

The University of Queensland  
Faculty of *Business Economics and Law*  
School of Economics

*Economic Evaluation of Clinical Gait Analysis: A Cost-  
Benefit Approach*

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of Queensland, in partial fulfilment of the requirements for  
the degree of *Masters of Health Economics (Advanced)*

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## **DECLARATION OF ORIGINALITY**

I declare that the work presented in this Masters thesis is, to the best of my knowledge and belief, original and my own work, except as acknowledged in the text, and the material has not been submitted, either in whole or in part, for a degree at this or any other university.

Keshwa Nand Reddy

17 June 2005

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## **ABSTRACT**

This research is concerned exclusively with children who are suffering from gait related abnormalities. The purpose of this thesis was to conduct an economic evaluation of alternative means of treating gait. More specifically, the answer to the following was sought: “which method of treating cerebral palsy (clinical gait analysis or the current method of clinical observation) maximises the difference between social benefits and social costs?” The technique of cost-benefit analysis was employed to answer this question.

In order to conduct an economic evaluation, information on the marginal costs and benefits of conducting gait analyses was estimated using data obtained from the Royal Children’s Hospital in Brisbane. Of the 15 patients identified for the study, 10 responses were obtained. Three of six physicians who were approached for the study responded to the questionnaire. Of the ten respondents, six either had their treatment options changed or deferred, three had no changes but wanted confirmation and one had CGA to assure family of the initial diagnosis by the physician. Results of the analysis of the raw data suggest that the marginal benefits of conducting clinical gait analysis are greater than its marginal costs. The bootstrapping technique used also used to simulate a larger sample (of 2000 iterations) and the results also confirmed the initial finding.

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# GLOSSARY<sup>1</sup>

**Baclofen** - is a muscle relaxant and an antispastic agent. It is used to relieve the muscle spasms, pain, and muscular rigidity associated with multiple sclerosis and other medical conditions.

**Botox** - is a highly purified preparation of botulinum toxin A, which is produced by the bacterium *Clostridium Botulinum*. Botox is injected, in very small amounts, into specific muscles. It blocks the transmission of nerve impulses to muscles and so paralyses the muscles. Botox is a brand name, a synonym for Botulinum toxin.

**Cerebral palsy** – “cerebral” refers to the brain and “palsy” to a disorder of movement or posture. If someone has cerebral palsy it means that because of an injury to their brain (cerebral) they are not able to use some of the muscles in their body in the normal way (palsy).

**Cost–benefit analysis (CBA)** - A method of estimating the net benefit of a program — that is, total benefit less total cost, with all benefits and costs measured in monetary value.

**Cost–effectiveness analysis (CEA)** - A method of comparing a health program to its alternative(s) based on the ratio of total incremental cost to total

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<sup>1</sup> Source of medical terms are from Martin (2002), Brooker (2003) and Department of Health and Human Services, (2005).

incremental benefit, with all benefits measured in a natural unit such as the number of disease cases treated or the number of years of life saved.

**Cost–utility analysis (CUA)** - A method of comparing a health program to its alternative(s) based on the ratio of total incremental cost to total incremental benefit, with all benefits measured in a health related wellbeing unit such as the mortality rate or life expectancy adjusted or not for differences in the functional capability or quality of life.

**Discounting** - The process of converting future costs and benefits to their present values.

**Dorsal rhizotomy** - for some children with spasticity affecting both legs, a surgical technique called selective dorsal rhizotomy may permanently reduce spasticity and improve the ability to sit, stand and walk. In this procedure, doctors identify and cut some of the nerve fibres that are contributing most to spasticity.

**Efficacy** - The extent to which health programs would achieve health improvements under ideal settings.

**Electromyography** - provides information on the timing of muscle activation.

**Endocrinologist** - an endocrinologist is a specially trained doctor who diagnoses diseases that affect the glands.

**Gait analysis** – is the process of quantification and interpretation of human locomotion.

**Iliopsoas muscles** - A blending of two muscles (the iliacus and psoas major) that run from the lumbar portion of the vertebral column to the femur. The main action of the iliopsoas is to flex the thigh at the hip joint.

**Kinematics** - the study of joint movement.

**Kinetics** - the study that provides information on the movements of joints.

**Morbidity rate** - A measure of the incidence of diseases or illnesses in a particular population.

**Mortality rate** - A measure of the incidence of death due to diseases and injuries in a particular population.

**Myelodysplasia** - refers to a developmental anomaly of the spinal cord.

**Net present value** - The value of a stream of net benefits to be received in future, discounted to the equivalent of present dollars.

**Opportunity cost** - The value of the best alternative foregone in order to obtain or produce more of the health services under consideration.

**Orthopaedics** - the branch of surgery broadly concerned with the skeletal system (bones).

**Orthotic** - a support, brace, or splint used to support, align, prevent, or correct the function of movable parts of the body.

**Paraparesis** - weakness of the lower extremities.

**Parkinson's disease** – a slowly progressive neurologic disease characterized by a fixed inexpressive face, a tremor at rest, slowing of voluntary movements, a gait with short accelerating steps, peculiar posture and muscle weakness, caused by degeneration of an area of the brain called the basal ganglia, and by low production of the neurotransmitter dopamine.

**Prosthetic** - referring to prosthesis, an artificial substitute or replacement of a part of the body such as a tooth, eye, a facial bone, the palate, a hip, a knee or another joint, the leg, an arm, etc.

**Rectus femoris** - one of the anterior thigh muscles forming part of the quadriceps femoris complex.

**Spasticity** - a state of increased tone of a muscle (and an increase in the deep tendon reflexes). For example, with spasticity of the legs (spastic paraplegia) there is an increase in tone of the leg muscles so they feel tight and rigid and the knee jerk reflex is exaggerated.

**Spina bifida** - is a broad term that may be used to describe a number of open defects of the spinal column.

**Technical efficiency** - Situation in which health care interventions for particular health states are each performed with the least amount of inputs.

**Tendo Achilles** - One of the longest tendons in the body is a tough sinew that attaches the calf muscle to the back of the heel bone.

## LIST OF ACRONYMS AND ABBREVIATIONS

3DGA	- 3 Dimensional Gait Analysis
BCR	- Benefit-Cost Ratio
CBA	- Cost Benefit Analysis
CEA	- Cost Minimisation Analysis
CGA	- Clinical Gait Analysis
CMA	- Cost Minimisation Analysis
COOHTA	- Canadian Co-ordinating Office for Health Technology Assessment
CP	- Cerebral Palsy
CUA	- Cost Utility Analysis
CV	- Contingent Valuation
EGM	- Electromyogram
ESB	- European Society of Biomechanics
EW	- Extra Welfarist
FCM	- Friction Cost Method
GDP	- Gross Domestic Product
HCA	- Human Capital Approach
ISB	- International Society of Biomechanics
IRR	- Internal Rate of Return
MBS	- Medicare Benefits Schedule
MSAC	- Medical Services Advisory Committee
MVA	- Motor Vehicle Accidents
NICE	- National Institute for Clinical Excellence
NPV	- Net Present Value
QCGL	- Queensland Children's Gait Laboratory
WE	- Welfare Economics
WTP	- Willingness to Pay
WTA	- Willingness to Accept

# CHAPTER ONE

## INTRODUCTION

### 1.1 Definition of the problem

This research is concerned exclusively with children who are suffering from gait related abnormalities, and who are assessed by the Queensland Children's Gait Laboratory (QCGL) during the normal course of their treatment. The purpose of this thesis is to conduct an economic evaluation of alternative means of treating gait.<sup>2</sup> More specifically, the answer to the following is sought: "which method of treating *cerebral palsy*<sup>3</sup> (clinical gait analysis or current method of observation) maximises the difference between social benefits and social costs?" The technique of cost-benefit analysis (CBA) is employed to answer this question.

Health continues to be a growing and increasingly complex field of competing priorities from all perspectives – from the individuals to governments, businesses, health professionals and the health services system. Health care currently costs Australia over nine percent of its gross domestic product (GDP), or on average over \$3,500 per person in health care (AIHW, 2004). Thus, knowing the least cost of treatment of a particular case will enhance the allocation of resources,

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<sup>2</sup> Gait is commonly defined as the process of walking and/or running.

<sup>3</sup> Cerebral Palsy (CP) is a group of non-progressive disorders in young children in which disease of the brain causes impairment of motor function. Motor disorders that are result of progressive brain disease or spinal cord impairment are excluded and are usually termed as static encephalopathy. There are basically 4 motor manifestations of CP namely, spastic, athetoid, ataxic and tremor (Staheli, 2003).

improving health outcomes and reducing the costs of treating those who suffer from gait-related problems.

