THE USE OF PHARMACOECONOMICS AS A DECISION MAKING TOOL IN SOUTH AFRICAN HEALTHCARE

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ABSTRACT

The high cost of healthcare is of major concern to healthcare providers throughout the world. Globally there has been an increase in the use of pharmacoeconomic tools to help providers to make healthcare reimbursement decisions .South Africa has also become increasingly sensitive to healthcare spend and the South African government has announced proposals to make pharmacoeconomic evaluations part of the drug registration process in the country. It is unclear to what extent pharmacoeconomic evaluations are currently being used in decision making in healthcare.

In this research, decision makers from the payer, healthcare prescriber and pharmaceutical manufacturer sectors were interviewed to evaluate the level of current use of pharmacoeconomic evaluations so as to determine the factors driving and inhibiting the use of pharmacoeconomic evaluation tools. Twenty-five semi-structured interviews were conducted and the data obtained were analysed using content analysis, allowing for an in-depth assessment of responses.

The research found that pharmacoeconomic evaluations are used at payer and pharmaceutical manufacturer level but its use is limited at the healthcare provider level. The need for cost containment, harmonisation and globalisation in the pharmaceutical industry is a factor driving the use of pharmacoeconomic evaluations. Although these evaluations are not yet a requirement in South Africa, government regulations and requirements are an emerging factor. The use of such evaluations is, however, limited by a lack of education and skills, perceived bias, lack of credibility and perceived poor quality, and lack of methodology, applicability and relevance of economic evaluations in the decision maker's context and the poor communication and reporting of data.

DECLARATION

I, Prenisha Naidoo, declare that this research report is my own work except as indicated in the references and acknowledgements. It is submitted in partial fulfilment of the requirements for the degree of Master of Business Administration in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination in this or any other university.

Prenisha Naidoo

Signed at …….

On the …….. day of ……. 2009

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My sincere gratitude and appreciation to my respondents for their frank, open discussion.

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1. CHAPTER ONE: INTRODUCTION

1.1 PURPOSE OF THE RESEARCH REPORT

The purpose of this study was firstly to determine to what extent pharmacoeconomic studies are influencing decisions made in South African healthcare. This then formed the basis for a more focused interpretation of the promoters of and barriers to the use of pharmacoeconomic evaluations. Insight into the views expressed by the decision makers at different levels was also required to foster an understanding of these elements.

1.2 PHARMACOECONOMICS IN THE HEALTH ECONOMICS CONTEXT

Health Economics has been defined as the study of how scarce resources are allocated among alternative users for the care of sickness and the promotion, maintenance and improvement of health, including the study of how healthcare and health-related services, their costs and benefits, and health itself are distributed among individuals and groups in society. Health Economics is also seen as “a broad-based sub-discipline of economics” which lies at the interface of economics and medicine and seeks to examine choice within healthcare. It is concerned with maximising benefits within available resources. Health economics, as a discipline, encompasses more than just economic or pharmacoeconomic evaluations (Lee & Mills, 1979; 1983).

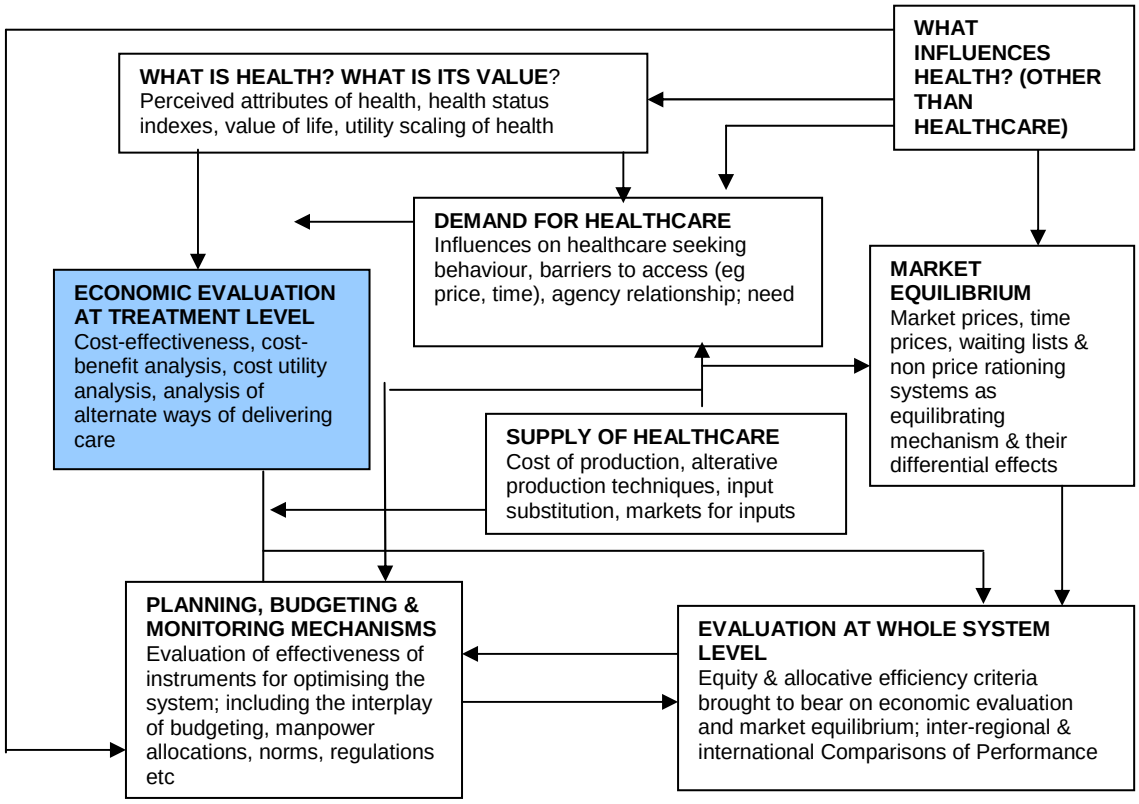

Figure 1.1: Structure of Health Economics as a discipline
(Source: Adapted from Williams, Culyer & Maynard 1997**)**

Pharmacoeconomics combines the use of economics, epidemiology, decision analysis and biostatistics into a comprehensive evaluation of treatment and technological interventions in healthcare. Practically, it is that information that is used to assess and compare the value of pharmaceutical products and services (Grizzle, Olson, Motheral & Armstrong, 2000). It enables an assessment of the full economic value of treatment, which can then be used to balance the supply of healthcare with the demand for health resources under the umbrella of health economics as a discipline (Williams et al, 1997). Pharmacoeconomics is not merely a monetary costing exercise.

Pharmacoeconomics can also be seen as an evidence-based approach to determine whether the benefit derived from a healthcare intervention is worth the additional cost. The three basic tools of pharmacoeconomic analyses are cost-effectiveness studies, cost-benefit evaluations and cost-utility evaluations (Spencer-Jones, 2006). A cost-effectiveness study compares the clinical effects

of competing interventions to the costs of those interventions. A cost-benefit evaluation is one where the outcome of the intervention is expressed in monetary value. It is an attempt to determine how much society would be expected to pay for the ascribed outcomes of healthcare interventions. A cost-utility evaluation attempts to convert the intervention's outcomes into a measure that takes into account morbidity and mortality, and the quality adjusted life-year (QALY). Thus pharmacoeconomic evaluations consider not only the financial, but also the humanitarian, cultural and ethical, aspects of healthcare (Langley, 2004).

Internationally, the use of pharmacoeconomic tools has increased dramatically over the last 12 to 15 years, driven largely by the need for cost containment (Drummond, Dubois & Grattini, 1999). Initially, pharmacoeconomic evaluations were conducted and submitted voluntarily. However, countries like Australia, Canada and the UK have now set up Health Technology Assessment Agencies, which has made economic evaluations of new drugs to aid reimbursement (e.g. medical aid claims payouts), market access and pricing decisions a mandatory requirement.

South Africa is faced with the daunting task of providing healthcare against the backdrop of an ever-increasing disease burden, the challenge of the HIV pandemic, escalating medical costs, a weakening infrastructure and limited resources. Efficient and effective management of healthcare spend is therefore of paramount importance in the South African healthcare arena. Whilst pharmacoeconomic evaluations are increasingly being recognised and used as a means of facilitating cost-effective healthcare decisions internationally, limited academic research is available on their use in South Africa.

1.3 RESEARCH PROBLEM

This research aims to determine a number of factors relating to the use of pharmacoeconomic evaluations at the level of funders/payers, pharmaceutical manufacturers and medical practitioners. It will firstly focus on ascertaining the extent of their current use at the above levels in the South African context. It will then explore the promoters of the successful implementation of such evaluations and the barriers to the effective establishment of health economic evaluations as a decision-making tool. Finally, the perceptions of the different levels of decision makers with regard to these factors will be analysed.

1.3.1 Sub-problems

1) Determine the use of pharmacoeconomic evaluations in the South African healthcare sector at the level of funders/payers, the pharmaceutical manufacturers and healthcare providers.
2) Identify promoters of the successful use of pharmacoeconomics as a decision-making tool.
3) Identify barriers to the effective establishment of pharmacoeconomics as a decision-making tool.

1.4 SIGNIFICANCE

According to Dr Anban Pillay, director of pharmaceutical economic evaluations in the South African Department of Health (DOH), the introduction of mandatory pharmacoeconomic guidelines by the South African government is inevitable. However, he concedes that the DOH will have to first decide whether capacity exists in the healthcare industry and within the DOH before implementation (Spencer-Jones, 2006).

