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Master of Medicine in General Surgery



Surgical resources: an observational study of suture material use and cost in three general surgery units in Gauteng South Africa

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DECLARATION

I Brooke Puttergill the primary author declare that the contents of this MMED entitled: Surgical resources: Suture material use and cost in three general surgery units in Gauteng South Africa- is original work and recognises the work in this field done by preceding researchers as appropriately referenced.



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The staff of the study institutions in the relevant departments

Conrad Viedge

I dedicate this work to Julian and Austen.

ABSTRACT

Introduction: Surgical systems are integral to successful, safe and cost effective clinical practice and must balance surgical demands on consumable items and their costs. Suture material is a key consumable resource, and will be evaluated as a surrogate for consumable use and cost as well as the procurement systems within the South African public health care sector.

Aims: To determine suture use and cost in four commonest general surgical procedures - abdominal wall closure, mastectomy, appendicectomy and inguinal hernia repair - in three academic Gauteng hospitals.

Methods: A prospective observational study. Suture use was documented by the surgeon at the time of the procedure and qualitative investigation at relevant hospital departments determined suture material procurement and expenditure. A descriptive analysis was completed.

Results: The surgeons documented in three facilities consistent use of material type and average number of units used; availability of appropriate material and breakage of generic material intraoperatively were identified by surgeons to be problematic. There is no consistent and consolidated electronic record keeping of suture stock and cost in all three hospitals therefore cost of suture material used was not obtainable in any of the facilities.

Discussion: Generic suture material quality is not optimal and may have adverse implications for patient health, healthcare costs and budgets through procedure related complications. There is a lack of communication between the financial management, procurement officers, hospital and theatre stores and theatre staff; therefore I suggest that clinical protocols and system-based strategies be put in place to manage surgical consumables.

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Suture material use, availability and performance in four common General Surgical procedures in three Gauteng Academic Hospitals

LIST OF ABBREVIATIONS:

CHBH Chris Hani Baragwanath Hospital

CMJAH Charlotte Maxeke Johannesburg Academic Hospital

H1 Hospital 1

H2 Hospital 2

H3 Hospital 3

HJ Helen Joseph Hospital

HREC Human research Ethics Committee

PDS Polydiaxanone

PGA Polyglycolic acid

WHO World Health Organisation

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1. Background

1.1 Introduction

The World Health Organisation (WHO) defines a health system as a service delivering quality of care to a population's specific needs; elaborated this includes the necessary concepts of 'robust financial mechanisms, reliable information to base decision and policy and logistics to ensure the delivery of service'.[1] This study was designed to illustrate these principles within our public surgical health care system using suture material as a surrogate for the system structure that exists at a clinical and administration level.

Sutures, or wound closure biomaterials, are an irreplaceable tool in a surgeon's technical repertoire, existing in society from as early as 3000 BC [2] - long before the formal institution of surgical practice. An ideal suture is expected to combine strength, ease of handling and formation of secure knots with minimal inflammation, post-operative infection and/or subsequent complication. With increasing surgical technology many modern bonding materials have been developed such as staples and glue, however no material has surpassed traditional suture materials in clinical practice. This discussion will evaluate suture material - a surgical biomaterial: a tool for a surgeon and optimal material with application to surgical patient/disease.

There is a wide range of natural and synthetic suture materials that differ in structure and consequently have differing strengths, durability and rates of degradation. Although suture materials are mechanically evaluated by manufacturers with regards to their mechanistic quality and in-vivo usage, there is little published literature that standardises suture material use in general surgical procedures. This may be due to surgeon input, variability in technique

and consideration for the primary outcome of the operation. Therefore this literature review considers studies that illustrate the proposed concepts.

1.2 Classification of sutures

Sutures are classified by the United States of America Pharmacopoeia.[2] The simplest classification defines sutures as absorbable or non-absorbable sutures. Common absorbable sutures include vicryl, vicryl rapide, polydioxanone (PDS®), monocryl and chromic. Common non-absorbable sutures include nylon, prolene, silk and steel. The structure of the material is further characterised as either natural or synthetic, and the nature of the thread is characterised as monofilament, polyfilament, braided or unbraided.[3] The thread is sized 0 to 11/0 largest to smallest diameter, respectively, and can be threaded to a variety of needles, accommodating use within various tissues; therefore the body and point of the needle can vary accordingly.[2] Table 1 and 2 classify the absorbable and non-absorbable sutures, respectively, the latter of which are either encapsulated into connective tissue or remain non-absorbable .[4]

Table 1: Absorbable Suture Classification [4]

Absorbable suture	**Raw Material**	**Absorption average**
Surgical gut (including chromic)	Sub mucosa sheep intestine and serosa of beef intestine	Strength reduction 7-28 days Complete at 70 days
Polyglactin 910 VICRYL® • Coated • Uncoated (antibiotic) • Rapid	Copolymer of glucolide and lactide with polyglactin 370 and calcium stearate if coated	Within proteolytic digestive enzymes 50-70 days (vicryl rapide® within 42 days)
Polyglycolic acid (PGA CliniSorb®)	Homopolymer glycolide	
Poliglecaprone 25 MONOCRYL®	Copolymer of glycolide and epsilon-caprolactone	91-119 days
Polyglyconate MAXON®	Copolymer of glycolide and trimethylene carbonate	
Polydioxanone PDS®	Polyester of Poly (p-diaxanone)	Within 6 months

Table 2: Non-Absorbable Suture Classification [4]

Non-absorbable sutures	**Raw Material**
Surgical silk	Spun silk
Stainless steel	Iron-chromium-nickel-molybdenum alloy
Nylon	Polyamide polymer
Polypropylene (Prolene®)	Polymer of propylene
Poly (hexaflouropropylene-VDF) PRONOVA®	Polymer of poly(vinylidene flouride and cohexaflouropropylene)
Polyester ETHIBOND®	Polymer of polyethylene terephthalate
Gore-tex®	Polytetrefluroethylene

