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A Retrospective pharmacoeconomic analysis comparing the cost effectiveness of two treatment groups in patients with complicated intra-abdominal infections

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A Retrospective Pharmacoeconomic Analysis Comparing the Cost Effectiveness of Two Treatment Groups in Patients with Complicated Intra-abdominal Infections

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements of the degree of Master of Science in Medicine in Pharmaceutical Affairs.

2005

DECLARATION

I, M.E. (Marlize) Schmitt, declare that this research report is my own work. It is being submitted for the degree of Master of Science in Medicine in the branch of Pharmaceutical affairs at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

Signature: 

22 March 2005

Dedicated to my parents for their support, love and trust!

ABSTRACT

"Many will be disappointed to learn that pharmacoeconomic evaluations provide information, not answers. Although pharmacoeconomics broadens the perspective taken in evaluating drug therapies, the final drug therapy decision is still influenced by clinician preferences, patient desires, and the working and politics of the healthcare delivery system". [1]

Globally and in South Africa there is an increasing pressure on healthcare resources. These pressures have exponents both in the supply and demand arms of the economic equation and have set the scene for the development of a new discipline in healthcare. Pharmacoeconomics can be defined as "*the description and analysis of the cost of drug therapy of health care systems and society*". [2] Pharmacoeconomics assesses the ratio of the cost to the consequences of specific drug therapies using a technique called Cost Effective analysis which uses tools such as Cost Minimisation analysis, Cost Effective analysis and Cost Benefit analysis.

A retrospective pharmacoeconomic analysis is to be performed on two treatment groups in the treatment of Complicated Intra Abdominal Infections. The aim of this study is to determine whether the medication used in treatment for Group A is more cost effective than the medication used in treatment for Group B.

The purpose of this research was to compare the cost effectiveness, using a tool called cost minimisation, to determine which treatment group (A or B) is more cost effective in the treatment of intra-abdominal infections. Treatment group B is currently available on the South African market and is referred to as standard treatment when treating intra-abdominal infections. Treatment group A is a new product not yet registered for the treatment of intra-abdominal infections.

The one hundred patients recruited for the Bayer clinical study in South Africa were included in the analysis and the data collected was used retrospectively to determine the cost using certain health economic parameters.

The results demonstrated no statistically significant difference in the clinical outcome between the two treatment groups, which therefore resulted in clinical equivalency. Treatment group A was the least cost efficient treatment group.

The results clearly show that treatment for group A (CM ratio = R 1, 045, 222.09) was less cost efficient than the treatment for group B (CM ratio = R 877, 106.22) (efficiency = cost effectiveness). Therefore the treatment for group B was the most efficient (cost effective) treatment regimen to use when treating patients with intra abdominal infections.

It was clear that not all factors impacting on the cost could be included in this analysis. When looking at the final results the following aspects should be kept in mind:

- Treatment for group B consisted of generic drugs which are much cheaper
- Treatment for group A consisted of ethical products which were only recently registered and marketed and therefore more expensive.
- Two of the drugs in treatment for group B were eight hourly administered which could have led to an increase in resource cost (nursing personnel time and cost was not included in this analysis) and which could impact on patient compliance if the patient was not hospitalised till the end of the treatment.
- Treatment group A was a once a day consequential (IV and oral) therapy with the same drug and dosage. This could lead to a decrease in the nursing cost and an improved patient compliance after hospitalisation.
- This data was compiled during a clinical study. Therefore the conditions were more controlled, which does not necessarily reflect the real world.
- The original study was a randomised open label study. This could lead to more attentiveness of the investigators. Adverse events could have been more accurately documented when patients were randomised to treatment group A. The patients could have been switched to alternative antimicrobial therapy sooner in group A than in group B.
- This study was conducted at a government institution. Government patients are treated differently to patients in private institutions because their living conditions at home are not always acceptable for rehabilitation after major surgery. Therefore most of the patients were hospitalised until the treating investigator was ensured of a complete cure prior to discharge. This could lead to increased hospitalisation cost which would not necessarily be the case at private hospitals.

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ABBREVIATIONS

CEA – Cost effective analysis

CM – Cost minimisation

CMA – Cost minimisation analysis

ITT – Intention to treat population

IV – Intravenous

PP – Per protocol population

DEFINITIONS

Cost Minimisation Analysis - type of analysis that finds the least costly program among those shown or assumed to be of equal benefit.

Cost Effective Analysis - is an approach used for identifying, measuring and comparing the significant costs and consequences.

Effectiveness (of a drug) - The therapeutic outcome in a real world patient population (usually differs from efficacy determined in controlled clinical trials).

Efficiency - can be defined as achieving the maximal increment in health benefit (that is, improvements in the health status of a target population) for a fixed amount of resources.

"Per protocol patients" includes all patients randomised according to the inclusion- and exclusion- criteria, who were treated and have completed the study as described in the original protocol.

"Intention to treat patients" includes all patients randomised per inclusion and exclusion criteria and who received at least one dose of study medication. These patients did not complete the study due to an adverse event, treatment failure, death and / or lost to follow up.

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A Retrospective Pharmacoeconomic Analysis Comparing the Cost Effectiveness of Two Treatment Groups in Patients with Complicated Intra-abdominal Infections

1. INTRODUCTION

1.1 What is Pharmacoeconomics?

Pharmacoeconomics has been defined as "*the description and analysis of the cost of drug therapy of health care systems and society*" [2]. Pharmacoeconomics assesses the ratio of the cost to the consequences of specific drug therapies using the four major types of pharmacoeconomic evaluation:

- Cost minimisation analysis (CMA) [3]
- Cost effectiveness analysis (CEA) [3]
- Cost benefit analysis (CBA) [3]
- Cost utility analysis (CUA) [3 & 4]

Pharmacoeconomic research identifies, measures and compares the cost (i.e. resources consumed) and consequences (clinical, economic and humanistic) of pharmaceutical products and services. In essence, pharmacoeconomic analyses are tools for examining the impact of alternative drug therapies and other medical interventions. [5]

At its core, use of pharmacoeconomic principles to develop formulary medications is an attempt to quantify cost per outcome of different therapies. The basic criteria should be economic, clinical, and humanistic outcomes. The goal is to secure the lowest cost for the desired outcome. [5]

Pharmacoeconomics is the benchmark for practical authoritative reviews of the application of health economics to disease management outcomes and optimum drug therapy. [6]

The science of pharmacoeconomics evolved as a result of the scarcity principle in the healthcare environment. Its aim is to enable key decision-makers to allocate scarce productive resources that could have alternative uses. Various healthcare commodities can be produced and distributed in a more cost effective way for similar applications.

The objectives of pharmacoeconomic analyses are to improve health through better decision making and to determine relative values of alternative therapies.

Economic evaluations are becoming increasingly important foci in the delivery of healthcare and in particular in the choice of medical therapies.

Pharmacoeconomic data is thus a necessary component of drug development especially in diseases with a number of therapeutic alternatives. Individual products in a given class may differ in cost as well as therapeutic efficacy.

Pharmacoeconomics aims to promote the development and study of health economics as applied to rational drug therapy and disease management. [6]

For the aim of this research project the following parameters were used for pharmacoeconomic evaluations:

1. Type of therapy
2. Duration of therapy (IV and oral)
3. Duration of hospitalisation
4. Consumables
5. Concomitant medication
6. Alternative antimicrobial therapy
7. Professional fees
8. Adverse events
9. Outcome

1.2 Complicated Intra-abdominal Infections

The term "intra-abdominal infection" is used to describe a broad range of infectious disease processes. The pathophysiology of most cases of intra-abdominal infections is a breach in the integrity of the gastrointestinal tract. This breach can occur due to natural courses or as a result of external forces like abdominal gunshot or stab wounds. Involvement of colonic type flora (gram negative bacilli and anaerobes) is especially common. The infection in the abdominal cavity may be monomicrobial or polymicrobial (with 2 -3 types of aerobic bacteria and up to 9 types of anaerobes) based on the number of

species at the infected site.[7] Intra-abdominal infections occur in two broad forms: peritonitis and abscess formation.[8]

The term "complicated" infection is defined per protocol as an infection requiring an initial operative therapeutic intervention followed by an antibiotic as a treatment. The treatment for complicated intra-abdominal infections should include antibacterial therapy, which is active against both aerobic gram negative bacilli and anaerobes since these are the prevailing organisms in complicated intra-abdominal infections.

A common standard treatment (ceftriaxone 2000mg IV, in combination with metronidazole 500mg IV, followed by co-amoxiclav 635mg oral) was used as a comparator in this study. Ceftriaxone is an effective and well tolerated broad-spectrum antibacterial with a long half-life, which permits once a day administration. Once daily, ceftriaxone has been associated with significantly reduced acquisition, preparation and administration costs.[9] In addition, ceftriaxone has achieved considerable savings in hospitalisation costs in patients with serious bacterial infection who where able to receive all or part of the therapy on an outpatient basis.[9] Metronidazole should be added to this treatment regimen because of ceftriaxone's limited activity against anaerobic organisms. Metronidazole requires eight hourly administrations.

Moxifloxacin is a new fluoroquinolone which is currently in development and not yet registered for the treatment of complicated intra-abdominal sepsis. The aim of the original protocol was to establish the effectiveness of moxifloxacin in the treatment of complicated intra-abdominal sepsis.

Other treatment regimens for complicated intra-abdominal sepsis include: other third generation cephalosporins (e.g. cefotaxime), quinolones (e.g. ciprofloxacin), second generation cephalosporins (e.g. cefuroxime), or an amoxicillin-clavulanate combination (Augmentin). These other agents should all be used in combination with metronidazole for anaerobic cover. Carbapenems e.g. imipenem (e.g. Tienam), piperacillin (Pipril), tazobactan (e.g. Tazocin) or fourth generation cephalosprins (e.g. cefepime – with metronidazole) are normally reserved for cases with expected or proven resistance.

1.3 Original Study Protocol

The title of the original study protocol: [10]

A prospective, randomized, non-blind, multicenter trial assessing the safety and efficacy of sequential (intravenous/oral) BAY 12-8039 (moxifloxacin) 400 mg every 24 hr compared to intravenous ceftriaxone 2g every 24 hr and metronidazole 500 mg every 8 hr followed by oral amoxicillin/clavulanic acid tablets 625 mg every 8 hr for the treatment of patients with complic**A**ted **I**ntra-ab**D**omin**A**l infections. (In short: The **AIDA** protocol.)

Trial Objectives of the original study protocol: [10]

To compare the safety and efficacy of sequential (intravenous/oral) moxifloxacin every 24 hours with the combination of intravenous ceftriaxone every 24 hours and metronidazole every 8 hours followed by oral co-amoxiclav tablets every 8 hours for the treatment of adult patients with complicated intra-abdominal infections.

Inclusion Criteria [10]

Patients with the following:

- Hospitalised male or female patients ≥ 18 years of age
- Documented intra-abdominal infection by

A either **Laparotomy** reveals any of the following:

- Gross peritoneal inflammation with purulent exudate
- Intra-abdominal abscess
- Macroscopic gastrointestinal perforation

OR

B **Percutaneous aspiration** reveals purulent material from the abdominal cavity

OR

C **Suspected** intra-abdominal infection and scheduled for a laparotomy or percutaneous aspiration by at least three of the following criteria:

- Fever (Temperature >38.°C oral or rectal; >38.5°C core temperature)
- Leukocytosis (WBC ≥ 12,000 cells/mm^3)
- Symptoms referable to the abdominal cavity (e.g., anorexia, nausea, vomiting or pain)

- Tenderness (with or without rebound), absent or diminished bowel sounds, or abdominal wall rigidity
- Radiological evidence (Abdominal Plain Films, CT, MRI or Ultrasound) of gastrointestinal perforation or localized collections of potentially infected material

• Written Informed Consent

The clinical picture must be compatible with an intra-abdominal infection. Patients must have one of the following infections requiring anti-infective therapy and an operative procedure or percutaneous drainage:

- Intra-abdominal abscess
- Bacterial peritonitis
- Appendicitis with evidence of a perforation or abscess, duration of symptoms ≥24 hours
- Acute perforations of the stomach or duodenum only if not operated on within 24 hours of perforation
- Traumatic perforation of the small bowel (excluding the duodenum) or large bowel only if not operated on within 12 hours of perforation
- Perforation unrelated to trauma of the small bowel (excluding duodenum) or large bowel
- Intra-abdominal infections related to previous intra-abdominal surgery
- Intra-abdominal infections following penetrating and blunt trauma

The duration of treatment of the intra-abdominal infection is anticipated to be at least 5 days.

Patients may receive prior anti-infective therapy under the following conditions:

- Previous anti-infective therapy was given for < 24 hours.
- Patients with a known intra-abdominal abscess may be enrolled into the study despite receiving empirical therapy for several days if pre-treatment (i.e., prior to study drug) cultures at the time of surgery or percutaneous drainage yield bacterial pathogens likely to be susceptible to both treatment regimens.

Exclusion Criteria: [10]

Patients with the following:

- an indwelling peritoneal catheter
- pre-existing ascites who present with spontaneous bacterial peritonitis
- pancreatic, peripancreatic sepsis, or an intra-abdominal infection secondary to pancreatitis
- a perforated peptic ulcer or traumatic upper gastrointestinal tract (duodenal) perforation of < 24 hours duration
- a traumatic perforation of the small or large bowel of < 12 hours duration
- transmural necrosis of the intestine due to acute embolic, thrombotic, or obstructive occlusions
- acute cholecystitis with infection confined to the gallbladder
- early acute or suppurative (non perforated) appendicitis unless there is evidence of an abscess or peritoneal fluid containing leukocytes and micro organisms suggestive of regional contamination
- an infection that requires treatment with an anti-infective agent other than the study drugs. Patients requiring antibiotic irrigations of the abdominal cavity or surgical wound are not suitable for entry.
- require "open abdomen" techniques for management
- perinephric infections
- infections of the female genital tract (gynecological infections)
- multiple re-laparotomies planned
- Known hypersensitivity to any of the study drugs
- Pregnancy, nursing or in whom pregnancy cannot be excluded
- Receiving hemodialysis or peritoneal dialysis
- Severe, life-threatening disease with a life expectancy of less than 48 hours or their acute physiology score and chronic health evaluation (APACHE) scores are > 35
- Neutropenia (neutrophil count < 1000 cells/μl) due to malignancy or chemotherapy
- Receiving chronic treatment with known immunosuppressant therapy (including chronic treatment with > 15 mg/day of systemic prednisone or equivalent)
- HIV- seropositives with a CD4 count < 200 cells/μl or HIV-seropositives who are

receiving HAART (**NOTE**: HIV testing is not required for this study protocol)

- End stage hepatic cirrhosis (Child-Pugh C)
- Known congenital or sporadic syndromes of QTc prolongation or use of concomitant medications reported to increase the QTc interval (e.g. cisapride, Class IA and III anti-arrhythmic agents [amiodarone, sotalol, disopyramide, quinidine, and procainamide])
- Uncorrected hypokalemia
- Previous history of tendinopathy with quinolones
- Previously enrolled in this trial or use of any investigational drug within the previous 30 days
- Known or suspected concomitant bacterial infection requiring additional systemic antibacterial treatment
- Pre-treatment with a systemic (i.e., oral or parenteral) antibacterial agent for > 24 hours unless conditions, as outlined in Inclusion Criteria, can be met

1.3.1 Treatment Group A

1.3.1.1 Moxifloxacin 400 mg [11, 12 & 13]

Moxifloxacin is a methoxy-fluoroquinolone. It has a broad spectrum and is bactericidal against gram positive and gram negative micro-organisms as well as gram positive and gram negative anaerobes.

The mean elimination half-life of this product is 12 hours (± 1.3 hours) and steady state is achieved after at least 3 days with a 400 mg once daily (IV or oral) regimen.

Moxifloxacin is metabolised via glucuronide and sulphate conjugation and is eliminated primarily in the faeces. A very limited amount is excreted via the urine due to the glucoronide conjugate conversion.

1.3.2 Treatment Group B

1.3.2.1 Ceftriaxone 2000 mg [9 & 14]

Ceftriaxone is a third generation cephalosporin. It is a broad-spectrum cephalosporin and is bactericidal against gram positive and gram negative organisms (Gram positive organisms include: Streptococcus sp., Staphylococcus sp., Peptostreptococcus sp. and

Clostrium sp. and Gram negative organisms include: Haemophilus sp., Neisseria sp., Escherichia sp., Klebisella sp. and Enterobacter sp.). Anaerobes are only partially sensitive to ceftriaxone and it should therefore be used in combination with an anaerobe bactericidal agent, such as metronidazole.

The mean elimination half-life of this product is 6 to 9 hours. Bactericidal effects last up to 24 hours. Administration of this product is 2g once a day IV.

Ceftriaxone is primarily excreted unchanged in the urine by glomerular filtration. The remainder is excreted by the bile and is found unchanged in the faeces.

1.3.2.2 Metronidazole 500 mg [8, 9 & 13]

Metronidazole is an anti-protozoal agent and is active against most infections involving anaerobic bacteria and certain parasitic infections (such as Bacteroides fragilis, Selenomonas sp, Fusobacterium sp. Anaerobic gram negative cocci, Anaerobic gram positive cocci, Clostridium sp., Gram positive non-sporulating bacilli and Capnocytophaga sp.). It has the best bactericidal effect against anaerobic organisms of all drugs.

The mean elimination half-life of this product is 8 hours and should be administered 8 hourly (three times daily)

Metronidazole is excreted primarily in the urine and the remainder is excreted via faeces.

1.3.2.3 Co-amoxiclav 625 mg [9 & 15]

This is a combination of amoxicillin 500mg and clavulanate 125mg. Amoxicillin is a broad-spectrum antibiotic but is inactivated by ß-lactamases produced by various micro-organisms. Clavulanate is an irreversible inhibitor on ß-lactamases.

Amoxicillin exerts a bactericidal action against gram positive and gram negative organisms. Clavulanate has no bactericidal action but it does protect amoxicillin from

degradation by inactivating the ß-lactamase enzyme produced by penicillin resistant strains of organisms.

The plasma half-life of amoxicillin is 1 – 1.5 hours and is widely distributed at varying concentrations in the body. Approximately 60% of amoxicillin is excreted unchanged *via* urine and a limited extent is metabolised to penicilloic acid, which is also excreted in the urine but this is not important for its antibacterial activity.

Clavulanic acid's pharmacokinetics is similar to amoxicillin with a half-life of 1 hour and 60% is excreted unchanged in the urine.

Co-amoxiclav 625mg tablets (five parts amoxicillin and one part clavulanic acid) should be administered orally eight hourly (three times per day).

1.4 Rationale

The goal of managed care is to deliver medical and pharmaceutical care cost-effectively. The consequence of healthcare's spiralling costs is that a greater premium has been placed on employing available resources as efficiently and effectively as possible. With this in mind pharmacoeconomics may serve to identify the most cost-effective treatment alternatives in managed care. [16]

A retrospective pharmacoeconomic analysis is to be performed on two treatment groups in the treatment of complicated intra abdominal infections. The term "complicated" infection is defined per protocol as an infection requiring an initial operative therapeutic intervention followed by an antibiotic as a treatment. The treatment for complicated intra-abdominal infections should include antibacterial therapy, which is active against both aerobic gram negative bacilli and anaerobes since these are the prevailing organisms in complicated intra-abdominal infections. Depending on the p-value derived from the eradication rate (clinical cure result) a decision will be made whether this will be a cost minimisation study or a cost effective study.

Due to the spectrum of ceftriaxone (no activity against anaerobes), metronidazole should be added to the treatment regimen. Together with this, metronidazole as well as the oral follow up drug, co-amoxiclav, have an eight hourly administration interval which could increase the resource cost and can negatively influence compliance, resulting in possible prolonged treatment.

Moxifloxacin, has a twenty four hour administration interval for both oral and IV treatment, which could reduce resource cost and the treatment period with an increase in compliance, resulting in a shorter hospital stay and thus reducing the number of disability days. In view of the fact that intra-abdominal infections are typically polymicrobial and are often treated empirically, the selected antibacterial agent must cover the likely spectrum of bacterial pathogens, moxifloxacin's good tissue penetration, broad spectrum of activity and particularly its activity against both gram negative pathogens and anaerobic organisms suggest that it would be effective in the treatment of intra-abdominal infections.

The aim of this study is to determine whether the medication used in treatment for Group A is more cost effective than the medication used in treatment for Group B.

1.5 Objectives

This health-economic analysis is to quantify and compare the cost of healthcare infrastructure used in both treatment groups.

The following health economic parameters will be used:

1. Type of therapy
2. Duration of therapy (IV and oral)
3. Duration of hospitalisation
4. Consumables
5. Concomitant medication
6. Alternative antimicrobial therapy
7. Professional fees
8. Adverse events
9. Outcome

Pharmacoeconomic data is a necessary component of drug development especially in diseases with a number of therapeutic alternatives. Individual products in a given class may differ in cost as well as therapeutic efficacy.

Direct costs for patients diagnosed with infectious diseases include the drug acquisition cost. Other direct medical costs include the duration of hospitalisation, professional fees, the cost of consumables, treatment of adverse events, and concomitant medication prescribed to treat adverse events and symptoms of the disease. The option to switch from intravenous therapy to oral therapy could lower the cost of care by potentially reducing both the length of stay in hospital and the number of disability days.

"Cost Effective Analysis" (CEA) is an approach used for identifying, measuring and comparing the significant costs and consequences. CEA also measures some non-monetary terms. Traditionally, CEA has quantified all costs of providing a service or treatment in monetary terms, while measuring consequences as non-monetary health outcomes [2].

More recent research tends to combine Cost Beneficiary Analysis with Cost-Utility Analysis and CEA to create a hybrid economic evaluation. Such studies generally subtract cost savings induced by an intervention from the costs of the intervention itself to arrive at a net cost. Cost effectiveness should be used to imply value for money.

Cost-Minimisation Analysis is a type of analysis that finds the least costly program among those shown or assumed to be of equal benefit (clinically equivalent [17]). This analytical technique is applied in situations where the outcomes associated with two (or more) alternative means of intervention are equivalent and the objective is thus to compare the total resource cost associated with using the different treatments [1].

2. SUBJECTS AND METHODS

The original study commenced during February 2001 and continued till August 2002.

The following three end points were evaluated in the original study: efficacy, safety and pharmacoeconomics.[10]

The primary aim of the original study was to prove that a sequential therapy with group A, IV once daily (for 3 to 14 days) followed by oral treatment once daily to complete a total treatment period of 7 to 14 days, is not inferior to a sequential treatment with group B, IV (for 3 to 14 days) followed by oral treatment three times daily to complete a total treatment period of 7 to 14 days of therapy. Efficacy is based on the clinical success rate 28-42 days after the start of therapy (test-of-cure visit {TOC}). [10]

Efficacy Analysis [10]

The primary efficacy variable for the original study was the clinical response, determined by the treating investigator (clinician) at the test of cure visit (TOC) (day 28-42 after entry into the study). The primary efficacy analysis was performed on the valid-per-protocol population, which is defined as:

- Complicated intra-abdominal infection requiring surgery or percutaneous drainage for diagnosis and management
- No other systemic antibacterial agents administered concomitantly with the study drug except in cases of treatment failure
- Study drugs given for a minimum of 48 hours (in case of clinical failure) or ≥ 5 days (in case of clinical cure)
- Documented compliance with ≥ 80% of the study medication administered
- No protocol violations influencing the treatment efficacy
- Successful completion of an assessment at the TOC visit (days 28-42 after entry into the study)

Secondary efficacy parameters included: [10]

- Clinical and bacteriological response on day 3-5 or on the day of IV to PO switch if the day of switch is different than day 4 or 5
- Bacteriological and radiological response at the TOC visit (28-42 days after entry into the study)
- Clinical response at the TOC visit in patients with bacteriologically proven intra-abdominal infection

- Mortality attributable to intra-abdominal infection at the time of the TOC visit (28-42 days after entry into the study)
- Clinical response at the TOC visit according to disease severity stratum
- Duration of hospitalization (total days)
- Duration of hospitalization post-operatively (days)
- Duration of intravenous therapy (days)

Safety Analysis [10]

As safety analysis, the treatment groups were compared with respect to the incidence of premature termination subdivided by primary reason for discontinuation, laboratory abnormalities, and treatment emerging adverse events.

The safety analysis also included tabulation of the type and frequency of all adverse events as well as events considered by the investigator to be at least possibly drug related. All laboratory data were analysed using descriptive statistics including identification of laboratory data outside normal ranges. Incidence tables were presented separately for all adverse events and for all adverse events occurring during IV therapy

Pharmacoeconomic evaluation [10]

The economic analysis will concentrate on the cost difference in resource use between the two treatments.

For those resources found to be quantitatively important in the pooled analysis of the differences between regimens, an estimate of the costs differences was done. In that case, costs will be estimated by multiplying the physical quantities of resource use observed by the unit cost of the resource.

Perspective of the Pharmacoeconomic Analysis [1]

The design of pharmacoeconomic analysis will depend on the perspective taken in the study. The perspective identifies the audience targeted in the study and will define the desired measure of benefits, effectiveness and cost to be included in the analysis. Several

perspectives are possible; the most commonly used are those of the society, patient, provider, medical institution, regulatory body and the re-imburser.

Because the perspective determines the cost and benefits collected and recorded for a specific study, studies with different perspectives may not lead to the same conclusions. Investigating the most cost effective treatment from a medical aid (funder) perspective will involve only direct medical cost. The medical aid perspective was used for this pharmacoeconomic analysis.

2.1 Study Sample

The one hundred patients recruited for the Bayer study at Tygerberg Hospital with complicated intra-abdominal infections were included in this analysis. Three investigators (clinicians) participated in this prospective, randomised and non blind trial. The investigator (clinician) on call was responsible for patient inclusion, treatment and follow up.

Fifty patients were randomly assigned to treatment group A and they received moxifloxacin 400mg IV daily for a minimum of 2 days with an option to continue with moxifloxacin tablets administered daily. Total treatment period should not have exceeded 15 days (including IV and oral treatment).

Fifty patients were randomly assigned to treatment group B and they received ceftriaxone 200mg IV daily for a minimum of 3 days in combination with metronidazole 500mg IV (which could be stopped at any time by the treating investigator {clinician}) followed by co-amoxiclav 625mg tablets three times a day. Total treatment period should not have exceeded 15 days (including IV and oral treatment).

2.2 Treatment Allocation

Each patient was randomly allocated to either treatment group A or B. The treating clinical investigator was blinded until after randomisation when the blinded code was opened to reveal the treatment allocation. Once the blinded code was opened the treating clinical

investigator was unblinded. Intravenous therapy commenced and was continued for a minimum of three days. See table 2.1 and table 2.2

Table 2.1 – Treatment Group A

Treatment Group A				
Treatment :	**Strength:**	**Route:**	**Dosage Interval:**	**Number of days of treatment:**
moxifloxacin	400 mg	IV	24 hours	Minimum of 3 days and a maximum of 15 days.
moxifloxacin	400 mg	Oral	24 hours	Minimum of 2 days and a maximum of 12 days.

Table 2.2 – Treatment Group B

Treatment Group B				
Treatment :	**Strength:**	**Route:**	**Dosage Interval:**	**Number of days of treatment:**
ceftriaxone	2 000 mg	IV	24 hours	Minimum of 3 days and a maximum of 15 days.
metronidazole	500 mg	IV	8 hours	Optional and to be discontinued at the treating physician's discretion.
co-amoxiclav *	625 mg	Oral	8 hours	Minimum of 2 days and a maximum of 12 days.

* 500mg amoxicillin, 125 mg clavulanate

At any time after the minimum of three days and at the discretion of the treating clinical investigator, the patient could be switched to oral therapy if gastro-intestinal function had returned. According to the study protocol (section 1.3 page 4), therapy (IV and/or IV + oral) should have been continued for a minimum of five days. Thereafter, the decision to end therapy was at the discretion of the treating clinical investigator i.e. when a patient was judged to be clinically cured (vital signs returned to normal).

2.3 Study Population

After the clinical study was completed, patients were categorized as per definition for the "per protocol patients" and the "intention to treat patients" within group A and group B.

"Per protocol patients" includes all patients randomised according to the inclusion- and exclusion- criteria, who were treated and have completed the study as described in the original protocol.

"Intention to treat patients" includes all patients randomised per inclusion and exclusion criteria and who received at least one dose of study medication. These patients did not complete the study due to an adverse event, treatment failure, and death or lost to follow up.

For this study the intention to treat population will be used as the primary input. It will be supported by the per protocol population.

2.4 Pharmacoeconomics

Pharmacoeconomics is a sub division of health economics, which is based on principles of economics. Pharmacoeconomics mainly deals with unlimited demands of people and with limited ability to respond to these demands with production of drugs and services. It actually analysis the various treatments (alternatives) and thus highlights their pros and cons. The comparative account of different treatments is essential to optimise the patient comfort and healthcare.[4]

The earliest definitions of pharmacoeconomics were very narrowly focused on the analysis of costs of the drug therapy to healthcare systems and society. But recently a much broader view of pharmacoeconomics involved assessing the implications of projected outcomes and costs of pharmaceutical products for decision making. [4]

The expanded definition has the advantage of incorporating the pharmacoeconomical research into the process of drug development for pre-clinical studies to phase IV clinical studies including post marketing surveillance. Pharmacoeconomics is a tool of management, which should be applied to strategies and operational decisions about pharmaceutical development, production and consumption. [4]

The aim of pharmacoeconomics is to ensure the most efficient use of limited resources. On the whole, pharmacoeconomics should be thought of as a dynamic ongoing process,

which communicates between research and development and marketing departments of the pharmaceutical industry. However, with its continued interventions, it helps in the metamorphosis of the structure of the industry towards and efficient use with sustenance. [4]

The ultimate aim of pharmacoeconomic evaluation is to provide a menu of choice for decision-making regarding the allocation of resources between different programs. To this end, at least two alternatives (not only the funder's perspective) need to be considered at the time. [4]

There are four major types of pharmacoeconomic evaluation:

- Cost minimisation analysis (CMA) [3]
- Cost effectiveness analysis (CEA) [3]
- Cost benefit analysis (CBA) [3]
- Cost utility analysis (CUA) [3 & 4]

The ultimate objective of all four types of evaluation it to compare the cost and outcome of the alternative regimens ideally by generating a single index or cost outcome ratio. [4]

Pharmacoeconomics is a growing discipline, which has relevance to industrial practice as well. It addresses problems in healthcare which are very difficult to assess prima-facie and also clarifies situations which are complex by nature and thus helps in decision making.[4]

The role of pharmacoeconomics includes assessing the implications of projected outcomes and products to decide whether to continue or stop drug development; it also helps in global pricing strategy. [4]

Pharmaceutical companies market products in complex and diverse markets where cost containment is an important goal for drug purchasers. These buyers are demanding new types of information from companies on product performance and cost before the product will be added to formularies or approved for payment. Canada is considering a

policy and Australia has enacted legislation that requires incorporation of economic evaluation into the regulatory process for determining drug coverage and payment.

Most European countries use economic data to help determine coverage and payment for new agents. In the USA, policy makers and health care purchasers are using economic data to develop institutional drug formularies and treatment guidelines.

Up to date, little has been written on the practical aspects of design, implementation and monitoring of a clinical trial that includes a pharmacoeconomic component. Many of these activities could be part of a model of good pharmacoeconomics practice for clinical studies, which would parallel current good clinical practice standards for clinical data collection.

Cost in Health Economics

Cost in health economics refers to the resources consumed during the provision of health care. [18]

There are generally three types of cost:

- Direct cost [3 & 18]
- Indirect cost [3 & 18]
- Intangible cost [18]

Direct cost refers to those resources whose consumption is wholly attributable to the use of the health care intervention in question. Direct costs include resources such as physical goods, labour and time. [3 & 18]

Indirect cost is used differently in different disciplines; however, in pharmacoeconomics and outcomes research it generally refers to lost productivity (paid or unpaid) resulting from morbidity or mortality. Both direct and indirect costs are typically presented in monetary terms. [3 & 18]

Intangible cost refers to the pain and suffering imposed by disease and its treatment and is typically more difficult to quantify in monetary terms. [18]

The objectives of pharmacoeconomic analysis are to improve health through better decision making and to determine relative values of alternative therapies. Pharmacoeconomics is, therefore, the benchmark for practical authoritative reviews of the application of health economics to disease management and optimal drug therapy.

For the aim of this research project the following parameters were used for health economic evaluations:

1. Type of therapy - study medication the patient was randomised to - name, dose and duration of treatment
2. Duration of therapy – number of days the patient was treated with IV and oral study medication
3. Duration of hospitalisation – type of ward and length of stay in each ward
4. Consumables – therapeutic adjuncts (oxygen mask, urinary catheter, nasogastric tubes, packed red cells, frozen plasma, central venous catheter, chest tubes etc.), alcohol swabs, IV lines, needles, syringes etc.
5. Concomitant medications - name, dose and duration of treatment, for treatment of chronic diseases, current disease and adverse events during the study period
6. Alternative antimicrobial treatment – name, dose and duration of treatment used to treat any persistent or recurrent intra-abdominal infection or extra abdominal or non-abdominal infection during the study period.
7. Professional fees - initial visit, in hospital visits, follow up visits to the surgeon
8. Adverse events
9. Outcome – Clinical Cure or Clinical Failure

3. ANALYSIS

Cost Minimisation Ratio (i.e. cost per successfully treated patient)

Incremental Cost Minimisation Ratio (i.e. the amount representing the cost associated with each additional successful treatment, when a switch to moxifloxacin is made)

p-value (i.e. the statistical difference (comparison) between the eradication rates associated between group A and group B respectively.)

The above three are the pharmacoeconomic and statistical parameters that will be used and be described in this section.

3.1 Demographic Data

In total 100 patients were randomised in the original study protocol. Treatment group A and group B consisted of 50 patients each in the intention to treat population group. Treatment group A had 42 patients in the per protocol population and treatment group B had 43 patients in the per protocol population (Table 3.2).

Table 3.1 - Age

Age	Mean ± SD		Median	
	Group A	Group B	Group A	Group B
Per Protocol	38.1 ± 14.1	35.8 ± 13.1	36	34
Intention To Treat	38.4 ± 15.4	37.1 ± 13.9	37	34

See Appendix C 4.1 & 4.2
See Appendix D 4.1 & 4.2

Table 3.2 - Gender

Gender	Group A			Group B		
	Male	Female	Sample Size	Male	Female	Sample Size
Per Protocol	32 (76%)	10 (24%)	42 (100%)	33 (77%)	10 (23%)	43 (100%)
Intention To Treat	37 (74%)	13 (26%)	50 (100%)	39 (78%)	11 (22%)	50 (100%)

See Appendix C 4.1 & 4.2
See Appendix D 4.1 & 4.2

3.2 Nature of Surgery

Table 3.3 – Nature of Surgery

Nature of Surgery	Group A		Group B		Group A		Group B	
	Per Protocol				Intention to Treat			
Appendectomy	17	41%	16	36%	18	36%	19	37%
Cholecystectomy	1	2%	2	5%	1	2%	2	4%
Laparatomy	20	48%	23	52%	25	50%	26	51%
Sigmoidectomy	1	2%	2	5%	1	2%	2	4%
Incision and Drainage	0	0%	0	0%	0	0%	0	0%
Exploratory Laparoscopy	3	7%	1	2%	5	10%	2	4%
Other	0	0%	0	0%	0	0%	0	0%
TOTAL	**42**	**100%**	**44***	**100%**	**50**	**100%**	**51***	**100%**

*One patient in group B had two types of surgeries.

See Appendix C 4.1 & 4.2
See Appendix D 4.1 & 4.2

3.3 Outcomes

Table 3.4 – Outcomes

	Group A			Group B		
	Cured	**Failed**	**Sample Size**	**Cured**	**Failed**	**Sample Size**
Per Protocol Patients	39 (93%)	3 (7%)	42 (100%)	42 (98%)	1 (2%)	43 (100%)
Intention To Treat Patients	44 (88%)	6 (12%)	50 (100%)	43 (86%)	7* (14%)	50 (100%)

** One death in group B*

See Appendix C 7.1 & 7.2
See Appendix D 7.1 & 7.2

3.4 Adverse Events

Table 3.5 – Adverse Events

	GROUP A	GROUP B
Per Protocol Patients	13 (31%)	14 (33%)
Intention To Treat Patients	29 (58%)	22 (44%)

See Appendix C 1.1 & 1.2
See Appendix D 1.1 & 1.2

3.5 Cost Summary and Cost Minimisation Ratio

To calculate the cost of each parameter the cost was applied as per May 2002 (MIMS, May 2002 [11]), private hospital rates and professional medical aid rates.

The results of this cost comparing study are summarised in table 3.6 and table 3.7.

Table 3.6 – Cost summary – intention to treat population

INTENTION TO TREAT POPULATION					
GROUP A			**GROUP B**		
1.	Clinical Cure	88% (44)	**1.**	Clinical Cure	86% (43)
		p = 0.766			
2.	Number of Patients	50	**2.**	Number of Patients	50
3.	Days of Hospitalisation	482	**3.**	Days of Hospitalisation	474
4.	Days of Out Patient Care	0	**4.**	Days of Out Patient Care	0
5.	Days of IV Treatment	246	**5.**	Days of IV Treatment	249
6.	Days of Oral Treatment	72	**6.**	Days of Oral Treatment	46
7.	**Study Medication**		**7.**	**Study Medication**	
7.1	IV – moxifloxacin	R 56,334.00	**7.1**	IV – ceftriaxone	R 79,597.19
7.2	Not applicable	R 0.00	**7.2**	IV – metronidazole	R 19,420.13
7.3	Oral – moxifloxacin	R 2,260.01	**7.3**	Oral	R 1,565.71
8.	**Hospitalisation Costs (Including Treatment)**		**8.**	**Hospitalisation Costs (Including Treatment)**	
8.1	Concomitant Medication	R 62,321.00	**8.1**	Concomitant Medication	R 42,363.55
8.2	Other Antimicrobials	R 85,689.86	**8.2**	Other Antimicrobials	R 57,034.35
8.3	Consumables	R 36,535.65	**8.3**	Consumables	R 19,488.78
8.4	Professional Fee	R 155,061.20	**8.4**	Professional Fee	R 125,338.80
8.5	**Accommodation**		**8.5**	**Accommodation**	
8.5.1	ICU	R 135,805.50	**8.5.1**	ICU	R 93,554.90
8.5.2	General Ward	R 375,336.00	**8.5.2**	General Ward	R 324,719.00
TOTAL COST		**R 909,343.22**	**TOTAL COST**		**R 763,082.41**
CM RATIO		**R 1,045,222.09**	**CM RATIO**		**R 877,106.22**

Pooled Rate: 0.87 (the eradication rate which is estimated to be common to group A and group B)

See Appendix C: Intention to Treat Population group A and group B
See Appendix D: Per Protocol Population group A and group B

Table 3.7 – Cost Summary – per protocol population

PER PROTOCOL POPULATION					
GROUP A			**GROUP B**		
1.	Clinical Cure	93% (39)	1.	Clinical Cure	98% (42)
		p = 0.294			
2.	Number of Patients	42	2.	Number of Patients	43
3.	Days of Hospitalisation	431	3.	Days of Hospitalisation	390
4.	Days of Out Patient Care	0	4.	Days of Out Patient Care	0
5.	Days of IV Treatment	202	5.	Days of IV Treatment	217
6.	Days of Oral Treatment	63	6.	Days of Oral Treatment	45
7.	**Study Medication**		7.	**Study Medication**	
7.1	IV – moxifloxacin	R 46,258.00	7.1	IV – ceftriaxone	R 69,367.83
7.2	Not applicable	R 0.00	7.2	IV – metronidazole	R 16,399.22
7.3	Oral – moxifloxacin	R 1,985.14	7.3	Oral	R 1,510.19
8.	**Hospitalisation Costs (Including Treatment)**		8.	**Hospitalisation Costs (Including Treatment)**	
8.1	Concomitant Medication	R 24,716.00	8.1	Concomitant Medication	R 13,157.51
8.2	Other Antimicrobials	R 27,623.62	8.2	Other Antimicrobials	R 12,709.70
8.3	Consumables	R 24,296.15	8.3	Consumables	R 15,133.93
8.4	Professional Fee	R 122,675.00	8.4	Professional Fee	R 104,098.50
8.5	**Accommodation**		8.5	**Accommodation**	
8.5.1	ICU	R 48,286.40	8.5.1	ICU	R 24,143.20
8.5.2	General Ward	R 293,200.00	8.5.2	General Ward	R 280,006.00
TOTAL COST		**R 589,040.31**	**TOTAL COST**		**R 536,526.08**
CM RATIO		R 618 609.34	CM RATIO		R 563 352.38

Pooled Rate: 0.9529 (the eradication rate which is estimated to be common to group A and group B)

See Appendix C: Intention to Treat Population group A and group B
See Appendix D: Per Protocol Population group A and group B

4. DISCUSSION

4.1 General

For the purpose of this study the "Intention to Treat" population will be the one focussed on. Reference will be made to the "Per Protocol" population to support the data.

*"**Intention to treat patients**" includes all patients randomised per inclusion and exclusion criteria and who received at least one dose of study medication. These patients did not complete the study due to an adverse event, treatment failure, and death or lost to follow up.*

*"**Per protocol patients**" includes all patients randomised according to the inclusion- and exclusion-criteria, who were treated and have completed the study as described in the original protocol.*

Both statistical non significance and clinical equivalence were demonstrated in the two treatment groups regarding the clinical cure rate. For a cost effective analysis a statistical significant difference should be observed in the clinical outcomes. No significant differences were observed in the recovery rate and therefore the technique of cost minimisation will be used to interpret the data instead of cost effectiveness. Cost-Minimisation Analysis is a type of analysis that finds the least costly program among those shown or assumed to be of equal benefit (clinically equivalent). [17] This analytical technique is applied in situations where the outcomes associated with two (or more) alternative means of intervention are equivalent and the objective is thus to compare the total resource cost associated with using the different treatments. [1]

For the purpose of this study the funder's perspective was chosen. The approach of the funders, in this case the medical aid schemes, is based on economic principles without violating the viability and successful treatment of the patient. With the outcomes of this pharmacoeconomic study in hand, funders may be persuaded to list a new drug in the treatment of intra-abdominal infections on the formulary of the medical aid scheme.

4.2 Intention to Treat Population (ITT)

4.2.1 Treatment Group A

4.2.1.1 Demographic Data – Age and Gender (Table 3.1 and 3.2)

The study population consisted of a single diagnostic group of intra-abdominal infection patients in a relatively narrow age group (38.4 years with a standard deviation of 15.4). Treatment group A was represented by 37 males and 13 females. Male patients formed the majority of the patient population mainly due to the nature of their illness or injury. Many male patients were included in the study with either abdominal gunshot or stab wounds.

The female patients' intra-abdominal infections were mainly due to natural courses. Therefore, this population group (female) was older and had more severe cases.

4.2.1.2 Parameters per Health Economic Evaluation

4.2.1.2.1 Nature of Surgery

Patients in this group all had one type of surgery performed during their hospitalisation. The main surgeries performed were laparotomies (25) followed by appendectomies (18) and exploratory laparoscopies (5). One cholecystectomy and one sigmoidectomy were performed in this group of patients (table 3.3). No incision and drainage or other procedures were performed.

Fifty patients were randomised to treatment group A. This resulted in a cost of R56, 334.00 for IV medication treatment and R 2, 260.01 for oral medication treatment (table 3.6).

4.2.1.2.2 Duration of Therapy

In total 246 days of IV treatment and 72 days of oral treatment were administered to patients in treatment group A (table 3.6)

4.2.1.2.3 Duration of Hospitalisation

In total 482 days of hospitalisation was recorded for all 50 patients in treatment group A (table 3.6)

Per patient this can be expressed as 9.64 days hospitalisation at R 19, 149.80 per patient (per 1000 patients 9640 days at a cost of R 19, 149, 800.00).

4.2.1.2.4 Consumables

A total amount of R 36, 535.65 was recorded to have been spent on consumables to treat patients in treatment group A (table 3.6)

4.2.1.2.5 Concomitant Medication

A total amount of R 62, 321.00 was recorded to have been spent on concomitant medication to treat patients in treatment group A's chronic diseases, current disease (intra-abdominal infection) and adverse events (table 3.6).

4.2.1.2.6 Alternative Antimicrobial Therapy

In some cases it was necessary to either administer alternative antimicrobial therapy to the patients either prior to surgery or during surgery prior to the establishment of eligibility to the study and the signing of consent. Some patients received alternative antimicrobials because of treatment failure to study medication or relapse. This resulted in a total cost of R 85, 689.86 (table 3.6).

4.2.1.2.7 Professional Fee

The professional fee was established by using the medical aid rates for a surgeon seeing a patient for an initial visit, in hospital visits (one per day) and a follow-up visit. In total this amounted up to R 155, 061.20 (table 3.6)

4.2.1.2.8 Adverse Events

The adverse events documented were 29 for patients in group A (table 3.5 and appendix C 1.1).

4.2.1.2.9 Outcome

Clinical cure was documented for 44 out of the 50 patients in this group (88%) (table 3.6). Seeing that no hypothesis is tested, no p value is applicable.

4.2.1.3 Total Cost and Cost Minimisation Ratio

The total cost for patients in treatment group A was R 909, 343.22 with a CM ratio of R 1, 045, 222.09. This represents the average cost per successfully treated patient, where "success" is defined as clinical eradication.