This study will identify the current level of use of pharmacoeconomic evaluations and thus provide some indication of the existing capacity. It will also help identify factors which will allow for the more effective use of economic

evaluations in the South African healthcare setting. Government, healthcare consultancies, pharmaceutical companies and medical researchers can draw on the results of this study.

Furthermore, this study will identify factors that may be distinctive to the South African context. This is important since no studies have as yet been undertaken in the subject area in South Africa. This study may therefore help in understanding the use pharmacoeconomics in the South African context and act as a catalyst for further studies.

1.5 PROBLEM DELINEATION

1.5.1 Limitations and delimitations

The research will evaluate a sample from a population of various people involved in decision making in healthcare. The researcher will select respondents who have the experience needed to answer the research questions and, as such, no attempt will be made to ensure that the sample is random or representative of the population. Furthermore, a ‘snowball’ sampling methodology will be used to identify the most appropriate respondents.

1.5.2 Assumptions

It is assumed that respondents will answer as objectively, accurately and honestly as possible.

CHAPTER 2: LITERATURE REVIEW

This literature review will first look at the methods of pharmacoeconomic evaluation and the introduction of pharmacoeconomic guidelines internationally in an attempt to determine the methods and trends. It will then review literature looking at the promoters of and the barriers to the use of economic evaluations in healthcare decision making.

2.1 Pharmacoeconomic evaluation methods

The most frequently used analytical methods in pharmacoeconomics are cost-effectiveness analysis, cost-benefit analysis and cost-utility analysis (Langley, 2004; Spencer-Jones, 2006).

2.1.1 Cost-effectiveness analysis

Drummond et al, as cited by Langley (2004), define a cost-effectiveness study as “a form of economic evaluation where potentially competing therapies are assessed by comparing the costs of the therapies and the outcomes achieved, where these outcomes are measured in terms specific to that disease or therapy area”.

Cost-effectiveness analyses are thus used to assess an intervention that has a single clearly defined objective or objectives that are highly correlated and therefore create an impact of similar magnitude. Cost-effectiveness implies value for money; the cheapest may not necessarily be the most effective in terms of the desired outcomes. The decision maker then has to decide if the additional cost is worth the added effectiveness. Cost-effectiveness studies therefore aid decision makers in choosing between alternative healthcare interventions or drugs. Cost is measured in terms of monetary value and outcomes in ‘natural’ units, usually in terms of the outcomes related to the

problem under investigation, for example patients cured of a specific disease and unwanted pregnancies (Bootman, Townsend & McGhan,1996; Drummond, Schulper, Torrance, O'Brien & Stoddart, 2005).

Bootman et al (1996) identify the fact that, in conducting a cost-effectiveness analysis, one needs to define the problem, identify the alternative interventions and describe the production relationships between inputs and outcomes. It is then necessary to identify and measure the outcomes of the alternative interventions, the value costs and effectiveness before interpreting and presenting results.

Problem definition requires identifying the perspective of the intended user. Hospitals are concerned with 'in-hospital costs' and therefore have no interest in the patients' rehabilitation or productivity. The medical aid or managed healthcare organisation, on the other hand, is interested only in those costs that they are bound to cover. Government, however, may have a societal perspective and require that all costs and effects be included in the study. This also requires that the problem to be solved is clearly identified and that the objective, in terms of how the effectiveness of the intervention is to be measured, is selected appropriately. In establishing the production relationships, one considers the resources and the related costs used in each of the interventions being evaluated, with the aim of determining the unit of additional output being gained for each unit of further input. Modelling techniques used in this process include flow Markov Models, Monte Carlo Simulation and decision trees, with decision trees being the most commonly used method in cost-effectiveness analysis (Bootman et al, 1996).

Expert opinion, published literature and primary data collection can be used to measure outcomes. Whatever method is used, it is important that one review one's source critically to ensure accuracy. Discounting is important in the valuing of economic and health variables as it allows for future costs and effectiveness to be measured. Finally, cost-effectiveness analyses are often

presented as an average cost-effectiveness ratio or as an incremental cost-effectiveness ratio (Bootman et al, 1996; Langley, 2004).
The average cost-effectiveness ratio is also described as the cost per specific clinical outcome. This ratio allows for the costs and outcomes to be viewed as a single value, facilitating comparison. The incremental cost-effectiveness ratio (ICER) measures the benefits and costs associated with changing patients from one drug therapy to another. It shows the additional cost required to obtain the additional effect gained by switching from one drug to the other (Langley, 2004).

2.1.2 Cost-benefit analysis

Cost-benefit studies compare the costs of all resources used in the provision of a drug or intervention with the value of the outcome. This requires that the outcomes be translated into monetary units so that costs and benefits are expressed in the same units. It therefore allows for the value of diverse programmes, which may not have the same objectives, to be compared (Drummond et al, 2005):

In performing a cost-benefit analysis one first identifies the interventions to be evaluated. Costs of all resources used in the provision of the intervention must be identified. Similarly, the benefits to be derived from the intervention must be recognised and valued in monetary terms (Bootman et al, 1996). The net benefit is then calculated by subtracting the total cost from the total benefits, yielding a monetary value. It is also possible to present the results in terms of a cost-to-benefit ratio or benefit-to-cost ratio (B/C), which may be more suitable as total benefits are expected to surpass total costs (Bootman et al, 1996; Langley, 2004).

A B/C > 1 implies that the intervention is economically feasible as benefits exceed the costs, whilst B/C < 1 suggests that the intervention is not economically beneficial.

Unlike cost-effectiveness evaluations, cost-benefit studies may be used to evaluate one or several interventions to compare these interventions with differing outcomes and yield a result that can be expressed in pure monetary value. Thus cost-benefit analyses are of value to the decision maker who has to make budget allocation decisions with regard to interventions that have disparate outcomes and/or to evaluate single interventions (Bootman et al, 1996; Langley, 2004).

2.1.3 Cost-utility analysis

The primary focus of cost-utility analysis is the quality of the health intervention outcomes. This third method of evaluation is concerned with measuring the cost per unit of healthcare outcome. The quality adjusted life year (QALY), which incorporates both morbidity and mortality dimensions, is used as the unit of outcome. Costs are measured in monetary terms and the study results are presented as a ratio or 'cost per quality-adjusted-life year gained' (Langley, 2004).

Utility refers to the preferences or weighting attached to particular health states and is used to capture the morbidity characteristics of that particular state. QALY measures are arrived at by combining these morbidity weightings or preferences with the expected mortality or survival profiles of the population for whom the intervention is intended. The QALY can address the need to compare interventions that have an impact on quality and quantity of life, that is, morbidity and mortality. Thus, cost-utility analyses allow health outcomes to be measured in a way that offers an indication of the impact of a condition on a patient's life and how and if the intervention improves the quality and quantity of his or her life (Langley, 2004; Drummond et al, 2005).

Cost-utility studies are therefore useful when the quality of life is an important outcome, when the intervention being investigated affects both morbidity and mortality or when the interventions being compared have a wide range of

outcomes and a single unit of outcome is required to allow for comparison. Compared to cost-benefit analysis, cost-utility analysis does not require all costs and outcomes to be converted into monetary values. Cost-utility studies are able to incorporate multiple outcomes of the same intervention and to compare interventions with different outcomes, unlike cost-effectiveness analyses. However, cost-utility studies have been criticised for oversimplifying all aspects of the quality of life into one outcome measure. There are also concerns around the numerical nature of QALYs, as well as difficulty in reaching agreement on utilities, comparing QALYs between different populations and placing values on outcome preferences. However, it is anticipated that the use of cost-utility analyses will increase as the need to evaluate disparate interventions increases and with the need to consider not only financial but also the humanitarian, cultural and ethical aspects of healthcare.

2.2 The international introduction of pharmacoeconomic evaluations

Whilst the pressure of increasing demands on healthcare providers is similar worldwide, available literature suggests that pharmacoeconomic evaluations are still mainly undertaken in the developed world and little data is available on their introduction and use in developing countries. Even in developed countries, the extent of use varies and different approaches have been used to introduce economic evaluations in healthcare (Davey, Price, Lees, Makino, Birinyi-Strachan & Frost, 2004).

Pharmacoeconomics and outcomes research were initially introduced in the western world as early as the 1970s. In 1992/1993, the Australian government became the first country to make pharmacoeconomic evaluations compulsory and to establish formal submission guidelines for formulary listing, which were reviewed in 2002 (Doherty, Kamae, Lee, Li, Liu, Tarn, & Yang, 2004). The objective of these guidelines is to guide manufacturers who are making recommendations on the suitability of their drugs for subsidy by the Australian Government on the preparation of clinical and economic data. They specify, among other parameters, the types of cost to be included, the preferred

methods of economic evaluation and the discount factors to be used (International Society for Pharmacoeconomics Website, 2005c).