A gait laboratory can be described as a place where an individual's gait can be assessed.<sup>4</sup> In its simple form, a gait analysis consists of the study of videotape reviewed in slow motion of an individual walking. When this information is coupled with physical examination, a medical practitioner has an enhanced understanding of an individual's gait (Staheli, 2003; Whittle, 2002).

Gait analysis is used as a diagnostic tool that can improve the information available to clinical decision makers and thereby improve the diagnosis and prognosis of people with problems of gait. While there is substantial literature on the efficacy and effectiveness of gait analysis, little is presently known about its cost-effectiveness or its costs and benefits. This preliminary study is designed to shed light on this question and will provide a useful initial assessment of the necessary scope for a larger study of the costs and benefits of gait analysis.

## **1.2 The study group**

In order to conduct an economic evaluation, information about the costs and benefits of conducting gait analyses was estimated using data obtained from the

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<sup>4</sup> In this thesis references to "3DGA" (3 Dimensional Gait Analysis) or "CGA" (Clinical Gait Analysis) or "2<sup>nd</sup> generation CGA" mean "gait analysis conducted in specialised laboratory". The current practice of observation (traditional method) will be also referred to as 1<sup>st</sup> generation CGA.

Royal Children's Hospital (RCH) in Brisbane. In this preliminary pragmatic study, a well-defined set of direct and indirect clinical costs were estimated to conduct the CBA. Children ages 6-11 years (inclusive) who were assessed at the QCGL during the period 1 October, 2004 to 31 May, 2005 were included in the study.<sup>5</sup> Clinician advice was sought from treating medical consultants, prior to the conduct of gait analysis, of the diagnosis, differential diagnoses (where applicable) and proposed intervention(s) and treatment pathways that would be recommended for subjects in the absence of further diagnostic information becoming available. Then, in the light of the results of gait analysis, the same clinical experts were asked to provide another assessment and recommend an appropriate clinical treatment pathway. These pre- and post-gait-analysis assessments and clinical decisions were compared and the costs and consequences of the gait analyses were estimated with reference to direct clinical costs.

### **1.3 Relevance and importance of this study**

The importance of this research is three-fold. Firstly, it fills a gap in the literature by undertaking the first CBA of clinical gait analysis (CGA). Secondly, this research could assist as a building block for cost recovery and could also reveal

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<sup>5</sup> The initial inclusion criteria were to include children ages 6-10 years during the period 1 March to 31 May, 2005. However, it was realised that during this period most patients gait analysis would not have been analysed by their physician. This would significantly reduce the sample size.

information that may help to enhance the efficiency of QCGL. Finally, CBA could assist in the overall allocation of resources and assist in priority setting decisions.

An important issue and a reason for the current study is that gait laboratory outcome studies have been limited in scope and number. The critical studies found in the literature are mostly critiques of individual procedures such as *selective dorsal rhizotomy*, *tendo Achilles lengthening*, or *rectus femoris transfer* (Hausdorff et al., 2000; Ounpuu, Muik, Davis, Gage, & DeLuca, 1993a; 1993b). However, there is *de facto*/common acceptance of its use in evaluating different treatment options in the literature. A keyword search of Medline (06/04/05) identified some 758 papers, since 1996, using “gait analysis”, 145 papers listing “gait analysis laboratory”, no papers listing “gait analysis and cost utility or cost effective analysis” and one paper listing “gait analysis and cost benefit”.

The latter study, by Cooper *et al.* (1999), states that “the highest priority in this study was assigned to research on the efficacy, outcomes, and the cost-effectiveness of gait analysis”. The primary goal of this research was to develop priorities for future research, development, and standardization in gait analysis. A multistep approach was used that included expert testimony, group discussions, individually developed priorities, and a ranking process. Although the study itself did not, in fact, conduct a CBA as the keyword search suggested (“gait analysis and cost benefit”), it is important to note that expert opinions also suggest the importance of an economic evaluation for priority setting goals for gait analysis in

rehabilitation. Thus this thesis is unique as it is the first attempt at determining the costs and benefits of CGA and, as such, it is the first step in filling the current gap in the literature.

This research will address an international paucity in the clinical gait arena by determining the costs as well as the benefits of CGA. The most likely groups of clients to benefit will be those who have acquired brain injuries, CP, spina bifida and amputees.<sup>6</sup> It is hypothesised that the QCGL will assist the treating practitioners in these groups to improve their patients' gait, balance and upper-limb movement.

This research will consider the estimation of the costs and benefits of CGA as compared to current methods of intervention. Although recognised as clinically useful and financially reimbursable for certain medical conditions in countries such as the US and UK, the routine clinical use of gait analysis has seen limited growth (Hailey & Tomie, 2000; Staheli, 2003). An important issue and a reason for the current study is that gait laboratory outcome studies have given limited consideration to economics.

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<sup>6</sup> Spina bifida is a broad term that may be used to describe a number of open defects of the spinal column.

## 1.4 Structure of the thesis

The structure of the thesis is as follows: Chapter 2 examines the historical overview of gait analysis and the introduction of gait laboratories in Australia. The importance of gait and the literature that is concerned with its clinical relevance and its influence in clinical decision making follows. While this literature generally acknowledges the importance of gait analysis, some light is also thrown on its limitations and critiques.

Chapter 3 briefly outlines the theoretical foundations of CBA and other economic evaluation techniques. It provides a defence of the use of CBA to address the topic of this thesis. As we will see in this chapter, such bases are important in making decisions for optimal resource allocation.

The theory behind economic evaluation of health care and the need for such evaluation is discussed in chapter 4. Discussions on the basic characteristics of the various forms of economic evaluation techniques with particular emphasis on cost-effectiveness analysis (CEA), cost-utility analysis (CUA) and cost-benefit analysis (CBA) are discussed. It shows that the cost-benefit analysis is a technique, although first used by engineers, finds its justification in the theory of welfare economics.<sup>7</sup> Emphasis is placed on the assumptions of fact and value

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<sup>7</sup> The logic of economic efficiency has been used for decades. The use of CBA, in order to promote efficiency, was first used by engineers for flood control projects. The USA's Flood Control Act 1936 stated that projects would only be considered for congressional action if "the benefits to whomever they accrue exceed their costs" (Johannesson, 1996).

that underlie the technique. The chapter concludes with discussions on the measurement of the costs and consequences and how consequences of health care programmes can be valued in money terms based on the fundamentals of welfare economics.

One of the overall objectives of this thesis is to develop a framework for the quantification of the effect of CGA. Chapter 5 explains the method of data collection, the inclusion and exclusion criteria and the techniques used in assessing and quantifying the costs and consequences of CGA. From this analysis some justifications are made on the inclusion and exclusion of various costs and consequences.

The methodology and technique developed for the estimation of CGA is then applied to the data collected from the QCGL and specialists. The results from the data generated in chapter 5 are discussed in chapter 6. Chapter 7 makes some concluding comments followed by recommendations for further research.

# CHAPTER TWO

## CLINICAL GAIT ANALYSIS

### 2.1 Introduction

Until recently, clinicians working with adults or children with motor disorders had to rely on visual observations to evaluate their gait. However, because human gait is quite complex, interpretation by the eye, even for experienced clinicians, is difficult. Recent advances in both video technology and computer systems provide accurate tracking and digitisation of human movement, by the use of video cameras and reflective markers.

The assessment of gait abnormalities using clinical data from technologically advanced gait laboratories as compared to current methods of physical examination and observation is still under debate. Many commentators have suggested that the current (1<sup>st</sup> generation) method of gait analysis with basic scanning is sufficient to make informed decision. Proponents of CGA, however, do not concur with this view and suggest that more informed decisions and cost savings could be made with specialised technologies such as 3DGA. However, there is no published evidence on the economics of CGA.

This chapter examines the historical overview of gait analysis and the introduction of gait laboratories in Australia. The debate on the value of the current generation of gait analysis technologies is also discussed.

## **2.2 History of gait analysis**

The first person to appreciate the significance of cinematography in the analysis of motion was Eadweard Muybridge in 1877 (McCoy & Rodda, 1996). Muybridge devised a system in which a number of cameras, the shutters of which could be opened in rapid succession when triggered by trip wires struck by moving horses, would capture their movements. This interest subsequently switched from horses to humans. Figure 1 below demonstrates a subject with a possible peripheral neuropathy (sensory impairment in the limb) with evidence of foot drop in the swing phase of gait. The white patches on the body shows reflective markers used in the gait analysis.

It was not until the World War II when the value of gait analysis and the need to design lower limb *prostheses* for war veterans was realised. By using gait analysis descriptive data on below and above knee amputees could be obtained to allow for improvement in prosthetic design.