1.3 Procedure-specific applications

Suture material is one of the oldest surgical technologies, therefore one would assume it has specified applications in procedures to attain the best possible outcomes; yet when reviewing the literature there is little conclusive data to guide practice and resource management of suture materials, possibly due to the multitude of variables that affect outcomes of surgical practice as well as the lack of randomised control trials. [5]

An example of this is that current data regarding abdominal wall closure following laparotomy suggests using a non-absorbable continuous suture, however higher complication rates of sinus development and pain are reported with this material compared to absorbable suture materials.[6-7] Even from this well-conducted meta-analysis it is still hard to define the optimal suture to use for abdominal wall closure, one of the most common general surgical closures. Furthermore, it is important to know what is currently being practised in order to determine if change needs to occur and to promote advancement in technique and training within a facility, as well as to reduce complications. Incisional hernias remain a significant complication of abdominal wound closure regardless of optimal technique and suture material use; therefore reinforcing the need to identify suture use and practice for abdominal wall closure within a general surgical facility. [7]

Knowing whether the outcomes of various suture materials for a particular procedure is patient-, operation- and post-operative course-related can be difficult to differentiate and hence specific associations between suture use and outcome are difficult to define. Animal studies performed under controlled environments can be important in understanding materials better as illustrated by a study investigating intestinal anastomosis in rodents.[8] Outcomes favoured smoother monofilament sutures, such as polydiaxone (PDS®); this method of trial enables the investigator to define primary and secondary outcomes on biological and physiological processes that occur at tissue level post suturing. [9] This is replicated data from

as early as the 1980's when monofilament sutures were used for bowel anastomosis because they lack bacterial adherence, are slower to reabsorb and have improved handling through delicate visceral tissues. [10]

In obstetrics and gynaecology evidence for two common procedures have yielded different results in the ability to address procedure application for suture material. In uterine closure data regarding suture material choice, use and implication thereof is inconclusive; however for tissue closure of the perineum, Vicryl®, a soft, absorbable suture with little inflammatory response and easy handling is preferred, achieving desired procedure outcome and comfort for the patient. These two contrasting findings illustrate that studies to determine suture material use are valuable for the clinician and patient but procedural dependant.[11]

Surgical departments have to assess their procedure, type, volume and suture application in order to identify consistent use of suture materials in order to develop procedure and stock protocols as accurate clinical data to improve clinical service and procurement systems and cost efficiencies.

1.4 Complications as a result of suture material

Further considerations are complications as a result of inappropriate suture material choice; these include infection, foreign body granuloma, wound dehiscence, anastomostic breakdown, breakage and incisional hernia development.

Antimicrobial-coated suture materials such as Vicryl Plus® have been developed to reduce infection; however the effectiveness of this antimicrobial coating failed to reduce infection at the post-appendicectomy surgical site when compared to uncoated sutures. In this study infection was most commonly associated with a contaminated surgical field from perforated appendicitis.[12] This latter study highlights the impact of the disease itself causing higher infection rates regardless of suture material choice.

Historically, studies have shown that newer synthetic suture materials result in fewer post-operative complications, specifically infection and fistulae, when compared with older suture materials for procedures such as abdominal wound closures and visceral surgery.[13]

When considering incisional hernias, a well recognised complication of abdominal laparotomy, suture technique and biomaterial use play significant roles in the development of this complication. Comparisons between rapidly and slowly absorbable sutures show polydioxanone (PDS®) to be superior to Vicryl® with regards to incisional hernia and recurrence after abdominal sheath closure. However a recent multicentre randomized trial demonstrated that the optimal suture for abdominal wall closure remains undefined.[7]

In addition to suturing complications, the cosmetic result of skin closure is often a significant consideration as the aesthetic outcome is of relevance in a patient's perception of post-operative success. Sockly et al. illustrated that wound closure could result in significant patient morbidity following poor suturing technique with inappropriately chosen suture materials. [13]

1.5 Resource management of sutures

Suture material is a consumable resource and therefore it is important to identify the processes governing the management of this resource within our environment. Current South African Government goals for healthcare include improving the effectiveness of the healthcare system. [13] In a general surgery department, suture material is a readily accessible variable to evaluate the use, cost and management/procurement system. Characterisation of one such resource could form a basic model which could possibly be used to introduce standardisation systems for surgical resources in alignment with clinical practice and healthcare reform, and thereby '*improving resource mobilization and the management*

without neglecting the attainment of equity in resource allocation' as defined by Gauteng Health. [14]

The majority of literature available on surgical resource management is derived from international data. During the period 1976-2003, a financial audit across Canadian healthcare services reported that designated expenditure on medical resources increased from 2.9% to 6% of total expenditure in healthcare. Surgical costs of resources amounted to near 50% of medical supplies expenditure. [15] An appreciable portion of all healthcare budgets are allocated to disposable resources. In the 2011/2012 financial year, the South African Department of Health had a budget of R 25,2 billion [16] and if the above figures can at all be extrapolated to South Africa, a significant amount of money will be budgeted for resources. However, and regardless of the magnitude of the budget for surgical resources in South Africa, appropriate allocation and optimal expenditure of such resources can only be achieved if an effort is made to establish material usage and basis of decision making.

1.6 Conclusion

In conclusion, with the increasing economic pressures and consequent need for management protocols for resources it is important to define the use, management and cost of suture materials within surgical departments. This will enable us to develop appropriate procedures for resource management in alignment with surgical and facility requirements, keeping both surgeon and administrator happy and, ultimately, resulting in effective surgical care for patients whilst advancing surgical practice through appropriate resource use. Therefore, this study aims to define the current surgical practice by determining the suture choice for specific surgical procedures and the procurement of these suture materials.

1.7 Study development and limitation

Through investigation of costs of suture material in the study facilities it became apparent to the investigator that because of the lack of electronic platforms used in the management of consumables it was difficult to obtain costing data from administrative departments. Information was dependant on verbal interviews and staff obtaining data from incomplete electronic and paper based records. The system of procurement and management of material was different in each facility therefore during investigation data was difficult to obtain due to the variable complexities in each administrative structure.