4.3 Intention to Treat Population (ITT)

4.3.1 Treatment Group B

4.3.1.1 Demographic Data – Age and Gender (Table 3.1 and 3.2)

The study population consisted of a single diagnostic group of intra-abdominal infection patients in a relatively narrow age group (37.1 years with a standard deviation of 13.9). (table 3.1). Treatment group B was represented by 39 males and 11 females (table 3.2). Male patients formed the majority of the patient population mainly due to the nature of their illness or injury. Many male patients were included with either abdominal gunshot or stab wounds. The female patients' intra-abdominal infections were mainly due to natural courses. Therefore this population group (female) was older and had more severe cases.

4.3.1.2 Parameters per Health Economic Evaluation

4.3.1.2.1 Nature of Surgery

One patient in treatment group B had two procedures, appendectomy and laparotomy. This was due to the nature of the injury as well as to natural courses identified by the treating investigator.

The main surgeries performed were laparotomies (26) followed by appendectomies (19). Two of each the following procedures were performed, exploratory laparoscopies, cholecystectomy and sigmoidectomy (table 3.3). No incision and drainage or other procedures were performed.

Fifty patients were randomised to treatment group B. This resulted in a cost of R 99, 017.32 for IV medication treatment and R 1, 565.71 for oral medication treatment (table 3.6).

4.3.1.2.2 Duration of Therapy

In total 249 days of IV treatment and 46 days of oral treatment were administered to patients in treatment group B (table 3.6)

4.3.1.2.3 Duration of Hospitalisation

In total 474 days of hospitalisation was recorded for all 50 patients in this treatment group (table 3.6).

Per patient this can be expressed as 9.48 days hospitalisation at R 13, 249.99 per patient (per 1000 patients 9480 days at a cost of R 13, 249, 990,00).

4.3.1.2.4 Consumables

A total amount of R 19, 488.78 was recorded to have been spent on consumables to treat patients in this treatment group (table 3.6)

4.3.1.2.5 Concomitant Medication

A total amount of R 42, 363.55 was recorded to have been spent on concomitant medication to treat patients in treatment group B's chronic diseases, current disease and adverse events (table 3.6).

4.3.1.2.6 Alternative Antimicrobial Therapy

In some cases it was necessary to either administer alternative antimicrobial therapy to the patients either prior to surgery or during surgery prior to the establishment of eligibility to the study and the signing of consent. Some patients received alternative antimicrobials because of treatment failure to study medication or relapse. This resulted in a total cost of R 57, 034.35 (table 3.6).

4.3.1.2.7 Professional Fee

The professional fee was established by using the medical aid rates for a surgeon seeing a patient for an initial visit, in hospital visits (one per day) and a follow up visit. In total this was R 125, 338.80 (table 3.6)

4.3.1.2.8 Adverse Events

The adverse events documented were 22 for patients in group B (table 3.5 and appendix C 1.2).

4.3.1.2.9 Outcome

Clinical cure was documented for 43 out of the 50 patients in this group (86%) (table 3.6). Seeing that no hypothesis is tested, no p value is applicable.

4.3.1.3 Total Cost and Cost Minimisation Ratio

The total cost for patients in treatment group B was R 763, 082.41 with a CM ratio of R 877, 106.22 (table 3.6). This represents the average cost per successfully treated patient, where "success" is defined as clinical eradication.

4.4 Per Protocol Population (PPP)

4.4.1 Treatment Group A

Forty two patients were allocated per definition to this group. An eradication rate of 93% was calculated and these patients were hospitalised for 431 days in total. The total cost was R 589, 040.31.

4.4.2 Treatment Group B

Forty three patients were classified per definition to this group. An eradication rate of 98 % was calculated and these patients were hospitalised for 390 days. The total cost was R 536, 52.08.

4.5 Cost Minimisation Ratio

A pooled eradication rate was used to determine the ratio of Cost Minimisation. This was calculated as the weighted average of the respective eradication rates. In this trial the ITT population consisted of 50 patients in both treatment groups. The PP populations consisted of 42 patients in group A and 43 in group B. The weighted average therefore equals the arithmetic mean, 87% (pooled rate = 0.87).

The following formula was used to determine the CM ratio:
CM = Total Costs / Outcome (eradication rate %)

See Table 3.6 and 3.7

4.6 Incremental Cost Minimisation Ratio

Cost and effects must be reported as increments (these are differences between two alternatives) and as totals.

The CM ratio should not be used as a single figure because this can be misleading.
To prove this result the Incremental CM Ratio was also calculated.

The Incremental CM Ratio was calculated as follows:

$$\frac{\text{ITT Cost Group A} - \text{ITT Cost Group B}}{\text{ITT eradication rate Group A} - \text{ITT eradication rate Group B}}$$

$$= \frac{\text{R } 909, 343.22 - \text{R } 763, 082.41}{0.88 - 0.86}$$

$$= \text{R } 7, 313, 040.00$$

This amount represents the cost associated with each additional successful treatment when a switch to moxifloxacin is made.

4.7 Statistical values

The Chi^2 (χ^2) score with one degree of freedom was calculated and equals 0.088 with a p value of 0.766 in the ITT population (PP population Chi^2 (χ^2) = 1.911 and p = 0.294). Both these values are not statistically significant and therefore equivalence in clinical outcomes is present in both treatment groups.

Any p value greater that the conventional 0.05 would be considered as being statistical non significant.

5. CONCLUSION

The objective of the study was to perform a health-economic analysis to quantify and compare the cost of healthcare infrastructure used in treatment group A and group B. According to the definition of a Cost Minimisation Analysis it is:

a " type of analysis that finds the least costly program among those shown or assumed to be of equal benefit".

The challenge in utilising pharmacoeconomic data is in the interpretation of the study results. [16]

From the results in tables 3.6 it clearly shows that treatment for group A (CM ratio = R 1, 045, 222.09) was less cost efficient than the treatment for group B (CM ratio = R 877, 106.22) (efficiency = cost effectiveness). Therefore, the treatment for group B was the most efficient (cost effective) treatment regimen to use when treating patients with intra abdominal infections.

Although, not all factors impacting on the cost could be included in this analysis, results demonstrated no statistically difference in the clinical outcome in the two treatment groups.

The following aspects should be taken into account when examining the results of this study:

- Treatment for group B consisted of generic drugs which are much cheaper
- Treatment for group A consisted of ethical products which were only recently registered and marketed and were therefore more expensive.
- Two of the drugs in treatment for group B were eight hourly administered which could have led to an increase in resource cost (nursing personnel time and nursing personnel cost was not included in this analysis due to the original aims of the trial) and which could impact on patient compliance if the patient was not hospitalised till the end of the treatment.
- Treatment group A was a once a day consequential (IV and oral) therapy with the same drug and dosage. This could lead to a decrease in the nursing cost and an improved patient compliance after hospitalisation.

- This data was compiled during a clinical study. Therefore the conditions were more controlled, which does not necessarily reflect the real world.
- The original study was a randomised open label study. This could lead to more attentiveness of the investigators. Adverse events could have been more accurately documented when patients were randomised to treatment group A. The patients could have been switched to alternative antimicrobial therapy sooner in treatment group A than B.
- This study was conducted at a government institution. Patients in government institutions are treated differently to patients in private institutions because their living conditions at home are not always favourable for rehabilitation after major surgery. Therefore most of the patients were hospitalised until the treating investigator was ensured of a complete cure prior to discharge. This will not necessarily be the case at private hospitals and in turn could have led to increased hospitalisation cost.

Treatment Group A is a new fluoroquinolone antibiotic registered in South Africa and was recently investigated in the treatment of intra-abdominal infections at Tygerberg Hospital. Due to the once a day administration and IV / oral treatments available on the South African market this makes it a very convenient treatment to the nursing personnel and could improve patient compliance when the patient is discharged from hospital. The sequential follow up treatment available in oral treatment could lead to a quicker switch to oral treatment and therefore to a sooner discharge from hospital for patients in the private hospital environment. Therefore, this could lead to a decrease in hospitalisation cost and could therefore be an option to the funder to reimburse the use of treatment group A in private hospitals.

This outcome is only applicable to the perspective of the medical aid (funder) which was chosen for this pharmacoeconomic analysis. If a different perspective were chosen i.e. the hospital perspective, a completely different outcome could be expected. This statement leads to the conclusion that a multi perspective approach is needed to come to a comprehensive and acceptable result.

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APPENDIX A: THE RELEVANT COMMITTEE APPROVALS

1. Original Ethics Committee Approval by the University of Stellenbosch
2. Wits Health Consortium Ethics Committee Approval
3. Approval by the Post Graduate Committee

Original Ethics Committee Approval by the University of Stellenbosch (Pharmaceutical Trial Advisory Committee)

UNIVERSITEIT VAN STELLENBOSCH
UNIVERSITY OF STELLENBOSCH

22 January 2001

Prof BL Warren
Department of Surgery

Dear Prof Warren

RESEARCH PROJECT : **"A PROSPECTIVE, RANDOMIZED, NON-BLIND, MULTICENTRE TRIAL ASSESSING THE SAFETY AND EFFICACY OF SEQUENTIAL (INTRAVENOUS/ORAL) BAY 12-8039 (MOXIFLOXACIN) 400 mg EVERY 24hr COMPARED TO INTRAVENOUS CEFTRIAXONE 2 g EVERY 24hr AND METRONIDAZOLE 500 mg EVERY 8hr FOLLOWED BY ORAL AMOXICILLIN/CLAVULANIC ACID TABLETS 625 mg EVERY 8hr FOR THE TREATMENT OF PATIENTS WITH COMPLICATED INTRA-ABDOMINAL INFECTIONS"**
PROTOCOL NUMBER : **BAY 12-8039**
PROJECT NUMBER : **2001/M006**

At a meeting of the Pharmaceutical Trial Advisory Committee that was held on 13 November 2000 the above project was approved on condition that further information that was required, be submitted.

This information was supplied and the project was finally approved on 22 January 2001. Please quote the abovementioned project number in all future correspondence.

The following documents were reviewed and approved by the Committee:

Protocol: BAY 12-8039; Impact no. 10209; 08.09.00/Version 4; Controlled copy 007.

Investigator's Brochure: BAY 12-8039; Version 6; 31/12/99; International amendment 1; 18/04/00; International amendment 2; 09/06/2000.

Information Sheet for Patients and Informed Consent Form: Prof BL Warren; Version 4.0; 16 January 2001.

"Inligtingsblad vir Pasiënte" and "Ingeligte Toestemmingsvorm": "Prof BL Warren; Weergawe 2.0; 16 January 2001".

The study has been accepted as complying to the Ethics Standards for Clinical Research with a new medicine in patients, based on FDA, ICH, GCP and Declaration of Helsinki guidelines.

A list of the members constituting the Pharmaceutical Trial Advisory Committee is attached.

Yours faithfully

CJ VAN TONDER
for MANAGER: RESEARCH DEVELOPMENT

G:\DOCUMENTS\M A K\PROJECTS\2001-M006-001.DOC

Universiteitskantoor • University Office, Tygerbergkampus • Tygerberg Campus
Posbus 19063, 7505 Tygerberg
(021) 938 9267, Faks (021) 931 7810, Suid-Afrika / South Africa

Wits Health Consortium Ethics Committee Approval

University of the Witwatersrand, Johannesburg

Committee for Research on Human Subjects (Medical): Clinical Trials
FWA Registered No IRB 00001233

SECRETARIAT: Suite 189, Private Bag x2600, Houghton 2041, South Africa • Tel: +27-11-717-2800 • Fax: +27-11-717-2833

07 November 2002

FAX TO

Miss ME Schmitt,
Pharmacist
Healthcare Division
P.O Box 198
Isando
Gauteng
1600

Fax: 011 921 5075

Dear Miss Schmitt,

PROTOCOL: BAY 10209 - A RETROSPECTIVE PHARMACOENOMIC ANALYSIS COMPARING THE COST EFFECTIVENESS OF TWO TREATMENTS GROUP IN PATIENTS WITH COMPLICATED INTRA-ABDOMINAL INFECTIONS.

ETHICS REFERENCE NO: 020903

1. This is to certify that the above-mentioned trial was reviewed and approved by the University of the Witwatersrand, Human Research Ethics Committee Medical (HREC).

2. THIS APPROVAL IS SUBJECT TO THE FOLLOWING PROVISOS:
* A copy of the MCC approval letter must be submitted to the Ethics Regulatory Office Secretariat before the study commences / the changes are implemented.

* The study is conducted according to the protocol submitted to the University of the Witwatersrand, Human Research Ethics Committee. Any amendments to the protocol must first be submitted to the Human Research Ethics Committee (Medical) for approval.

* During the study, the University of the Witwatersrand, Human Research Ethics Committee (Medical) is informed immediately of :
- Any Unexpected Serious Adverse Events or Unexpected Adverse Drug Reactions, which, in the Investigator and/or the Sponsor's opinion are suspected to be related to the study drug. (International and Local Reports).
- Any data received during the trial which, may cast doubt on the validity of the continuation of the study .

* The University of the Witwatersrand, Human Research Ethics Committee (Medical) is notified of any decision to discontinue the study and the reason stated.

* The Investigators authorised by this approval participate in this study. Additional Investigators shall be submitted to the University of the Witwatersrand, Human Research Ethics Committee (Medical) for approval prior to their participation in the study.

* In the event of an authorised Investigator ceasing to participate in the study, the University of the Witwatersrand, Human Research Ethics Committee (Medical) must be informed and the reason for such cessation given.

PRINCIPLES OF INFORMED CONSENT:
3. The University of the Witwatersrand, Human Research Ethics Committee (Medical) requires that in all studies, the Principles of Informed Consent are adhered to. This applies to volunteers as well as patients.

PROGRESS REPORTS:
4. The University of the Witwatersrand, Human Research Ethics Committee (Medical) requests that the MCC Progress Reports be submitted twice a year (March and September) and a report of the final results. At the conclusion of the study.

THE SUPPORTING APPROVAL DOCUMENTS ARE ATTACHED:

a. Ethics Approval Form signed by the Chairperson of HREC - Kindly return the copy of the Approval Form signed by the Principal Investigator per fax 011 711-2833 for our records.

b. List of the members present at the HREC meeting held 27 SEPTEMBER 2002.

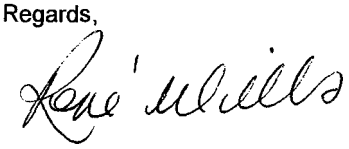
* WE AWAIT YOUR RESPONSES AS REQUESTED:

* Copy of Approval Form signed by the Principal Investigator.

The above has been noted for the Ethics Committee information and records.

KINDLY FORWARD TO THE RELEVANT INVESTIGATORS / CRA / SPONSOR / STUDY CO-ORDINATORS - WHERE APPLICABLE

Regards,



RENÉ WILLS
For and on behalf of the Committee for Research on Human Subjects (Medical)

Attendance Register for the Ethics Meeting held on 27 September 2002 from 13:00 - 15:00

Venue: PPS Boardroom, Faculty of Health Sciences, Medical School,

FILIATED TO THE UNIVERSITY IF THE WITWATERSRAND

name	Initials	Title	Discipline/s	Academic Qualifications	Gender	Present
agwanjee	S	Prof	Anaesthesia	MBBCh, FCA, DA (SA), FFA (SA)	M	Absent
aton-Jones hairperson)	P	Prof	Medical Practitioner	BDS, MBBCh, PhD, DTM&H, DPH, DA (SA), DSc (Dent), Hon PhD, MASSAfr	M	Present
oper	P.A	Prof	Paediatrics	MBBCh, PhD, DCH (SA), DCH, FCPaed (SA)	M	Absent
onde	B	Prof	Radiation Oncology	MBBCh, MMed Rad (T)	M	Present
ower	SJ	Prof	Social Worker	BSocSci (Hons), PhD, RSW	F	Present
agle	GT	Prof	Physiology	BA (Hons) MA (Clin Psych), PhD, FRCP	F	Absent
eldman Deputy Chairperson)	C	Prof	Pulmonology	MBBCh, PhD, FCP (SA) (Respiratory) FRCP	M	Present
angley	G	Mrs	Nursing	MSc (Nursing)	F	Present
ownie	MA	Dr	Maxillo-Facial & Oral Surgery	BDS, BA (Hons), DipMFOS, FCMFOS (SA)	F	Present
cLean	GR	Dr	Philosopher and Ethicist	BA (Hons) MA B Phil DPhil	M	Present
okhachane Deputy Chairperson)	M.	Dr	Paediatrics	MBBCh, FCP (Paeds) SA, MMed (Wits)	F	Absent
ettle	GJ	Prof	Surgery	BSc (Hons), MBBCh, FRCS	M	Present
aizes	A.	Prof	Lawyer	BCom, LLB, PhD	M	Present
enn	C	Prof	Speech Pathology	BA (S&HT), PhD	F	Present
oss	E	Prof	Social Worker	BA, MA, PhD	F	Absent
chuklenk	U	Prof	Biomedical Ethics	PhD	M	Present
keen	AS	Prof	Lawyer	BA (Hons), BL (Hons), LLB, MPhil	M	Absent
zabo	CP	Prof	Psychiatry	MBBCh, MMed, PhD	M	Absent
an Gelderen	CJ	Prof	Obstetrics & Gynaecology	MBBCh, FRCOG, FCPsych	M	Absent
elaphi	S	Dr	Paediatrics	MBBCh, FCPaeds, Mmed	M	Present
orster Deputy Chairperson)	M	Prof	Psychiatry	BA (Crim), MBBCh, MMed, FCPsych(SA), PhD	F	Present
adee	A	Prof	Immunology	BSc, MSc, PhD	M	Present
oodiwiss	A	Prof	Cardiovascular Pathophysiology	BSc, BSc (Physio) MSc, PhD	F	Present

OT AFFILIATED TO THE UNIVERSITY IF THE WITWATERSRAND

urname	Initials	Title	Discipline/s	Academic Qualifications	Gender	Present
/burgh	C	Prof	Educationist	B.Sc (Hons), M.Com DEd NED	M	Absent
oggenpoel	M	Prof	Psychiatry Nurse	RN, PhD	F	Present

te 1: This committee has been in continuous operation since October 1996.
te 2: The large committee size is to ensure a good attendance at meetings.
te 3: A Quorom consists of 6 members, of which 1 non-affiliate and 1 non-medical member to be present
te 4: The following members alternate: Prof A.S. Skeen/Prof A. Paizes
Prof C. Penn/ Dr E. Ross
Prof C.P. Szabo /Prof M. Vorster

WITS - INDEPENDENT ETHICS COMMMITTEE APPROVAL FORM 2002

INDEPENDENT ETHICS COMMITTEE FORM

Ethics Reference No	**020903**	**Date of Meeting**	**27 September 2002**
Principal Investigator	**1 MISS M SCHMITT**	**Sub-Investigator**	
Protocol title	A Retrospective Pharmacoenomic Analysis Comparing the Cost Effectiveness of Two Treatments Group in Patients with Complicated Intra-Abdominal Infections.		

DOCUMENTS REVIEWED				**TICK AS APPROPRIATE**
Protocol Name:	**BAY 10209, Version 1.0**	Date:	**9 September 02**	✔
Protocol Amendment No		Date:		
Investigator's Brochure				
Subject Information/consent form:	**Patient Information Leaflet & Informed Consent BAY 12-8039/10209 AIDA Study**			✔
Advertisements				
Insurance/Compensation				
Relevant Site/(s) where Trial is being conducted	**• University of Stellenbosch, Department General Surgery, Tygerberg Hospital, Cape Town**			✔
Syndicate Name				
Synopsis of Study:	**Summary of retrospective study**			✔
Other				

DETAILS OF COMMITTEE	
Name:	University of the Witwatersrand Committee for Research on Human Subjects (Medical)
Address:	Division of the Deputy Registrar (Research), Department of Research, Senate House University of the Witwatersrand, 1 Jan Smuts Avenue, BRAAMFONTEIN, Johannesburg, 2000

DETAILS OF MEETING	**YES**	**NO**
Is the Investigator a member of the committee?		✔
If 'Yes" did he/she vote?		
Is the Committee organized and operated according to applicable laws and regulations together with?		
Local GCP requirements?	✔	
ICH GCP requirements?	✔	
FDA GCP requirements?	✔	
Progress reports required on a 6 monthly basis?	✔	

DECISION ON APPROVAL: Is approval given to conduct the trial?	**Tick as appropriate**
Yes – with no conditions	✔
Yes – with conditions	
Specify conditions:	
No	
Specify reasons	

SIGNATURES

I confirm that the details on this form are correct:

Name: **Prof P Cleaton Jones** **Chairperson of Committee**	**Signature:**	**Date:** **06 November 2002**

DECLARATION OF INVESTIGATOR/ (S)

To be completed in duplicate and **ONE *COPY*** returned to the Secretariat for the CHRS at Wits Health Consortium, Healthcare Park, 27 Eton Road, Parktown, 2193.

I/We fully understand the conditions under which I am/we are authorised to carry out and complete the above-mentioned research and I/we agree to ensure full compliance with these conditions. Should any amendment, alteration or departure be contemplated from the research procedure methodology or manner of execution I/we will communicate with the Chairman of the Committee for Research on Human Subjects (Medical) for approval prior to acting on any of the above mentioned proposed amendments, alterations or departures. I am/we are fully aware that any unauthorised amendment, alteration or departure as above will amount to misconduct and may lead to the institution of disciplinary procedures.

Any approval given by the CRHS is conditional upon consent being obtained by the investigator/s from the Superintendent (or equivalent official) of the hospital, clinic or institution in which the research is, in part or in full, to take place.
The Chairman may of course at his discretion place the matter before the full committee.

DATE _____ SIGNATURE _____ NAME: _____

PROTOCOL NUMBER: **BAY 10209**

Approval by the Post Graduate Committee

Faculty of Health Sciences
UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

7 York Road PARKTOWN Johannesburg 2193 Telegrams WITSMED Telex 4-24655.SA
FAX 643-4318 TELEPHONE 717-2075/2076
E-MAIL healthpg@health.wits.ac.za

MS ME SCHMITT
P O BOX 914 348
WINGATE PARK
0153

APPLICATION NUMBER 0214825K
STATUS (DEG 97) (MM044) PZZ

2002-12-03

Dear Ms Schmitt

Approval of protocol entitled A retrospective pharmacoeconomic analysis comparing the cost effectiveness of two treatment groups in patients with complicated intra-abdominal infections

I should like to advise you that the protocol and title that you have submitted for the degree of Master Of Science In Medicine (Part-Time).(Coursework) have been approved by the Postgraduate Committee at its recent meeting. Please remember that any amendment to this title has to be endorsed by your Head of Department and formally approved by the Postgraduate Committee.

Dr GJ Lowndes has/have been appointed as your supervisor/s. Please maintain regular contact with your supervisor who must be kept advised of your progress.

Please note that approval by the Postgraduate Committee is always given subject to permission from the relevant Ethics Committee, and a copy of your clearance certificate should be lodged with the Faculty Office as soon as possible, if this has not already been done.

Yours sincerely

ME Fick (Mrs)
Faculty Registrar
Faculty of Health Sciences

Telephone 717-2075/2076

Copies - Head of Department____Supervisor/s

Plan your career and first-year curriculum online - explore our website: www.wits.ac.za/ec2
The University seeks to serve South Africa by furthering access to equal opportunity while striving for excellence in teaching, learning and research

APPENDIX B: PATIENT INFORMATION LEAFLET AND INFORMED CONSENT

PATIENT INFORMATION LEAFLET & INFORMED CONSENT
BAYER HEALTHCARE: BAY 12-8039/10209 AIDA Study

A prospective, randomized, non-blind, multicenter trial assessing the safety and efficacy of sequential (intravenous/oral) BAY 12-8039 (moxifloxacin) 400 mg every 24 hr compared to intravenous ceftriaxone 2g every 24 hr and metronidazole 500 mg every 8 hr followed by oral amoxycillin/clavulanic acid tablets 625 mg every 8 hr for the treatment of patients with complicated intra-abdominal infections. **AIDA** – Study no.: IMPACT 10209

(You should keep a signed and dated copy of the Patient Information Leaflet & Informed Consent Form until the end of the study)

You are being asked to participate in a research project. This document aims to give you important information regarding the procedures involved, the visits to your doctor, the study medication, possible side-effects, alternative treatments and your right to withdraw. Please take the opportunity to discuss any aspect of the study and this document with the doctor. If you agree to participate, you will be asked to sign the attached Consent Form. **Your participation is entirely voluntary and if you do not wish to take part, this will not affect the future treatment that you will receive or are entitled to in any way.**

THE STUDY

This is a research study, which will compare the effects of a new antibiotic, moxifloxacin, with currently available antibiotics, ceftriaxone, metronidazole and amoxycillin/clavulanic acid, in the treatment of your condition (known as intra-abdominal infection). In total 566 patients will take part world wide and approximately 100 patients will be recruited in South Africa. If you agree to participate, you will be allocated to one of the two treatment groups and will be treated with either moxifloxacin, or ceftriaxone/metronidazole/amoxycillin/clavulanic acid. The total length of your treatment will be between 5 and 14 days, but you will remain in the study for 14-28 days after the treatment ends. The recruitment period for this trial will be approximately 18 months. Bayer provides the trial medication.

As moxifloxacin is a new antibiotic (as oral medication approved in the USA and most EU countries), it is important to check how well it is tolerated and the effect. Therefore, your doctor will assess your progress carefully during the study. You will be assessed every day while you are still in the hospital and will be asked to return to visit your doctor again after you have been discharged from hospital.

PROCEDURE

If you agree to participate in the study, the doctor will take a medical history, collect demographic data, vital signs, examine you and arrange for you to have either a x-ray, an ultrasound or any other radiographic procedure that is medically indicated in order to precisely diagnose your intra-abdominal infection. In addition an ECG (a measurement of your heart function) will be performed. Blood and urine samples will be taken for laboratory testing to determine how severe you infection is. To do this, 35 milliliters (seven teaspoons) of blood will be drawn on day 1. To determine how well the medication is working against the infection 15 – 35 millilitres will then again be taken once between days 3-5 and or the day you start taking oral medication and again once between days 5 –14 and one last time between days 28 – 42. The volume of blood will change between 15 – 35 milliters depending on how well the infection respond to the medication you are taking. On the same days when blood is taken 50 milliliters (10 teaspoons) of urine will be collected. Samples (drainage, fluid, tissue) from the infected area will be obtained to identify the bacteria which is causing the infection. This will only be done at the beginning of your treatment to help the doctor.

If you are willing to take part you will have to give written consent by signing this form after which the above tests will be done. If these tests also indicate that you can enter the study you will be given either moxifloxacin

or a combination of ceftriaxone and metronidazole. If you receive the moxifloxacin you will receive the medication once a day directly into a vein. If you receive the combination the treatment will be three times a day directly into a vein. After at least three days if you are well enough according to your doctor this medication can be stopped and changed to oral medication. If you receive the moxifloxacin you will have to take one tablet per day and if you are on the combination treatment you will receive amoxycillin/clavulanic acid three times a day. You will receive oral medication for up to 11 days depending on you progress and therefore in total you will receive study medication for a maximum of 14 days. The medication you will receive will be decided on randomly. If the treatment you are given does not cure your infection, it will be replaced by another standard treatment.

Full assessments will be carried out once between days 3-5 after the start of your treatment, on the day you are switched from infusion to tablets (if this is different from day 4 or 5 of treatment). This will be repeated once between days 5-14 and 28-42 days after your last dose of medicine to check that you have fully recovered from your infection. At all of these visits you will be examined and have blood, urine and if appropriate, microbiological tests repeated. The ECG (heart function test) will be repeated after the end of the morning infusion on days 1 and 3. At all visits, you will be asked about any side effects which you may have had.

It is not permitted to take part in other trials at the same time. Please inform your doctor if you are already participating in another trial.

WITHDRAWAL FROM STUDY

As your participation in this study is entirely voluntary, you may withdraw from the study at any time that you wish even without stating your reasons. Your doctor may also withdraw you from the study should he/she consider that continued involvement on your part is inappropriate or may affect your well-being. If you withdraw from the study, this will not affect your future treatment in any way. However, if you decide to withdraw, you will need to visit your doctor so that he/she can examine you and arrange further assessments if necessary.

POTENTIAL RISKS, DISCOMFORTS, SIDE-EFFECTS

Possible side-effects of moxifloxacin include nausea, stomach pains, diarrhoea, mild headache, rash, dizziness, allergic reactions and reversible changes to your liver function.

Possible side-effects of the combination medication:

Ceftriaxone	-	abdominal disturbances (for example cramps and diarrhoea), skin effects (example rash, peeling, itchiness) and allergic reactions.
Metronidazole	-	abdominal disturbances (for example cramps and diarrhoea), allergic reactions, weaknesses, dizziness, vomiting, nausea, skin rashes, darkly coloured urine, reaction to the use of alcohol (including perfume, deodorants etc.)
Amoxycillin/ clavulanic acid	-	abdominal disturbances (for example cramps and diarrhoea), reversible effects to your liver such as pain and jaundice, allergic reactions, possible effects to you kidneys, hot flushes, skin effects (rash, peeling, itchiness), changes in tooth colour and fungal infections

Your ability to drive or operate machinery might be impaired, particularly in conjunction with alcohol.

New findings: You will be informed as soon as possible about any new findings which could cause you to reconsider your decision to participate in this clinical trial.

EXPECTED BENEFITS

Moxifloxacin is a new antibiotic which is active against a very wide variety of bacteria which cause infection. Laboratory tests indicate that moxifloxacin is at least as effective as other commercially available antibiotics and it is expected that moxifloxacin will treat your condition successfully. The aim of this study is to check, by detailed and regular testing, the safety and tolerability of moxifloxacin. The medical knowledge gained from the study may benefit others in the future.

ALTERNATIVE TREATMENT

There are other antibiotics (Piperacillin, Imipenem) available in addition to those used in this study which may be used to treat your condition.

CONFIDENTIALITY

Your medical data and the results of this trial will be recorded and transferred anonymously to Bayer (local and international) for scientific evaluation. If the results of this trial is published your identity will remain confidential. Correct recording of the measured values and clinical findings is vital for research purposes and therefore serves to improve drug safety. In order to ensure complete and correct transfer of the data required for scientific evaluation, authorized personnel / specialists from Bayer, the local ethics committtee and regulatory body, auditors and the supervisory authorities in Germany and abroad who are responsible for the clinical trials will be granted permission by the investigator to view your personal original medical documents. Your express permission is required for this. By signing the attached Informed Consent Form, your are legally authorizing such access.

COMPENSATION

The sponsor company has taken out insurance for this study. This will compensate you for any significant deterioration in your health caused by the trial medication during the study. The trial is being conducted subject to the Association of the British Pharmaceutical Industry (ABPI) Guidelines, rlating to compensation for injury arising in the course of clinical trials. Copies of these guidelines are available from your study doctor, should they be requested.

Bayer will pay for all trial related expenses. You will not receive remuneration for taking part in this trial except for re-imbursement for travel expenses while meeting study commitments.

OTHER INFORMATION

(i) The local Research Ethics Committee, ***Pharmaceutical Trial Advisory Committee of the University of Stellenbosch***, has reviewed and approved the study. The conduct of this study will be according to ICH guidelines and the Declaration of Helsinki.

(ii) You should inform your doctor immediately if you develop a rash or if you experience any unexpected reactions.

(iii) Please inform your referring/family practitioner and your life insurer of your study participation.

If you are a female patient of childbearing potential, a urine pregnancy test must be performed prior to study entry. The effect of this drug on the unborn baby or nursing infant is not known and therefore it is important for you not do become pregnant or breast feed while on the trial. A reliable method of contraception must be used during the study and it is recommended that female patients taking oral contraceptives use additional barrier contraception (e.g. condoms) or do not have sex during treatment.

CONTACT NUMBERS

Any symptoms, adverse events or injuries occurring during the course of the trial must be reported without delay the study staff, by telephone if necessary:

Prof. Brian L Warren at 021 938 9274 / 082 557 2625
Sr Marinda Perry at 021 938 9534 / 082 371 9291

OPPORTUNITY TO DISCUSS FURTHER QUERIES

Your doctor and his staff are available to answer any further questions arising concerning this clinical trial. They will also be happy to answer any questions affecting your rights as a patient and participant in this trial.

WRITTEN INFORMED CONSENT

Dr/Prof/Mr/Ms_____ _____
(LAST AND FIRST NAME OF PATIENT BLOCK LETTERS PLEASE) RANDOM NUMBER

I agree to participate in this clinical study, which has been explained to me, and any questions I have asked have been answered to my satisfaction. I have been informed about the purpose of the trial, treatment alternatives, potential side effects, as well as the possibility to withdraw my participation in this study at any time, without any disadvantages for me in such a case.

I agree that my medical data obtained from this trial will be documented. To prove the accuracy of the data experts from BAYER and/or registration authorities may inspect the data in presence of the investigator.

I further agree that the anonymous data will be transmitted to BAYER and/or registration authorities to maintain patient safety in clinical trials.

I have received a signed and dated copy of the Patient Information Leaflet and Informed Consent for BAY 12-8039/10209 clinical trial.

Signed at Tygerberg on _____ _____
Date ***Patient's signature***

Signed at Tygerberg on _____ _____
Date ***Investigator's signature***

APPENDIX C: INTENTION TO TREAT POPULATION GROUP A AND GROUP B

APPENDIX C 1.1: Adverse events treatment group A
APPENDIX C 1.2: Adverse events treatment group B

APPENDIX C 2.1: Concomitant antimicrobial medication treatment group A
APPENDIX C 2.2: Concomitant antimicrobial medication treatment group B

APPENDIX C 3.1: Concomitant medication treatment group A
APPENDIX C 3.2: Concomitant medication treatment group B

APPENDIX C 4.1: Demographic data treatment group A
APPENDIX C 4.2: Demographic data treatment group B

APPENDIX C 5.1: Hospitalisation treatment group A
APPENDIX C 5.2: Hospitalisation treatment group B

APPENDIX C 6.1: Professional fees treatment group A
APPENDIX C 6.2: Professional fees treatment group B

APPENDIX C 7.1: Study medication treatment group A
APPENDIX C 7.2: Study medication treatment group B

APPENDIX C 8.1: Therapeutic adjunctions treatment group A
APPENDIX C 8.2: Therapeutic adjunctions treatment group B

Appendix C 1.1

RANDOM NUMBER	ADVERSE EVENTS / TREATMENT GROUP A / ITT		
	ADVERSE EVENT	START DATE	STOP DATE
003	Wound Infection	01-Mar-01	08-Mar-01
005	Laparotomy wound infection	24-Mar-01	29-Mar-01
005	Systemic septic inflammatory response	17-Mar-01	28-Mar-01
014	Incomplete small bowel obstruction	17-May-01	28 Ma y 01
014	Vomiting	05-Jun-01	05-Jun-01
016	Cerebro-vascular accident	24-May-01	03-Jun-01
016	Pneumonia	28-May-01	03-Jun-01
016	Septicaemia	30-May-01	03-Jun-01
018	Haemoptysis	18-May-01	18-May-01
021	Hyperkalaemia	11-Jun-01	15-Jun-01
021	Left subphrenic abscess	06-Jun-01	19-Jun-01
021	Prolonged QT interval	29-May-01	30-May-01
036	Woung Sepsis	18-Aug-01	30-Aug-01
040	Laparotomy	11-Oct-01	24-Oct-01
042	Subphrenic abscess	25-Oct-01	28-Oct-01
042	Viginal candidasis	06-Nov-01	08-Nov-01
047	Partial small bowel obstuction	02-Nov-01	06-Nov-01
049	Headache	04-Nov-01	04-Nov-01
055	Abdomen and thigh Urticaria	22-Nov-01	26-Nov-01
068	Adult respiratory distress syndrome	12-Jan-02	18-Jan-02
073	Large abscess surgically drained	08-Feb-02	08-Feb-02
073	Pelvic abscess	07-Feb-02	14-Feb-02
078	Atrial fibrillation	02-Mar-02	07-Mar-02
078	Candida septicaemia	07-Mar-02	16-Mar-02
078	Multiple organ disfunction syndrome	26-Feb-02	15-Mar-02
078	Respiratory failure	25-Feb-02	07-Mar-02
079	Enterocutaneous Fistula	07-Mar-02	18-Mar-02
079	Multiple organ dysfunction syndrome	14-May-02	Ongoing
095	Small bowel obstruction	06-Jul-02	09-Jul-02

Appendix C 1.2

RANDOM NUMBER	ADVERSE EVENTS / TREATMENT GROUP B / ITT		
	ADVERSE EVENT	START DATE	STOP DATE
001	Abdominal Pain	17-Mar-01	19-Mar-01
006	Delirium Tremens (Mental Confusion)	29-Mar-01	18-Apr-01
006	Laparotomy wound sepsis	08-Apr-01	30-Apr-01
006	Multiple intr-abdominal acscesses	03-Apr-01	03-Apr-01
006	Nosocomial Pneumonia	04-Apr-01	18-Apr-01
008	Pneumocystic carini penumonia	30-Mar-01	17-Apr-01
008	Pneumothorax	15-Apr-01	15-Apr-01
013	Otitis Externa	22-May-01	ongoing
029	Gastril Stasis	13-Aug-01	17-Aug-01
048	Left Pleural Effusion	02-Nov-01	13-Nov-01
052	Ventricular	17-Nov-01	17-Nov-01
056	Partial Dehiscence- Appendeltmy wound	08-Dec-01	04-Jan-02
056	Thrumboplebitis	30-Nov-01	01-Dec-01
070	Perianal abscess	17-Jan-02	17-Jan-02
087	Bronchitis	19-Apr-02	24-Apr-02
087	Diarrheoa	19-Apr-02	21-Apr-02
087	Wound Abscess	22-Apr-02	24-Apr-02
089	Central Venuos Cetheter	17-Apr-02	23-Apr-02
089	Nasogastric Tube	17-Apr-02	22-Apr-02
089	Oxygen Facemask	17-Apr-02	22-Apr-02
089	Urinary Atheter	17-Apr-02	22-Apr-02
099	Superficial laparotomy wound infection	04-Sep-02	11-Sep-02

Appendix C 2.1

RANDOM NUMBER	CONCOMITANT ANTI MICROBIAL MEDICATION / TREATMENT GROUP A / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	START DATE	STOP DATE	COST	CONSUM-ABLES
003	Flagyl	500	mg	IV	22-Feb-01	22-Feb-01	R 33.20	R 0.92
003	Gentamycin	160	mg	IV	22-Feb-01	22-Feb-01	R 255.98	R 0.92
004	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
005	Amikacin	1	g	IV	23-Mar-01	27-Mar-01	R 6,795.00	R 0.92
005	Flagyl	500	mg	IV	15-Mar-01	15-Mar-01	R 33.20	R 0.92
005	Tienam	3	g	IV	23-Mar-01	30-Mar-01	R 6,866.88	R 0.92
005	Zinacef	1.5	mg	IV	15-Mar-01	15-Mar-01	R 82.51	R 0.92
007	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
009	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
010	Flagyl	500	mg	IV	08-Apr-01	08-Apr-01	R 33.20	R 0.92
010	Zinacef	1.5	g	IV	08-Apr-01	08-Apr-01	R 82.51	R 0.92
014	Kefzol	2	g	IV	06-May-01	06-May-01	R 247.84	R 0.92
016	Amikacin	500-1000	mg	IV	31-May-01	02-Jun-01	R 4,077.00	R 0.92
016	Amoxil	750	mg	PO	28-May-01	30-May-01	R 19.93	R 0.00
016	Augmentin	3.6	mg	PO	29-May-01	30-May-01	R 319.68	R 0.00
016	Ciprobay	200-400	mg	IV	31-May-01	02-Jun-01	R 1,762.08	R 0.92
016	Flagyl	400-1200	mg	PO	30-May-01	31-May-01	R 19.86	R 0.00
016	Gentamycin	240	mg	IV	30-May-01	31-May-01	R 767.94	R 0.92
016	Rocephin	1	g	IV	30-May-01	30-May-01	R 185.83	R 0.92
018	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
019	Augmentin	1.2	g	IV	16-May-01	16-May-01	R 53.28	R 0.92
021	Augmentin	1.2	g	IV	29-May-01	29-May-01	R 53.28	R 0.92
021	Augmentin	1.2-3.6	g	IV	30-May-01	10-Jun-01	R 639.36	R 0.92
021	Flagyl	500	mg	IV	29-May-01	29-May-01	R 33.20	R 0.92
021	Flagyl	500-1500	mg	IV	30-May-01	04-Jun-01	R 597.60	R 0.92
021	Flagyl	2	g	PR	05-Jun-01	09-Jun-01	R 250.60	R 0.00
021	Gentamycin	340	mg	IV	04-Jun-01	09-Jun-01	R 3,071.76	R 0.92
021	Tazocin	4.5-13.5	g	IV	10-Jun-01	19-Jun-01	R 9,205.50	R 0.92
022	Flagyl	500	mg	IV	30-May-01	30-May-01	R 33.20	R 0.92
022	Zinacef	1.5	g	IV	30-May-01	30-May-01	R 82.51	R 0.92
025	Flagyl	500	mg	IV	20-Jun-01	20-Jun-01	R 33.20	R 0.92
025	Zinacef	1.5	mg	IV	20-Jun-01	20-Jun-01	R 82.51	R 0.92
028	Augmentin	2.4	g	IV	03-Aug-01	03-Aug-01	R 106.56	R 0.92
028	Flagyl	1000	mg	IV	03-Aug-01	03-Aug-01	R 66.40	R 0.92
030	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
031	Kefzol	1	g	IV	23-Aug-01	23-Aug-01	R 123.92	R 0.92
036	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
038	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
040	Flagyl	500	mg	IV	06-Oct-01	06-Oct-01	R 33.20	R 0.92
040	Kefzol	1	g	IV	06-Oct-01	06-Oct-01	R 123.92	R 0.92
040	Zinacef	750	mg	IV	06-Oct-01	06-Oct-01	R 41.26	R 0.92
042	Augmentin	1.2	g	IV	18-Oct-01	18-Oct-01	R 53.28	R 0.92
042	Ciprobay	250-500	mg	PO	10-Nov-01	15-Nov-01	R 164.22	R 0.00
042	Flagyl	400-1200	mg	PO	03-Nov-01	15-Nov-01	R 129.09	R 0.00
042	Flagyl	500	mg	IV	18-Oct-01	18-Oct-01	R 33.20	R 0.92
042	Flagyl	400-1200	mg	PO	28-Oct-01	01-Nov-01	R 49.65	R 0.00
042	Gentamycin	240	mg	IV	19-Oct-01	19-Oct-01	R 383.97	R 0.92
042	Gentamycin	240	mg	IV	06-Nov-01	07-Nov-01	R 767.94	R 0.92
042	Gentamycin	240	mg	IV	09-Nov-01	09-Nov-01	R 383.97	R 0.92
042	Gentamycin	240	mg	IV	28-Oct-01	04-Nov-01	R 3,071.76	R 0.92
042	Penicillin G	12-16	12-16	PO	06-Nov-01	07-Nov-01	R 66.40	R 0.00
042	Penicillin G	1	mu	IV	19-Oct-01	19-Oct-01	R 29.94	R 0.92
042	Penicillin G	4-12	mu	IV	09-Nov-01	10-Nov-01	R 66.40	R 0.92
042	Penicillin G	4-16	mu	IV	29-Oct-01	04-Nov-01	R 21,502.32	R 0.92
044	Flagyl	500	mg	IV	20-Nov-01	20-Nov-01	R 33.20	R 0.92
044	Zinacef	750	mg	IV	20-Nov-01	21-Nov-01	R 94.90	R 0.92
045	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
047	Flagyl	500	mg	IV	28-Oct-01	28-Oct-01	R 33.20	R 0.92
047	Zinacef	1.5	g	IV	28-Oct-01	28-Oct-01	R 82.51	R 0.92
049	Augmentin	1.2	g	IV	04-Nov-01	04-Nov-01	R 53.28	R 0.92
051	Augmentin	1.2	g	IV	11-Nov-01	11-Nov-01	R 53.28	R 0.92
051	Mandokef	1	g	IV	11-Nov-01	11-Nov-01	R 119.31	R 0.92
054	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
055	Augmentin	1.2	g	IV	20-Nov-01	20-Nov-01	R 53.28	R 0.92
059	Flagyl	1000	mg	IV	09-Dec-01	09-Dec-01	R 66.40	R 0.92
059	Kefzol	1	g	IV	09-Dec-01	09-Dec-01	R 123.92	R 0.92
059	Zinacef	1.5	g	IV	09-Dec-01	09-Dec-01	R 82.51	R 0.92
060	Augmentin	1.2	g	IV	11-Dec-01	12-Dec-01	R 106.56	R 0.92
060	Kefzol	1	g	IV	12-Dec-01	12-Dec-01	R 123.92	R 0.92
061	Flagyl	1000	mg	IV	15-Dec-01	15-Dec-01	R 66.40	R 0.92
061	Kefzol	1	g	IV	15-Dec-01	15-Dec-01	R 123.92	R 0.92
061	Zinacef	1.5	g	IV	15-Dec-01	15-Dec-01	R 82.51	R 0.92
062	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
066	Flagyl	500	mg	IV	05-Jan-02	05-Jan-02	R 33.20	R 0.92
068	Amoxil	750	mg	PO	07-Jan-02	10-Jan-02	R 26.52	R 0.00
071	Flagyl	1000	mg	IV	22-Jan-02	22-Jan-02	R 66.40	R 0.92
071	Gentamycin	240	mg	IV	22-Jan-02	22-Jan-02	R 383.97	R 0.92
071	Penicillin G	2	mu	IV	22-Jan-02	22-Jan-02	R 29.94	R 0.92
072	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
073	Augmentin	1.2-3.6	mg	IV	09-Feb-02	14-Feb-02	R 319.68	R 0.92
073	Flagyl	500	mg	IV	24-Jan-02	24-Jan-02	R 33.20	R 0.92
073	Flagyl	500-1500	mg	IV	09-Feb-02	14-Feb-02	R 597.60	R 0.92