**Figure 1: Patient with peripheral neuropathy**



Source: Flavin (2000)

However, these early gait analyses were still not suited for clinical applications. It was only in the past decade having critical advances in motion analysis systems made a “user friendly” approach to gait analysis possible (Lovejoy, 2005; McCoy & Rodda, 1996; Staheli, 2003).

### **2.3 Gait analysis in Australia**

Only two gait laboratories currently exist in Australia– one in Melbourne and one in Brisbane.<sup>8</sup> These facilities are owned by and funded by an annual grant from the respective state governments. CGA is not presently eligible for

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<sup>8</sup> Australia’s first gait laboratory for children, the Hugh Williamson Gait Laboratory at the Royal Children’s Hospital (RCH) in Melbourne, was opened in June 1995, bringing Australia in line with overseas paediatric centres (McCoy & Rodda, 1996).

Commonwealth subsidies under the Medicare scheme in Australia. Thus the use of gait analysis has seen limited growth in Australia in terms of financing and the number of gait laboratories.

Since commencing its operations in 2000, the QCGL has developed itself in providing excellent service, conducting gait research, clientele, experienced specialist clinicians and university collaborations. Many treatments are currently determined and assessed by CGA and demand for its services has continued to increase since its establishment. Over 350 patients have been assessed since 2000, most of whom are children with *CP*. However, those with acquired brain injury, amputees, *spina bifida*, and *hereditary spastic paraparesis* have also been assessed. 17 adults, 50% of whom were injured in road traffic crashes were also assessed since its inception in 2000. Referrals for gait analysis are made by orthopaedic surgeons, rehabilitation specialists, paediatricians, neurologists and endocrinologists. The patients come from Brisbane, regional Queensland, and Northern New South Wales. Referrals to the QCGL have also been made from as far away as Darwin and Hong Kong (one each).

CGA is provided by specialist health professionals including physiotherapists, medical engineers, orthopaedic surgeons and rehabilitation specialists in a purpose-built laboratory with dedicated equipment. The equipped facility has a fixed (fit-out) cost of \$0.75 million and was established by Queensland Health with supplementary funding from Royal Children's Hospital Fund (RCHF), Clubs

Queensland, Wesfarmers, Woolworths and Coles. Since 2000, the QCGL has increased its capacity from one patient a day to three with bookings for appointments being completely filled for the next eight months as from March 2005.<sup>9</sup> The capacity of the QCGL is three analyses a day, which is consistent with similar gait laboratories, elsewhere. Although increasing referrals are an indication of the perceived importance of gait analysis, little is known on the true economic cost of such analyses. With increasing demand for evidence based practice followed by constrained health budgets, it is timely that a full economic evaluation is conducted to evaluate the costs and benefits of such practice.

## **2.4 Characteristics and the importance of modern gait analysis**

Medical research on human locomotion has been ongoing for several decades. This has led to significant advancement in the technology that supports the analysis of human motion (Lovejoy, 2005; Simon, 2004; Whittle, 2002).

Clinical three-dimensional gait analysis is now accepted in many countries as the gold-standard measure of gait used prior to intervention planning (surgery, pharmaceuticals etc.) for patients with complex neurological and / or orthopaedic problems which have an impact upon their walking ability (Cooper et al., 1999; Gage, DeLuca, & Renshaw, 1995; Staheli, 2003). These conditions may have

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<sup>9</sup> These include patients requiring 3DGA, botox, physio exam, split screen video and COSMOD. There is an average of 2.5 patients (per week) analysed for 3DGA. This can be increased to 5 per week with existing resources allocated for 3DGA.

arisen due to a number of factors such as trauma, disease or by an idiopathic process (Staheli, 2003).<sup>10</sup>

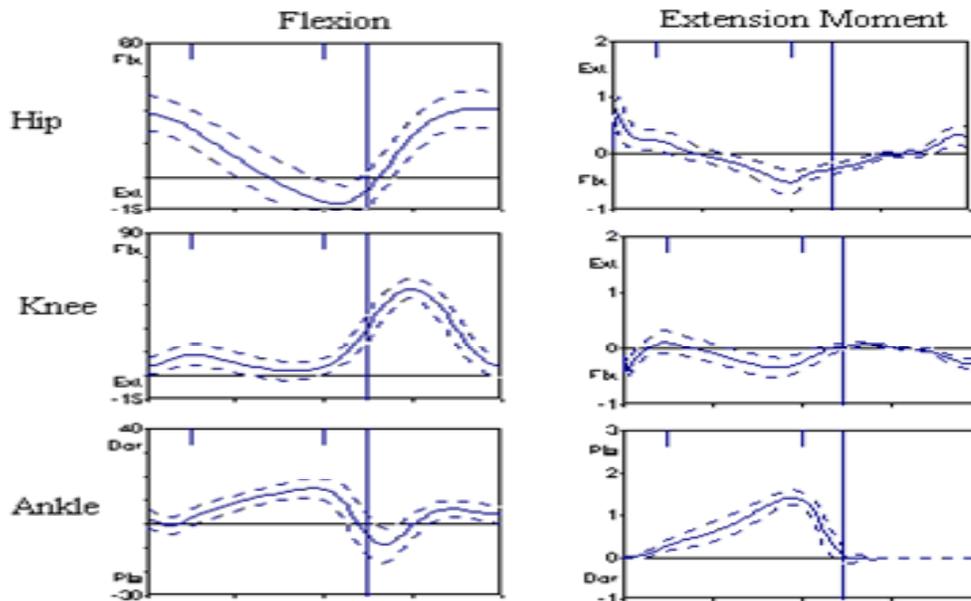
The study of joint movement is called *kinematics*. In recent years technological advances have resulted in more precise information that can be used to evaluate three-dimensional joint movement. When this kinematic information is combined with force-plate data, joint movements and powers can also be studied. This is called *kinetics* and it provides information as to how and why particular movements of the human anatomy arise. A dynamic electromyography (EMG) provides information on the timing of muscle activation. With the aid of a computer and specialised software, data is then collated, stored, manipulated and evaluated (Duhamela et al., 2004; Gage, 1995; Staheli, 2003; Woollacott & Shumway-Cook, 2002).

In a normal clinical procedure, clinicians usually determine the cause of movement abnormality in a patient by evaluating the patient's history, physical examination results and radiographs. Occasionally, the nature and cause of the abnormality is not, however, determinate (Staheli, 2003). In such situations, the gait laboratory may be useful as a dynamic assessment tool. Figure 2 below shows how an *interactive 3D model* animates a normal adult male gait using a video motion capture system at a gait laboratory.

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<sup>10</sup> Idiopathies are diseases of unknown cause.

**Figure 2: 3D gait analysis joint rotations**



Source: QCGL

The most common referrals to gait laboratories tend to be for the management of neuromuscular conditions such as CP and/or myelodysplasia (Noonan et al., 2003; Staheli, 2003).<sup>11</sup> In the following section discussions will briefly follow on the importance of gait analysis to the elderly as well. Thereafter, the discussion will mainly concentrate on issues relating to children.

The understanding of human gait is considered valuable not only in the field of medicine but also in the fields of sports and manufacturing (Maluf et al., 2001). In the field of medicine, which is a focus of this study, research in gait is considered important for people of all ages. In children, applying proper procedures in

<sup>11</sup> Myelodysplasia is a developmental anomaly of the spinal cord.

abnormalities can result in faster healing and at lower costs while in the elderly, detecting abnormal gait earlier could prevent future fall-related injuries that could have significant impacts on health and health care costs (Hausdorff et al., 1997). Falling injuries represent a significant cost in Australia (estimated to be \$4.1 billion in 2000-01) (AIHW, 2004).<sup>12</sup>

Increased gait instability, unsteadiness, and inconsistency from one stride to another are common in older adults. In persons with neurodegenerative (e.g., *Parkinson's*) disease, deficits in the central nervous system's ability to regulate and coordinate motor outputs are largely responsible for locomotor instability (Hausdorff, Edelberg et al., 1997; Hausdorff, Mitchell et al., 1997; Hausdorff et al., 2001a). In Australia, nervous system disorders (including dementia) were the second-largest consumer of health care resources (\$4.9 billion) followed by musculoskeletal conditions (\$4.7 billion) in year 2000-01 (AIHW, 2004). With an ageing population the number of falls injuries in Australia and associated cost of treatment is expected to rise dramatically (Moller, 2005). As such, proper gait analysis in the elderly could prevent fall-related injuries.

