

**AN INVESTIGATION INTO THE COST-
EFFECTIVENESS OF RE-USABLE
INSTRUMENTATION IN MINIMAL ACCESS
SURGERY**

By

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CONFIDENTIALITY CLAUSE

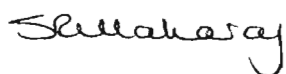
15 September 2003 – September 2008

TO WHOM IT MAY CONCERN

RE: CONFIDENTIALITY CLAUSE

Due to the strategic importance of this research it would be appreciated if the contents remain confidential and not be circulated for a period of five years.

Sincerely



S. R. Maharaj

DECLARATION

I declare that this research report submitted in partial fulfillment of the requirements of the degree of Masters in Business Administration at the University of Natal, Durban has been completed entirely by myself. This research has not been previously accepted for any degree and is not being currently submitted in candidature for any degree.

Signed.....*Swarup Rani Maharaj*.....*096400*

Swarup Rani Maharaj

Date.....*8 September 2003*.....

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I would like to thank my family, special friends and colleagues for their support and help during my studies. Special thanks go to my supervisor Professor Elza Thomson for all her assistance.

ABSTRACT

This study was an investigation into the cost-effectiveness of using re-usable instrumentation in laparoscopic surgery. The model used for the study was the laparoscopic cholecystectomy which is the commonest laparoscopic procedure performed by the general surgeons. The study was done at KZNGOV Hospital in Kwazulu Natal, one of the largest tertiary hospitals in the province. The research done was both qualitative and quantitative. An exploratory study was conducted initially by drawing up the case study, and then quantitative and qualitative research was conducted to evaluate the use of re-usable instrumentation in laparoscopic surgery. In order to conduct a more focused design, the three most commonly used laparoscopic instruments were evaluated. These were the trocars (sizes 11.0mm and 5.0mm), the endoshears / scissors and the clip applicators. The study aimed to assess whether the use of the re-usable instruments was more cost-effective, whether their use in minimal access surgery was feasible, and whether the use of re-usable instrumentation compromised patient well-being. Information for the case study was obtained from the hospital notes of the patients who had a laparoscopic cholecystectomy at KZNGOV Hospital, and from interviews with experienced surgeons.

The study found that the re-usable instrumentation used at KZNGOV Hospital had no adverse effects on the patients. The Department of Surgery and the theatre committee at this hospital have chosen an excellent and cost-effective protocol for laparoscopic surgery, and the choice of instrumentation cannot be faulted. Analysis of the results showed a large cost saving obtained by using the re-usable laparoscopic instrumentation, with no adverse patient outcomes.

...(W)e have not had any formal instruction in the morality of
spending other people's money or in the practical
details of the economics that underpin the health care
field. Like our patients, we have not had any
incentive to change.
But we do now.

ALEXANDER WALT, 1994.

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CHAPTER ONE: INTRODUCTION TO THE RESEARCH

1.1. Introduction

The term *Minimally Invasive Surgery* describes those diagnostic or therapeutic procedures that can be performed using smaller, and in some cases, no incisions in the abdomen and chest. George Kelling was the first physician to examine the abdominal cavity with an endoscope in 1901. Patients and physicians alike, have rapidly embraced these procedures because they are perceived to be associated with less post-operative pain, shorter recovery periods, and fewer complications than traditional open surgery.

Some examples of minimally invasive surgical procedures are:

- Laparoscopic cholecystectomy.
- Laparoscopic appendectomy.
- Thoracoscopic sympathectomy.
- Nissan fundoplication.

The model used for this research project is the **Laparoscopic Cholecystectomy**, and specifically the instrumentation that is used in these procedures. This model was chosen because it continues to be the most common therapeutic rigid endoscopic procedure performed by general surgeons (Zucker and Curet, 1995).

1.2. Background into the Research

Within our present economic situation in South Africa, inflation has been steadily rising. This also impacts on medical costs to the patient and the health insurance companies. Medical aid companies and patients are finding it difficult to cope with the increasing costs of drugs, doctors' fees and hospitalisation costs. Health insurance premiums are increasing constantly. In many instances the patient has to bear a large part of the costs of medical and hospital fees him/herself, as medical aid companies do not always cover the full costs of medical bills.

The laparoscopic cholecystectomy is performed both in the private hospitals, and in the public-sector or government-funded hospitals. The instrumentation used during the cholecystectomy in these two sectors is slightly different. The private sector uses disposable instruments, which are pre-packed by the pharmaceutical companies, whereas in the public-sector, due to budgetary constraints, non-disposable instruments are used. These are re-sterilised after each procedure.

In medical practice, costs and quality are inextricably intertwined (Traverso 1996). The quality of our health care service has to be assessed, increased, and then maintained before cost is considered. Because of technological advancements, many surgeons are now able to incorporate minimally invasive techniques into everyday practice. Unfortunately the costs for these procedures, and specifically the instrumentation they use, is steadily increasing.

The problem at the forefront of laparoscopic surgery today is the use of disposable instrumentation, rather than the re-usable type. Disposable instruments cost far more than their re-usable counterparts. This cost is eventually borne by the medical aid companies and the patients. Pharmaceutical companies that manufacture these instruments advocate the use of the disposable types. Their arguments are that disposable instruments cause less injury to the patients and decrease the rate of post-operative complications, especially infections.

The research problem for this study is whether using disposable instruments for minimally invasive surgery is more cost effective than using the re-usable ones.

With the current economic situation in South Africa and the HIV/AIDS pandemic, funds for health care have to go further. The technology of laparoscopy has been explosive, and has thereby increased health costs dramatically. Surgeons now have to contend with a multifaceted force that drives health care. This force is confusing to surgeons because many do not understand the business of medicine and business administrators do not understand the science of medicine (Traverso 1996).

Traverso says that surgeons should first be interested in quality, and then dwell on a reasonable cost for their health care product. The clinical perspective of quality is an important concept to understand because quality must become part of any long-term business decision.

The *value* of a procedure can be defined as a *quality* product provided at a reasonable cost (Traverso 1996). The components of quality are appropriate utilisation of the procedure with outcomes that fall within standardised short- and long-term results. Traverso uses the following equation to equate these concepts:

$$\text{Value} = \text{Appropriateness} \times \frac{\text{Quality}}{\text{Cost}}$$

1.3. Motivation for the Research

The current South African economic climate is forcing doctors to take a closer look at the costs involved in delivering a quality health care product. The advent of laparoscopic cholecystectomy has been of great economic benefit both to surgeons and patients. This is in part due to a reduced length of hospital stay, reduced post-operative morbidity and a quicker resumption to normal activities of the patient. However, the cost of laparoscopic procedures is increasing due to more “technologically advanced” instrumentation.

Pharmaceutical companies have had an enormous impact on minimal access surgery (MAS). The use of the instrumentation and equipment has not adequately been judged or challenged up to now. This research aims to challenge the standard practice of minimal access surgery with respect to the instrumentation used. If non-disposable equipment is shown to be equally efficacious (as compared to the disposable instruments), this has far-reaching implications with regard to cost savings to the health industry, medical aid schemes and to the patient in particular.

Disposable equipment for minimal access surgery is not widely available in the public sector or government-funded hospitals. This research also aims to reveal if patients

treated in government hospitals are compromised in any way by these hospitals not having access to disposable instrumentation for MAS.

This research aims to find an objective viewpoint with respect to the use of this instrumentation and equipment, which is a costly component of minimal access surgical procedures.

1.4. Value of the Research

The costs of health care in South Africa and throughout the world have gone up considerably. The laparoscopic procedures and laparoscopic technology has increased dramatically over the last few decades. This has brought with it increasing equipment costs. More and more newer and more advanced instruments are coming onto the market almost every day. The number of laparoscopies being done now is also increasing. There is especially an increase in laparoscopic cholecystectomies. This is due to two factors:

- There is now an increased patient demand for these procedures.
- Relaxation of criteria by gastro-enterologists for referral of patients with gallstones for surgery is also a contributing factor.

A study done by Orlando and Russel in Connecticut in 1996 showed a 29% increase in the overall rate of laparoscopic cholecystectomies.

South Africa is both a first world and a third world country rolled into one. This has impacted on health care in this country. The public and private sectors are vastly different from each other, yet they influence each other greatly, especially from a financial viewpoint. Private patients who run out of medical aid cover eventually become a burden to the state. Thus medical aid funds should be used with care. If private charges decrease because of careful use of funds for medication, instrumentation and hospitalisation, the medical aid premiums will subsequently decrease. This would be of enormous benefit to the patient. More people may be able to afford health insurance and this would reduce the load on the already over-burdened public sector.

Many patients without medical insurance also seek private care in order to avoid the long waiting times in the government hospitals. If medical costs can be brought down, these patients would also benefit. Many of these patients are not wealthy and can ill afford the high cost of medical care. Government is also one of the largest employers in the country and subsidise their employees' medical aid schemes heavily. If health insurance premiums continue to rise due to the escalating costs of medical care, government may not be able to sustain these subsidies indefinitely (Cornell, McIntyre and Mbatsha, 2001).

1.5. Problem statement

Does the use of re-usable instrumentation in laparoscopic cholecystectomies decrease overall costs for the operation, and do they compromise patient well-being in any way?

1.6. Research Questions

This research aims to answer three specific questions:

1. Is the use of the instrumentation used in minimal access surgery cost-effective? The equipment currently used in MAS is either disposable or re-usable. This research aims to specifically evaluate the implications of using re-usable equipment. With regard to the cost-effectiveness of MAS, we are looking at this from purely an instrumentation point of view. Surgeon's fees, theatre fees and hospitalisation costs will not be investigated.
2. Is the use of re-usable instrumentation in MAS feasible? Does the use of re-usable equipment compromise surgical technique, or patient well-being?
3. What is the outcome of using re-usable equipment? Here we will look specifically at patient outcome. The outcome evaluated will include:
 - The intra-operative procedure – do instruments (disposable or re-usable) impact on surgical technique?
 - Are there any complications that develop consequent to using the re-usable instruments?

- Is the hospital stay of the patient, patient recovery time, and return of the patient to normal activity in any way affected?

By answering the above questions, this dissertation hopes to add new knowledge to the field of study of the cost implications of the use of specific instrumentation in minimal access surgical procedures. This research also hopes to stimulate further study into this relatively new area of surgery, which is increasing at a phenomenal rate in both the private and public health sectors.

1.7. Objectives of the Study

The following are the objectives of the study:

- To evaluate the different types of laparoscopic equipment on offer at present, and to ascertain their impact on health care costs.
- To determine whether medical care available in South Africa is based on sound principles of cost-effectiveness.
- To establish the most cost effective way to deliver quality health care to the South African population. Quality of health care should be uppermost in the surgeon's mind, and costs should take second place. The model of the laparoscopic cholecystectomy is used in this study, because it is one of the most common laparoscopic procedures in general surgery. It must also be remembered that many other laparoscopic procedures are being performed in general surgery and in other medical specialities. Thus the findings of this study may be extrapolated to many other disciplines in medicine.

1.8. Research Methodology

This is the description of the research methodology used to conduct the research for this case study on KZNGOV Hospital in Kwazulu Natal. The research question is:

Does the use of re-usable instrumentation in laparoscopic cholecystectomies affect the patient in any adverse way?

After identifying the research problem, the conclusion derived from the literature review was based on the following constructs:

- Cost-effectiveness
- Feasibility of the use of re-usable instruments
- Patient outcome.

1.8.1. Research Method

Both quantitative and qualitative research was carried out for this study. The qualitative study was done in order to ascertain what the senior surgeons from the Department of Surgery at KZNGOV Hospital thought about the use of re-usable instruments in laparoscopic cholecystectomies. Thereafter a quantitative study was done to verify the results from the qualitative study. This type of research design is known as the triangulation method. This research methodology involves the use of both qualitative and quantitative research approaches.

1.8.2. Sample

The sampling method used was non-probability sampling, obtaining a convenience sample. Two sets of samples were used:

- All patients who had undergone a laparoscopic cholecystectomy from the beginning of January 2002 to the end of January 2003. The fifty patients chosen from these were the ones who had complete in-patient and out-patient notes.
- All senior surgical registrars and consultants from the Department of Surgery at KZNGOV Hospital.

1.8.3. Qualitative Design

The research study attempts to evaluate whether the use of re-usable instrumentation in laparoscopic cholecystectomies is cost-effective, affects surgical technique and adversely affects patient well-being. An exploratory study using the case-study method was used.

1.8.4. Sources of Evidence

- Interviews

Semi-structured interviews were conducted with three of the senior surgical registrars and the surgical consultants from the six surgical units of the Department of Surgery at KZNGOV Hospital. The rest of the consultants and registrars were either unavailable or had emigrated. Some questions were open-ended, whereas others required shorter and more precise answers. These questions attempted to bring out respondents' opinions about the three constructs that were described earlier. The interview questions set-up followed a focused interview style. The respondents were interviewed for a short period of time. Although interviews were open-ended and took on a conversational manner, the interviewer followed a set of questions.

1.8.5. Measuring Instrument

- Interviews

The interview questions dealt with the three constructs described before. These are:

- a. Cost-effectiveness
- b. Feasibility of using re-usable instruments
- c. Patient outcome.

The main stakeholders interviewed were the senior surgical registrars and the surgical consultants from the Department of Surgery. All these surgeons have their surgical degrees and are comparable to the surgeons that work in the private sector. The questions were specific and were appropriate to all the interviewees.

Construct One: Cost-effectiveness

The questions posed had to indicate whether these experienced surgeons thought that disposable instruments were in any way more cost-effective or superior to their re-usable counterparts.

Question 5: In your opinion are disposable instruments used in laparoscopic cholecystectomies more cost effective?

Question 6: Do you consider disposable instrumentation superior in quality to the re-usable devices?

Question 7: Which of the two types of instruments – disposable or re-usable – do you prefer to use? Why?

Construct Two: Feasibility

The following questions focused on the practicality and convenience of using re-usable laparoscopic instrumentation.

Question 8: Is it more difficult to perform a laparoscopic cholecystectomy using re-usable devices?

Question 9: Do re-usable instruments hamper the operative technique of laparoscopic cholecystectomies in any way?

Construct Three: Patient outcome

For this construct the most common complications that arise from performing laparoscopic procedures were considered. Manufacturers of disposable laparoscopic devices say that these arise more commonly with the use of re-usable instruments.

Question 10: Have you had any of the following adverse patient outcomes by using re-usable instruments during laparoscopic cholecystectomies?

- Bowel / other organ injury?
- Increased rate of intra-abdominal infection?
- Excessive intra-abdominal bleeding immediately post-operatively?
- Delayed intra-abdominal bleeding post-operatively?
- Increased rate of wound sepsis?

1.8.6. Quantitative Design

Quantitative research describes, explains and tests relationships. Techniques that are used generate numerical data. Evaluation of the cost-effectiveness in using the different types of laparoscopic instrumentation is very important to KZNGOV Hospital, and to the health care sector as a whole. As can be seen from previous discussions, the public and private sectors do not work in isolation. For the evaluation process the complete hospital records of fifty patients that underwent laparoscopic cholecystectomies were scrutinised. The following information was extracted from these records:

- Age
- Gender
- Length of hospital stay.
- Duration of operation
- Organ injury at operation
- Bleeding during the operation
- Immediate bleeding after the operation
- Infection two weeks post-operatively
- Difficulty with surgical technique
- Additional medical conditions of patient

1.8.7. Patient Sample

The patient sample chosen was a convenience sample. All patients who had had a laparoscopic cholecystectomy at KZNGOV Hospital between the periods 1 January 2002 to 31 January 2003 were chosen. A minimum number of 50 patients were needed for this study. Only patients with both complete in-patient and out-patient notes were selected for the study. This had to be done in order to evaluate both the immediate and the 6-week post-operative time periods. The following table summarises the numbers of patients who had had laparoscopic cholecystectomies during this time frame:

Table 1.1: Patients that Underwent Lap Choles from 1/1/2002 to 31/1/2003

Total number of Lap Choles from 1/1/2002 to 21/1/2003	95
No. of patients with complete in-patient notes only	13
No. of patients with complete out-patient notes only	14
No. of patients with both in-patient and out-patient notes (complete)	50
No. of patients whose in-patient and outpatients files were missing	18

The difficulty of obtaining both complete in-patient and out-patient files of all the laparoscopic cholecystectomy patients from 1/1/2002 to 31/1/2003 was due to two factors:

- There was a computer crash at the hospital in November 2002, thus the notes were not filed according to their computer numbers, and
- There was wilful damage to the outpatient filing area in December 2002.