Appendix C 2.1

RANDOM NUMBER	CONCOMITANT ANTI MICROBIAL MEDICATION / TREATMENT GROUP A / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	START DATE	STOP DATE	COST	CONSUM-ABLES
073	Gentamycin	340	mg	IV	09-Feb-02	13-Feb-02	R 2,559.85	R 0.92
073	Zinacef	750	mg	IV	24-Jan-02	24-Jan-02	R 41.26	R 0.92
074	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
075	Augmentin	2.4	g	IV	18-Feb-02	18-Feb-02	R 106.56	R 0.92
075	Flagyl	1000	mg	IV	18-Feb-02	18-Feb-02	R 66.40	R 0.92
078	Kefzol	1	g	IV	23-Feb-02	23-Feb-02	R 123.92	R 0.92
078	Meropenem	1-3	g	IV	27-Feb-02	07-Mar-02	R 19,179.72	R 0.92
079	Cefuroxime	4.5	g	IV	24-Feb-02	24-Feb-02	R 247.53	R 0.92
079	Flagyl	4	g	IV	23-Feb-02	23-Feb-02	R 132.80	R 0.92
079	Flagyl	500	mg	IV	24-Feb-02	24-Feb-02	R 33.20	R 0.92
079	Zinacef	1.5	mg	IV	23-Feb-02	23-Feb-02	R 82.51	R 0.92
081	Augmentin	1.2	g	IV	26-Feb-02	27-Feb-02	R 106.56	R 0.92
081	Augmentin	1.2	g	IV	13-Mar-02	13-Mar-02	R 53.28	R 0.92
081	Augmentin	1.2-3.6	g	IV	22-Mar-02	28-Mar-02	R 1,118.88	R 0.92
081	Flagyl	500	mg	IV	26-Feb-02	27-Feb-02	R 66.40	R 0.92
085	Flagyl	500	mg	IV	16-Mar-02	16-Mar-02	R 33.20	R 0.92
085	Zinacef	1.5	g	IV	16-Mar-02	16-Mar-02	R 82.51	R 0.92
088	Augmentin	1.2	g	IV	03-Apr-02	03-Apr-02	R 53.28	R 0.92
090	Flagyl	500-1000	mg	IV	20-Apr-02	21-Apr-02	R 132.80	R 0.92
090	Zinacef	1.5-3	mg	IV	20-Apr-02	21-Apr-02	R 330.04	R 0.92
091	Amfoteracin B	50	mg	IV	17-May-02	17-May-02	R 215.46	R 0.92
091	Amikacin	1	g	IV	14-May-02	14-May-02	R 1,359.00	R 0.92
091	Amikacin	1	g	IV	17-May-02	17-May-02	R 1,359.00	R 0.92
091	Augmentin	1.2-3.6	g	IV	29-Apr-02	30-Apr-02	R 310.68	R 0.92
091	Flagyl	500-1500	mg	IV	29-Apr-02	30-Apr-02	R 199.20	R 0.92
091	Fluconazole	200	mg	IV	15-May-02	17-May-02	R 495.42	R 0.92
091	Gentamycin	240	mg	IV	09-May-02	13-May-02	R 1,919.85	R 0.92
091	Tazocin	4.5-18	g	IV	09-May-02	15-May-02	R 8,591.80	R 0.92
091	Tienam	1.5-2	g	IV	15-May-02	17-May-02	R 1,716.72	R 0.92
093	Augmentin	3.6	g	IV	12-May-02	12-May-02	R 159.84	R 0.92
093	Flagyl	1500	mg	IV	12-May-02	12-May-02	R 99.60	R 0.92
095	Augmentin	1.2	g	IV	20-Jun-02	20-Jun-02	R 53.28	R 0.92
097	Augmentin	1.2	mg	IV	25-Jul-02	25-Jul-02	R 53.28	R 0.92
097	Flagyl	500	mg	IV	25-Jul-02	25-Jul-02	R 33.20	R 0.92
100	Augmentin	2.4	g	IV	02-May-02	02-May-02	R 106.56	R 0.92
100	Flagyl	1000	mg	IV	02-May-02	02-May-02	R 66.40	R 0.92
TOTAL							R 106,995.64	R 89.24

Appendix C 2.2

RANDOM NUMBER	CONCOMITANT ANITMICROBIAL MEDICATION / TREATMENT GROUP B / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	START DATE	STOP DATE	COST	CONSUM-ABLES
001	Amikacin	500	mg	IV	14-Feb-01	14-Feb-01	R 679.50	R 0.92
001	Claforan	1	g	IV	14-Feb-01	14-Feb-01	R 143.15	R 0.92
002	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
006	Amikacin	1	g	IV	05-Apr-01	08-Apr-01	R 5,436.00	R 0.92
006	Augmentin	2.4-3.6	g	IV	03-Apr-01	05-Apr-01	R 479.52	R 0.92
006	Augmentin	1.2-2.4	g	IV	15-Apr-01	17-Apr-01	R 319.68	R 0.92
006	Augmentin	3.6	mg	IV	18-Apr-01	22-Apr-01	R 799.20	R 0.92
006	Flagyl	500-1500	mg	IV	03-Apr-01	09-Apr-01	R 697.20	R 0.92
006	Flagyl	500	mg	IV	26-Mar-01	26-Mar-01	R 33.20	R 0.92
006	Tienam	1-2	g	IV	05-Apr-01	09-Apr-01	R 2,861.20	R 0.92
006	Zinacef	750	mg	IV	26-Mar-01	26-Mar-01	R 41.15	R 0.92
008	Ampicillin	2-4	g	IV	09-Apr-01	12-Apr-01	R 378.40	R 0.92
008	Bactrim	3840	mg	IV	04-Apr-01	17-Apr-01	R 7,945.28	R 0.92
008	Gentamycin	240	mg	IV	03-Apr-01	16-Apr-01	R 5,375.58	R 0.92
008	Tazocin	4.5-13.5	g	IV	13-Apr-01	16-Apr-01	R 3,682.20	R 0.92
008	Tienam	1-3	g	IV	03-Apr-01	07-Apr-01	R 4,291.80	R 0.92
008	Tienam	2	g	IV	16-Apr-01	16-Apr-01	R 572.24	R 0.92
008	Zinacef	3	mg	IV	12-Apr-01	13-Apr-01	R 330.04	R 0.92
011	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
012	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
013	Flagyl	500	mg	IV	30-Apr-01	30-Apr-01	R 33.20	R 0.92
013	Zinacef	1.5	mg	IV	30-Apr-01	30-Apr-01	R 82.51	R 0.92
015	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
017	Augmentin	1.2	g	IV	15-May-01	15-May-01	R 53.28	R 0.92
020	Augmentin	1.2	g	IV	22-May-01	22-May-01	R 53.28	R 0.92
023	Flagyl	1	g	PR	10-Jun-01	10-Jun-01	R 66.40	R 0.00
023	Gentamycin	240	mg	IV	10-Jun-01	10-Jun-01	R 383.97	R 0.92
023	Pennicillin G	4	mu	IV	10-Jun-01	10-Jun-01	R 29.46	R 0.92
024	Augmentin	1.2	g	IV	19-Jun-01	19-Jun-01	R 53.28	R 0.92
024	Flagyl	500	mg	IV	19-Jun-01	19-Jun-01	R 33.20	R 0.92
026	Ampicillin	1	g	IV	30-Jul-01	30-Jul-01	R 23.65	R 0.92
027	Flagyl	1000	mg	IV	02-Aug-01	01-Aug-01	R 132.80	R 0.92
027	Zinacef	1.5	g	IV	02-Aug-01	02-Aug-01	R 82.51	R 0.92
029	Augmentin	1.2	g	IV	09-Aug-01	09-Aug-01	R 53.28	R 0.92
029	Flagyl	500	mg	IV	09-Aug-01	09-Aug-01	R 33.20	R 0.92
032	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
033	Augmentin	1.2	g	IV	10-Sep-01	10-Sep-01	R 53.28	R 0.92
033	Flagyl	1500	mg	IV	10-Sep-01	10-Sep-01	R 99.60	R 0.92
033	Kefzol	1	g	PO	10-Sep-01	10-Sep-01	R 123.92	R 0.00
033	Zinacef	1.5	g	IV	10-Sep-01	10-Sep-01	R 82.51	R 0.92
034	Flagyl	500	mg	IV	12-Sep-01	12-Sep-01	R 33.20	R 0.92
034	Zinacef	1.5	g	IV	12-Sep-01	12-Sep-01	R 82.51	R 0.92
035	Flagyl	500	mg	IV	12-Sep-01	12-Sep-01	R 33.20	R 0.92
035	Zinacef	750	mg	IV	12-Sep-01	12-Sep-01	R 41.26	R 0.92
037	Augmentin	1.2	g	IV	27-Oct-01	27-Oct-01	R 53.28	R 0.92
037	Flagyl	500	mg	IV	27-Oct-01	27-Oct-01	R 33.20	R 0.92
037	Zinacef	750	mg	IV	27-Oct-01	27-Oct-01	R 41.26	R 0.92
039	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
041	Flagyl	1000	mg	IV	10-Oct-01	10-Oct-01	R 66.40	R 0.92
041	Zinacef	1.5	g	IV	10-Oct-01	10-Oct-01	R 82.51	R 0.92
043	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
046	Augmentin	1.2	g	IV	23-Oct-01	23-Oct-01	R 53.28	R 0.92
046	Cefepime	2-4	g	IV	29-Oct-01	04-Nov-01	R 1,575.00	R 0.92
046	Gentamycin	240	mg	IV	29-Oct-01	03-Nov-01	R 2,303.82	R 0.92
046	Mandokef	1	g	IV	22-Oct-01	22-Oct-01	R 119.31	R 0.92
048	Tazocin	13.5	g	IV	05-Nov-01	14-Nov-01	R 9,205.50	R 0.92
050	Augmentin	1.2	g	IV	07-Nov-01	07-Nov-01	R 53.28	R 0.92
052	Flagyl	500	mg	IV	17-Nov-01	17-Nov-01	R 33.20	R 0.92
052	Mandokef	1	g	IV	17-Nov-01	17-Nov-01	R 119.31	R 0.92
053	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
056	Augmentin	1.2	g	IV	27-Nov-01	27-Nov-01	R 53.28	R 0.92
056	Augmentin	1.2	g	IV	27-Nov-01	27-Nov-01	R 53.28	R 0.92
056	Flagyl	500	mg	IV	27-Nov-01	27-Nov-01	R 33.20	R 0.92
056	Flagyl	500	mg	IV	27-Nov-01	27-Nov-01	R 33.20	R 0.92
057	Flagyl	500	mg	IV	03-Dec-01	03-Dec-01	R 33.20	R 0.92
057	Flagyl	500	mg	IV	03-Dec-01	03-Dec-01	R 33.20	R 0.92
057	Kefzol	1	g	IV	03-Dec-01	03-Dec-01	R 123.92	R 0.92
057	Kefzol	1	g	IV	03-Dec-01	03-Dec-01	R 123.92	R 0.92
058	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
058	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
063	Flagyl	500	mg	IV	16-Dec-01	16-Dec-01	R 33.20	R 0.92
063	Kefzol	1	g	IV	17-Dec-01	17-Dec-01	R 123.92	R 0.92
063	Zinacef	1.5	g	IV	16-Dec-01	16-Dec-01	R 82.51	R 0.92
064	Kefzol	1	g	IV	17-Dec-01	17-Dec-01	R 123.92	R 0.92
065	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
067	Flagyl	500	mg	IV	05-Jan-02	05-Jan-02	R 33.20	R 0.92
067	Kefzol	1	g	IV	05-Jan-02	05-Jan-02	R 123.92	R 0.92

Appendix C 2.2

RANDOM NUMBER	CONCOMITANT ANITMICROBIAL MEDICATION / TREATMENT GROUP B / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	START DATE	STOP DATE	COST	CONSUM-ABLES
069	Flagyl	500	mg	IV	12-Jan-02	12-Jan-02	R 33.20	R 0.92
069	Zinacef	1.5	g	IV	12-Jan-02	12-Jan-02	R 82.51	R 0.92
070	Augmentin	1.2	g	IV	14-Jan-02	14-Jan-02	R 53.28	R 0.92
076	Ampicillin	1	g	IV	19-Feb-02	19-Feb-02	R 23.65	R 0.92
076	Flagyl	1000	mg	IV	19-Feb-02	19-Feb-02	R 66.40	R 0.92
076	Gentamycin	240	mg	IV	19-Feb-02	19-Feb-02	R 383.97	R 0.92
076	Kefzol	1	g	IV	19-Feb-02	19-Feb-02	R 123.92	R 0.92
077	Flagyl	50	mg	IV	20-Feb-02	20-Feb-02	R 33.20	R 0.92
077	Kefzol	1	g	IV	20-Feb-02	20-Feb-02	R 123.92	R 0.92
080	Augmentin	1.2	g	IV	24-Feb-02	24-Feb-02	R 53.28	R 0.92
080	Flagyl	500	mg	IV	24-Feb-02	24-Feb-02	R 33.20	R 0.92
080	Kefzol	1	g	IV	24-Feb-02	24-Feb-02	R 1,323.23	R 0.92
082	Augmentin	1.2	g	IV	07-Mar-02	07-Mar-02	R 53.28	R 0.92
083	Augmentin	3.6	mg	PO	25-Mar-02	29-Mar-02	R 799.20	R 0.00
083	Flagyl	500	mg	IV	10-Mar-02	10-Mar-02	R 33.20	R 0.92
083	Kefzol	1	g	IV	10-Mar-02	10-Mar-02	R 1,323.23	R 0.92
086	Flagyl	500-1000	mg	IV	17-Mar-02	18-Mar-02	R 132.80	R 0.92
086	Zinacef	1.5-3.0	g	IV	17-Mar-02	18-Mar-02	R 330.04	R 0.92
087	Augmentin	1.2-4.8	g	IV	22-Apr-02	24-Apr-02	R 639.36	R 0.92
087	Augmentin	1.2	g	IV	29-Mar-02	30-Mar-02	R 106.56	R 0.92
089	Augmentin	1.2	g	IV	17-Apr-02	17-Apr-02	R 53.28	R 0.92
089	Betadine	1	applic	TOP	18-Apr-02	18-Apr-02	R 45.37	R 0.00
092	Augmentin	1.2	g	IV	08-May-02	08-May-02	R 53.28	R 0.92
092	Flagyl	500	mg	IV	08-May-02	08-May-02	R 33.20	R 0.92
094	Augmentin	1.2	g	IV	08-Jun-02	09-Jun-02	R 106.56	R 0.92
094	Flagyl	500	mg	IV	08-Jun-02	09-Jun-02	R 66.40	R 0.92
096	Augmentin	1.2	g	IV	09-Jul-02	09-Jul-02	R 53.28	R 0.92
096	Flagyl	500	mg	IV	09-Jul-02	09-Jul-02	R 33.20	R 0.92
098	Flagyl	500	mg	IV	11-Aug-02	11-Aug-02	R 33.20	R 0.92
098	Kefzol	1	g	IV	11-Aug-02	11-Aug-02	R 123.92	R 0.92
099	Amoxicillin	1500	mg	PO	04-Sep-02	09-Sep-02	R 89.46	R 0.00
099	Flagyl	500	mg	IV	11-Aug-02	11-Aug-02	R 33.20	R 0.92
099	Zinacef	1.5	g	IV	11-Aug-02	11-Aug-02	R 82.51	R 0.92
TOTAL							R 57,034.35	R 86.48

Appendix C 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
003	Dolorol Forte	1016 - 2032	mg	PO	R 0.00	27-Feb-01	01-Mar-01	**R 11.28**
003	Dolorol Forte	1016	mg	PO	R 0.00	08-Mar-01	12-Mar-01	**R 9.40**
003	Maxalon	10	mg	IM	R 21.36	23-Feb-01	24-Feb-01	**R 6.88**
003	Pethedine	150 - 300	mg	IM	R 53.40	23-Feb-01	27-Feb-01	**R 119.92**
004	Dolorol Forte	2032	mg	PO	R 0.00	26-Feb-01	26-Feb-01	**R 3.76**
004	Doxyfene	2	tabs	PO	R 0.00	28-Feb-01	28-Feb-01	**R 7.19**
004	Morphine	20-30	mg	IM	R 53.40	23-Feb-01	27-Feb-01	**R 106.31**
005	Adrenaline	10-15	mg	IV	R 0.92	20-Mar-01	25-Mar-01	**R 410.19**
005	Aminophylin	250-1500	mg	IV	R 0.92	23-Mar-01	28-Mar-01	**R 875.71**
005	Dolorol Forte	2032	mg	PO	R 0.00	30-Mar-01	30-Mar-01	**R 3.76**
005	Dormicum	200-250	mg	IV	R 19.39	17-Mar-01	26-Mar-01	**R 8,212.56**
005	Heparin	15000	iu	SC	R 138.84	16-Mar-01	28-Mar-01	**R 272.61**
005	Lasix	10-15	mg	IV	R 0.92	20-Mar-01	27-Mar-01	**R 89.44**
005	Morphine	10-20	mg	IM	R 138.84	15-Mar-01	27-Mar-01	**R 113.40**
005	Panado	30-120	ml	PO	R 0.00	19-Mar-01	26-Mar-01	**R 17.64**
005	Serepax	10	mg	PO	R 0.00	20-Mar-01	20-Mar-01	**R 0.71**
005	Ulsanic	4	g	PO	R 0.00	15-Mar-01	28-Mar-01	**R 159.51**
005	Valium	10	mg	PO	R 0.00	30-Mar-01	31-Mar-01	**R 23.45**
007	Morphine	10-30	mg	IM	R 53.40	26-Mar-01	30-Mar-01	**R 106.31**
009	Morphine	20-40	mg	IM	R 42.72	07-Apr-01	10-Apr-01	**R 113.40**
010	Atrovent	0.5-1.5	mg	INH	R 0.00	11-Apr-01	13-Apr-01	**R 95.75**
010	Berotec	1.25-3.75	mg	INH	R 0.00	11-Apr-01	13-Apr-01	**R 50.35**
010	Morphine	10-20	mg	IM	R 42.72	09-Apr-01	12-Apr-01	**R 56.70**
014	Dolorol Forte	1016-2032	mg	PO	R 0.00	09-May-01	12-May-01	**R 15.04**
014	Morphine	10-20	mg	IM	R 42.72	07-May-01	10-May-01	**R 56.70**
014	Pethedine	0-50	mg	IM	R 64.08	21-May-01	26-May-01	**R 44.30**
016	Atenolol	25	mg	PO	R 0.00	17-May-01	23-May-01	**R 44.33**
016	Atrovent	3		INH	R 0.00	29-May-01	01-Jun-01	**R 255.36**
016	Berotec	3.75	mg	INH	R 0.00	29-May-01	01-Jun-01	**R 67.08**
016	Dolorol Forte	3048	mg	PO	R 0.00	21-May-01	23-May-01	**R 16.92**
016	Doxyfene	2-6	tabs	PO	R 0.00	29-May-01	31-May-01	**R 64.62**
016	Glucophage forte	1700	mg	PO	R 0.00	22-May-01	23-May-01	**R 4.78**
016	Glycomen	10	mg	PO	R 0.00	22-May-01	23-May-01	**R 5.36**

Appendix C 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
016	Heparin	5000-15000	iu	SC	R 85.44	14-May-01	21-May-01	**R 167.76**
016	Indocid	100-200	mg	PR	R 0.00	18-May-01	20-May-01	**R 73.80**
016	Insulin	0-15	iu	SC	R 96.12	13-May-01	21-May-01	**R 1,167.05**
016	Lasix	60	mg	PO	R 0.00	29-May-01	02-Jun-01	**R 39.22**
016	Lasix	40	mg	PO	R 0.00	16-May-01	23-May-01	**R 30.49**
016	Maxalon	10	mg	IV	R 19.39	13-May-01	13-May-01	**R 6.88**
016	Pethedine	50-100	mg	IM	R 64.08	12-May-01	17-May-01	**R 44.30**
016	Renitec	20	mg	IV	R 0.92	20-May-01	23-May-01	**R 30.53**
016	Tryptanol	25	mg	PO	R 0.00	29-May-01	29-May-01	**R 0.49**
016	Voltaren supository	50	mg	PR	R 0.00	15-May-01	15-May-01	**R 16.17**
018	Morphine	10-30	mg	IM	R 74.76	15-May-01	21-May-01	**R 148.83**
018	Neostigmine	2.5	mg	IV	R 0.92	15-May-01	15-May-01	**R 6.54**
018	Nimbex	8	mg	IV	R 19.39	15-May-01	15-May-01	**R 198.78**
018	Pethedine	50	mg	IM	R 32.04	15-May-01	17-May-01	**R 22.14**
018	Robinul	0.6	mg	IV	R 0.92	15-May-01	15-May-01	**R 220.59**
018	Tetanus toxoid	0.5	ml	IM	R 3.56	13-May-01	13-May-01	**R 35.68**
019	Dolorol Forte	1016-2032	mg	PO	R 0.00	19-May-01	22-May-01	**R 15.04**
019	Morphine	20-30	mg	IV	R 19.39	17-May-01	18-May-01	**R 42.52**
021	Brufen	400-1200	mg	PO	R 0.00	30-May-01	09-Jun-01	**R 34.31**
021	Dolorol Forte	1016	mg	PO	R 0.00	11-Jun-01	14-Jun-01	**R 7.52**
021	Doxyfene	1	tabs	PO	R 0.00	15-Jun-01	15-Jun-01	**R 3.59**
021	Heparin	2000	iu	SC	R 117.48	30-May-01	09-Jun-01	**R 30.80**
021	Kexelate	60	g	PO	R 0.00	12-Jun-01	15-Jun-01	**R 521.55**
021	Lasix	20	mg	IV	R 19.39	04-Jun-01	04-Jun-01	**R 2.61**
021	Morphine	10	mg	IM	R 3.56	29-May-01	29-May-01	**R 7.09**
021	Pethedine	75	mg	IM	R 3.56	04-Jun-01	04-Jun-01	**R 14.03**
021	Pethedine	50	mg	IM	R 3.56	14-Jun-01	14-Jun-01	**R 7.38**
021	Phenargan	25	mg	IM	R 3.56	14-Jun-01	14-Jun-01	**R 0.84**
021	Voltaren	75	mg	IM	R 32.04	15-Jun-01	17-Jun-01	**R 23.56**
021	Voltaren	75	mg	IM	R 3.56	04-Jun-01	04-Jun-01	**R 7.85**
022	Atrovent	0.25-1.25	mg	INH	R 0.00	30-May-01	03-Jun-01	**R 132.98**
022	Morphine	10-40	mg	IM	R 53.40	30-May-01	03-Jun-01	**R 141.75**
022	Pethedine	50	mg	IM	R 3.56	03-Jun-01	03-Jun-01	**R 7.38**

Appendix C 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
022	Pethedine	75	mg	IM	R 3.56	30-May-01	30-May-01	**R 14.03**
022	Tetanus toxoid	0.5	ml	IM	R 3.56	30-May-01	30-May-01	**R 35.68**
022	Valium	10	mg	PO	R 0.00	03-Jun-01	03-Jun-01	**R 11.72**
022	Valium	20	mg	IM	R 3.56	03-Jun-01	03-Jun-01	**R 23.45**
022	Ventolin	5-25	mg	INH	R 0.00	30-May-01	03-Jun-01	**R 76.61**
025	Maxalon	10	mg	IM	R 3.56	21-Jun-01	21-Jun-01	**R 6.99**
025	Maxalon	10	mg	IM	R 3.56	23-Jun-01	23-Jun-01	**R 6.88**
025	Morphine	20-40	mg	IV	R 19.39	20-Jun-01	25-Jun-01	**R 170.10**
028	Brufen	1200	mg	PO	R 0.00	07-Aug-01	16-Aug-01	**R 31.19**
028	Dolorol Forte	2032	mg	PO	R 0.00	07-Aug-01	12-Aug-01	**R 22.56**
028	Morphine	10	mg	IM	R 32.04	03-Aug-01	05-Aug-01	**R 21.27**
028	Stemetil	12.5	mg	IM	R 3.56	05-Aug-01	05-Aug-01	**R 9.19**
030	Heparin	10000	iu	SC	R 64.08	15-Aug-01	20-Aug-01	**R 83.88**
030	Losec	20	mg	PO	R 0.00	21-Aug-01	continuing	**R 393.77**
030	Morphine	10-20	mg	IM	R 3.56	15-Aug-01	15-Aug-01	**R 14.18**
030	Pethedine	75	mg	IM	R 3.56	15-Aug-01	15-Aug-01	**R 14.03**
030	Stemetil	12.5	mg	IM	R 3.56	17-Aug-01	17-Aug-01	**R 9.19**
030	Tagamet	400-800	mg	IV	R 19.39	15-Aug-01	20-Aug-01	**R 88.92**
031	Lamictin	400	g	PO	R 0.00	23-Aug-01	30-Aug-01	**R 103.84**
031	Morphine	10-30	mg	IM	R 53.40	23-Aug-01	27-Aug-01	**R 106.35**
031	Stemetil	12.5	mg	IM	R 3.56	24-Aug-01	24-Aug-01	**R 9.19**
036	Amytryptiline	25	mg	PO	R 0.00	13-Sep-01	26-Sep-01	**R 15.49**
036	Isordil	0.5	mg	SL	R 0.00	17-Sep-01	26-Sep-01	**R 7.18**
036	Lasix	5-10	mg	IV	R 19.39	15-Sep-01	18-Sep-01	**R 22.36**
036	Losec	200	mg	PO	R 0.00	17-Sep-01	18-Oct-01	**R 449.92**
036	Morphine	10-50	mg	IM	R 85.44	14-Sep-01	21-Sep-01	**R 283.60**
036	Stemetil	25	mg	IM	R 3.56	14-Sep-01	14-Sep-01	**R 212.70**
036	Stemetil	12.5	mg	IM	R 21.36	22-Sep-01	23-Sep-01	**R 18.38**
038	Morphine	10-30	mg	IM	R 21.36	28-Oct-01	29-Oct-01	**R 42.54**
040	Atrovent	0.25-1	mg	INH	R 0.00	10-Oct-01	15-Oct-01	**R 127.66**
040	Berotec	1.25-6.25	mg	INH	R 0.00	10-Oct-01	15-Oct-01	**R 167.82**
040	Morphine	20-40	mg	IM	R 53.40	06-Oct-01	10-Oct-01	**R 141.80**
040	Pneumovax	0.5	ml	IM	R 3.56	06-Oct-01	06-Oct-01	**R 106.00**

Appendix C 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
042	Atrovent	0.5-1.5	mg	INH	R 0.00	19-Oct-01	10-Nov-01	**R 734.16**
042	Berotec	1.25-3.75	mg	INH	R 0.00	19-Oct-01	10-Nov-01	**R 385.71**
042	Canestan Cream	UNK	UNK	PV	R 0.00	06-Nov-01	08-Nov-01	**R 167.22**
042	Dolorol Forte	1016	mg	PO	R 0.00	29-Oct-01	29-Oct-01	**R 1.88**
042	Dolorol Forte	1016	mg	PO	R 0.00	31-Oct-01	31-Oct-01	**R 1.88**
042	Dolorol Forte	1016-4064	mg	PO	R 0.00	03-Nov-01	15-Nov-01	**R 97.76**
042	Heparin	5000-20000	iu	SC	R 74.76	31-Oct-01	06-Nov-01	**R 195.72**
042	Isordil	5	mg	SL	R 0.00	30-Oct-01	30-Oct-01	**R 0.72**
042	Lasix	20-40	mg	PO	R 0.00	23-Oct-01	16-Nov-01	**R 95.29**
042	Maxalon	10	mg	IM	R 3.56	27-Oct-01	27-Oct-01	**R 6.88**
042	Maxalon	10-20	mg	IM	R 42.72	31-Oct-01	03-Nov-01	**R 55.01**
042	Maxalon	10	mg	IM	R 21.36	05-Nov-01	06-Nov-01	**R 6.88**
042	Maxalon	20-30	mg	PO	R 0.00	09-Nov-01	10-Nov-01	**R 9.54**
042	Maxalon	20	mg	PO	R 0.00	12-Nov-01	13-Nov-01	**R 6.36**
042	Maxalon	10	mg	PO	R 0.00	15-Nov-01	15-Nov-01	**R 1.59**
042	Morphine	10-40	mg	IM	R 117.48	01-Nov-01	11-Nov-01	**R 311.96**
042	Morphine	10-20	mg	IM	R 74.76	19-Oct-01	25-Oct-01	**R 99.26**
042	Morphine	20	mg	SC	R 32.04	28-Oct-01	30-Oct-01	**R 42.54**
042	Pethedine	50-100	mg	IM	R 42.72	27-Oct-01	30-Oct-01	**R 31.98**
042	Senokot	4	tabs	PO	R 0.00	13-Nov-01	13-Nov-01	**R 1.76**
044	Morphine	15-60	mg	IM	R 53.40	21-Nov-01	25-Nov-01	**R 212.70**
045	Dolorol Forte	3048	mg	PO	R 0.00	24-Oct-01	25 Oct 01	**R 11.28**
045	Morphine	20-30	mg	IV	R 19.39	21-Oct-01	23-Oct-01	**R 63.81**
047	Doxyfene	4	tabs	PO	R 0.00	31-Oct-01	03-Nov-01	**R 57.49**
047	Morphine	20-50	mg	IV	R 19.39	28-Oct-01	30-Oct-01	**R 106.35**
049	Amiloretic	55	mg	PO	R 0.00	04-Nov-01	08-Nov-01	**R 33.50**
049	Dolorol Forte	2032	mg	PO	R 0.00	07-Nov-01	07-Nov-01	**R 3.76**
049	Premarin	0.625	mg	PO	R 0.00	04-Nov-01	08-Nov-01	**R 71.81**
051	Atrovent	0.75-2.25	mg	INH	R 0.00	12-Nov-01	19-Nov-01	**R 382.99**
051	Berotec	2.5-7.5	mg	INH	R 0.00	12-Nov-01	19-Nov-01	**R 179.01**
051	Dolorol forte	1016-3048	mg	PO	R 0.00	17-Nov-01	20-Nov-01	**R 22.56**
051	Losec	20	mg	PO	R 0.00	16-Nov-01	continuing	**R 393.77**
051	Morphine	10-20	mg	IM	R 42.72	12-Nov-01	15-Nov-01	**R 56.72**

Appendix C 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
054	Dolorol Forte	1016-2032	mg	PO	R 0.00	22-Nov-01	24-Nov-01	**R 11.28**
054	Morphine	10	mg	IM	R 32.04	19-Nov-01	21-Nov-01	**R 21.27**
055	Dolorol Forte	1016	mg	PO	R 0.00	24-Nov-01	26-Nov-01	**R 5.64**
055	Losec	20	mg	PO	R 0.00	22-Nov-01	continuing	**R 393.77**
055	Morphine	10-40	mg	IM	R 32.04	10-Dec-01	12-Dec-01	**R 85.08**
055	Pethedine	150-200	mg	IM	R 32.04	20-Nov-01	22-Nov-01	**R 47.97**
055	Phenargan	10-30	mg	PO	R 0.00	22-Nov-01	26-Nov-01	**R 7.10**
055	Stemetil	12.5	mg	IM	R 3.56	14-Dec-01	14-Dec-01	**R 9.19**
055	Tagamet	400-1200	mg	PO	R 0.00	20-Nov-01	22-Nov-01	**R 66.66**
055	Valium	10-20	mg	PO	R 0.00	11-Dec-01	13-Dec-01	**R 70.35**
059	Dolorol Forte	1016	mg	PO	R 0.00	14-Dec-01	14-Dec-01	**R 1.88**
059	Morphine	10-40	mg	IM	R 32.04	10-Dec-01	12-Dec-01	**R 85.08**
059	Stemetil	12.5	mg	IM	R 3.56	14-Dec-01	14-Dec-01	**R 9.19**
059	Valium	10-20	mg	PO	R 0.00	11-Dec-01	13-Dec-01	**R 70.35**
060	Atrovent	0.25-1	mg	INH	R 0.00	11-Dec-01	16-Dec-01	**R 127.66**
060	Berotec	1.25-5	mg	INH	R 0.00	11-Dec-01	16-Dec-01	**R 134.26**
060	Pethedine	100-300	mg	IM	R 74.76	10-Dec-01	16-Dec-01	**R 167.89**
061	Atrovent	0.25-1	mg	INH	R 0.00	17-Dec-01	21-Dec-01	**R 106.38**
061	Berotec	1.25-5	mg	INH	R 0.00	17-Dec-01	21-Dec-01	**R 111.88**
061	Dolorol	3	g	PO	R 0.00	21-Dec-01	21-Dec-01	**R 2.76**
061	Dulcolax	10	mg	PR	R 0.00	21-Dec-01	21-Dec-01	**R 4.14**
061	Morphine	20-30	mg	IM	R 53.40	15-Dec-01	19-Dec-01	**R 106.35**
062	Morphine	10-50	mg	IM	R 32.04	17-Dec-01	19-Dec-01	**R 106.35**
062	Panado	1000-2000	mg	PO	R 0.00	20-Dec-01	21-Dec-01	**R 4.28**
062	Serepax	10	mg	PO	R 0.00	19-Dec-01	20-Dec-01	**R 1.42**
066	Dolorol Forte	1016-2032	mg	PO	R 0.00	06-Jan-02	09-Jan-02	**R 15.04**
066	Morphine	20	mg	IM	R 3.56	06-Jan-02	06-Jan-02	**R 14.18**
068	Atrovent	0.25-3	mg	INH	R 0.00	15-Jan-02	21-Jan-02	**R 446.82**
068	Berotec	1.25-7.5	mg	INH	R 0.00	15-Jan-02	21-Jan-02	**R 234.95**
068	Dolorol Forte	2032-4064	mg	PO	R 0.00	21-Jan-02	23-Jan-02	**R 22.56**
068	Dormicum	9	mg	IV	R 0.92	12-Jan-02	12-Jan-02	**R 53.63**
068	Heparin	5000-15000	iu	SC	R 96.12	12-Jan-02	20-Jan-02	**R 188.73**
068	Lasix	5-10	mg	IV	R 0.92	15-Jan-02	16-Jan-02	**R 11.18**

Appendix C 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
068	Morphine	10-30	mg	IM	R 21.36	11-Jan-02	12-Jan-02	**R 42.54**
068	Morphine	10-50	mg	IV	R 19.39	12-Jan-02	17-Jan-02	**R 212.70**
068	Morphine	10-20	mg	IM	R 21.36	18-Jan-02	19-Jan-02	**R 28.36**
068	Panado	30-60	ml	PO	R 0.00	12-Jan-02	16-Jan-02	**R 17.64**
068	Panado	30	ml	PO	R 0.00	19-Jan-02	19-Jan-02	**R 17.64**
068	Ulsanic	4	g	PO	R 0.00	12-Jan-02	18-Jan-02	**R 74.44**
071	Atrovent	1.5-2.5	mg	INH	R 0.00	23-Jan-02	28-Jan-02	**R 319.15**
071	Berotec	3.75-6.25	mg	INH	R 0.00	23-Jan-02	28-Jan-02	**R 167.82**
071	Dolorol Forte	1016-2032	mg	PO	R 0.00	25-Jan-02	29-Jan-02	**R 18.80**
071	Losec	20	mg	PO	R 0.00	25-Jan-02	continuing	**R 393.77**
071	Morphine	10-30	mg	IM	R 32.04	22-Jan-02	24-Jan-02	**R 63.81**
071	Neostigmine	0.5	mg	IV	R 0.92	22-Jan-02	22-Jan-02	**R 3.09**
071	Nimbex	12	mg	IV	R 0.92	22-Jan-02	22-Jan-02	**R 298.17**
071	Phenylephrine	250	mg	IV	R 0.92	22-Jan-02	22-Jan-02	**R 993.58**
071	Robinul	2.5	mg	IV	R 0.92	22-Jan-02	22-Jan-02	**R 882.36**
071	Tagamet	800	mg	IV	R 19.39	24-Jan-02	25-Jan-02	**R 29.64**
072	Dolorol Forte	1016-2032	mg	PO	R 0.00	25-Jan-02	10-Feb-02	**R 63.92**
072	Morphine	20-30	mg	IM	R 21.36	23-Jan-02	24-Jan-02	**R 42.54**
073	Atrovent	0.5-2	mg	INH	R 0.00	01-Feb-02	04-Feb-02	**R 170.22**
073	Berotec	1.25-5	mg	INH	R 0.00	01-Feb-02	04-Feb-02	**R 89.50**
073	Dolorol Forte	1016	mg	PO	R 0.00	13-Feb-02	15-Feb-02	**R 5.64**
073	Maxalon	10-20	mg	IM	R 53.40	08-Feb-02	12-Feb-02	**R 68.76**
073	Morphine	10-50	mg	IM	R 64.08	08-Feb-02	13-Feb-02	**R 212.70**
073	Pethedine	75-300	mg	IM	R 85.44	23-Jan-02	30-Jan-02	**R 191.88**
073	Pethedine	75	mg	IM	R 3.56	08-Feb-02	08-Feb-02	**R 14.03**
074	Dolorol	3	g	PO	R 0.00	03-Feb-02	06-Feb-02	**R 10.96**
074	Maxalon	10	mg	IM	R 3.56	30-Jan-02	30-Jan-02	**R 6.88**
074	Morphine	10-30	mg	IM	R 42.72	29-Jan-02	01-Feb-02	**R 85.08**
074	Voltaren	75-150	mg	IM	R 21.36	30-Jan-02	31-Jan-02	**R 31.42**
075	Dolorol Forte	1016-2032	mg	PO	R 0.00	25-Feb-02	03-Mar-02	**R 26.32**
075	Losec	20	mg	PO	R 0.00	22-Feb-02	continuing	**R 393.77**
075	Morphine	10-30	mg	IM	R 53.40	18-Feb-02	22-Feb-02	**R 106.35**
075	Pethedine	350	mg	IM	R 3.56	18-Feb-02	18-Feb-02	**R 31.37**

Appendix C 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
075	Tagamet	800-1200	mg	IM	R 53.40	18-Feb-02	22-Feb-02	**R 111.15**
078	Actrapid	5-10	iu	IV	R 0.92	28-Feb-02	01-Mar-02	**R 233.41**
078	Adrenaline	2-30	mg	IV	R 0.92	25-Feb-02	10-Mar-02	**R 1,367.32**
078	Amiodarone	150-300	mg	IV	R 0.92	02-Mar-02	07-Mar-02	**R 143.09**
078	Amiodarone	200	mg	IV	R 0.92	08-Mar-02	13-Mar-02	**R 81.77**
078	Atrovent	1-3	mg	INH	R 0.00	26-Feb-02	26-Feb-02	**R 63.83**
078	Atrovent	1-3	mg	INH	R 0.00	11-Mar-02	12-Mar-02	**R 127.68**
078	Berotec	2.5-7.5	mg	INH	R 0.00	26-Feb-02	26-Feb-02	**R 33.56**
078	Berotec	2.5-7.5	mg	INH	R 0.00	11-Mar-02	12-Mar-02	**R 67.08**
078	Digoxin	0.75	mg	IV	R 19.39	27-Feb-02	27-Feb-02	**R 14.48**
078	Digoxin	0.125-0.5	mg	PO	R 0.00	13-Mar-02	15-Mar-02	**R 4.50**
078	Digoxin	0.125-0.5	mg	PO	R 0.00	13-Mar-02	15-Mar-02	**R 1.80**
078	Ditropan	5-15	mg	PO	R 0.00	07-Mar-02	12-Mar-02	**R 73.38**
078	Dobutrex	300-600	mg	IV	R 0.92	01-Mar-02	11-Mar-02	**R 11,525.00**
078	Dobutrex	20-25	mg	IV	R 0.92	26-Feb-02	27-Feb-02	**R 12.00**
078	Dobutrex	100-500	mg	IV	R 0.92	13-Mar-02	15-Mar-02	**R 2,881.26**
078	Heparin	5000-10000	iu	SC	R 42.72	25-Feb-02	28-Feb-02	**R 55.92**
078	Heparin	5000-15000	iu	SC	R 64.08	28-Feb-02	03-Mar-02	**R 125.82**
078	Heparin	10000-15000	iu	SC	R 96.12	04-Mar-02	12-Mar-02	**R 188.73**
078	Intropin	100-400	mg	IV	R 0.92	27-Feb-02	06-Mar-02	**R 1,100.05**
078	Kexelate	20-90	g	PO	R 0.00	27-Feb-02	02-Mar-02	**R 782.32**
078	Lasix	10-1500	mg	IV	R 0.92	26-Feb-02	09-Mar-02	**R 3,161.11**
078	Lasix	20	mg	IV	R 0.92	11-Mar-02	12-Mar-02	**R 22.36**
078	Losec	20	mg	PO	R 0.00	27-Feb-02	12-Mar-02	**R 393.77**
078	Morphine	10-30	mg	IM	R 32.04	23-Feb-02	25-Feb-02	**R 63.81**
078	Morphine	2-30	mg	IV	R 0.92	25-Feb-02	28-Feb-02	**R 85.08**
078	Panado	30	ml	PO	R 0.00	02-Mar-02	02-Mar-02	**R 15.47**
078	Renitec	20	mg	PO	R 0.00	12-Mar-02	12-Mar-02	**R 213.72**
078	Renitec	20	mg	PO	R 0.00	12-Mar-02	12-Mar-02	**R 213.72**
078	Sprinolactine	50	mg	PO	R 0.00	08-Mar-02	12-Mar-02	**R 25.73**
078	Stemetil	12.5	mg	IM	R 3.56	24-Feb-02	24-Feb-02	**R 9.19**
078	Thiamine	100	mg	IV	R 0.92	14-Mar-02	12-Mar-02	**R 41.33**
078	Ulsanic	1-4	g	PO	R 0.00	26-Feb-02	02-Mar-02	**R 53.17**

Appendix C 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
078	Vitamine B Complex	1	ml	IV	R 0.92	14-Mar-02	12-Mar-02	**R 24.20**
079	Dolorol Forte	1016-4064	mg	PO	R 0.00	08-Mar-02	23-Mar-02	**R 45.12**
079	Lasix	20-40	mg	IV	R 19.39	24-Feb-02	25-Feb-02	**R 44.72**
079	Morphine	30	mg	IM	R 3.56	24-Feb-02	24-Feb-02	**R 21.27**
079	Morphine	20	mg	IM	R 3.56	26-Feb-02	26-Feb-02	**R 14.18**
081	Atrovent	1.5-2	mg	INH	R 0.00	14-Mar-02	19-Mar-02	**R 255.32**
081	Berotec	1.25-5	mg	IM	R 74.76	26-Feb-02	04-Mar-02	**R 156.63**
081	Berotec	3.76-5	mg	INH	R 0.00	14-Mar-02	19-Mar-02	**R 134.26**
081	Brufen	200	mg	PO	R 0.00	05-Mar-02	12-Mar-02	**R 4.16**
081	Dolorol Forte	1016-2032	mg	PO	R 0.00	05-Mar-02	12-Mar-02	**R 30.08**
081	Dolorol Forte	1016	mg	PO	R 0.00	26-Mar-02	30-Mar-03	**R 9.40**
081	Heparin	5000-10000	iu	SC	R 74.76	20-Mar-02	26-Mar-02	**R 97.86**
081	Heparin	5000	iu	SC	R 3.56	20-Mar-02	20-Mar-02	**R 6.99**
081	Maxalon	10	mg	IM	R 3.56	20-Mar-02	20-Mar-02	**R 6.88**
081	Maxalon	10	mg	IV	R 0.92	20-Mar-02	20-Mar-02	**R 6.99**
081	Morphine	40	mg	IV	R 19.39	20-Mar-02	20-Mar-02	**R 28.36**
081	Morphine	10-20	mg	IM	R 42.72	27-Feb-02	02-Mar-02	**R 56.72**
081	Morphine	10-40	mg	IM	R 138.84	13-Mar-02	25-Mar-02	**R 368.68**
081	Neostigmine	2.5	mg	IV	R 0.92	20-Mar-02	20-Mar-02	**R 6.54**
081	Pethedine	100	mg	IM	R 3.56	20-Mar-02	20-Mar-02	**R 7.99**
081	Robinul	0.8	mg	IV	R 0.92	20-Mar-02	20-Mar-02	**R 294.12**
081	Stemetil	12.5	mg	IM	R 21.36	15-Mar-02	16-Mar-02	**R 18.38**
081	Stemetil	12.5	mg	IM	R 3.56	20-Mar-02	20-Mar-02	**R 9.19**
081	Ventolin	200	ug	INH	R 0.00	1990	ongoing	**R 46.26**
085	Dolorol Forte	1016-2032	mg	PO	R 0.00	20-Mar-02	21-Mar-02	**R 7.52**
085	Morphine	30-40	mg	IV	R 19.39	18-Mar-02	19-Mar-02	**R 56.72**
088	Dolorol Forte	1016	mg	PO	R 0.00	07-Apr-02	11-Apr-02	**R 9.40**
088	Pethedine	50-100	mg	IV	R 19.39	03-Apr-02	05-Apr-02	**R 23.98**
090	Dolorol Forte	1016-3048	mg	PO	R 0.00	23-Apr-02	02-May-02	**R 56.40**
090	Morphine	20-30	mg	IM	R 21.36	21-Apr-02	22-Apr-02	**R 42.54**
090	Stemetil	12.5	mg	IM	R 3.56	21-Apr-02	21-Apr-02	**R 9.19**
091	Acebutolol	1	mg	IV	R 0.92	17-May-02	17-May-02	**R 47.30**
091	Actrapid			IV	R 0.92	17-May-02	17-May-02	**R 233.41**

