4	3.5–4.9 or <500 ml/d	≥5.0 or <200 ml/d
Hepatic: bilirubin (mg/dl)	<1.2	1.2–1.9	2.0–5.9	6.0–11.9	≥12.0
Cardiovascular: hypotension	No hypotension	MAP <70 mmHg	Dopamine ≤5 or dobutamine (any dose)[a]	Dopamine >5 or epinephrine ≤0.1 or norepi-nephrine ≤0.1[a]	Dopamine >15 or epinephrine >0.1 or norepi nephrine >0.1[a]
Hematologic: platelet count ($\times 10^3/mm^3$)	>150	≤150	≤100	≤50	≤20
Neurologic: Glasgow Coma Score	15	13–14	10–12	6–9	<6

[a] Adrenergic agents administered for at least 1 h (doses given are in µg/kg/min)
[b] With ventilatory support

Appendix C

Mannheim Peritonitis Index[40]

Risk Factor	Weighting if present
Age > 50	5
Female Sex	5
Organ Failure	7
Malignancy	4
Preoperative duration of peritonitis > 24 hours	4
Origin of sepsis not colonic	4
Diffuse generalized peritonitis	6
Exudate	
Clear	0
Cloudy, purulent	6
Faecal	12

Definitions of Organ Failure

Kidney	Creatinine >177 μmol/l
	Urea > 167 mmol/l
	Oliguria < 20ml/hr
Lung	P02 < 50 mmHg
	PCO2 > 50 mmHg
Shock	Hypodynamic or hyperdynamic
Intestinal obstruction (profound)	Paralysis >24 hours or complete ileus

Appendix D

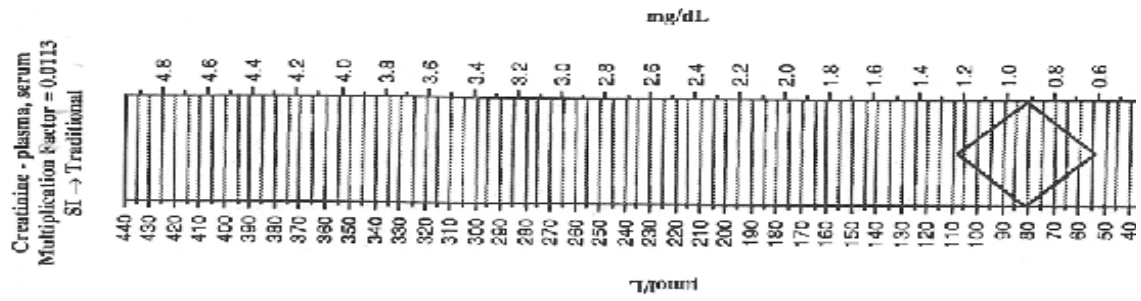
Relook Laparotomy Study
Patient Number _____
Hospital Number _____
Data Entry Form Day _____
Date_____

From reference 1:

Appendix Table 1. The APACHE II Severity of Disease Classification System

Physiologic Variable	+4	+3	+2	+1	0	+1	+2	+3	+4
Temperature—rectal (°C)	≥41	39–40.9		38.5–38.9	36–38.4	34–35.9	32–33.9	30–31.9	≤29.9
Mean arterial pressure (mm Hg)	≥160	130–159	110–129		70–109		50–69		≤49
Heart rate	≥180	140–179	110–139		70–109		55–69	40–54	≤39
Respiratory rate (nonventilated or ventilated)	≥50	35–49		25–34	12–24	10–11	6–9		≤5
Oxygenation (mm Hg) a. $FiO_2 > 0.5$ use A-aDO_2	a ≥500	350–499	200–349		<200				
b. $FiO_2 < 0.5$ use PaO_2	b				>70	61–70		55–60	<55
Arterial pH	≥7.7	7.6–7.69		7.5–7.59	7.33–7.49		7.25–7.32	7.15–7.24	<7.15
Serum sodium (mmol/L)	≥180	160–179	155–159	150–154	130–149		120–129	111–119	≤110
Serum potassium (mmol/L)	≥7	6–6.9		5.5–5.9	3.5–5.4	3–3.4	2.5–2.9		<2.5
Serum creatinine (mg/dl, Double point score for acute renal failure)	≥3.5	2–3.4	1.5–1.9		0.6–1.4		<0.6		
Hematocrit (%)	≥60		50–59.9	46–49.9	30–45.9		20–29.9		<20
White blood count (in 1000/mm^3)	≥40		20–39.9	15–19.9	3–14.9		1–2.9		<1
Glasgow-Coma-Scale (GCS)	Score = 15 minus actual GCS								
Serum HCO_3 (venous, mmol/L use if no ABGs)	≥52	41–51.9		32–40.9	22–31.9		18–21.9	15–17.9	<15
A = Total Acute Physiology Score APS	Sum of the 12 individual variable points								
B = Age Points	C = Chronic Health Points								
≤44 years 0 points	If the patient has a history of severe organ system insufficiency or is immunocompromised assign points as follows:								
45–54 years 2 points									
55–64 years 3 points	a. For nonoperative or emergency postoperative patients—5 points								
65–74 years 5 points	b. For elective postoperative patients—2 points								
≥75 years 6 points									