1.9. Limitations of the Study

- The major limitation of this study was to get sales representatives from disposable instrument manufacturers to divulge any information about the costs of their instruments.
- Another limitation was to obtain interviews with general surgeons in private practice i.e. surgeons who utilise disposable instruments most of the time. Only one private surgeon was agreeable to the interview. The rest politely declined or were unavailable.
- The third limitation to the study was that only three instruments were investigated. Many disposable device manufacturers make up special sterile surgical packs of disposable equipment for the private surgeons to utilise for their various procedures. This will obviously increase the cost of the procedure quite dramatically. However, the three instruments that were the focus of this study are common to most laparoscopic procedures, and are the most costly.

1.10. Summary

The debate over whether to use re-usable instruments or the disposable types in laparoscopic surgery has been an ongoing and controversial one. Disposable device manufacturers have maintained that their products are safer, easier to use, cause less infections and cause fewer injuries to the patients. These are the arguments that these manufacturers use to justify the high costs of the disposable instrumentation. The next chapter investigates the theories behind these claims and looks at various studies done throughout the world.

CHAPTER TWO: LITERATURE REVIEW

2.1. Introduction

The literature review section is centred around the research questions stated in the previous chapter. These factors are:

- Cost-effectiveness of the instrumentation used in Minimal Access Surgery.
- Feasibility of the use of re-usable instruments in Minimal Access Surgery.
- Patient outcome when re-usable instrumentation is employed in Minimal Access Surgery.

Before these questions are examined in greater detail, the South African health budget, health legislation and the different health sectors will be looked at. The health sectors concerned include the public and the private sectors. This is an important part of this report as it gives one a background to the way health care is funded and regulated in South Africa. Cost-effectiveness in the health care sector cannot be viewed in isolation.

2.2. The 2003/2004 Health Budget

The aim of the Department of Health is to promote the health of all people in South Africa through a caring and effective national health system based on the primary health care approach. This aim is to be achieved through three programmes.

- Programme 1: Administration

The purpose of this programme is to provide for the overall management of the department and provide legislative and communication services and centralised administrative support.

- Programme 2: Strategic Health Programmes

These programmes co-ordinate a range of strategic national health programmes through the development of policy, systems and monitoring, and manage and fund key programmes. One of the objectives of Programme 2 is to support the development of affordable health services and coherent service provision and financing in the private health sector.

- Programme 3: Health Service Delivery

This programme supports the delivery of services primarily in the provincial and local spheres of Government.

2.2.1. Strategic Overview and Key Policy Developments of the Department of Health: 1999/2000 – 2005/2006

Key functions of the national Department of Health are to lead and co-ordinate the national health system through the development of policy, legislation and national health programmes, and to support and monitor the implementation of policy by provincial and local governments. A small core budget of about R582 million for 2003/2004 funds this co-ordinating and support role in relation to a range of departmental transfers to public entities and provinces as well as broader health spending funded from provincial equitable share allocations. The total public sector health budget, including provincial and national public health spending, will exceed R43 billion in 2005/2006.

Ongoing programmes are in place to improve the quality of hospital services. These span the areas of infrastructure improvement, management improvement, norms and standards for service delivery, and the increased use of public-private partnerships in the operation of hospitals. The Inkosi Albert Luthuli Hospital in Durban is an example of a large health infrastructure project that is being managed through a public-private partnership. Other significant public-private partnerships are under investigation in the Free State and will be boosted by the drive for differential amenities in public hospitals to use capacity more effectively by providing services to private medical scheme patients.

The financial year of 2001/2002 was characterised by sharp increases in the prices of medical consumables and equipment as the Rand depreciated. This threatened service delivery levels in provincial health departments.

2.2.2. Council for Medical Schemes

The Council for Medical Schemes regulates the private medical schemes industry in terms of the Medical Schemes Act (131 of 1998), and is funded mainly through levies on

the industry in terms of the Council for Medical Schemes Levies Act (58 of 2000). In addition it receives a small transfer from the Department of Health, increasing from R2.6 million in 2002/2003 to R3.0 million in 2005/2006. The Council for Medical Schemes is a public entity that reports to the Minister of Health.

2.3. Health Legislation in South Africa

Health legislation is recognised the world over as being both complex and fraught with stakeholder interests (South African Health Review 2001). The World Health Organisation states “the careful and responsible management of the well-being of the population is the very essence of good government”. In the South African context this means the establishment of the best and fairest health system possible with available resources.

The private healthcare sector consumes well over half of all healthcare resources in South Africa (South African Health Review 1998). In 1995 medical schemes spent more than four times as much as the state per head of covered population.

2.3.1. The Regulation of Private Health Care Financing in South Africa

The medical schemes have been regulated by the Medical Schemes Act of 1968. The medical schemes industry underwent many de-regulations in the late 1980s and early 1990s. This resulted in the current level of regulation of health insurers to be minimal by international standards. Thus there has been high levels of fraud and insolvency in this sector, as well as insecurity for those patients who develop chronic illnesses or are elderly (South African Health Review 1998).

The Committee of Enquiry into a National Health Insurance System for South Africa recommended three broad areas of new regulation to be introduced. These are:

- Regulation enforcing risk-pooling between high and low risk enrolees.
- Regulation requiring that all cover include at least a minimum package of essential hospital care.

- Regulation regarding oversight, financial reserves and guarantees, reporting requirements, etc., to bolster the financial stability of the industry.

2.3.2. Medical Schemes Act of 1998

An important piece of legislation which was passed during 1998 was the Medical Schemes Act of 1998 which repealed the Medical Schemes Act of 1967. It includes measures that aim to achieve an appropriate demarcation between medical schemes and insurance products. Thus it eliminates “cherry picking” of the healthiest clients by the insurance industry.

The act prohibits risk-rating and exclusion from membership on the basis of age, gender and state of health. Provision is also made for the introduction of a prescribed set of minimum health care benefits that must be offered by medical schemes. A number of requirements are proposed which are aimed at ensuring improved governance, financial administration and accountability of schemes. In terms of this Act the Council for Medical Schemes will gain corporate status and be funded in part by levies on medical schemes, while remaining ultimately accountable to the Minister of Health.

Cumulatively, the amendments will:

- Reform the financing of private health care in South Africa.
- Improve equity of access to private medical insurance.
- Lead to greater efficiency in the use of resources in this sector.

This act was promulgated in the first week of January 1999 and finally published on 20 October 1999. It came into effect on 1st January 2000. The most significant component of the regulations is a list of prescribed minimum benefit conditions. In respect of these conditions, medical schemes are required to reimburse in full, without co-payment or the use of deductibles, the diagnostic, treatment and care costs in at least one provider or provider network, which must include the public hospital system. While medical schemes may still employ techniques such as pre-authorisation, they are not entitled to

refuse authorisation in a public hospital of standard treatment for any prescribed minimum benefit.

Due to constant change in medical practice and available medical technology, the Department of Health will review the list of prescribed minimum benefits every two years, in consultation with the council for medical schemes, stakeholders, Provincial Health Departments and consumer representatives. These reviews will provide recommendations for revision of the regulations based on, amongst others, considerations of:

- Cost-effectiveness
- Health policy developments
- The impact on medical scheme viability and its affordability to members.

The stated objectives of specifying a set of prescribed minimum benefits are:

- To avoid incidents where individuals lose their medical scheme cover in the event of serious illness and the consequent risk of unfunded utilisation of public hospitals
- To encourage improved efficiency in the allocation of private and public health care resources.

The regulations hold potentially significant advantages for the public health sector which has virtually attained a preferred provider status in terms of the regulations. If public hospitals structure and market their services appropriately, they have the potential to attract many more private patients and thereby attract a greater share of the revenue from the private medical aid market.

2.4. Health Care Financing and Expenditure

This section looks at the National Health Accounts Project that was done in the 1990s.

2.4.1. Introduction

The National Health Accounts (NHA) Project was conducted in the late 1990s. The NHA project was funded by the European Union. The NHA Project is the successor of the Health Expenditure Review. The Review described patterns of health care financing in apartheid South Africa, and highlighted extensive geographic disparities, disproportionate spending on hospital-based care in the public sector, and severe cost escalation in the private sector. The NHA Project evaluates the extent to which these problems have been addressed by the reforms put in place by the new South African Government during its first term in office. Doherty, Thomas, Muirhead and McIntyre have summarised the findings of the NHA Project in the South African Health Review 2002. Some of their findings follow.

The NHA Project reveals two eras of **public** health sector financing:

- *Era 1: From 1992/93 to 1997/98.* During this time there was:
 - a. Substantial growth in government financing of health care.
 - b. The redistribution of health sector funds across provinces.
 - c. The shift of resources to primary health care.

- *Era 2: 1998/1999.* This shows:
 - a. Falling per capita financing of health care by government.
 - b. Reversal of redistribution trends between provinces.
 - c. Limited growth in the primary health care sector.

The NHA Project also shows several key features of **private** health sector development in the post-apartheid era. These include:

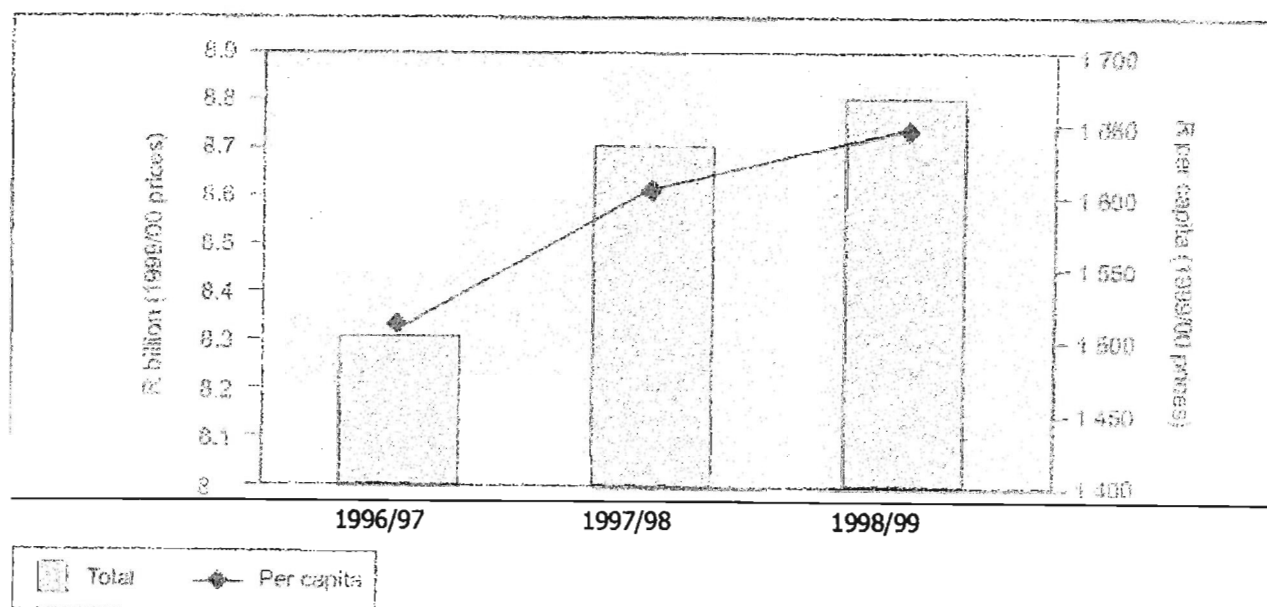
- Growth in private sector provision (this is most marked in the bed numbers).
- Rapid growth in expenditure.
- Decrease in the number of people with regular access to private care.

These trends suggest an overall decline in value-for-money in the private sector prior to the implementation in 2000 of the Medical Schemes Act of 1998.

2.4.2. Trends in the Overall Level of Finances Available for Health Care

In 1998/1999 South Africa devoted R70.2 billion to health care (SAHR 2000). This is an unusually high proportion by international standards. This represented 8.8% of Gross Domestic Product. The equivalent average figure for middle-income countries was 5.7%. There are also indications that South Africa is devoting increasing amounts to health care. These findings are shown in the following graph.

Figure 2.1: Total and per capita financing of the health care sector using total population figures, 1996/ 97-1998/99 (1999/00 prices)



Source: South African Health Review 2002

2.4.3. Trends in the Sources of Finance

There are four main sources of finance for health care:

- Government
- Households
- Employers
- Donors and non-governmental organisations.

The changing relationships between these different sources show decreasing financial support by government of health services for public sector dependants. This has increased the burden on households and employers and funders of health care. The following table shows the sources and the proportion of finances provided.

Table 2.1: Sources of Finance in the South African Health Care Sector, 1998/99

Sources of Finance	1999/00 prices (Rand billion)	% of total sources	Change in %, 1997/98-1998/99
Government	31.1	44.2	-4.8
Households	27.4	39.0	4.5
Employers	11.7	16.6	3.4
Donors and non-governmental organisations	0.1	0.1	Unknown
Total	70.2	100.0	

Source: South African Health Review 2002

2.4.4. Trends in Government Funding of Health Care

Government is the largest source of health care finance. The health sector is allocated a portion of government finances which is raised from:

- Taxes – income tax, company tax, sales tax (VAT)
- Licences
- Sales of utilities such as electricity and water.

94% of the amount of money raised by Government was contributed by central government (1998/99 figures). Provincial and local government provided only 2.7% and 3.3% of total government health care finances from their own revenues respectively.

Signs that government financing was beginning to decrease started showing in 1997/98, although government as a whole had increased its contributions to health care between

1992/93 and 1997/98. Government financing per person dependent on the public sector increased by 4.3% between 1996/97 and 1997/98, but decreased by 2.5% between 1997/98 and 1998/99. Between 1996/97 and 1998/99 government finances declined continually as a proportion of total health care finance, at an average annual rate of 3.6%.

This trend is due to two factors:

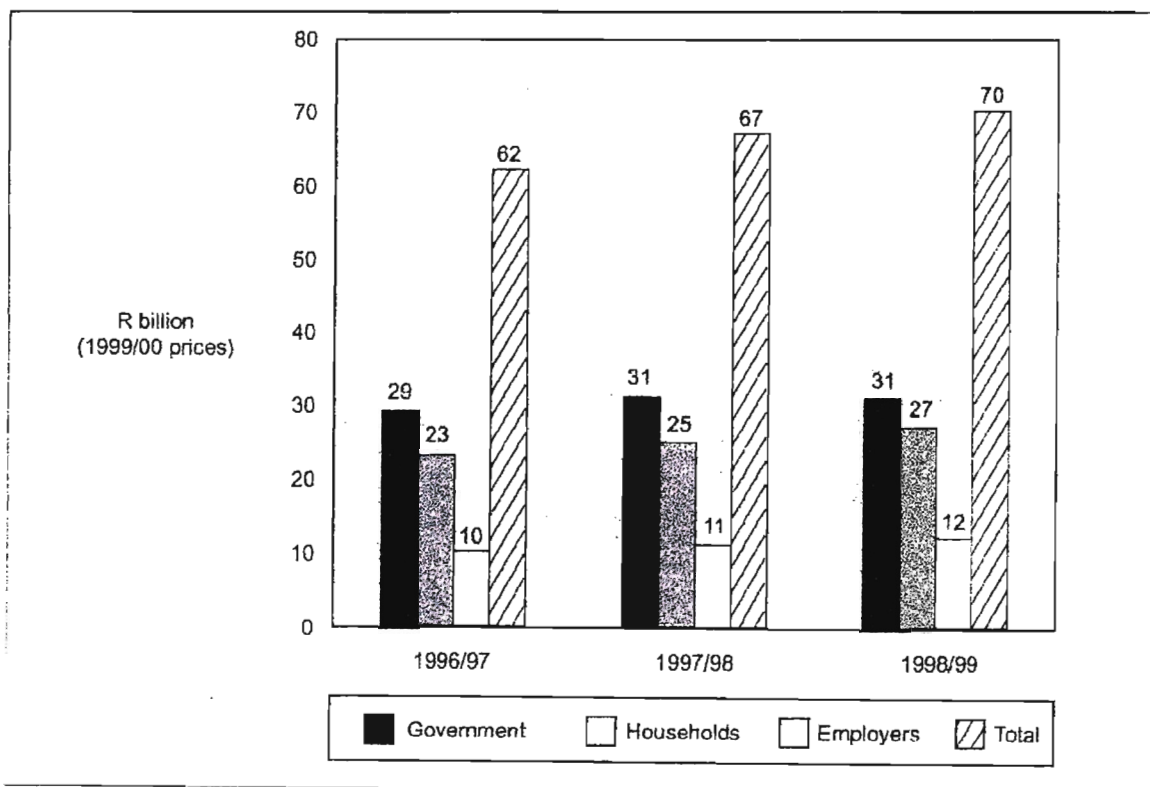
- i. A decline in GDP per capita (Department of Finance 1999). This was largely due to the global economic recession (South African Reserve Bank 2001).
- ii. Decreased government spending on health care was also a direct consequence of the performance of the economy that faltered towards the end of the 1990s, leading to this government policy. Between 1996/97 and 1998/99, government health care financing declined as a proportion of GDP, of total government financing, and of total government financing less debt servicing. Health care was de-prioritised towards the end of the new government's first term of office. This was due to the following factors:
 - The government's macro-economic policy, the Growth, Employment and Redistribution Strategy (GEAR) was initiated in 1996. The GEAR policy sets limits on the tax to GDP ratio. This places a constraint on the finances available to government, especially during an economic recession.
 - The GEAR policy also insists that public expenditure growth be lower than overall economic growth. This means that public expenditure is likely to decrease in real per-capita terms (Thomas and Muirhead 2000).
 - The social sector budgets are projected to increase between 1999/2000 and 2002/03 at a rate less than the increase in the overall government budget (Department of Finance 1999).
 - Other sectors, including Defence, will grow at a faster rate.