Apart from using CGA for diagnostic purposes, it can also be used to monitor the effects of interventions and hence may contribute to the ongoing management of the condition. An example of its use includes the recommendation of surgery to

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<sup>12</sup> Mathers and Penm (1999) in Moller (2005) estimated the cost of providing health services related to fall injury to persons 55 years of age or older in Australia to be 465.5 million dollars in 1993-1994. In an ageing society, without prevention, it is estimated that New South Wales alone will require four 200-bed hospitals and 1,200 nursing home beds to cope with the predictable increase in fall-related injuries by 2050 (Lord, 2003).

correct mal-alignments caused by spasticity, or the use of Botulinum toxin (or “*Botox*”)<sup>13</sup> to reduce spasticity in a specific muscle which is determined following the combination of assessing synchronised electromyographic, kinematic and kinetic data and finally delaying of proposed surgery (Simon, 2004).

A good gait analysis is proposed to make changes in the use of other services such as orthopaedic surgery, prosthetic and orthotic prescription, the use of *botox* and *baclofen*, physiotherapy and occupational therapy as CGA will provide quantitative evidence for best practice for these interventions, thereby targeting their use to achieve optimal health outcomes. There is also, therefore, the possibility of improved economic outcomes.

## **2.5 Gait analysis in clinical decision making**

Proponents of modern gait analysis emphasise the increased ability gait analysis provides to document and quantify preoperative abnormalities (Gage,1991; Saleh & Murdoch, 1985). Such assessments enable the surgeon to detect all pathologic and compensatory components of gait in order to plan and perform all procedures required for their correction during the same operative session. When performed postoperatively, gait analysis generates objective data that allow for

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<sup>13</sup> “*Botox*” is a highly purified preparation of botulinum toxin A, which is produced by the bacterium *Clostridium Botulinum*. *Botox* is injected, in very small amounts, into specific muscles. It blocks the transmission of nerve impulses to muscles and so paralyses the muscles. *Botox* is a brand name, a synonym for Botulinum toxin (Department of Health and Human Services, 2005).

assessment of treatment and guides further treatment in similar patients (Gage, 1991; Saleh & Murdoch, 1985).

Although in practice its use has seen limited growth/use amongst government organisations and medical practitioners, research on CGA has proven that it can have a significant and positive influence on clinical decision making. There are various published studies that have evaluated the influence of CGA on clinical decision making (DeLuca et al., 1997; Fabry et al., 1999; Hausdrof et al., 1997; 2000; Kay et al., 2000a).

Cook *et al.* (2003), in an article based on 102 patients with CP, demonstrated the value of CGA for decision making. They found that gait analysis “altered the treatment decision in 40% of operations”. They controlled for inter-observer differences by using the same staff throughout the study. On two separate occasions, firstly following an orthopaedic clinical exam (1<sup>st</sup> generation) and secondly following the 3DGA, which also included *coronal* and *sagittal video recording*, decisions were made for surgery and its type and level. The surgical recommendations from these two occasions were grouped, compared and analysed by an independent observer. This is the only paper that was found that discusses the effect of CGA as a tool of primary diagnosis, rather than its use to validate a treatment option.

Fabry *et al.* (1999), monitored 15 children with spastic diplegia CP for 9.5 years after operations were conducted. The results gave unpredictable results in surgical corrections of contractures of three most common muscle-tendon complexes (*hamstring, Achilles tendon, and iliopsoas* muscles). The recommendations from this research, derived from sequential 3D gait studies, favoured multilevel simultaneous corrections. In other words more surgical procedures were carried out in a single surgical procedure.

DeLuca *et al.* (1997), examined 91 children having surgery for CP. Clinicians who examined the gait analysis for every child changed their initial opinion in about half (52%) of the cases. This change in opinion as a result led to a reduction in the number of procedures being carried out and an overall reduction in the cost of surgery. To determine the impact on cost of these changes in surgical decisions, the authors evaluated changes in terms of relative value units (RVUs) for each surgical procedure. Average reduction of four RVUs in the surgery that was finally recommended was valued and this represented about half of the cost of a gait analysis at the hospital. However, in this study the actual pathway to calculating costs and benefits was not discussed and as such the validity of the results cannot be assessed.

In a study by Kay *et al.* (2000a), approximately 89 percent of surgical procedures were changed in individuals following the review of a preoperative gait analysis. In the 97 children with CP that were studied, 1.6 additional procedures per

patient were added whilst 1.5 procedures that were initially planned had to be removed. These decisions were solely based on clinical considerations. In another study by Kay *et al.* (2000b) on the impact of postoperative gait analysis on orthopaedic care, the authors studied 38 subjects with static encephalopathy who had gait study of an average 16.7 months after multiple procedure orthopaedic surgery which averaged of 6.1. The recommendation was for change in care in 32 of the cases. Of the cases that required changes 13 required further surgery, 17 required bracing, and 7 required changes to specific physical therapy.

In another study of 23 children with spastic CP, 16 were treated with the clinical recommendation whilst 7 were not. Of those who followed the recommendations, 14 (88%) showed improved walking abilities in a year while only 2 (29%) out of the 7 whose surgical procedures did not follow the recommendations improved. The study basically shows that clinical recommendations are important components in decision making (Lee & Goh, 1992).

Simon (2004) discusses how gait analysis assists the correction of peak swing phase knee flexion in children with CP. This condition limits the foot clearing the ground and results in tripping. However, while Chambers *et al.* (1998) in Simon (2004) state that the surgery (without gait analysis) of the quadriceps (*rectus femoris*) can help to correct this condition in children with CP, greater clinical evidence provided by Ounpuu *et al.* (1993a; 1993b) does not support the

method of direct surgery of the quadriceps as indicated by Chambers et al., (1998).

Similarly, there are also other ways in which clinical gait research has provided valuable clinical information. For instance, measuring and monitoring the variability of gait in various neurological conditions can determine the severity of the disease (Hageman & Thomas, 2002; Hausdorff et al., 1997; 2000; 2001a; 2001b; Maluf et al., 2001). Once the important parameters of a particular disorder are quantified, the further evaluation and treatment of the patient becomes simpler. Also, it may not be necessary to implement all treatment parameters from the gait analysis. Only a selected few parameters could suffice for treatment of a particular disorder (multilevel and single-setting surgical procedures). These positive effects of gait analysis are also emphasised by DeLuca *et al.* (1997): they argue that the computerized gait-analysis process as well as detailed gait data review, multilevel, single-setting surgery, and associated rehabilitation all favourably affect the care of the child with CP.

Clinical gait analysis/research has not only proven to be of importance for the treatment of the foregoing medical conditions but has proven to be of substantial importance to a variety of other medical conditions such as endocrinology, orthopaedics, neurology, and rheumatology (Hageman & Thomas (2002); Hausdorff et al., (2001a; 2001b); Mitoma et al., (2000); Mitoma (1997); Sacco & Amadio (2003); Perry (1999); and Hillman et al., (2000)).

## 2.6 Critiques of gait analysis

Detractors of modern gait analysis believe that past methods (such as physical examination, x-rays and video), are perfectly adequate for assessing gait abnormalities. These physicians also cite costs greater than US\$1,000 for each clinical gait analysis (using 3DGA, EMG, kinematics and kinetic data) and the difficulty in reproducing similar data in the same patient (see Noonan et al., 2003). Also, there is general agreement amongst economists that technology is a driving force behind the long term rise in health care spending (Fuchs, 1999).<sup>14</sup> However, a *de facto* argument associated with increasing sophisticated diagnostic technology is the diminishing returns associated with it.

Noonan *et al.* (2003), evaluated 11 patients with spastic CP. Each patient had gait analysis at four different centres. After the review of the data, each medical director chose from a list of treatment options. The degree of agreement in treatment recommendations (nonoperative, soft tissue, bony surgery and combined surgery) lessened as the complexity (mild, moderate and severe) in clinical presentation increased. For example, mild patients had concurrent treatment plans (67%) as compared to moderate and severely affected patients which had conflicting treatment plans (60% and 30% respectively). Even where

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<sup>14</sup> The report of the Health and Medical Research Strategic Review (1999) provides an estimate of the likely impact of increasing application of technology to health systems expenditure in Australia from 1996 to 2016.

the treatment recommendation was same for the four gait laboratories, the proposed surgical procedures had substantial variations. The authors concluded that substantial variations in raw data exist when the same CP patient is evaluated at different gait centres. The data did not yield the same recommendations in the majority of the patients. This view, however, has been countered by Chambers (1998) stating that it is not the reproducibility of gait laboratory results that is inconsistent, but rather the interpretation them. Although the latter argument suggests that gait laboratories produce consistent data, the consistency of their interpretation is clearly a fundamental issue. Expressed differently, there could be limitations in gait analysis due to inconsistencies in the analysis and the interpretation of the analysis.