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MANUSCRIPT SUBMISSION AND GUIDELINES

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http://www.samj.org.za/index.php/samj/about/submissions

LETTER TO EDITOR

7 September 2016

Dear Editor,

Please find attached my submission to your journal entitled, *Surgical resources: An observational study of suture use and cost in three general surgery units in Gauteng South Africa.*

Our submission for publication in your journal is due to the journal's coverage of not only clinical work but it also encompasses public health and service related issues. Our research assesses the function of a surgical system in the public health sector illustrating the clinical and procurement/administrative systems that manage consumable resources; highlighting several areas within which service delivery may be streamlined and made more effective, both with patient and cost effectiveness outcomes; information not yet available (assessed) in our public health care facilities.

Kind Regards

Dr Brooke Puttergill

Surgical resources: an observational study of suture use and cost in three general surgery units in Gauteng South Africa.

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INTRODUCTION

Quality of medical care has been defined as 'the degree to which health services for individuals and populations increase the likelihood of desired health outcomes'. [1, 2] To this end the Lancet Commission on Global Surgery and World Health Organisation (WHO) surgical service guidelines recognise that efficient, cost effective systems and clinical protocols are important if improved surgical access and care is to be achieved in developing countries.[3,4] One aspect of this strategy is to improve resource management through cost containment procurement systems development without compromising clinical standards; a relevant factor in South Africa's financial and resource constrained developing public healthcare sector.

One such system is the efficient provision of consumable surgical items that meet clinical demands and international product standards; and as suture material has been integral to surgical practice for more than 5000 years it is an inherently central consumable. Even though numerous studies have evaluated various suture materials there is no standardised material for use in specific procedures as they are unable to control for disease-, patient- and care-dependant variables. As a result use of material is usually empirical and based on habit and personal preferences. [5-8] Consequently a wide variety of suture materials must be on hand in a busy operating facility to accommodate a wide range of requests by individual surgeons due to a lack of protocols. These large quantities of suture materials may not be cost-effective and can be unwieldy to manage.

To date no South African study has investigated surgical consumable resources and the systems that governs the provision, costs and clinical use thereof. The lack of protocols for use of consumables or evidence of the systems that govern the provision of stock and costs to

surgical departments in South Africa; may hinder improvement of ineffective systems and poor clinical outcomes. The aim of this study was therefore to evaluate the use of suture material as a surrogate marker for surgical consumables in use at clinical level and its costs through understanding procurement and managing this resource for common general surgical procedures in three Gauteng academic hospitals.

METHODS

A prospective observational study was approved by University of Witwatersrand Human Research Ethics Committee (M111127), to determine suture use in the four most common surgical registrar training procedures [9], and the cost of these suture materials.

Three academic facilities within the Public sector of Gauteng were the study sites and will be described as case studies and referred to as hospital 1, 2 and 3 (H1-H3).

Surgeons completed a questionnaire following abdominal wall closure at laparotomy, mastectomy, appendicectomy or inguinal hernia repair. Information included hospital, procedure, suture material type, needle type, suture size, brand, quantity used and user satisfaction. Satisfaction was defined by the availability/ non-availability of the primary choice of suture material and whether or not it broke. Cost involved collection of procurement data through qualitative investigation and quantitative data collection at the procurement and financial departments, hospital and theatre stock rooms at each hospital.

Statistical analysis

Descriptive statistics were used in the analyses using SAS version 9.4. The qualitative information obtained from the costing departments was combined by the investigators to provide an evaluation of cost based on stock and procurement mechanisms of each hospital.

RESULTS

Suture material usage, availability and performance

The data collection was completed over a 12 month period. 203 datasheets detailing operative use of suture material was collected (85% response rate) with a 75% completion rate. The three hospitals contributed equally to the study with 71, 66 and 66 procedures from H1, H2 and H3, respectively. Suture material use, availability and breakage for each procedure at each hospital are provided in Table 1.

Of the 203 cases, on 53 occasions (26%) surgeons reported suture materials were either unavailable or evaluated to be of inferior quality; the most commonly cited issue was no stock of the preferred material in 37 cases (18%). Suture availability and performance was reported as adequate in appendicectomy and inguinal hernia repair as opposed to abdominal wall closure and mastectomy. During abdominal wall closure in 46.6% of cases, surgeons were not satisfied with the type of suture available. 67% used a generic product but were only satisfied in 52% of cases with this material; compared to 33% use of a branded product with 73% satisfaction when using this material(P value = 0.06). For mastectomy procedures generic product made up 52% of suture product used. Intraoperative suture material breakages occurred with 12 units (5%) of material, six during abdominal wall closures and six during mastectomy, all occurred with generic suture use.

Suture material procurement and cost

There is no consistent electronic method of consolidation of suture stock information from the clinical level up to the procurement, stock control/receiving and the finance departments in all three hospitals; with differences in categorization of suture material in procurement and financial departments. Cost data of specific suture material for procedures is not obtainable in

any of the facilities. The information attained for the stock management and costing system at each hospital is described below.

H1 operating theatres order suture materials directly from the Procurement Department, stock is delivered directly to theatre, with no handling in the Hospital Stores Department. The quantity of stock received is not recorded centrally, nor is its use. The Procurement Department orders stock on a monthly basis; no consolidation of annual volumes of individually ordered items is recorded. The finance department was able to supply annual suture material expenditure for 3 years from 2011-2013 and were as follows: R7, 691,951.93, R 14,287,362.48 and R6, 641,681.29, respectively. In 2012 a debt previously contracted and now included as paid inflated the figure in that year. It is not possible to state what the exact suture material usage and cost is from these figures.

At H2 some suture material stock is held as dry stock in the Stores Department and other suture material is ordered in a 'buy out' (purchase and delivery of non tender items) manner. At H2 'buy out' in the theatre complex included most of the suture material types used in this study and this material is delivered directly to the theatre. No electronic records are kept of volumes of suture materials used, ordered or received. The dry stores, which hold a minimum required volume of suture material, recorded items ordered, received and distributed. The only readily available costs were for 2 years from the dry stores and were R603, 559.00 for 2011 and R272, 638.00 for 2012. The cost of 'buy outs' (which include regularly used material in general surgical procedures) was not available.