Thus it is likely that the year-on-year growth in the health budget will average only 0.8% for the period 2000/01 to 2002/03 (Thomas and Muirhead 2000). In terms of per capita figures, this means a decline every year.

2.4.5. Trends in Household Funding of Health Care

The second largest source of finances for health care is households. Households either pay contributions to medical schemes and other forms of private insurance, or pay directly (“out-of-pocket”) for services provided by health workers and facilities, and for pharmaceuticals. Households contributed over a third of total health care finances in 1998/99. The increasing burden shouldered by households was mainly due to increased out-of-pocket expenditure.

Figure 2.2: Sources of Finance for the Health Care sector, 1996/97 – 98/99
(R billion, 1999/00 prices)



Note: The contributions by donors are so small that they do not register on the graph.

Source: South African Health Review 2002.

2.4.6. Trends in Funding of Health Care by Employers

The third major source of finances is the employers. They also paid out more for the health care of their employees over the period 1996/97 to 1998/99. The employers

include private firms as well as government-owned entities. They fund health care for their employees either directly through health services provided at the workplace, or indirectly through contributing to different forms of private insurance on behalf of their employees. The proportion of finances contributed by employers grew at a slightly lower rate than that of households. This represented a fifth or less of total resources. Most of the sources of finance were contributed by private employers. The growth was due to increases in employers' contributions to employees' medical schemes. (This was an annual average rate of approximately 11% in real terms). Employers also contributed to the Workers' Compensation Fund at an annual rate of approximately 6%.

2.4.7. The Contributions of Donors and NGOs

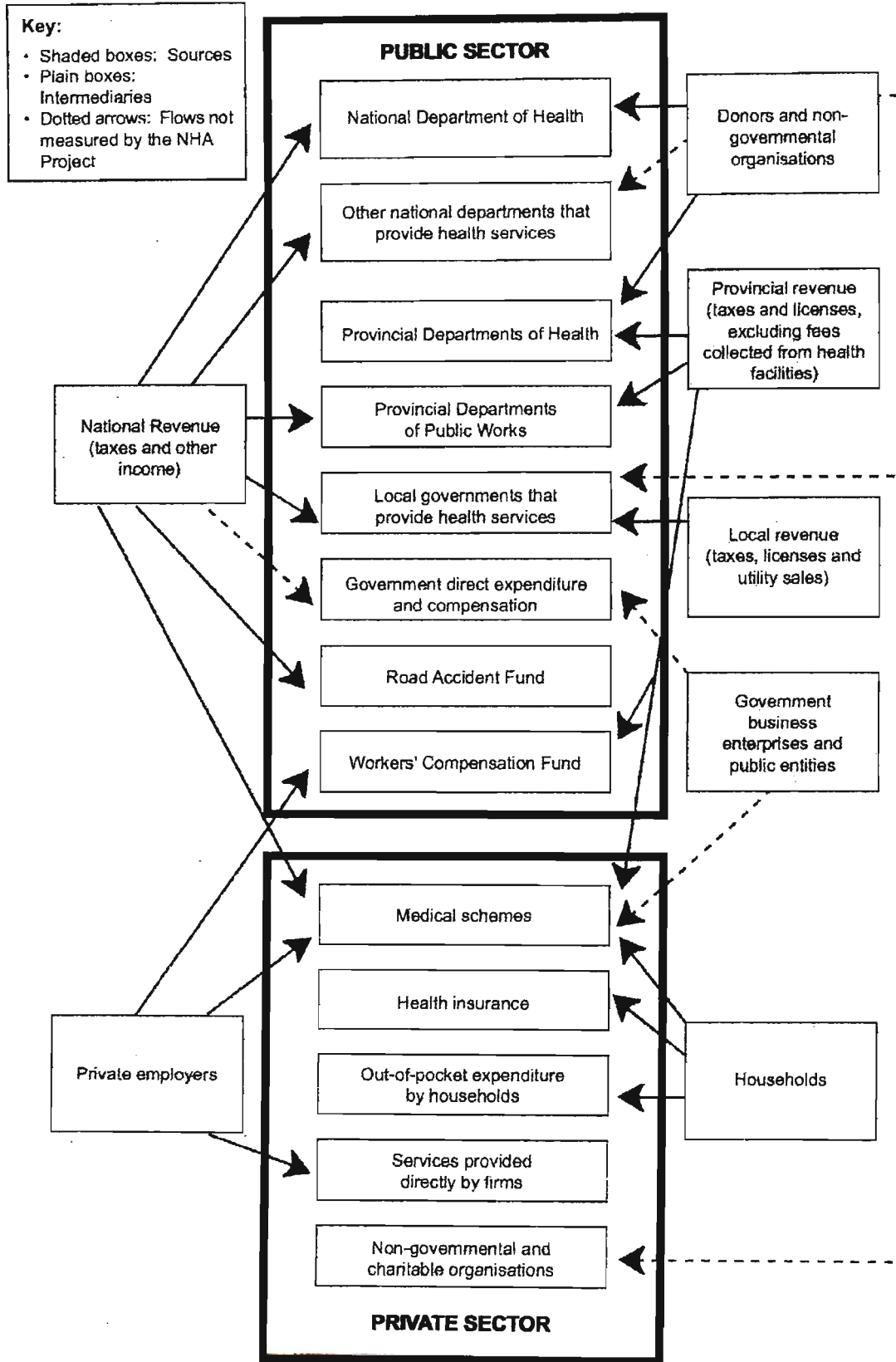
Donors and non-governmental organisations are the fourth source of health care finance. Unlike most countries in Africa, donor contributions represent only a very small proportion of overall health care financing in South Africa. The source appears to be growing as donors take an interest in the new government's policy to extend health care services to the disadvantaged. But this does not alleviate the growing health care financial burden shouldered by households in general.

2.5. The Flow of Finances Through Financing Intermediaries

Finances that are raised from a source flow through one or more financing intermediaries before being passed on to a health care provider. The financing intermediaries who control finances have a pronounced effect on efficiency and equity within the health system, as they determine what resources are allocated to which populations, and for which services. The following flow chart shows how finances for health care in South Africa flow from financing sources to financing intermediaries.

Figure 2.3: The Flow of Financing Sources to Financing Intermediaries

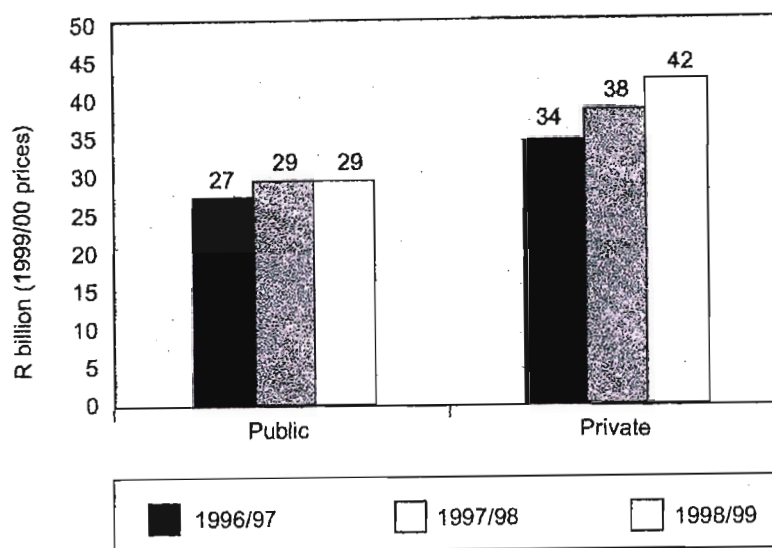
Source: South African Health Review 2002



2.6. The Relative Size of Public and Private Financing Intermediaries

In South Africa the proportion of total finances controlled by privately owned intermediaries increased from 56% to 59% between 1996/97 and 1998/99. This represents an absolute increase of R8.8 billion in 1999/00 prices. Public sector intermediaries grew at a much slower pace between 1996/97 and 1997/98, and actually shrank between 1997/98 and 1998/99, as the following graph shows:

Figure 2.4: The total Size of Public and Private Sector Financing Intermediaries, 1996/97 – 1998/99 (R billion, 1999/00 prices).



Source: South African Health Review 2002

Despite the growing dominance of the private sector, it is estimated that less than 20% of the total population made regular use of the full range of services in the private sector in 1998/99. The private sector coverage also decreased as a proportion of the total population between 1996/97 and 1998/99 (Cornell, McIntyre and Mbatsha, 2001). This suggests that an increasing proportion of the population became reliant on public services even as the public sector received a declining share of health care finance. This reflected the increasing un-affordability of scheme membership as costs escalated in the private sector.

2.7. The Main Financing Intermediaries

Medical schemes are the main type of private insurance, the other much smaller type being health insurance. Medical schemes are non-profit associations, but are operated by professional administrators that are essentially for-profit companies. Schemes receive monthly premiums from households and employers. Health insurance is offered by life and short term insurance companies, and bought by households. Some of these households also belong to medical schemes.

Table 2.2: Financing Intermediaries in South Africa

Financing Intermediary	% of Sector
<i>Public sector</i>	
Central government	9.5
National Department of Health	2.7
Other national departments (Defence, Education, Correctional Services, and Safety and Security)	6.8
Regional government	82.0
Provincial Departments of Health	79.3
Provincial Departments of Works	2.7
Local government	5.6
Statutory Security Schemes	2.8
Workers' Compensation Fund	1.6
Road Accident Fund	1.2
Government direct expenditures and compensation for health care for employees	0.1
<i>Private sector</i>	
Private health insurance	68.3
Medical schemes	64.8
Health insurance	3.5
Households' out-of-pocket payments made directly to public or private health services	30.1
Private firms' direct expenditure on workplace health services	1.6

Source: South African Health Review 2002

Table 2.2 breaks the public and private sectors into their component parts. The largest intermediaries in 1998/99 were medical schemes (accounting for R2.9 billion in 1999/00

prices or 38% of total finances), and the provincial level government departments (accounting for R23.5 billion in 1999/00 prices, or 34% of total finances). These two groups were the dominant financing intermediaries in the South African health sector, channeling over 70% of finances.

Some of the finances flowing through medical schemes are derived through government sources. In 1998/99, at least 10.3% of medical scheme finances, or R2.8 billion in 1999/00 prices, were contributed by government as a subsidy to its employees. This is of great significance for two reasons:

- Firstly, tax finances are being used to provide health care to civil servants at a much higher cost than public sector care (the maximum *monthly* government subsidy is just over R800, while public per capita funding of health care for those without medical aid was just over R800 *per annum* in 1998/99). Thus government is becoming increasingly concerned, from an equity and efficiency perspective, that civil servants receive cost-effective care.
- Second, it is estimated that only half of civil servants who are eligible for the government subsidy have chosen to take up medical scheme membership (Cornell, McIntyre and Mbatsha, 2001). Given the existing burden on government of the present subsidies, government is concerned about being able to sustain these subsidies.

2.8. Private Health Care Providers

In South Africa private health care can be crudely divided into a large corporate private for-profit hospital sector, and a smaller private not-for-profit sector which includes workplace health services and non-governmental organisations. The private for-profit hospital industry is by far the largest section of non-state hospital provision. It generally does not employ its own health professionals. Doctors make use of facilities and bill the health insurers separately.

The following table (Table 2.3) indicates the number of specialist clinicians in private practice in 1998.

**TABLE 2.3: PERCENTAGE OF PRACTISING CLINICIANS IN PRIVATE
PRACTICE BY SPECIALITY**

	<u>Total number</u>	<u>% private</u>
Anaesthetics	764	75
Cardio-thoracic surgery	58	48
Cardiology	54	63
Community Health	77	22
Dermatology	119	66
Diagnostic Radiology	472	69
Medicine	705	51
Neurology	83	57
Neurosurgery	91	62
Obstetrics & Gynaecology	636	65
Ophthalmology	243	60
Orthopaedics	413	69
ENT Surgery	197	64
Paediatrics	504	43
Pathology	448	60
Plastic Surgery	112	54
Psychiatry	345	55
General Surgery	489	48
Urology	133	58
All specialities	6 134	59
General Practice	15 376	45

Source: MASA Database 1998

The above table indicates the number of specialist clinicians in private practice. There are 489 general surgeons in the country. 48% of these are in the private sector. This can give an indication of the number of operations performed in the private sector, and the urgent need to cut costs on certain surgical instrumentation. Laparoscopies are also done often by gynaecologists, of which 65% are in private practice.

2.8.1. The Importance of the Private Sector

Jane Goudge from the Centre for Health Policy in South Africa has the following to say about the importance of the private sector and its link with public health provision:

The public and private sectors within health care are often perceived as two distinct entities – a public sector providing care for the majority of the public, and a private sector, providing care for the wealthy who are able to afford medical scheme coverage. If the concern of the Department of Health is meeting the needs of the poorer majority of the population, why should it be concerned with the private sector? Private providers are primarily motivated by the aim of making a profit, and as a result their objectives do not coincide with the public goal of providing universally acceptable health care for the whole population.

This mismatch of objectives results in particular problems for health provision (Bennet and Mills 1994). The problems are:

- the profit motive may override good clinical practice
- a failure to address public health issues, such as prevention
- a lack of integration with government health services
- attraction of health professionals out of the public sector
- the provision of poor quality care, or inappropriate services and distribution of facilities.

Goudge goes on to say that the government is unlikely to either ban the private sector (politically unfeasible and practically impossible given government capacity), or ignore

it, given the impact of private sector provision on the public sector. The government's response to the private sector has to have three aims:

- To plan for the impact of changes that are likely to influence the absolute and relative distribution of resources between the two sectors.
- To build constructive public-private partnerships from which the public sector can benefit.
- To influence private sector behaviour through regulation – both in the form of legislation, and through a framework of incentives (financial and non-financial). The aim of regulation should be not only to limit the problems listed above, but to ensure that the public health sector benefits from its interaction with the private sector, and vice versa.

The public sector could proactively use public-private partnerships as a means of increasing the resources available to the public sector, enabling it to improve the quality of care. Regulation would be crucial to ensure both that those using the private sector receive a reasonable quality of care, and that the public sector benefits from public-private partnerships.

In order to maintain and improve health care for all in South Africa there needs to be closer co-operation between the private and the public health sectors. It is essential that both sectors identify and examine the unique challenges facing them. Both need to become more cost-efficient and effective. Future co-operation between these sectors may introduce new opportunities and the private sector should not be considered in isolation (Veliotis, Magennis and Brown 1993).

Veliotis, Magennis and Brown go on to say that world-wide technology is a major factor driving the global medical inflation spiral. International developments in medicine result in the ongoing discovery of new procedures and equipment that affect diagnostic and treatment methods. Because the cost of such technology usually tends to be substantially higher than that of older technology, it often increases expenditure disproportionately. This phenomenon is particularly prevalent in the private health sector in South Africa,

where modern technology is used by private hospitals to attract health care providers. Since most sophisticated medical equipment has to be imported by South Africa, the devaluation of the Rand against most major international currencies increases the cost of technology.

2.9. Cost-effectiveness in General Surgery

Surgical training has a definite influence on the practice of surgery. Both are subject to the governmental and market forces that are revolutionising the delivery of health care today.

2.9.1. Surgical Training

Surgical education and practice are inextricably linked. Each is essential to the other's existence, and what happens in one area inevitably affects the other (Stone and Doyle, 1996). Efforts to reduce costs impact profoundly on surgical practice and will therefore have a significant impact on surgical education. Surgical educators need to adapt to many changes in surgical practice while opposing some potential changes that may be harmful to the learning process (Stone and Doyle, 1996). A balance must be struck. Medical students must be exposed to the new economics of health care early in their pre-clinical years. This will provide a fundamental understanding of the rationale for cost efficiency. Business principles e.g. costing, margin, should be taught.