Appendix C 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
091	Adrenaline	20-50	mg	IV	R 19.39	10-May-02	12-May-02	**R 683.66**
091	Adrenaline	40-100	mg	IV	R 0.92	14-May-02	18-May-02	**R 2,278.86**
091	Atrovent	0.25-1.25	mg	INH	R 0.00	06-May-02	17-May-02	**R 319.15**
091	Berotec	1.25-7.5	mg	INH	R 0.00	06-May-02	17-May-02	**R 402.77**
091	Dobutrex	200	mg	IV	R 0.92	17-May-02	17-May-02	**R 384.17**
091	Dolorol Forte	1016-3048	mg	PO	R 0.00	07-May-02	09-May-02	**R 16.92**
091	Dormicum	4	mg	IV	R 0.92	09-May-02	09-May-02	**R 26.81**
091	Dormicum	2-50	mg	IV	R 0.92	13-May-02	14-May-02	**R 328.50**
091	Duratears	02-Jan	drops	EYE	R 0.00	16-May-02	17-May-02	**R 46.16**
091	Heparin	5000-10000	iu	SC	R 64.08	12-May-02	17-May-02	**R 83.88**
091	Lasix	10-20	mg	PO	R 0.00	09-May-02	11-May-02	**R 7.84**
091	Lasix	40-500	mg	IV	R 0.92	14-May-02	17-May-02	**R 351.23**
091	Lorazepan	2	mg	IV	R 0.92	11-May-02	11-May-02	**R 2.40**
091	Losec	20	mg	PO	R 0.00	03-May-02	09-May-02	**R 112.50**
091	Losec	20	mg	PO	R 0.00	11-May-02	17-May-02	**R 98.44**
091	Morphine	10-20	mg	IM	R 53.40	01-May-02	05-May-02	**R 70.90**
091	Morphine	2-20	mg	IV	R 0.92	09-May-02	16-May-02	**R 113.44**
091	Panado	30-120	ml	PO	R 0.00	10-May-02	17-May-02	**R 17.64**
091	Pavulon	12.5	mg	IV	R 0.92	17-May-02	17-May-02	**R 92.07**
091	Penieleferine	10-40	mg	IV	R 0.92	17-May-02	18-May-02	**R 397.43**
091	Propofol	12	ml	IV	R 0.92	14-May-02	14-May-02	**R 174.43**
091	Serepax	10	mg	PO	R 0.00	05-May-02	07-May-02	**R 2.12**
091	Serepax	10	mg	PO	R 0.00	09-May-02	14-May-02	**R 4.25**
091	Solu-cortef	100	mg	IV	R 0.92	17-May-02	17-May-02	**R 31.82**
091	Ulsanic	1	g	PO	R 0.00	09-May-02	11-May-02	**R 7.98**
091	Ulsanic	1	g	PO	R 0.00	15-May-02	17-May-02	**R 7.98**
093	Dolorol Forte	2032	mg	PO	R 0.00	14-May-02	14-May-02	**R 3.76**
093	Morphine	20	mg	IV	R 19.39	12-May-02	13-May-02	**R 28.36**
093	Pethedine	100	mg	IM	R 21.36	11-May-02	12-May-02	**R 15.99**
093	Voltaren	75	mg	IM	R 10.68	13-May-02	13-May-02	**R 7.85**
095	Dolorol Forte	1016-4064	mg	PO	R 0.00	25-Jun-02	30-Jun-02	**R 45.12**
095	Dolorol Forte	1016-4064	mg	PO	R 0.00	10-Jul-02	12-Jul-02	**R 10.82**
095	Maxalon	10	mg	PO	R 0.00	22-Jun-02	22-Jun-02	**R 1.59**

Appendix C 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
095	Maxalon	10	mg	PO	R 0.00	24-Jun-02	24-Jun-02	**R 1.59**
095	Morphine	10-40	mg	IM	R 53.40	20-Jun-02	24-Jun-02	**R 141.80**
095	Pethedine	50	mg	IM	R 32.04	07-Jul-02	09-Jul-02	**R 22.15**
095	Stemetil	25	mg	IM	R 7.12	22-Jun-02	22-Jun-02	**R 18.38**
095	Stemetil	12.5	mg	IM	R 3.56	24-Jun-02	24-Jun-02	**R 9.19**
097	Morphine	30-40	mg	IV	R 0.92	25-Jul-02	26-Jul-02	**R 56.72**
097	Tagamet	200-800	mg	IV	R 19.39	25-Jul-02	29-Jul-02	**R 74.10**
100	Atrovent	0.5-2.5	mg	INH	R 0.00	04-May-02	12-May-02	**R 478.73**
100	Berotec	1.25-6.25	mg	INH	R 0.00	04-May-02	12-May-02	**R 251.73**
100	Dolorol Forte	1016-3048	mg	IV	R 19.39	04-May-02	05-May-02	**R 11.28**
100	Dolorol Forte	1016-2032	mg	IV	R 0.92	09-May-02	12-May-02	**R 15.04**
100	Heparin	5000-10000	iu	SC	R 106.80	02-May-02	11-May-02	**R 139.80**
100	Morphine	10-40	mg	IM	R 72.45	02-May-02	08-May-02	**R 198.52**
TOTAL					**R 4,495.72**			**R 62,278.43**
							TOTAL COST	**R 66,774.15**

Appendix C 3.2

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP B / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
001	Akineton	4	g	PO	R 0.00	10-Mar-01	ongoing	**R 128.79**
001	Bayer Aspirin	2	g	PO	R 0.00	16-Mar-01	18-Mar-01	**R 25.99**
001	Dormicum	7.5	mg	IV	R 0.92	16-Feb-01	16-Feb-01	**R 40.22**
001	Maxalon	10	mg	IV	R 19.39	17-Feb-01	21-Feb-01	**R 6.88**
001	Morphine	10	mg	IM	R 96.12	16-Feb-01	24-Feb-01	**R 63.81**
001	Servatrin	37.5	mg	PO	R 0.00	unk	ongoing	**R 54.40**
002	Dolorol	2000	mg	PO	R 0.00	23-Feb-01	23-Feb-01	**R 0.91**
002	Morphine	10-40	mg	IM	R 53.40	20-Feb-01	24-Feb-01	**R 141.80**
006	Atrovent	0.25-1.5	mg	INH	R 0.00	05-Apr-01	29-Apr-01	**R 797.89**
006	Berotec	1.25-7.5	mg	INH	R 0.00	05-Apr-01	29-Apr-01	**R 839.10**
006	Brufen	400	mg	PO	R 0.00	22-Apr-01	29-Apr-01	**R 28.07**
006	Dolorol Forte	1016-3048	mg	PO	R 0.00	15-Apr-01	29-Apr-01	**R 84.44**
006	Fybogel	3.5-7	g	PO	R 0.00	22-Apr-01	28-Apr-01	**R 32.24**
006	Heparin	5000-10000	iu	SC	R 64.08	05-Apr-01	10-Apr-01	**R 83.88**
006	Morphine	20	mg	IM	R 32.04	03-Apr-01	05-Apr-01	**R 42.54**
006	Panado	30-120	ml	PO	R 0.00	05-Apr-01	08-Apr-01	**R 17.64**
006	Pethidine	75-300	mg	IM	R 53.40	26-Mar-01	30-Mar-01	**R 119.92**
006	Stemetil	12.5	mg	IM	R 3.56	04-Apr-01	04-Apr-01	**R 9.19**
006	Valium	10-30	mg	PO	R 0.00	30-Mar-01	02-Apr-01	**R 140.69**
006	Voltaren	75	mg	IM	R 32.04	27-Mar-01	29-Mar-01	**R 23.56**
008	Adrenaline	5-15	mg	IV	R 0.92	04-Apr-01	17-Apr-01	**R 68.37**
008	Atrovent	2	mg	INH	R 0.00	29-Mar-01	17-Apr-01	**R 851.08**
008	Berotec	5	mg	INH	R 0.00	29-Mar-01	17-Apr-01	**R 447.52**
008	Dobutrex	250	mg	IV	R 0.92	29-Mar-01	06-Apr-01	**R 4,321.89**
008	Dormicum	200-250	mg	IV	R 19.39	31-Mar-01	17-Apr-01	**R 14,782.61**
008	Heparin	5 - 25000	iu	SC	R 96.12	29-Mar-01	06-Apr-01	**R 311.31**
008	Insulin	5-15	iu	IV	R 0.92	07-Apr-01	17-Apr-01	**R 2,567.51**
008	Lasix	20-40	mg	IV	R 0.92	01-Mar-01	12-Apr-01	**R 983.94**
008	Maxalon	20	mg	IV	R 0.92	30-Mar-01	30-Mar-01	**R 13.76**
008	Morphine	5-10	mg	IV	R 0.92	31-Mar-01	17-Apr-01	**R 127.62**
008	Panado	60	ml	PO	R 0.00	04-Apr-01	17-Apr-01	**R 17.64**

Appendix C 3.2

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP B / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
008	Pavulon	8-20	mg	IV	R 0.92	16-Apr-01	17-Apr-01	**R 263.04**
008	Pethidine	150	mg	IM	R 10.68	28-Mar-01	28-Mar-01	**R 15.38**
008	Prednisone	40	mg	PO	R 0.00	07-Apr-01	12-Apr-01	**R 105.17**
008	Solu Cortef	100-300	mg	INH	R 0.00	29-Mar-01	06-Apr-01	**R 859.07**
011	Dolorol Forte	1016-2032	mg	PO	R 0.00	18-Apr-01	19-Apr-01	**R 7.51**
011	Morphine	10-30	mg	IM	R 42.72	11-Apr-01	14-Apr-01	**R 113.44**
012	Panado	1-3	g	PO	R 0.00	16-Apr-01	19-Apr-01	**R 12.83**
012	Pethidine	75-200	mg	IM	R 32.04	15-Apr-01	17-Apr-01	**R 47.97**
013	Atrovent	0.5-0.75	mg	INH	R 0.00	01-May-01	07-May-01	**R 111.70**
013	Berotec	2.5-3.75	mg	INH	R 0.00	01-May-01	07-May-01	**R 117.47**
013	Flamazine	1	applic	TOP	R 0.00	02-May-01	09-May-01	**R 89.90**
013	Morphine	20-40	mg	IM	R 21.36	01-May-01	02-May-01	**R 56.72**
013	Thiamine	100	mg	IM	R 42.72	04-May-01	07-May-01	**R 82.66**
013	Valium	10	mg	PO	R 0.00	04-May-01	05-May-01	**R 23.45**
015	Pethidine	150-200	mg	IM	R 64.08	09-May-01	14-May-01	**R 95.94**
017	Brufen	600	mg	PO	R 0.00	20-May-01	27-May-01	**R 16.02**
017	Dolorol Forte	1016	mg	PO	R 0.00	16-May-01	20-May-01	**R 9.40**
017	Dolorol Forte	3048	mg	PO	R 0.00	21-May-01	27-May-01	**R 39.48**
017	Morphine	10-30	mg	IM	R 42.72	15-May-01	18-May-01	**R 85.08**
017	Pethidine	75	mg	IM	R 10.68	15-May-01	15-May-01	**R 14.03**
017	Stemetil	12.5	mg	IM	R 7.12	16-May-01	17-May-01	**R 18.38**
020	Dolorol Forte	1016	mg	PO	R 0.00	21-May-01	21-May-01	**R 1.88**
020	Morphine	10-30	mg	IM	R 64.08	22-May-01	27-May-01	**R 127.62**
020	Morphine	10	mg	IV	R 19.39	27-May-01	27-May-01	**R 7.09**
020	Pethidine	50-100	mg	IV	R 0.92	20-May-01	21-May-01	**R 15.99**
020	Tetanus Toxoid	0.5	ml	IM	R 3.56	20-May-01	20-May-01	**R 35.68**
023	Heparin	4000	iu	SC	R 32.04	11-Jun-01	13-Jun-01	**R 16.80**
023	Morphine	20	mg	IM	R 3.56	11-Jun-01	11-Jun-01	**R 14.18**
023	Pethidine	50	mg	IM	R 3.56	10-Jun-01	10-Jun-01	**R 7.38**
024	Atrovent	0.25	mg	INH	R 0.00	23-Jun-01	25-Jun-01	**R 15.96**
024	Berotec	1.25	mg	INH	R 0.00	23-Jun-01	25-Jun-01	**R 16.78**

Appendix C 3.2

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP B / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
024	Dolorol Forte	1016	mg	PO	R 0.00	25-Jun-01	25-Jun-01	**R 1.88**
024	Heparin	5000-10000	iu	SC	R 32.04	19-Jun-01	21-Jun-01	**R 41.94**
024	Morphine	10-30	mg	IM	R 74.76	19-Jun-01	25-Jun-01	**R 148.89**
024	Stemetil	12.5	mg	IM	R 3.56	23-Jun-01	23-Jun-01	**R 9.19**
026	Morphine	20-50	mg	IM	R 53.40	01-Jul-01	05-Jul-01	**R 212.70**
026	Pethidine	75	mg	IM	R 3.56	30-Jul-01	30-Jul-01	**R 14.03**
027	Losec	20	mg	PO	R 0.00	06-Aug-01	06-Aug-01	**R 14.06**
027	Morphine	10	mg	IM	R 53.40	02-Aug-01	06-Aug-01	**R 42.54**
027	Stemetil	12.5	mg	IM	R 3.56	06-Aug-01	06-Aug-01	**R 9.19**
027	Tagamet	800-600	mg	IV	R 19.39	03-Aug-01	06-Aug-01	**R 49.32**
029	Heparin	5000-10000	iu	SC	R 74.76	10-Aug-01	16-Aug-01	**R 97.86**
029	Morphine	10-30	mg	IM	R 53.40	10-Aug-01	14-Aug-01	**R 106.35**
029	Stemetil	12.5	mg	IV	R 19.39	12-Aug-01	18-Aug-01	**R 64.33**
032	Losec	20	mg	PO	R 0.00	27-Aug-01	continueing	**R 393.77**
032	Pethidine	75-400	mg	IM	R 85.44	23-Aug-01	30-Aug-01	**R 255.83**
032	Stemetil	12.5-25	mg	IM	R 7.12	26-Aug-01	27-Aug-01	**R 36.76**
033	Dolorol	1-3	g	PO	R 0.00	14-Sep-01	15-Sep-01	**R 5.52**
033	Morphine	30-60	mg	IM	R 42.72	10-Sep-01	13-Sep-01	**R 170.16**
033	Stemetil	12.5	mg	IM	R 3.56	10-Sep-01	10-Sep-01	**R 9.19**
033	Tetanus Toxoid	0.5	ml	SC	R 3.56	09-Sep-01	09-Sep-01	**R 5.68**
033	Thiamine	200	mg	PO	R 0.00	13-Sep-01	14-Sep-01	**R 0.90**
033	Vit C	1000	mg	PO	R 0.00	13-Sep-01	14-Sep-01	**R 0.81**
034	Morphine	10-40	mg	IM	R 32.04	12-Sep-01	14-Sep-01	**R 85.08**
035	Atrovent	0.25-0.75	mg	INH	R 0.00	14-Sep-01	24-Sep-01	**R 159.58**
035	Berotec	1.25-3.75	mg	INH	R 0.00	14-Sep-01	24-Sep-01	**R 184.60**
035	Disprin	150	mg	PO	R 0.00	19-Sep-01	26-Sep-01	**R 1.12**
035	Doxyfene	2-4	tablets	PO	R 0.00	19-Sep-01	21-Sep-01	**R 43.08**
035	Fleet Enema	1	bottle	PR	R 0.00	18-Sep-01	20-Sep-01	**R 15.05**
035	Heparin	5000-15000	iu	SC	R 85.44	13-Sep-01	20-Sep-01	**R 167.76**
035	Maxalon	20	mg	PO	R 0.00	18-Sep-01	20-Sep-01	**R 3.18**
035	Morphine	10-30	mg	IM	R 64.08	13-Sep-01	18-Sep-01	**R 127.62**

Appendix C 3.2

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP B / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
035	Zestoretic	1	tablets	PO	R 0.00	NA	NA	**R 123.82**
037	Dolorol Forte	1016-2032	mg	PO	R 0.00	01-Oct-01	03-Oct-01	**R 5.64**
037	Morphine	30	mg	IM	R 3.56	27-Sep-01	27-Sep-01	**R 21.27**
037	Morphine	10	mg	IM	R 3.56	29-Oct-01	29-Oct-01	**R 7.09**
039	Morphine	30	mg	IM	R 32.04	01-Oct-01	03-Oct-01	**R 63.81**
039	Stemetil	12.5	mg	IM	R 3.56	02-Oct-01	02-Oct-01	**R 9.19**
041	Dolorol Forte	1016-3048	mg	PO	R 0.00	18-Oct-01	30-Oct-01	**R 73.32**
041	Doxyfene	4	caps	PO	R 0.00	18-Oct-01	22-Oct-01	**R 71.80**
041	Heparin	5000-15000	iu	SC	R 74.76	12-Oct-01	18-Oct-01	**R 125.82**
041	Pethidine	150-200	mg	IM	R 53.40	10-Oct-01	14-Oct-01	**R 79.95**
043	Morphine	10-30	mg	IM	R 64.08	19-Oct-01	24-Oct-01	**R 127.62**
046	Canesten Cream	1-3	NA	PV	R 0.00	01-Nov-01	05-Nov-01	**R 167.22**
046	Dormicum	100-140	mg	IV	R 0.92	23-Oct-01	25-Oct-01	**R 1,478.26**
046	Heparin	10000-15000	iu	SC	R 117.48	24-Oct-01	03-Nov-01	**R 230.67**
046	Maxalon	10-30	mg	IM	R 32.04	28-Oct-01	30-Oct-01	**R 61.89**
046	Maxalon	10	mg	IM	R 3.56	02-Nov-01	02-Nov-01	**R 6.99**
046	Morphine	5-70	mg	IV	R 19.39	23-Oct-01	31-Oct-01	**R 446.67**
046	Morphine	10-30	mg	IM	R 32.04	31-Oct-01	02-Nov-01	**R 63.81**
046	Serapax	20	mg	PO	R 0.00	29-Oct-01	30-Oct-01	**R 2.83**
046	Ulsanic	1-4	g	PO	R 0.00	25-Oct-01	01-Nov-01	**R 85.07**
046	Voltaren	150	mg	IM	R 21.36	29-Oct-01	30-Oct-01	**R 31.42**
046	Voltaren	75	mg	IM	R 3.56	03-Nov-01	03-Nov-01	**R 7.85**
048	Atrovent	0.5-2.5	mg	INH	R 0.00	30-Oct-01	05-Nov-01	**R 372.35**
048	Berotec	1.25-6.25	mg	INH	R 0.00	30-Oct-01	05-Nov-01	**R 195.79**
048	Morphine	10-30	mg	IM	R 64.08	29-Oct-01	03-Nov-01	**R 127.62**
050	Depo Pruvera	1	amp	IM	R 3.56			**R 21.01**
050	Dolorol Forte	1016	mg	PO	R 0.00	10-Nov-01	12-Nov-01	**R 5.64**
050	Indocid	100-300	mg	PR	R 0.00	08-Nov-01	11-Nov-01	**R 147.59**
050	Maxalon	10	mg	IM	R 3.56	09-Nov-01	09-Nov-01	**R 6.88**
050	Morphine	7.5-30	mg	IM	R 21.36	08-Nov-01	09-Nov-01	**R 42.54**
052	Adrenaline	12	mg	IV	R 19.39	17-Nov-01	17-Nov-01	**R 54.69**

Appendix C 3.2

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP B / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
052	Atropine	3	mg	IV	R 0.92	17-Nov-01	17-Nov-01	**R 16.67**
052	Calcium Glusonate	10	ml	IV	R 0.92	17-Nov-01	17-Nov-01	**R 9.14**
052	Lignocaine	80	mg	IV	R 0.92	17-Nov-01	17-Nov-01	**R 37.67**
052	Morphine	20	mg	IM	R 3.56	17-Nov-01	17-Nov-01	**R 14.18**
053	Dolorol Forte	1016-2032	mg	PO	R 0.00	21-Nov-01	23-Nov-01	**R 11.28**
053	Morphine	20	mg	IM	R 3.56	19-Nov-01	19-Nov-01	**R 14.18**
056	Brufen	600	mg	PO	R 0.00	01-Dec-01	08-Dec-01	**R 16.02**
056	Dolorol Forte	3048	mg	PO	R 0.00	01-Dec-01	18-Dec-01	**R 101.52**
056	Voltaren	75	mg	IM	R 32.04	27-Nov-01	29-Nov-01	**R 23.56**
056	Voltaren	75	mg	IM	R 32.04	27-Nov-01	29-Nov-01	**R 23.56**
057	Morphine	10-30	mg	IM	R 32.04	03-Dec-01	05-Dec-01	**R 63.81**
058	Dolorol Forte	1016	mg	PO	R 0.00	10-Dec-01	11-Dec-01	**R 3.76**
058	Dolorol Forte	1016	mg	PO	R 0.00	15-Dec-01	15-Dec-01	**R 1.88**
058	Dolorol Forte	1016	mg	PO	R 0.00	10-Dec-01	11-Dec-01	**R 3.76**
058	Morphine	20-30	mg	IM	R 32.04	09-Dec-01	10-Dec-01	**R 42.54**
058	Morphine	20-30	mg	IV	R 0.92	09-Dec-01	10-Dec-02	**R 42.54**
058	Stemetil	12.5-25	mg	IM	R 32.04	11-Dec-01	13-Dec-01	**R 55.14**
058	Stemetil	12.5-25	mg	IM	R 32.04	11-Dec-01	13-Dec-01	**R 55.14**
063	Morphine	20-40	mg	IM	R 53.40	17-Dec-01	21-Dec-01	**R 141.80**
063	Morphine	10	mg	IM	R 3.56	23-Dec-01	23-Dec-01	**R 7.09**
063	Voltaren	75	mg	IM	R 74.76	17-Dec-01	23-Dec-01	**R 54.98**
064	Dolorol Forte	2032	mg	PO	R 0.00	21-Dec-01	21-Dec-01	**R 3.76**
064	Morphine	10-40	mg	IM	R 53.40	17-Dec-01	21-Dec-01	**R 141.80**
065	Dolorol Forte	2032-3048	mg	PO	R 0.00	07-Jan-02	11-Jan-02	**R 28.20**
065	Morphine	30-40	mg	IM	R 53.40	02-Jan-02	06-Jan-02	**R 170.16**
067	Pethidine	75-150	mg	IM	R 32.04	05-Jan-02	07-Jan-02	**R 46.14**
069	Atrovent	0.25-1	mg	INH	R 0.00	14-Jan-02	18-Jan-02	**R 106.38**
069	Berotec	1.25-5	mg	INH	R 0.00	14-Jan-02	18-Jan-02	**R 111.88**
069	Maxalon	10-20	mg	IM	R 21.36	13-Jan-02	14-Jan-02	**R 27.51**
069	Morphine	10-30	mg	IM	R 42.72	13-Jan-02	16-Jan-02	**R 85.08**
070	Atrovent	0.5-2	mg	INH	R 0.00	16-Jan-02	18-Jan-02	**R 127.66**

Appendix C 3.2

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP B / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
070	Berotec	2.5-5	mg	INH	R 0.00	16-Jan-02	18-Jan-02	**R 67.13**
070	Dolorol Forte	1016	mg	PO	R 0.00	18-Jan-02	18-Jan-02	**R 1.88**
070	Heparin	5000-10000	iu	SC	R 42.72	15-Jan-02	18-Jan-02	**R 55.92**
070	Losec	20	mg	PO	R 0.00	19-Jan-02	continuing	**R 393.77**
070	Morphine	20	mg	IM	R 3.56	15-Jan-02	15-Jan-02	**R 14.18**
070	Morphine	10	mg	IM	R 3.56	18-Jan-02	18-Jan-02	**R 7.09**
070	Pethidine	125-200	mg	IM	R 21.36	14-Jan-02	15-Jan-02	**R 31.98**
070	Tagamet	400-1200	mg	IV	R 19.39	15-Jan-02	18-Jan-02	**R 200.07**
070	Theophylin	400	mg	PO	R 0.00	19-Jan-02	02-Feb-02	**R 45.85**
076	Buscopan	20-60	mg	IM	R 32.04	20-Feb-02	22-Feb-02	**R 141.73**
076	Buscopan	20	mg	IM	R 21.36	25-Feb-02	26-Feb-02	**R 31.50**
076	Dolorol Forte	1016-3048	mg	PO	R 0.00	24-Feb-02	29 Feb 02	**R 33.84**
076	Maxalon	10	mg	IV	R 0.92	20-Feb-02	20-Feb-02	**R 6.88**
076	Morphine	10	mg	IM	R 3.56	21-Feb-02	21-Feb-02	**R 7.09**
076	Pethidine	50	mg	IM	R 21.36	19-Feb-02	20-Feb-02	**R 14.77**
077	Alphagan	2	drops	EYE	R 0.00	20-Feb-02	continuing	**R 130.12**
077	Betagan	2	drops	EYE	R 0.00	20-Feb-02	continuing	**R 116.33**
077	Dolorol Forte	1016	mg	PO	R 0.00	25-Feb-02	01-Mar-02	**R 9.40**
077	Morphine	7.5-20	mg	IM	R 32.04	20-Feb-02	22-Feb-02	**R 42.54**
077	Serapax	10	mg	PO	R 0.00	23-Feb-02	24-Feb-02	**R 0.71**
080	Maxalon	10	mg	IM	R 3.56	24-Feb-02	24-Feb-02	**R 6.88**
080	Morphine	10-20	mg	IM	R 42.72	24-Feb-02	27-Feb-02	**R 56.72**
080	Pethidine	75	mg	IM	R 3.56	24-Feb-02	24-Feb-02	**R 14.03**
082	Dolorol Forte	1016-3048	mg	PO	R 0.00	07-Mar-02	11-Mar-02	**R 28.20**
082	Dolorol Forte	1016-3048	mg	PO	R 0.00	11-Mar-02	15-Mar-02	**R 28.20**
082	Pethidine	50	mg	IV	R 0.92	07-Mar-02	07-Mar-02	**R 7.38**
082	Pethidine	200	mg	IM	R 21.36	07-Mar-02	08-Mar-02	**R 31.98**
083	Dolorol Forte	1016-3048	mg	PO	R 0.00	13-Mar-02	15-Mar-02	**R 16.92**
083	Dolorol Forte	1046-2032	mg	PO	R 0.00	17-Mar-02	18-Mar-02	**R 7.52**
083	Dolorol Forte	1016	mg	PO	R 0.00	22-Mar-02	22-Mar-02	**R 1.88**
083	Dolorol Forte	1016	mg	PO	R 0.00	25-Mar-02	29-Mar-02	**R 9.40**

Appendix C 3.2

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP B / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
083	Morphine	7.5-20	mg	IM	R 42.72	10-Mar-02	13-Mar-02	**R 56.72**
083	Pethidine	50	mg	IM	R 3.56	17-Mar-02	17-Mar-02	**R 7.38**
083	Stemetil	12.5	mg	IM	R 3.56	11-Mar-02	11-Mar-02	**R 9.19**
086	Dolorol Forte	1016-2032	mg	PO	R 0.00	20-Mar-02	23-Mar-02	**R 15.04**
086	Morphine	30	mg	IM	R 32.04	17-Mar-02	19-Mar-02	**R 63.81**
087	Atrovent	0.5-1	mg	INH	R 0.00	23-Apr-02	24-Apr-02	**R 42.55**
087	Berotec	1.25-2.5	mg	INH	R 0.00	23-Apr-02	24-Apr-02	**R 22.38**
087	Buscopan	20	mg	IM	R 3.56	19-Apr-02	19-Apr-02	**R 15.75**
087	Dolorol Forte	4064	mg	PO	R 0.00	03-Apr-02	08-Apr-02	**R 45.12**
087	Morphine	10	mg	IM	R 3.56	30-Mar-02	30-Mar-02	**R 7.09**
089	Atrovent	0.5-2	mg	INH	R 0.00	20-Apr-02	22-Apr-02	**R 127.66**
089	Berotec	1.25-5	mg	INH	R 0.00	20-Apr-02	22-Apr-02	**R 67.13**
089	Dolorol Forte	1016	mg	PO	R 0.00	25-Apr-02	29-Apr-02	**R 9.40**
089	Morphine	10-30	mg	IM	R 53.40	17-Apr-02	21-Apr-02	**R 106.35**
092	Dolorol Forte	1016-3048	mg	PO	R 0.00	14-May-02	21-May-02	**R 45.12**
092	Pethidine	75-300	mg	IM	R 64.08	08-May-02	13-May-02	**R 143.91**
094	Dolorol Forte	1016-2032	mg	PO	R 0.00	15-Jun-02	28-Jun-02	**R 48.88**
094	Heparin	5000-15000	iu	SC	R 74.76	09-Jun-02	15-Jun-02	**R 146.79**
094	Losec	20	mg	PO	R 0.00	14-Jun-02	continuing	**R 393.77**
094	Morphine	10-40	mg	IM	R 64.08	09-Jun-02	14-Jun-02	**R 170.16**
096	Atrovent	1-1.5	mg	INH	R 0.00	09-Jul-02	11-Jul-02	**R 95.75**
096	Berotec	2.5-3.75	mg	INH	R 0.00	09-Jul-02	11-Jul-02	**R 50.35**
096	Dolorol Forte	3048-4064	mg	PO	R 0.00	12-Jul-02	19-Jul-02	**R 60.16**
096	Pethidine	75-150	mg	IM	R 53.40	08-Jul-02	12-Jul-02	**R 76.89**
098	Antabuse implant	unk	unk	SC	R 3.56	July 2002	Ongoing	**R 4.14**
098	DF118	30-90	mg	PO	R 0.00	13-Aug-02	13-Aug-02	**R 9.11**
098	Dolorol Forte	3048	mg	PO	R 0.00	17-Aug-02	27-Aug-02	**R 62.04**
098	Dulcolax	10	mg	PR	R 0.00	18-Aug-02	18-Aug-02	**R 170.16**
098	Fybogel	3.5	g	PO	R 0.00	22-Aug-02	Ongoing	**R 69.10**
098	Morphine	30-40	mg	IM	R 42.72	10-Aug-02	13-Aug-02	**R 113.44**
098	Senekot	15	mg	PO	R 0.00	02-Aug-02	16-Sep-02	**R 41.44**

Appendix C 3.2

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP B / ITT							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
098	Stemetil	12.5	mg	IM	R 3.56	11-Aug-02	11-Aug-02	**R 9.19**
099	Atrovent	0.5-2	mg	INH	R 0.00	13-Aug-02	18-Aug-02	**R 8.01**
099	Berotec	1.25-5	mg	INH	R 0.00	13-Aug-02	18-Aug-02	**R 255.32**
099	Brufen	600	mg	PO	R 0.00	04-Sep-02	07-Sep-02	**R 15.99**
099	Heparin	10000-15000	iu	SC	R 53.40	12-Aug-02	16-Aug-02	**R 134.26**
099	Morphine	10-40	mg	IM	R 64.08	11-Aug-02	16-Aug-02	**R 9.19**
099	Pethidine	50-100	mg	IM	R 21.36	11-Sep-02	12-Sep-02	**R 15.99**
099	Stemetil	12.5	mg	IM	R 3.56	12-Aug-02	12-Aug-02	**R 104.85**
TOTAL					**R 3,573.20**			**R 42,363.55**
							TOTAL COST	**R 45,936.75**

Appendix C 4.1

RANDOM NUMBER	DEMOGRAPHIC DATA / TREATMENT GROUP A / ITT										
	DATE OF BIRTH	AGE	GENDER		NATURE OF SURGERY						
			FEMALE	MALE	APPENDECTOMY	CHOLECYSTECOMY	LAPARATOMY	SIGMOIDECTOMY	INCISION AND DRAINAGE	EXPLORATORY LAPAROSCOPY	OTHER
005	15-May-61	41		1						1	
016	14-Jun-26	76	1				1				
021	10-Jan-77	24		1	1						
040	10-Mar-71	18	1				1				
047	03-Nov-65	37		1			1				
073	19-Sep-73	30		1			1				
078	23-Mar-33	69	1				1				
085	31-Dec-82	20		1						1	
003	11-Dec-65	37		1	1						
004	03-Nov-38	64		1				1			
007	14-Dec-79	23		1			1				
009	12-Feb-75	27		1			1				
010	15-Aug-82	20		1			1				
014	26-Apr-62	40		1	1						
018	13-Apr-80	22		1						1	
019	14-Feb-40	62		1						1	
021											
022	06-Feb-52	50		1			1				
025	01-Jan-38	64		1						1	
028	17-Dec-65	37		1	1						
030	12-Feb-60	42		1			1				
031	16-Aug-80	22		1	1						
036	13-Mar-33	69	1				1				
038	28-Jan-81	21		1	1						
042	05-Mar-67	35	1				1				
044	01-Nov-78	24		1			1				
045	20-Nov-81	21		1			1				
049	07-Jul-30	72	1			1					
051	27-Nov-71	31		1			1				
054	11-Oct-74	28		1			1				
055	07-Aug-55	45	1				1				
059	29-Jul-64	38		1			1				
060	29-Jan-60	42	1		1						
061	21-Dec-80	22		1			1				
062	18-Jul-62	40		1			1				
066	14-Jul-57	45		1	1						
068	16-Apr-72	30		1	1						
071	17-Sep-50	51		1			1				
072	12-Jun-75	25		1	1						

Appendix C 4.1

RANDOM NUMBER	DEMOGRAPHIC DATA / TREATMENT GROUP A / ITT										
	DATE OF BIRTH	AGE	GENDER		NATURE OF SURGERY						
			FEMALE	MALE	APPENDECTOMY	CHOLECYSTECOMY	LAPARATOMY	SIGMOIDECTOMY	INCISION AND DRAINAGE	EXPLORATORY LAPAROSCOPY	OTHER
074	6-Sep-76	26		1	1						
075	21-May-59	43	1				1				
079	1-Jan-60	41		1			1				
081	18-Mar-59	43		1	1						
084	30-Nov-65	35	1		1						
088	8-Jul-74	28	1		1						
090	16-Apr-66	34		1			1				
091	29-Dec-50	51		1			1				
093	28-Aug-52	50		1	1						
095	3-Nov-78	24	1		1						
097	6-Jun-74	28		1	1						
100	12-Oct-52	50	1		1						
	TOTAL	1917	13	37	18	1	25	1	0	5	0
	Mean	38.3		Std Deviation	15.4		Median	37.0		50	

Appendix C 4.2

RANDOM NUMBER	DEMOGRAPHIC DATA / TREATMENT GROUP B / ITT										
	DATE OF BIRTH	AGE	GENDER		NATURE OF SURGERY						
			FEMALE	MALE	APPENDECTOMY	CHOLECYSTECOMY	LAPARATOMY	SIGMOIDECTOMY	INCISION AND DRAINAGE	EXPLORATORY LAPAROSCOPY	OTHER
006	17-Nov-56	46		1			1				
008	05-Aug-69	33	1		1						
048	22-Jun-62	40		1			1				
052	17-Feb-52	50		1	1						
067	27-Jun-67	35		1			1				
077	19-Nov-22	80		1	1						
080	10-Mar-70	32		1						1	
001	12-Jul-30	71	1			1					
002	03-Jul-78	24		1			1				
011	15-May-58	44		1	1						
012	07-Jan-77	25		1	1						
013	28-Dec-58	44		1			1				
015	01-Aug-64	38		1			1				
017	11-Nov-82	30	1		1						
020	15-Jul-70	32		1		1					
023	31-Dec-54	48	1		1						
024	31-Mar-52	50		1	1						
026	24-Mar-72	30		1			1				
027	15-Nov-68	34		1			1				
029	08-Oct-63	39		1			1				
032	30-Apr-59	43		1			1				
033	29-Sep-68	34		1			1				
034	192/12/16	40		1			1				
035	05-Mar-23	79		1				1			
037	21-Sep-79	23		1	1						
039	15-Feb-65	37		1			1				
041	27-Jan-63	39	1				1				
043	13-Mar-83	19		1	1						
046	02-Mar-81	21	1				1				
050	02-Mar-74	28	1		1						
053	21-Jul-59	43		1			1				
056	14-Oct-73	29	1		1						
057	19-Dec-81	21		1			1				
058	28-Jul-53	49		1	1						
063	1-Jan-81	21		1			1				
064	21-Jan-81	21		1			1				
065	24-Oct-68	34		1			1				
069	23-Mar-74	28		1			1				
070	28-Jan-62	40		1			1				
076	31-Jul-79	22	1		1						

Appendix C 4.2

RANDOM NUMBER	DEMOGRAPHIC DATA / TREATMENT GROUP B / ITT											
	DATE OF BIRTH	AGE	GENDER		NATURE OF SURGERY							
			FEMALE	MALE	APPENDECTOMY	CHOLECYSTECOMY	LAPARATOMY	SIGMOIDECTOMY	INCISION AND DRAINAGE	EXPLORATORY LAPAROSCOPY	OTHER
082	1-Jan-76	25		1	1						
083	5-Apr-57	45	1		1						
086	8-Apr-51	51		1			1				
087	26-Jul-68	34		1	1		1				
089	4-Aug-78	23		1	1						
092	14-Mar-80	22		1						1	
094	6-Apr-46	56		1			1				
096	5-Jan-72	30	1		1						
098	23-Sep-64	38		1				1			
099	3-Apr-68	34		1			1				
	TOTAL	1854	11	39	19	2	26	2	0	2	0
	Mean	37.1		Std Deviation	13.9		Median	34.0		51	

Appendix C 5.1

RANDOM NUMBER	HOSPITALISATION / TREATMENT GROUP A / ITT						
	DATE ADMITTED TO HOSPITAL	DATE DISCHARGED FROM HOSPITAL	NUMBER OF DAYS IN ICU	COST R 3,017.90	NUMBER OF DAYS IN GENERAL WARD	COST R 733.00	TOTAL COST
003	20-Feb-01	08-Mar-01	0	R 0.00	17	R 12,461.00	**R 12,461.00**
004	22-Feb-01	01-Mar-01	0	R 0.00	8	R 5,864.00	**R 5,864.00**
004	28-Mar-01	02-Apr-01	0	R 0.00	3	R 2,199.00	**R 2,199.00**
005	15-Mar-01	28-Mar-01	14	R 42,250.60	0	R 0.00	**R 42,250.60**
005	28-Mar-01	02-Apr-01	0	R 0.00	3	R 2,199.00	**R 2,199.00**
007	26-Mar-01	05-Apr-01	0	R 0.00	11	R 8,063.00	**R 8,063.00**
009	07-Apr-01	12-Apr-01	0	R 0.00	6	R 4,398.00	**R 4,398.00**
010	09-Apr-01	10-Apr-01	0	R 0.00	6	R 4,398.00	**R 4,398.00**
014	06-May-01	14-May-01	0	R 0.00	9	R 6,597.00	**R 6,597.00**
014	21-May-01	28-May-01	0	R 0.00	8	R 5,864.00	**R 5,864.00**
016	12-May-01	21-May-01	0	R 0.00	10	R 7,330.00	**R 7,330.00**
016	24-May-01	03-Jun-01	0	R 0.00	11	R 8,063.00	**R 8,063.00**
018	15-May-01	22-May-01	0	R 0.00	8	R 5,864.00	**R 5,864.00**
019	15-May-01	24-May-01	0	R 0.00	8	R 5,864.00	**R 5,864.00**
021	28-May-01	20-Jun-01	0	R 0.00	24	R 17,592.00	**R 17,592.00**
022	30-May-01	03-Jun-01	0	R 0.00	5	R 3,665.00	**R 3,665.00**
025	19-Jun-01	28-Jun-01	0	R 0.00	10	R 7,330.00	**R 7,330.00**
028	03-Aug-01	07-Aug-01	0	R 0.00	5	R 3,665.00	**R 3,665.00**
030	14-Aug-01	21-Aug-01	0	R 0.00	8	R 5,864.00	**R 5,864.00**
031	23-Aug-01	30-Aug-01	0	R 0.00	8	R 5,864.00	**R 5,864.00**
036	13-Sep-01	26-Sep-01	0	R 0.00	14	R 10,262.00	**R 10,262.00**
038	28-Sep-01	01-Oct-01	0	R 0.00	4	R 2,932.00	**R 2,932.00**
040	06-Oct-01	25-Oct-01	0	R 0.00	20	R 14,660.00	**R 14,660.00**
042	18-Oct-01	20-Nov-01	0	R 0.00	34	R 24,922.00	**R 24,922.00**
044	20-Oct-01	26-Oct-01	0	R 0.00	7	R 5,131.00	**R 5,131.00**
045	20-Oct-01	26-Oct-01	0	R 0.00	7	R 5,131.00	**R 5,131.00**
047	28-Oct-01	08-Nov-01	0	R 0.00	12	R 8,796.00	**R 8,796.00**
049	04-Nov-01	08-Nov-01	0	R 0.00	5	R 3,665.00	**R 3,665.00**
051	11-Nov-01	21-Nov-01	0	R 0.00	11	R 8,063.00	**R 8,063.00**
054	18-Nov-01	24-Nov-01	0	R 0.00	7	R 5,131.00	**R 5,131.00**
055	19-Nov-01	26-Nov-01	0	R 0.00	8	R 5,864.00	**R 5,864.00**
055	05-Dec-01	05-Dec-01	0	R 0.00	1	R 733.00	**R 733.00**
059	09-Dec-01	14-Dec-01	0	R 0.00	6	R 4,398.00	**R 4,398.00**

Appendix C 5.1

RANDOM NUMBER	HOSPITALISATION / TREATMENT GROUP A / ITT						
	DATE ADMITTED TO HOSPITAL	DATE DISCHARGED FROM HOSPITAL	NUMBER OF DAYS IN ICU	COST R 3,017.90	NUMBER OF DAYS IN GENERAL WARD	COST R 733.00	TOTAL COST
060	10-Dec-01	17-Dec-01	0	R 0.00	8	R 5,864.00	**R 5,864.00**
061	15-Dec-01	21-Dec-01	0	R 0.00	7	R 5,131.00	**R 5,131.00**
062	16-Dec-01	21-Dec-01	0	R 0.00	6	R 4,398.00	**R 4,398.00**
066	04-Jan-02	10-Jan-02	0	R 0.00	7	R 5,131.00	**R 5,131.00**
068	10-Jan-02	11-Jan-02	0	R 0.00	2	R 1,466.00	**R 1,466.00**
068	12-Jan-02	17-Jan-02	6	R 18,107.40	0	R 0.00	**R 18,107.40**
068	18-Jan-02	21-Jan-02	0	R 0.00	4	R 2,932.00	**R 2,932.00**
071	22-Jan-02	29-Jan-02	0	R 0.00	8	R 5,864.00	**R 5,864.00**
072	22-Jan-02	28-Jan-02	0	R 0.00	7	R 5,131.00	**R 5,131.00**
073	23-Jan-02	04-Feb-02	0	R 0.00	13	R 9,529.00	**R 9,529.00**
073	07-Feb-02	15-Feb-02	0	R 0.00	9	R 6,597.00	**R 6,597.00**
074	29-Jan-02	04-Feb-02	0	R 0.00	7	R 5,131.00	**R 5,131.00**
075	17-Feb-02	26-Feb-02	0	R 0.00	10	R 7,330.00	**R 7,330.00**
078	22-Feb-02	24-Feb-02	0	R 0.00	3	R 2,199.00	**R 2,199.00**
078	25-Feb-02	12-Mar-02	15	R 45,268.50	0	R 0.00	**R 45,268.50**
079	23-Feb-02	03-Mar-02	0	R 0.00	9	R 6,597.00	**R 6,597.00**
081	26-Feb-02	05-Mar-02	0	R 0.00	8	R 5,864.00	**R 5,864.00**
084	12-Mar-02	26-Mar-02	0	R 0.00	14	R 10,262.00	**R 10,262.00**
085	16-Mar-02	22-Mar-02	0	R 0.00	7	R 5,131.00	**R 5,131.00**
088	02-Apr-02	07-Apr-02	0	R 0.00	6	R 4,398.00	**R 4,398.00**
090	20-Apr-02	25-Apr-02	0	R 0.00	6	R 4,398.00	**R 4,398.00**
091	29-Apr-02	08-May-02	0	R 0.00	10	R 7,330.00	**R 7,330.00**
091	09-May-02	18-May-03	10	R 30,179.00	0	R 0.00	**R 30,179.00**
093	11-May-02	16-May-02	0	R 0.00	6	R 4,398.00	**R 4,398.00**
095	20-Jun-02	25-Jun-02	0	R 0.00	6	R 4,398.00	**R 4,398.00**
095	06-Jul-02	10-Jul-02	0	R 0.00	5	R 3,665.00	**R 3,665.00**
097	24-Jul-02	30-Jul-02	0	R 0.00	7	R 5,131.00	**R 5,131.00**
100	02-May-02	12-May-02	0	R 0.00	11	R 8,063.00	**R 8,063.00**
TOTALS			**45**	**R 135,805.50**	**512**	**R 375,296.00**	**R 511,101.50**