In H3 the theatre stores department is responsible for ordering suture material, a completely paper based system. Orders are placed and processed in the Theatre Complex store room, then sent to the Procurement Department. Once the ordered stock arrives it is registered at Main Stores but not itemised and is subsequently delivered to the Theatre Stores. There is no electronic record of residual stock or rate of suture use in the theatre stores department.

Suture material costs are not available for individual items in the study years. For H3 the suture material expenditure for two the consecutive years 2012 and 2013 was R9, 097,308 and R15, 744,915 respectively, these figures include debt roll over and actual suture material cost cannot be deduced.

DISCUSSION

This study investigated suture material use, cost and ultimately procurement systems as a surrogate marker of how consumables are used and ordered in three Gauteng academic hospitals. A key consumable resource in surgery department armamentarium is suture material; despite many innovations, no technique has yet surpassed the suture in its scope of application or functional durability. [5] Our findings demonstrated that there was consistent use of suture type and unit volume, although there were concerns of quality and handling with generic materials, and failure to cost suture material in these procedures.

The implications of using of defective material for abdominal sheath closure are well documented; abdominal sheath dehiscence that has a 34-44% mortality rate [10] and dehiscence results in an incisional hernia rate of 40-60% which has its own morbidities. In 2012 approximately 11 500 general surgical procedures were performed: 3500 in H1, 1500 in H2 and 6500 in H3. Hospital cost following prolonged hospitalization and long term economic and quality of life implications for the patient are further considerations that outweigh costs discrepancies between superior and inferior material.

Impaired flow of information, either as feedback or feed forward, is a key feature of dysfunctional healthcare organizations, with partial systems and executive dissociation further hindering processes designed to enable efficient health care [11]; as well as fracturing

organisations into independent components instead of functioning as a 'whole' [12]. All of these problems are illustrated by the procurement processes of each hospital.

In the 2012 financial year the national Department of Health budget was R125.2 billion; all medical supplies (consumable materials) were budgeted at R112.4 million in 2012[13-14]. The cost of suture material ordered in 2012 as obtained in this study was R23 657 308, which would amount to 48% of the national budget for medical supplies; international literature on expenditure documents an average expenditure on surgical consumables at 2%. [15, 16] The appropriate allocation and use of financial budgets can only be achieved through meticulous processes that control the recording of stock use and ordering in a hospital. These currently do not exist within the study hospitals.

This study has shown that the choice of suture material in clinical practice is not protocol driven despite consistent clinical use as described in this study. Protocols may facilitate improved handling of suture materials as a consumable stock item through accurate procurement of quality materials in appropriate quantities. Generic suture material quality is not optimal and may have adverse implications for patient health, healthcare costs and budgets. Finally, there is a lack of communication between the clinical, financial management, procurement officers, hospital and theatre stores, and theatre staff in this surgical system. Based on this information we suggest that protocols and system-based strategies be put in place to manage surgical consumables ultimately to enable safe and cost-effective clinical practice.

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TABLE 1. **Suture material use, availability and performance in four common General Surgical procedures in three Gauteng Academic Hospitals**

Procedure	**Suture Material**	**Number of procedures & suture material**			
		Total	**H 1**	**H2**	**H 3**
Abdominal Wall Closure	Number of Procedures	**60**	**20**	**20**	**20**
	Number of suture materials	83	27	29	27
	Polydiaxone Looped	38	11	16	11
	Polydiaxone 1	22	10	2	10
	Polyglactin 2/0	17	6	8	3
	Polyamide Polymer 1	6	0	3	3
	% use of Local brand	67%	15%	90%	95%
	% use of Proprietary brand	33%	75%	10%	10%
	Satisfied with availability	47%	75%	25%	50%
	Breakages	7%	0	0	22%
Mastectomy	Number of Procedures	**60**	**20**	**20**	**20**
	Number of suture materials	160	51	43	66
Skin	Polyglecaperone 3/0	42	20	0	22
	Staples	21	0	20	1
Fascia	Polyglactin 2/0	81	28	14	39
Drain	Polyamide Polymer 1	10	0	6	4
	Silk	6	3	3	0
	% use of Local brand	52%	50%	80%	25%
	% use of Proprietary brand	48%	50%	20%	75%
	Satisfied with availability and performance	88%	75%	85%	75%
	Breakages	4%	0	4%	6%

Appendicectomy	Number of Procedures	**50**	**17**	**15**	**18**
	Number of suture materials	90	36	21	29
	Polyglactin 2/0	34	17	6	11
	Polyglactin 3/0	22	7	8	7
	Polydiaxone 1	9	2	0	3
	Polyglecaperone 3/0	13	9	2	2
	Polyamide Polymer 3/0	12	1	5	6
	% use of Local brand	54%	44%	80%	41%
	% use of Proprietary brand	26%	39%	13%	18%
	% use of Unknown Brand	20%	17%	7%	41%
	Satisfied with availability and performance	90%	89%	80%	88%
	Breakages	0	0	0	0
Inguinal Hernia	Number of Procedures	**33**	**14**	**11**	**8**
	Number of suture materials	86	47	21	18
	Polypropylene 2/0	26	11	7	8
	Polypropylene3/0	7	7	0	0
	Polydiaxone	14	5	9	0
	Polyglactin 2/0	21	16	2	3
	Polyglecaperone 3/0	18	8	3	7
	% use of Local brand	59%	26%	99%	63%
	% use of Proprietary brand	32%	74%	0%	12%
	% use Unknown brand	9%	0%	1%	25%
	Satisfied with availability and performance	88%	44%	18%	26%
	Breakages	0	0	0	0

6.1



MMED PROTOCOL 2011

Surgical resources: An observational study of suture material use and cost in three general surgery units in Gauteng, South Africa

Dr Brooke Puttergill

MBBCh WITS

Supervisors:

Professor Martin G Veller

Dr Deirdré Kruger

Department of General Surgery

University of the Witwatersrand Johannesburg South Africa

Abstract

Sutures are one of the oldest surgical technologies existing in society from as early as 3000 BC and currently there is a wide range of suture materials classified by the United States Pharmacopeia (1). Within the healthcare environment suture materials are: a tool for a surgeon with procedure specific applications, an optimal material for patient/disease to attain healing with minimal associated complications and a health facility resource requiring appropriate management and budget allocations. Therefore the objectives are: to identify the sutures used during the following general surgery procedures: 1) abdominal wall closure 2) appendectomy 3) mastectomy and 4) inguinal hernia repair; and to identify the established processes in the management of suture material stock and procurement expenditure. The data will be obtained with hospital CEO approval in the General Surgery theatres of the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), the Chris Hani Baragwanath Academic Hospital (CHBAH) and the Helen Joseph Hospital (HJ) over duration of a month per facility in 4 consecutive months. Quantification of suture use is by means of data collection from a data sheet completed at the time of procedure. This study will also entail an interview to determine expenditure on suture materials determined through an interview with the procurement and finance department. The anonymous quantitative data from the data sheet will be captured into Excel for analysis and further statistical analysis will be by use of Statistica as appropriate. In conclusion, with the increasing economic pressures and consequent need for rationale of resources; it is important to define the use and cost of suture materials within the surgical departments.

Background

Sutures, or wound closure biomaterials, are an irreplaceable tool in a surgeon's technical repertoire, existing in society from as early as 3000 BC (1) - long before the formal institution of surgical practice. An ideal suture is expected to combine strength, ease of handling and formation of secure knots with minimal inflammation, post-operative infection and/or subsequent complication. With increasing surgical technology many newer bonding materials have been developed, such as staples and glue, however no material has surpassed the handling, application and functional durability of a traditional suture. This discussion will evaluate suture material - a surgical biomaterial: a tool for a surgeon, an optimal material for patient/disease and a health facility resource.

There is a wide range of suture materials that differ in natural and synthetic structure and, consequently, they have different strength, durability and subsequent degradation. They are used to oppose different tissues in the vast extent of general surgical procedures. Although suture materials are mechanically evaluated by manufacturers with regards to their quality and in vivo usage, there is not much published literature that broadly standardises suture material application in general surgical procedures. This could be due to surgeon input, variability in technique and consideration for the primary outcome of the operation. Therefore this literature review considers articles that illustrate the proposed concepts yet cannot cover the enormity of data for each surgical procedure. Although the trend to use newer synthetic materials over traditional biologic materials is apparent, due to reduced immunogenicity and associated post operative infections (1).

Classification of sutures:

Sutures are classified by the United States Pharmacopeia (1) and, in the broadest classification, are defined as absorbable or non-absorbable sutures. Common absorbable sutures include vicryl, vicryl rapide, polydioxanone (PDS), monocryl and chromic. Common non-absorbable sutures include nylon, prolene, steel and silk. The structure of the material is further characterised as either natural or synthetic, and the nature of the thread is characterised as monofilament, polyfilament, braided or unbraided (1). The thread is sized 0 to 11/0 largest to smallest diameter, respectively, and can be threaded to a variety of needles, accommodating use within various tissues; therefore the body and point of the needle can vary accordingly (1). Table 1 and 2 classify the absorbable and non-absorbable sutures, respectively, the latter of which are either encapsulated into connective tissue or remain non-absorbable (3).

Table 1: Absorbable Suture Classification (3)

Absorbable suture	**Raw Material**	**Absorption average**
Surgical gut (including chromic)	Submucosa sheep intestine and serosa of beef intestine	
Polyglactin 910 VICRYL • Coated • Uncoated (antibiotic) • Rapid	Copolymer of glucolide and lactide with polyglactin 370 and calcium stearate if coated	Within proteolytic digestive enzymes (vicryl rapide within 42 days)
Polyglycolic acid (PGA CliniSorb)	Homopolymer glycolide	
Poliglecaprone 25	Copolymer of glycolide and epsilon-	91-119 days

MONOCRYL	caprolactone	
Polyglyconate MAXON	Copolymer of glycolide and trimethylene carbonate	
Polydioxanone PDS	Polyester of Poly (p-diaxanone0	Within 6 months

Table 2: Non-Absorbable Suture Classification (3)

Non-absorbable sutures	**Raw Material**
Surgical silk	Spun silk
Stainless steel	Iron-chromium-nickel-molybdenum alloy
Nylon	Polyamide polymer
Polypropylene (Prolene)	Polymer of propylene
Poly (hexaflouropropylene-VDF) PRONOVA	Polymer of poly(vinylidene flouride and cohexaflouropropylene)
Polyester ETHIBOND	Polymer of polyethylene terephthalate

Procedure-specific applications:

Suture material is one of the oldest surgical technologies, therefore one would assume it has specified applications in procedures to attain the best possible outcomes; yet when reviewing the data on sutures there is little conclusive data to guide practice and resource management of suture materials, possibly due to 1) the multitude of variables impacting on the outcomes of surgical practice and 2) the lack of comparable randomised control trials (4).

To illustrate; current data on abdominal wall closure after laparotomy suggests a non-absorbable continuous suture, without specifying which non-absorbable product to be ideal. However, higher complication rates of sinus development and pain are reported with this

material when compared to absorbable suture materials (5-6). Even from this well-reviewed meta-analysis it is still hard to define the optimal suture to use for abdominal wall closure, one of the most common general surgical closures. However, it is important to know what is currently being practiced in order to determine if change needs to occur and to promote advancement in technique and training within a facility and to reduce complications. Also, incisional hernias remain a high complication of abdominal wound closure regardless of optimal technique and suture material use according to current data; therefore strengthening the need to identify suture use and practice for abdominal wall closure within a general surgical facility (6).

The difficulty in knowing the outcome of various sutures for a particular procedure is patient-, operation- and post-operative course-related, therefore associations between suture use and outcome are difficult to define. Studies done on animals in well controlled environments may bear importance for understanding materials better as illustrated by a study on intestinal anastomosis in rodents (7). Outcomes favoured smoother monofilament sutures, such as polydiaxone (PDS); this method of trial enables the investigator to define primary and secondary outcomes on biological and physiological processes that occur at tissue level post suturing (8). This is replicated data from as early as the 1980's when monofilament sutures were favoured for bowel anastomosis, for lack of bacterial adherence, non absorbable and improved handling through delicate visceral tissues (9).