Simon (2004), apart from discussing the benefits (section 2.5), also discussed some major limitations of CGA. The most common limitations cited by clinicians are that: (1) gait analyses are not user friendly as compared to other new technologies such as magnetic resonance imaging (MRI) or computed tomography (CT). Most physicians, for instance, can look at the MRI or CT scans and apply their knowledge of anatomy and see the disorder that is present; (2) the graphs and charts of a gait analysis are thought to be difficult to interpret unless one is trained to do so; and (3) the accuracy, reproducibility, and variability in the test data and clinical report remained a concern (Simon, 2004).

While there may be some merit in the first limitation above, in general this may not be a valid argument in the sense that gait analysis is about functional assessment and not structural assessment *per se*. While structural problems may cause functional limitations, some problems of function will have no obvious structural genesis on X-ray or MRI, for example.

On the second and third limitations, the accuracy and repeatability of gait variables (kinematic, kinetic, and EMG data) of normal subjects has been tested (Andrews et al., 1996; Kadaba et al., 2005). To verify the reproducibility of the data, gait analysis testing was performed on each lower limb on two separate days for each subject. An analysis of variance showed that there was no significant difference between test limbs or test days for each subject. The results suggested that the alignment of the lower limb and the foot progression angle, which can be readily measured in a clinical setting, can serve as predictors of knee joint loading in healthy individuals (Andrews et al., 1996). These findings may have important implications for both surgical and non-surgical treatment of abnormalities of the knee joint. Kadaba *et al.* (2005), carried out statistical measures to evaluate repeatability of kinematic, kinetic, and EMG data waveforms of 40 normal subjects. Subjects were evaluated three times on each test day and on three different test days while walking at their preferred or natural speed. The general conclusion was that the variables were quite reproducible. These observations suggest that it may be reasonable to base significant clinical decisions on the results of a single gait evaluation.

Another common reason cited as a weakness of a gait laboratory is that, it's set up in studio type setting does not measure walking in real conditions. This means that in its current state, a gait analysis does not measure actual everyday walking performance and hence may not accurately produce results. While the above issues has been a concern amongst most physicians, recent improvements in gait analysis technologies, which are relatively inexpensive, simple to use and interpret when incorporated with the existing technology, are supposed to enhance its capability and performance (Aminian & Najafi, 2004; Maluf et al., 2001). The recent enhancement in the use of gait technology has increased its ability even to measure gait in everyday situations.

## **2.7 Conclusion**

Whilst gait analysis reduces the chances of multiple surgical procedures, it may also reduce psychological sequelae. With reductions in multiple surgical procedures total medical costs may be reduced as compared to performing each procedure separately. Also improvements to individual's functional form can be enhanced in a single surgical session as compared to multiple surgical procedures over a longer period of time. This study seeks to measure a subset, albeit a potentially critical subset, of the benefits associated with these improvements.

# CHAPTER THREE

## THEORETICAL FOUNDATIONS OF CBA

### 3.1 Introduction

*“Since cost-benefit is an application of the theory of resource allocation, itself a subject at the core of welfare economics, the rationale of such analysis can be understood and vindicated only by reference to propositions at the centre of welfare economics (Mishan, 1988).”*

While evaluating health care projects various forms of economic evaluation techniques have been used to identify, measure and value the inputs and outputs of a program. In this thesis a cost-benefit approach is used to assess the impact of quantifiable avoided costs and indirect benefits on the outcomes from clinical gait analysis. A cost-benefit analysis is an analytical tool designed to promote economic efficiency in the allocation of scarce resources. This could assist in decision making by physicians in terms of optimal diagnosis and to funding agencies such as donors and governments to decide funding priorities. The rationale behind a cost benefit analysis (CBA) is the measurement and comparison of the costs and benefits between alternatives. The theoretical basis for the measurement of benefits in a cost-benefit analysis is economic welfare theory and the concept of consumer surplus (Pearce & Dasgupta, 1971; Sudgen & William, 1978). The relevant concept of cost, in economics, is opportunity cost.

## 3.2 Historical background

Whilst the logic of CBA has been used for decades, its first use, in order to promote efficiency was by USA's Army Corps Engineers enacted by the USA's Flood Control Act of 1936 (Mishan, 1988). It stated that projects would be considered for congressional action only if the benefits to whomever they accrue exceeded their costs. However, their method of evaluation, using the general criterion, was not based on the model of cost benefit analysis that we know today. The intellectual roots of CBA are traced as far as 19<sup>th</sup> century French economist Jules Dupuit (1844). The ethical underpinnings of economic efficiency were further refined by Vilfredo Pareto, Nicholas Kaldor and Sir John Hicks in late 1930. In 1971, Edward Mishan authored the first comprehensive book on the subject entitled Cost-Benefit Analysis (Hanley & Spash, 1993; Johannesson, 1996).

The next section provides some discussions on the theoretical basis of cost-benefit analysis and the literature that widely acknowledges its use in all fields including health.<sup>15</sup>

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<sup>15</sup> See Arrow, 1963; Birch & Donaldson, 2003; Boardman, Greenberg, Vining, & Weimer, 2001; Brent, 2003; Brouwer & Koopmanschap, 2000; M. Drummond & McGuire, 2001; M. Drummond, O'Brien, Stoddart, & Torrance, 2003; Johannesson, 1996; Johannesson & Jönsson, 1991; Jönsson, 1976; Mishan, 1969, 1971, 1981, 1988; Sudgen & William, 1978; Torrance, 1986.

### **3.3 Theoretical basis of cost-benefit analysis**

#### ***3.3.1 Paretian welfare economics***

Welfare economics (WE) is described as a branch of economics that uses microeconomic techniques to simultaneously determine the allocative efficiency of the whole economy and the income distribution consequences associated with it.<sup>16</sup> Social welfare has, in the utilitarian tradition, been considered as the sum of the utilities of individuals who comprise society. That is, welfare economics is about social welfare and which is a function of individual utilities. It assumes that individuals are the best judges of their own welfare which is the opportunity cost of their decisions.

Decision making is an essential aspect of resource allocation for any individual, household or organization. Given that resources are scarce and human wants are seemingly unlimited, choices between alternatives are inevitable. This is the process where individuals, as utility maximisers, ensure that there is no alternative mix of goods that would increase welfare further (McPake et al., 2002). Similarly, when a decision is made on behalf of society to provide some services collectively, the aim is to maximise the welfare of the whole of society,

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<sup>16</sup> Welfare economics is a branch of economics which grew from the ideas expressed by Adam Smith.

so no change in the combination of goods and services could increase social welfare.

In WE, normative questions that embody value judgments can be addressed. However, much of economics is positive because predictions are made without value judgments (e.g. raising price of a product to reduce its quantity demanded). Value judgment in this context thus refers to two key components of WE based on the principles of nineteenth century sociologist Vilfredo Pareto (Mishan, 1969). The general question he sought to answer was “how would we judge whether society as a whole was better off from a policy or program? The following key assumptions and principles underlie the Pareto condition: (1) social welfare is made up from the welfare (or utilities) of each individual member of society; and (2) individuals are the best judges of their own welfare (consumer sovereignty). This is the basis of welfare economics (Mishan, 1969, 1971).

WE states that the resource allocation should be decided on the basis of the utility levels attained by individuals. It excludes all non-utility aspects of the situation. Another feature in WE is individual sovereignty. It generally assumes that individuals are the best judges of their own welfare. So it assumes that people know what they want and so are able to demand that level of health care that maximises their utility. The word demand led to the assumption of utility maximisation in the WE model. The demand curve for any good or service is defined as the schedule of willingness to pay.

A policy that makes one or more person better off and makes no person any worse off constitutes an actual Pareto improvement. However, in reality, changes usually make some people better off while making others worse off, so these tests ask what would happen if the winners were to compensate the losers. Using the Kaldor criterion an activity will contribute to Pareto optimality if the maximum amount the gainers are prepared to pay is greater than the minimum amount that the losers are prepared to accept. Under the Hicks criterion, an activity will contribute to Pareto optimality if the maximum amount the losers are prepared to offer to the gainers in order to prevent the change is less than the minimum amount the gainers are prepared to accept to forgo the change. The Hicks compensation test is from the losers point of view, while the Kaldor compensation test is from the gainers point of view. If both conditions are satisfied, both gainers and losers will agree that the proposed activity will move the economy towards Pareto optimality. This is referred to as Kaldor-Hicks efficiency or Skitovsky criterion (Baumol & Wilson, 2001; Boadway, 1984; Price, 1997).

According to this criterion a project should proceed if the beneficiaries are willing to compensate the losers and that the losers are willing to accept the compensation for their losses. An individual's willingness to pay is described as the price paid plus the consumer surplus.<sup>17</sup> Consumer and producer surplus are

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<sup>17</sup> Consumer surplus (producer surplus) is the amount that a consumer (producer) is willing to pay for a good above a price.

considered to be important concepts in cost-benefit analysis, as the value of individual preferences can, in theory, be determined by measuring the consumer and producer surplus (Boardman et al., 2001; Mishan, 1971; Sudgen & William, 1978).