Table 2.1: Submission guidelines in Australia

	Submission Guidelines - Australia
Title and year of the Document	Guidelines for the pharmaceutical industry on preparation of submissions to the Pharmaceutical Benefits Advisory Committee (PBAC), 2002
Main policy objective	Provide manufacturers with guidance to prepare the clinical and economic data for submissions to the PBAC. PBAC and Economics Sub-Committee (ESC) making recommendations on the suitability of drug products for subsidy by the Australian Government.
Preferred analytical technique	Any one of CEA, CUA, CBA. Need justification.
Preferred outcome measure	Effectiveness in natural and patient relevant units. Both general and disease-specific QoL instruments can be used, and are valid, reliable, and responsive ones.
Discounting costs	Yes, 5%
Sensitivity analysis-parameters and range	One-way SA must be conducted on all variables using extreme values. Conduct two-way SA on all variables shown to be sensitive in the one-way SA.
Sensitivity analysis-methods	One-way, and two-way SA

Source: Adapted from International Society for Pharmacoeconomics Website, 2005c

In Canada, pharmacoeconomic evaluations have been the result of a collaborative undertaking between the pharmaceutical industry, academic experts in the field, and the provincial and federal government (Doherty et al, 2004). The Canadian pharmacoeconomic guidelines document titled 'Guidelines for Economic Evaluation of Pharmaceuticals' was prepared in 1997 by the Directorate at Canadian Coordinating Office for Health Technology Assessment (CCOHTA), the Department of Health, the pharmaceutical industry and academia (International Society for Pharmacoeconomics Website, 2005c). Canada has also published specific submission guidelines largely based on its pharmacoeconomic guidelines document. Although these submission guidelines are very similar to those of Australia, the Canadian guidelines specify that cost-benefit and cost-utility analyses be used, that health-related quality of life, QALY and willingness to pay are the outcome measures and also specify a range for the discount factor.

In the European region, Belgium, Hungary, Poland, the Russian Federation, France, Germany, the Netherlands, Switzerland, the Baltic states, Finland, Ireland, Norway, Scotland, Portugal, Spain and Italy have all published pharmacoeconomic guidelines. Of these only Belgium, England and Wales have issued formal submission guidelines for formulary listing as well (International Society for Pharmacoeconomics Website, 2005c).

Table 2.2: Submission guidelines for Belgium and England and Wales

	Belgium	**England & Wales**
Title and year of the document	Recommended structure for reporting economic evaluation on pharmaceuticals, 2002	NICE Technology Appraisals No. 5, 2001 Guidance for manufacturers and sponsors
Main policy objective	To develop guidelines for complete and well-structured reporting for reimbursement purposes	Assist manufacturers and sponsors to frame their submissions and help the NICE discharge its duty to the Secretary of State in identifying clinically effective and cost-effective technologies for the NHS, to remove unfairness in the availability of technologies in different localities and to minimise the possibility of inequity being introduced.
Preferred analytical technique	Any one of CMA, CCA, CEA, CUA, CBA	CEA or CUA
Costs to be included	Need clear description of direct versus indirect costs, health-related versus unrelated costs	All relevant direct costs and social services costs from NHS and PPS. Resources used by patients should be recorded separately.
Preferred outcome measure	Not stated	Default: quality of life, final outcomes. Health improvement should be expressed in "standard measures for combining life years and quality of life"
Discounting costs	Not stated	Base and SA: at 6%
Sensitivity analysis – parameters and range	State which elements of uncertainty were taken into account	All data sources must be justified and point estimate, ranges and distribution of values identified to test best-case and worst-case scenario.
Sensitivity analysis methods	State how the uncertainty was investigated	Probabilistic SA, Baysian approaches

Source: Adapted from International Society for Pharmacoeconomics Website, 2005c

Drummond et al (1999), in looking at the current trends in pharmacoeconomics and outcomes research in Europe, conclude that whilst the situation varied among the 13 countries studied, more European countries are introducing

formal guidelines for economic evaluations. They also found that there are more similarities than differences in these guidelines.

The United Kingdom has set up the National Institute of Clinical Excellence. This unit, which is funded by the British government, is tasked with managing the collection and interpretation of economic evaluation data. The data come from pharmaceutical companies and academic researchers and are evaluated by healthcare policymakers, prescribing medical specialists and patient groups (Greenberg, Arcelus, Birnbaum, Cremieux, LeLorier, Ouellette & Slavin, 1999: & Nishimura, Torrance, Ikegami, Fukuhara, Drummond & Schubert, 2002).

The Asia Pacific region is also characterised by diversity. Japan, faced with increasing healthcare costs resulting from an aging population, held a workshop in September 2000 to look at how Japan could implement economic evaluations of healthcare technologies. Although pharmacoeconomics remains in an early evolutionary stage in Japan, interest and use is increasing in Taiwan, with Singapore and Korea at similar stages (Doherty et al, 2004).

The Korean National Insurance Fund, challenged with a financial crisis, has shown an increasing interest in economic evaluations and is currently considering making such evaluations mandatory. Korea has proposed formal guidelines, but these are yet to be adopted (Lee, Brouwer, Lee & Koo, 2005). Of the Asia Pacific countries, China has been the first to publish pharmacoeconomic guidelines in a document entitled ‘Chinese Pharmacoeconomic Evaluation Guideline 2006’. However, China has not issued formal submission guidelines (International Society for Pharmacoeconomics Website, 2005c).

Davey et al (2004) included two African and four Middle Eastern countries in a comparative study of reimbursement systems of various countries. They found that in Algeria, South Africa, Turkey, UAE, Saudi Arabia and Israel, no pharmacoeconomic guidelines existed and the levels of awareness of the

subject varied. South Africa was the only one of these countries that had a World Health Organisation (WHO) presence. However, of the countries studied, Israel does in fact have submission guidelines documented in 'Guidelines for the Submission of a Request to include a Pharmaceutical Product in the National List of Health Services' published in 2002 (International Society for Pharmacoeconomics Website, 2005c).

Table 2.3: Submission guidelines for Israel

	Israel
Title and year of the document	Guidelines for the submission of a request to include a pharmaceutical product in the national list of health services, 2002
Cv cvfffMain policy objective	Submission for a listing of new drug products
Preferred analytical technique	Cost-effectiveness evaluation
Costs to be included	Treatment costs, resources to support therapy and treat side-effects and treatment failures
Preferred outcome measure	Final outcomes
Discounting costs	Not stated
Sensitivity analysis – parameters and range	Impact of the uncertainty of the different data on the strength of the assessments.
Sensitivity analysis – methods	Not stated

Source: Adapted from International Society for Pharmacoeconomics Website, 2005c

Although research is available on individual countries' regional and, in a few instances, trans-regional use of pharmacoeconomics, the literature review did not reveal any comprehensive studies that looked at the total worldwide extent and trends of use of pharmacoeconomics. In some regions, particularly Africa, there is a dearth of information with only the study by Davey et al (2004) including two African countries.

2.3 The use of pharmacoeconomic evaluations by decision makers

The use of pharmacoeconomic studies also varies at the different levels of decision making. Van Velden, Severens and Novak *(*2005) divide these levels into

- decisions taken at a national or regional level i.e. the macro level
- decisions taken at a healthcare facility level i.e. meso level
- decisions at the healthcare provider level i.e. micro level

Thirty-six empirical studies looking at the influence of economic evaluations on these different healthcare decision-making levels were reviewed by Van Velden et al in 2005. Although they concluded that this influence was limited, there were variations in the importance of these evaluations at the different levels. The greatest influence was observed in decisions made within healthcare organisations, that is, at the meso level, where cost/economics, especially drug acquisition costs, are of paramount importance. There was less influence at the macro level where policy and regulatory requirements were more influential. Although they found a moderate influence at the micro level, this was based on a review of just eight studies.

Van Velden et al's (2005) findings at the meso level contrast somewhat with those of Motheral, Grizzle, Armstrong, Cox and Fairman (2000), who looked specifically at the role of pharmacoeconomics in drug benefit decision making by healthcare organisations. This study found that the impact of pharmacoeconomics on decision making remains unclear. Although 50% of the population interviewed claimed to have considered economic evaluations in their decision making, only 62% of these indicated that this actually translated into action.

Grizzle et al *(*2000) asked participants from the managed healthcare and pharmaceutical industry to identify factors that influenced decisions to cover

drugs under health plans. Although the respondents rated evaluation data towards the middle on a scale of importance, pharmacoeconomics was not mentioned as a factor in decision making in the open-ended questions section of their questionnaires, suggesting that this was not a major factor in their decision making.

Langley (2004) identifies three audience groups for pharmacoeconomic evaluations. These are drug manufacturers, that is, the pharmaceutical industry, reimbursers (and insurers), and managers and clinical directors in healthcare systems. Langley (2004) suggests that the pharmacoeconomic needs of these different groups vary. Whilst the latter two audience groups could be incorporated into Van Velden et al's (2000) three decision-making levels, the pharmaceutical industry was excluded in the Van Velden et al study.

The global trend towards the increased use of pharmacoeconomics is well described in current literature. However, there are variations in the international usage of outcomes evaluations, as well as differences between different levels of decision makers.

The next part of the literature review looks at factors influencing these differences in an attempt to identify the drivers of and the barriers to the use of pharmacoeconomic evaluations.

2.4 Promoters and barriers

Scarce resources are demanding an economically sound allocation of resources and pharmacoeconomic evaluation is increasingly being recognised as a reliable and useful tool for doing this. However, as outlined in the preceding section, the extent of its use is varied.

2.4.1 Promoters

Davey et al (2004), in their comparative study of reimbursement systems, found that although only eight of the 22 countries in their study had pharmacoeconomic guidelines in place or were actively planning to introduce them, the remaining countries were becoming increasingly aware of the importance of such guidelines and were planning to develop them in the future. In the countries studied, the researchers concluded that the use of pharmacoeconomic evaluations was driven by

- the influence of the WHO and government regulations
- a desire to control costs
- the perception that pharmacoeconomics was inevitable

- **Government endorsements and mandatory requirements**

Drummond et al (1999) propose that government endorsements, in particular mandatory requirements, are the greatest driver of economic evaluations. Similarly, Doherty et al *(*2004), in their Asia Pacific study, found that those countries in the region that had systems in place requiring pharmacoeconomic studies for reimbursement had the greatest level of pharmacoeconomic activity. The Davey et al (2004) study suggests that exposure to WHO programmes that require drug and economic evaluations resulted in some of these countries proceeding to actually develop guidelines of their own or work actively towards this.