Within another surgical discipline, obstetrics and gynaecology, a well-formulated article on suture material use identified two key procedures in which there is a differing level of evidence. Firstly for uterine closure, a common obstetric and gynaecological surgical procedure, there is poor data on suture material choice, use and implication thereof; as outlined by Chocrane collaboration 2009. However it was further discussed that there are well researched procedure specific suture applications, such as tissue closure for the

perineum, in which- vicryl- a soft, absorbable suture with little inflammatory response is preferably used for handling by surgeon, achieveing desired procedure outcome and comfort for the patient. Therefore these two contrasting findings illustrate that studies to determine suture material use is valuable for clinician and patient. (10)

Complications from sutures:

A further consideration is complications from inappropriate suture material choice; such as: infection, foreign body granuloma, wound dehiscence, anastomostic breakdown, breakage and subsequent incisional hernia development.

Antimicrobial-coated suture materials, such as VICRYL plus, have been developed to reduce infection, however the effectiveness of this antimicrobial coating failed to reduce infection at the post-appendectomy surgical site when compared to uncoated sutures; infection was most commonly associated with a contaminated surgical field from advanced perforated appendicitis (11). This latter study highlights the impact of the condition itself in causing higher infection rates regardless of the suture choice.

Historically, studies have shown that newer synthetic suture materials result in fewer post-operative complications, specifically infections and fistulae, compared with older suture materials for procedures such as abdominal wound closures and visceral surgery (12).

When considering the example of incisional hernias, a well recognised complication of abdominal laparotomy, suture technique and biomaterial use play significant roles in the development of such a complication. Comparisons between late and early absorbable sutures show polydioxanone (PDS) to be superior to vicryl with regards to incisional hernia complication and recurrence in abdominal sheath closure. However, it is clear from a recent multicentre randomized trial that the optimal suture for abdominal wall closure remains undefined (6).

In addition to suturing complications, the cosmetic result of a skin closure is often a significant consideration as the aesthetic outcome is of utmost relevance in a patient's perception of post-operative success. Sockly et al. (1987) illustrated in their study that wound closure could result in significant patient morbidity following poor suturing technique with inappropriately chosen suture materials (13).

Resource management of sutures:

Suture material is a consumable resource and therefore it is important to identify the processes governing the management of this resource within our environment. Current South African Government goals for healthcare include improving the effectiveness of the healthcare system (14). In the general surgery department, suture material is a readily accessible variable to evaluate the use, cost and management thereof. Characterisation of one such resource could form a basic model which could possibly be used to introduce standardisation systems for surgical resources in alignment with clinical practice and healthcare reform, and thereby '*improving resource mobilization and the management without neglecting the attainment of equity in resource allocation*' as defined by Gauteng Health (14).

The majority of literature available on surgical resource management is derived from international data. During the period 1976-2003, a financial audit across Canadian healthcare services reported that designated expenditure on medical resources increased from 2.9% to 6% of total expenditure in healthcare. Surgical costs of resources amounted to near 50% of medical supplies expenditure (15). A recent audit of medical devices from an Italian facility determined suture materials to be 2.85% of expenditure for medical devices (16). Also noted were economic differences between suture types, as suture material has a variable cost implication based on type and quantity used (16). It can be concluded that a significant

portion of all healthcare budgets are allocated to disposable resources. In the 2011/2012 financial year, the South African Department of Health has a budget of R 25,2 billion (17) and if the above figures can at all be extrapolated to South Africa, a significant amount of money will be budgeted for resources. However, and regardless of the magnitude of the budget for surgical resources in South Africa, appropriate allocation and optimal expenditure of such resources can only be achieved if an effort is made to establish material usage and basis of decision making.

In conclusion, with the increasing economic pressures and consequent need for management protocols for resources it is important to define the use, management and cost of suture materials within the surgical departments. This will enable us to develop appropriate procedures for resource management in alignment with surgical and facility requirements, keeping both surgeon and administrator happy and, ultimately, resulting in effective surgical care for patients whilst advancing surgical practice through appropriate resource use. Therefore, this study aims to define the current surgical practice by determining the suture choice for specific surgical procedures.

Objectives

For the duration of a four month period in the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), the Chris Hani Baragwanath Academic Hospital (CHBAH) and the Helen Joseph Hospital (HJ), the objectives of this study are:

1. To identify the sutures used during the following surgery procedures: 1) abdominal wall closure 2) appendectomy 3) mastectomy 4) inguinal hernia repair

2. To identify the establish expenditure for each hospital.
3. To compare the differences in suture material use and expenditure between the three central Gauteng hospitals.

Study design and Methods

This is a prospective, observational study investigating the suture material choice and use for common surgical procedures performed over a period of 1 month in 3 Gauteng Teaching Hospitals' General Surgery Departments. The 3 mentioned study sites are: CMJAH General Surgery theatre complex; HJ General Surgery theatre complex and CHBAH General Surgery theatre complex.

A variety of common surgical procedures, which may broadly identify the use of suture material within a department, were identified from the final general surgical logbooks of training registrars of the University of the Witwatersrand General Surgery Department. These procedures include (in no specific order): 1) abdominal wall closure 2) appendectomy 3) mastectomy and 4) inguinal hernia repair.

The numbers needed in this study is suture material use for 20 non consecutive cases of the above procedures per facility.

The data collection is by use of a data sheet completed at the time of procedure. The study will run concurrently in each facility. The total time for data collection is estimated to be longer than four months.