Pareto optimality entails both technical efficiency and allocative efficiency, and is achieved when four criteria are met: (1) the marginal rates of substitution in consumption must be identical for all consumers; (2) the marginal rate of transformation in production must be identical for all products (it is impossible to increase the production of any good without reducing the production of other goods); (3) the marginal resource cost must equal the marginal revenue product for all production processes; and (4) the marginal rates of substitution in consumption must be equal to the marginal rates of transformation in production. See, e.g. Baumol & Wilson (2003) and Boadway (1984).

The mechanism to measure potential Pareto improvements is cost-benefit analysis. However, there are a number of assumptions that underlie a Pareto optimum condition which may lead to inefficiency. A Pareto optimal condition assumes that the market is perfectly competitive and that benefits are valued according to an individual's willingness to pay and costs (opportunity costs) are measured according to other individuals' willingness to pay an amount that reflects the next best alternative use. A competitive market assumes that consumers are: rational, have a diminishing willingness to substitute goods,

preferences are independent of others and producers are profit maximisers. It also assumes that there is perfect knowledge of the market, goods are identical and no existence of influencing price by either producer or consumer. It is in a competitive market that prices are used for resource allocation and the above assumptions ensure that prices are not distorted. In a cost-benefit analysis decisions to accept or reject a project are made by looking at the marginal cost and marginal benefits of a program (we will discuss the marginal cost and benefit concept more in chapter 4).

As stated in Drummond *et al.* (2003), for a meaningful comparison, it is necessary to examine the additional costs that one health program imposes over another, compared to the additional benefits provided. Costs are valued in units of local currency and any future costs are valued in constant dollars of the same base year.

If costs or benefits do not occur in the present, these are usually discounted on the basis of time preference.<sup>18</sup> Given that different values are given to goods and services now or in the future, costs and benefits that occur at different points in time cannot be summed without making adjustments to reflect the time value of the cash flows. There have been various arguments on the use of a range of discount rates in an economic evaluation (including the argument of zero

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<sup>18</sup> This is based on the assumption that individuals have a preference of consuming goods in the present rather than in the future and thus place less value on benefits and costs in the future.

discount rate by Goodin (1982) in Cullis & Jones (1992)).<sup>19</sup> Mishan (1975) makes the distinction between  $r$ , the social time preference rate (STPR);  $\rho$ , the social opportunity cost (SOC) of capital and what he calls  $p$ , the opportunity rate of discount. When  $r=p$ , there is no dilemma. However, when  $r \neq p$ , provided government is able to invest in projects with rates that are  $>r$ ,  $r < p < \rho$ . In such cases, Mishan recommends a “compromise” (i.e., use  $p$ ).

There are a number of decision criteria that could be used in an economic evaluation. These are the net present value (NPV), internal rate of return (IRR) and benefit-cost ratio (BCR). The NPV is the most frequently used. Projects with an NPV greater than zero are considered to provide a net social benefit. A further discussion of the time value for money is provided in chapter 4.

The decision criteria outlined above do not expressly consider uncertainty. Given the uncertainty involved in identifying projects and consistent with the welfare economics of health care market as outlined by Arrow (1963), it is important that the inherent uncertainty in using the CBA methodology is assessed. This will be further discussed in chapter 4.

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<sup>19</sup> The use of discount rates of 10% and even 15% are not unusually high. Even higher rates have been used in economic evaluation. See for instance, Cropper & Aydede (1992), Warner & Pleeter (2001) and Weitzman (2001).

### 3.4 Valuing benefits in monetary terms

In a well-functioning market, as was discussed above, willingness to pay can represent the users' own measure of benefit (benefit is equal to the price for the marginal user). However, there are objections to using willingness to pay as a measure of benefit because it is related to ability to pay. While the Pareto optimality theorem applies to competitive markets, many markets are subject to various forms of market failure.<sup>20</sup> As such, the benefit to the marginal user may not equal to the marginal social cost. Also since there may not be full information, the willingness to pay may not reflect their preferences fully.

Eliciting views on preferences may have different willingness to pay for an individual with or without a disease.<sup>21</sup> However, the continued interest and the insights of continuous improvements to the current methods of qualitative assessment has kept researchers to continue its development (Donaldson et al., 1995). The measurement of benefits will be further discussed in chapter 4.

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<sup>20</sup> A classic example is the market for health care. For details on the nature of health care markets and the uncertainty with regards to welfare economics reference is made to Arrow (1963), Folland *et al.*, (2003) and Grossman (1972a; 1972b) .

<sup>21</sup> For more information on the quantitative measures of benefits reference is made to Ried (1988); Gafni & Birch (1997); Bleichrodt *et al.*, (2004).

### **3.5 Critiques of welfare economics**

As the literature on WE demonstrates, the Paretian welfare economics provides a theoretical framework for economic evaluation (Mishan, 1969, 1981). However, some of the recent literature in health economics has argued for the rejection of Paretian ideas as the basis for economic evaluation in the health sector. It has been argued that the Pareto criterion will not lead to a single-best allocation in health care markets.

The concept behind the alternative framework is often associated with the ideas of Amartya Sen (1979) and the application of his notion of capabilities (Sen, 1986) for resource allocation in health care. Culyer and others (Culyer, 1991; Culyer & Maynard, 1997; Mooney, 1998) who have promoted these alternative “extra-welfarist” (EW) ideas and approaches in application to health and a move away from welfarist basis of economic evaluation. Proponents of WE (Birch & Donaldson, 2003; Williams, 2003) show that the alleged limitations of the welfarist approach are essentially limitations in its application and not in the capacity of the approach to accommodate the concerns of EW. It is further stated that the arguments used to justify the application of EW framework are essentially welfarist (Birch & Donaldson, 2003) and thus there is no justification for such an approach.

Culyer (1991) considers the assumptions of WE as restrictive in analysing social welfare because under such assumptions (a) social welfare is independent of non-utility aspects of alternative allocations of resources and (b) individual utilities are independent of non-goods characteristics on individuals (Birch & Donaldson, 2003). He argues that health, not utility, is the most relevant outcome in health sector analysis. Thus extra-welfarist approach states that health care affects both utility and non utility characteristics such as whether people are happy, out of pain, free to choose etc. Proponents of EW also believe that resource allocation in the health sector should be directed according to the need for health care, and not merely by individual demand. For EW, the priority setting criterion is to maximise health. It implies that health care resources should be directed towards the program where the health gains are at its maximum.

According to Birch and Donaldson (2003) extra welfarist approach does not consider the opportunity cost of using resources in health sector only. For instance, if more resources are allocated in health sector then it needs to forgo some resources in other sectors. This may reduce the individual utility and thus social welfare. They also criticise the choices of health as an outcome measure, because extra welfarist does not take account of the value of goods in terms of happiness or utility gain from the same unit of health. For example, there are two treatments available to cure a disease – treatment A and treatment B. Assuming both treatments provide same level of output but treatment A incurs lower cost than treatment B. But individuals get more utilities from treatment A than

treatment B. According to the extra welfarist concept, individual will be provided treatment A. So it ensures technical efficiency but will not maximise individual utility. Therefore a policy that maximises health does not necessarily maximise utility. Thus extra welfarist fails to ensure allocative efficiency.

Culyer and Evans (1996) dismissed the claim of the welfarist that maximising individual utility is an important criteria for measuring social welfare. Further, Rice (1998) in Birch & Donaldson (2003) in his critique of WE approach argued that individuals need to be protected from their own foolishness and hence cannot be left to make their own choices. However, he acknowledges that individual utility may be greater where the individual's bundle of commodities are decided by the individual's own choices rather than imposing the same bundle by some one else.

Some extra welfarist (Culyer, 1991; Mooney, 1998) suggests that individual may not manage to desire adequately. Therefore, they suggest that communities would be asked what they want. But this approach involves risks to the well being of population sub groups within communities where communities are thought to be wicked. In contrast it is argued by Mooney that the probability of a community being wicked would seem to be less in a communitarian community. However, the question how does one decide whether a community is communitarian is still unanswered (Birch & Donaldson, 2003; Richardson & McKie, 2004; Sen, 2002; Williams, 2003).

In the above section we have basically discussed the arguments between welfarist and extra-welfarist on individuals' utility as the criteria for measuring social welfare. There are other arguments such as the methods of measurement (willingness to pay and QALY) and their aggregation. For further discussions reference is made Birch and Donaldson (2003).