Managed health care plans aim to reduce costs by emphasising out-patient care and decreasing hospital utilisation. Surgical lengths of stay have decreased dramatically in the years between 1991 and 1996 and an increasing number of surgical procedures are performed on an out-patient basis or in free-standing ambulatory surgery centres (Stone and Doyle, 1996). Between 1980 and 1992 the average length of hospital stay for a patient undergoing a cholecystectomy decreased from 10.9 days (Haug and Seeger, 1982) to 4.9 days (Rogers, 1995). Thus surgical training must emphasise the importance of reducing the length of stays.

Malcolm Knowles (Knowles, 1980) is a premier theorist of adult education. He acknowledged that educational goals in the real world must be filtered through the needs of the institution and society as a whole. Health care institutions must define their mission and the strength of their commitment to education. Cost of medical care is the driving force behind the current changes in the surgical practice (Stone and Doyle, 1996).

2.9.2. Cost-effective Management of Gall-bladder Disease

These are times of world-wide economic retraction, therefore much interest is now focused on the money we spend on health care. Surgeons perform costly procedures; so the health care system has focused on them and specifically on laparoscopy. Laparoscopic technology has been explosive and unfortunately has come with increasing equipment costs. On one hand surgeons have to deal with appropriate utilisation of laparoscopy, and its additional impact on a surgeon's daily life through increased operating time, increased risk to the patient and the provider, and increased cost to health care from the incorrect utilisation of pioneering procedures (Traverso 1996).

There is no doubt in anyone's mind that the advent of laparoscopic procedures has had enormous benefits, both social and economic, for both surgeons and patients. Laparoscopic cholecystectomy used as a long-term solution to symptomatic gall-stone disease has obvious advantages when compared to open cholecystectomy. These advantages include:

- Shorter length of hospital stay.
- Decreased post-operative morbidity.
- More rapid resumption of normal daily activities.

However, a study done by Legoretta et al suggested an overall negative economic impact of laparoscopic cholecystectomy. This is partly due to increased patient demand for these services. An informal survey done by Orlando III(1996) also showed that 17 of 19 gastro-enterologists stated that they had relaxed their criteria for referral of patients with gallstones for surgery. Orlando III and Russel did a survey in Connecticut in 1996 which showed that the advent of the technique of laparoscopic cholecystectomy resulted

in a 29% increase in the overall rate of cholecystectomy. Similar increases were reported in New York, Maryland and Pennsylvania. This increased rate is evenly distributed over all age groups.

Due to these increases in the number of laparoscopic cholecystectomies now being performed, the cost of these procedures needs to be carefully evaluated. The areas that can be controlled by the surgeons relate to clinical care of the patient and selection of appropriate instrumentation for the procedure. Attempts to reduce hospital charges must focus on controlling length of hospital stay and supply charges, which include disposable instrumentation (Orlando and Russel 1996).

The role of instrumentation costs in laparoscopic surgery has thus far been controversial. Many authors have attempted to compare disposable instrumentation costs with re-usable costs. A study done by MacFayden et al reported disposable instrumentation costs of \$806, compared with \$503 for re-usable instruments. This included a \$200 per case reprocessing charge for the re-usables.

Deloitte and Touche, a health care consulting firm, conducted a study in nine hospitals across the United States. This study was requested by a disposable instrument manufacturer. They concluded that the average cost per case was \$740 for a mixture of disposable and re-usable instruments, and \$725 per case for an approach using only disposable instruments. However, in this study, using the mix of disposables and re-usables, costs as low as \$501 per case were observed.

Voyles has demonstrated that low hospital charges can be achieved with a programme that is organised around good re-usable instrumentation. In a German study, Lefering et al documented reduced costs and no difference in outcome with the use of re-usable instrumentation. Other surgeons have analysed the cost effectiveness of particular instruments. Re-usable trocars have been suggested to have a cost advantage (Duppler, 1992). However, this advantage must be weighed against concerns about device wear and dulling of the points (Orlando and Russel 1996). Orlando and Russel also go on to

say that the disposable multi-fire clip applicator is particularly expensive compared with a re-usable single-fire clip applicator that takes no more than one minute to use.

Instrument processing costs must be evaluated with a view to instrument design. Many newer re-usable instruments have features to permit ease of cleansing (Orlando and Russel, 1996). Despite disposables manufacturers' alarms about sterility of re-usable instrumentation, no evidence of infection or contamination exists assuming that standard steam sterilisation has been used.

Orlando and Russel advocate a pragmatic analysis of each instrument. The most important factor for the surgeon is the clinical suitability of the instrument. Once clinically satisfactory performance is assured, hidden costs, in addition to acquisition costs must be considered in assessing re-usable instruments. Hidden expenses include costs for repair, processing, replacement and back-up requirements. An assessment of the useful life of the instrument is also necessary. These factors vary depending on the instrument. In the experience of Orlando and Russel grasping forceps have a life of 200 cases. Re-usable scissors (endoshears) have a much shorter life-span. Orlando and Russel have adopted hybrid re-usable scissors with disposable tips. These tips last for 5 – 10 procedures after which they are discarded. De Vos et al supported the use of re-usable and hybrid instrumentation in an abstract written in 1999.

The three specific laparoscopic instruments that this study will focus on are:

- Clip applicators.
- Endo-shears / Scissors.
- Trocars.

Much has been written and said about which type of laparoscopic trocar should be used. Although individuals surgeons may have preferences, there does not appear to be any great difference between the conical- and pyramidal-tip trocars, as long as they are sharp (Duppler, 1992). Several types of disposable trocars are available as well. These are routinely sharp and often come with a safety shield, which is said to decrease the risk of

intra-abdominal injury. It is important that these safety shields do not lull the surgeon into a false sense of security, however, as injuries can still occur despite their use.

2.10. Re-sterilisation of Disposable Laparoscopic Instruments.

K. M. Ulualp et al conducted a study in 1999 on whether it is possible to re-sterilise disposable laparoscopy trocars in a hospital setting. Disposable instruments have a relatively more complex design than their re-usable counterparts, and the study was undertaken to investigate the safety of hospital disinfection of disposable laparoscopic trocars. Although the pharmaceutical companies that manufacture these disposables have adamantly maintained that single use devices (disposable devices) are *not* to be re-sterilised, this practice is occurring regularly in some hospitals. This is probably due to the high cost of the disposable instruments, and the increasing number of patients undergoing laparoscopic procedures. The result of the above study showed that disinfection for multiple use of disposable laparoscopic instruments with a relatively complex structure is not effective and may result in nosocomial disease transmission by bacteria, fungi and viruses.

The above study appeared in the journal "Surgical Laparoscopy, Endoscopy and Percutaneous Techniques, Volume 10, no.2" in 2000. Maurice E. Arregui, one of the editors of the journal wonders why this question even has to be asked. He goes on to say that when many of these devices were originally developed, the medical economy was quite different. Hospitals were able to make a profit on disposable devices. They marked up the cost by a factor of 2.5, and encouraged surgeons to use these devices. The argument of the hospitals at the time was that the use of re-usables was costly because of the added work of cleaning and re-sterilising. It was also maintained that re-usable instruments were not as safe as disposable instruments because of the risk of injury to the bowel or blood vessels. Eventually there was no incentive for manufacturers to make re-usable instruments.

Surgeons were also encouraged to use the disposable trocars because of the supposed increased safety from the safety shield included in some of these disposable devices.

Surgeons became afraid not to use the disposable devices because they had become the standard of care, and most feared that if a viscus or vessel injury occurred, they would not stand a chance in a court of law. We now know that there is very little merit to the safety shield; it has not prevented serious injury, and its use will not protect against litigation if an injury does occur.

Arregui goes on to say that in his own practice, he does not use disposable trocars, disposable clip applicators, disposable tackers or disposable balloons. He has saved several hundreds of dollars on laparoscopic cholecystectomies. In his practice sterility, safety and efficacy were not affected. In 1992, the cost of disposable trocars versus reusable trocars for laparoscopic cholecystectomies would cost \$162 million annually based on 500 000 cholecystectomies performed in the United States alone.

2.10.1. Why Hospitals Try to Sterilise Disposable Trocars

The medical economy since the beginning of the laparoscopic era has changed dramatically. Because of the increased health costs in the United States there was a risk that Medicare would go bankrupt, thus the US government and health insurers have stopped paying line-item billing. Hospitals are getting paid a fixed amount for a particular surgical procedure. There is no incentive in the US now to use disposable devices because the expenses and the mark-up are no longer paid for and there is no profit margin. In the US, many companies have developed which reprocess disposable devices. This has been allowed by the US Food and Drug Administration (FDA), but now there is concern that many of these devices are not suitable for reprocessing. There are the issues of sterility and also of the potential degradation of products, which may dislodge or malfunction if repeated sterilisation is performed. In the US the tide has now changed back to using re-usable instruments.

In countries other than the US, the price of disposable instruments is double or more of that in the US. These countries have economies that are not as good as that of the US, thus the cost considerations of laparoscopic procedures is much more significant.

Therefore it is not surprising that in these countries disposable instruments are re-sterilised.

The manufacturers of disposable trocars have no practical economic reason to stop making these disposable products. If they did, their profits would rapidly decrease. Arregui does blame these companies for marketing to surgeons and convincing them that it is unsafe to use trocars without a protective shield. He also blames the hospitals for promoting the disposable trocars because it was profitable for them to do so. As long as there is a market for disposable trocars, there will continue to be manufacturers. This makes economic sense, although it may not make sense for medical and medico-economic purposes.

2.10.2. Why Disposable Laparoscopic Instruments should not be Re-used

Carol Scott-Connor says that re-usable medical devices are designed to be cleaned mechanically, and then sterilised or subjected to high level disinfection. A re-usable metal trocar is easily taken apart and cleaned. A disposable trocar cannot be dismantled for thorough mechanical cleansing, yet this cleansing is the crucial first step toward effective infection control. Blood or other tissue fluids that remain in inaccessible crevices of these devices significantly impede the efficiency of disinfection. Even if one could assure mechanical cleansing, any sterilising or disinfecting agent must contact all surfaces of a device to work properly.

In a study done by H. Gundogdu et al in 1998, a positive bacterial culture was obtained from one of thirty disposable trocars subjected to high-level disinfection with gluteraldehyde. Laparoscopy has been in use for decades and there is no known case of infection transmission by laparoscopic instruments that have undergone proper cleansing and steam sterilisation.

Additional concerns arise when instruments designed for single use are re-used. The electrical insulating material is not designed for multiple use. Mechanical fatigue may produce instrument failure.

2.11. Quality in Health Services

A focus on quality in health services has been developing world wide in the last two decades (Gary Morris, SAHR 1999). Efforts to improve quality are slowly coming together in a type of quality movement throughout South Africa. The focus on quality has its origins in Japanese industry in the 1950s.

The dimensions of quality generally taken as the most important are:

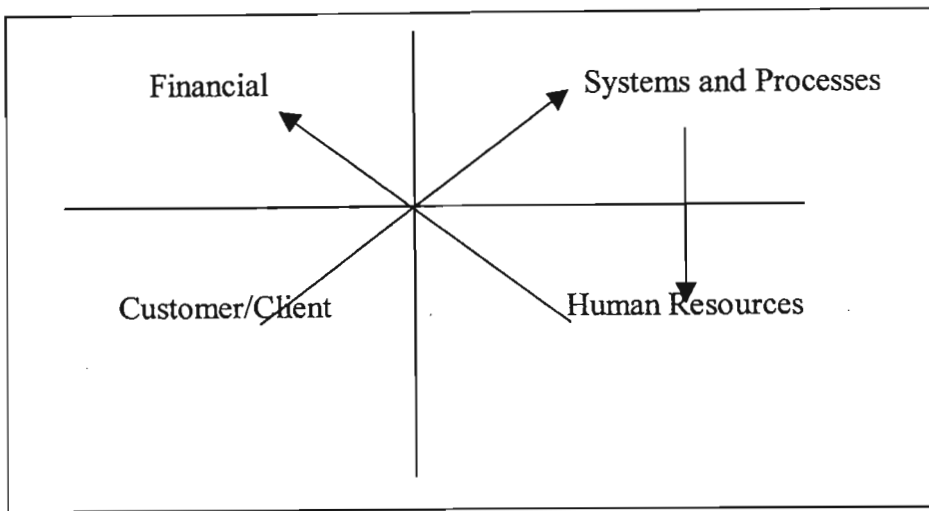
- Interpersonal relationships
- Access to service
- Effectiveness
- Consistency and continuity of service
- Efficiency
- Technical competence of the provider
- Safety
- Comfort and amenities.

Modern thinking recognises the need for a quality workforce with a clear vision of what the quality movement entails, and an explicit commitment to that vision. The **Balanced Scorecard** is one tool that can assist in integrating various aspects of the service. It measures core business across four inter-linked quadrants:

- Starting from needs and services to be provided for the client, then...
- Setting up systems and processes to provide those, then...
- Developing the human resources in terms of knowledge, skills and attitudes, then...
- Determining the financial needs and getting the most out of the financial resources.

The following figure (Figure 2.5) is a diagrammatic representation of the Balanced Scorecard.

Figure 2.5: The Balanced Scorecard (Source: SAHR 1999)



2.12. Conclusion

The public and private sectors in the health care industry are often regarded as two separate entities – a public sector which provides care for the majority of the population, and a private sector that provides care for the wealthy who are able to afford medical scheme coverage. But as can be seen from the previous discussion, these two sectors are inextricably linked.

In order to improve health care for all of South Africa's population, there must be closer co-operation between the private and the public health sectors. Both sectors have to identify and examine all the challenges facing them. Both need to become more effective and cost-efficient.

Veliotes, Magennis and Brown suggest that world-wide advances in medicine and technology is a major factor that is driving the global inflation spiral. The cost of this

technology is usually far greater than that of the older technology. This often increases health care expenditure disproportionately. This price increase is particularly prevalent in South Africa where modern technology is used by private hospitals to attract health care providers.

Laparoscopic procedures have undoubtedly had enormous social and economic benefits for both surgeons and patients. Because of the explosive increase in the number of these procedures now being performed, costs of these operations have to be carefully evaluated. The areas that can be controlled by the surgeons relate to the clinical care of the patient, and selection of appropriate instrumentation for the procedure (Orlando and Russel, 1996).

The main driving force behind the selection of laparoscopic instrumentation is economic. The manufacturers of disposable laparoscopic instruments have no sound economic reason to stop making disposable devices. In the same vein, because of economic reasons, the dangerous practice of re-sterilising single-use devices at some hospitals is becoming more rampant. There is no clear evidence thus far that re-usable laparoscopic instruments are in any way inferior to the disposable ones. The usual documented complications following laparoscopic cholecystectomies have no direct link to the type of instrumentation used.

CHAPTER 3: CASE STUDY

3.1. Background Information

KZNGOV Hospital was opened approximately 65 years ago in Durban. This is a fictitious name for the purposes of confidentiality in this study. Its original purpose was to provide general medical care for Indian and Black patients, as this was not adequately provided for by the existing provincial hospitals. The hospital originally comprised two large separate blocks of general wards. In addition to these blocks were the administrative block, a theatre complex, an X-ray department and surgical and medical outpatient facilities.

Upon opening, the hospital was functioning as a 720- bed hospital, but this bed space was rapidly outgrown because of the burgeoning population in the Durban area. This increase in population growth was due to deteriorating conditions in the rural areas and rapid industrialisation. The following table shows how fast the hospital expanded in the early years:

Table 3.1: Patient Statistics at KZNGOV Hospital between 1937 and 1950.

Year	1937	1940	1944	1950
Average no. of occupied beds	500	820	1 100	1 636
Patients admitted	13 350	27 125	36 345	45 447
Outpatients	29 100	69 000	302 315	415 293
Births	300	2 000	3 520	6 347

Source: Golden Jubilee Brochure KZNGOV Hospital

There were many crises in the 1940s: the Second World War (1939 – 1945), the smallpox epidemics, the poliomyelitis epidemic and the 1949 riots. These increased the pressures on the hospital. During the war, extra bed space was required by the military authorities. Five new prefabricated wards were constructed which were still in use until about three years ago. Other temporary structures were also created to alleviate the fast growing

maternity section. Further outpatient facilities were created away from the hospital to meet the growing demand for health care provision.