- **Need for cost containment**

The increasing need to contain costs has been cited as another factor promoting the use of pharmacoeconomics. Van Oostenbruggen, Jansen, Mur and Kooijman (2005) suggest that the dramatic change in the Netherlands financial situation in the preceding three years, which has seen lower than anticipated incomes coupled with increasing healthcare costs, was a driving

force behind the increased use of pharmacoeconomic evaluations. As of January 2005, economic justification has become mandatory in the Netherlands before a new drug is added to the reimbursement list.
Similarly, Lee et al (2005) suggest a growing interest in the use of economic evaluations since the financial crises of the Korean National Health Insurance Fund in 2000.

A relatively healthy population and the Japanese governmental approach to cost containment have seen Japan's healthcare expenditure kept considerably lower than that of other industrialised nations. However, faced with an aging population and the increasing costs of pharmaceuticals and other healthcare interventions, Japan now has to contend with cost containment pressures similar to the rest of the world. Recent health policy initiatives suggest a greater interest in cost-effective delivery of healthcare and, therefore, a greater role for economic evaluations (Ikegami, Drummond, Shunichi & Shuzo, 2002; Doherty et al, 2004).

- **Harmonisation and globalisation in the pharmaceutical industry**

In addition, Ikegami et al (2002) suggest that the pharmaceutical industry is another driver of economic evaluations, particularly with new harmonisation rules for the conduct of clinical trials and the need for international standardisation to meet global market requirements.

To meet the growing demand for information about economic valuations of drugs, there has been an increase in pharmacoeconomic studies. According to Pang (2002), the majority of these have been commissioned by pharmaceutical firms to demonstrate the cost-effectiveness of their products.

Whilst literature suggests that it is mandatory requirements and government guidelines that are the major promoter of pharmacoeconomic studies, the need for cost containment cannot be underestimated for it can argued that it is this

very need that drives governments and regulatory bodies to implement such guidelines and requirements. Even with clear guidelines in place pharmacoeconomic usage varies. The following section of the review looks at barriers and inhibitors to the use of economic evaluations.

2.4.2 Barriers

Studies that have looked at the use of economic evaluations have in many instances revealed barriers to use. In February 1999, ISPOR convened an advisory panel to identify the issues around the use of pharmacoeconomic studies. Gagnon, Smith and Rindress (1999) divide these into the following:

- methodological Issues
- education and skills
- application of economic evaluations in decision making
- bias, credibility and quality of economic evaluations
- communication and reporting

- **Methodological issues**

Pharmacoeconomic study methods are broadly divided into the following methods, which Gagnon et al (1999) found presented some distinct problems:

1. Clinical studies

These studies, used to demonstrate the clinical efficacy of drugs, provide data that are not sufficient to assess the value of drugs, which is in essence the aim of pharmacoeconomic evaluations.

2. Modelling studies

Biostatistical programmes like linear programming and decision tree analysis are used in these studies to inform the decision-making process. However, these methods are neither widely accepted, nor widely used and there are questions concerning the usefulness of the information produced.

3. Retrospective and claims database studies

These studies rely on existing databases to provide the information required and are therefore affected by the availability, quality and access to this information source.

Van Velden et al (2005) also found that the methodology of the research was an important study-related barrier. A critical review of published Korean economic evaluations by Lee et al in 2005 cited weaknesses in study design, imprecise databases and simplistic, unrealistic assumptions in study models as problems plaguing pharmacoeconomics in Korea. In addition, limited time periods, poor choice of outcome measures and omission of some relevant costs also contributed to poor study design. The availability of relevant data to conduct studies is also a barrier in the Japanese healthcare industry (Doherty & Sato, 2003 Nishimura et al, 2002). In 2004, Doherty et al cited data availability and the need for country-specific data in the diverse arena as challenges in the Asia Pacific region. Zwart-van-Rijkom, Leufkens, Busschbach, Broekmans and Rutten (2000) also included methodology as a category in their discussion of factors that cause controversy and therefore hinder the use of economic evaluations in the Netherlands.

- **Education and skills**

The increasing use of pharmacoeconomic evaluations has led to a shortage of trained health economists. Thus decision makers often have limited knowledge of pharmacoeconomics which is a barrier to their use (Stratchounski & Rozenson, 1999; Davey et al, 2004; Bridges, 2005). Although many universities

have developed training programmes, these fail to provide the skills needed and government regulation of the industry is seen as a disincentive to those looking to undergo further training in the field (Bridges, 2005). This has resulted in the recognition of a need for more formal training in the subject, not only for those tasked with actual performance of the studies, but also for those who use the results of these evaluations. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) has thus embarked on an endeavour to define the outcome measures for the various courses offered in an attempt to define standards (Maio & Lofland, 2004).

According to the International Society for Pharmacoeconomics and Outcomes Research Advisory Panel Report (2005), presentation of health economics data fails to provide decision makers with relevant information. Again, a lack of experts is cited as a key issue, together with language and definitional barriers, which hinders communication and exacerbates the lack of dialogue between users and providers of the information.

- **Applicability and relevance of economic evaluations in the decision maker's context**

Failure of decision makers to appreciate the relevance and applicability of economic evaluations is due not only to limited knowledge, but also to a lack of user-friendliness and the failure of researchers to provide data that are applicable to the context in which decision makers work (Gagnon et al, 1999)

- **Bias, credibility and quality of economic evaluations**

Pharmacoeconomic studies require that assumptions be made and the use of these assumptions is thought to introduce bias. In addition, credibility issues are raised particularly when evaluations are sponsored by pharmaceutical companies as part of marketing campaigns and in an effort to demonstrate the superiority of their products. Quality of outcomes research is also dependant on the quality of input data (Gagnon et al, 1999). Nishimura et al (2005) cite data

limitations as an informational barrier to economic evaluations in Japan and this, Lee et al (2005) conclude, was also the reason for the poor quality, suboptimal studies published in Korea and a hindrance to the more extensive use of evaluation studies in that country.

- **Communication and reporting**

There is a communication gap between the producers of economic evaluation data and their intended users, which results from a lack of transparency in the way studies are conducted and reported. The choice of terminology is often not defined, and little attention is paid to the relevance of the analytical perspectives chosen for studies to the contexts of its intended users (Motheral, et al, 2000; Pang, 2002).

2.5 CONCLUSION

The literature reviewed suggests that whilst there are differences in the use of pharmacoeconomic evaluations by decision makers at the different levels of decision making in healthcare, there is no consensus on what these differences are and whether pharmacoeconomic evaluations are being used. The review does reveal that common themes underlie perceived barriers to and promoters of the use of pharmacoeconomic evaluations in healthcare decision making.

The question and propositions developed below emerged from the literature reviewed.

CHAPTER 3: RESEARCH QUESTION AND PROPOSITIONS

3.1 Research Question 1

Are pharmacoeconomic evaluations being used and are they informing and influencing decisions in South African healthcare

- at a payer/funder level, that is, medical aid schemes and managed healthcare organisations?
- by healthcare providers, that is, medical doctors?
- by pharmaceutical manufacturers?

3.2 Proposition 1

The main promoters of the use of pharmacoeconomic evaluations are

- government regulations and requirements
- the need for cost containment
- harmonisation and globalisation in the pharmaceutical industry

3.3 Proposition 2

The main barriers to the use of pharmacoeconomic evaluations are

- poor methodology
- lack of education and skills
- poor applicability and relevance of economic evaluations in the decision-makers' context
- bias, lack of credibility and poor quality of economic evaluations
- poor communication and reporting of data

CHAPTER 4: RESEARCH METHODOLOGY

4.1 Qualitative paradigm

Leedy and Ormrod (2001) suggest that the research paradigm is governed by, *inter alia*, the nature of the research, the method of data collection and the purpose of the research. To this end the research was qualitative in nature as it had the following features:

- It was exploratory in nature.
- In-depth semi-structured interviews were used to collect data.
- The data collected were descriptive and encompassed personal views.
- The aim was to describe, explain and interpret the data that were collected.

4.2 Methodology

Information was gathered through a survey of the sample that used a semi-structured interview format. This allowed for focused two-way communication and for flexibility in probing for details or discussing issues that arose.

This survey process was made up of five phases:

- Firstly, an in-depth literature review of pharmacoeconomic evaluations and the pertinent issues relating to their use was conducted.

- Secondly, a draft interview protocol was created using information obtained from the literature review.

- Thirdly, the protocol was reviewed and further validated, both in conjunction with the research supervisor and with members of the research proposal panel.

- Fourthly, interviews were conducted with respondents drawn from the target population. The semi-structured interview process allowed interviewees the opportunity to provide information they considered relevant, even if it had not been included in the questionnaire.

- Finally, the information from each of these interviews was analysed. This allowed for the research question to be answered and the propositions responded to.

4.3 Population and sample

The population comprised all individuals who are decision makers within the healthcare sector in South Africa. The sample was made up of respondents drawn from one of the following decision-making levels, that is, the funder/payer level (medical aid societies, managed healthcare organisations), at the prescribing medical practitioner level and at the pharmaceutical manufacturer level. Convenience sampling was used owing to financial and time constraints and the sample was drawn from the Gauteng region.

The sample was purposive in that the researcher purposefully selected respondents with the required experience to answer the research questions. No attempt was made to ensure randomness. Respondents were also asked to suggest appropriate interviewees that is, a ‘snowball’ research approach was used. The researcher attempted to select respondents who were representative of the population and to be objective in this selection process (Leedy & Ormrod, 2001).