### **3.6 Conclusion**

The argument between welfarist and extra-welfarist continues on the basis of being technical or allocative efficient. Most economists believe that economic evaluation has its foundations in Paretian welfare economics, and that it offers a justification for measurement of costs and benefits (Birch & Donaldson, 2003; McPake et al., 2002; Williams, 2003). The proponents of EW have drawn on Sen's concerns with the WE (on inability to desire adequately), to justify the EW perspective. They have rejected individuals' preferences by supplementing the preference of others (decision makers or the community) (Birch & Donaldson, 2003). However, in contrast, Sen's approach was on the opportunity set of individuals (i.e., functioning and capabilities) and that individuals' preferences remained paramount and the challenge was to address the inequalities in the opportunity sets (Sen, 1986, 2002). Due to the sound theoretical foundations of welfare economics, this study will base its justifications on the welfarist approach.

# CHAPTER FOUR

## ECONOMIC EVALUATION OF HEALTH CARE PROGRAMS

### 4.1 Introduction

Economic analyses in any business, organisation or household are conducted to determine appropriate allocation of funds for the basic reason that resources are scarce and that choices need to be made. It makes comparative analysis of costs versus consequences of programs/projects of interest. In the field of health care, it provides a guide for service providers to select cost-effective care procedures: improving technical efficiency and, for policy makers at national levels, to determine health care priorities, improving allocative efficiency (Drummond et al., 2003; Johannesson, 1996). Basically, the purpose of an economic evaluation is to assess whether one situation is preferable to another so that a decision-maker can make the best possible use of the available resources.<sup>22</sup>

The aim of this chapter is to explain how the theory and practice of CBA apply in the context of making health care expenditure decisions. Discussions then follow on the basic economic evaluation tools (CEA, CUA and CBA) and clarify ways in which CBA differs from these. CBA will be demonstrated to be the primary

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<sup>22</sup> For further readings, reference is made to (Drummond & McGuire 2001; Drummond et al., 2003; Grossman, 1972a; Torrance, 1986).

evaluation technique, so the basic concept behind this approach will be outlined in detail.

## **4.2 Background**

An economic evaluation includes cost benefit analysis and other related tools such as cost utility analysis (CUA), cost effectiveness analysis (CEA) and cost minimisation analysis (CMA). Interest in the economic evaluation of health care programs started in the early 1960s. Weisbrod (1961) first conducted the pioneering economic evaluation of public health programs such as vaccination of children against measles. He used the theory of human capital to measure health benefits. The limitations of human capital approach (HCA) were realized by Schelling in 1968. He argued that the theoretical foundations of the HCA were not consistent to willingness to pay as required for an application of the principles of Kaldor and Hicks (refer to chapter 3). The weakness of the HCA had led to the development of methods to measure willingness to pay for improved health and the development of CEA. Due to the challenges of CEA to have a single outcome measure and not including the element of risk that incorporated the quality as well as length of life, CUA was developed and included outcome measures such as quality adjusted life years (QALYs) (Drummond et al. 2003; Johannesson, 1996; Johannesson & Jönsson, 1991; Jönsson, 1976; Weisbrod, 1961).

The use of a CBA in sectors such as transportation, environment and housing etc. is widespread. However, CBA has not been extensively used in the health sector basically due to the complexities of measuring health outcomes in dollar values, a feature of CBA. In the health literature there are studies claiming to be a CBA but does not meet the contemporary definition of CBA. Zarnke *et al.* (1997) in a literature review of 95 cases found that 53% of the studies were cost comparisons with no attempt to measure benefits in dollars. Among the 32% considered *bona fide* CBAs, the HCA was used (70%) to value health outcomes and 13% used *ad hoc* contingent valuation methods. This study added to the keyword Medline search discussed earlier that there was no literature found that specifically discussed CBA of clinical gait. Recent texts giving detailed exposition of the theory and practice of CBA in health care include Drummond *et al.* (2003), Johansson (1995) and (Johannesson, 1996).

### **4.3 The demand for health care**

As discussed in chapter 3, the fundamental building block of consumer demand theory is based on the concept that it is the “good” that increases a person’s utility. Grossman (1972a) has prominently explored the idea of health as an economic good and showed how a rational economic person would have a demand curve for medical services that is “derived” from the underlying demand for health. He further explored the idea of a stock of health and the derived demand for medical care.

Adding on to Grossman's theorem, health can be considered as a durable good such as automobile or home. Every individual would have a different "stock" of "health". A normal healthy baby has a high stock of health as compared to an infant born with lung or heart disease and any action taken during the course of life has an impact on the health stock.

If we take C as a bundle of other goods and the stock of health (unobservable) as H, we can say that a person's utility function is of the form:

$$\text{Utility} = U(C, H) \quad (4.1)$$

As more good is considered better, so is more health creates more utility. It is also plausible that the pleasure of other goods and services might increase with health.

Generally, it can be said that people's demand for medical care flows from their underlying demand for health. Therefore, if there are exogenous changes to the initial health stock the likely result will be a change in the demand for health care. If we take for example a person's health stock at the beginning of a year as  $H_0$  and if there is no sickness or injury, then his/her health stock may degrade slightly due to aging. If there is a serious illness or injury, the health stock falls

say by  $\ell$  (for loss). Any medical care ( $m$ ) bought will offset that by  $g(m)$ . So the stock of health left at the end of a period will be:

$$H = H_0 - \ell + g(m) \quad (4.2)$$

Generally, the bigger the loss “ $\ell$ ”, the more a person will try to restore – buying more medical care. Thus the medical care demand will vary directly with illness if medical care has ability to heal the patient (Folland et al., 2003; Grossman, 1972a, 1972b).

#### ***4.3.1 Time spent producing health***

Prior to Grossman, studies of the demand for medical care were typically set in the framework of consumer demand for a final product and were thought to depend upon prices, income and taste (Folland et al., 2003). Grossman (1972a; 1972b) used the theory of human capital to explain the demand for health and health care. According to the human capital theory individuals invest in themselves through education, training and health to increase their earnings and utility.

An investment to capital stock such as health is called an investment ( $I$ ). It is produced by time spent improving health ( $T_H$ ) and market health inputs such as

drugs and medical services ( $M$ ). Likewise, home goods ( $B$ ) are produced with time ( $T_B$ ) and market purchased goods ( $X$ ). Thus we may write:

$$I = I(M, T_H; E) \quad (4.3)$$

$$B = B(X, T_B; E) \quad (4.4)$$

These relationships suggest that increasing amounts of  $M$  and  $T_H$  increases  $I$  and  $X$  and  $T_B$  increases  $B$ .  $E$  is a stochastic error term and is included to indicate that productivity is included to produce  $I$  and  $B$  and which may vary from person to person. Grossman considers this as technical efficiency and can be achieved higher if education is higher (Folland et al., 2003). In order to produce  $M$  and  $X$  in a given year (365 days) one must earn an income and this, in turn, is a function of time devoted to work ( $T_W$ ). Also some of this time in the year could be lost due to illness, or  $T_L$ . The total time budget is thus:

$$\begin{aligned} \text{Total Time (365 days)} = T &= T_H \text{ (total time spent in improving health)} \\ &+ T_B \text{ (time spent producing home good)} + T_L \text{ (time lost due to illness)} \\ &+ T_W \text{ (time devoted to work)} \end{aligned} \quad (4.5)$$

In an economic evaluation such as the cost benefit analysis of clinical gait, the above components are measured in dollar terms. The main focus would be to measure the time lost due to illness and the costs associated with it. The costs are defined as the amount of compensation the losers would require to accept

that the project is carried out (willingness to accept, WTA). The benefits are defined as the amount of money the gainers are willing to pay to make sure that a project is carried out (willingness to pay, WTP) (Johannesson, 1996). The resource consequences are defined as the effect on the consumption of goods and services and the effect on the consumption of leisure. In the case of a cost-benefit analysis this would be the amount individuals are willing to pay for a particular treatment to achieve their optimal health status.

#### **4.4 Some basic principles of economic evaluation**

Economic evaluation of health sector interventions basically has the following two guiding principles (Drummond et al. 2003):

- accounting for costs and consequences; and
- making comparisons amongst various health programs.

A program is considered worthwhile if the value of its benefits exceeds the value of its costs. Benefits arise as a consequence of a health program on the wellbeing of individuals and the society whilst costs refer to the value of opportunities or benefits foregone as resources are consumed for a particular health program (Boardman et al., 2001).