In 1947 the establishment of a medical school in Durban under the aegis of the University of Natal was approved in principle by the cabinet. Treasury approval was only granted in 1950. The medical school opened in 1951 and clinical training of the first group of students commenced in 1955. KZNGOV Hospital was then established as a teaching hospital. The establishment of the medical school was an extremely important development as, until this time, few black medical students were given places in the existing medical schools in the country, and many were forced to train overseas.

With the inception of the medical school, a major expansion of the hospital building programme commenced. A complete new surgical block, a new outpatients and casualty block, operating theatres and a fully equipped x-ray department were built. The maternity department was also extended. The original intended complement for this hospital was 720 beds in 1936, and it had now grown to a registered bed state of more than 2000. The following table shows the hospital's growth as reflected by admission statistics:

Table 3.2: Admission Statistics at KZNGOV Hospital between 1937 to 1980

	1937	1940	1950	1960	1970	1980
Patients Admitted	13 350	27 125	45 447	70 572	93 599	106 993
Outpatients	29 100	69 000	415 293	558 146	673 433	835 606
Births	300	2 000	6 347	13 908	20 090	21 221

Source: KZNGOV Hospital Golden Jubilee Brochure

The creation of a medical school also brought about other changes at KZNGOV Hospital. From a purely service type of hospital, the emphasis now changed to teaching as well as service. Members of the staff of the Faculty of Medicine have made valuable contributions to medical research and to the advancement of medical knowledge over the

years. The medical school and its teaching hospital are highly regarded in South Africa and abroad.

The teaching complex generated a progressive change in medical and scientific technology. Specialist expertise evolved and specialist departments and sub-disciplines evolved, e.g. orthopaedics, ophthalmology, ENT, urology, neurosurgery and paediatric surgery. Each of these specialities was under the charge of a surgeon of professional rank. With the creation of the various sub-specialities more work was generated and patient flow to the hospital increased. Since the hospital could not be physically expanded, existing beds and square –footage in outpatient departments had to be shared. More general as well as specialised nurses were needed, and the number of doctors had to be increased considerably. The numbers of undergraduate medical students also increased, and this added to the congestion everywhere in the hospital. Later paramedical training in such fields as physiotherapy, radiotherapy, nuclear medicine, ultrasound, pharmacy, speech and occupational therapy and medical technology was well established in the hospital.

Over the years the increase in patient numbers overwhelmed available facilities to an extent that patients used to sleep on mattresses at night. The daily average of 150 “floor beds” greatly reduced physical ward space and increased cross-infection. It also added a considerable burden on the nursing staff. Thankfully this is not the case any more. These floor beds caused an urgent need to increase service needs such as catering, laundry, maintenance, laboratories, mortuary, central sterilising and the internal communicating system.

Today, with the opening of the Inkosi Albert Luthuli Hospital in Cato Manor, KZNGOV Hospital is in a process of decommissioning. Many of the specialist departments have moved over to the new hospital, and KZNGOV Hospital will be re-graded as a regional and not a tertiary hospital. However, the main departments e.g. general surgery, internal medicine and obstetrics and gynaecology will remain.

3.2. Surgical Technique of Laparoscopic Cholecystectomy

This section will not describe in detail the exact methods and technicalities of performing a laparoscopic cholecystectomy, but will concentrate mainly on the instruments that are being investigated in this study and their respective uses.

3.2.1. Exposure of the Peritoneal Cavity and its Contents

The patient is positioned on the operating table in a supine position i.e. the patient is lying on his/her back. This position is used to create the pneumoperitoneum (air in the peritoneal cavity) and it also allows for manipulation of the small and large bowel. When a view is required of the stomach, liver and spleen, a head-up tilt of the operating table allows the bowel to move inferiorly (downward) by gravity. Care must be taken to stabilise the patient on the table during any tilting away from the horizontal. The stomach is decompressed by means of a nasogastric tube. This decompression serves three purposes:

- Accidental penetration of the stomach is less likely.
- Visualisation of the gall-bladder, liver and the free edge of the lesser sac of the stomach is easier.
- When anaesthesia is reversed the risk of vomiting due to a bloated stomach is decreased.

3.2.2. Insufflation of the Peritoneal Cavity

Carbon dioxide is the standard gas used for most operative laparoscopy, mainly because it does not support combustion. After absorption from the peritoneum it is readily excreted via the lungs. If carbon dioxide is accidentally injected into a blood vessel resulting in carbon dioxide embolism, this is more easily treated than air or nitrous oxide embolism.

Optimum exposure is obtained with a constant pneumoperitoneum of 12.0 – 16.0 mmHg pressure. Because operative laparoscopy entails the use of multiple cannulae and the frequent changing of instruments, there is intermittent gas leakage throughout the procedure. This problem has been resolved by the introduction of the automatic

electronic insufflator. This insufflator is capable of automatic flow rates of up to 8.0 litres/minute. Operative procedures without this machine are tedious and time consuming. The insufflator also provides good monitoring of the pressure within the abdomen. Figure 3.1. shows a picture of an insufflator that is commonly used in laparoscopic procedures.

Figure 3.1: Insufflator



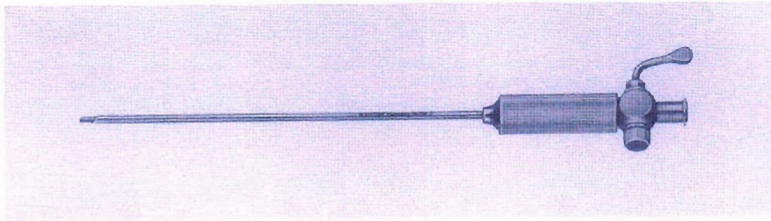
Source: Storz Catalogue

3.2.3. Placement of the Veress Needle

The initial induction of the pneumoperitoneum is still most often performed with the **Veress Needle**. It consists of a sharp outer sheath and a blunt spring-loaded inner cannula which helps protect intra-abdominal organs from injury (Cuschieri, 1984). The spring-loaded central trocar retracts as the needle encounters resistance, and retracts back on entering the peritoneal cavity. The function of the spring-loader snap mechanism should be confirmed prior to initial insertion, as should the patency of the lumen of the needle. This is done by checking gas flow through it. The Veress needle is most often

inserted just below the umbilicus. This is where the laparoscope trocar and cannula will be inserted. The following is an example of a Veress needle.

Fig. 3.2: The Veress Needle



Source: Storz Catalogue

3.2.4. Insertion of Initial Trocar/Cannula

The site for insertion of the first trocar is usually around the umbilicus. This first trocar should have an external diameter of 11.0mm and is used to hold the video laparoscope. The Veress needle is withdrawn and the skin incision used for the Veress needle is extended to 1.5cm. The trocar/cannula is then inserted into the incision. As soon as complete penetration of the abdominal wall is achieved by the trocar, one gets a sudden escape of intra-peritoneal gas. The trocar is then removed and the cannula is advanced further into the abdomen. The gas line is then connected to the side port of the cannula and the tap opened to maintain insufflation of the peritoneal cavity.

3.2.5. Insertion of Accessory Trocars / Cannulae

The accessory trocars / cannulae are usually 5.0mm and 10.0mm in diameter. These are required for the insertion or withdrawal of the various laparoscopic instruments. In the majority of patients three accessory cannulae are needed. The French technique places these three accessory cannulae in the following positions:

- A 10.0mm cannula is placed in the upper left paramedian area; this port is used for the electrosurgical hook knife, scissors.
- A 5.0mm cannula is placed in the upper medial subcostal area; this port is used for retraction of organs, suction and irrigation.

- A 5.0mm cannula is placed in the lower right hypochondrial region; this port is used for the grasping forceps.

The techniques for dissecting out the gallbladder and removing it will not be discussed as there is too much surgical technical detail involved. However, we will be discussing the other two instruments that are under consideration in this study, namely the endoshears / scissors and the clip applicator.

3.3.Instruments Under Consideration in this Study

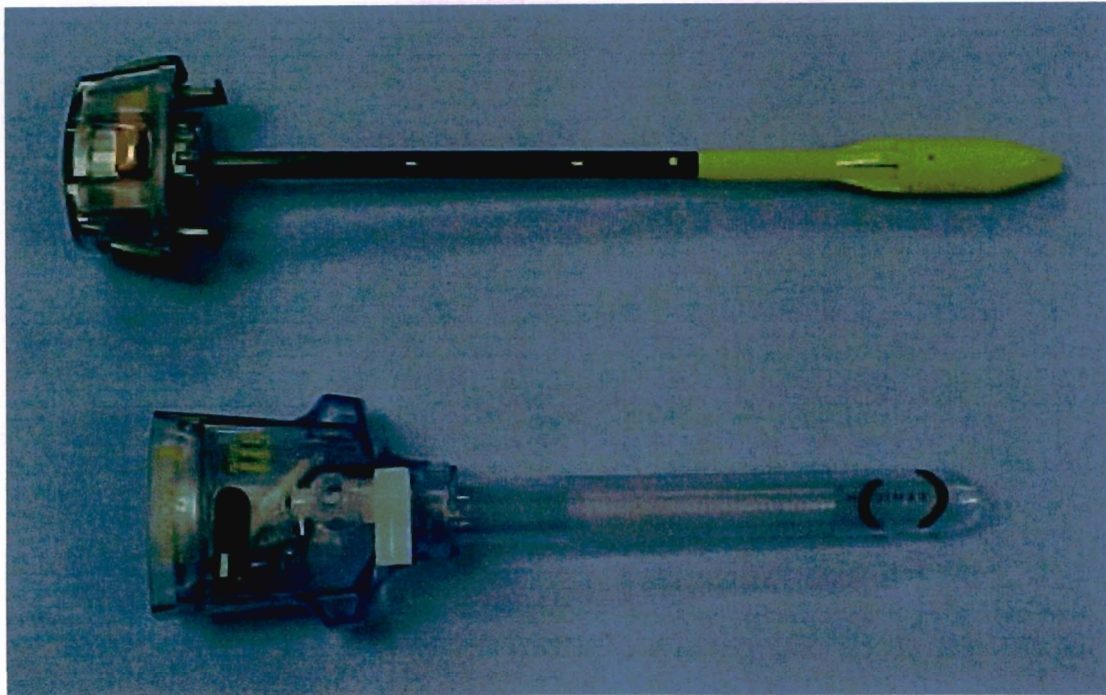
The three instruments that are going to be considered in this study are:

- Trocars and cannulae
- Endoshears / Scissors
- Clip applicator

3.3.1. Trocar/Cannula

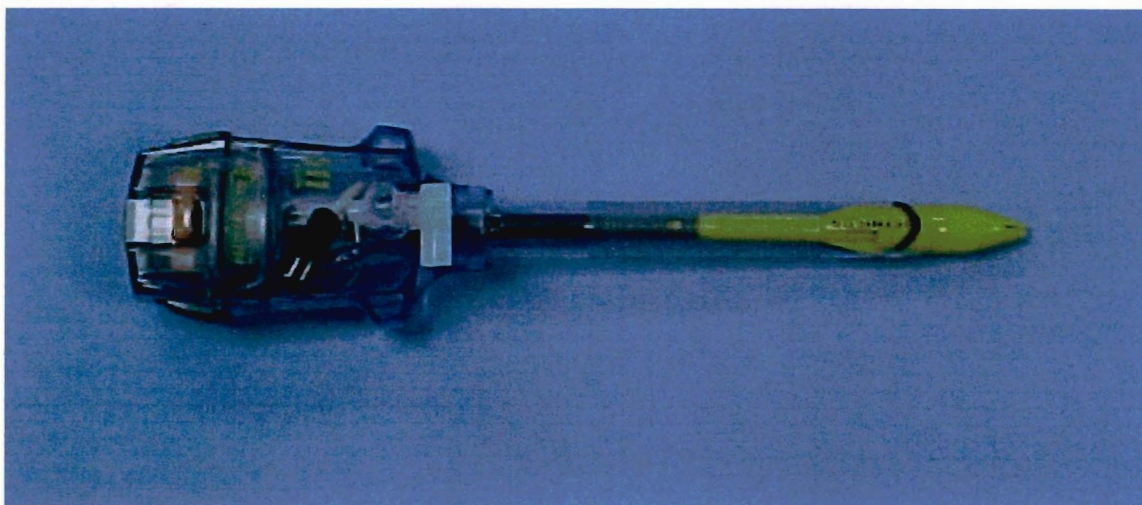
A trocar is an instrument which is inserted into a body cavity through which the laparoscopic instruments are inserted. It comprises an outer tube containing an inner removable shaft that has a sharp point. The shaft is withdrawn after the trocar has been inserted into the body cavity. The trocars used today can be either re-usable or disposable. The re-usable trocars are made of stainless steel. These instruments are sterilised by steam using an autoclave. The disposable instruments are strictly for single use only and made of a plastic material. The following figures show the disposable and the re-usable trocars within and separate from their sleeves / cannulae.