The sample included at least five respondents from each of the decision-making levels identified.

4.4 Data collection

The questionnaire (Appendix 1) was used to interview the respondents selected. The questions were open ended, as it was hoped that this would allow the interviewees to express their opinions on the use of pharmacoeconomic evaluations in their healthcare sector, as well as their views on the promoters of and barriers to the effective implementation of these evaluations. As the data collected were qualitative, the use of open-ended questions allowed for the capture of higher quality data. Since pharmacoeconomics is at best in its early evolutionary stages in South Africa, this reduced the constraints on the interviewees and hopefully enhanced the quality and spectrum of data collected. Semi-structured interviews also allowed ambiguous answers to be clarified (Leedy & Ormrod, 2001).

Respondents were selected on the basis of the role they play in decision making in healthcare. As pharmacoeconomics is in its infancy in this country, a 'snowball' approach to sampling was used. It was hoped that this method would enable the researcher to draw up a contact list of possible respondents who had the required experience.

The nominated interviewees were contacted telephonically. The purpose of the research and the data collection process was explained and, if the respondent agreed to participate in the study, an appointment was made to interview the respondent in person.

It was proposed that interviews be conducted at the offices of interviewees or other appropriate locations to ensure their convenience. Notes were taken during the interview and interviews taped with respondents' permission. Data were analysed and tabulated as soon as possible. Any uncertainty about the remarks made by the respondent was clarified during the interview and permission was sought at the end of the interview for the researcher to contact the respondent should any uncertainty arise later.

4.5 Data analysis

Data were analysed using content analysis. This allowed for an in-depth assessment with the aim of identifying common themes (Leedy & Ormrod, 2001). Initially, data were examined in their entirety in an attempt to identify recurring themes. Data were then clustered into broad categories based on these themes, after which these clustered responses were tabulated according to the different levels of the decision makers. A total frequency of response per cluster category was calculated. This allowed for promoters and barriers to be ranked according to frequency overall and within each decision-making group. It is acknowledged that, in this type of study, researcher bias is inevitable. Therefore several perspectives from each decision-making level were sought and a resolute effort was made to look for data that differed from the research propositions.

4.6 Validity and reliability

Research needs to be both valid and reliable. Validity refers to the “accuracy, meaningfulness, and credibility” of the study as a whole (Leedy & Ormrod, 2001:103), whilst reliability can be defined as “the consistency with which a measuring instrument yields a certain result when the entity being measured hasn’t changed” (Leedy & Ormrod, 2001:31). Furthermore, as Leedy and Ormrod (2001) point out, validity can only occur if there is reliability.

4.6.1 Reliability

All interviews were conducted by the researcher herself ensuring that all terms were explained to aid reliability. Particular attention was paid to the questions and the style of the interviews during the process in order to ensure consistency.

4.6.2 External validity

External validity refers to the extent to which conclusions drawn from the research can be generalised to a broader context (Leedy & Ormrod, 2001). As this research was qualitative in nature and the sample purposive, the relevance of external validity is questionable. Although a random sampling technique would have better served external validity, it was hoped that the snowballing technique would ensure that there would be adequate coverage of the different levels of decision making and that the sample would be representative.

4.6.3 Internal validity

Internal validity is the degree to which the conclusions drawn from the data accurately reflect the relationships within the data (Leedy & Ormrod, 2001). As such, validity is particularly relevant in research that seeks to determine causal relationships, which this research did not do. However, internal validity can also be seen as “the freedom from bias in forming conclusions in view of the data” (Leedy,& Ormrod,2001 As the goal of this research was to determine the views of decision makers at different levels of the healthcare sector, care was taken to reflect these views accurately and fairly. Feedback from people in the field and respondent validation was also sought.

CHAPTER 5: PRESENTATION OF RESEARCH RESULTS

5.1 Respondents

Twenty-five semi-structured interviews were conducted. The respondents were classified into three broad groups: payers/funders, the pharmaceutical industry, and healthcare providers, as presented in section 3.1.

The ten employees interviewed from the pharmaceutical industry worked in their companies' access departments or in the medical functional areas. All respondents were involved in reimbursement negotiations for their companies' products. They included eight access managers, one medical affairs manager and a medical advisor whose portfolio included access.

Interviews were also conducted with ten people in the payer/funder environment. Respondents were drawn from medical schemes, managed healthcare organisations, pharmaceutical benefit management companies and an independent company that consulted in the area of pharmacoeconomics. These interviewees were selected because they were involved in the decision making around formulary development and reimbursement of pharmaceutical products. The interviewees included five medical advisors from medical schemes and managed healthcare organisations, two managers from pharmacoeconomics and health economics departments at medical schemes, two clinical pharmacists in charge of protocols and drug utilisation and one head of medical affairs at a pharmaceutical benefit management company.

Five healthcare providers in private medical practice and at state institutions were interviewed to provide a perspective from a prescriber level. Three respondents in this group were solely in private practice but had previously worked in the public sector; one was a superintendent at a regional hospital and one was head of a clinical unit at an academic hospital but still did limited private practice.

Early on in the interview process, there were numerous requests for anonymity. The researcher agreed to confidentiality as it was believed that this would allow for more open, honest answers that would add to the qualitative value of the research.

5.2 Presentation of results

The purpose of this research was to determine whether pharmacoeconomic evaluations are being used and whether they are informing and influencing decisions in South African healthcare. The research also sought to ascertain what the promoters of and barriers to their use are. To facilitate the interpretation of the results a tabulated content analysis was used.

5.3 Tabulated content analysis

Tables 5.1–5.3 represent data obtained on the research question and the two research propositions from the semi-structured interviews.

Question 1

Are pharmacoeconomic evaluations being used and are they informing and influencing decisions in South African healthcare at the following levels?

- payers/funders (medical schemes, managed healthcare organisations, pharmaceutical benefit management companies)
- pharmaceutical manufacturers
- healthcare providers, i.e. independent medical practitioners

Proposition 1

The main promoters of the use of pharmacoeconomic evaluations are

- government regulations and requirements
- the need for cost containment

- the harmonisation and globalisation in the pharmaceutical industry

Proposition 2

The main barriers to the use of pharmacoeconomic evaluations are

- poor methodology
- lack of education and skills
- poor applicability and relevance of economic evaluations in the decision-makers' context
- bias, lack of credibility and poor quality of economic evaluations
- poor communication and reporting of data

5.3.1 Use of pharmacoeconomic evaluations as a decision-making tool

Respondents were asked whether they applied pharmacoeconomic evaluations in their decision making or in the course of their work. This question was aimed at obtaining a baseline assessment of the current use of pharmacoeconomics. During the literature review it became apparent that it would also be useful to broadly ascertain the individuals own assessment of their understanding of pharmacoeconomics and to determine whether they had any formal training and education in pharmacoeconomics.

Table 5.1: Use of pharmacoeconomics and understanding of pharmacoeconomics

	No of respondents	Use pharmaco-economic evaluations	Understand pharmaco-economics	Formal pharmaco-economic training, i.e. degree /diploma
Payers/ funders	10	10	9	1
Pharmaceutical manufacturers	10	8	5	0
Health care providers	5	2	0	0

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5.3.2 Main promoters of the use of pharmacoeconomic evaluations are

- government regulations and requirements
- the need for cost containment
- harmonisation and globalisation in the pharmaceutical industry

This question was aimed at understanding the factors precipitating the use of pharmacoeconomic evaluations within the healthcare industry.

Again responses are presented in tabular form for each of the three subgroups. This has been done to retain data collected and to improve the quality of the research results. Frequency of responses for the cluster groups was recorded for each of the three subgroups as differences between the subgroups were noted.

Table 5.2: Main promoters to the use of pharmacoeconomic evaluations

Cluster	Response	Payers	Pharmaceutical industry	Healthcare providers	Total
Government regulations and requirements	South African government's plan to legislate PE evaluations as part of drug approval	5	5	0	10
	International governments requirements	0	7	0	7
		5	**13**	**0**	**17**
Cost containment	Need to manage budgets	10	7	2	19
	High cost of pharmaceutical products	10	5	2	17
	Need for consistent and transparent decision making	6	4	0	10
		26	**16**	**4**	**46**
Harmonisation and globalisation in the pharmaceutical industry	Need to demonstrate cost-effectiveness of products in multiple international markets	4	7	0	11
	Pharmaceutical industry provide PE data	4	6	2	10
		8	**13**	**2**	**23**

5.3.3 Barriers to the use of pharmacoeconomic evaluations

Respondents were asked what factors presented an obstacle to the use of pharmacoeconomics in decision making. All factors considered to be barriers were documented, and again differences between the subgroups emerged.

A process similar to that used with the previous questions was used and data is presented in the form of a tabulated content analysis with frequency of responses per subgroup for each cluster being documented.