RANDOM NUMBER	HOSPITALISATION / TREATMENT GROUP B / ITT						
	DATE ADMITTED TO HOSPITAL	DATE DISCHARGED FROM HOSPITAL	NUMBER OF DAYS IN ICU	COST R 3,017.90	NUMBER OF DAYS IN GENERAL WARD	COST R 733.00	TOTAL COST
001	30-Jan-01	27-Feb-01	0	R 0.00	29	R 21,257.00	R 21,257.00
001	18-Mar-01	20-Mar-01	0	R 0.00	3	R 2,199.00	R 2,199.00
002	20-Feb-01	24-Feb-01	0	R 0.00	5	R 3,665.00	R 3,665.00
006	26-Mar-01	03-Apr-01	3	R 9,053.70	0	R 0.00	R 9,053.70
006	04-Apr-01	09-Apr-01	0	R 0.00	10	R 7,330.00	R 7,330.00
006	10-Apr-01	23-Apr-01	0	R 0.00	14	R 10,262.00	R 10,262.00
008	29-Mar-01	17-Apr-01	20	R 60,358.00	0	R 0.00	R 60,358.00
011	10-Apr-01	19-Apr-01	0	R 0.00	10	R 7,330.00	R 7,330.00
012	14-Apr-01	19-Apr-01	0	R 0.00	6	R 4,398.00	R 4,398.00
013	30-Apr-01	09-May-01	0	R 0.00	10	R 7,330.00	R 7,330.00
015	08-May-01	16-May-01	0	R 0.00	9	R 6,597.00	R 6,597.00
017	14-May-01	20-May-01	0	R 0.00	7	R 5,131.00	R 5,131.00
020	20-May-01	29-May-01	0	R 0.00	10	R 7,330.00	R 7,330.00
023	10-Jun-01	15-Jun-01	0	R 0.00	6	R 4,398.00	R 4,398.00
024	19-Jun-01	27-Jun-01	0	R 0.00	9	R 6,597.00	R 6,597.00
026	30-Jun-01	07-Jul-01	0	R 0.00	8	R 5,864.00	R 5,864.00
027	02-Aug-01	08-Aug-08	0	R 0.00	8	R 5,864.00	R 5,864.00
029	09-Aug-01	20-Aug-01	0	R 0.00	12	R 8,796.00	R 8,796.00
032	23-Aug-01	30-Aug-01	0	R 0.00	8	R 5,864.00	R 5,864.00
033	09-Sep-01	15-Sep-01	0	R 0.00	7	R 5,131.00	R 5,131.00
034	12-Sep-01	18-Sep-01	0	R 0.00	7	R 5,131.00	R 5,131.00
035	12-Sep-01	26-Sep-02	0	R 0.00	15	R 10,995.00	R 10,995.00
037	26-Sep-01	01-Oct-01	0	R 0.00	6	R 4,398.00	R 4,398.00
039	30-Sep-01	07-Oct-01	0	R 0.00	8	R 5,864.00	R 5,864.00
041	10-Oct-01	23-Oct-01	0	R 0.00	14	R 10,262.00	R 10,262.00
043	18-Oct-01	24-Oct-01	0	R 0.00	3	R 2,199.00	R 2,199.00
046	23-Oct-01	30-Oct-01	8	R 24,143.20	0	R 0.00	R 24,143.20
046	31-Oct-01	06-Nov-01	0	R 0.00	7	R 5,131.00	R 5,131.00
048	29-Oct-01	14-Nov-01	0	R 0.00	17	R 12,461.00	R 12,461.00
050	07-Nov-01	12-Nov-01	0	R 0.00	12	R 8,796.00	R 8,796.00
052	16-Nov-01	17-Nov-01	0	R 0.00	2	R 1,466.00	R 1,466.00
053	18-Nov-01	24-Nov-01	0	R 0.00	7	R 5,131.00	R 5,131.00
056	26-Nov-01	01-Dec-01	0	R 0.00	6	R 4,398.00	R 4,398.00
057	02-Dec-01	09-Dec-01	0	R 0.00	8	R 5,864.00	R 5,864.00
058	08-Dec-01	15-Dec-01	0	R 0.00	8	R 5,864.00	R 5,864.00

Appendix C 5.2

RANDOM NUMBER	HOSPITALISATION / TREATMENT GROUP B / ITT						
	DATE ADMITTED TO HOSPITAL	DATE DISCHARGED FROM HOSPITAL	NUMBER OF DAYS IN ICU	COST R 3,017.90	NUMBER OF DAYS IN GENERAL WARD	COST R 733.00	TOTAL COST
063	16-Dec-01	26-Dec-01	0	R 0.00	11	R 8,063.00	R 8,063.00
064	17-Dec-01	22-Dec-01	0	R 0.00	6	R 4,398.00	R 4,398.00
065	02-Jan-01	07-Jan-02	0	R 0.00	6	R 4,398.00	R 4,398.00
067	05-Jan-02	08-Jan-02	0	R 0.00	4	R 2,932.00	R 2,932.00
069	12-Jan-02	18-Jan-02	0	R 0.00	7	R 5,131.00	R 5,131.00
070	14-Jan-02	19-Jan-02	0	R 0.00	6	R 4,398.00	R 4,398.00
076	18-Feb-02	26-Feb-02	0	R 0.00	9	R 6,597.00	R 6,597.00
077	19-Feb-02	25-Feb-02	0	R 0.00	7	R 5,131.00	R 5,131.00
080	23-Feb-02	01-Mar-02	0	R 0.00	7	R 5,131.00	R 5,131.00
082	06-Mar-02	11-Mar-02	0	R 0.00	6	R 4,398.00	R 4,398.00
083	09-Mar-02	15-Mar-02	0	R 0.00	7	R 5,131.00	R 5,131.00
083	16-Mar-02	25-Mar-02	0	R 0.00	10	R 7,330.00	R 7,330.00
086	17-Mar-02	23-Mar-02	0	R 0.00	7	R 5,131.00	R 5,131.00
087	29-Mar-02	03-Apr-02	0	R 0.00	6	R 4,398.00	R 4,398.00
087	22-Apr-02	24-Apr-02	0	R 0.00	3	R 2,199.00	R 2,199.00
089	16-Apr-02	25-Apr-02	0	R 0.00	9	R 6,597.00	R 6,597.00
092	08-May-02	14-May-02	0	R 0.00	7	R 5,131.00	R 5,131.00
094	08-Jun-02	15-Jun-02	0	R 0.00	8	R 5,864.00	R 5,864.00
096	08-Jul-02	14-Jul-02	0	R 0.00	7	R 5,131.00	R 5,131.00
098	10-Aug-02	19-Aug-02	0	R 0.00	10	R 7,330.00	R 7,330.00
099	10-Aug-02	18-Aug-02	0	R 0.00	9	R 6,597.00	R 6,597.00
TOTALS			**31**	**R 93,554.90**	**443**	**R 324,719.00**	**R 418,273.90**

Appendix C 6.1

RANDOM NUMBER	PROFESSIONAL FEE / TREATMENT GROUP A / ITT			
	Initial Visit	Hospital Visit	Final Visit	TOTAL COST
003	R 841.20	R 2,383.40	R 210.30	R 3,434.90
004	R 841.20	R 1,121.60	R 210.30	R 2,173.10
004	R 841.20	R 420.60	R 210.30	R 1,472.10
005	R 841.20	R 1,962.80	R 210.30	R 3,014.30
005	R 841.20	R 420.60	R 210.30	R 1,472.10
007	R 841.20	R 1,542.20	R 210.30	R 2,593.70
009	R 841.20	R 841.20	R 210.30	R 1,892.70
010	R 841.20	R 841.20	R 210.30	R 1,892.70
014	R 841.20	R 1,261.80	R 210.30	R 2,313.30
014	R 841.20	R 1,121.60	R 210.30	R 2,173.10
016	R 841.20	R 1,402.00	R 210.30	R 2,453.50
016	R 841.20	R 1,542.20	R 210.30	R 2,593.70
018	R 841.20	R 1,121.60	R 210.30	R 2,173.10
019	R 841.20	R 1,121.60	R 210.30	R 2,173.10
021	R 841.20	R 3,364.80	R 210.30	R 4,416.30
022	R 841.20	R 701.00	R 210.30	R 1,752.50
025	R 841.20	R 1,402.00	R 210.30	R 2,453.50
028	R 841.20	R 701.00	R 210.30	R 1,752.50
030	R 841.20	R 1,121.60	R 210.30	R 2,173.10
031	R 841.20	R 1,121.60	R 210.30	R 2,173.10
036	R 841.20	R 1,962.80	R 210.30	R 3,014.30
038	R 841.20	R 560.80	R 210.30	R 1,612.30
040	R 841.20	R 2,804.00	R 210.30	R 3,855.50
042	R 841.20	R 4,766.80	R 210.30	R 5,818.30
044	R 841.20	R 981.40	R 210.30	R 2,032.90
045	R 841.20	R 981.40	R 210.30	R 2,032.90
047	R 841.20	R 1,682.40	R 210.30	R 2,733.90
049	R 841.20	R 701.00	R 210.30	R 1,752.50
051	R 841.20	R 1,542.20	R 210.30	R 2,593.70
054	R 841.20	R 981.40	R 210.30	R 2,032.90
055	R 841.20	R 1,121.60	R 210.30	R 2,173.10
055	R 841.20	R 140.20	R 210.30	R 1,191.70
059	R 841.20	R 841.20	R 210.30	R 1,892.70
060	R 841.20	R 1,121.60	R 210.30	R 2,173.10
061	R 841.20	R 981.40	R 210.30	R 2,032.90
062	R 841.20	R 841.20	R 210.30	R 1,892.70
066	R 841.20	R 981.40	R 210.30	R 2,032.90
068	R 841.20	R 280.40	R 210.30	R 1,331.90
068	R 841.20	R 0.00	R 210.30	R 1,051.50
068	R 841.20	R 560.80	R 210.30	R 1,612.30
071	R 841.20	R 1,121.60	R 210.30	R 2,173.10
072	R 841.20	R 981.40	R 210.30	R 2,032.90
073	R 841.20	R 1,822.60	R 210.30	R 2,874.10
073	R 841.20	R 1,261.80	R 210.30	R 2,313.30
074	R 841.20	R 981.40	R 210.30	R 2,032.90
075	R 841.20	R 1,402.00	R 210.30	R 2,453.50
078	R 841.20	R 420.60	R 210.30	R 1,472.10
078	R 841.20	R 2,103.00	R 210.30	R 3,154.50
079	R 841.20	R 1,261.80	R 210.30	R 2,313.30
081	R 841.20	R 1,121.60	R 210.30	R 2,173.10
	R 841.20	R 0.00	R 210.30	R 1,051.50
081	R 841.20	R 1,121.60	R 210.30	R 2,173.10
084	R 841.20	R 1,962.80	R 210.30	R 3,014.30
	R 841.20	R 0.00	R 210.30	R 1,051.50
	R 841.20	R 0.00	R 210.30	R 1,051.50
	R 841.20	R 0.00	R 210.30	R 1,051.50
	R 841.20	R 0.00	R 210.30	R 1,051.50
	R 841.20	R 0.00	R 210.30	R 1,051.50

Appendix C 6.1

RANDOM NUMBER	PROFESSIONAL FEE / TREATMENT GROUP A / ITT			
	Initial Visit	Hospital Visit	Final Visit	TOTAL COST
	R 841.20	R 0.00	R 210.30	R 1,051.50
	R 841.20	R 0.00	R 210.30	R 1,051.50
	R 841.20	R 0.00	R 210.30	R 1,051.50
	R 841.20	R 0.00	R 210.30	R 1,051.50
	R 841.20	R 0.00	R 210.30	R 1,051.50
084	R 841.20	R 1,962.80	R 210.30	R 3,014.30
085	R 841.20	R 981.40	R 210.30	R 2,032.90
088	R 841.20	R 841.20	R 210.30	R 1,892.70
090	R 841.20	R 841.20	R 210.30	R 1,892.70
091	R 841.20	R 1,402.00	R 210.30	R 2,453.50
091	R 841.20	R 1,402.00	R 210.30	R 2,453.50
093	R 841.20	R 841.20	R 210.30	R 1,892.70
095	R 841.20	R 841.20	R 210.30	R 1,892.70
095	R 841.20	R 701.00	R 210.30	R 1,752.50
097	R 841.20	R 981.40	R 210.30	R 2,032.90
100	R 841.20	R 1,542.20	R 210.30	R 2,593.70
TOTALS	**R 62,248.80**	**R 77,250.20**	**R 15,562.20**	**R 155,061.20**

Appendix C 6.2

RANDOM NUMBER	PROFESSIONAL FEE / TREATMENT GROUP B / ITT			
	Initial Visit	Hospital Visit	Final Visit	TOTAL COST
001	R 841.20	R 4,065.80	R 210.30	R 5,117.30
001	R 841.20	R 420.60	R 210.30	R 1,472.10
002	R 841.20	R 701.00	R 210.30	R 1,752.50
006	R 841.20	R 420.60	R 210.30	R 1,472.10
006	R 841.20	R 1,402.00	R 210.30	R 2,453.50
006	R 841.20	R 1,962.80	R 210.30	R 3,014.30
008	R 841.20	R 2,804.00	R 210.30	R 3,855.50
011	R 841.20	R 1,402.00	R 210.30	R 2,453.50
012	R 841.20	R 841.20	R 210.30	R 1,892.70
013	R 841.20	R 1,402.00	R 210.30	R 2,453.50
015	R 841.20	R 1,261.80	R 210.30	R 2,313.30
017	R 841.20	R 981.40	R 210.30	R 2,032.90
020	R 841.20	R 1,402.00	R 210.30	R 2,453.50
023	R 841.20	R 841.20	R 210.30	R 1,892.70
024	R 841.20	R 1,261.80	R 210.30	R 2,313.30
026	R 841.20	R 1,121.60	R 210.30	R 2,173.10
027	R 841.20	R 1,121.60	R 210.30	R 2,173.10
029	R 841.20	R 1,682.40	R 210.30	R 2,733.90
032	R 841.20	R 1,121.60	R 210.30	R 2,173.10
033	R 841.20	R 981.40	R 210.30	R 2,032.90
034	R 841.20	R 981.40	R 210.30	R 2,032.90
035	R 841.20	R 2,103.00	R 210.30	R 3,154.50
037	R 841.20	R 841.20	R 210.30	R 1,892.70
039	R 841.20	R 1,121.60	R 210.30	R 2,173.10
041	R 841.20	R 1,962.80	R 210.30	R 3,014.30
043	R 841.20	R 420.60	R 210.30	R 1,472.10
046	R 841.20	R 1,121.60	R 210.30	R 2,173.10
046	R 841.20	R 981.40	R 210.30	R 2,032.90
048	R 841.20	R 2,383.40	R 210.30	R 3,434.90
050	R 841.20	R 1,682.40	R 210.30	R 2,733.90
052	R 841.20	R 280.40	R 210.30	R 1,331.90
053	R 841.20	R 981.40	R 210.30	R 2,032.90
056	R 841.20	R 841.20	R 210.30	R 1,892.70
057	R 841.20	R 1,121.60	R 210.30	R 2,173.10
058	R 841.20	R 1,121.60	R 210.30	R 2,173.10
063	R 841.20	R 1,542.20	R 210.30	R 2,593.70
064	R 841.20	R 841.20	R 210.30	R 1,892.70
065	R 841.20	R 841.20	R 210.30	R 1,892.70
067	R 841.20	R 560.80	R 210.30	R 1,612.30
069	R 841.20	R 981.40	R 210.30	R 2,032.90
070	R 841.20	R 841.20	R 210.30	R 1,892.70
076	R 841.20	R 1,261.80	R 210.30	R 2,313.30
077	R 841.20	R 981.40	R 210.30	R 2,032.90
080	R 841.20	R 981.40	R 210.30	R 2,032.90
082	R 841.20	R 841.20	R 210.30	R 1,892.70
083	R 841.20	R 981.40	R 210.30	R 2,032.90
083	R 841.20	R 1,402.00	R 210.30	R 2,453.50
086	R 841.20	R 981.40	R 210.30	R 2,032.90
087	R 841.20	R 841.20	R 210.30	R 1,892.70
087	R 841.20	R 420.60	R 210.30	R 1,472.10
089	R 841.20	R 1,261.80	R 210.30	R 2,313.30
092	R 841.20	R 981.40	R 210.30	R 2,032.90
094	R 841.20	R 1,121.60	R 210.30	R 2,173.10
096	R 841.20	R 981.40	R 210.30	R 2,032.90
098	R 841.20	R 1,402.00	R 210.30	R 2,453.50
099	R 841.20	R 1,261.80	R 210.30	R 2,313.30
TOTALS	**R 47,107.20**	**R 66,454.80**	**R 11,776.80**	**R 125,338.80**

Appendix C7.1

RANDOM NUMBER	STUDY MEDICATION / TREATMENT GROUP A7.1.1										CLINICAL EVALUATION DAY 5 -14	CONSUM-ABLES
	MOXIFLOXACIN IV				MOXIFLOXACIN TABLETS							
	DATE IV TREATEMENT STARTED	DATE IV TREATMENT STOPPED	NUMBER OF DOSES IV TREATMENT	COST	DATE ORAL TREATMENT STARTED	DATE ORAL TREATMENT STOPPED	NUMBER OF DOSES ORAL TREATMENT	NUMBER OF OUT PATIENT TREATMENT	COST	TOTAL COST		
003	23-Feb-02	01-Mar-01	7	R 1,827.42	NA	NA	0	0	R 0.00	R 1,827.42	Cure	R 109.04
004	23-Feb-01	28-Feb-01	6	R 1,566.36	NA	NA	0	0	R 0.00	R 1,566.36	Cure	R 109.04
005	15-Mar-01	22-Mar-01	8	R 2,088.48	NA	NA	0	0	R 0.00	R 2,088.48	Failure	R 109.04
007	26-Mar-01	30-Mar-01	5	R 1,305.30	NA	NA	0	0	R 0.00	R 1,305.30	Cure	R 109.04
009	07-Apr-01	10-Apr-01	4	R 1,044.24	11-Apr-01	11-Apr-01	1	0	R 30.54	R 1,074.78	Cure	R 109.04
010	09-Apr-01	13-Apr-01	5	R 1,305.30	NA	NA	0	0	R 0.00	R 1,305.30	Cure	R 109.04
014	07-May-01	09-May-01	3	R 783.18	10-May-01	12-May-01	3	0	R 91.62	R 874.80	Cure	R 109.04
016	13-May-01	18-May-01	6	R 1,566.36	19-May-01	20-May-01	2	0	R 61.08	R 1,627.44	Cure	R 109.04
018	15-May-01	19-May-01	5	R 1,305.30	20-May-01	22-May-01	3	0	R 91.62	R 1,396.92	Cure	R 109.04
019	16-May-01	22-May-01	7	R 1,827.42	23-May-01	24-May-01	2	0	R 61.08	R 1,888.50	Cure	R 109.04
021	29-May-01	30-May-01	2	R 522.12	NA	NA	0	0	R 0.00	R 522.12	Indeterminate	R 109.04
022	30-May-01	03-Jun-01	5	R 1,305.30	NA	NA	0	0	R 0.00	R 1,305.30	Cure	R 109.04
025	20-Jun-01	25-Jun-01	6	R 1,566.36	NA	NA	0	0	R 0.00	R 1,566.36	Cure	R 109.04
028	04-Aug-01	06-Aug-01	3	R 783.18	07-Aug-01	08-Aug-01	2	0	R 61.08	R 844.26	Cure	R 109.04
030	15-Aug-01	20-Aug-01	6	R 1,566.36	NA	NA	0	0	R 0.00	R 1,566.36	Cure	R 109.04
031	23-Aug-01	28-Aug-01	5	R 1,305.30	29-Aug-01	30-Aug-01	2	0	R 61.08	R 1,366.38	Cure	R 109.04
036	14-Sep-01	18-Sep-01	5	R 1,305.30	19-Sep-01	20-Sep-01	1	0	R 30.54	R 1,335.84	Cure	R 109.04
038	28-Sep-01	30-Sep-01	3	R 783.18	01-Oct-01	04-Oct-01	4	0	R 122.16	R 905.34	Cure	R 109.04
040	06-Oct-01	10-Oct-01	5	R 1,305.30	11-Oct-01	15-Oct-01	5	0	R 152.70	R 1,458.00	Cure	R 109.04
042	19-Oct-01	24-Oct-01	6	R 1,566.36	24-Oct-01	28-Oct-01	5	0	R 152.70	R 1,719.06	Failure	R 109.04
044	21-Oct-01	24-Oct-01	4	R 1,044.24	25-Oct-01	26-Oct-01	2	0	R 61.08	R 1,105.32	Cure	R 109.04
045	21-Oct-01	25-Oct-01	5	R 1,305.30	26-Oct-01	26-Oct-01	1	0	R 30.54	R 1,335.84	Cure	R 109.04
047	30-Oct-01	05-Nov-01	7	R 1,827.42	NA	NA	0	0	R 0.00	R 1,827.42	Cure	R 109.04
049	04-Nov-01	06-Nov-01	3	R 783.18	07-Nov-01	07-Nov-01	1	0	R 30.54	R 813.72	Cure	R 109.04
051	12-Nov-01	16-Nov-01	5	R 1,305.30	17-Nov-01	21-Nov-01	5	0	R 152.70	R 1,458.00	Cure	R 109.04
054	19-Nov-01	22-Nov-01	4	R 1,044.24	23-Nov-01	24-Nov-01	2	0	R 61.08	R 1,105.32	Cure	R 109.04
055	20-Nov-01	22-Nov-01	3	R 783.18	23-Nov-01	25-Nov-01	3	0	R 91.62	R 874.80	Cure	R 109.04
059	09-Dec-01	12-Dec-01	4	R 1,044.24	13-Dec-01	14-Dec-01	2	0	R 61.08	R 1,105.32	Cure	R 109.04
060	12-Dec-01	15-Dec-01	4	R 1,044.24	16-Dec-01	16-Dec-01	1	0	R 30.54	R 1,074.78	Cure	R 109.04
061	15-Dec-01	19-Dec-01	5	R 1,305.30	20-Dec-01	21-Dec-01	2	0	R 61.08	R 1,366.38	Cure	R 109.04
062	16-Dec-01	20-Dec-01	5	R 1,305.30	21-Dec-01	21-Dec-01	1	0	R 30.54	R 1,335.84	Cure	R 109.04
066	05-Jan-02	07-Jan-02	3	R 783.18	08-Jan-02	10-Jan-02	3	0	R 91.62	R 874.80	Cure	R 109.04
068	11-Jan-02	18-Jan-02	8	R 2,088.48	19-Jan-02	20-Jan-02	2	0	R 61.08	R 2,149.56	Cure	R 109.04
071	22-Jan-02	28-Jan-02	7	R 1,827.42	NA	NA	0	0	R 0.00	R 1,827.42	Cure	R 109.04
072	23-Jan-02	26-Jan-02	4	R 1,044.24	27-Jan-02	28-Jan-02	2	0	R 61.08	R 1,105.32	Cure	R 109.04
073	24-Jan-02	01-Feb-02	9	R 2,349.54	NA	NA	0	0	R 0.00	R 2,349.54	Cure	R 109.04
074	30-Jan-02	01-Feb-02	3	R 783.18	02-Feb-02	03-Feb-02	2	0	R 61.08	R 844.26	Cure	R 109.04
075	18-Feb-02	24-Feb-02	7	R 1,827.42	NA	NA	0	0	R 0.00	R 1,827.42	Cure	R 109.04
078	23-Feb-02	26-Feb-02	4	R 1,044.24	NA	NA	0	0	R 0.00	R 1,044.24	Failure	R 109.04
079	24-Feb-02	26-Feb-02	3	R 783.18	27-Feb-02	01-Mar-02	3	0	R 91.62	R 874.80	Cure	R 109.04
081	27-Feb-02	04-Mar-02	6	R 1,566.36	NA	NA	0	0	R 0.00	R 1,566.36	Cure	R 109.04
084	13-Mar-02	18-Mar-02	6	R 1,566.36	NA	NA	0	0	R 0.00	R 1,566.36	Indeterminate	R 109.04
085	18-Mar-02	20-Mar-02	3	R 783.18	21-Mar-02	22-Mar-02	2	0	R 61.08	R 844.26	Cure	R 109.04
088	03-Apr-02	05-Apr-02	3	R 783.18	06-Apr-02	07-Apr-02	2	0	R 61.08	R 844.26	Cure	R 109.04
090	21-Apr-02	23-Apr-02	3	R 783.18	24-Apr-02	25-Apr-02	2	0	R 61.08	R 844.26	Cure	R 109.04
091	01-May-02	07-May-02	7	R 1,827.42	NA	NA	0	0	R 0.00	R 1,827.42	Failure	R 109.04
093	12-May-02	14-May-02	3	R 783.18	15-May-02	16-May-02	2	0	R 61.08	R 844.26	Cure	R 109.04
095	20-Jun-02	23-Jun-02	4	R 1,044.24	24-Jun-02	25-Jun-02	2	0	R 61.08	R 1,105.32	Cure	R 109.04
097	25-Jul-02	28-Jul-02	4	R 1,044.24	29-Jul-02	30-Jul-02	2	0	R 61.08	R 1,105.32	Cure	R 109.04
100	02-May-02	09-May-02	8	R 2,088.48	NA	NA	0	0	R 0.00	R 2,088.48	Cure	R 109.04
TOTALS			246	R 64,220.76			72	0	R 2,260.00	R 66,480.76		R 5,452.00

TOTAL COST	R 71,932.76

Appendix C 7.2

RANDOM NUMBER	STUDY MEDICATION / TREATMENT GROUP B / ITT														CLINICAL EVALUATION DAY 5 -14	CONSUM- ABLES
	CEFTRIAXONE TREATMENT				METRONIDAZOLE TREATMENT				CO-AMOXICLAV TABLETS					TOTAL COST		
	DATE IV TREATEMENT STARTED	DATE IV TREATMENT STOPPED	NUMBER OF DOSES IV TREATMENT	COST	DATE IV TREATEMENT STARTED	DATE IV TREATMENT STOPPED	NUMBER OF DOSES IV TREATMENT	COST	DATE ORAL TREATMENT STARTED	DATE ORAL TREATMENT STOPPED	NUMBER OF DOSES ORAL TREATMENT	NUMBER OF OUT PATIENT TREATMENT	COST			
001	16-Feb-01	23-Feb-01	8	R 2,557.34	16-Feb-01	18-Feb-01	6	R 199.18	NA	NA	0	0	R 0.00	R 2,756.52	Cure	R 109.04
002	20-Feb-01	24-Feb-01	5	R 1,598.34	20-Feb-01	23-Feb-01	9	R 298.77	NA	NA	0	0	R 0.00	R 1,897.11	Cure	R 109.04
006	26-Mar-01	02-Apr-01	8	R 2,557.34	26-Mar-01	02-Apr-01	23	R 763.53	NA	NA	0	0	R 0.00	R 3,320.87	Failure	R 109.04
008	29-Mar-01	02-Apr-01	5	R 1,598.34	29-Mar-01	03-Apr-01	14	R 464.76	NA	NA	0	0	R 0.00	R 2,063.09	Failure	R 109.04
011	14-Apr-01	15-Apr-01	5	R 1,598.34	14-Apr-01	16-Apr-01	15	R 497.95	16-Apr-01	19-Apr-01	9	0	R 99.94	R 2,196.23	Cure	R 109.04
012	15-Apr-01	18-Apr-01	4	R 1,278.67	15-Apr-01	18-Apr-01	10	R 331.97	18-Apr-01	20-Apr-01	6	0	R 66.63	R 1,677.26	Cure	R 109.04
013	01-May-01	07-May-01	7	R 2,237.67	01-May-01	07-May-01	21	R 697.13	NA	NA	0	0	R 0.00	R 2,934.80	Cure	R 109.04
016	09-May-01	14-May-01	6	R 1,918.00	09-May-01	14-May-01	15	R 497.95	14-May-01	16-May-01	5	0	R 55.52	R 2,471.48	Cure	R 109.04
017	15-May-01	20-May-01	6	R 1,918.00	15-May-01	20-May-01	14	R 464.76	NA	NA	0	0	R 0.00	R 2,382.76	Cure	R 109.04
020	22-May-01	27-May-01	6	R 1,918.00	27-May-01	28-May-01	4	R 132.79	27-May-01	28-May-01	4	0	R 44.42	R 2,095.21	Cure	R 109.04
023	11-Jun-01	13-Jun-01	3	R 959.00	11-Jun-01	13-Jun-01	6	R 199.18	13-Jun-01	14-Jun-01	5	0	R 55.52	R 1,213.70	Cure	R 109.04
024	19-Jun-01	25-Jun-01	7	R 2,237.67	19-Jun-01	26-Jun-01	19	R 630.74	NA	NA	0	0	R 0.00	R 2,868.41	Cure	R 109.04
026	30-Jun-01	05-Jul-01	6	R 1,918.00	01-Jul-01	06-Jul-01	15	R 497.95	06-Jul-01	07-Jul-01	4	0	R 44.42	R 2,460.37	Cure	R 109.04
027	02-Aug-01	06-Aug-01	5	R 1,598.34	02-Aug-01	06-Aug-01	11	R 365.16	NA	NA	0	0	R 0.00	R 1,963.50	Cure	R 109.04
029	10-Aug-01	17-Aug-01	8	R 2,557.34	10-Aug-01	17-Aug-01	21	R 697.13	NA	NA	0	0	R 0.00	R 3,254.47	Cure	R 109.04
032	23-Aug-01	28-Aug-01	6	R 1,918.00	23-Aug-01	25-Aug-01	7	R 232.38	29-Aug-01	30-Aug-01	3	0	R 33.31	R 2,183.70	Cure	R 109.04
033	10-Sep-01	15-Sep-01	4	R 1,278.67	10-Sep-01	13-Sep-01	9	R 298.77	14-Sep-01	15-Sep-01	4	0	R 44.42	R 1,621.86	Cure	R 109.04
034	12-Sep-01	15-Sep-01	4	R 1,278.67	13-Sep-01	16-Sep-02	8	R 265.57	16-Sep-01	18-Sep-01	6	0	R 66.63	R 1,610.87	Cure	R 109.04
035	13-Aug-01	17-Aug-01	5	R 1,598.34	NA	NA	0	R 0.00	18-Aug-01	20-Aug-01	3	0	R 33.31	R 1,631.65	Cure	R 109.04
037	27-Sep-01	30-Sep-01	4	R 1,278.67	27-Sep-01	30-Sep-01	11	R 365.16	01-Sep-01	01-Sep-01	1	0	R 11.10	R 1,654.94	Cure	R 109.04
039	01-Oct-01	01-Oct-01	4	R 1,278.67	01-Oct-01	05-Oct-01	12	R 398.36	05-Oct-01	06-Oct-01	5	0	R 55.52	R 1,732.55	Cure	R 109.04
041	10-Oct-01	16-Oct-01	7	R 2,237.67	11-Oct-01	16 Oc 01	18	R 597.54	17-Oct-01	19-Oct-01	5	0	R 55.52	R 2,890.74	Cure	R 109.04
043	19-Oct-01	23-Oct-01	5	R 1,598.34	19-Oct-01	23-Oct-01	10	R 331.97	23-Oct-01	26-Oct-01	4	0	R 44.42	R 1,974.72	Cure	R 109.04
046	23-Oct-01	29-Oct-01	7	R 2,237.67	24-Oct-01	29-Oct-01	17	R 564.35	NA	NA	0	0	R 0.00	R 2,802.02	Failure	R 109.04
048	30-Oct-01	04-Nov-01	6	R 1,918.00	30-Oct-01	05-Nov-01	19	R 630.74	NA	NA	0	0	R 0.00	R 2,548.74	Failure	R 109.04
050	08-Nov-01	12-Nov-01	5	R 1,598.34	08-Nov-01	11-Nov-01	11	R 365.16	NA	NA	0	0	R 0.00	R 1,963.50	Cure	R 109.04
052	17-Nov-01	17-Nov-01	1	R 319.67	17-Nov-01	17-Nov-01	1	R 33.20	NA	NA	0	0	R 0.00	R 352.86	Death	R 109.04
053	19-Nov-01	22-Nov-01	4	R 1,278.67	19-Nov-01	22-Nov-01	9	R 298.77	23-Nov-01	23-Nov-01	1	0	R 11.10	R 1,588.55	Cure	R 109.04
056	27-Nov-01	29-Nov-01	3	R 959.00	27-Nov-01	30-Nov-01	9	R 298.77	30-Nov-01	01-Dec-01	4	0	R 44.42	R 1,302.19	Cure	R 109.04
057	03-Dec-01	07-Dec-01	5	R 1,598.34	03-Dec-01	07-Dec-01	12	R 398.36	NA	NA	0	0	R 0.00	R 1,996.70	Cure	R 109.04
058	09-Dec-01	14-Dec-01	6	R 1,918.00	09-Dec-01	14-Dec-01	16	R 531.15	NA	NA	0	0	R 0.00	R 2,449.15	Cure	R 109.04
063	17-Dec-01	25-Dec-01	9	R 2,877.01	17-Dec-01	25-Dec-01	22	R 730.33	NA	NA	0	0	R 0.00	R 3,607.34	Cure	R 109.04
064	18-Dec-01	20-Dec-01	3	R 959.00	18-Dec-01	21-Dec-01	8	R 265.57	21-Dec-01	22-Dec-01	3	0	R 33.31	R 1,257.89	Cure	R 109.04
065	02-Jan-02	05-Jan-02	4	R 1,278.67	N/A	N/A	0	R 0.00	06-Jan-02	07-Jan-02	3	0	R 33.31	R 1,311.98	Cure	R 109.04
067	05-Jan-02	07-Jan-02	3	R 959.00	05-Jan-02	08-Jan-02	8	R 265.57	08-Jan-02	08-Jan-02	1	0	R 11.10	R 1,235.68	Indeterminate	R 109.04
069	13-Jan-02	16-Jan-02	4	R 1,278.67	13-Jan-02	17-Jan-02	11	R 365.16	17-Jan-02	18-Jan-02	5	0	R 55.52	R 1,699.36	Cure	R 109.04
070	14-Jan-02	18-Jan-02	5	R 1,598.34	14-Jan-02	18-Jan-02	12	R 398.36	18-Jan-02	19-Jan-02	4	0	R 44.42	R 2,041.12	Cure	R 109.04
076	19-Feb-02	22-Feb-02	4	R 1,278.67	19-Feb-02	22-Feb-02	10	R 331.97	22-Feb-02	26-Feb-02	11	0	R 122.15	R 1,732.79	Cure	R 109.04
077	20-Feb-02	24-Feb-02	5	R 1,598.34	20-Feb-02	24-Feb-02	14	R 464.76	NA	NA	0	0	R 0.00	R 2,063.09	Indeterminate	R 109.04
080	24-Feb-02	27-Feb-02	4	R 1,278.67	24-Feb-02	28-Feb-02	12	R 398.36	28-Feb-02	01-Mar-02	4	0	R 44.42	R 1,721.45	Cure	R 109.04
082	07-Mar-02	09-Mar-02	3	R 959.00	07-Mar-02	09-Mar-02	9	R 298.77	10-Mar-02	11-Mar-02	4	0	R 44.42	R 1,302.19	Cure	R 109.04
083	10-Mar-02	14-Mar-02	5	R 1,598.34	10-Mar-02	14-Mar-02	12	R 398.36	14-Mar-02	15-Mar-02	4	0	R 44.42	R 2,041.12	Cure	R 109.04
086	18-Mar-02	20-Mar-02	3	R 959.00	18-Mar-02	21-Mar-02	9	R 298.77	21-Mar-02	23-Mar-02	6	0	R 66.63	R 1,324.40	Cure	R 109.04
087	29-Mar-02	02-Apr-02	4	R 1,278.67	30-Mar-02	02-Apr-02	9	R 298.77	02-Apr-02	02-Apr-02	1	0	R 11.10	R 1,588.55	Cure	R 109.04
089	16-Apr-02	25-Apr-02	6	R 1,918.00	17-Apr-02	23-Apr-02	16	R 531.15	23-Apr-02	25-Apr-02	6	0	R 66.63	R 2,515.78	Cure	R 109.04
092	09-May-02	12-May-02	4	R 1,278.67	09-May-02	13-May-02	12	R 398.36	13-May-02	14-May-02	3	0	R 33.31	R 1,710.34	Cure	R 109.04
094	09-Jun-02	13-Jun-02	5	R 1,598.34	09-Jun-02	13-Jun-02	12	R 398.36	13-Jun-02	15-Jun-02	6	0	R 66.63	R 2,063.32	Cure	R 109.04
096	09-Jul-02	11-Jul-02	3	R 959.00	09-Jul-02	12-Jul-02	8	R 265.57	12-Jul-02	14-Jul-02	6	0	R 66.63	R 1,291.20	Cure	R 109.04
098	11-Aug-02	15-Aug-02	5	R 1,598.34	11-Aug-02	16-Aug-02	15	R 497.95	NA	NA	0	0	R 0.00	R 2,096.29	Cure	R 109.04
099	11-Aug-02	15-Aug-02	5	R 1,598.34	11-Aug-02	16-Aug-02	14	R 464.76	16-Aug-02	18-Aug-02	5	0	R 55.52	R 2,118.61	Cure	R 109.04
TOTALS			249	R 79,597.18			581	R 19,420.13			141	0	R 1,565.71	R 100,583.03		R 5,452.00

TOTAL COST	R 106,035.03

Appendix C 8.1

RANDOM NUMBER	THERAPEUTIC ADJUNCTIONS / TREATMENT GROUP A / ITT				
	THERAPEUTIC ADJUNCTIONS	UNITS	START DATE	STOP DATE	COST
003	Nasogastric Tube	1	22-Feb-01	23-Feb-01	**R 16.30**
003	Urinary Catheter	1	22-Feb-01	23-Feb-01	**R 23.46**
004	Nasogastric Tube	1	23-Feb-01	25-Feb-01	**R 16.30**
004	Urinary Catheter	1	23-Feb-01	25-Feb-01	**R 23.46**
005	Central Venous Catheter	1	15-Mar-01	25-Mar-01	**871.13**
005	Chest Physiotherapy	1	15-Mar-01	28-Mar-01	**R 1,913.10**
005	Nasogastric Tube	1	15-Mar-01	16-Mar-01	**R 16.30**
005	Oxygen Face Mask	1	17-Mar-01	26-Mar-01	**R 50.00**
005	Oxygen Face Mask	1	15-Mar-01	17-Mar-01	**R 50.00**
005	Oxygen Face Mask	1	23-Mar-01	28-Mar-01	**R 50.00**
005	Urinary Catheter	1	15-Mar-01	28-Mar-01	**R 23.46**
007	Urinary Catheter	1	26-Mar-01	04-Apr-01	**R 23.46**
009	Chest Physiotherapy	1	07-Apr-01	09-Apr-01	**R 409.95**
009	Nasogastric Tube	1	06-Apr-01	07-Apr-01	**R 16.30**
009	Urinary Catheter	1	06-Apr-01	08-Arp-01	**R 23.46**
010	Chest Physiotherapy	1	10-Apr-01	12-Apr-01	**R 409.95**
010	Nasogastric Tube	1	09-Apr-01	09-Apr-01	**R 16.30**
010	Urinary Catheter	1	08-Apr-01	09-Apr-01	**R 23.46**
014	Nasogastric Tube	1	06-May-01	07-May-01	**R 16.30**
014	Urinary Catheter	1	06-May-01	07-May-01	**R 23.46**
016	Central Venous Catheter	1	13-May-01	20-May-01	**871.13**
016	Oxygen Face Mask	1	13 Ma y 01	13-May-01	**R 50.00**
016	urinary catheter	1	13-May-01	19-May-01	**R 23.46**
018	Urinary Catheter	1	15-May-01	17-May-01	**R 23.46**
019	Nasogastric Tube	1	16-May-01	18-May-01	**R 16.30**
019	Oxygen Face Mask	1	16-May-01	17-May-01	**R 50.00**
019	Urinary catheter	1	16-May-01	18-May-01	**R 23.46**
021	Urinary Catheter	1	29-May-01	01-Jun-01	**R 23.46**
022	NA	0	NA	NA	**R 0.00**
025	Nasogastric Tube	1	19-Jun-01	21-Jun-01	**R 16.30**
025	Urinary Catheter	1	20-Jun-01	21-Jun-01	**R 23.46**
028	Urinary Catheter	1	03-Aug-01	04-Aug-01	**R 23.46**
030	Nasogastric Tube	1	14-Aug-01	17-Aug-01	**R 16.30**
030	Urinary Catheter	1	14-Aug-01	16-Aug-01	**R 23.46**
031	Urinary Catheter	1	23-Aug-01	24-Aug-01	**R 23.46**
036	Nasogastric Tube	1	13-Aug-01	17-Aug-01	**R 16.30**
036	Oxygen Face Mask	1	14-Aug-01	16-Aug-01	**R 50.00**
036	Urinary Catheter	1	13-Aug-01	16-Aug-01	**R 23.46**
038	NA	0	NA	NA	**R 0.00**
040	Chest tubes	1	03-Oct-01	15-Oct-01	**R 87.52**
040	Packed Red cells	4	06-Oct-01	NA	**R 2,100.00**
040	Urinary Catheter	1	06-Oct-01	09-Oct-01	**R 23.46**
042	Nasogastrlc Tube	1	19-Oct-01	22-Oct-01	**R 16.30**
042	Packed Red cells	2	19-Oct-01	19-Oct-01	**R 1,050.00**
042	Urinary Catheter	1	19-Oct-01	22-Oct-01	**R 23.46**
042	Urinary Catheter	1	28-Oct-01	03-Nov-01	**R 23.46**
044	Nasogastric Tube	1	21-Nov-01	22-Nov-01	**R 16.30**
044	Urinary catheter	1	21-Nov-01	22-Nov-01	**R 23.46**
045	Urinary Catheter	1	21-Nov-01	22-Nov-01	**R 23.46**
047	Nasogastric Tube	1	30-Oct-01	31-Oct-01	**R 16.30**
047	Nasogastric Tube	1	03-Nov-01	05-Nov-01	**R 16.30**
047	Urinary Catheter	1	30-Oct-01	30-Oct-01	**R 23.46**
049	NA	0	NA	NA	**R 0.00**
051	Central Venous Catheter	1	12-Nov-01	13-Nov-01	**871.13**
051	Nasogastric Tube	1	11-Nov-01	14-Nov-01	**R 16.30**

Appendix C 8.1

RANDOM NUMBER	THERAPEUTIC ADJUNCTIONS / TREATMENT GROUP A / ITT				
	THERAPEUTIC ADJUNCTIONS	UNITS	START DATE	STOP DATE	COST
051	Oxygen Face Mask	1	12-Nov-01	12-Nov-01	**R 50.00**
051	Urinary Catheter	1	11-Nov-01	13-Nov-01	**R 23.46**
054	Nasogastric Tube	1	19-Nov-01	22-Nov-01	**R 16.30**
054	Packed Red cells	4	19-Nov-01	19-Nov-01	**R 2,100.00**
054	Urinary Catheter	1	19-Nov-01	20-Nov-01	**R 23.46**
055	Nasogastric Tube	1	20-Nov-01	20-Nov-01	**R 16.30**
055	Urinary Catheter	1	20-Nov-01	21-Nov-01	**R 23.46**
059	Oxygen Face Mask	1	09-Dec-01	10-Dec-01	**R 50.00**
059	Urinary Catheter	1	09-Dec-01	10-Dec-01	**R 23.46**
060	Nasogastric Tube	1	12-Dec-01	12-Dec-01	**R 16.30**
060	Urinary Catheter	1	12-Dec-01	12-Dec-01	**R 23.46**
061	Chest Tubes	1	15-Dec-01	18-Dec-01	**R 87.52**
061	Nasogastric Tube	1	15-Dec-01	16-Dec-01	**R 16.30**
061	Oxygen Face Mask	1	15-Dec-01	16-Dec-01	**R 50.00**
061	Urinary Catheter	1	15-Dec-01	17-Dec-01	**R 23.46**
062	Central Venous Catheter	1	16-Dec-01	17-Dec-01	**871.13**
062	Urinary Catheter	1	16-Dec-01	18-Dec-01	**R 23.46**
066	NA	0	NA	NA	**R 0.00**
068	Nasogastric tube	1	11-Jan-02	16-Jan-02	**R 16.30**
068	Oxygen Face Mask	1	12-Jan-02	16-Jan-02	**R 50.00**
068	Oxygen Face mask	1	12-Jan-02	12-Jan-02	**R 50.00**
068	Oxygen Face mask	1	16-Jan-02	19-Jan-02	**R 50.00**
068	Urinary Catheter	1	11-Jan-02	19-Jan-02	**R 23.46**
071	Nasogastric Tube	1	22-Jan-02	24-Jan-02	**R 16.30**
071	Oxygen Face Mask	1	22-Jan-02	23-Jan-02	**R 50.00**
071	Urinary Catheter	1	22-Jan-02	24-Jan-02	**R 23.46**
072	Urinary Catheter	1	23-Jan-02	24-Jan-02	**R 23.46**
073	Chest tubes	1	24-Jan-02	29-Jan-02	**R 87.52**
073	Nasogastric Tube	1	24-Jan-02	25-Jan-02	**R 16.30**
073	Nasogastric Tube	1	30-Jan-02	31-Jan-02	**R 16.30**
073	Nasogastric Tube	1	08-Feb-02	10-Feb-02	**R 16.30**
073	Packed Red cells	2	23-Jan-02	24-Jan-02	**R 1,050.00**
073	Urinary Catheter	1	23-Jan-02	25-Jan-02	**R 23.46**
073	Urinary Catheter	1	08-Feb-02	11-Feb-02	**R 23.46**
074	Urinary Catheter	1	31-Jan-02	31-Jan-02	**R 23.46**
075	Nasogastric tube	1	18-Feb-02	20-Feb-02	**R 16.30**
075	Urinary Catheter	1	18-Feb-02	20-Feb-02	**R 23.46**
078	Fresh frozen plasma	2	26-Feb-02	26-Feb-02	**R 1,560.00**
078	Packed Red cells	2	26-Feb-02	26-Feb-02	**R 1,050.00**
079	Nasogastric Tube	1	23-Feb-02	25-Feb-02	**R 16.30**
079	Oxygen Face mask	1	25-Feb-02	25-Feb-02	**R 50.00**
079	Urinary catheter	1	24-Feb-02	25-Feb-02	**R 23.46**
081	Urinary Catheter	1	27-Feb-02	28-Feb-02	**R 23.46**
084	Nasogastric Tube	1	20-Mar-02	21-Mar-02	**R 16.30**
084	Urinary Catheter	1	13-Mar-02	14-Mar-02	**R 23.46**
084	Urinary Catheter	1	20-Mar-02	24-Mar-02	**R 23.46**
085	Oxygen Face Mask	1	18-Mar-02	18-Mar-02	**R 50.00**
085	Urinary Catheter	1	18-Mar-02	18-Mar-02	**R 23.46**
088	Urinary Catheter	1	03-Apr-02	04-Apr-02	**R 23.46**
090	Nasogastric Tube	1	21-Apr-02	22-Apr-02	**R 16.30**
090	Urinary Catheter	1	20-Apr-02	22-Apr-02	**R 23.46**
091	Chest Tubes	1	15-May-02	Ongoing	**R 87.52**
091	Dialisis Catheter	1	16-May-02	Ongoing	**R 1,649.31**
091	Fresh Frozen Plasma	4	15-May-02	15-May-02	**R 3,120.00**
091	Fresh Frozen Plasma	2	16-May-02	16-May-02	**R 1,560.00**