Fig. 3.3: Disposable Trocar with Sleeve Removed



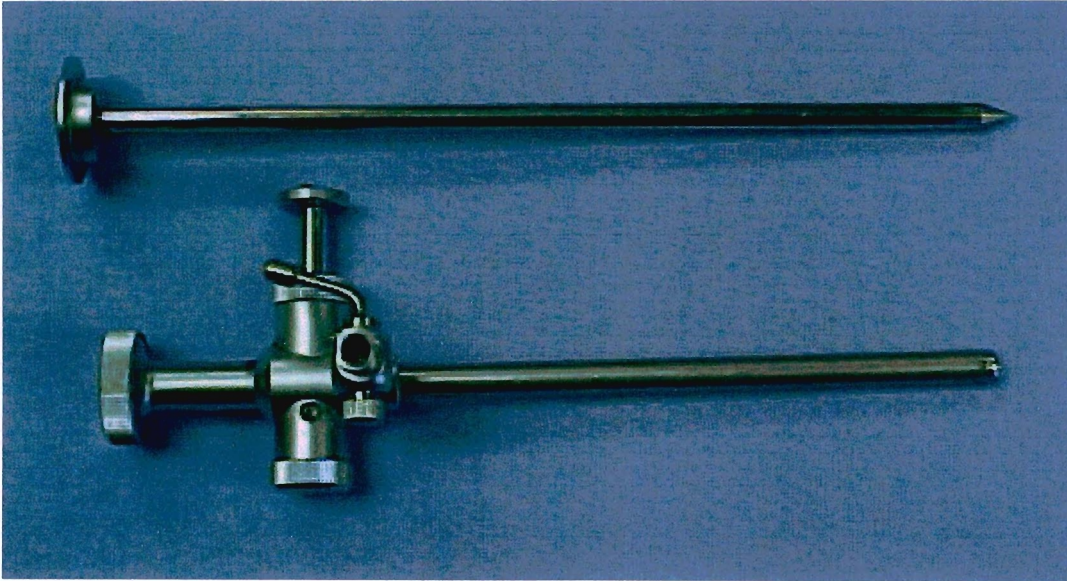
Source: KZNGOV Operating Theatre

Figure 3.4: Disposable Trocar in Sleeve



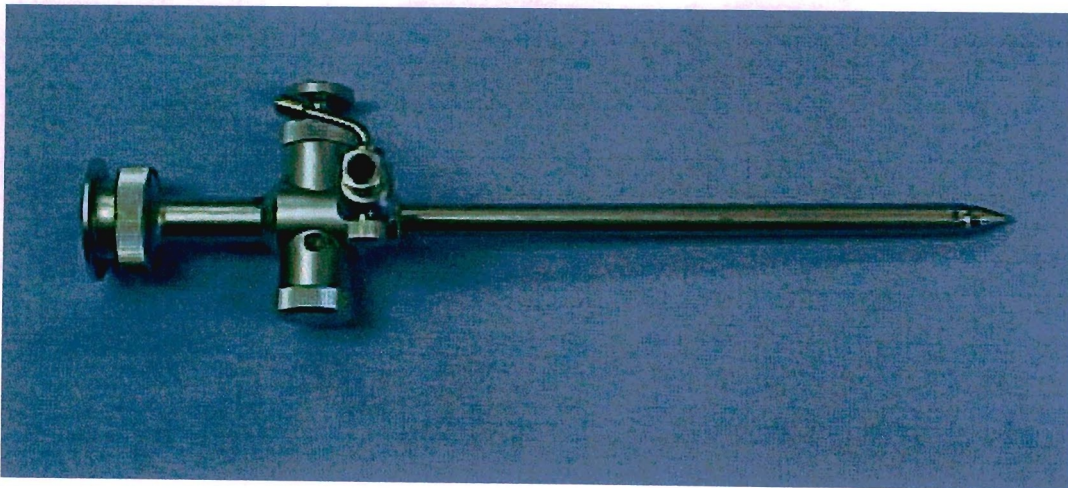
Source: KZNGOV Operating Theatre

Figure 3.5: Re-usable Trocar with Sleeve Removed



Source: KZNGOV Operating Theatre

Figure 3.6: Re-usable Trocar within Sleeve



Source: KZNGOV Operating Theatre

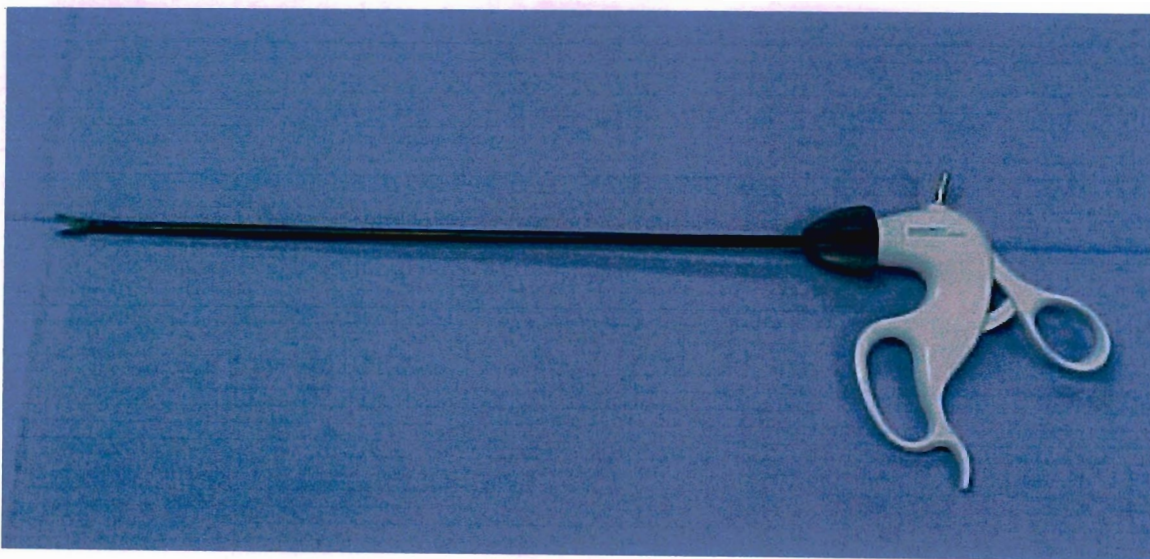
3.3.2. Endoshears / Scissors

The endoshears or scissors are used for tissue dissection. As in open surgery, various methods of dissection along tissue planes are used. As every minor blood loss considerably impairs vision during laparoscopic surgery, a meticulous bloodless dissection is essential. There are six types of dissection used:

- Blunt dissection with a “peanut” swab, or hydro-dissection with a pressurised jet of warm saline.
- Sharp dissection using scalpels of various sizes and shapes.
- Scissors or endoshears dissection.
- High frequency electrosurgical dissection with monopolar current.
- Laser dissection.
- Ultrasonic dissection.

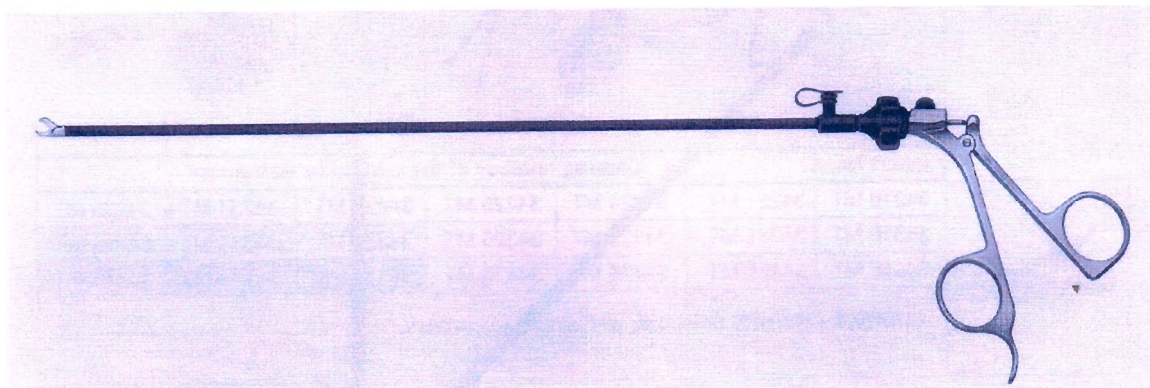
Endoshears or scissors dissection is used commonly. Recently there has been significant progress in the design, size and type of scissors for laparoscopic work. Scissors, in terms of the mechanical function are either single- or twin-action. The former have only one moveable blade, and in the twin variety both blades move. A large blunt-nosed scissor is available for use with the 11.0mm cannula. Figures 3.7 and 3.8 show the disposable and re-usable endoshears / scissors respectively.

Figure 3.7: Disposable Scissors / Endoshears



Source: KZNGOV Operating Theatre

Figure 3.8: Re-usable Scissors / Endoshears



Source: STORZ Catalogue

3.3.3. Clip Applicators and Clips

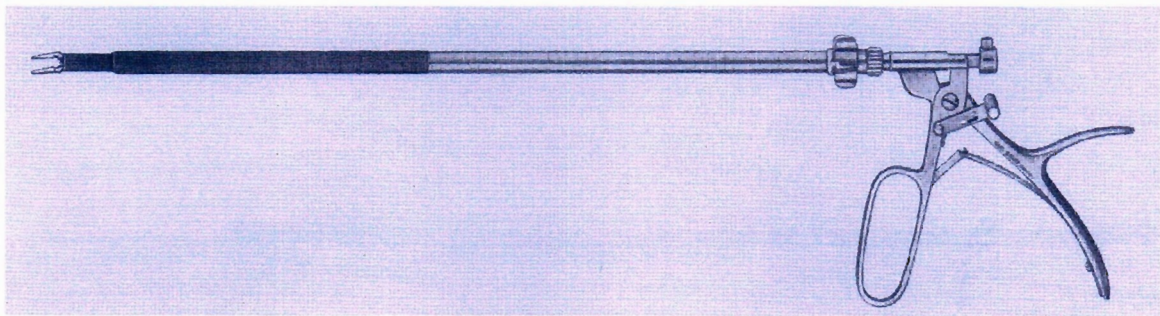
Clips are used to secure haemostasis during the operation. Control of bleeding is usually more difficult in laparoscopic surgery than in open surgery. Clips are usually used to clamp blood vessels of between 3.0mm and 5.0mm in diameter.

The non-absorbable metal clips are made of stainless steel or titanium, and are available in different sizes. Clip applicators are available in two sizes – one for clips of 6.0mm in length, and one for clips of 9.0mm in length. Application of clips must be done carefully, and a second clip should be used on the proximal section of the artery. Disposable preloaded clip applicators with automatic delivery of the clip to the jaws of the applicator are useful for long procedures and do have certain advantages. These instruments allow for rapid, precise, repeated clipping without the need of withdrawal of the instrument for loading. This speeds up the procedure quite considerably. But these instruments are costly and are not essential for routine cholecystectomy.

The current limitation of all clip applicators (disposable and re-usable) relates to the fixed size clip that each instrument can apply. This entails the use of different clip applicators for small, medium and large clips. This is an important practical consideration because clip security after application is dependent on using the appropriate size of clip in relation to the occluded vessel. The risk of slippage is especially high if the clip is too small and

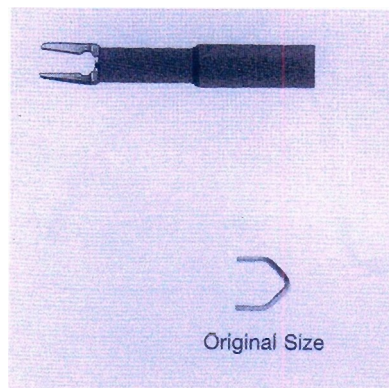
does not project beyond the whole width of the vessel, or is not applied at right angles to its long axis. Accidental brushing or traction can also result in the slippage of clips.

Figure 3.9: Re-usable Clip Applicator



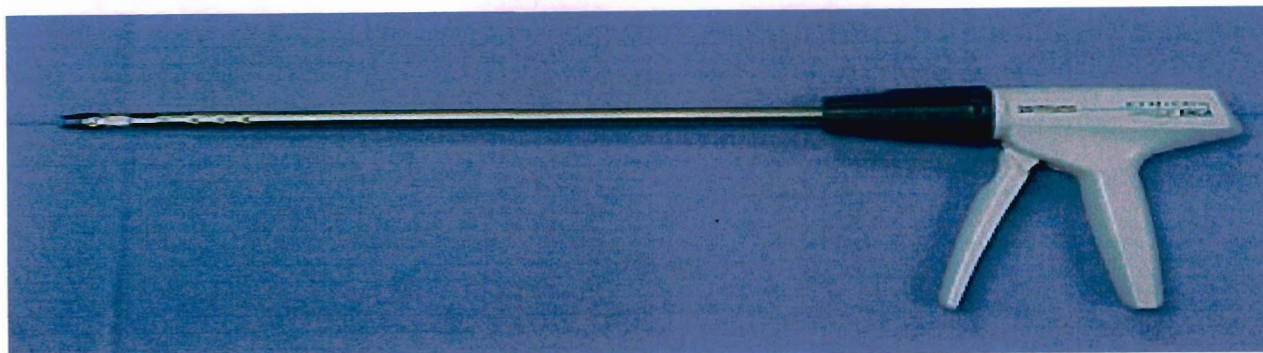
Source: STORZ Catalogue

Figure 3.10: Tip of Re-usable Clip Applicator showing a Titanium Clip Below



Source: STORZ Catalogue

Figure 3.11: Disposable Clip Applicator



Source: KZNGOV Operating Theatre

3.4. Disposable and Re-usable Instruments

Almost all laparoscopic instruments are now available as disposable items from several well established and many newer companies, with the exception of optics. There are obvious advantages that are inherent to disposable products. The disposable instrument when used is guaranteed to be at its peak functional state, and therefore the risk of malfunction is decreased. This is undoubtedly an important consideration, especially when it applies to complex instrumentation such as disposable cartridge staplers and pre-loaded clip applicators. However, when it is extended to the more common instruments there are practical disadvantages that must be taken into consideration. These disadvantages are:

- The increasing cost – this is directly proportional to the number of disposable items used per case.
- The disposable instruments create additional problems for the hospital by increasing the administrative task of ordering, inventory and storage. An adequate stock of disposable equipment to cover all contingencies is essential for a successful practice and to ensure the uninterrupted progress of laparoscopic operations.
- Human nature being what it is contributes to the risk that disposable equipment will be cleaned, sterilised and re-used a number of times. This is a dangerous practice

and the ability of these disposable items to be cleaned is limited, and cleaning causes their functional performance to deteriorate rapidly. They are safe and reliable if only used once.

- The ecological consequences inherent to the disposal of the plastic material are real and will assume increasing importance.

With regard to the common laparoscopic instruments e.g. graspers, scissors and hooks, a good re-usable instrument is much cheaper in the long run, even if additional manpower and time are needed for maintenance, cleaning and sterilisation. We now have the development of semi-disposable instruments, where the functional part is disposable, but the rest of the instrument is re-usable.

3.5. Sterilisation and Disinfection

Medical instruments to undergo sterilisation and disinfection are divided into three categories based on the degree of risk of infection involved in the use of these items: Critical, semi-critical and non-critical.

- *Critical* items are those entering sterile tissue or the vascular space, such as laparoscopic instruments.
- *Semi-critical* items are those that come into contact with skin that is not intact, or with mucous membranes, e.g. gastrointestinal endoscopes and respiratory therapy equipment.
- *Non-critical* items come into contact with skin only e.g. blood pressure cuffs.

Ideally, critical items such as laparoscopic equipment should be sterilised. If this is not feasible, however, high level disinfection may be appropriate.

3.5.1. Sterilisation

The term “sterile” refers to the inability of living organisms to reproduce. Sterility of micro-organisms is synonymous with death because their activities are usually undetectable in the absence of multiplication. Articles that are free from living

organisms are also termed sterile. The presence of a single micro-organism renders an article unsterile.

Sterilisation is a process that kills or removes all types of micro-organisms, including resistant bacterial spores. It is impossible to guarantee that every micro-organism exposed to a particular treatment has been killed or that every article has been sterilised. Thus, realistically, sterilisation is defined as a process that provides an acceptably low probability (e.g. one chance in a million) that any micro-organism will survive the treatment.

It is important to know when sterilisation, which may involve severe treatment of equipment and materials, is required. It is essential for articles that enter the blood or tissues, e.g. surgical instruments, syringes, needles and solutions for intravenous infusion or injection. Diagnostic instruments that come into contact with delicate mucous membranes, like those lining the urinary tract or peritoneal cavity, should also be used in a sterile condition.

3.5.2. Disinfection

A disinfection process is intended to kill or remove pathogenic (disease-producing) micro-organisms with the exception of bacterial spores. Spores can be killed only by a sterilisation process. Terminal disinfection of used equipment which may be contaminated with harmful micro-organisms is commonly referred to as “decontamination”. Antisepsis is *not* synonymous with disinfection; this term should be reserved for the prevention of infection by topical application of anti-microbial agents to injured tissue.

Disinfection is divided into three levels depending on the amount of micro-organisms eliminated:

- *High level* – eliminates all organisms with the exception of large numbers of bacterial spores.

- *Intermediate level* – destroys all organisms except spores, some viruses and some fungi.
- *Low level* - can destroy most bacteria and some fungi, but cannot eliminate spores or tuberculosis bacilli.

Disinfection is adequate for the preparation of many articles intended for use in patient care. These include bedpans, urinals, clinical thermometers and eating and drinking utensils. Floors, walls, tables, trolleys and work benches require disinfection as well as cleaning if contaminated with blood, tissues, exudates or microbial cultures has occurred. Disinfection by chemical agents is the only method applicable to the skin of hands, operation sites and injection sites for killing transient contaminants or reducing the resident microbial flora to a low level.

Disinfection by pasteurisation, boiling or chemical agents does not make surgical instruments safe to use. Its use as a substitute for sterilisation cannot be justified. When this is unavoidable because a costly instrument, in short supply, is heat sensitive and insufficient time is available for the slower process of gas sterilisation, a broad spectrum disinfectant should be chosen. An example of a broad spectrum disinfectant is glutaraldehyde. However, the person responsible should be fully aware of the risk involved.

3.6. Essential Pre-requisites for Sterilisation and Disinfection

The efficiency of sterilisation and disinfection depends on:

- Biocidal action
- Effective contact between the biocidal agent and the micro-organisms
- Appropriate biocidal agents and apparatus
- Severity of treatment.

3.6.1. Biocidal Action

Biocidal action implies the death of micro-organisms, as indicated by their failure to multiply in any situation. It must be distinguished from reversible inhibition of

multiplication (biostasis), from which the organisms may recover on return to favourable conditions. Biocidal action is essential for sterilisation and disinfection. A biocidal agent is one that is capable of killing micro-organisms. The term is sometimes restricted to agents that kill all types of micro-organisms but is also used in a less exact sense to imply that some organisms are killed. Biocidal action against micro-organisms of a specified type is termed bactericidal, sporicidal, virucidal or fungicidal.

3.6.2. Effective Contact

Effective contact between a biocidal agent and its microbial target requires penetration of the physical or chemical agent to all sites at which the organism may be located.

a. Saturated Steam

Steam under pressure reaches the outer surfaces of solid objects and penetrates into accessible cavities and packed cotton textiles if the air has been completely removed. It cannot penetrate into non-aqueous liquids or impervious solids. Effective contact involves condensation to water. The latent heat that is released brings the articles rapidly to the sterilising temperature and the film of moisture ensures that conditions are optimal for biocidal action. Wrapping materials must be permeable to steam and also to the removal of air. In sterilisers that rely on gravity for the downward displacement of air by steam, the articles must be packed and loaded to facilitate drainage of the heavier air from trays, bowls, tubes and textiles. Flexible tubes should not be tightly coiled.

b. Gaseous Chemicals

Gas sterilisation by ethylene oxide requires penetration of the chemical agent and also of water vapour, which is essential for biocidal action. Ethylene oxide is highly diffusible, passing through many materials including thin polyethylene films.

c. Dry Heat

Dry heat sterilisation does not involve penetration of vapours but the articles must be heated to the sterilising temperature by conduction or convection. Metals are good conductors, but glass and oily materials are poor conductors of heat.

d. Ionising Radiation

The penetrating power of sterilising radiations depends on the type of radiation and the energy level. Electromagnetic gamma radiation penetrates deeply into large cartons containing materials of unit density. Accelerated electrons have greater energy than gamma radiation but less penetrating power because they are particulate.

e. Chemical Disinfectants

Effective contact between the solutions and the articles to be disinfected depends on the nature of the articles and the condition of the micro-organisms. Contact is unlikely to be achieved if the micro-organisms are located in pores or crevices or are protected by hardened deposits of organic or crystalline material. The complex, lipid-rich cell walls of Gram-negative bacteria, especially *Pseudomonas* species, present a barrier to the entry of some bactericidal agents into the cells. The wetting power of disinfectants is enhanced by alcohol or detergents.