Table 5.3: Barriers to use of pharmacoeconomic evaluations

Cluster	Response	Payers	Pharmaceutical industry	Healthcare providers	Total
Poor methodology	Clinical studies usually phase 3b may not reflect real-life data and data is insufficient to show value of drug	7	2	0	9
	Use of statistical modelling, based on assumptions and can be manipulated	10	4	0	14
	International databases, Results may not be extrapolated or relevant to South African context	6	7	0	13
		23	**13**	**0**	**36**
Lack of education and skills	Few formally trained people in the SA environment	10	10	5	25
	Not part of medical or pharmaceutical curriculum	8	7	5	20
	Reputable courses expensive	2	3	0	5
		20	**20**	**10**	**50**

Cluster	Response	Payers	Pharmaceutical industry	Healthcare providers	Total
Poor applicability and relevance of economic evaluations in decision makers context	Limited specifically South African data and studies	10	9	0	19
	No SA specific thresholds and ICERS	5	6	0	11
	Not relevant	0	0	3	3
		15	**15**	**1**	**33**
Bias, lack of credibility and poor quality of economic evaluations	Assumptions in statistical tools and modelling allow for bias	8	7	0	15
	Most studies are funded by manufacturers, therefore of questionable credibility	8	3	2	13
	Quality of data limits quality of evaluation	7	6	1	12
		23	**16**	**3**	**40**
Poor communication and reporting of data	Data is not presented in a user friendly format	3	2	2	7
	Lack of transparency	6	2	2	10
		9	**4**	**4**	**17**

CHAPTER 6: INTERPRETATION OF RESULTS

The data presented in chapter 5 is analysed in this chapter.

The objectives of the study were to

- determine whether pharmacoeconomic evaluations are used by decision makers in the South African healthcare industry
- determine the promoters of the use of pharmacoeconomic evaluations
- determine the barriers to the use of pharmacoeconomic evaluations

Insights gained and concepts developed in the review of literature aided the interpretation of the results in the context of the above objectives.

6.1 Research question 1

This question asked the respondents whether pharmacoeconomic evaluations are being used and whether are they informing and influencing decisions in South African healthcare

- at a payer/funder level
- by pharmaceutical manufacturers
- by healthcare providers, that is, medical doctors

The responses to this question are presented in Table 5.1 in chapter 5.

6.1.1 Payer/funder

One hundred percent of respondents in the payer/funder subgroup use pharmacoeconomic evaluations in their decision making. Ninety percent indicated that they understood the principles of pharmacoeconomics although only one had formal training, that is, a Masters in Health Economics. All of the

respondents in this subgroup had attended in-house workshops or informal courses in pharmacoeconomics.

Through further probing which took place during the interviews it became apparent that there was a difference in the extent to which the interviewees made use of pharmacoeconomic evaluations. This use was to a degree dependent on the infrastructure and resources at their disposal, which ranged from a very basic level “I do my own research using Medscape, the internet and see what I can find out about the product and use that to inform my decision on whether to recommend approval of the drug’s use” at a company that had no dedicated in-house expertise to “I am directly involved in the building of models and the evaluations” in a company that had its own Health Economics unit.

6.1.2 Pharmaceutical manufacturer

In the pharmaceutical manufacturer subgroup, 80% of respondents use pharmacoeconomic evaluations in the course of their work. Of the two who did not, one said that it had never been asked for by payers and therefore was not done (this was a company that manufactures generic products), whilst the second said that whilst such evaluations had not been used yet, the company was in the process of contracting an external consultant in response to requests from funders. Fifty percent of the respondents in this subgroup said that they understood pharmacoeconomics, having attended courses and workshops; however, none of the interviewees in this subgroup had any formal postgraduate training (i.e. a Masters or PhD in Pharmacoeconomics). Whilst the majority of the respondents alluded to using pharmacoeconomic evaluations, none of them considered themselves experts in the field.

“Rudimentary”, “I know enough to talk the language and have a basic understanding of the data I present” were recurring themes within this group when respondents were asked to comment on their level of training or qualifications.

6.1.3 Healthcare providers

Of the five healthcare providers interviewed, two had used pharmacoeconomic evaluations but none had any knowledge of the subject or any formal training. The two who responded positively alluded to attempting to use information found in the literature or provided by companies to support motivations to payers to pay for drugs prescribed.

It was stated that pharmacoeconomic evaluations did not come into their decision making as this was driven purely by actual drug costs, budget constraints and cost minimisation. Some expressed the view that pharmacoeconomic evaluations were largely the domain of the payers who were now the key decision makers in prescribing, as prescriptions were largely limited to drugs payers placed on drug formularies. Comments included: “We have spent many years studying and in clinical practice; yet this all counts for nought as the drugs we use are now dictated to us by funders. I am reduced, in some cases, to discussing my motivation for the use of a drug to a clinical case manager who is often not a medical doctor” and “Payers are doing financial analyses, presenting these as pharmacoeconomic evaluations to support their non-reimbursement decisions”.

Whilst the majority of respondents across the three sectors believed that they had some understanding of pharmacoeconomics, formal qualifications were limited. No attempt was made to test the respondents’ knowledge of pharmacoeconomic evaluations in this research.

6.1..4 Answer to research question 1

The research findings suggest that pharmacoeconomic evaluations are used at payer and pharmaceutical manufacturer levels but their use is very limited at the healthcare provider level in South African healthcare. Where they are being used the extent to which they are used and the expertise of the users vary considerably.

This is in keeping with the findings of Van Velden et al *(*2005) that the greatest influence of pharmacoeconomics was in decisions made within healthcare organisations, that is, medical aid schemes and managed healthcare organisations, where cost/economics especially drug acquisition costs are of paramount importance. In addition, this supports Langley (2004) who identifies the pharmaceutical industry as an audience group for pharmacoeconomic evaluations, and Pang (2002), who states that most pharmacoeconomics evaluations are being done by pharmaceutical companies. The results suggest that the use of pharmacoeconomic evaluations at the prescriber level appears to be less than that proposed by Van Velden et al *(*2005), who describe use at this level, that is, the micro level, as moderate.

6. 2 Proposition 1

Based on the literature reviewed, research proposition 1 stated that the main promoters of the use of pharmacoeconomic evaluations are

- government regulations and requirements
- the need for cost containment
- harmonisation and globalisation in the pharmaceutical industry

Whilst no rating was applied to the drivers, as elucidated by the literature review, the frequency of citing by respondents was used to order these drivers.

The research findings documented in Table 5.2 confirm that the factors (in descending order) driving the use of pharmacoeconomic evaluations in South Africa are

- the need for cost containment
- harmonisation and globalisation in the pharmaceutical industry
- government regulations and requirements

The original research proposition is accepted with a minor amendment being made to the order of the drivers. The interview process expanded on the driver clusters and the major drivers are discussed in greater detail in the following section.

6. 2.1 The need for cost containment

Cost containment was the driver most frequently cited by the interviewees overall, and it was the driver cited most frequently by each of the three subgroups.

Respondents in the payer subgroup felt that there was increasing pressure from healthcare providers to pay for high cost medicines and from patients who are now more informed and knowledgeable about their disease states, treatment options and rights. Therefore there was a need to manage budgets more effectively and a need to make reimbursement decisions in a consistent and transparent manner. Pharmacoeconomics was thought to be a tool that could be used to achieve this.

As a subgroup, pharmaceutical manufacturers also rated cost containment as the strongest driver. Probing during the interviews revealed that this was the need for cost containment by the payer subgroup within the South African environment and not within the pharmaceutical industry per se.

On the issue of the cost of medicines, whilst respondents were split in their perception of the cost of their products, there was consensus that the cost of ethical new chemical entities was justified given the high research and development costs incurred by the manufacturers. It emerged, however, that there was a sense of distrust between the payer and manufacturer subgroups; some respondents believed that many payers developed pharmacoeconomic models internally, were unwilling to share these models and that these evaluations, that were not transparent, were then used to turn down reimbursement requests. Within the funding sector, it was believed that pharmaceutical manufacturers are selective in the data they present; that the price of some of the newer, 'innovative' drugs is "exorbitant".

Although respondents within the healthcare provider subgroup made limited use of pharmacoeconomic evaluations, they were impacted by their use within the other subgroups. It was believed that cost containment was the major driver, with limited budgets and the high cost of pharmaceuticals playing important roles in this cluster.

During the course of interviews with the payer segment, a difference in the approach to the use of pharmacoeconomic evaluations emerged between 'closed' medical aid schemes that accept members from a certain company or industry only and 'open' medical schemes that accept members from the general public. Closed schemes were more likely to consider benefits beyond efficacy, for example quality of life benefits, and therefore more likely to reimburse for drugs with these benefits rather than having a purely cost-driven approach. "Closed schemes are more empathic, are prepared to go the extra mile".

One respondent stated that "a closed scheme is more likely to consider pharmacoeconomic evaluations in the reimbursement decision as they see the value of quality of life benefits like a decrease in the number of days off work; it impacts the company or industry directly; not just an 'indirect' benefit."

6.2.2 Harmonisation and globalisation in the pharmaceutical industry

This was the second highest cluster cited by all three subgroups, with the pharmaceutical manufacturers, not surprisingly, citing this cluster more frequently than the other two subgroups. Harmonisation of clinical trial requirements for registration and the demand for pharmacoeconomic evaluations across global markets are considered drivers particularly by many pharmaceutical companies now operating in multinational markets.

Manufacturers are now increasingly being asked by payers or, as in many countries, the government across the world to justify the cost of their products. Thus most pharmacoeconomic studies are conducted by manufacturers in multiple countries to address the needs of payers globally.

Manufacturers, particularly multinationals, have this data available for use by any of their affiliates in their local markets. Hence, this has driven the proactive use of pharmacoeconomic studies by manufacturers in the South African environment. One respondent stated “we have an entire health economics and health outcomes team that sits in Europe. We are able to draw on their expertise and work and proactively to present pharmacoeconomic data in our reimbursement negotiations”.

Some respondents within the payer subgroup stated that it was globalisation in the industry that saw the pharmaceutical industry drive the use of these evaluations early on. “They (pharmaceutical companies) come to us with product dossiers that have economic evaluations that are based on models run for other markets where they have launched the products.”
This proactive use by the pharmaceutical industry was cited as a driver by two of the respondents in the healthcare provider subgroup.