Appendix C 8.1

RANDOM NUMBER	THERAPEUTIC ADJUNCTIONS / TREATMENT GROUP A / ITT				
	THERAPEUTIC ADJUNCTIONS	UNITS	START DATE	STOP DATE	COST
091	Nasogastric Tube	1	01-May-02	03-May-02	**R 16.30**
091	Nasogastric Tube	1	10-May-02	Ongoing	**R 16.30**
091	Packed Red cells	2	15-May-02	15-May-02	**R 1,050.00**
091	Packed Red cells	4	17-May-02	17-May-02	**R 1,050.00**
091	Urinary Catheter	1	01-May-02	03-May-02	**R 23.46**
091	Urinary Catheter	1	10-May-02	Ongoing	**R 23.46**
093	Oxygen Face Mask	1	12-May-02	12-May-02	**R 50.00**
093	Urinary Catheter	1	12-May-02	13-May-02	**R 23.46**
095	Nasogastric Tube	1	06-Jul-02	08-Jul-02	**R 16.30**
095	Oxygen Face Mask	1	20-Jun-02	20-Jun-02	**R 50.00**
095	Urinary Catheter	1	20-Jun-02	21-Jun-02	**R 23.46**
097	Urinary Catheter	1	25-Jul-02	26-Jul-02	**R 23.46**
100	Urinary Catheter	1	02-May-02	03-May-02	**R 23.46**
100	Urinary Catheter	1	04-May-02	08-May-02	**R 23.46**
TOTAL					**R 26,435.21**

Appendix C 8.2

RANDOM NUMBER	THERAPEUTIC ADJUNCTIONS / TREATMENT GROUP B / ITT				
	THERAPEUTIC ADJUNCTIONS	UNITS	START DATE	STOP DATE	COST
001	Central Venous Catheter		16-Feb-01	23-Feb-01	R 871.13
002	Nasogastric Tube		20-Feb-01	21-Feb-01	R 16.30
002	Urinary Catheter		19-Feb-01	21-Feb-01	R 23.46
006	Arterial Catheter		04-Apr-01	10-Apr-01	R 303.18
006	Chest Tube	Left & right	26-Mar-01	01-Apr-01	R 87.52
006	Nasal C-pap		04-Apr-01	10-Apr-01	R 765.36
006	Nasogastric Tube		26-Apr-01	26-Apr-01	R 16.30
006	Nasogastric Tube		03-Apr-01	10-Apr-01	R 16.30
006	Oxygen Face Mask		26-Mar-01	23-Apr-01	R 50.00
006	Oxygen Face Mask		10-Apr-01	16-Apr-01	R 50.00
006	Urinary Catheter		26-Apr-01	26-Apr-01	R 23.46
008	Arterial Catheter		29-Mar-01	17-Apr-01	R 303.18
008	Central Venous Catheter		29-Mar-01	17-Apr-01	R 971.13
008	Nasogastric Tube		29-Mar-01	17-Apr-01	R 16.30
008	Oxygen Face Mask		31-Mar-01	17-Apr-01	R 50.00
008	Oxygen Face Mask		29-Mar-01	31-Mar-01	R 50.00
008	Urinary catheter		29-Mar-01	17-Apr-01	R 23.46
011	Urinary Catheter		11-Apr-01	12-Apr-01	R 23.46
012	Nasogastric Tube		15-Apr-01	15-Apr-01	R 16.30
012	Urinary catheter		15-Apr-01	15-Apr-01	R 23.46
013	Nasogastric Tube		01-May-01	02-May-01	R 16.30
013	Urinary catheter		30-Apr-01	03-May-01	R 23.46
015	Urinary Catheter		09-May-01	10-May-01	R 23.46
017	NA		NA	NA	R 0.00
020	Nasogastric Tube		22-May-01	23-May-01	R 16.30
020	Urinary catheter		22-May-01	23-May-01	R 23.46
023	Urinary Catheter		11-Jun-01	12-Jun-01	R 23.46
024	Nasogastric Tube		19-Jun-01	20-Jun-01	R 16.30
024	Oxygen Face Mask		19-Jun-01	24-Jun-01	R 50.00
024	Urinary Catheter		19-Jun-01	20-Jun-01	R 23.46
026	Chest Tube	Left & right	30-Jun-01	06-Jun-01	R 84.52
026	Nasogastric tube		20-Jun-01	01-Jul-01	R 16.30
026	Urinary Catheter		30-Jun-01	02-Jul-01	R 23.46
027	Nasogastric Tube		02-Aug-01	03-Aug-01	R 16.30
027	Urinary Catheter		02-Aug-01	03-Aug-01	R 23.46
029	Nasogastric Tube		09-Aug-01	11-Aug-01	R 16.30
029	Nasogastric Tube		15-Aug-01	18-Aug-01	R 16.30
029	Urinary Catheter		09-Aug-01	11-Aug-01	R 23.46
032	Urinary Catheter		23-Aug-01	24-Aug-01	R 23.46
033	Oxygen Face Mask		10-Aug-01	10-Aug-01	R 50.00
033	Urinary Catheter		10-Aug-01	11-Aug-01	R 23.46
034	Urinary Catheter		12-Aug-01	14-Aug-01	R 23.46
035	Urinary Catheter		13-Aug-01	18-Aug-01	R 23.46
037	NA		NA	NA	R 0.00
039	Urinary Catheter		01-Oct-01	02-Oct-01	R 23.46
043	NA		NA	NA	R 0.00
046	Central Venous Catheter		23-Oct-01	NA	R 871.13
046	Fresh frozen plasma	3	23-Oct-01	25-Oct-01	R 2,340.00
046	Nasogastric tube		23-Oct-01	01-Nov-01	R 16.30
046	Oxygen Face Mask		29-Oct-01	03-Nov-01	R 50.00
046	Urinary catheter		22-Oct-01	01-Nov-01	R 23.46
048	Chest Tube	Left & right	02-Nov-01	13-Nov-01	R 87.52
048	Nasogastric Tube		29-Oct-01	31-Oct-01	R 16.30
048	Oxygen Face Mask		02-Nov-01	22-Nov-01	R 50.00
048	Urinary Catheter		29-Oct-01	31-Oct-01	R 23.46
050	Urinary Catheter		08-Nov-01	09-Nov-01	R 23.46
052	Urinary Catheter		17-Nov-01	17-Nov-01	R 23.46
053	Nasogastric Tube		19-Nov-01	20-Nov-01	R 16.30
053	Urinary Catheter		19-Nov-01	20-Nov-01	R 23.46
056	NA		NA	NA	R 0.00
056	NA		NA	NA	R 0.00
057	Urinary Catheter		03-Dec-01	04-Dec-01	R 23.46
057	Urinary Catheter		03-Dec-01	04-Dec-01	R 23.46
058	Urinary Catheter		09-Dec-01	10-Dec-01	R 23.46

Appendix C 8.2

RANDOM NUMBER	THERAPEUTIC ADJUNCTIONS / TREATMENT GROUP B / ITT				
	THERAPEUTIC ADJUNCTIONS	UNITS	START DATE	STOP DATE	COST
058	Urinary Catheter		09-Dec-01	10-Dec-01	R 23.46
063	Nasogastric Tube		17-Dec-01	18-Dec-01	R 16.30
063	Urinary Catheter		16-Dec-01	18-Dec-01	R 23.46
064	Chest Tube	Left	18-Dec-01	20-Dec-01	R 43.76
064	Chest Tube	Right	18-Dec-01	21-Dec-01	R 43.76
064	Nasogastric tube		18-Dec-01	19-Dec-01	R 16.30
064	Oxygen Face Mask		18-Dec-01	20-Dec-01	R 50.00
064	Urinary catheter		18-Dec-01	19-Dec-01	R 23.46
065	Urinary Catheter		02-Jan-02	03-Jan-02	R 23.46
067	Urinary Catheter		05-Jan-02	06-Jan-02	R 23.46
069	Oxygen Face Mask		14-Jan-02	16-Jan-02	R 50.00
069	Urinary Catheter		12-Jan-02	14-Jan-02	R 23.46
070	Nasogastric tube		14-Jan-02	15-Jan-02	R 16.30
070	Oxygen Face Mask		15-Jan-02	18-Jan-02	R 50.00
070	Oxygen Face Mask		14-Jan-02	15-Jan-02	R 50.00
070	Urinary catheter		14-Jan-02	15-Jan-02	R 23.46
076	Nasogastric tube		19-Feb-02	20-Feb-02	R 16.30
076	Urinary Catheter		19-Feb-02	20-Feb-02	R 23.46
077	Oxygen Face Mask		20-Feb-02	20-Feb-02	R 50.00
077	Urinary catheter		20-Feb-02	21-Feb-02	R 23.46
080	Urinary catheter		24-Feb-02	25-Feb-02	R 23.46
082	NA		NA	NA	R 0.00
083	Oxygen Face Mask		10-Mar-02	11-Mar-02	R 50.00
086	Urinary Catheter		18-Mar-02	19-Mar-02	R 23.46
087	Urinary Catheter		30-Mar-02	31-Mar-02	R 23.46
089	NA		NA	NA	R 0.00
092	Arterial Catheter		08-May-02	13-May-02	R 303.18
092	Nasogastric Tube		08-May-02	11-May-02	R 16.30
092	Urinary Catheter		09-May-02	10-May-02	R 23.46
094	Nasogastric Tube		09-Jun-02	11-Jun-02	R 16.30
094	Oxygen Face Mask		09-Jun-02	10-Jun-02	R 50.00
094	Urinary Catheter		09-Jun-02	10-Jun-02	R 23.46
096	NA		NA	NA	R 0.00
098	Oxygen Face Mask		11-Aug-02	12-Aug-02	R 50.00
098	Urinary Catheter		10-Aug-02	12-Aug-02	R 23.46
099	Arterial Catheter		11-Aug-02	12-Aug-02	R 303.18
099	Central Venous Catheter		11-Aug-02	12-Aug-02	R 871.13
099	Urinary Catheter		11-Aug-02	12-Aug-02	R 23.46
TOTAL					R 10,377.30

APPENDIX D: PER PROTOCOL POPULATION GROUP A AND GROUP B

APPENDIX D 1.1: Adverse events treatment group A
APPENDIX D 1.2: Adverse events treatment group B

APPENDIX D 2.1: Concomitant antimicrobial medication treatment group A
APPENDIX D 2.2: Concomitant antimicrobial medication treatment group B

APPENDIX D 3.1: Concomitant medication treatment group A
APPENDIX D 3.2: Concomitant medication treatment group B

APPENDIX D 4.1: Demographic data treatment group A
APPENDIX D 4.2: Demographic data treatment group B

APPENDIX D 5.1: Hospitalisation treatment group A
APPENDIX D 5.2: Hospitalisation treatment group B

APPENDIX D 6.1: Professional fees treatment group A
APPENDIX D 6.2: Professional fees treatment group B

APPENDIX D 7.1: Study medication treatment group A
APPENDIX D 7.2: Study medication treatment group B

APPENDIX D 8.1: Therapeutic adjunctions treatment group A
APPENDIX D 8.2: Therapeutic adjunctions treatment group B

Appendix D 1.1

RANDOM NUMBER	ADVERSE EVENTS / TREATMENT GROUP A / PPP		
	ADVERSE EVENT	START DATE	STOP DATE
003	Wound Infection	01-Mar-01	08-Mar-01
014	Incomplete small bowel obstruction	17-May-01	28 Ma y 01
	Vomiting	05-Jun-01	05-Jun-01
018	Haemoptysis	18-May-01	18-May-01
036	Woung Sepsis	18-Aug-01	30-Aug-01
042	Subphrenic abscess	25-Oct-01	28-Oct-01
	Viginal candidasis	06-Nov-01	08-Nov-01
049	Headache	04-Nov-01	04-Nov-01
055	Abdomen and thigh Urticaria	22-Nov-01	26-Nov-01
068	Adult respiratory distress syndrome	12-Jan-02	18-Jan-02
079	Enterocutaneous Fistula	07-Mar-02	18-Mar-02
	Multiple organ dysfunction syndrome	14-May-02	Ongoing
095	Small bowel obstruction	06-Jul-02	09-Jul-02

Appendix D 1.2

RANDOM NUMBER	ADVERSE EVENTS / TREATMENT GROUP B / PPP		
	ADVERSE EVENT	START DATE	STOP DATE
001	Abdominal Pain	17-Mar-01	19-Mar-01
013	Otitis Externa	22-May-01	ongoing
029	Gastril Stasis	13-Aug-01	17-Aug-01
056	Partial Dehiscence- Appendeltmy wound	08-Dec-01	04-Jan-02
	Thrumboplebitis	30-Nov-01	01-Dec-01
070	Perianal abscess	17-Jan-02	17-Jan-02
087	Diarrheoa	19-Apr-02	21-Apr-02
	Bronchitis	19-Apr-02	24-Apr-02
	Wound Abscess	22-Apr-02	24-Apr-02
089	Central Venuos Cetheter	17-Apr-02	23-Apr-02
	Nasogastric Tube	17-Apr-02	22-Apr-02
	Urinary Atheter	17-Apr-02	22-Apr-02
	Oxygen Facemask	17-Apr-02	22-Apr-02
099	Superficial laparotomy wound infection	04-Sep-02	11-Sep-02

Appendix D 2.1

RANDOM NUMBER	CONCOMITANT ANTI MICROBIAL MEDICATION / TREATMENT GROUP A / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	START DATE	STOP DATE	COST	CONSUM-ABLES
003	Gentamycin	160	mg	IV	22-Feb-01	22-Feb-01	R 255.98	R 0.92
003	Flagyl	500	mg	IV	22-Feb-01	22-Feb-01	R 33.20	R 0.92
004	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
007	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
009	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
010	Zinacef	1.5	g	IV	08-Apr-01	08-Apr-01	R 82.51	R 0.92
010	Flagyl	500	mg	IV	08-Apr-01	08-Apr-01	R 33.20	R 0.92
014	Kefzol	2	g	IV	06-May-01	06-May-01	R 247.84	R 0.92
018	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
019	Augmentin	1.2	g	IV	16-May-01	16-May-01	R 53.28	R 0.92
022	Zinacef	1.5	g	IV	30-May-01	30-May-01	R 82.51	R 0.92
022	Flagyl	500	mg	IV	30-May-01	30-May-01	R 33.20	R 0.92
025	Zinacef	1.5	mg	IV	20-Jun-01	20-Jun-01	R 82.51	R 0.92
025	Flagyl	500	mg	IV	20-Jun-01	20-Jun-01	R 33.20	R 0.92
028	Augmentin	2.4	g	IV	03-Aug-01	03-Aug-01	R 106.56	R 0.92
028	Flagyl	1000	mg	IV	03-Aug-01	03-Aug-01	R 66.40	R 0.92
030	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
031	Kefzol	1	g	IV	23-Aug-01	23-Aug-01	R 123.92	R 0.92
036	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
038	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
042	Augmentin	1.2	g	IV	18-Oct-01	18-Oct-01	R 53.28	R 0.92
042	Flagyl	500	mg	IV	18-Oct-01	18-Oct-01	R 33.20	R 0.92
042	Penicillin G	1	mu	IV	19-Oct-01	19-Oct-01	R 29.94	R 0.92
042	Gentamycin	240	mg	IV	19-Oct-01	19-Oct-01	R 383.97	R 0.92
042	Gentamycin	240	mg	IV	28-Oct-01	04-Nov-01	R 3,071.76	R 0.92
042	Flagyl	400-1200	mg	PO	28-Oct-01	01-Nov-01	R 49.65	R 0.00
042	Penicillin G	4-16	mu	IV	29-Oct-01	04-Nov-01	R 209.58	R 0.92
042	Ciprobay	250-500	mg	PO	10-Nov-01	15-Nov-01	R 164.22	R 0.00
042	Penicillin G	12-16	12-16	PO	06-Nov-01	07-Nov-01	R 59.88	R 0.00
042	Gentamycin	240	mg	IV	06-Nov-01	07-Nov-01	R 767.94	R 0.92
042	Penicillin G	4-12	mu	IV	09-Nov-01	10-Nov-01	R 59.88	R 0.92
042	Gentamycin	240	mg	IV	09-Nov-01	09-Nov-01	R 383.97	R 0.92
042	Flagyl	400-1200	mg	PO	03-Nov-01	15-Nov-01	R 129.09	R 0.00
044	Zinacef	750	mg	IV	20-Nov-01	21-Nov-01	R 94.90	R 0.92
044	Flagyl	500	mg	IV	20-Nov-01	20-Nov-01	R 33.20	R 0.92
045	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
049	Augmentin	1.2	g	IV	04-Nov-01	04-Nov-01	R 53.28	R 0.92
051	Augmentin	1.2	g	IV	11-Nov-01	11-Nov-01	R 53.28	R 0.92
051	Mandokef	1	g	IV	11-Nov-01	11-Nov-01	R 119.31	R 0.92
054	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
055	Augmentin	1.2	g	IV	20-Nov-01	20-Nov-01	R 53.28	R 0.92
059	Zinacef	1.5	g	IV	09-Dec-01	09-Dec-01	R 82.51	R 0.92
059	Flagyl	1000	mg	IV	09-Dec-01	09-Dec-01	R 66.40	R 0.92
059	Kefzol	1	g	IV	09-Dec-01	09-Dec-01	R 123.92	R 0.92
060	Kefzol	1	g	IV	12-Dec-01	12-Dec-01	R 123.92	R 0.92
060	Augmentin	1.2	g	IV	11-Dec-01	12-Dec-01	R 106.56	R 0.92
061	Zinacef	1.5	g	IV	15-Dec-01	15-Dec-01	R 82.51	R 0.92
061	Flagyl	1000	mg	IV	15-Dec-01	15-Dec-01	R 66.40	R 0.92
061	Kefzol	1	g	IV	15-Dec-01	15-Dec-01	R 123.92	R 0.92
062	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
066	Flagyl	500	mg	IV	05-Jan-02	05-Jan-02	R 33.20	R 0.92
068	Amoxil	750	mg	PO	07-Jan-02	10-Jan-02	R 26.52	R 0.00
071	Flagyl	1000	mg	IV	22-Jan-02	22-Jan-02	R 66.40	R 0.92
071	Gentamycin	240	mg	IV	22-Jan-02	22-Jan-02	R 383.97	R 0.92
071	Penicillin G	2	mu	IV	22-Jan-02	22-Jan-02	R 29.94	R 0.92
072	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
074	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
075	Augmentin	2.4	g	IV	18-Feb-02	18-Feb-02	R 106.56	R 0.92
075	Flagyl	1000	mg	IV	18-Feb-02	18-Feb-02	R 66.40	R 0.92
079	Zinacef	1.5	mg	IV	23-Feb-02	23-Feb-02	R 82.51	R 0.92
079	Flagyl	4	g	IV	23-Feb-02	23-Feb-02	R 132.80	R 0.92
079	Cefuroxime	4.5	g	IV	24-Feb-02	24-Feb-02	R 247.53	R 0.92
079	Flagyl	500	mg	IV	24-Feb-02	24-Feb-02	R 33.20	R 0.92
081	Augmentin	1.2	g	IV	26-Feb-02	27-Feb-02	R 106.56	R 0.92
081	Flagyl	500	mg	IV	26-Feb-02	27-Feb-02	R 66.40	R 0.92
081	Augmentin	1.2	g	IV	13-Mar-02	13-Mar-02	R 53.28	R 0.92
081	Augmentin	1.2-3.6	g	IV	22-Mar-02	28-Mar-02	R 1,118.88	R 0.92
088	Augmentin	1.2	g	IV	03-Apr-02	03-Apr-02	R 53.28	R 0.92
090	Zinacef	1.5-3	mg	IV	20-Apr-02	21-Apr-02	R 330.04	R 0.92
090	Flagyl	500-1000	mg	IV	20-Apr-02	21-Apr-02	R 132.80	R 0.92
091	Augmentin	1.2-3.6	g	IV	29-Apr-02	30-Apr-02	R 310.68	R 0.92
091	Flagyl	500-1500	mg	IV	29-Apr-02	30-Apr-02	R 199.20	R 0.92
091	Gentamycin	240	mg	IV	09-May-02	13-May-02	R 1,919.85	R 0.92
091	Tazocin	4.5-18	g	IV	09-May-02	15-May-02	R 8,591.80	R 0.92
091	Amikacin	1	g	IV	14-May-02	14-May-02	R 1,359.00	R 0.92
091	Amikacin	1	g	IV	17-May-02	17-May-02	R 1,359.00	R 0.92
091	Tienam	1.5-2	g	IV	15-May-02	17-May-02	R 1,716.72	R 0.92
091	Fluconazole	200	mg	IV	15-May-02	17-May-02	R 495.42	R 0.92
091	Amfoteracin B	50	mg	IV	17-May-02	17-May-02	R 215.46	R 0.92
093	Augmentin	3.6	g	IV	12-May-02	12-May-02	R 159.84	R 0.92
093	Flagyl	1500	mg	IV	12-May-02	12-May-02	R 99.60	R 0.92
095	Augmentin	1.2	g	IV	20-Jun-02	20-Jun-02	R 53.28	R 0.92

Appendix D 2.1

RANDOM NUMBER	CONCOMITANT ANTI MICROBIAL MEDICATION / TREATMENT GROUP A / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	START DATE	STOP DATE	COST	CONSUM-ABLES
097	Augmentin	1.2	mg	IV	25-Jul-02	25-Jul-02	R 53.28	R 0.92
097	Flagyl	500	mg	IV	25-Jul-02	25-Jul-02	R 33.20	R 0.92
100	Augmentin	2.4	g	IV	02-May-02	02-May-02	R 106.56	R 0.92
100	Flagyl	1000	mg	IV	02-May-02	02-May-02	R 66.40	R 0.92
TOTAL							R 27,623.62	R 83.48

Appendix D 2.2

RANDOM NUMBER	CONCOMITANT ANITMICROBIAL MEDICATION / TREATMENT GROUP B / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	START DATE	STOP DATE	COST	CONSUM-ABLES
001	Amikacin	500	mg	IV	14-Feb-01	14-Feb-01	R 679.50	R 0.92
001	Claforan	1	g	IV	14-Feb-01	14-Feb-01	R 143.15	R 0.92
002	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
011	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
012	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
013	Zinacef	1.5	mg	IV	30-Apr-01	30-Apr-01	R 82.51	R 0.92
013	Flagyl	500	mg	IV	30-Apr-01	30-Apr-01	R 33.20	R 0.92
015	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
017	Augmentin	1.2	g	IV	15-May-01	15-May-01	R 53.28	R 0.92
020	Augmentin	1.2	g	IV	22-May-01	22-May-01	R 53.28	R 0.92
023	Pennicillin G	4	mu	IV	10-Jun-01	10-Jun-01	R 29.46	R 0.92
023	Gentamycin	240	mg	IV	10-Jun-01	10-Jun-01	R 383.97	R 0.92
023	Flagyl	1	g	PR	10-Jun-01	10-Jun-01	R 66.40	R 0.00
024	Augmentin	1.2	g	IV	19-Jun-01	19-Jun-01	R 53.28	R 0.92
024	Flagyl	500	mg	IV	19-Jun-01	19-Jun-01	R 33.20	R 0.92
026	Ampicillin	1	g	IV	30-Jul-01	30-Jul-01	R 23.65	R 0.92
027	Zinacef	1.5	g	IV	02-Aug-01	02-Aug-01	R 82.51	R 0.92
027	Flagyl	1000	mg	IV	02-Aug-01	01-Aug-01	R 132.80	R 0.92
029	Flagyl	500	mg	IV	09-Aug-01	09-Aug-01	R 33.20	R 0.92
029	Augmentin	1.2	g	IV	09-Aug-01	09-Aug-01	R 53.28	R 0.92
032	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
033	Zinacef	1.5	g	IV	10-Sep-01	10-Sep-01	R 82.51	R 0.92
033	Flagyl	1500	mg	IV	10-Sep-01	10-Sep-01	R 99.60	R 0.92
033	Augmentin	1.2	g	IV	10-Sep-01	10-Sep-01	R 53.28	R 0.92
033	Kefzol	1	g	PO	10-Sep-01	10-Sep-01	R 123.92	R 0.00
034	Zinacef	1.5	g	IV	12-Sep-01	12-Sep-01	R 82.51	R 0.92
034	Flagyl	500	mg	IV	12-Sep-01	12-Sep-01	R 33.20	R 0.92
035	Zinacef	750	mg	IV	12-Sep-01	12-Sep-01	R 41.26	R 0.92
035	Flagyl	500	mg	IV	12-Sep-01	12-Sep-01	R 33.20	R 0.92
037	Zinacef	750	mg	IV	27-Oct-01	27-Oct-01	R 41.26	R 0.92
037	Flagyl	500	mg	IV	27-Oct-01	27-Oct-01	R 33.20	R 0.92
037	Augmentin	1.2	g	IV	27-Oct-01	27-Oct-01	R 53.28	R 0.92
039	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
041	Zinacef	1.5	g	IV	10-Oct-01	10-Oct-01	R 82.51	R 0.92
041	Flagyl	1000	mg	IV	10-Oct-01	10-Oct-01	R 66.40	R 0.92
043	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
046	Augmentin	1.2	g	IV	23-Oct-01	23-Oct-01	R 53.28	R 0.92
046	Cefepime	2-4	g	IV	29-Oct-01	04-Nov-01	R 1,575.00	R 0.92
046	Gentamycin	240	mg	IV	29-Oct-01	03-Nov-01	R 2,303.82	R 0.92
046	Mandokef	1	g	IV	22-Oct-01	22-Oct-01	R 119.31	R 0.92
050	Augmentin	1.2	g	IV	07-Nov-01	07-Nov-01	R 53.28	R 0.92
053	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
056	Augmentin	1.2	g	IV	27-Nov-01	27-Nov-01	R 53.28	R 0.92
056	Flagyl	500	mg	IV	27-Nov-01	27-Nov-01	R 33.20	R 0.92
057	Kefzol	1	g	IV	03-Dec-01	03-Dec-01	R 123.92	R 0.92
057	Flagyl	500	mg	IV	03-Dec-01	03-Dec-01	R 33.20	R 0.92
058	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
063	Zinacef	1.5	g	IV	16-Dec-01	16-Dec-01	R 82.51	R 0.92
063	Flagyl	500	mg	IV	16-Dec-01	16-Dec-01	R 33.20	R 0.92
063	Kefzol	1	g	IV	17-Dec-01	17-Dec-01	R 123.92	R 0.92
064	Kefzol	1	g	IV	17-Dec-01	17-Dec-01	R 123.92	R 0.92
065	NA	NA	NA	NA	NA	NA	R 0.00	R 0.00
069	Zinacef	1.5	g	IV	12-Jan-02	12-Jan-02	R 82.51	R 0.92
039	Flagyl	500	mg	IV	12-Jan-02	12-Jan-02	R 33.20	R 0.92
070	Augmentin	1.2	g	IV	14-Jan-02	14-Jan-02	R 53.28	R 0.92
076	Ampicillin	1	g	IV	19-Feb-02	19-Feb-02	R 23.65	R 0.92
076	Gentamycin	240	mg	IV	19-Feb-02	19-Feb-02	R 383.97	R 0.92
076	Flagyl	1000	mg	IV	19-Feb-02	19-Feb-02	R 66.40	R 0.92
076	Kefzol	1	g	IV	19-Feb-02	19-Feb-02	R 123.92	R 0.92
082	Augmentin	1.2	g	IV	07-Mar-02	07-Mar-02	R 53.28	R 0.92
083	Kefzol	1	g	IV	10-Mar-02	10-Mar-02	R 1,323.23	R 0.92
083	Flagyl	500	mg	IV	10-Mar-02	10-Mar-02	R 33.20	R 0.92
083	Augmentin	3.6	mg	PO	25-Mar-02	29-Mar-02	R 799.20	R 0.00
086	Zinacef	1.5-3.0	g	IV	17-Mar-02	18-Mar-02	R 330.04	R 0.92
086	Flagyl	500-1000	mg	IV	17-Mar-02	18-Mar-02	R 132.80	R 0.92
087	Augmentin	1.2	g	IV	29-Mar-02	30-Mar-02	R 106.56	R 0.92
087	Augmentin	1.2-4.8	g	IV	22-Apr-02	24-Apr-02	R 639.36	R 0.92
089	Augmentin	1.2	g	IV	17-Apr-02	17-Apr-02	R 53.28	R 0.92
089	Betadine	1	applic	TOP	18-Apr-02	18-Apr-02	R 45.37	R 0.00
092	Augmentin	1.2	g	IV	08-May-02	08-May-02	R 53.28	R 0.92
092	Flagyl	500	mg	IV	08-May-02	08-May-02	R 33.20	R 0.92
094	Augmentin	1.2	g	IV	08-Jun-02	09-Jun-02	R 106.56	R 0.92
094	Flagyl	500	mg	IV	08-Jun-02	09-Jun-02	R 66.40	R 0.92

Appendix D 2.2

RANDOM NUMBER	CONCOMITANT ANITMICROBIAL MEDICATION / TREATMENT GROUP B / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	START DATE	STOP DATE	COST	CONSUM-ABLES
096	Augmentin	1.2	g	IV	09-Jul-02	09-Jul-02	**R 53.28**	**R 0.92**
096	Flagyl	500	mg	IV	09-Jul-02	09-Jul-02	**R 33.20**	**R 0.92**
098	Kefzol	1	g	IV	11-Aug-02	11-Aug-02	**R 123.92**	**R 0.92**
098	Flagyl	500	mg	IV	11-Aug-02	11-Aug-02	**R 33.20**	**R 0.92**
099	Zinacef	1.5	g	IV	11-Aug-02	11-Aug-02	**R 82.51**	**R 0.92**
099	Flagyl	500	mg	IV	11-Aug-02	11-Aug-02	**R 33.20**	**R 0.92**
099	Amoxicillin	1500	mg	PO	04-Sep-02	09-Sep-02	**R 89.46**	**R 0.00**
TOTAL							**R 12,466.10**	**R 59.80**

Appendix D 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
003	Pethedine	150 - 300	mg	IM	R 53.40	23-Feb-01	27-Feb-01	**R 119.92**
	Maxalon	10	mg	IM	R 21.36	23-Feb-01	24-Feb-01	**R 6.88**
	Dolorol Forte	1016 - 2032	mg	PO	R 0.00	27-Feb-01	01-Mar-01	**R 11.28**
	Dolorol Forte	1016	mg	PO	R 0.00	08-Mar-01	12-Mar-01	**R 9.40**
004	Morphine	20-30	mg	IM	R 53.40	23-Feb-01	27-Feb-01	**R 106.31**
	Dolorol Forte	2032	mg	PO	R 0.00	26-Feb-01	26-Feb-01	**R 3.76**
	Doxyfene	2	tabs	PO	R 0.00	28-Feb-01	28-Feb-01	**R 7.19**
007	Morphine	10-30	mg	IM	R 53.40	26-Mar-01	30-Mar-01	**R 106.31**
009	Morphine	20-40	mg	IM	R 42.72	07-Apr-01	10-Apr-01	**R 113.40**
010	Morphine	10-20	mg	IM	R 42.72	09-Apr-01	12-Apr-01	**R 56.70**
	Berotec	1.25-3.75	mg	INH	R 0.00	11-Apr-01	13-Apr-01	**R 50.35**
	Atrovent	0.5-1.5	mg	INH	R 0.00	11-Apr-01	13-Apr-01	**R 95.75**
014	Morphine	10-20	mg	IM	R 42.72	07-May-01	10-May-01	**R 56.70**
	Dolorol Forte	1016-2032	mg	PO	R 0.00	09-May-01	12-May-01	**R 15.04**
	Pethedine	0-50	mg	IM	R 64.08	21-May-01	26-May-01	**R 44.30**
018	Morphine	10-30	mg	IM	R 74.76	15-May-01	21-May-01	**R 148.83**
	Pethedine	50	mg	IM	R 32.04	15-May-01	17-May-01	**R 22.14**
	Tetanus toxoid	0.5	ml	IM	R 3.56	13-May-01	13-May-01	**R 35.68**
	Nimbex	8	mg	IV	R 19.39	15-May-01	15-May-01	**R 198.78**
	Neostigmine	2.5	mg	IV	R 0.92	15-May-01	15-May-01	**R 6.54**
	Robinul	0.6	mg	IV	R 0.92	15-May-01	15-May-01	**R 220.59**
019	Morphine	20-30	mg	IV	R 19.39	17-May-01	18-May-01	**R 42.52**
	Dolorol Forte	1016-2032	mg	PO	R 0.00	19-May-01	22-May-01	**R 15.04**
022	Ventolin	5-25	mg	INH	R 0.00	30-May-01	03-Jun-01	**R 76.61**
	Atrovent	0.25-1.25	mg	INH	R 0.00	30-May-01	03-Jun-01	**R 132.98**
	Morphine	10-40	mg	IM	R 53.40	30-May-01	03-Jun-01	**R 141.75**
	Valium	10	mg	PO	R 0.00	03-Jun-01	03-Jun-01	**R 11.72**
	Valium	20	mg	IM	R 3.56	03-Jun-01	03-Jun-01	**R 23.45**
	Pethedine	50	mg	IM	R 3.56	03-Jun-01	03-Jun-01	**R 7.38**

Appendix D 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
	Pethedine	75	mg	IM	R 3.56	30-May-01	30-May-01	**R 14.03**
	Tetanus toxoid	0.5	ml	IM	R 3.56	30-May-01	30-May-01	**R 35.68**
025	Morphine	20-40	mg	IV	R 19.39	20-Jun-01	25-Jun-01	**R 170.10**
	Maxalon	10	mg	IM	R 3.56	21-Jun-01	21-Jun-01	**R 6.99**
	Maxalon	10	mg	IM	R 3.56	23-Jun-01	23-Jun-01	**R 6.88**
028	Morphine	10	mg	IM	R 32.04	03-Aug-01	05-Aug-01	**R 21.27**
	Stemetil	12.5	mg	IM	R 3.56	05-Aug-01	05-Aug-01	**R 9.19**
	Brufen	1200	mg	PO	R 0.00	07-Aug-01	16-Aug-01	**R 31.19**
	Dolorol Forte	2032	mg	PO	R 0.00	07-Aug-01	12-Aug-01	**R 22.56**
030	Pethedine	75	mg	IM	R 3.56	15-Aug-01	15-Aug-01	**R 14.03**
	Morphine	10-20	mg	IM	R 3.56	15-Aug-01	15-Aug-01	**R 14.18**
	Stemetil	12.5	mg	IM	R 3.56	17-Aug-01	17-Aug-01	**R 9.19**
	Heparin	10000	iu	SC	R 64.08	15-Aug-01	20-Aug-01	**R 83.88**
	Tagamet	400-800	mg	IV	R 19.39	15-Aug-01	20-Aug-01	**R 88.92**
	Losec	20	mg	PO	R 0.00	21-Aug-01	continuing	**R 393.77**
031	Morphine	10-30	mg	IM	R 53.40	23-Aug-01	27-Aug-01	**R 106.35**
	Stemetil	12.5	mg	IM	R 3.56	24-Aug-01	24-Aug-01	**R 9.19**
	Lamictin	400	g	PO	R 0.00	23-Aug-01	30-Aug-01	**R 103.84**
036	Stemetil	25	mg	IM	R 3.56	14-Sep-01	14-Sep-01	**R 18.38**
	Morphine	10-50	mg	IM	R 85.44	14-Sep-01	21-Sep-01	**R 283.60**
	Lasix	5-10	mg	IV	R 19.39	15-Sep-01	18-Sep-01	**R 22.36**
	Losec	200	mg	PO	R 0.00	17-Sep-01	18-Oct-01	**R 449.92**
	Isordil	0.5	mg	SL	R 0.00	17-Sep-01	26-Sep-01	**R 7.18**
	Amytryptiline	25	mg	PO	R 0.00	13-Sep-01	26-Sep-01	**R 15.49**
	Stemetil	12.5	mg	IM	R 21.36	22-Sep-01	23-Sep-01	**R 18.38**
038	Morphine	10-30	mg	IM	R 21.36	28-Oct-01	29-Oct-01	**R 42.54**
042	Morphine	10-20	mg	IM	R 74.76	19-Oct-01	25-Oct-01	**R 99.26**
	Berotec	1.25-3.75	mg	INH	R 0.00	19-Oct-01	10-Nov-01	**R 385.71**
	Atrovent	0.5-1.5	mg	INH	R 0.00	19-Oct-01	10-Nov-01	**R 734.16**

Appendix D 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
	Lasix	20-40	mg	PO	R 0.00	23-Oct-01	16-Nov-01	**R 95.29**
	Maxalon	10	mg	IM	R 3.56	27-Oct-01	27-Oct-01	**R 6.88**
	Dolorol Forte	1016	mg	PO	R 0.00	29-Oct-01	29-Oct-01	**R 1.88**
	Pethedine	50-100	mg	IM	R 42.72	27-Oct-01	30-Oct-01	**R 31.98**
	Heparin	5000-20000	iu	SC	R 74.76	31-Oct-01	06-Nov-01	**R 195.72**
	Isordil	5	mg	SL	R 0.00	30-Oct-01	30-Oct-01	**R 0.72**
	Canestan Cream	UNK	UNK	PV	R 0.00	06-Nov-01	08-Nov-01	**R 167.22**
	Maxalon	10-20	mg	IM	R 42.72	31-Oct-01	03-Nov-01	**R 55.01**
	Dolorol Forte	1016	mg	PO	R 0.00	31-Oct-01	31-Oct-01	**R 1.88**
	Dolorol Forte	1016-4064	mg	PO	R 0.00	03-Nov-01	15-Nov-01	**R 97.76**
	Morphine	20	mg	SC	R 32.04	28-Oct-01	30-Oct-01	**R 42.54**
	Morphine	10-40	mg	IM	R 117.48	01-Nov-01	11-Nov-01	**R 311.96**
	Maxalon	10	mg	IM	R 21.36	05-Nov-01	06-Nov-01	**R 6.88**
	Maxalon	20-30	mg	PO	R 0.00	09-Nov-01	10-Nov-01	**R 9.54**
	Maxalon	20	mg	PO	R 0.00	12-Nov-01	13-Nov-01	**R 6.36**
	Maxalon	10	mg	PO	R 0.00	15-Nov-01	15-Nov-01	**R 1.59**
	Senokot	4	tabs	PO	R 0.00	13-Nov-01	13-Nov-01	**R 1.76**
044	Morphine	15-60	mg	IM	R 53.40	21-Nov-01	25-Nov-01	**R 212.70**
045	Morphine	20-30	mg	IV	R 19.39	21-Oct-01	23-Oct-01	**R 63.81**
	Dolorol Forte	3048	mg	PO	R 0.00	24-Oct-01	25 Oct 01	**R 11.28**
049	Amiloretic	55	mg	PO	R 0.00	04-Nov-01	08-Nov-01	**R 33.50**
	Premarin	0.625	mg	PO	R 0.00	04-Nov-01	08-Nov-01	**R 71.81**
	Dolorol Forte	2032	mg	PO	R 0.00	07-Nov-01	07-Nov-01	**R 3.76**
051	Berotec	2.5-7.5	mg	INH	R 0.00	12-Nov-01	19-Nov-01	**R 179.01**
	Atrovent	0.75-2.25	mg	INH	R 0.00	12-Nov-01	19-Nov-01	**R 382.99**
	Losec	20	mg	PO	R 0.00	16-Nov-01	continuing	**R 393.77**
	Dolorol forte	1016-3048	mg	PO	R 0.00	17-Nov-01	20-Nov-01	**R 22.56**
	Morphine	10-20	mg	IM	R 42.72	12-Nov-01	15-Nov-01	**R 56.72**
054	Dolorol Forte	1016-2032	mg	PO	R 0.00	22-Nov-01	24-Nov-01	**R 11.28**

Appendix D 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
	Morphine	10	mg	IM	R 32.04	19-Nov-01	21-Nov-01	**R 21.27**
055	Pethedine	150-200	mg	IM	R 32.04	20-Nov-01	22-Nov-01	**R 47.97**
	Tagamet	400-1200	mg	PO	R 0.00	20-Nov-01	22-Nov-01	**R 66.66**
	Losec	20	mg	PO	R 0.00	22-Nov-01	continuing	**R 393.77**
	Phenargan	10-30	mg	PO	R 0.00	22-Nov-01	26-Nov-01	**R 7.10**
	Dolorol Forte	1016	mg	PO	R 0.00	24-Nov-01	26-Nov-01	**R 5.64**
	Morphine	10-40	mg	IM	R 32.04	10-Dec-01	12-Dec-01	**R 85.08**
	Stemetil	12.5	mg	IM	R 3.56	14-Dec-01	14-Dec-01	**R 9.19**
	Valium	10-20	mg	PO	R 0.00	11-Dec-01	13-Dec-01	**R 70.35**
059	Morphine	10-40	mg	IM	R 32.04	10-Dec-01	12-Dec-01	**R 85.08**
	Stemetil	12.5	mg	IM	R 3.56	14-Dec-01	14-Dec-01	**R 9.19**
	Valium	10-20	mg	PO	R 0.00	11-Dec-01	13-Dec-01	**R 70.35**
	Dolorol Forte	1016	mg	PO	R 0.00	14-Dec-01	14-Dec-01	**R 1.88**
060	Pethedine	100-300	mg	IM	R 74.76	10-Dec-01	16-Dec-01	**R 167.89**
	Atrovent	0.25-1	mg	INH	R 0.00	11-Dec-01	16-Dec-01	**R 127.66**
	Berotec	1.25-5	mg	INH	R 0.00	11-Dec-01	16-Dec-01	**R 134.26**
061	Morphine	20-30	mg	IM	R 53.40	15-Dec-01	19-Dec-01	**R 106.35**
	Berotec	1.25-5	mg	INH	R 0.00	17-Dec-01	21-Dec-01	**R 111.88**
	Atrovent	0.25-1	mg	INH	R 0.00	17-Dec-01	21-Dec-01	**R 106.38**
	Dulcolax	10	mg	PR	R 0.00	21-Dec-01	21-Dec-01	**R 4.14**
	Dolorol	3	g	PO	R 0.00	21-Dec-01	21-Dec-01	**R 2.76**
062	Morphine	10-50	mg	IM	R 32.04	17-Dec-01	19-Dec-01	**R 106.35**
	Serepax	10	mg	PO	R 0.00	19-Dec-01	20-Dec-01	**R 1.42**
	Panado	1000-2000	mg	PO	R 0.00	20-Dec-01	21-Dec-01	**R 4.28**
066	Morphine	20	mg	IM	R 3.56	06-Jan-02	06-Jan-02	**R 14.18**
	Dolorol Forte	1016-2032	mg	PO	R 0.00	06-Jan-02	09-Jan-02	**R 15.04**
068	Morphine	10-30	mg	IM	R 21.36	11-Jan-02	12-Jan-02	**R 42.54**
	Morphine	10-50	mg	IV	R 19.39	12-Jan-02	17-Jan-02	**R 212.70**
	Panado	30-60	ml	PO	R 0.00	12-Jan-02	16-Jan-02	**R 17.64**