3.6.3. Appropriate Agents and Apparatus

Biocidal agents that are used for sterilisation are listed with main applications and sterilisers in the following table: (Table:3.3).

Table 3.3: Biocidal Agents for Sterilisation

Agent	Applications	Apparatus
Saturated Steam	Wrapped articles Unwrapped instruments and utensils Aqueous liquids	Prevacuum steriliser, 134°C Downward displacement steriliser, 132-134°C Downward displacement steriliser, 121°C
Dry Heat	Metal articles, glassware, oils	Hot air oven, 160°C
Gaseous Chemicals	Heat-sensitive instruments and medical devices	Ethylene oxide steriliser or Low temperature steam and formaldehyde steriliser
Ionising Radiation	Medical devices	⁶⁰ Co installation or Electron accelerator

Source: Introduction to Sterilisation and Disinfection

Physical and chemical agents of disinfection are listed in the table that follows:

Table 3.4: Biocidal Agents for Disinfection

Agent	Applications	Apparatus
Hot Water	Heat sensitive instruments Anaesthetic apparatus Blankets and linen Mop heads Eating and drinking utensils	Temperature-controlled water bath, 75°C Washing machine, 75°C
Low-temperature steam	Heat-sensitive instruments	Low-temperature steam and formaldehyde steriliser (without the formaldehyde)
Ultraviolet Radiation	Room air	Germicidal lamps
Formaldehyde Vapour	Contaminated rooms	Electrical vaporiser
Chemical Disinfectants	Articles not required in sterile condition Decontamination of used articles Skin and mucous membranes	Suitable containers

Source: Introduction to Sterilisation and Disinfection

a. Steam Sterilisers

Pressure steam sterilisers are specially designed for porous loads (comprising all wrapped articles), unwrapped instruments and utensils, or aqueous liquids. Prevacuum sterilisers, with mechanical air removal, are required for efficient sterilisation of porous loads. The downward displacement type may also be used but is more liable to error and the cycle is longer. Downward displacement steam sterilisers should be used for unwrapped instruments and utensils and also for bottled liquids. The provision of a spray-cooling

system for liquids reduces the time required for sterilisation and minimises the deterioration of heat-sensitive ingredients.

b. Gas Sterilisers

Sterilisers for heat-sensitive equipment are designed for the removal of air by mechanical evacuation, vaporisation of the chemical agent (ethylene oxide or formaldehyde) and maintenance of the relative humidity required for biocidal action.

c. Dry Heat Sterilisers

Dry heat sterilisation is usually carried out in hot air ovens with forced air convection. Direct flaming is used to sterilise some laboratory bench tools such as inoculating loops. Incineration of waste material is also a form of dry heat sterilisation; the design of incinerators is critical as live micro-organisms escape with the effluent if burning is incomplete.

d. Radiation Installations

Radiation sterilisation is virtually restricted to industrial installations because of the complexity of the equipment and the essential safety precautions. A Cobalt-60 (^{60}Co) gamma radiation source or an electron accelerator may be used.

e. Chemical Disinfectants

Chemical disinfection does not require complex apparatus. Containers should be of suitable shape and size and filled with sufficient solution to ensure that the articles are completely immersed and that cavities are free from trapped air. The selection of an appropriate disinfectant is based on its range and degree of bactericidal activity (determined by an approved method), its compatibility with the articles to be disinfected and other materials with which it may come into contact during use.

f. Bacterial Filtration

The physical removal of bacteria from liquids and air is accomplished by filters of appropriate pore diameter and retention efficiency. Suitable filter holders and other

accessories are required. Membrane filters that have an average pore diameter of 0.22 μ m or 0.45 μ m and act as mechanical sieves are most suitable for filtration of liquids. Fibrous filters have a greater bacterial load capacity but the flow rate is low and the quality of the solution may be affected by adsorption of solutes, alteration of pH or addition of fibres. Fibrous filters in the form of packed columns or thin paper sheets, are commonly used for air filtration, but membrane filters are suitable for some applications. The fibrous sheets have a large surface area and are used in conventional or laminar flow ventilation systems. Each sheet is pleated and all the edges are sealed into a frame to form a compact unit.

3.6.4. Severity of Treatment

Heat sterilisation processes are defined by time at a specified temperature. Recommended times for steam sterilisation are 15 minutes at 121°C and 3 minutes at 132-134°C. These represent the minimum holding times for which the whole of the material treated must be held at the selected sterilising temperature to kill the microbial contaminants. They are based on the resistance of *Bacillus stearothermophilus* spores to moist heat. In dry heat sterilisation, a holding time of 60 minutes at 160°C allows for the possibility of a 10°C variation in temperature within the oven.

The parameters of a gas sterilisation process are more complex. The conditions required for sterilisation in a hospital ethylene oxide process operated within a temperature range of 45°C - 60°C are:

- Ethylene oxide: 400 – 1000 mg/litre
- Relative humidity: 70%
- Time: 4 hours.

A radiation sterilisation process is described by a single value, the minimum absorbed dose. A minimum dose of 25kGy (2.5 Mrad) is commonly used in the commercial production of medical devices but is increased if the contamination level of the articles exceeds the level for which the dose has been calculated.

The efficiency of chemical disinfection depends on the concentration and the time for which the solution is in contact with the articles or surfaces to be disinfected.

3.7. Procedure at KZNGOV Hospital's Operating Theatre

Approximately four to five laparoscopic cholecystectomies are performed at KZNGOV Hospital per week. Many other laparoscopic procedures are also done e.g. by the gynaecologists and the urologists. Specially packed sterilised sets are reserved for the general surgeons doing the laparoscopic cholecystectomies. These sets comprise mainly re-usable instrumentation, except for the fibre-optic instruments.

The general surgeons at KZNGOV Hospital use the three-port technique to perform the laparoscopic cholecystectomy. One 5.0mm trocar and two 11.0mm trocars are used. Using the Veress needle a pneumoperitoneum is created with carbon dioxide. This is maintained at a pressure of 15mmHg. The cystic duct is usually first identified and secured with two clips, after which it is divided. Two clips are also used to ligate the cystic artery. The gall-bladder is then dissected off the gall-bladder bed using blunt and scissors dissection. It is then removed through one of the accessory ports. The abdominal cavity is checked thoroughly for any bleeding. Any gall-stones that have fallen out of the gall-bladder are retrieved as well, and haemostasis is secured. The abdominal cavity is then washed out with sterile normal saline and the rectus sheath and skin are sutured.

The professional theatre sister who is the main scrub nurse for the laparoscopic cholecystectomy is solely responsible for cleaning, packing and caring for the instruments. The re-usable trocars, endoshears and clip-applicators are carefully and thoroughly cleaned after each laparoscopy with water and special custom manufactured brushes. These brushes are specially made to fit into the cannulae and to access all crevices on the instrument. Cleaning is thorough, and all visible organic matter like blood or tissue and other debris are carefully removed. The instruments are then re-packed and sent to one of the large autoclaves in theatre for steam sterilisation.

In KZNGOV Hospital theatres, the 11.0mm and the 5.0mm trocars are used. These are re-usable instruments made from stainless steel. The scissors used are of the hybrid variety. They comprise a stainless steel autoclavable handle, and black disposable tips. The handles are steam-sterilised and the disposable tips are sterilised with ethylene dioxide. This is after thorough mechanical cleansing. The disposable tips are used approximately five times then discarded. This practice is similar to that employed by Orlando and Russel in their practice in the United States of America. The clip applicators used at KZNGOV Hospital are also of the re-usable variety, and are cleaned and autoclaved like the rest of the instruments. They are used with pre-packed titanium clips that are sterilised at the manufacturing facility by means of gamma radiation. These clips come in a cartridge of eight clips. This is usually sufficient for one laparoscopic cholecystectomy.

The theatre committee has found that the above protocol for dealing with laparoscopic instruments to be the most cost-effective one thus far. In a government hospital, or in any other for that matter, one cannot afford to waste the dwindling financial resources. The protocol used at KZNGOV Hospital is similar to that used by Arregui in his practice. Arregui is the editor of the American journal "Surgical Laparoscopy, Endoscopy and Percutaneous Techniques".

3.8. Conclusion

KZNGOV Hospital is an old and established institution that was also one of the main vehicles for teaching the under-privileged non-white medical students during the apartheid days. Despite its limitations when it came to financial resources and the latest modern medical technology, it grew to be recognised world-wide as a top training and teaching institution that produced medical graduates of high calibre in conjunction with the attached medical school. Just prior to the opening of the Inkosi Albert Luthuli Hospital, KZNGOV was the main tertiary hospital in Kwazulu Natal, with modern technology that was comparable to other first-world hospitals.

The senior medical staff - including the nurses and doctors – are well qualified and their services are excellent. This statement can be borne out by the so-called “poaching” of our medical staff by other first-world countries like the United Kingdom and Australia. The practice of medicine and surgery cannot be faulted at KZNGOV Hospital, although the unfortunate epidemic of HIV / AIDS and tuberculosis is placing extreme pressure on the human and financial resources at the hospital. The hospital administration and the heads of the various departments have to evaluate costs carefully, and still provide a quality health service to the patients.

The department of general surgery and the theatre staff have succeeded in providing quality surgical care to the hospital’s patients. Their sterilisation and disinfection procedures are excellent, and there have been very few adverse effects on patients undergoing surgery. The surgical procedures themselves are done by experienced surgeons, and are performed according to international standards. Patient care is not compromised. The instruments used in theatre are well cared for, and in good working order. The operating theatre staff ensure that defective instruments are not used, as this will affect the standard of treatment given to the patients.

CHAPTER 4: RESULTS AND ANALYSIS OF THE RESULTS

4.1. Introduction

This chapter presents, discusses and attempts to analyse the results of the study. The three areas to be analysed are:

- The profiles of the fifty patients that underwent a laparoscopic cholecystectomy during the period 1/1/2002 to 31/1/2003.
- Discussion and analysis of the interviews with the consultant surgeons.
- A comparison of the costs of the different instruments – both re-usable and disposable- and their marginal contribution to the cost of the laparoscopic cholecystectomy as a whole.

4.2. The Patients

A convenience sample of fifty patients was chosen for this study. All these patients are hospital patients who had had a laparoscopic cholecystectomy at KZNGOV Hospital during the period 1/1/2002 to 31/1/2003. Re-usable instrumentation was used for all these procedures.

The profiles that were considered were:

- Gender
- Age
- Length of hospital stay in days
- Duration of operation in minutes
- Intra-operative complications: Organ injury and bleeding
- Post-operative complications: Immediate bleeding, infection at 2 weeks post-op, and infection at 6 weeks post-op.
- Difficulty with surgical technique.

4.2.1. Gender of the Patients

In the sample of fifty patients, 5 were male and 45 were female. The male patients comprised 10% of the sample. Of the original 95 patients who had had laparoscopic

cholecystectomies from 1/1/2002 to 31/1/2003, and complete notes could not be obtained for them all, 14 were male. In percentage terms this is 14.7%. This finding is consistent with the fact that gall-bladder disease is more common in females.

4.2.2. Age

Table 4.1: Analysis of the ages of the fifty patients.

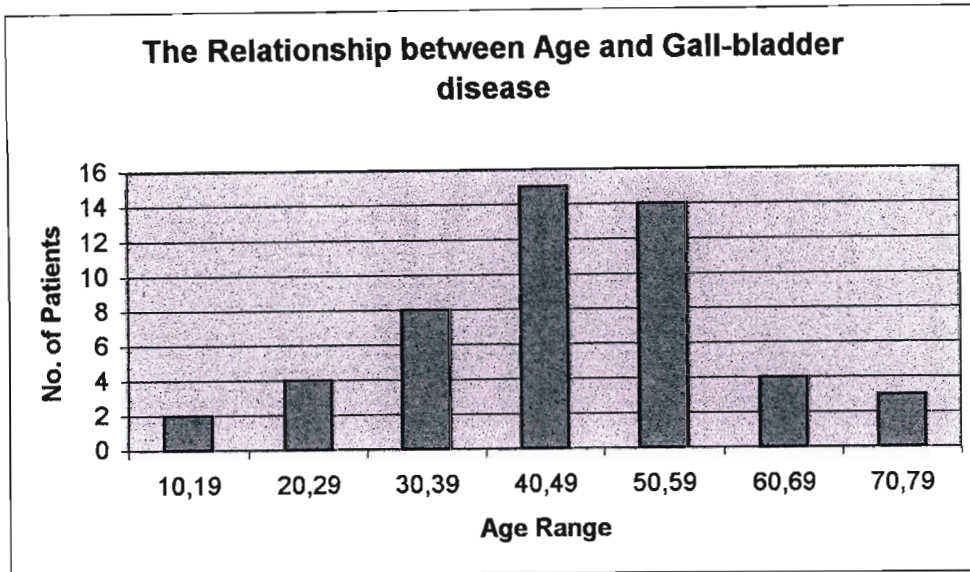
Average age	47 years
Median age	41 years
Mode (most frequently appearing age)	41 years
Minimum age (Youngest patient)	16 years
Maximum age (Oldest patient)	78 years

Table 4.2: The numbers of patients in different age groups.

Age Group (in years)	Number of Patients
10 – 19	2
20 – 29	4
30 – 39	8
40 – 49	15
50 – 59	14
60 – 69	4
70 – 79	3

The following graph (Figure 4.1) shows the relationship between the different age ranges and the number of patients that have had laparoscopic cholecystectomies.

Figure 4.1: Relationship between Age and Gall-bladder Disease



It can be seen that the majority of the patients fall between the ages of 40 years and 59 years. This is also in keeping with the age incidence of gall-bladder disease in the general population.

4.2.3. Length of Hospital Stay in Days

Table 4.3: Length of Hospital Stay

Average length of stay	4 days
Median length of stay	3 days
Maximum (longest stay)	18 days
Minimum (shortest stay)	2 days
Mode (most frequently occurring length of stay)	2 days

The mode is the most important indicator in this set of values, as it shows the most frequently occurring value in this range. A hospital stay of 2 days after a laparoscopic cholecystectomy is in keeping with first world standards. The outlier, i.e. the patient who stayed in hospital for 18 days, had no post-operative complications. She had a

social problem and had to wait for relatives to fetch her from the hospital as she had no means to go home.

4.2.4. Duration of Operation in Minutes

Table4.4: Duration of Operation in minutes.

Average	58 minutes
Median	55 minutes
Mode	55 minutes
Maximum (longest operating time)	120 minutes
Minimum (shortest operating time)	15 minutes

The Society of American Gastrointestinal Endoscopy surgery did a study in 1996 on the time taken to perform a laparoscopic cholecystectomy. Their preliminary results suggest that operative time averages 76 minutes, but the range is from 40 minutes to 89 minutes. Only four of the operations in this study took longer than 89 minutes. Thus these are acceptable values for the duration of laparoscopic cholecystectomies in general.

4.2.5. Intra-operative Complications

None of the fifty patients in the sample had any intra-operative complications. There was no bleeding nor any organ injury.

4.2.6. Post-operative Complications.

None of the fifty patients in the study developed any post-operative complications. None had any immediate post-operative bleeding, or developed infection later. All these patients attended the surgical follow-up clinics, first at two weeks post-operatively and again at six weeks post-operatively. There was no intra-abdominal infections or wound sepsis.

4.2.7. Difficulty with Surgical Technique

No problems arose during any of the fifty laparoscopic cholecystectomies in this study. The surgeons had no difficulty with their surgical techniques before or during the operation.

4.3. Interviews with the Surgeons: Results and Analysis

Only three of the consultant surgeons agreed to participate in the interview. The rest were not available, inaccessible or had emigrated.

4.3.1. Number of Years as a Practising Surgeon

Two of the three surgeons interviewed were practising for more than 16 years. The third surgeon was in practice for between 12 to 16 years. Thus all three are experienced in their field.

4.3.2. Type Of Practice

Of the three surgeons interviewed:

- One is mainly in private practice, but works as a part-time consultant at various government hospitals.
- One surgeon works full-time in a government hospital, but also does some part-time private work.
- The third surgeon is a surgical consultant and in hospital practice only.