Data collection on suture use:

Quantification of suture use is by means of data collection from a data sheet (appendix 1 and 2). This Data sheet will detail the following: hospital, procedure, suture material type, needle type, suture size, brand and quantity used and whether or not this was the surgeon's primary

choice of suture material and, if not, what was ordered. The data sheet will be completed by the surgeon for the procedure as they determine the use of suture materials during the procedures. The senior surgical registrar within the relevant General surgical units will be the point of contact for the investigator to communicate and motivate the appropriate completion of data sheets for all relevant procedures. The data sheet will be available in each appropriate general surgical theatre within a box, to which the completed data sheet will be returned. Once weekly the investigator will collect completed data sheets and replenish stock of new data sheets. This weekly visit will also allow the investigator to continually monitor whether data integrity is being maintained. A total of 50 data sheets, based on current knowledge of procedure numbers, will be placed in each theatre. Upon collection of the data sheets a comparison will be made with the theatre registers, which details procedures completed within the complex, to highlight if accurate data collection has been done in each facility. Posters to advertise the study will be placed in each general surgical theatre to motivate surgeon involvement in the study.

Data collection on the cost of suture material:

This study will entail a determination of cost quoted from procurement and finance departments. In order to obtain this data, the investigator will undertake a voluntary interview with the senior level staff in the procurement. (Appendix 3). All interview and hospital identification will remain anonymous in the final research report.

Data analysis

The anonymous quantitative data from the data sheet will be captured into Excel for analysis. Further statistical analysis will be by use of Statistica and statistical guidance will be sought from the Department of Surgery, WITS Medical School. The qualitative data obtained from

the interview will be interpreted to provide a summary of the costs in each facility and differences and/or similarities discussed.

Ethics

A submission for ethical approval will be made to the University of the Witwatersrand Human Research Ethics Committee (HREC)

Approval to do the study data collection and interviews will also be obtained from the CEO's of CMJAH, CHBAH and HJ.

Funding

The costs of the study are for photocopying of data sheets and petrol to cover the travel between facilities. The following costs will be covered by the primary investigator and no application for external funding will be made.

Problems

The data sheet

1. The data sheet requires time taken by the surgeon to be completed which may impede successful and accurate collection of data for a procedure.
2. The distribution, access and collection of the data sheet will need to be well managed in order to ensure each appropriate case is included in the study.
3. The data sheet is also a paper based data collection which can lead to a certain loss of integrity due to a 'paper trail'.

The interview

The determination of expenditure through procurement and finance may present a problem due to the involvement of multiple departments/ levels of staff in resource management.

Future studies and ongoing data evaluation

This observational study to determine suture material use and cost at the 3 hospitals could serve as a basis in a future study to determine which suture material would be the best to standardise to, i.e. which is the best price for the best quality. This could ultimately lead to the implementation of standardization of specific suture material for specific procedures across all academic hospitals in Gauteng.

Furthermore, a record of patient surgeries with the suture used can be associated with post-operative complications and this could further define the need for resource standardisation. Also, surgeon satisfaction regarding the technicality and complications of using specific sutures could be investigated.

Ongoing management of stock to determine volumes for effective costing and departmental budgeting should persist beyond this study.

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6.2 Theatre Data Sheet

MMED STUDY - THEATRE DATA SHEET

Surgical resources: An observational study of suture material use, management and cost in 3 general surgery units in Gauteng, South Africa

Contact: Dr B Puttergill 0826503934 Hospital: CMJAH/ CHBH/ HJH

Patient Number:

Date of Procedure:

1. Please tick appropriate column:

Procedure:	
Abdominal wall closure	
Mastectomy	
Appendicectomy	
Inguinal hernia repair	

2. Please fill in appropriate columns:

Suture:	Number used:	Size:	Needle:
Absorbable sutures			
Chromic			
Monocryl			
PDS			
Vicryl			
Vicryl rapide			
Non-Absorbable sutures			
Nylon			
Prolene			
Steel			
Silk			
Staples			Skin or Intra abdominal

3. Surgeon preferred choice of suture available? YES / NO

If NO, please complete preferred suture choice:

6.3 Staff Interview Data Sheet

MMED STUDY – STAFF INTERVIEW DATA SHEET

Surgical resources: An observational study of suture material use, management and cost in 3 general surgery units in Gauteng, South Africa

Contact: Dr B Puttergill 0826503934

Hospital: .....

Department: .....

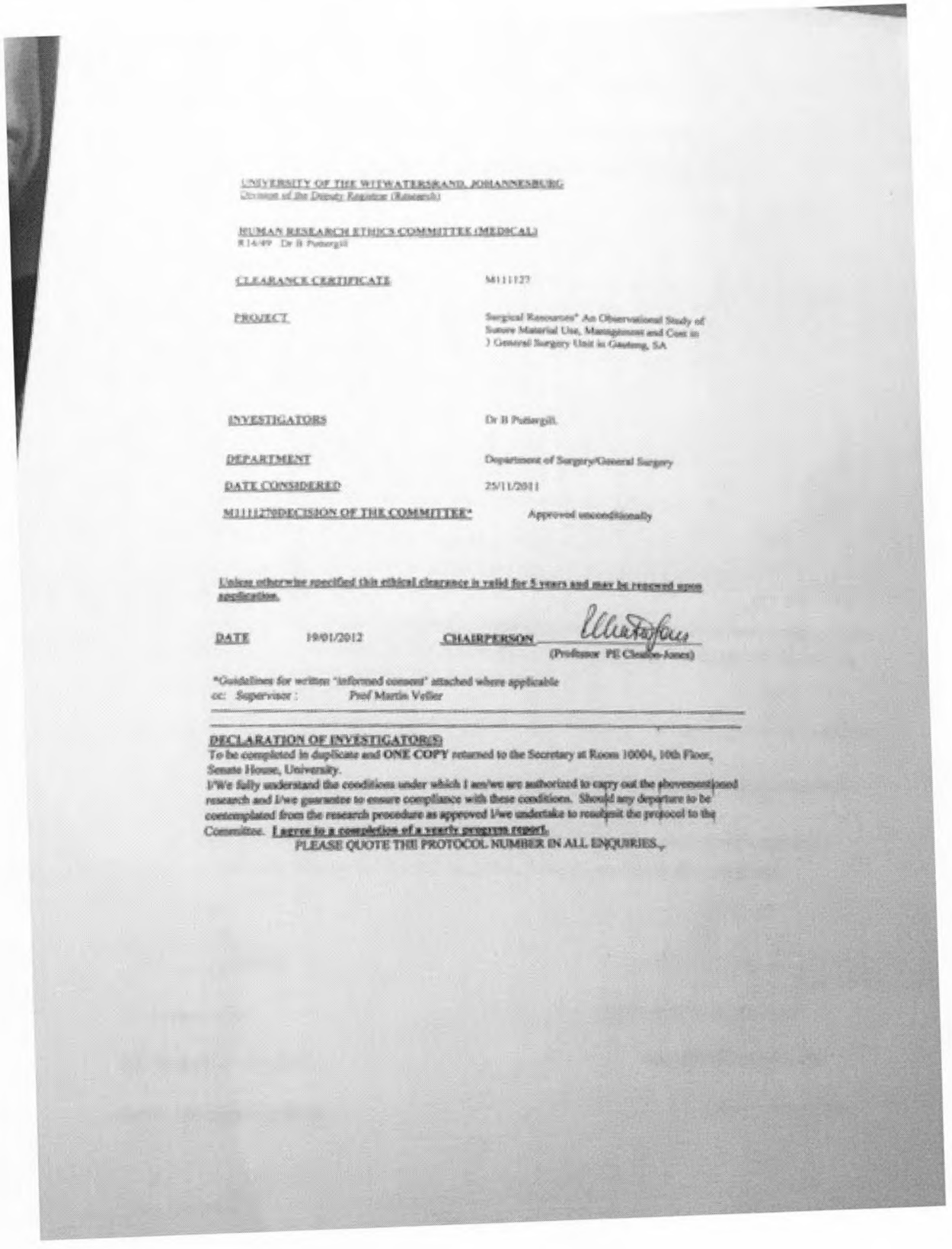
Cost per annum for the facility?