Appendix D 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
	Heparin	5000-15000	iu	SC	R 96.12	12-Jan-02	20-Jan-02	**R 188.73**
	Ulsanic	4	g	PO	R 0.00	12-Jan-02	18-Jan-02	**R 74.44**
	Berotec	1.25-7.5	mg	INH	R 0.00	15-Jan-02	21-Jan-02	**R 234.95**
	Atrovent	0.25-3	mg	INH	R 0.00	15-Jan-02	21-Jan-02	**R 446.82**
	Panado	30	ml	PO	R 0.00	19-Jan-02	19-Jan-02	**R 17.64**
	Morphine	10-20	mg	IM	R 21.36	18-Jan-02	19-Jan-02	**R 28.36**
	Dormicum	9	mg	IV	R 0.92	12-Jan-02	12-Jan-02	**R 53.63**
	Lasix	5-10	mg	IV	R 0.92	15-Jan-02	16-Jan-02	**R 11.18**
	Dolorol Forte	2032-4064	mg	PO	R 0.00	21-Jan-02	23-Jan-02	**R 22.56**
071	Morphine	10-30	mg	IM	R 32.04	22-Jan-02	24-Jan-02	**R 63.81**
	Dolorol Forte	1016-2032	mg	PO	R 0.00	25-Jan-02	29-Jan-02	**R 18.80**
	Berotec	3.75-6.25	mg	INH	R 0.00	23-Jan-02	28-Jan-02	**R 167.82**
	Atrovent	1.5-2.5	mg	INH	R 0.00	23-Jan-02	28-Jan-02	**R 319.15**
	Tagamet	800	mg	IV	R 19.39	24-Jan-02	25-Jan-02	**R 29.64**
	Losec	20	mg	PO	R 0.00	25-Jan-02	continuing	**R 393.77**
	Nimbex	12	mg	IV	R 0.92	22-Jan-02	22-Jan-02	**R 298.17**
	Phenylephrine	250	mg	IV	R 0.92	22-Jan-02	22-Jan-02	**R 993.58**
	Neostigmine	0.5	mg	IV	R 0.92	22-Jan-02	22-Jan-02	**R 3.09**
	Robinul	2.5	mg	IV	R 0.92	22-Jan-02	22-Jan-02	**R 882.36**
072	Morphine	20-30	mg	IM	R 21.36	23-Jan-02	24-Jan-02	**R 42.54**
	Dolorol Forte	1016-2032	mg	PO	R 0.00	25-Jan-02	10-Feb-02	**R 63.92**
074	Morphine	10-30	mg	IM	R 42.72	29-Jan-02	01-Feb-02	**R 85.08**
	Voltaren	75-150	mg	IM	R 21.36	30-Jan-02	31-Jan-02	**R 31.42**
	Maxalon	10	mg	IM	R 3.56	30-Jan-02	30-Jan-02	**R 6.88**
	Dolorol	3	g	PO	R 0.00	03-Feb-02	06-Feb-02	**R 10.96**
075	Pethedine	350	mg	IM	R 3.56	18-Feb-02	18-Feb-02	**R 31.37**
	Morphine	10-30	mg	IM	R 53.40	18-Feb-02	22-Feb-02	**R 106.35**
	Tagamet	800-1200	mg	IM	R 53.40	18-Feb-02	22-Feb-02	**R 111.15**
	Losec	20	mg	PO	R 0.00	22-Feb-02	continuing	**R 393.77**

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RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
	Dolorol Forte	1016-2032	mg	PO	R 0.00	25-Feb-02	03-Mar-02	**R 26.32**
079	Morphine	30	mg	IM	R 3.56	24-Feb-02	24-Feb-02	**R 21.27**
	Morphine	20	mg	IM	R 3.56	26-Feb-02	26-Feb-02	**R 14.18**
	Lasix	20-40	mg	IV	R 19.39	24-Feb-02	25-Feb-02	**R 44.72**
	Dolorol Forte	1016-4064	mg	PO	R 0.00	08-Mar-02	23-Mar-02	**R 45.12**
081	Morphine	10-20	mg	IM	R 42.72	27-Feb-02	02-Mar-02	**R 56.72**
	Berotec	1.25-5	mg	IM	R 74.76	26-Feb-02	04-Mar-02	**R 156.63**
	Ventolin	200	ug	INH	R 0.00	1990	ongoing	**R 46.26**
	Dolorol Forte	1016-2032	mg	PO	R 0.00	05-Mar-02	12-Mar-02	**R 30.08**
	Brufen	200	mg	PO	R 0.00	05-Mar-02	12-Mar-02	**R 4.16**
	Morphine	10-40	mg	IM	R 138.84	13-Mar-02	25-Mar-02	**R 368.68**
	Stemetil	12.5	mg	IM	R 21.36	15-Mar-02	16-Mar-02	**R 18.38**
	Stemetil	12.5	mg	IM	R 3.56	20-Mar-02	20-Mar-02	**R 9.19**
	Berotec	3.76-5	mg	INH	R 0.00	14-Mar-02	19-Mar-02	**R 134.26**
	Atrovent	1.5-2	mg	INH	R 0.00	14-Mar-02	19-Mar-02	**R 255.32**
	Maxalon	10	mg	IM	R 3.56	20-Mar-02	20-Mar-02	**R 6.88**
	Heparin	5000-10000	iu	SC	R 74.76	20-Mar-02	26-Mar-02	**R 97.86**
	Pethedine	100	mg	IM	R 3.56	20-Mar-02	20-Mar-02	**R 7.99**
	Morphine	40	mg	IV	R 19.39	20-Mar-02	20-Mar-02	**R 28.36**
	Maxalon	10	mg	IV	R 0.92	20-Mar-02	20-Mar-02	**R 6.99**
	Neostigmine	2.5	mg	IV	R 0.92	20-Mar-02	20-Mar-02	**R 6.54**
	Robinul	0.8	mg	IV	R 0.92	20-Mar-02	20-Mar-02	**R 294.12**
	Heparin	5000	iu	SC	R 3.56	20-Mar-02	20-Mar-02	**R 6.99**
	Dolorol Forte	1016	mg	PO	R 0.00	26-Mar-02	30-Mar-03	**R 9.40**
088	Pethedine	50-100	mg	IV	R 19.39	03-Apr-02	05-Apr-02	**R 23.98**
	Dolorol Forte	1016	mg	PO	R 0.00	07-Apr-02	11-Apr-02	**R 9.40**
090	Morphine	20-30	mg	IM	R 21.36	21-Apr-02	22-Apr-02	**R 42.54**
	Dolorol Forte	1016-3048	mg	PO	R 0.00	23-Apr-02	02-May-02	**R 56.40**
	Stemetil	12.5	mg	IM	R 3.56	21-Apr-02	21-Apr-02	**R 9.19**

Appendix D 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
091	Morphine	10-20	mg	IM	R 53.40	01-May-02	05-May-02	**R 70.90**
	Heparin	5000-10000	iu	SC	R 64.08	12-May-02	17-May-02	**R 83.88**
	Losec	20	mg	PO	R 0.00	03-May-02	09-May-02	**R 112.50**
	Losec	20	mg	PO	R 0.00	11-May-02	17-May-02	**R 98.44**
	Serepax	10	mg	PO	R 0.00	05-May-02	07-May-02	**R 2.12**
	Serepax	10	mg	PO	R 0.00	09-May-02	14-May-02	**R 4.25**
	Berotec	1.25-7.5	mg	INH	R 0.00	06-May-02	17-May-02	**R 402.77**
	Atrovent	0.25-1.25	mg	INH	R 0.00	06-May-02	17-May-02	**R 319.15**
	Dolorol Forte	1016-3048	mg	PO	R 0.00	07-May-02	09-May-02	**R 16.92**
	Lasix	10-20	mg	PO	R 0.00	09-May-02	11-May-02	**R 7.84**
	Panado	30-120	ml	PO	R 0.00	10-May-02	17-May-02	**R 17.64**
	Duratears	02-Jan	drops	EYE	R 0.00	16-May-02	17-May-02	**R 46.16**
	Adrenaline	20-50	mg	IV	R 19.39	10-May-02	12-May-02	**R 683.66**
	Adrenaline	40-100	mg	IV	R 0.92	14-May-02	18-May-02	**R 2,278.86**
	Morphine	2-20	mg	IV	R 0.92	09-May-02	16-May-02	**R 113.44**
	Dormicum	4	mg	IV	R 0.92	09-May-02	09-May-02	**R 26.81**
	Dormicum	2-50	mg	IV	R 0.92	13-May-02	14-May-02	**R 328.50**
	Dobutrex	200	mg	IV	R 0.92	17-May-02	17-May-02	**R 384.17**
	Penieleferine	10-40	mg	IV	R 0.92	17-May-02	18-May-02	**R 397.43**
	Lasix	40-500	mg	IV	R 0.92	14-May-02	17-May-02	**R 351.23**
	Propofol	12	ml	IV	R 0.92	14-May-02	14-May-02	**R 174.43**
	Acebutolol	1	mg	IV	R 0.92	17-May-02	17-May-02	**R 47.30**
	Solu-cortef	100	mg	IV	R 0.92	17-May-02	17-May-02	**R 31.82**
	Pavulon	12.5	mg	IV	R 0.92	17-May-02	17-May-02	**R 92.07**
	Actrapid			IV	R 0.92	17-May-02	17-May-02	**R 233.41**
	Lorazepan	2	mg	IV	R 0.92	11-May-02	11-May-02	**R 2.40**
	Ulsanic	1	g	PO	R 0.00	09-May-02	11-May-02	**R 7.98**
	Ulsanic	1	g	PO	R 0.00	15-May-02	17-May-02	**R 7.98**
093	Morphine	20	mg	IV	R 19.39	12-May-02	13-May-02	**R 28.36**

Appendix D 3.1

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP A / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
	Dolorol Forte	2032	mg	PO	R 0.00	14-May-02	14-May-02	**R 3.76**
	Voltaren	75	mg	IM	R 10.68	13-May-02	13-May-02	**R 7.85**
	Pethedine	100	mg	IM	R 21.36	11-May-02	12-May-02	**R 15.99**
095	Morphine	10-40	mg	IM	R 53.40	20-Jun-02	24-Jun-02	**R 141.80**
	Stemetil	25	mg	IM	R 7.12	22-Jun-02	22-Jun-02	**R 18.38**
	Stemetil	12.5	mg	IM	R 3.56	24-Jun-02	24-Jun-02	**R 9.19**
	Maxalon	10	mg	PO	R 0.00	22-Jun-02	22-Jun-02	**R 1.59**
	Maxalon	10	mg	PO	R 0.00	24-Jun-02	24-Jun-02	**R 1.59**
	Dolorol Forte	1016-4064	mg	PO	R 0.00	25-Jun-02	30-Jun-02	**R 45.12**
	Pethedine	50	mg	IM	R 32.04	07-Jul-02	09-Jul-02	**R 22.15**
	Dolorol Forte	1016-4064	mg	PO	R 0.00	10-Jul-02	12-Jul-02	**R 10.82**
097	Tagamet	200-800	mg	IV	R 19.39	25-Jul-02	29-Jul-02	**R 74.10**
	Morphine	30-40	mg	IV	R 0.92	25-Jul-02	26-Jul-02	**R 56.72**
100	Dolorol Forte	1016-3048	mg	IV	R 19.39	04-May-02	05-May-02	**R 11.28**
	Dolorol Forte	1016-2032	mg	IV	R 0.92	09-May-02	12-May-02	**R 15.04**
	Heparin	5000-10000	iu	SC	R 106.80	02-May-02	11-May-02	**R 139.80**
	Berotec	1.25-6.25	mg	INH	R 0.00	04-May-02	12-May-02	**R 251.73**
	Atrovent	0.5-2.5	mg	INH	R 0.00	04-May-02	12-May-02	**R 478.73**
	Morphine	10-40	mg	IM	R 72.45	02-May-02	08-May-02	**R 198.52**
TOTAL					**R 3,171.14**			**R 24,479.11**
							TOTAL COST	**R 27,650.25**

Appendix D 3.2

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP B / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
001	Maxalon	10	mg	IV	R 19.39	17-Feb-01	21-Feb-01	**R 6.88**
	Servatrin	37.5	mg	PO	R 0.00	unk	ongoing	**R 54.40**
	Dormicum	7.5	mg	IV	R 0.92	16-Feb-01	16-Feb-01	**R 40.22**
	Bayer Aspirin	2	g	PO	R 0.00	16-Mar-01	18-Mar-01	**R 25.99**
	Akineton	4	g	PO	R 0.00	10-Mar-01	ongoing	**R 128.79**
	Morphine	10	mg	IM	R 96.12	16-Feb-01	24-Feb-01	**R 63.81**
002	Morphine	10-40	mg	IM	R 53.40	20-Feb-01	24-Feb-01	**R 141.80**
	Dolorol	2000	mg	PO	R 0.00	23-Feb-01	23-Feb-01	**R 0.91**
011	Morphine	10-30	mg	IM	R 42.72	11-Apr-01	14-Apr-01	**R 113.44**
	Dolorol Forte	1016-2032	mg	PO	R 0.00	18-Apr-01	19-Apr-01	**R 7.51**
012	Pethidine	75-200	mg	IM	R 32.04	15-Apr-01	17-Apr-01	**R 47.97**
	Panado	1-3	g	PO	R 0.00	16-Apr-01	19-Apr-01	**R 12.83**
013	Berotec	2.5-3.75	mg	INH	R 0.00	01-May-01	07-May-01	**R 117.47**
	Atrovent	0.5-0.75	mg	INH	R 0.00	01-May-01	07-May-01	**R 111.70**
	Valium	10	mg	PO	R 0.00	04-May-01	05-May-01	**R 23.45**
	Thiamine	100	mg	IM	R 42.72	04-May-01	07-May-01	**R 82.66**
	Morphine	20-40	mg	IM	R 21.36	01-May-01	02-May-01	**R 56.72**
	Flamazine	1	applic	TOP	R 0.00	02-May-01	09-May-01	**R 89.90**
015	Pethidine	150-200	mg	IM	R 64.08	09-May-01	14-May-01	**R 95.94**
017	Pethidine	75	mg	IM	R 10.68	15-May-01	15-May-01	**R 14.03**
	Stemetil	12.5	mg	IM	R 7.12	16-May-01	17-May-01	**R 18.38**
	Morphine	10-30	mg	IM	R 42.72	15-May-01	18-May-01	**R 85.08**
	Dolorol Forte	1016	mg	PO	R 0.00	16-May-01	20-May-01	**R 9.40**
	Brufen	600	mg	PO	R 0.00	20-May-01	27-May-01	**R 16.02**
	Dolorol Forte	3048	mg	PO	R 0.00	21-May-01	27-May-01	**R 39.48**
020	Morphine	10-30	mg	IM	R 64.08	22-May-01	27-May-01	**R 127.62**
	Morphine	10	mg	IV	R 19.39	27-May-01	27-May-01	**R 7.09**
	Pethidine	50-100	mg	IV	R 0.92	20-May-01	21-May-01	**R 15.99**
	Tetanus Toxoid	0.5	ml	IM	R 3.56	20-May-01	20-May-01	**R 35.68**
	Dolorol Forte	1016	mg	PO	R 0.00	21-May-01	21-May-01	**R 1.88**
023	Morphine	20	mg	IM	R 3.56	11-Jun-01	11-Jun-01	**R 14.18**

Appendix D 3.2

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP B / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
	Heparin	4000	iu	SC	R 32.04	11-Jun-01	13-Jun-01	**R 16.80**
	Pethidine	50	mg	IM	R 3.56	10-Jun-01	10-Jun-01	**R 7.38**
024	Heparin	5000-10000	iu	SC	R 32.04	19-Jun-01	21-Jun-01	**R 41.94**
	Morphine	10-30	mg	IM	R 74.76	19-Jun-01	25-Jun-01	**R 148.89**
	Stemetil	12.5	mg	IM	R 3.56	23-Jun-01	23-Jun-01	**R 9.19**
	Dolorol Forte	1016	mg	PO	R 0.00	25-Jun-01	25-Jun-01	**R 1.88**
	Berotec	1.25	mg	INH	R 0.00	23-Jun-01	25-Jun-01	**R 16.78**
	Atrovent	0.25	mg	INH	R 0.00	23-Jun-01	25-Jun-01	**R 15.96**
026	Morphine	20-50	mg	IM	R 53.40	01-Jul-01	05-Jul-01	**R 212.70**
	Pethidine	75	mg	IM	R 3.56	30-Jul-01	30-Jul-01	**R 14.03**
027	Morphine	10	mg	IM	R 53.40	02-Aug-01	06-Aug-01	**R 42.54**
	Stemetil	12.5	mg	IM	R 3.56	06-Aug-01	06-Aug-01	**R 9.19**
	Tagamet	800-600	mg	IV	R 19.39	03-Aug-01	06-Aug-01	**R 49.32**
	Losec	20	mg	PO	R 0.00	06-Aug-01	06-Aug-01	**R 14.06**
029	Morphine	10-30	mg	IM	R 53.40	10-Aug-01	14-Aug-01	**R 106.35**
	Stemetil	12.5	mg	IV	R 19.39	12-Aug-01	18-Aug-01	**R 64.33**
	Heparin	5000-10000	iu	SC	R 74.76	10-Aug-01	16-Aug-01	**R 97.86**
032	Pethidine	75-400	mg	IM	R 85.44	23-Aug-01	30-Aug-01	**R 255.83**
	Stemetil	12.5-25	mg	IM	R 7.12	26-Aug-01	27-Aug-01	**R 36.76**
	Losec	20	mg	PO	R 0.00	27-Aug-01	continueing	**R 393.77**
033	Thiamine	200	mg	PO	R 0.00	13-Sep-01	14-Sep-01	**R 0.90**
	Vit C	1000	mg	PO	R 0.00	13-Sep-01	14-Sep-01	**R 0.81**
	Morphine	30-60	mg	IM	R 42.72	10-Sep-01	13-Sep-01	**R 170.16**
	Stemetil	12.5	mg	IM	R 3.56	10-Sep-01	10-Sep-01	**R 9.19**
	Dolorol	1-3	g	PO	R 0.00	14-Sep-01	15-Sep-01	**R 5.52**
	Tetanus Toxoid	0.5	ml	SC	R 3.56	09-Sep-01	09-Sep-01	**R 5.68**
034	Morphine	10-40	mg	IM	R 32.04	12-Sep-01	14-Sep-01	**R 85.08**
035	Morphine	10-30	mg	IM	R 64.08	13-Sep-01	18-Sep-01	**R 127.62**
	Zestoretic	1	tablets	PO	R 0.00	NA	NA	**R 123.82**
	Berotec	1.25-3.75	mg	INH	R 0.00	14-Sep-01	24-Sep-01	**R 184.60**
	Atrovent	0.25-0.75	mg	INH	R 0.00	14-Sep-01	24-Sep-01	**R 159.58**

Appendix D 3.2

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP B / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
	Heparin	5000-15000	iu	SC	R 85.44	13-Sep-01	20-Sep-01	**R 167.76**
	Fleet Enema	1	bottle	PR	R 0.00	18-Sep-01	20-Sep-01	**R 15.05**
	Disprin	150	mg	PO	R 0.00	19-Sep-01	26-Sep-01	**R 1.12**
	Doxyfene	2-4	tablets	PO	R 0.00	19-Sep-01	21-Sep-01	**R 43.08**
	Maxalon	20	mg	PO	R 0.00	18-Sep-01	20-Sep-01	**R 3.18**
037	Morphine	30	mg	IM	R 3.56	27-Sep-01	27-Sep-01	**R 21.27**
	Dolorol Forte	1016-2032	mg	PO	R 0.00	01-Oct-01	03-Oct-01	**R 5.64**
	Morphine	10	mg	IM	R 3.56	29-Oct-01	29-Oct-01	**R 7.09**
039	Morphine	30	mg	IM	R 32.04	01-Oct-01	03-Oct-01	**R 63.81**
	Stemetil	12.5	mg	IM	R 3.56	02-Oct-01	02-Oct-01	**R 9.19**
041	Pethidine	150-200	mg	IM	R 53.40	10-Oct-01	14-Oct-01	**R 79.95**
	Heparin	5000-15000	iu	SC	R 74.76	12-Oct-01	18-Oct-01	**R 125.82**
	Doxyfene	4	caps	PO	R 0.00	18-Oct-01	22-Oct-01	**R 71.80**
	Dolorol Forte	1016-3048	mg	PO	R 0.00	18-Oct-01	30-Oct-01	**R 73.32**
043	Morphine	10-30	mg	IM	R 64.08	19-Oct-01	24-Oct-01	**R 127.62**
046	Heparin	10000-15000	iu	SC	R 117.48	24-Oct-01	03-Nov-01	**R 230.67**
	Ulsanic	1-4	g	PO	R 0.00	25-Oct-01	01-Nov-01	**R 85.07**
	Maxalon	10-30	mg	IM	R 32.04	28-Oct-01	30-Oct-01	**R 61.89**
	Voltaren	150	mg	IM	R 21.36	29-Oct-01	30-Oct-01	**R 31.42**
	Serapax	20	mg	PO	R 0.00	29-Oct-01	30-Oct-01	**R 2.83**
	Voltaren	75	mg	IM	R 3.56	03-Nov-01	03-Nov-01	**R 7.85**
	Canesten Cream	1-3	NA	PV	R 0.00	01-Nov-01	05-Nov-01	**R 167.22**
	Maxalon	10	mg	IM	R 3.56	02-Nov-01	02-Nov-01	**R 6.99**
	Morphine	5-70	mg	IV	R 19.39	23-Oct-01	31-Oct-01	**R 446.67**
	Morphine	10-30	mg	IM	R 32.04	31-Oct-01	02-Nov-01	**R 63.81**
	Dormicum	100-140	mg	IV	R 0.92	23-Oct-01	25-Oct-01	**R 1,478.26**
050	Maxalon	10	mg	IM	R 3.56	09-Nov-01	09-Nov-01	**R 6.88**
	Indocid	100-300	mg	PR	R 0.00	08-Nov-01	11-Nov-01	**R 147.59**
	Morphine	7.5-30	mg	IM	R 21.36	08-Nov-01	09-Nov-01	**R 42.54**
	Dolorol Forte	1016	mg	PO	R 0.00	10-Nov-01	12-Nov-01	**R 5.64**
	Depo Pruvera	1	amp	IM	R 3.56			**R 21.01**

Appendix D 3.2

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP B / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
053	Morphine	20	mg	IM	R 3.56	19-Nov-01	19-Nov-01	**R 14.18**
	Dolorol Forte	1016-2032	mg	PO	R 0.00	21-Nov-01	23-Nov-01	**R 11.28**
056	Voltaren	75	mg	IM	R 32.04	27-Nov-01	29-Nov-01	**R 23.56**
	Dolorol Forte	3048	mg	PO	R 0.00	01-Dec-01	18-Dec-01	**R 101.52**
	Brufen	600	mg	PO	R 0.00	01-Dec-01	08-Dec-01	**R 16.02**
058	Morphine	20-30	mg	IM	R 32.04	09-Dec-01	10-Dec-01	**R 42.54**
	Stemetil	12.5-25	mg	IM	R 32.04	11-Dec-01	13-Dec-01	**R 55.14**
	Dolorol Forte	1016	mg	PO	R 0.00	10-Dec-01	11-Dec-01	**R 3.76**
	Dolorol Forte	1016	mg	PO	R 0.00	15-Dec-01	15-Dec-01	**R 1.88**
056	Voltaren	75	mg	IM	R 32.04	27-Nov-01	29-Nov-01	**R 23.56**
057	Morphine	10-30	mg	IM	R 32.04	03-Dec-01	05-Dec-01	**R 63.81**
058	Morphine	20-30	mg	IV	R 0.92	09-Dec-01	10-Dec-02	**R 42.54**
	Stemetil	12.5-25	mg	IM	R 32.04	11-Dec-01	13-Dec-01	**R 55.14**
	Dolorol Forte	1016	mg	PO	R 0.00	10-Dec-01	11-Dec-01	**R 3.76**
063	Morphine	20-40	mg	IM	R 53.40	17-Dec-01	21-Dec-01	**R 141.80**
	Voltaren	75	mg	IM	R 74.76	17-Dec-01	23-Dec-01	**R 54.98**
	Morphine	10	mg	IM	R 3.56	23-Dec-01	23-Dec-01	**R 7.09**
064	Dolorol Forte	2032	mg	PO	R 0.00	21-Dec-01	21-Dec-01	**R 3.76**
	Morphine	10-40	mg	IM	R 53.40	17-Dec-01	21-Dec-01	**R 141.80**
065	Morphine	30-40	mg	IM	R 53.40	02-Jan-02	06-Jan-02	**R 170.16**
	Dolorol Forte	2032-3048	mg	PO	R 0.00	07-Jan-02	11-Jan-02	**R 28.20**
069	Morphine	10-30	mg	IM	R 42.72	13-Jan-02	16-Jan-02	**R 85.08**
	Maxalon	10-20	mg	IM	R 21.36	13-Jan-02	14-Jan-02	**R 27.51**
	Berotec	1.25-5	mg	INH	R 0.00	14-Jan-02	18-Jan-02	**R 111.88**
	Atrovent	0.25-1	mg	INH	R 0.00	14-Jan-02	18-Jan-02	**R 106.38**
070	Pethidine	125-200	mg	IM	R 21.36	14-Jan-02	15-Jan-02	**R 31.98**
	Dolorol Forte	1016	mg	PO	R 0.00	18-Jan-02	18-Jan-02	**R 1.88**
	Heparin	5000-10000	iu	SC	R 42.72	15-Jan-02	18-Jan-02	**R 55.92**
	Tagamet	400-1200	mg	IV	R 19.39	15-Jan-02	18-Jan-02	**R 200.07**
	Morphine	20	mg	IM	R 3.56	15-Jan-02	15-Jan-02	**R 14.18**
	Berotec	2.5-5	mg	INH	R 0.00	16-Jan-02	18-Jan-02	**R 67.13**

Appendix D 3.2

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP B / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
	Atrovent	0.5-2	mg	INH	R 0.00	16-Jan-02	18-Jan-02	**R 127.66**
	Morphine	10	mg	IM	R 3.56	18-Jan-02	18-Jan-02	**R 7.09**
	Losec	20	mg	PO	R 0.00	19-Jan-02	continuing	**R 393.77**
	Theophylin	400	mg	PO	R 0.00	19-Jan-02	02-Feb-02	**R 45.85**
076	Pethidine	50	mg	IM	R 21.36	19-Feb-02	20-Feb-02	**R 14.77**
	Maxalon	10	mg	IV	R 0.92	20-Feb-02	20-Feb-02	**R 6.88**
	Morphine	10	mg	IM	R 3.56	21-Feb-02	21-Feb-02	**R 7.09**
	Buscopan	20-60	mg	IM	R 32.04	20-Feb-02	22-Feb-02	**R 141.73**
	Dolorol Forte	1016-3048	mg	PO	R 0.00	24-Feb-02	29 Feb 02	**R 33.84**
	Buscopan	20	mg	IM	R 21.36	25-Feb-02	26-Feb-02	**R 31.50**
082	Pethidine	50	mg	IV	R 0.92	07-Mar-02	07-Mar-02	**R 7.38**
	Pethidine	200	mg	IM	R 21.36	07-Mar-02	08-Mar-02	**R 31.98**
	Dolorol Forte	1016-3048	mg	PO	R 0.00	07-Mar-02	11-Mar-02	**R 28.20**
	Dolorol Forte	1016-3048	mg	PO	R 0.00	11-Mar-02	15-Mar-02	**R 28.20**
083	Morphine	7.5-20	mg	IM	R 42.72	10-Mar-02	13-Mar-02	**R 56.72**
	Stemetil	12.5	mg	IM	R 3.56	11-Mar-02	11-Mar-02	**R 9.19**
	Dolorol Forte	1016-3048	mg	PO	R 0.00	13-Mar-02	15-Mar-02	**R 16.92**
	Dolorol Forte	1046-2032	mg	PO	R 0.00	17-Mar-02	18-Mar-02	**R 7.52**
	Dolorol Forte	1016	mg	PO	R 0.00	22-Mar-02	22-Mar-02	**R 1.88**
	Dolorol Forte	1016	mg	PO	R 0.00	25-Mar-02	29-Mar-02	**R 9.40**
	Pethidine	50	mg	IM	R 3.56	17-Mar-02	17-Mar-02	**R 7.38**
086	Morphine	30	mg	IM	R 32.04	17-Mar-02	19-Mar-02	**R 63.81**
	Dolorol Forte	1016-2032	mg	PO	R 0.00	20-Mar-02	23-Mar-02	**R 15.04**
087	Morphine	10	mg	IM	R 3.56	30-Mar-02	30-Mar-02	**R 7.09**
	Dolorol Forte	4064	mg	PO	R 0.00	03-Apr-02	08-Apr-02	**R 45.12**
	Berotec	1.25-2.5	mg	INH	R 0.00	23-Apr-02	24-Apr-02	**R 22.38**
	Atrovent	0.5-1	mg	INH	R 0.00	23-Apr-02	24-Apr-02	**R 42.55**
	Buscopan	20	mg	IM	R 3.56	19-Apr-02	19-Apr-02	**R 15.75**
089	Morphine	10-30	mg	IM	R 53.40	17-Apr-02	21-Apr-02	**R 106.35**
	Berotec	1.25-5	mg	INH	R 0.00	20-Apr-02	22-Apr-02	**R 67.13**
	Atrovent	0.5-2	mg	INH	R 0.00	20-Apr-02	22-Apr-02	**R 127.66**

Appendix D 3.2

RANDOM NUMBER	CONCOMITANT MEDICATION / TREATMENT GROUP B / PPP							
	IN HOSPITAL MEDICATION	DAILY DOSAGE	UNITS	ROUTE	CONSUM-ABLES	START DATE	STOP DATE	COST
	Dolorol Forte	1016	mg	PO	R 0.00	25-Apr-02	29-Apr-02	**R 9.40**
092	Pethidine	75-300	mg	IM	R 64.08	08-May-02	13-May-02	**R 143.91**
	Dolorol Forte	1016-3048	mg	PO	R 0.00	14-May-02	21-May-02	**R 45.12**
094	Morphine	10-40	mg	IM	R 64.08	09-Jun-02	14-Jun-02	**R 170.16**
	Heparin	5000-15000	iu	SC	R 74.76	09-Jun-02	15-Jun-02	**R 146.79**
	Losec	20	mg	PO	R 0.00	14-Jun-02	continuing	**R 393.77**
	Dolorol Forte	1016-2032	mg	PO	R 0.00	15-Jun-02	28-Jun-02	**R 48.88**
096	Pethidine	75-150	mg	IM	R 53.40	08-Jul-02	12-Jul-02	**R 76.89**
	Dolorol Forte	3048-4064	mg	PO	R 0.00	12-Jul-02	19-Jul-02	**R 60.16**
	Berotec	2.5-3.75	mg	INH	R 0.00	09-Jul-02	11-Jul-02	**R 50.35**
	Atrovent	1-1.5	mg	INH	R 0.00	09-Jul-02	11-Jul-02	**R 95.75**
098	Morphine	30-40	mg	IM	R 42.72	10-Aug-02	13-Aug-02	**R 113.44**
	DF118	30-90	mg	PO	R 0.00	13-Aug-02	13-Aug-02	**R 9.11**
	Stemetil	12.5	mg	IM	R 3.56	11-Aug-02	11-Aug-02	**R 9.19**
	Dolorol Forte	3048	mg	PO	R 0.00	17-Aug-02	27-Aug-02	**R 62.04**
	Fybogel	3.5	g	PO	R 0.00	22-Aug-02	Ongoing	**R 69.10**
	Senekot	15	mg	PO	R 0.00	02-Aug-02	16-Sep-02	**R 41.44**
	Antabuse implant	unk	unk	SC	R 3.56	July 2002	Ongoing	**R 4.14**
	Dulcolax	10	mg	PR	R 0.00	18-Aug-02	18-Aug-02	**R 170.16**
099	Morphine	10-40	mg	IM	R 64.08	11-Aug-02	16-Aug-02	**R 9.19**
	Stemetil	12.5	mg	IM	R 3.56	12-Aug-02	12-Aug-02	**R 104.85**
	Heparin	10000-15000	iu	SC	R 53.40	12-Aug-02	16-Aug-02	**R 134.26**
	Berotec	1.25-5	mg	INH	R 0.00	13-Aug-02	18-Aug-02	**R 255.32**
	Atrovent	0.5-2	mg	INH	R 0.00	13-Aug-02	18-Aug-02	**R 8.01**
	Brufen	600	mg	PO	R 0.00	04-Sep-02	07-Sep-02	**R 15.99**
	Pethidine	50-100	mg	IM	R 21.36	11-Sep-02	12-Sep-02	**R 15.99**
TOTAL					**R 3,051.74**			**R 13,157.51**
							TOTAL COST	**R 16,209.25**

Appendix D 4.1

RANDOM NUMBER	DEMOGRAPHIC DATA / TREATMENT GROUP A / PPP										
	DATE OF BIRTH	AGE	GENDER		NATURE OF SURGERY						
			FEMALE	MALE	APPENDECTOMY	CHOLECYSTECOMY	LAPARATOMY	SIGMOIDECTOMY	INCISION AND DRAINAGE	EXPLORATORY LAPAROSCOPY	OTHER
003	11-Dec-65	37		1	1						
004	03-Nov-38	64		1				1			
007	14-Dec-79	23		1			1				
009	12-Feb-75	27		1			1				
010	15-Aug-82	20		1			1				
014	26-Apr-62	40		1	1						
018	13-Apr-80	22		1						1	
019	14-Feb-40	62		1						1	
022	06-Feb-52	50		1			1				
025	01-Jan-38	64		1						1	
028	17-Dec-65	37		1	1						
030	12-Feb-60	42		1			1				
031	16-Aug-80	22		1	1						
036	13-Mar-33	69	1				1				
038	28-Jan-81	21		1	1						
042	05-Mar-67	35	1				1				
044	01-Nov-78	24		1			1				
045	20-Nov-81	21		1			1				
049	07-Jul-30	72	1			1					
051	27-Nov-71	31		1			1				
054	11-Oct-74	28		1			1				
055	07-Aug-55	45	1				1				
059	29-Jul-64	38		1			1				
060	29-Jan-60	42	1		1						
061	21-Dec-80	22		1			1				
062	18-Jul-62	40		1			1				
066	14-Jul-57	45		1	1						
068	16-Apr-72	30		1	1						
071	17-Sep-50	51		1			1				
072	12-Jun-75	25		1	1						
074	6-Sep-76	26		1	1						
075	21-May-59	43	1				1				
079	1-Jan-60	41		1			1				
081	18-Mar-59	43		1	1						
084	30-Nov-65	35	1		1						
088	8-Jul-74	28	1		1						
090	16-Apr-66	34		1			1				
091	29-Dec-50	51		1			1				

Appendix D 4.1

RANDOM NUMBER	DEMOGRAPHIC DATA / TREATMENT GROUP A / PPP										
	DATE OF BIRTH	AGE	GENDER		NATURE OF SURGERY						
			FEMALE	MALE	APPENDECTOMY	CHOLECYSTECOMY	LAPARATOMY	SIGMOIDECTOMY	INCISION AND DRAINAGE	EXPLORATORY LAPAROSCOPY	OTHER
093	28-Aug-52	50		1	1						
095	3-Nov-78	24	1		1						
097	6-Jun-74	28		1	1						
100	12-Oct-52	50	1		1						
	TOTAL	1602	10	32	17	1	20	1	0	3	0

Mean 38.1 **Std Deviation** 14.1 **Median** 37.0 **42**

Appendix D 4.2

RANDOM NUMBER	DEMOGRAPHIC DATA / TREATMENT GROUP B / PPP										
	DATE OF BIRTH	AGE	GENDER		NATURE OF SURGERY						
			FEMALE	MALE	APPENDECTOMY	CHOLECYSTECOMY	LAPARATOMY	SIGMOIDECTOMY	INCISION AND DRAINAGE	EXPLORATORY LAPAROSCOPY	OTHER
001	12-Jul-30	71	1			1					
002	03-Jul-78	24		1			1				
011	15-May-58	44		1	1						
012	07-Jan-77	25		1	1						
013	28-Dec-58	44		1			1				
015	01-Aug-64	38		1			1				
017	11-Nov-82	30	1		1						
020	15-Jul-70	32		1		1					
023	31-Dec-54	48	1		1						
024	31-Mar-52	50		1	1						
026	24-Mar-72	30		1			1				
027	15-Nov-68	34		1			1				
029	08-Oct-63	39		1			1				
032	30-Apr-59	43		1			1				
033	29-Sep-68	34		1			1				
034	192/12/16	40		1			1				
035	05-Mar-23	79		1				1			
037	21-Sep-79	23		1	1						
039	15-Feb-65	37		1			1				
041	27-Jan-63	39	1				1				
043	13-Mar-83	19		1	1						
046	02-Mar-81	21	1				1				
050	02-Mar-74	28	1		1						
053	21-Jul-59	43		1			1				
056	14-Oct-73	29	1		1						
057	19-Dec-81	21		1			1				
058	28-Jul-53	49		1	1						
063	1-Jan-81	21		1			1				
064	21-Jan-81	21		1			1				
065	24-Oct-68	34		1			1				
069	23-Mar-74	28		1			1				
070	28-Jan-62	40		1			1				
076	31-Jul-79	22	1		1						
082	1-Jan-76	25		1	1						
083	5-Apr-57	45	1		1						
086	8-Apr-51	51		1			1				
087	26-Jul-68	34		1	1		1				
089	4-Aug-78	23		1	1						
092	14-Mar-80	22		1						1	

Appendix D 4.2

RANDOM NUMBER	DEMOGRAPHIC DATA / TREATMENT GROUP B / PPP											
	DATE OF BIRTH	AGE	GENDER		NATURE OF SURGERY							
			FEMALE	MALE	APPENDECTOMY	CHOLECYSTECOMY	LAPARATOMY	SIGMOIDECTOMY	INCISION AND DRAINAGE	EXPLORATORY LAPAROSCOPY	OTHER
094	6-Apr-46	56		1			1				
096	5-Jan-72	30	1		1						
098	23-Sep-64	38		1				1			
099	3-Apr-68	34		1			1				
	TOTAL	1538	10	33	16	2	23	2	0	1	0

Mean	35.8	Std Deviation	13.1	Median	34.0	44

Appendix D 5.1

RANDOM NUMBER	HOSPITALISATION / TREATMENT GROUP A / PPP						
	DATE ADMITTED TO HOSPITAL	DATE DISCHARGED FROM HOSPITAL	NUMBER OF DAYS IN ICU	COST R 3,017.90	NUMBER OF DAYS IN GENERAL WARD	COST R 733.00	TOTAL COST
003	20-Feb-01	08-Mar-01	0	R 0.00	17	R 12,461.00	**R 12,461.00**
004	22-Feb-01	01-Mar-01	0	R 0.00	8	R 5,864.00	**R 5,864.00**
	28-Mar-01	02-Apr-01	0	R 0.00	3	R 2,199.00	**R 2,199.00**
007	26-Mar-01	05-Apr-01	0	R 0.00	11	R 8,063.00	**R 8,063.00**
009	07-Apr-01	12-Apr-01	0	R 0.00	6	R 4,398.00	**R 4,398.00**
010	09-Apr-01	10-Apr-01	0	R 0.00	6	R 4,398.00	**R 4,398.00**
014	06-May-01	14-May-01	0	R 0.00	9	R 6,597.00	**R 6,597.00**
	21-May-01	28-May-01	0	R 0.00	8	R 5,864.00	**R 5,864.00**
018	15-May-01	22-May-01	0	R 0.00	8	R 5,864.00	**R 5,864.00**
019	15-May-01	24-May-01	0	R 0.00	8	R 5,864.00	**R 5,864.00**
022	30-May-01	03-Jun-01	0	R 0.00	5	R 3,665.00	**R 3,665.00**
025	19-Jun-01	28-Jun-01	0	R 0.00	10	R 7,330.00	**R 7,330.00**
028	03-Aug-01	07-Aug-01	0	R 0.00	5	R 3,665.00	**R 3,665.00**
030	14-Aug-01	21-Aug-01	0	R 0.00	8	R 5,864.00	**R 5,864.00**
031	23-Aug-01	30-Aug-01	0	R 0.00	8	R 5,864.00	**R 5,864.00**
036	13-Sep-01	26-Sep-01	0	R 0.00	14	R 10,262.00	**R 10,262.00**
038	28-Sep-01	01-Oct-01	0	R 0.00	4	R 2,932.00	**R 2,932.00**
042	18-Oct-01	20-Nov-01	0	R 0.00	34	R 24,922.00	**R 24,922.00**
044	20-Oct-01	26 Oct 017	0	R 0.00	7	R 5,131.00	**R 5,131.00**
045	20-Oct-01	26-Oct-01	0	R 0.00	7	R 5,131.00	**R 5,131.00**
049	04-Nov-01	08-Nov-01	0	R 0.00	5	R 3,665.00	**R 3,665.00**
051	11-Nov-01	21-Nov-01	0	R 0.00	11	R 8,063.00	**R 8,063.00**
054	18-Nov-01	24-Nov-01	0	R 0.00	7	R 5,131.00	**R 5,131.00**
055	19-Nov-01	26-Nov-01	0	R 0.00	8	R 5,864.00	**R 5,864.00**
	05-Dec-01	05-Dec-01	0	R 0.00	1	R 733.00	**R 733.00**
059	09-Dec-01	14-Dec-01	0	R 0.00	6	R 4,398.00	**R 4,398.00**
060	10-Dec-01	17-Dec-01	0	R 0.00	8	R 5,864.00	**R 5,864.00**
061	15-Dec-01	21-Dec-01	0	R 0.00	7	R 5,131.00	**R 5,131.00**
062	16-Dec-01	21-Dec-01	0	R 0.00	6	R 4,398.00	**R 4,398.00**
066	04-Jan-02	10-Jan-02	0	R 0.00	7	R 5,131.00	**R 5,131.00**
068	10-Jan-02	11-Jan-02	0	R 0.00	2	R 1,466.00	**R 1,466.00**
	12-Jan-02	17-Jan-02	6	R 18,107.40	0	R 0.00	**R 18,107.40**

Appendix D 5.1

RANDOM NUMBER	HOSPITALISATION / TREATMENT GROUP A / PPP						
	DATE ADMITTED TO HOSPITAL	DATE DISCHARGED FROM HOSPITAL	NUMBER OF DAYS IN ICU	COST R 3,017.90	NUMBER OF DAYS IN GENERAL WARD	COST R 733.00	TOTAL COST
	18-Jan-02	21-Jan-02	0	R 0.00	4	R 2,932.00	**R 2,932.00**
071	22-Jan-02	29-Jan-02	0	R 0.00	8	R 5,864.00	**R 5,864.00**
072	22-Jan-02	28-Jan-02	0	R 0.00	7	R 5,131.00	**R 5,131.00**
074	29-Jan-02	04-Feb-02	0	R 0.00	7	R 5,131.00	**R 5,131.00**
075	17-Feb-02	26-Feb-02	0	R 0.00	10	R 7,330.00	**R 7,330.00**
079	23-Feb-02	03-Mar-02	0	R 0.00	9	R 6,597.00	**R 6,597.00**
081	26-Feb-02	05-Mar-02	0	R 0.00	8	R 5,864.00	**R 5,864.00**
084	12-Mar-02	26-Mar-02	0	R 0.00	14	R 10,262.00	**R 10,262.00**
088	02-Apr-02	07-Apr-02	0	R 0.00	6	R 4,398.00	**R 4,398.00**
090	20-Apr-02	25-Apr-02	0	R 0.00	6	R 4,398.00	**R 4,398.00**
091	29-Apr-02	08-May-02	0	R 0.00	10	R 7,330.00	**R 7,330.00**
	09-May-02	18-May-03	10	R 30,179.00	0	R 0.00	**R 30,179.00**
093	11-May-02	16-May-02	0	R 0.00	6	R 4,398.00	**R 4,398.00**
095	20-Jun-02	25-Jun-02	0	R 0.00	6	R 4,398.00	**R 4,398.00**
	06-Jul-02	10-Jul-02	0	R 0.00	5	R 3,665.00	**R 3,665.00**
097	24-Jul-02	30-Jul-02	0	R 0.00	7	R 5,131.00	**R 5,131.00**
100	02-May-02	12-May-02	0	R 0.00	11	R 8,063.00	**R 8,063.00**
TOTALS			**16**	**R 48,286.40**	**400**	**R 293,200.00**	**R 341,486.40**

Appendix D 5.2

RANDOM NUMBER	HOSPITALISATION / TREATMENT GROUP B / PPP						
	DATE ADMITTED TO HOSPITAL	DATE DISCHARGED FROM HOSPITAL	NUMBER OF DAYS IN ICU	COST R 3,017.90	NUMBER OF DAYS IN GENERAL WARD	COST R 733.00	TOTAL COST
001	30-Jan-01	27-Feb-01	0	R 0.00	29	R 21,257.00	R 21,257.00
	18-Mar-01	20-Mar-01	0	R 0.00	3	R 2,199.00	R 2,199.00
002	20-Feb-01	24-Feb-01	0	R 0.00	5	R 3,665.00	R 3,665.00
011	10-Apr-01	19-Apr-01	0	R 0.00	10	R 7,330.00	R 7,330.00
012	14-Apr-01	19-Apr-01	0	R 0.00	6	R 4,398.00	R 4,398.00
013	30-Apr-01	09-May-01	0	R 0.00	10	R 7,330.00	R 7,330.00
015	08-May-01	16-May-01	0	R 0.00	9	R 6,597.00	R 6,597.00
017	14-May-01	20-May-01	0	R 0.00	7	R 5,131.00	R 5,131.00
020	20-May-01	29-May-01	0	R 0.00	10	R 7,330.00	R 7,330.00
023	10-Jun-01	15-Jun-01	0	R 0.00	6	R 4,398.00	R 4,398.00
024	19-Jun-01	27-Jun-01	0	R 0.00	9	R 6,597.00	R 6,597.00
026	30-Jun-01	07-Jul-01	0	R 0.00	8	R 5,864.00	R 5,864.00
027	02-Aug-01	08-Aug-08	0	R 0.00	8	R 5,864.00	R 5,864.00
029	09-Aug-01	20-Aug-01	0	R 0.00	12	R 8,796.00	R 8,796.00
032	23-Aug-01	30-Aug-01	0	R 0.00	8	R 5,864.00	R 5,864.00
033	09-Sep-01	15-Sep-01	0	R 0.00	7	R 5,131.00	R 5,131.00
034	12-Sep-01	18-Sep-01	0	R 0.00	7	R 5,131.00	R 5,131.00
035	12-Sep-01	26-Sep-02	0	R 0.00	15	R 10,995.00	R 10,995.00
037	26-Sep-01	01-Oct-01	0	R 0.00	6	R 4,398.00	R 4,398.00
039	30-Sep-01	07-Oct-01	0	R 0.00	8	R 5,864.00	R 5,864.00
041	10-Oct-01	23-Oct-01	0	R 0.00	14	R 10,262.00	R 10,262.00
043	18-Oct-01	24-Oct-01	0	R 0.00	3	R 2,199.00	R 2,199.00
046	23-Oct-01	30-Oct-01	8	R 24,143.20	0	R 0.00	R 24,143.20
	31-Oct-01	06-Nov-01	0	R 0.00	7	R 5,131.00	R 5,131.00
050	07-Nov-01	12-Nov-01	0	R 0.00	12	R 8,796.00	R 8,796.00
053	18-Nov-01	24-Nov-01	0	R 0.00	7	R 5,131.00	R 5,131.00
056	26-Nov-01	01-Dec-01	0	R 0.00	6	R 4,398.00	R 4,398.00
057	02-Dec-01	09-Dec-01	0	R 0.00	8	R 5,864.00	R 5,864.00
058	08-Dec-01	15-Dec-01	0	R 0.00	8	R 5,864.00	R 5,864.00
063	16-Dec-01	26-Dec-01	0	R 0.00	11	R 8,063.00	R 8,063.00
064	17-Dec-01	22-Dec-01	0	R 0.00	6	R 4,398.00	R 4,398.00