Some respondents in all three groups believed that it was really government regulations and requirements that made pharmacoeconomic evaluations

mandatory in many countries and have forced the pharmaceutical industry to harmonise and globalise.

6. 2.3 Government regulations and requirements

This was the least frequently cited driver across all groups as being a driver in the South African environment.

Whilst the South African government's proposal to include pharmacoeconomic evaluations as a prerequisite for the registration of new drugs has not yet been legislated, there is little doubt that government will eventually introduce the requirement for pharmacoeconomic evaluations in some form.

Fifty percent of respondents in the payer and manufacturer subgroups cited local government plans to pass legislation for pharmacoeconomic evaluations as a driver for their current use and for the increase in their use. This supported the findings of Davey et al (2004), who found that the perception that the use of pharmacoeconomics was inevitable drove their use in countries where guidelines were not in place and pharmacoeconomic evaluations were not a mandatory requirement.

Seventy percent of respondents in the pharmaceutical industry cited requirements by international governments as a driver, rating them even higher than the South African government's proposal. On probing this issue it was established that this meant that multinational companies were conducting these studies to meet the needs of other markets and that these data were thus readily available for use in any market (see section 6.1.1.2).
Two schools of thought emerged around the South African government's planned introduction of pharmacoeconomic evaluations. The one school was of the opinion that the government could not make pharmacoeconomic evaluations a "fourth hurdle" to drug registration in the country, as many people funded their own healthcare and denying them access to drugs that had met

safety and efficacy standards and were registered and available in other countries could be seen as an infringement of their rights. It was also felt that if pharmacoeconomic evaluations were introduced as a fourth hurdle to registration, should a drug meet the requirements, then this drug should automatically be reimbursed at both private and public funder levels. This school was largely subscribed to by respondents in the pharmaceutical manufacturer segment.

The other school of thought was more embracing of government's proposal. It is thought that many new innovative drugs would not stand up to pharmacoeconomic scrutiny by government from a social viewpoint, as their costs are exorbitant. Mandatory pharmacoeconomic evaluations could therefore drive the cost of drugs down. Government would also assist by making these difficult reimbursement decisions that would then also apply to the private payers. This view was predominantly evident in the payer segment.

Irrespective of the school of thought or of the sector, the respondents were unanimous in the view that they doubted that government had the capacity or the resources to make pharmacoeconomic evaluations compulsory. "It currently takes about 3 years to get a drug registered; if introduced as a fourth hurdle, pharmacoeconomics would simply delay patients access to drugs even further" commented one healthcare provider.

6.2.4 Findings of proposition 1

In line with the research findings, research proposition 1 is accepted; in addition an attempt is made to rank the drivers.
Research proposition 1 states that the main drivers of pharmacoeconomic evaluations are

- the need for cost containment
- harmonisation and globalisation in the pharmaceutical industry
- government regulations and requirements

6.3 Proposition 2

Research proposition 2 states that the main barriers to the use of pharmacoeconomic evaluations are

- poor methodology
- lack of education and skills
- poor applicability and relevance of economic evaluations in decision makers' context
- bias, lack of credibility and poor quality of economic evaluations
- poor communication and reporting of data

The data collected and portrayed in table 3 confirm these barriers. Whilst no rating was applied to the barriers as elucidated from the literature review, the frequency of citing by respondents was used to rank these barriers in the presentation and analysis of the research findings.

The research findings presented in chapter 5 confirm that the barriers to the use of pharmacoeconomic evaluations as a decision-making tool in South African healthcare (in descending order) are

- lack of education and skills
- bias, lack of credibility and poor quality of economic evaluations
- poor methodology
- poor applicability and relevance of economic evaluations in decision-makers' context
- poor communication and reporting of data

The original research proposition is accepted. Again the barriers are ranked according to the frequency with which they were cited. The interview process expanded on the barrier clusters and these are discussed in greater detail in the section following.

6.3.1 Lack of education and skills

This was the most frequently cited barrier across all three subgroups. Whist the majority of respondents in the payer/funder and pharmaceutical manufacturer subgroup were using pharmacoeconomic evaluations, only one had any formal training. Two interviewees (both pharmacists) had been introduced to the concept as part of their undergraduate training, while the majority had been exposed to pharmacoeconomics in the course of their work and had attended informal courses and workshops.

Interviewees across all subgroups felt that the lack of pharmacoeconomic training as part of pharmacy and medical degrees largely contributed to the low levels of education and skills and that inclusion of pharmacoeconomics as a course in these degrees would increase skill levels.

Some also stressed that whilst the aim at undergraduate level should be to engender a basic understanding and a working knowledge of the subject matter, there was also the need for more advanced courses, that is, at masters or PhD level that would equip one to run pharmacoeconomic studies and to be expert evaluators. This was felt to be important, particularly in view of government's plan to introduce pharmacoeconomic evaluations into the medicines regulatory system. The perceived current lack of skills was an area for concern as many expressed the view that the addition of pharmacoeconomic evaluations to the approval process would add a further burden to the regulatory authority, which was already functioning sub-optimally.

Whilst many respondents expressed an interest in further education and training, most reputable courses were run by international universities and cost was a prohibitive factor for South Africans.

6. 3.2 Bias, lack of credibility and poor quality of economic evaluations

This was the second most frequently cited barrier. Pharmacoeconomics as a tool was considered to be open to much manipulation and therefore bias.

Within the payer subgroup, many respondents queried the credibility of the pharmacoeconomic evaluations that were conducted by manufacturers and felt that these studies were biased as the objectives of these studies were to secure reimbursement for manufacturers' products. There was often a lack of transparency and selective presentation of data. One respondent stated that evaluations presented by manufacturers were to be "taken with a pinch of salt" and that there was almost always a need for these studies to be rerun.

The manufacturer subgroup also alluded to the potential for bias to be introduced especially as these studies were based on statistical modelling and assumptions. Fewer respondents within this group thought that evaluations run by manufacturers lacked creditability.

In the multinational companies it was felt that these studies were run to meet requirements of international government agencies in many instances and that most companies had expert teams who ran models that were robust.

Some expressed the opinion that within the South African environment, it was the funder/payer groups that ran their own models and studies, which they were not willing to share, and which introduced bias and questionable credibility.

Some interviewees in the healthcare provider subgroup also questioned the credibility of studies by manufacturers.

The quality of data, in particular the lack thereof, within the South African environment was also considered a limiting factor impacting the quality of economic evaluations within the South African context across all subgroups.

The lack of trust between the subgroups, particularly funder and manufacturer, became evident during the interviews.

6.3.3 Poor methodology

Whilst this cluster was ranked as the second most frequent barrier overall, it was noted that healthcare providers did not consider poor methodology a barrier. On probing, the healthcare providers interviewed felt that they were not qualified and lacked the experience to comment on the methodology of the pharmacoeconomic evaluations.

The majority of interviewees from the payer segment thought that pharmacoeconomic evaluations were tagged onto phase 3b clinical trials and that this did not reflect real-life clinical practice. The use of statistical models that were sometimes not appropriate or made unrealistic assumptions were also cited by this group as poor methodology. One payer quoted being presented with a model than ran over 110 years: “How many people live to 110?” she questioned.

The reliance of studies on international databases that may not be robust or applicable to the South African environment also limited the outcomes and use of evaluations. According to one healthcare provider “it is difficult to extrapolate UK or USA experience to South Africa; we have different demographics, different social circumstances etc”.

Fewer of the subgroup of pharmaceutical manufacturers considered the use of phase 3b studies and statistical modelling a hindrance but most agreed that the use of international data was a barrier locally particularly as payers were now increasingly asking for South African-specific studies. It was acknowledged that international data was not fully reflective of the South African environment which had demographics, epidemiology and social circumstances that were unique.

6.3.4 Poor applicability and relevance of economic evaluations in decision maker's context

This was the fourth most frequently cited barrier overall. A strong majority of both the payer and the manufacturer subgroups stated that the lack of South African-specific studies limited the use of pharmacoeconomic evaluations. This group also strongly felt that the lack of good quality South African data limited the methods and techniques that could be used and therefore the quality and applicability of the results.

The lack of South African-specific thresholds and incremental cost-effectiveness ratios (ICERS) further limited the interpretation and therefore the use of pharmacoeconomic evaluations.

Three of the five healthcare providers interviewed stated that pharmacoeconomic evaluations were not relevant to their context because much of their prescribing decisions were "being dictated" to them by payers and affordability. Therefore, if a drug was shown to be cost-effective but the payer did not reimburse it or if the patient could not afford the drug out of his own pocket, pharmacoeconomic evaluations became irrelevant in the decision-making process.

6.3.5 Poor communication and reporting of data

Although this was the least frequently cited impediment to the use of pharmacoeconomic evaluations, some respondents stated that lack of transparency and user friendliness in the evaluations did inhibit their use. During the interviews it emerged that this was related in part to the lack of education on the part of the users who found it difficult to understand reports or misinterpreted them. To those more au fait with the subject matter, lack of transparency in the presentation of the data was a factor. Again issues around trust between the subgroups were apparent.

6.3.6 Findings of proposition 2

Based on the research findings, proposition 2 is accepted with a minor change to the order of barriers. The main barriers to the use of pharmacoeconomic evaluations are

- lack of education and skills
- bias, lack of credibility and poor quality of economic evaluations
- poor methodology
- poor applicability and relevance of economic evaluations in decision maker's context
- poor communication and reporting of data

6.4 Conclusion

The research findings did not differ significantly from the literature reviewed. This was a somewhat unexpected finding considering that pharmacoeconomics is still relatively new to the South African environment compared to the international scene. Given that the government plans to introduce pharmacoeconomic evaluations into the drug registration process in the

country, recommendations based on previous knowledge acquired and on the findings of this research are presented in chapter 7.