A. For general surgical resources

B. Suture materials for general surgery

C. Suture materials for the facility

6.4



UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr B Puttergill

CLEARANCE CERTIFICATE M111127

PROJECT Surgical Resources* An Observational Study of Suture Material Use, Management and Cost in) General Surgery Unit in Gauteng, SA

INVESTIGATORS Dr B Puttergill.

DEPARTMENT Department of Surgery/General Surgery

DATE CONSIDERED 25/11/2011

M111127DECISION OF THE COMMITTEE* Approved unconditionally

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

DATE 19/01/2012 CHAIRPERSON _____
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Prof Martin Veller

DECLARATION OF INVESTIGATOR(S)
To be completed in duplicate and ONE COPY returned to the Secretary at Room 10004, 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.

MEDICAL ADVISORY COMMITTEE

CHRIS HANI BARAGWANATH HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 20 January 2012

TITLE OF PROJECT: Surgical resources: An observational study of suture material use and the cost in 3 general surgery units in Gauteng, South Africa

UNIVERSITY: Witwatersrand:

Principal Investigator: Dr B Puttergill

Department: Surgery

Supervisor (If relevant): Prof M Veller and Dr D Kruger

Permission Head Department (where research conducted): Yes

Date of start of proposed study: December 2011

Date of completion of data collection: April 2012

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

.....

Recommended

(On behalf of the MAC)

Date: 20 January 2012

.....

Approved/Not Approved

Hospital Management

Date: 30 Jan 2012

health and social development
Department: Health and Social Development
GAUTENG PROVINCE

Umyango Wezwmpilo no Kuthuthukiswa Komphakathi
Lefapha La Maphelo le Tshebeletso le Ntshetsopele ya Sechaba
Department of Health and Social Development
Departmente van Gesondheid en Maatsplike Ontwikkelig

PERMISION FOR RESEARCH

DATE: 23/01/2012

NAME OF RESEARCH WORKER: DR B RATTEARIL

CONTACT DETAILS OF RESEARCH (INCLUDE ALTERNATE RESEARCHER):
072 650 3934

TITLE OF RESEARCH PROJECT SURGICAL RESOURCES: AN OBSERVATIONAL STUDY OF SUTURE MATERIAL USE & COST IN A GENERAL SURGERY UNIT IN GP, SA

OBJECTIVES OF STUDY (Briefly or include a protocol):
SEE ATTACHED PROTOCOL

METHODOLOGY (Briefly or include a protocol):
SEE ATTACHED PROTOCOL

GAUTENG PROVINCIAL GOVERNMENT
HELEN JOSEPH HOSPITAL
PRIVATE BAG X47
30 JAN 2012
AUCKLAND PARK 2006 JHB
HELEN JOSEPH HOSPITAL
GAUTENG PROVINCIAL GOVERNMENT

THE APPROVAL BY THE SUPERINTENDENT IS STRICTLY ON THE BASIS OF THE FOLLOWING:

(i) CONFIDENTIALITY OF PATIENTS MAINTAINED: YES
(ii) NO COSTS TO THE HOSPITAL: Yes
(iii) APPROVAL OF HEAD OF DEPARTMENT:
(iv) APPROVAL BY ETHICS COMMITTEE OF UNIVERSITY: Yes

SUPERINTENDENT PERMISION

Signature: _____ Date: 30/1/2012

SUBJECT TO ANY RESTRICTIONS:

Helen Joseph Hospital
Perth Road
Tel: 011 489 1011

Private Bag X47
Auckland Park
2006

health and
social development
Department: Health and Social Development
GAUTENG PROVINCE

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Office of the Chief Executive Officer
Charlotte Maxeke Johannesburg Academic Hospital
Tell: 011 488 3792
Fax: 011 488 3753
Email: lindiwe.mngomezulu@gauteng.gov.za
Date: 06th January 2012

Dr. Brooke Puttergill
WITS

Dear Dr. Puttergill

RE: "Surgical Resources: An observational study of suture material use and cost in 3 general surgery unit in Gauteng, South Africa"

Please note that your above request is provisionally approved. Your study can only commence once ethics approval is obtained.

Yours sincerely

Dr. Barney Selebano
Chief Executive Officer