4.3.3. Number of Laparoscopic Cholecystectomies done per month by each Surgeon

All three surgeons perform more than 16 laparoscopic cholecystectomies per month. They have extensive experience with the procedure and the instrumentation.

4.3.4. Use of Instruments

All three surgeons have used both re-usable and disposable laparoscopic instruments during their surgical careers. They are completely familiar with both types of devices.

4.3.5. Cost-effectiveness of Disposable Instruments

All three of the interviewees thought that disposable instrumentation was *not* cost-effective. A surprising aspect of this answer is that even the surgeon who is in private practice preferred to use the re-usable devices. He preferred these instruments despite the higher remuneration obtained in private hospitals when disposable instruments are used.

4.3.6. Quality of Instruments

All three surgeons agreed that the disposable instruments were not in any way superior to the re-usable counterparts. They did not regard the safety shield that comes with the disposable trocars to be an advantage. All three said that the shield did not really prevent all intra-abdominal injuries. Surgical technique and careful use of the trocars were more relevant to the prevention of injuries.

4.3.7. Preference of Type of Instruments

All three interviewees preferred the re-usable instruments. One reason was the relative simplicity of the design. The other important reason cited was the large cost saving obtained by using the re-usable devices.

4.3.8. Difficulty Encountered During Operations

None of the surgeons found the re-usable instrument more difficult to use as compared to the disposable device.

4.3.9. Hampering of Operative Technique

All of the three surgeons agreed that the re-usable devices did not cause difficulty with their surgical techniques. They are au fait with the use of both the disposable and re-

usable instruments, and often found the re-usable instrumentation more practical and easier to handle.

4.3.10. Adverse Patient Outcomes

No patient of any of the three interviewees suffered as a result of re-usable instrumentation being used on them. They did not encounter any bowel or other organ injuries, increased rates of infection, uncontrollable bleeding nor increased rates of wound sepsis.

4.4. Costs of the Instruments

This study is focusing on the use of only the three following instruments:

- Trocars (with cannulae/sleeves): 11.0mm and 6.0mm diameters
- Endoshears / scissors
- Clip Applicators and clips.

4.4.1. Costs of the Disposable Instruments

Quotes for the above instruments were obtained from three disposable device suppliers. The names of the companies will not be disclosed as they were promised confidentiality. The following table (Table 4.5) shows the prices of the disposable instruments, and an average price was calculated for the purposes of this study. This was done to simplify the costs involved.

Table 4.5: Comparison of the Costs of Disposable Instruments.

Instrument	Company A Price (Rands)	Company B Price (Rands)	Company C Price (Rands)	Average Price (Rands)
Trocar 11.0mm	1 134-75	908-34	1 295-00	1 112-70
Sleeve 11.0mm	401-33	368-34	370-00	379-89
Trocar 6.0mm	1 121-13	908-34	1069-00	1 032-82
Sleeve 6.0mm	337-96	368-34	297-00	328-43
Multiple Clip Applier	2 229-54	1 900-00	2 200-00	2 109-85
Endoshears	1 360-44	1 462-00	1 300	1 374-15

4.4.2. Costs of Re-usable Instruments

The following table gives the list of the re-usable instruments and their respective prices. I have specifically chosen the instruments that are used at KZNGOV Hospital. Each re-usable device is assumed to be used for 250 laparoscopic procedures. This is a conservative estimate that will be used for the purposes of this study.

Table 4.6: Costs of the Various Re-usable Instruments.

Instrument	Price (Rands)	Number of times Used	Price per Operation
Trocar 11.0mm	2 692-98	250	10-77
Sleeve 11.0mm	508-77	250	2-03
Trocar 6,0mm	2 434-21	250	9-74
Sleeve 6.0mm	671-05	250	2-68
Scissors – Reusable handle	2 240-00	250	8-96
Scissors – Disposable tip	857-28	5	171-46
Clip Applicator	9 117-38	250	36-47
Clips-8 per cartridge	501-60	1	501-60
Cleaning Brush for Sheath of Trocar	55-20	200	0-26
Cleaning Brush for Jaws of Scissors	91-50	200	0-46

4.5. Marginal Cost for One Procedure using Disposable and Re-usable Instruments

For the purpose of this study, only the cost of the above three instruments will be considered. The cost calculated will be the costs of these instruments only, all other instruments in the laparoscopic pack will be considered as standard. The average cost of the disposable instruments will be used. The calculation will be done assuming the 3-port technique for the laparoscopic cholecystectomy will be performed.

The costs of the brushes used to clean the re-usable instruments after surgery are negligible, but will be included in the calculation of marginal costs. The re-usable instruments are sterilised and disinfected with all the other surgical packs used in KZNGOV theatre, so this cost will not be included in the calculation.

The cartridge of eight titanium clips is offered to the government at a special tender price. This price will *not* be used in the calculation of the costs of the procedure. The price that is paid in the private sector will be used. This is done so that a fair estimate of the marginal costs of the laparoscopic procedures using either disposable or re-usable instrumentation can be calculated.

All other costs pertaining to the procedure of the laparoscopic cholecystectomy will not be taken into account, e.g. theatre costs, anaesthetic drugs and instruments, surgeon's fees. These have to be omitted as they vary in the private and public hospital sectors. Government hospital doctors earn a fixed monthly salary regardless of the number of operations they do, whereas, itemised billing is most often used in private practice.

Table 4.7: Marginal Cost of One Laparoscopic Cholecystectomy using Disposable Devices

Instrument	Number used	Cost (Rands)
Trocar 11,0mm	2	2 225-40
Sleeves 11.0mm	2	759-78
Trocar 6.0mm	1	1 032-82
Sleeve 6.0mm	1	328-43
Multiple Clip Applier	1	2 109-85
Endoshears / Scissors	1	1 374-15
TOTAL COST		7 830-43

Table 4.8: Marginal Cost of One Laparoscopic Cholecystectomy Using Re-usable Devices

Instrument	Number Used	Cost (Rands) per Procedure
Trocar 11.0mm	2	21-54
Sleeve 11.0mm	2	4-06
Trocar 6.0mm	1	9-74
Sleeve 6.0mm	1	2-68
Scissors Handle	1	8-96
Scissors Tip	1	171-46
Clip Applicator	1	36-47
Clips – 8 per cartridge	1	501-60
Cost of Cleaning Brushes		0-72
TOTAL COST		757-23

4.6. Conclusion

Three different areas pertaining to the laparoscopic cholecystectomy were analysed in this study:

- The patients that underwent the procedure between the periods 1/1/2002 to 31.1.2003 and their intra- and post-operatives outcomes.
- The input from the surgeons performing the procedure.
- The costs of the three common instruments used in the laparoscopic cholecystectomy – trocars, clip applicators and scissors.

4.6.1. The Patients' Profiles

A sample of fifty patients who underwent a laparoscopic cholecystectomy during the period 1/1/2002 to 31/1/2003 was chosen. Although this was a convenience sample, the patient profiles such as age and gender, fit in with the incidence of gallbladder disease in the general population, i.e. it is more common in females over the age of forty years. This sample could to some degree be called representative. The average length of hospital stay was four days, although 36% of the patients in the study had a hospital stay of two days and 22% of the patients stayed three days. This comprises 58% of the patients in the sample. The average operating time was 58 minutes which correlates well to the average time of 76 minutes in the previously mentioned American study. None of the surgeons had any problems with surgical technique using the re-usable instruments, and none of the patients in the sample developed any complications during or after the operation.

4.6.2. The Interviews with the Surgeons

The unfortunate aspect of the study was that only three surgeons were willing to be interviewed. These three surgeons, however, were well experienced in their fields, and two of them were practising general surgery for more than twenty years. All three surgeons had extensive experience with the procedure of the laparoscopic cholecystectomy. They all agreed that the re-usable instrumentation posed no threat to the patients, were easy to use and were far more cost-effective. All three surgeons actually preferred to use the re-usable instruments.

4.6.3. Costs of the Instruments

The three instruments that this study concentrated on are the trocars (11.0mm and 5.0mm), the clip applicator and the endoshears / scissors. These instruments were chosen because they are common to all laparoscopic cholecystectomies and are also expensive items in the laparoscopic surgical pack. The results show that the extra costs incurred by using the disposable equivalents of the above instruments in the procedure is approximately R7 000 – 00. This figure is the same as that obtained from one of the major health insurance companies in South Africa. It was not possible to obtain statistics about the number of laparoscopic cholecystectomies done in private hospitals, but a substantial number are being performed. Assuming a conservative estimate of a thousand of these operations being done in Kwazulu Natal per month in private hospitals, the use of these three particular disposable instruments adds a massive R7.073 million to the medical costs of the operation. This amount is borne by the medical aid companies and the patients.

CHAPTER 5: CONCLUSIONS AND RECOMMENDATIONS

5.1. Introduction

The evaluation of the use of re-usable instrumentation in laparoscopic surgery is only one of the many areas in the health industry where costs and outcomes can be evaluated. Costs in other areas of medicine can be re-evaluated and appropriate changes made. This is especially important in our present economic environment where medical costs are spiralling out of control. This conclusion was drawn from the literature review as well as from the case study.

5.2. Quality in Health Care

During these times of economic retraction, substantial interest had focused on the cost of health care. Because surgeons perform costly procedures, the health care system has focused on them, and particularly on laparoscopy (Traverso, 1996). Technology has allowed surgeons to spend more money, whereas, the business of health care concentrates on making a profit for its investors. The business of medicine should not be distracted, however, by costs when its priority is to provide quality health care to the patient population. Surgeons and other health care workers should first be interested in the quality of health care, and then dwell on a reasonable cost for the health care product. Industry has allowed surgeons to utilise advanced technology. The responsibility of the surgeons who use this technology is to avoid the gimmick and provide the quality at a reasonable cost (Traverso, 1996).

5.3. Definitions of Costs

The business method of evaluating costs begins by categorising costs into controllable (direct) versus uncontrollable (indirect) costs. This method allows for strategic analysis and planning (Traverso, 1996).

5.3.1. Direct versus Indirect Costs

A hospital provides hundreds of laparoscopic procedures. The inherent overhead costs of the hospital are not controllable e.g. mortgage payments, rent, electricity and salaries.

These do not change regardless of how many procedures are performed. These costs are not directly related to patient care and are therefore termed *indirect* costs. The remaining costs are termed *direct* because they arise directly from patient care e.g. nurses salaries and disposable equipment. These direct costs are controllable because the administration can choose how each patient's operation can be carried out most efficiently.

Variable costs are another category of costs – these costs increase with the number of procedures that are performed. The costs that fall within the direct variable category are those that can be most influenced by the surgeons e.g. the cost of the disposable instrumentation and the controversy that arises from this. Modifying a laparoscopic procedure with innovative ideas to decrease the need for costly equipment is a credible goal for pioneers of laparoscopy (Traverso,1996).

5.4.The Surgical Value Package

We know that quality of health care comes first, and then attention is directed towards costs. Value assessment is the knowledge of the strengths and weaknesses of both cost analysis and outcome. The key to evaluating a procedure is to determine its value (Traverso, 1996). The value is determined by assessing a procedure's utilisation, outcomes and costs. Utilisation involves early treatment and avoids neglected disease. Thus the appropriateness of the utilisation can be determined only by an outcome study.

An outcome study is synonymous with quality assessment. Outcomes deal with morbidity, mortality, and the short- and long-term effects of the procedure. The outcome study of the fifty patients that were selected for this work shows that the patients had suffered no adverse effects from the surgical techniques or from the use of re-usable laparoscopic instrumentation. Overall, an increase in quality in a global perspective decreases the costs of the procedure to the health care community. When the quality of patient management can be maintained, then a decrease in global costs increases value. The concept of increasing value by increasing quality without an attempt to decrease costs is a very important principle that the health care system must learn in our ever-challenging medical environment (Traverso, 1996).

5.5. Recommendations

This case study shows how the medical profession can influence the costs of health care –and in many cases – considerably. The Department of Surgery at KZNGOV Hospital in conjunction with the theatre committee have managed the very delicate balancing act of combining a quality health service (in terms of the operations performed) with financial resources that are stretched to a maximum. Their criteria for the choice of patients for laparoscopic cholecystectomies is a good benchmark for any other surgeon in practice. Laparoscopic procedures are not done unnecessarily as is the case in the United States and other developed countries. In these countries doctors are relaxing their selection and referral criteria, and more patients are undergoing laparoscopic cholecystectomies.

Because the private and public sectors cannot be considered as two completely separate entities, surgeons in private practice should take greater cognisance of the costs involved in every operation they perform. Medical aid schemes and patients who pay for health care out of their own pockets are finding it more and more difficult to keep up with ever increasing health care costs. Eventually the burden reverts to the State when medical aid funds run out, or patients cannot afford the high medical bills themselves. This ultimately forces health insurance companies to increase premiums, and it also places a larger load on the taxpayer. The government itself is also affected because it is also one of the largest employers in the country. Government heavily subsidises the health insurance premiums paid by its employees. All these factors eventually form a vicious never-ending cycle that does not benefit the South African economy as a whole.

Another area that I believe is a very important one to consider is the environment. Disposable commodities in general must impact negatively on the environment. Environmental damage is presently at the forefront of world debates. In the United States many companies developed during the “disposables boom” which reprocess disposable surgical devices. This has been approved by the American Food and Drug Administration. But now there is growing concern that many of these devices are not suitable for re-processing. There is an issue of guaranteed sterility, and of the potential degradation of products. These reprocessed products may dislodge or malfunction if

repeated sterilisation is performed. Disposable devices are not designed for re-use, are not easy to clean, and this practice is definitely not recommended by disposable device manufacturers.

Laparoscopy has been in use for many decades, and there is no known case of infection transmission by laparoscopic instruments. Surgeons must continually re-examine their own practices and see how they could achieve the balance between cost-effectiveness and patient protection.

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APPENDIX

APPENDIX 1

INTERVIEW SCHEDULE

COVERING LETTER

University of Natal
Graduate School of Business
DURBAN

The Surgeon

Dear Sir/Madam

I am a final year student at the Graduate School of Business, University of Natal, Durban. I am currently working on my dissertation towards an MBA degree in Strategic Financial Management. The title of my thesis is: "An Investigation into the Cost-effectiveness of using Re-usable Instrumentation in Laparoscopic Colectomy". My objective is to expand the body of knowledge about this important area of laparoscopic surgery.

To accomplish this, I need to approach qualified and experienced surgeons like you who have had much experience in this field of surgery. Your help with the questions on the attached pages will make a real contribution to the accuracy and success of this study.

Your input will be treated with strict confidence and will be available only to me and my supervisor. Any publication will only be of statistical totals, and will not include names.

Your assistance will be greatly appreciated and will help me to know more about the instrumentation used in laparoscopic cholecystectomies. It may also ultimately be of benefit to the patients who will undergo these procedures.

Yours Sincerely

Dr. S. R. Maharaj.

QUESTIONS

1. How long have you been practising as a surgeon?
 - a. 1 – 4 years
 - b. 4 – 8 years
 - c. 8 – 12 years
 - d. 12 – 16 years
 - e. More than 16 years.

2. Are you in :
 - a. Hospital practice only?
 - b. Private practice only?
 - c. Both hospital and private practice?

3. How many laparoscopic cholecystectomies do you do per month?
 - a. 1 – 4
 - b. 4 – 8
 - c. 8 – 12
 - d. 12 – 16
 - e. More than 16.

4. Have you used both disposable and re-usable instruments during a laparoscopic cholecystectomy?
 - a. Yes
 - b. No

Cost-Effectiveness

5. In your opinion are disposable instruments used in laparoscopic cholecystectomies more cost-effective?
 - a. Yes
 - b. No

6. Do you consider disposable instrumentation superior in quality as opposed to the re-usable devices?
 - a. Yes
 - b. No

7. Which of the two types of instruments – disposable or re-usable – do you prefer to use? Why?

Feasibility of Use

8. Is it more difficult to perform a laparoscopic cholecystectomy using a re-usable instrument?
 - a. Yes
 - b. No

9. Do re-usable instruments hamper the operative technique in any way?
 - a. Yes
 - b. No

Patient Outcome

10. Have you had any of the following adverse patient outcomes by using re-usable instruments during laparoscopic cholecystectomies?
 - a. Bowel / Other organ injury
 - Yes
 - No
 - b. Increased rate of intra-abdominal infection
 - Yes
 - No

- c. Increased rate of wound sepsis
 - Yes
 - No
- d. Immediate bleeding post-operatively
 - Yes
 - No
- e. Delayed bleeding post operatively
 - Yes
 - No

THANK YOU