Appendix D 5.2

RANDOM NUMBER	HOSPITALISATION / TREATMENT GROUP B / PPP						
	DATE ADMITTED TO HOSPITAL	DATE DISCHARGED FROM HOSPITAL	NUMBER OF DAYS IN ICU	COST R 3,017.90	NUMBER OF DAYS IN GENERAL WARD	COST R 733.00	TOTAL COST
065	02-Jan-01	07-Jan-02	0	R 0.00	6	R 4,398.00	R 4,398.00
069	12-Jan-02	18-Jan-02	0	R 0.00	7	R 5,131.00	R 5,131.00
070	14-Jan-02	19-Jan-02	0	R 0.00	6	R 4,398.00	R 4,398.00
076	18-Feb-02	26-Feb-02	0	R 0.00	9	R 6,597.00	R 6,597.00
082	06-Mar-02	11-Mar-02	0	R 0.00	6	R 4,398.00	R 4,398.00
083	09-Mar-02	15-Mar-02	0	R 0.00	7	R 5,131.00	R 5,131.00
	16-Mar-02	25-Mar-02	0	R 0.00	10	R 7,330.00	R 7,330.00
086	17-Mar-02	23-Mar-02	0	R 0.00	7	R 5,131.00	R 5,131.00
087	29-Mar-02	03-Apr-02	0	R 0.00	6	R 4,398.00	R 4,398.00
	22-Apr-02	24-Apr-02	0	R 0.00	3	R 2,199.00	R 2,199.00
089	16-Apr-02	25-Apr-02	0	R 0.00	9	R 6,597.00	R 6,597.00
092	08-May-02	14-May-02	0	R 0.00	7	R 5,131.00	R 5,131.00
094	08-Jun-02	15-Jun-02	0	R 0.00	8	R 5,864.00	R 5,864.00
096	08-Jul-02	14-Jul-02	0	R 0.00	7	R 5,131.00	R 5,131.00
098	10-Aug-02	19-Aug-02	0	R 0.00	10	R 7,330.00	R 7,330.00
099	10-Aug-02	18-Aug-02	0	R 0.00	9	R 6,597.00	R 6,597.00
TOTALS			**8**	**R 24,143.20**	**382**	**R 280,006.00**	**R 304,149.20**

Appendix D 6.1

RANDOM NUMBER	PROFESSIONAL FEE / TREATMENT GROUP A / PPP			
	Initial Visit	Hospital Visit	Final Visit	TOTAL COST
003	R 841.20	R 2,383.40	R 210.30	**R 3,434.90**
004	R 841.20	R 1,121.60	R 210.30	**R 2,173.10**
	R 841.20	R 420.60	R 210.30	**R 1,472.10**
007	R 841.20	R 1,542.20	R 210.30	**R 2,593.70**
009	R 841.20	R 841.20	R 210.30	**R 1,892.70**
010	R 841.20	R 841.20	R 210.30	**R 1,892.70**
014	R 841.20	R 1,261.80	R 210.30	**R 2,313.30**
	R 841.20	R 1,121.60	R 210.30	**R 2,173.10**
018	R 841.20	R 1,121.60	R 210.30	**R 2,173.10**
019	R 841.20	R 1,121.60	R 210.30	**R 2,173.10**
022	R 841.20	R 701.00	R 210.30	**R 1,752.50**
025	R 841.20	R 1,402.00	R 210.30	**R 2,453.50**
028	R 841.20	R 701.00	R 210.30	**R 1,752.50**
030	R 841.20	R 1,121.60	R 210.30	**R 2,173.10**
031	R 841.20	R 1,121.60	R 210.30	**R 2,173.10**
036	R 841.20	R 1,962.80	R 210.30	**R 3,014.30**
038	R 841.20	R 560.80	R 210.30	**R 1,612.30**
042	R 841.20	R 4,766.80	R 210.30	**R 5,818.30**
044	R 841.20	R 981.40	R 210.30	**R 2,032.90**
045	R 841.20	R 981.40	R 210.30	**R 2,032.90**
049	R 841.20	R 701.00	R 210.30	**R 1,752.50**
051	R 841.20	R 1,542.20	R 210.30	**R 2,593.70**
054	R 841.20	R 981.40	R 210.30	**R 2,032.90**
055	R 841.20	R 1,121.60	R 210.30	**R 2,173.10**
	R 841.20	R 140.20	R 210.30	**R 1,191.70**
059	R 841.20	R 841.20	R 210.30	**R 1,892.70**
060	R 841.20	R 1,121.60	R 210.30	**R 2,173.10**
061	R 841.20	R 981.40	R 210.30	**R 2,032.90**
062	R 841.20	R 841.20	R 210.30	**R 1,892.70**
066	R 841.20	R 981.40	R 210.30	**R 2,032.90**
068	R 841.20	R 280.40	R 210.30	**R 1,331.90**
	R 841.20	R 0.00	R 210.30	**R 1,051.50**
	R 841.20	R 560.80	R 210.30	**R 1,612.30**
071	R 841.20	R 1,121.60	R 210.30	**R 2,173.10**
072	R 841.20	R 981.40	R 210.30	**R 2,032.90**
074	R 841.20	R 981.40	R 210.30	**R 2,032.90**
075	R 841.20	R 1,402.00	R 210.30	**R 2,453.50**
079	R 841.20	R 1,261.80	R 210.30	**R 2,313.30**
	R 841.20	R 0.00	R 210.30	**R 1,051.50**
081	R 841.20	R 1,121.60	R 210.30	**R 2,173.10**
084	R 841.20	R 1,962.80	R 210.30	**R 3,014.30**
	R 841.20	R 0.00	R 210.30	**R 1,051.50**
	R 841.20	R 0.00	R 210.30	**R 1,051.50**
	R 841.20	R 0.00	R 210.30	**R 1,051.50**
	R 841.20	R 0.00	R 210.30	**R 1,051.50**
	R 841.20	R 0.00	R 210.30	**R 1,051.50**
	R 841.20	R 0.00	R 210.30	**R 1,051.50**
	R 841.20	R 0.00	R 210.30	**R 1,051.50**
	R 841.20	R 0.00	R 210.30	**R 1,051.50**
	R 841.20	R 0.00	R 210.30	**R 1,051.50**
	R 841.20	R 0.00	R 210.30	**R 1,051.50**
081	R 841.20	R 1,121.60	R 210.30	**R 2,173.10**
084	R 841.20	R 1,962.80	R 210.30	**R 3,014.30**
088	R 841.20	R 841.20	R 210.30	**R 1,892.70**
090	R 841.20	R 841.20	R 210.30	**R 1,892.70**
091	R 841.20	R 1,402.00	R 210.30	**R 2,453.50**
	R 841.20	R 1,402.00	R 210.30	**R 2,453.50**
093	R 841.20	R 841.20	R 210.30	**R 1,892.70**

Appendix D 6.1

RANDOM NUMBER	PROFESSIONAL FEE / TREATMENT GROUP A / PPP			
	Initial Visit	Hospital Visit	Final Visit	TOTAL COST
095	R 841.20	R 841.20	R 210.30	**R 1,892.70**
	R 841.20	R 701.00	R 210.30	**R 1,752.50**
097	R 841.20	R 981.40	R 210.30	**R 2,032.90**
100	R 841.20	R 1,542.20	R 210.30	**R 2,593.70**
TOTAL	**R 52,154.40**	**R 57,482.00**	**R 13,038.60**	**R 122,675.00**

Appendix D 6.2

RANDOM NUMBER	PROFESSIONAL FEE / TREATMENT GROUP B / PPP			
	Initial Visit	Hospital Visit	Final Visit	TOTAL COST
001	R 841.20	R 4,065.80	R 210.30	R 5,117.30
	R 841.20	R 420.60	R 210.30	R 1,472.10
002	R 841.20	R 701.00	R 210.30	R 1,752.50
011	R 841.20	R 1,402.00	R 210.30	R 2,453.50
012	R 841.20	R 841.20	R 210.30	R 1,892.70
013	R 841.20	R 1,402.00	R 210.30	R 2,453.50
015	R 841.20	R 1,261.80	R 210.30	R 2,313.30
017	R 841.20	R 981.40	R 210.30	R 2,032.90
020	R 841.20	R 1,402.00	R 210.30	R 2,453.50
023	R 841.20	R 841.20	R 210.30	R 1,892.70
024	R 841.20	R 1,261.80	R 210.30	R 2,313.30
026	R 841.20	R 1,121.60	R 210.30	R 2,173.10
027	R 841.20	R 1,121.60	R 210.30	R 2,173.10
029	R 841.20	R 1,682.40	R 210.30	R 2,733.90
032	R 841.20	R 1,121.60	R 210.30	R 2,173.10
033	R 841.20	R 981.40	R 210.30	R 2,032.90
034	R 841.20	R 981.40	R 210.30	R 2,032.90
035	R 841.20	R 2,103.00	R 210.30	R 3,154.50
037	R 841.20	R 841.20	R 210.30	R 1,892.70
039	R 841.20	R 1,121.60	R 210.30	R 2,173.10
041	R 841.20	R 1,962.80	R 210.30	R 3,014.30
043	R 841.20	R 420.60	R 210.30	R 1,472.10
046	R 841.20	R 1,121.60	R 210.30	R 2,173.10
	R 841.20	R 981.40	R 210.30	R 2,032.90
050	R 841.20	R 1,682.40	R 210.30	R 2,733.90
053	R 841.20	R 981.40	R 210.30	R 2,032.90
056	R 841.20	R 841.20	R 210.30	R 1,892.70
057	R 841.20	R 1,121.60	R 210.30	R 2,173.10
058	R 841.20	R 1,121.60	R 210.30	R 2,173.10
063	R 841.20	R 1,542.20	R 210.30	R 2,593.70
064	R 841.20	R 841.20	R 210.30	R 1,892.70
065	R 841.20	R 841.20	R 210.30	R 1,892.70
069	R 841.20	R 981.40	R 210.30	R 2,032.90
070	R 841.20	R 841.20	R 210.30	R 1,892.70
076	R 841.20	R 1,261.80	R 210.30	R 2,313.30
082	R 841.20	R 841.20	R 210.30	R 1,892.70
083	R 841.20	R 981.40	R 210.30	R 2,032.90
	R 841.20	R 1,402.00	R 210.30	R 2,453.50
086	R 841.20	R 981.40	R 210.30	R 2,032.90
087	R 841.20	R 841.20	R 210.30	R 1,892.70
	R 841.20	R 420.60	R 210.30	R 1,472.10
089	R 841.20	R 1,261.80	R 210.30	R 2,313.30
092	R 841.20	R 981.40	R 210.30	R 2,032.90
094	R 841.20	R 1,121.60	R 210.30	R 2,173.10
096	R 841.20	R 981.40	R 210.30	R 2,032.90
098	R 841.20	R 1,402.00	R 210.30	R 2,453.50
099	R 841.20	R 1,261.80	R 210.30	R 2,313.30
TOTALS	**R 39,536.40**	**R 54,678.00**	**R 9,884.10**	R 104 098.50

Appendix D 7.1

RANDOM NUMBER	STUDY MEDICATION / TREATMENT GROUP A / PPP										CLINICAL EVALUATION DAY 5 -14	CONSUM-ABLES
	MOXIFLOXACIN IV				MOXIFLOXACIN TABLETS							
	DATE IV TREATEMENT STARTED	DATE IV TREATMENT STOPPED	NUMBER OF DOSES IV TREATMENT	COST	DATE ORAL TREATMENT STARTED	DATE ORAL TREATMENT STOPPED	NUMBER OF DOSES ORAL TREATMENT	NUMBER OF OUT PATIENT TREATMENT	COST	TOTAL COST		
003	23-Feb-02	01-Mar-01	7	R 1,603.00	NA	NA	0	0	R 0.00	R 1,603.00	Cure	R 109.04
004	23-Feb-01	28-Feb-01	6	R 1,374.00	NA	NA	0	0	R 0.00	R 1,374.00	Cure	R 109.04
007	26-Mar-01	30-Mar-01	5	R 1,145.00	NA	NA	0	0	R 0.00	R 1,145.00	Cure	R 109.04
009	07-Apr-01	10-Apr-01	4	R 916.00	11-Apr-01	11-Apr-01	1	0	R 30.54	R 946.54	Cure	R 109.04
010	09-Apr-01	13-Apr-01	5	R 1,145.00	NA	NA	0	0	R 0.00	R 1,145.00	Cure	R 109.04
014	07-May-01	09-May-01	3	R 687.00	10-May-01	12-May-01	3	0	R 91.62	R 778.62	Cure	R 109.04
018	15-May-01	19-May-01	5	R 1,145.00	20-May-01	22-May-01	3	0	R 91.62	R 1,236.62	Cure	R 109.04
019	16-May-01	22-May-01	7	R 1,603.00	23-May-01	24-May-01	2	0	R 61.08	R 1,664.08	Cure	R 109.04
022	30-May-01	03-Jun-01	5	R 1,145.00	NA	NA	0	0	R 0.00	R 1,145.00	Cure	R 109.04
025	20-Jun-01	25-Jun-01	6	R 1,374.00	NA	NA	0	0	R 0.00	R 1,374.00	Cure	R 109.04
028	04-Aug-01	06-Aug-01	3	R 687.00	07-Aug-01	08-Aug-01	2	0	R 61.08	R 748.08	Cure	R 109.04
030	15-Aug-01	20-Aug-01	6	R 1,374.00	NA	NA	0	0	R 0.00	R 1,374.00	Cure	R 109.04
031	23-Aug-01	28-Aug-01	5	R 1,145.00	29-Aug-01	30-Aug-01	2	0	R 61.08	R 1,206.08	Cure	R 109.04
036	14-Sep-01	18-Sep-01	5	R 1,145.00	19-Sep-01	20-Sep-01	1	0	R 30.54	R 1,175.54	Cure	R 109.04
038	28-Sep-01	30-Sep-01	3	R 687.00	01-Oct-01	04-Oct-01	4	0	R 122.16	R 809.16	Cure	R 109.04
042	19-Oct-01	24-Oct-01	6	R 1,374.00	24-Oct-01	28-Oct-01	5	0	R 152.70	R 1,526.70	Failure	R 109.04
044	21-Oct-01	24-Oct-01	4	R 916.00	25-Oct-01	26-Oct-01	2	0	R 61.08	R 977.08	Cure	R 109.04
045	21-Oct-01	25-Oct-01	5	R 1,145.00	26-Oct-01	26-Oct-01	1	0	R 30.54	R 1,175.54	Cure	R 109.04
049	04-Nov-01	06-Nov-01	3	R 687.00	07-Nov-01	07-Nov-01	1	0	R 30.54	R 717.54	Cure	R 109.04
051	12-Nov-01	16-Nov-01	5	R 1,145.00	17-Nov-01	21-Nov-01	5	0	R 152.70	R 1,297.70	Cure	R 109.04
054	19-Nov-01	22-Nov-01	4	R 916.00	23-Nov-01	24-Nov-01	2	0	R 61.08	R 977.08	Cure	R 109.04
055	20-Nov-01	22-Nov-01	3	R 687.00	23-Nov-01	25-Nov-01	3	0	R 91.62	R 778.62	Cure	R 109.04
059	09-Dec-01	12-Dec-01	4	R 916.00	13-Dec-01	14-Dec-01	2	0	R 61.08	R 977.08	Cure	R 109.04
060	12-Dec-01	15-Dec-01	4	R 916.00	16-Dec-01	16-Dec-01	1	0	R 30.54	R 946.54	Cure	R 109.04
061	15-Dec-01	19-Dec-01	5	R 1,145.00	20-Dec-01	21-Dec-01	2	0	R 61.08	R 1,206.08	Cure	R 109.04
062	16-Dec-01	20-Dec-01	5	R 1,145.00	21-Dec-01	21-Dec-01	1	0	R 30.54	R 1,175.54	Cure	R 109.04
066	05-Jan-02	07-Jan-02	3	R 687.00	08-Jan-02	10-Jan-02	3	0	R 91.62	R 778.62	Cure	R 109.04
068	11-Jan-02	18-Jan-02	8	R 1,832.00	19-Jan-02	20-Jan-02	2	0	R 61.08	R 1,893.08	Cure	R 109.04
071	22-Jan-02	28-Jan-02	7	R 1,603.00	NA	NA	0	0	R 0.00	R 1,603.00	Cure	R 109.04
072	23-Jan-02	26-Jan-02	4	R 916.00	27-Jan-02	28-Jan-02	2	0	R 61.08	R 977.08	Cure	R 109.04
074	30-Jan-02	01-Feb-02	3	R 687.00	02-Feb-02	03-Feb-02	2	0	R 61.08	R 748.08	Cure	R 109.04
075	18-Feb-02	24-Feb-02	7	R 1,603.00	NA	NA	0	0	R 0.00	R 1,603.00	Cure	R 109.04
079	24-Feb-02	26-Feb-02	3	R 687.00	27-Feb-02	01-Mar-02	3	0	R 91.62	R 778.62	Cure	R 109.04
081	27-Feb-02	04-Mar-02	6	R 1,374.00	NA	NA	0	0	R 0.00	R 1,374.00	Cure	R 109.04
084	13-Mar-02	18-Mar-02	6	R 1,374.00	NA	NA	0	0	R 0.00	R 1,374.00	Indeterminate	R 109.04
088	03-Apr-02	05-Apr-02	3	R 687.00	06-Apr-02	07-Apr-02	2	0	R 61.08	R 748.08	Cure	R 109.04
090	21-Apr-02	23-Apr-02	3	R 687.00	24-Apr-02	25-Apr-02	2	0	R 61.08	R 748.08	Cure	R 109.04
091	01-May-02	07-May-02	7	R 1,603.00	NA	NA	0	0	R 0.00	R 1,603.00	Failure	R 109.04
093	12-May-02	14-May-02	3	R 687.00	15-May-02	16-May-02	2	0	R 61.08	R 748.08	Cure	R 109.04
095	20-Jun-02	23-Jun-02	4	R 916.00	24-Jun-02	25-Jun-02	2	0	R 61.08	R 977.08	Cure	R 109.04
097	25-Jul-02	28-Jul-02	4	R 916.00	29-Jul-02	30-Jul-02	2	0	R 61.08	R 977.08	Cure	R 109.04
100	02-May-02	09-May-02	8	R 1,832.00	NA	NA	0	0	R 0.00	R 1,832.00	Cure	R 109.04
TOTALS			202	R 46,258.00			63	0	R 1,985.14	R 48,243.14		R 4,579.68
											TOTAL COST	R 52,822.82

Appendix D 7.2

RANDOM NUMBER	STUDY MEDICATION / TREATMENT GROUP B / PPP														CLINICAL EVALUATION DAY 5-14	CONSUM-ABLES
	CEFTRIAXONE TREATMENT				METRONIDAZOLE TREATMENT				CO-AMOXICLAV TABLETS					TOTAL COST		
	DATE IV TREATEMENT STARTED	DATE IV TREATMENT STOPPED	NUMBER OF DOSES IV TREATMENT	COST	DATE IV TREATEMENT STARTED	DATE IV TREATMENT STOPPED	NUMBER OF DOSES IV TREATMENT	COST	DATE ORAL TREATMENT STARTED	DATE ORAL TREATMENT STOPPED	NUMBER OF DOSES ORAL TREATMENT	NUMBER OF OUT PATIENT TREATMENT	COST			
001	16-Feb-01	23-Feb-01	8	R 2,557.34	16-Feb-01	18-Feb-01	6	R 199.18	NA	NA	0	0	R 0.00	R 2,756.52	Cure	R 109.04
002	20-Feb-01	24-Feb-01	5	R 1,598.34	20-Feb-01	23-Feb-01	9	R 298.77	NA	NA	0	0	R 0.00	R 1,897.11	Cure	R 109.04
011	14-Apr-01	15-Apr-01	5	R 1,598.34	14-Apr-01	16-Apr-01	15	R 497.95	16-Apr-01	19-Apr-01	9	0	R 99.94	R 2,196.23	Cure	R 109.04
012	15-Apr-01	18-Apr-01	4	R 1,278.67	15-Apr-01	18-Apr-01	10	R 331.97	18-Apr-01	20-Apr-01	6	0	R 66.63	R 1,677.26	Cure	R 109.04
013	01-May-01	07-May-01	7	R 2,237.67	01-May-01	07-May-01	21	R 697.13	NA	NA	0	0	R 0.00	R 2,934.80	Cure	R 109.04
015	09-May-01	14-May-01	6	R 1,918.00	09-May-01	14-May-01	15	R 497.95	14-May-01	16-May-01	5	0	R 55.52	R 2,471.48	Cure	R 109.04
017	15-May-01	20-May-01	6	R 1,918.00	15-May-01	20-May-01	14	R 464.76	NA	NA	0	0	R 0.00	R 2,382.76	Cure	R 109.04
020	22-May-01	27-May-01	6	R 1,918.00	27-May-01	28-May-01	4	R 132.79	27-May-01	28-May-01	4	0	R 44.42	R 2,095.21	Cure	R 109.04
023	11-Jun-01	13-Jun-01	3	R 959.00	11-Jun-01	13-Jun-01	6	R 199.18	13-Jun-01	14-Jun-01	5	0	R 55.52	R 1,213.70	Cure	R 109.04
024	19-Jun-01	25-Jun-01	7	R 2,237.67	19-Jun-01	26-Jun-01	19	R 630.74	NA	NA	0	0	R 0.00	R 2,868.41	Cure	R 109.04
026	30-Jun-01	05-Jul-01	6	R 1,918.00	01-Jul-01	06-Jul-01	15	R 497.95	06-Jul-01	07-Jul-01	4	0	R 44.42	R 2,460.37	Cure	R 109.04
027	02-Aug-01	06-Aug-01	5	R 1,598.34	02-Aug-01	06-Aug-01	11	R 365.16	NA	NA	0	0	R 0.00	R 1,963.50	Cure	R 109.04
029	10-Aug-01	17-Aug-01	8	R 2,557.34	10-Aug-01	17-Aug-01	21	R 697.13	NA	NA	0	0	R 0.00	R 3,254.47	Cure	R 109.04
032	23-Aug-01	28-Aug-01	6	R 1,918.00	23-Aug-01	25-Aug-01	7	R 232.38	29-Aug-01	30-Aug-01	3	0	R 33.31	R 2,183.70	Cure	R 109.04
033	10-Sep-01	15-Sep-01	4	R 1,278.67	10-Sep-01	13-Sep-01	9	R 298.77	14-Sep-01	15-Sep-01	4	0	R 44.42	R 1,621.86	Cure	R 109.04
034	12-Sep-01	15-Sep-01	4	R 1,278.67	13-Sep-01	16-Sep-02	8	R 265.57	16-Sep-01	18-Sep-01	6	0	R 66.63	R 1,610.87	Cure	R 109.04
035	13-Aug-01	17-Aug-01	5	R 1,598.34	NA	NA	0	R 0.00	18-Aug-01	20-Aug-01	3	0	R 33.31	R 1,631.65	Cure	R 109.04
037	27-Sep-01	30-Sep-01	4	R 1,278.67	27-Sep-01	30-Sep-01	11	R 365.16	01-Sep-01	01-Sep-01	1	0	R 11.10	R 1,654.94	Cure	R 109.04
039	01-Oct-01	01-Oct-01	4	R 1,278.67	01-Oct-01	05-Oct-01	12	R 398.36	05-Oct-01	06-Oct-01	5	0	R 55.52	R 1,732.55	Cure	R 109.04
041	10-Oct-01	16-Oct-01	7	R 2,237.67	11-Oct-01	16 Oc 01	18	R 597.54	17-Oct-01	19-Oct-01	5	0	R 55.52	R 2,890.74	Cure	R 109.04
043	19-Oct-01	23-Oct-01	5	R 1,598.34	19-Oct-01	23-Oct-01	10	R 331.97	23-Oct-01	26-Oct-01	4	0	R 44.42	R 1,974.72	Cure	R 109.04
046	23-Oct-01	29-Oct-01	7	R 2,237.67	24-Oct-01	29-Oct-01	17	R 564.35	NA	NA	0	0	R 0.00	R 2,802.02	Failure	R 109.04
050	08-Nov-01	12-Nov-01	5	R 1,598.34	08-Nov-01	11-Nov-01	11	R 365.16	NA	NA	0	0	R 0.00	R 1,963.50	Cure	R 109.04
053	19-Nov-01	22-Nov-01	4	R 1,278.67	19-Nov-01	22-Nov-01	9	R 298.77	23-Nov-01	23-Nov-01	1	0	R 11.10	R 1,588.55	Cure	R 109.04
056	27-Nov-01	29-Nov-01	3	R 959.00	27-Nov-01	30-Nov-01	9	R 298.77	30-Nov-01	01-Dec-01	4	0	R 44.42	R 1,302.19	Cure	R 109.04
057	03-Dec-01	07-Dec-01	5	R 1,598.34	03-Dec-01	07-Dec-01	12	R 398.36	NA	NA	0	0	R 0.00	R 1,996.70	Cure	R 109.04
058	09-Dec-01	14-Dec-01	6	R 1,918.00	09-Dec-01	14-Dec-01	16	R 531.15	NA	NA	0	0	R 0.00	R 2,449.15	Cure	R 109.04
063	17-Dec-01	25-Dec-01	9	R 2,877.01	17-Dec-01	25-Dec-01	22	R 730.33	NA	NA	0	0	R 0.00	R 3,607.34	Cure	R 109.04
064	18-Dec-01	20-Dec-01	3	R 959.00	18-Dec-01	21-Dec-01	8	R 265.57	21-Dec-01	22-Dec-01	3	0	R 33.31	R 1,257.89	Cure	R 109.04
065	02-Jan-02	05-Jan-02	4	R 1,278.67	N/A	N/A	0	R 0.00	06-Jan-02	07-Jan-02	3	0	R 33.31	R 1,311.98	Cure	R 109.04
069	13-Jan-02	16-Jan-02	4	R 1,278.67	13-Jan-02	17-Jan-02	11	R 365.16	17-Jan-02	18-Jan-02	5	0	R 55.52	R 1,699.36	Cure	R 109.04
070	14-Jan-02	18-Jan-02	5	R 1,598.34	14-Jan-02	18-Jan-02	12	R 398.36	18-Jan-02	19-Jan-02	4	0	R 44.42	R 2,041.12	Cure	R 109.04
076	19-Feb-02	22-Feb-02	4	R 1,278.67	19-Feb-02	22-Feb-02	10	R 331.97	22-Feb-02	26-Feb-02	11	0	R 122.15	R 1,732.79	Cure	R 109.04
082	07-Mar-02	09-Mar-02	3	R 959.00	07-Mar-02	09-Mar-02	9	R 298.77	10-Mar-02	11-Mar-02	4	0	R 44.42	R 1,302.19	Cure	R 109.04
083	10-Mar-02	14-Mar-02	5	R 1,598.34	10-Mar-02	14-Mar-02	12	R 398.36	14-Mar-02	15-Mar-02	4	0	R 44.42	R 2,041.12	Cure	R 109.04
086	18-Mar-02	20-Mar-02	3	R 959.00	18-Mar-02	21-Mar-02	9	R 298.77	21-Mar-02	23-Mar-02	6	0	R 66.63	R 1,324.40	Cure	R 109.04
087	29-Mar-02	02-Apr-02	4	R 1,278.67	30-Mar-02	02-Apr-02	9	R 298.77	02-Apr-02	02-Apr-02	1	0	R 11.10	R 1,588.55	Cure	R 109.04
089	16-Apr-02	25-Apr-02	6	R 1,918.00	17-Apr-02	23-Apr-02	16	R 531.15	23-Apr-02	25-Apr-02	6	0	R 66.63	R 2,515.78	Cure	R 109.04
092	09-May-02	12-May-02	4	R 1,278.67	09-May-02	13-May-02	12	R 398.36	13-May-02	14-May-02	3	0	R 33.31	R 1,710.34	Cure	R 109.04
094	09-Jun-02	13-Jun-02	5	R 1,598.34	09-Jun-02	13-Jun-02	12	R 398.36	13-Jun-02	15-Jun-02	6	0	R 66.63	R 2,063.32	Cure	R 109.04
096	09-Jul-02	11-Jul-02	3	R 959.00	09-Jul-02	12-Jul-02	8	R 265.57	12-Jul-02	14-Jul-02	6	0	R 66.63	R 1,291.20	Cure	R 109.04
098	11-Aug-02	15-Aug-02	5	R 1,598.34	11-Aug-02	16-Aug-02	15	R 497.95	NA	NA	0	0	R 0.00	R 2,096.29	Cure	R 109.04
099	11-Aug-02	15-Aug-02	5	R 1,598.34	11-Aug-02	16-Aug-02	14	R 464.76	16-Aug-02	18-Aug-02	5	0	R 55.52	R 2,118.61	Cure	R 109.04
TOTALS			217	R 69,367.83			490	R 16,399.22			136	0	R 1,510.19	R 87,277.24		R 4,688.72
															TOTAL COST	R 91,965.96

Appendix D 8.1

RANDOM NUMBER	THERAPEUTIC ADJUNCTIONS / TREATMENT GROUP A / PPP				
	THERAPEUTIC ADJUNCTIONS	UNITS	START DATE	STOP DATE	COST
003	Urinary Catheter	1	22-Feb-01	23-Feb-01	**R 23.46**
	Nasogastric Tube	1	22-Feb-01	23-Feb-01	**R 16.30**
004	Urinary Catheter	1	23-Feb-01	25-Feb-01	**R 23.46**
	Nasogastric Tube	1	23-Feb-01	25-Feb-01	**R 16.30**
007	Urinary Catheter	1	26-Mar-01	04-Apr-01	**R 23.46**
009	Urinary Catheter	1	06-Apr-01	08-Arp-01	**R 23.46**
	Chest Physiotherapy	1	07-Apr-01	09-Apr-01	**R 409.95**
	Nasogastric Tube	1	06-Apr-01	07-Apr-01	**R 16.30**
010	Urinary Catheter	1	08-Apr-01	09-Apr-01	**R 23.46**
	Nasogastric Tube	1	09-Apr-01	09-Apr-01	**R 16.30**
	Chest Physiotherapy	1	10-Apr-01	12-Apr-01	**R 409.95**
014	Urinary Catheter	1	06-May-01	07-May-01	**R 23.46**
	Nasogastric Tube	1	06-May-01	07-May-01	**R 16.30**
018	Urinary Catheter	1	15-May-01	17-May-01	**R 23.46**
019	Nasogastric Tube	1	16-May-01	18-May-01	**R 16.30**
	Urinary catheter	1	16-May-01	18-May-01	**R 23.46**
	Oxygen Face Mask	11	16-May-01	17-May-01	**R 50.00**
022	NA	0	NA	NA	**R 0.00**
025	Nasogastric Tube	1	19-Jun-01	21-Jun-01	**R 16.30**
	Urinary Catheter	1	20-Jun-01	21-Jun-01	**R 23.46**
028	Urinary Catheter	1	03-Aug-01	04-Aug-01	**R 23.46**
030	Urinary Catheter	1	14-Aug-01	16-Aug-01	**R 23.46**
	Nasogastric Tube	1	14-Aug-01	17-Aug-01	**R 16.30**
031	Urinary Catheter	1	23-Aug-01	24-Aug-01	**R 23.46**
036	Urinary Catheter	1	13-Aug-01	16-Aug-01	**R 23.46**
	Nasogastric Tube	1	13-Aug-01	17-Aug-01	**R 16.30**
	Oxygen Face Mask	1	14-Aug-01	16-Aug-01	**R 50.00**
038	NA	1	NA	NA	**R 0.00**
042	Nasogastrlc Tube	1	19-Oct-01	22-Oct-01	**R 16.30**
	Urinary Catheter	1	19-Oct-01	22-Oct-01	**R 23.46**
	Urinary Catheter	1	28-Oct-01	03-Nov-01	**R 23.46**
	Packed Red cells	2	19-Oct-01	19-Oct-01	**R 1,050.00**
044	Nasogastric Tube	1	21-Nov-01	22-Nov-01	**R 16.30**
	Urinary catheter	1	21-Nov-01	22-Nov-01	**R 23.46**
045	Urinary Catheter	1	21-Nov-01	22-Nov-01	**R 23.46**
049	NA	0	NA	NA	**R 0.00**
051	Urinary Catheter	1	11-Nov-01	13-Nov-01	**R 23.46**
	Central Venous Catheter	1	12-Nov-01	13-Nov-01	**871.13**
	Oxygen Face Mask	1	12-Nov-01	12-Nov-01	**R 50.00**
	Nasogastric Tube	1	11-Nov-01	14-Nov-01	**R 16.30**
054	Urinary Catheter	1	19-Nov-01	20-Nov-01	**R 23.46**
	Nasogastric Tube	1	19-Nov-01	22-Nov-01	**R 16.30**
	Packed Red cells	4	19-Nov-01	19-Nov-01	**R 2,100.00**
055	Urinary Catheter	1	20-Nov-01	21-Nov-01	**R 23.46**
	Nasogastric Tube	1	20-Nov-01	20-Nov-01	**R 16.30**
059	Oxygen Face Mask	1	09-Dec-01	10-Dec-01	**R 50.00**
	Urinary Catheter	1	09-Dec-01	10-Dec-01	**R 23.46**
060	Urinary Catheter	1	12-Dec-01	12-Dec-01	**R 23.46**
	Nasogastric Tube	1	12-Dec-01	12-Dec-01	**R 16.30**
061	Urinary Catheter	1	15-Dec-01	17-Dec-01	**R 23.46**
	Nasogastric Tube	1	15-Dec-01	16-Dec-01	**R 16.30**
	Oxygen Face Mask	1	15-Dec-01	16-Dec-01	**R 50.00**
	Chest Tubes	1	15-Dec-01	18-Dec-01	**R 87.52**
062	Urinary Catheter	1	16-Dec-01	18-Dec-01	**R 23.46**
	Central Venous Catheter	1	16-Dec-01	17-Dec-01	**871.13**

Appendix D 8.1

RANDOM NUMBER	THERAPEUTIC ADJUNCTIONS / TREATMENT GROUP A / PPP				
	THERAPEUTIC ADJUNCTIONS	UNITS	START DATE	STOP DATE	COST
066	NA	0	NA	NA	R 0.00
068	Urinary Catheter	1	11-Jan-02	19-Jan-02	R 23.46
	Nasogastric tube	1	11-Jan-02	16-Jan-02	R 16.30
	Oxygen Face Mask	1	12-Jan-02	16-Jan-02	R 50.00
	Oxygen Facé mask	1	12-Jan-02	12-Jan-02	R 50.00
	Oxygen Face mask	1	16-Jan-02	19-Jan-02	R 50.00
071	Nasogastric Tube	1	22-Jan-02	24-Jan-02	R 16.30
	Urinary Catheter	1	22-Jan-02	24-Jan-02	R 23.46
	Oxygen Face Mask	1	22-Jan-02	23-Jan-02	R 50.00
072	Urinary Catheter	1	23-Jan-02	24-Jan-02	R 23.46
074	Urinary Catheter	1	31-Jan-02	31-Jan-02	R 23.46
075	Urinary Catheter	1	18-Feb-02	20-Feb-02	R 23.46
	Nasogastric tube	1	18-Feb-02	20-Feb-02	R 16.30
079	Oxygen Face mask	1	25-Feb-02	25-Feb-02	R 50.00
	Nasogastric Tube	1	23-Feb-02	25-Feb-02	R 16.30
	Urinary catheter	1	24-Feb-02	25-Feb-02	R 23.46
081	Urinary Catheter	1	27-Feb-02	28-Feb-02	R 23.46
084	Urinary Catheter	1	13-Mar-02	14-Mar-02	R 23.46
	Nasogastric Tube	1	20-Mar-02	21-Mar-02	R 16.30
	Urinary Catheter	1	20-Mar-02	24-Mar-02	R 23.46
088	Urinary Catheter	1	03-Apr-02	04-Apr-02	R 23.46
090	Urinary Catheter	1	20-Apr-02	22-Apr-02	R 23.46
	Nasogastric Tube	1	21-Apr-02	22-Apr-02	R 16.30
091	Urinary Catheter	1	01-May-02	03-May-02	R 23.46
	Nasogastric Tube	1	01-May-02	03-May-02	R 16.30
	Chest Tubes	1	15-May-02	Ongoing	R 87.52
	Dialisis Catheter	1	16-May-02	Ongoing	R 1,649.31
	Fresh Frozen Plasma	4	15-May-02	15-May-02	R 3,120.00
	Packed Red cells	2	15-May-02	15-May-02	R 1,050.00
	Fresh Frozen Plasma	2	16-May-02	16-May-02	R 1,560.00
	Packed Red cells	1	17-May-02	17-May-02	R 1,050.00
	Urinary Catheter	1	10-May-02	Ongoing	R 23.46
	Nasogastric Tube	1	10-May-02	Ongoing	R 16.30
093	Urinary Catheter	1	12-May-02	13-May-02	R 23.46
	Oxygen Face Mask	1	12-May-02	12-May-02	R 50.00
095	Urinary Catheter	1	20-Jun-02	21-Jun-02	R 23.46
	Nasogastric Tube	1	06-Jul-02	08-Jul-02	R 16.30
	Oxygen Face Mask	1	20-Jun-02	20-Jun-02	R 50.00
097	Urinary Catheter	1	25-Jul-02	26-Jul-02	R 23.46
100	Urinary Catheter	1	02-May-02	03-May-02	R 23.46
	Urinary Catheter	1	04-May-02	08-May-02	R 23.46
TOTAL					R 16,309.33

Appendix D 8.2

RANDOM NUMBER	THERAPEUTIC ADJUNCTIONS / TREATMENT GROUP B / PPP				
	THERAPEUTIC ADJUNCTIONS	UNITS	START DATE	STOP DATE	COST
001	Central Venous Catheter		16-Feb-01	23-Feb-01	R 871.13
002	Nasogastric Tube		20-Feb-01	21-Feb-01	R 16.30
002	Urinary Catheter		19-Feb-01	21-Feb-01	R 23.46
011	Urinary Catheter		11-Apr-01	12-Apr-01	R 23.46
012	Nasogastric Tube		15-Apr-01	15-Apr-01	R 16.30
012	Urinary catheter		15-Apr-01	15-Apr-01	R 23.46
013	Urinary catheter		30-Apr-01	03-May-01	R 23.46
013	Nasogastric Tube		01-May-01	02-May-01	R 16.30
015	Urinary Catheter		09-May-01	10-May-01	R 23.46
017	NA		NA	NA	R 0.00
020	Urinary catheter		22-May-01	23-May-01	R 23.46
020	Nasogastric Tube		22-May-01	23-May-01	R 16.30
023	Urinary Catheter		11-Jun-01	12-Jun-01	R 23.46
024	Nasogastric Tube		19-Jun-01	20-Jun-01	R 16.30
024	Urinary Catheter		19-Jun-01	20-Jun-01	R 23.46
024	Oxygen Face Mask		19-Jun-01	24-Jun-01	R 50.00
026	Nasogastric tube		20-Jun-01	01-Jul-01	R 16.30
026	Urinary Catheter		30-Jun-01	02-Jul-01	R 23.46
026	Chest Tube	Left & right	30-Jun-01	06-Jun-01	R 84.52
027	Urinary Catheter		02-Aug-01	03-Aug-01	R 23.46
027	Nasogastric Tube		02-Aug-01	03-Aug-01	R 16.30
029	Nasogastric Tube		09-Aug-01	11-Aug-01	R 16.30
029	Urinary Catheter		09-Aug-01	11-Aug-01	R 23.46
029	Nasogastric Tube		15-Aug-01	18-Aug-01	R 16.30
032	Urinary Catheter		23-Aug-01	24-Aug-01	R 23.46
033	Urinary Catheter		10-Aug-01	11-Aug-01	R 23.46
033	Oxygen Face Mask		10-Aug-01	10-Aug-01	R 50.00
034	Urinary Catheter		12-Aug-01	14-Aug-01	R 23.46
035	Urinary Catheter		13-Aug-01	18-Aug-01	R 23.46
037	NA		NA	NA	R 0.00
039	Urinary Catheter		01-Oct-01	02-Oct-01	R 23.46
041	NA		NA	NA	R 0.00
043	NA		NA	NA	R 0.00
046	Central Venous Catheter		23-Oct-01	NA	R 871.13
046	Fresh frozen plasma	3	23-Oct-01	25-Oct-01	R 2,340.00
046	Nasogastric tube		23-Oct-01	01-Nov-01	R 16.30
046	Urinary catheter		22-Oct-01	01-Nov-01	R 23.46
046	Oxygen Face Mask		29-Oct-01	03-Nov-01	R 50.00
050	Urinary Catheter		08-Nov-01	09-Nov-01	R 23.46
053	Urinary Catheter		19-Nov-01	20-Nov-01	R 23.46
053	Nasogastric Tube		19-Nov-01	20-Nov-01	R 16.30
056	NA		NA	NA	R 0.00
057	Urinary Catheter		03-Dec-01	04-Dec-01	R 23.46
058	Urinary Catheter		09-Dec-01	10-Dec-01	R 23.46
056	NA		NA	NA	R 0.00
057	Urinary Catheter		03-Dec-01	04-Dec-01	R 23.46
058	Urinary Catheter		09-Dec-01	10-Dec-01	R 23.46
063	Nasogastric Tube		17-Dec-01	18-Dec-01	R 16.30
064	Urinary Catheter		16-Dec-01	18-Dec-01	R 23.46
064	Urinary catheter		18-Dec-01	19-Dec-01	R 23.46
064	Nasogastric tube		18-Dec-01	19-Dec-01	R 16.30
064	Chest Tube	Left	18-Dec-01	20-Dec-01	R 43.76
064	Oxygen Face Mask		18-Dec-01	20-Dec-01	R 50.00
064	Chest Tube	Right	18-Dec-01	21-Dec-01	R 43.76
065	Urinary Catheter		02-Jan-02	03-Jan-02	R 23.46
069	Urinary Catheter		12-Jan-02	14-Jan-02	R 23.46
069	Oxygen Face Mask		14-Jan-02	16-Jan-02	R 50.00
070	Nasogastric tube		14-Jan-02	15-Jan-02	R 16.30
070	Oxygen Face Mask		15-Jan-02	18-Jan-02	R 50.00
070	Oxygen Face Mask		14-Jan-02	15-Jan-02	R 50.00
070	Urinary catheter		14-Jan-02	15-Jan-02	R 23.46
076	Nasogastric tube		19-Feb-02	20-Feb-02	R 16.30
076	Urinary Catheter		19-Feb-02	20-Feb-02	R 23.46

Appendix D 8.2

RANDOM NUMBER	THERAPEUTIC ADJUNCTIONS / TREATMENT GROUP B / PPP				
	THERAPEUTIC ADJUNCTIONS	UNITS	START DATE	STOP DATE	COST
082	NA		NA	NA	R 0.00
083	Oxygen Face Mask		10-Mar-02	11-Mar-02	R 50.00
086	Urinary Catheter		18-Mar-02	19-Mar-02	R 23.46
087	Urinary Catheter		30-Mar-02	31-Mar-02	R 23.46
089	NA		NA	NA	R 0.00
092	Arterial Catheter		08-May-02	13-May-02	R 303.18
092	Nasogastric Tube		08-May-02	11-May-02	R 16.30
092	Urinary Catheter		09-May-02	10-May-02	R 23.46
094	Urinary Catheter		09-Jun-02	10-Jun-02	R 23.46
094	Nasogastric Tube		09-Jun-02	11-Jun-02	R 16.30
094	Oxygen Face Mask		09-Jun-02	10-Jun-02	R 50.00
096	NA		NA	NA	R 0.00
098	Urinary Catheter		10-Aug-02	12-Aug-02	R 23.46
098	Oxygen Face Mask		11-Aug-02	12-Aug-02	R 50.00
099	Urinary Catheter		11-Aug-02	12-Aug-02	R 23.46
099	Arterial Catheter		11-Aug-02	12-Aug-02	R 303.18
099	Central Venous Catheter		11-Aug-02	12-Aug-02	R 871.13
TOTAL					R 7,329.99