APACHE II: Score = Sum of A (APS points) + B (Age points) + C (Chronic Health points)



Appendix E

Relook Laparotomy Study
Patient Number_____
Hospital Number_____
ICU discharge data

Mortality Y / N

Date of ICU discharge_____
Date of death_____
Date of hospital discharge_____

Total number of relook laparotomies – planned_____
demand_____

Length of ICU stay_____
Length of hospital stay_____

Appendix F

Subject Information Sheet

Relook Laparotomy study

Dear Patient/Family member

My name is Dr Dean Lutrin. I am a surgeon in training at the Johannesburg Hospital and University of the Witwatersrand. My field of interest is abdominal infection. I am doing a study into how we as doctors can better manage abdominal infections. It is often a very difficult decision whether to take a patient who is critically ill back to the operating theatre in order to treat a possible abdominal infection. Sometimes the second operation can be life-saving and sometimes may not be beneficial. The study that is being done will be looking at how we make the decision to perform a second operation on patients.

You or a member of your family is very sick. I am interested in checking the hospital records to see how the decision was made to treat the patient. If you agree to be included in this study, I need your permission to look at these records and analyse the information for the patient. There will be no change to care of the patient. The study will look at how the decision is made to re-operate on the patient and see whether an accurate decision was made.

By choosing to participate in this study you will help us better understand a very complicated problem. You will not receive any benefit by agreeing to participate in this study but future patients may benefit. If you choose not to participate in this study there will be no disadvantage to you. There will be no change to the way the patient will be treated but we will not use the hospital records for the patient. If you choose not to be involved you will still receive the best care available.

All details will remain completely confidential. Your/The patient’s name would not be used and information will be recorded with a patient number. We would only be interested in the average of all the patients, not the single patient.

Your participation in the study would be greatly appreciated. If you have any questions please feel free to contact me anytime on 083-377-6095.

Thank you
Dr Dean Lutrin

Appendix G

RELOOK LAPAROTOMY STUDY

INFORMED CONSENT STATEMENT

I have read and understand the subject information sheet. ☐

I have had an opportunity to ask questions ☐

I agree to participation in this study ☐

I understand that there are no positive or negative consequences to participating in this study ☐

I understand that all information is confidential ☐

I understand that once my relative is capable of making decisions him or herself, he or she will choose whether to participate in the study. ☐

If you choose not to be involved you will still receive the best care available

_____ _____
Signature of family member / authorised representative Date

_____
Hospital number of patient

Appendix H

RELOOK LAPAROTOMY STUDY

INFORMED CONSENT STATEMENT

I have read and understand the subject information sheet. ☐

I have had an opportunity to ask questions ☐

I agree to participation in this study ☐

I understand that there are no positive or negative consequences to participating in this study ☐

I understand that all information is confidential ☐

If you choose not to be involved you will still receive the best care available

_____ _____

Signature of patient Date

_____

Hospital number of patient

Appendix I

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Lutrin

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M050433**
PROJECT	An Assessment of the Accuracy of Decision Criteria Used to Determine the Need for Relook Laparotomy in ICU.....
INVESTIGATORS	Dr D Lutrin
DEPARTMENT	Surgery
DATE CONSIDERED	05.04.29
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 05.05.20 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Dr R Britz

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10005, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

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