CHAPTER 7: CONCLUSIONS AND RECOMMENDATIONS

In this chapter a summary of the major findings of the research are presented, together the limitations of the study. Some recommendations are made and a list of future research topics is suggested.

7.1 Major findings

7.1.1 Use of pharmacoeconomic evaluations

Pharmacoeconomic evaluations are being used at different levels in the South African healthcare environment. Whilst these evaluations are used to a greater extent by the payer and pharmaceutical manufacturer subgroups, their impact has a great influence on the prescribing habits of the healthcare provider group, which as a subgroup on its own does not personally use pharmacoeconomic evaluations routinely.

7.1.2 Promoters of the use of pharmacoeconomic evaluations

The use of pharmacoeconomic evaluations is certainly on the increase in South African healthcare. This is thought to be largely driven by the need to manage constrained budgets against the backdrop of increasing scrutiny from patients and providers.

Whilst the trend for harmonisation and globalisation in the pharmaceutical industry has been a driver for the use of pharmacoeconomic studies, this can be seen to be the result of many governments making the submission of pharmacoeconomic data mandatory for reimbursement decisions on new chemical entities.

Although the South African government has proposed an amendment to the Health Act that will see pharmacoeconomic evaluations introduced into the South African drug registration process, many of the interviewees were sceptical about how and when this would be introduced considering that the current regulatory authority appears to have severe resource challenges and that there is limited expertise on the subject matter within the country. Once pharmacoeconomic evaluations became mandatory as per government regulations, this would be a compelling driver.

7.1.3 Barriers to the use of pharmacoeconomic evaluations

Pharmacoeconomic evaluations have seen a resurgence in South Africa, but a major barrier to their appropriate use remains a lack of education and skills.

The paucity of relevant local pharmacoeconomic data is a further limiting factor. Pharmacoeconomic studies are expensive, demand highly skilled resources and require good quality databases, all of which hinder the application of pharmacoeconomics in the South African environment.

Lack of trust between the subgroups saw studies run by other subgroups being viewed as biased, of questionable credibility or not transparent and this further hindered the use of available pharmacoeconomic evaluations.

7.2 Limitations

The research evaluated a sample from a population of various people involved at three levels of decision making in healthcare based on their job profiles. No attempt was made to ensure that the sample was random or representative of the population.

The sample was drawn from the Gauteng region, owing to financial and time constraints, and was limited in size and not all inclusive.

It cannot be claimed that the conclusions drawn are fully representative of all decision makers in South African healthcare.

7.3 Recommendations

This research has shown that pharmacoeconomic evaluations are being used by decision makers in healthcare, particularly at the pharmaceutical manufacturer and the payer levels. This use is expected to increase with government's proposal to make pharmacoeconomic evaluations part of the drug registration process in South Africa. However, interviewees across the different levels were unanimous in the view that the country lacked the knowledge, skills and resources needed to implement pharmacoeconomic evaluations.

It is recommended that government drive the education and training in pharmacoeconomics. This has already been initiated with government having run pharmacoeconomic courses, however, a lot more is needed. To this end, other players in the healthcare sector could be engaged to help with the financing and structure of these courses, thereby easing some of the burden on government and helping to secure buy-in. The recently formed South African chapter of ISPOR could also be engaged in structuring an accredited programme/course for the South African environment to be run locally. Currently good quality courses are run through international institutions, but these are expensive and this has been an inhibiting factor to local upskilling in the field of pharmacoeconomic evaluations.

Although pharmacoeconomics is part of a pharmacist's training curriculum, there appears to be room for improvement, suggesting that the subject matter be covered in greater depth in the undergraduate syllabus and more intensively in postgraduate pharmacy degrees.

With an increasing number of medical doctors now employed within the pharmaceutical and payer sectors, it would also be of benefit if pharmacoeconomics were to be introduced into medical school curricula. Medical doctors in pharmaceutical companies are involved in pharmacoeconomic evaluations and present this data to payers during reimbursement negotiations. The payer subgroup itself is often tasked with evaluating pharmacoeconomic arguments as well as assessing motivations from the healthcare provider segment and making recommendations, for example to ex gratia committees. It would also be of benefit for prescribing doctors, who may be presented data by drug companies, or to empower them to make stronger arguments in their motivations for reimbursement of drugs for their patients.

Whilst it is unclear exactly how government will introduce pharmacoeconomic evaluations as part of the drug registration process, it is generally accepted that pharmacoeconomics will be introduced. There is a great deal of apprehension around the availability of government resources to roll this out given that the registration of new chemical entities in the country can now take over three years without pharmacoeconomic evaluations.

There also seems to be a good deal of mistrust between the different parties involved. The pharmaceutical industry, which currently conducts most of the pharmacoeconomic studies, is seen to be biased and lacking credibility. Payers, on the other hand, are seen to be looking for reasons not to reimburse drugs.

The introduction of pharmacoeconomic evaluations as mandatory by government could offer the opportunity for a type of public–private partnership. This could be in the form of board or committee made up of members from the various stakeholder groups. Government would provide a clear regulatory framework and guidelines and engage independent adjudicators/external evaluators to adjudicate. The private partners could assist with financing and bring private sector efficiency. The aim would be to engender a collaborative relationship between the different parties, which would allow for a greater

understanding of the requirements and help eliminate or reduce the lack of trust issues.

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APPENDIX 1: Interview Protocol

Thank you for agreeing to participate in this research. As I explained telephonically, I am looking at the current use of pharmacoeconomic evaluations by decision makers at different levels in the healthcare industry.

My research focuses on the promoters and barriers to effective use of pharmacoeconomic evaluations within the South African health sector. This interview is aimed at collecting data based on the answers given by respondents (such as yourself), who are involved in decision-making in healthcare.

Although the completed research falls under the ownership of Wits Business School the research findings will be public domain and as such, you as a respondent, will therefore have full access to the consolidated findings, should you wish.

DETAILS OF RESPONDENT

Respondent‘s Name:

Title:

Job Description:

Organisation:

Contact Telephone Number:

Email Address:

Date:

Time:

Questions

1. **Do you/ have you used pharmacoeconomic evaluations as a decision-making tool?**

   Probe questions
   When, how, why, why not

2. **What factors do you consider to be important in promoting the effective use pharmacoeconomic at your level as a decision maker?**

   Prompt
   And what about

- government endorsement and mandatory regulations
- need for cost containment
- pharmaceutical industry

Probe
Why would you consider these important/ unimportant?

3. **What factors do you consider to be the greatest hindrances to the effective use of economic evaluations in your healthcare sector?**

Prompt
.And what about

- methodology
- education and skills
- applicability and relevance of economic evaluations at your level
- bias, credibility and quality of economic evaluations
- communication and reporting of data

Probe

- Are these important, relevant or not?
- Do see potential problems arising from these factors?

4. **Are there any other comments you wish to make regarding the implementation, use and attitudes towards pharmacoeconomic evaluations? If so, please expand.**

Close of Interview

Thank you very much for your time.
Your contribution has been very valuable.
May I contact you again for clarification or further discussion should this be necessary? Y or N.
Thank you again.
Goodbye.

APPENDIX 2 Consistency matrix

Research problem: To determine the promoters and barriers to the use of pharmacoeconomics(PE) in South African Healthcare			
Question 1	Source of theory	Source of data	How analysed
Are pharmacoeconomic analyses being used & to what extent are they informing & influencing your decision making : At a national or regional level i.e. Provincial and National Departments of Health? At a healthcare facility level i.e. Hospitals and clinics, medical aid schemes? By healthcare providers i.e. medical doctors? By pharmaceutical manufacturers?	Van Velden et al (2005) Van Velden et al (2005), Grizzle et al (2000),Motheral et al (2000) Van Velden et al (2005) Grizzle et al (2000) Langley (2004)	Respondents answers to question 1 during the interview	Content analysis

Proposition 1	Source of theory	Source of data	How analysed
Promoters to the use of PE include : • government endorsement and mandatory regulations • need for cost containment • pharmaceutical industry	• Davey et al, 2004; Drummond *et al* 1999; Doherty *et al* 2004 • Van Oostenbruggen et al 2005; Lee et al 2005 ;Ikegami et al, 2002; Doherty et al 2004 • Ikegami et al, 2002; Pang ,2002	Subject Matter Interviewees to answers to Question 2 during semi-structured interviews	Content analysis
Proposition 2	Source of theory	Source of data	How analysed
Barriers to the use of PE include: • Methodological Issues • Education and skills • Application of Economic Evaluations in Decision –Making • Bias, Credibility and Quality of Economic Evaluations • Communication and Reporting	• Gagnon et al,1999; Von Velden et al ,2005; Lee et al , 2005; Nishimura et al ,2002 and Doherty and Sato, 2001 Zwart-van-Rijkom et al,2000 ; Doherty et al ,2004 • Bridges,J.F.P.,2005 ;Stratchounski ,L.S.,1999 and Davey et al, 2004; Maio,V. and Lofland,J.H.,2004) • Edmonson,2004 ; Gagnon et al, 1999 • Gagnon et al, 1999; Nishimura et al ,2005; Lee et al ,2005 • Motheral, et al, 2000 and Pang, 2002	Subject Matter Respondents answers to Question 3 from semi-structured interviews	Content analysis