Similar to evaluations of other sectors of transportation, environment, housing etc., economic evaluation in health care also compares two or more alternative

programs for their effectiveness in generating benefits to individuals. It is used to investigate two different sources of inefficiency in health services (Drummond et al. 2003). Firstly, it relates to the question on technical efficiency: Is a particular health program worth doing and, if it is, what is the optimal level of that program (i.e. how large should it be)? This question seeks the best health program available for a disease-specific group of patients. Secondly, inefficiency relates to the question on allocative efficiency. Given a program that is worth doing, what is the best way of providing it?<sup>23</sup>

Depending on the interest of the study, different measures of health benefits are used to compare alternative health programs. To assess technical efficiency, health benefits are expressed in terms of changes in life expectancy or the health related quality of life. Such outcome indicators are commonly used in cost minimisation analysis (CMA), cost-effectiveness analysis (CEA), or cost-utility analysis (CUA). To assess allocative efficiency, outcomes from different health programs are converted into a common denominator, such as the dollar value used in cost-benefit analysis (CBA).

As shown in figure 3 below, there are other forms of partial evaluation methods of health that are related to, but do not belong to, economic evaluation. Basically, partial evaluations do not answer the two basic guiding principles of economic evaluation as discussed above. Cells 1A, 1B and 2 do not make comparisons to

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<sup>23</sup> For further readings and graphical representation on technical and allocative efficiency in health care reference is made to Folland *et al.* (2003).

alternatives. Epidemiological studies (cell 3A) do not compare relative costs between different health programs. Burden or cost-of-disease studies (cell 3B) do not provide evidence on the effectiveness and availability of health programs to treat the disease under consideration (Drummond et al., 2003).

Although the partial evaluation approach can sometimes provide useful information for a full economic evaluation, it is limited because it ignores relative opportunity costs. As such, it does not answer efficiency questions.

**Figure 3: Distinguishing characteristics of health care evaluation**

		Are both costs (inputs) and consequences (outcomes) of the alternatives examined?		
		<b>NO</b>		<b>YES</b>
		Only consequences are examined	Only costs are examined	
Is there a comparison of two or more models?	<b>NO</b>	<b>1A Partial Evaluation</b> Outcome description	<b>1B</b> Cost description	<b>2 Partial Evaluation</b> Outcome and cost description
	<b>YES</b>	<b>3A Partial Evaluation</b> Epidemiological analysis (efficacy or effectiveness Analysis)	<b>3B</b> Burden or cost-of- disease analysis	<b>4 Full Economic Evaluation</b> Cost minimisation analysis Cost benefit analysis Cost utility analysis Cost benefit analysis

Source: Drummond *et al.*, (2003), pp. 10

The basic framework is similar for the above four full economic evaluation methods (cell 4 in figure 3). They all compare the costs and consequences of two or more competing health care programs.<sup>24</sup> The main difference is in the measurement and valuation of the consequences of the health care program that is being appraised. Table 1 below summarises the measurement of cost and consequences and the selection criteria in an economic evaluation.

Since the 1990s, CEA has grown rapidly and it is now the most common type of economic evaluation in use for health sector interventions (Brent, 2003; Jefferson, Demicheli, & Mugford, 1996). CUA is considered a more specialised version of a cost-effectiveness analysis (Jefferson et al., 1996). Cost benefit studies on the other hand have not been widely used in the evaluation of health care basically due to the difficulty of assigning dollar values to health outcomes (Drummond et al., 2003), or the unwillingness of policy-makers to do so explicitly.

Although CEA had been widely used in the economic evaluation of health care programs, greater emphasis is now being placed by some governments and other funding agencies on CBA. The basic reason is that CEA does not allow one to answer the question of whether the benefits of a program or intervention outweigh its costs (without an at-least-implicit assumption about the value of the benefits).

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<sup>24</sup> CMA makes comparisons between two or more programs for the same outcomes with the only difference between them is in their costs. In CMA the consequences are identical and as such can be ignored from further discussions.

**Table 1: Summary of measurement of costs and consequences in economic evaluation**

Type of study	Measurement/valuation of costs in both alternatives	Identification of consequences	Measurement/valuation of consequences	Selection criterion
Cost - minimisation analysis	Dollars	Identical in all relevant respects	None	Minimise program cost; rank alternative programs
Cost - effectiveness analysis	Dollars	Single effect of interest, common to both alternatives, but achieved to different degrees	Natural units (e.g. life-years gained, disability days saved, points of blood pressure, etc)	Minimise cost per unit of outcome or maximise outcome per unit of cost; rank alternative programs
Cost-utility analysis	Dollars	Single or multiple effects, not necessarily common to both alternatives	Quality adjusted life years or disability adjusted life years	Minimise cost per QALY gained or maximise QALYs per unit of cost; rank alternative programs
Cost-benefit analysis	Dollars	Single or multiple effects not necessarily common to both alternatives	Dollars	Benefits exceed costs

Source: Drummond *et al.*, (2003), pp. 2.

## **4.5 Tools in economic evaluation**

With reference to table 1 above, this section discusses the basic tool used in the economic evaluation (i.e., CEA and CUA) of health care programs and its strengths and weaknesses in relation to welfare economics and CBA.

### ***4.5.1 Cost–effectiveness analysis***

In health sector CEAs, the incremental cost of a program is compared with the incremental health outcome of a program, where health outcomes are measured in terms of a common physical or natural unit of health gains. Outcome measures commonly used in CEA are the numbers of lives saved, life years gained, life-years saved and reductions in disease incidence (Drummond et al. 2003). The results are expressed as cost per unit of effect.

The main strength of CEA is its ability to determine the least costly way to treat a given condition for different levels of health outcomes. It avoids the difficult step of monetary valuation of outcomes as in CBA. It can be also compared on alternatives, which have common effect (say life years saved on kidney transplant and heart surgery).

The requirement to measure outcomes in natural health units limits efficiency comparisons to a relatively small set of similar programs or conditions. CEA cannot be used to compare different programs that affect quality of life differently. For example, a program aimed at restoring the sight of patients is not comparable to a program for treating foot ulcers under CEA (Peacock et al., 2001). Most CEA studies consider only budgetary costs. Non-budgetary opportunity costs, such as the time taken by patient to travel to clinic between alternative cancer screening procedures, are often omitted. However, this is not a theoretical flare of CEA, but rather an example of its limited application.

More generally, though, it should be emphasised that CEA cannot be used to judge the allocative efficiency of alternative patterns of resource allocation. CBA is required when one is concerned with the latter issue.

#### ***4.5.2 Cost utility analysis***

CUA is a specialised version of a cost-effectiveness analysis (Jefferson et al., 1996). The terms CEA and CUA are used interchangeably, with the main difference between CUA and CEA is that in a CUA the consequences are expressed in quality-adjusted units. The most common CUA output measure is the quality-adjusted life year (QALY) or disability-adjusted life year (DALY).<sup>25</sup>

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<sup>25</sup> There are numerous debates as to which tool is better in answering efficiency questions. Both, in terms of technical and allocative efficiency. For a debate on this see Williams (1999; 2000);

The results in a CUA are usually expressed as cost per QALY (DALY) gained (averted). These measures capture changes in morbidity (quality of life) and mortality (quantity of life) and integrate them into a single measure of health output (Drummond et al. 2003). Thus these methods facilitate the comparison of programs that affect health outcomes in qualitatively (as well as quantitatively) different ways.

The benefit of CUA over a basic CEA is that it can be used to analyse programs that have multiple health outcomes and enables more important (i.e., utility-influencing) outcomes to be weighted more heavily. Utility based measures of health allow comparison across a diverse range of health programs that have effects on all types of health states for a range of conditions. Examples of CUA study design include the comparison of 'surgery plus radiotherapy' versus 'surgery plus radiotherapy plus chemotherapy' treatments for cancer, and the comparisons across programs for hip and heart problems, depression and diarrhoea, or prevention and palliative care (Benjamin et al., 2003).

As a consequence of considerable efforts being put into developing QALY and DALY measures, CUA is being increasingly used to make resource allocation in health care (McKie et al., 1998). Torrance (1987), in Peacock (2001) describes the relative utility level ascribed to various health states. QALYs involve weighting a life year by a utility index, expressed as a fraction between zero

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Mooney & Wiseman (2000); Anand & Hanson (1997), Murry & Acharya (1997), Murray & Lopez (2000).

(death) and one (full health) reflecting the health related quality of life.<sup>26</sup> A DALY on the other hand is expressed as a fraction between zero (full health) and one (death), and is compared by computing the years of life lost (mortality effects) plus the years of life lived with disability (morbidity effects). For a detailed discussion refer to Murray and Lopez (2000).

While CUA allows for comparisons of dissimilar health programs, it cannot be used to compare between health and non-health sector activities. This is because health outcomes are not measured in dollar values. This does not tell us if an outcome is worth achieving given the opportunity cost of the resources consumed. CUA and CEA are often referred to as the “decision maker approach” to economic evaluation, where the aim is to maximize whatever it is that the decision maker wants to maximise (Sudgen & William, 1978). Due to the fact that both CEA/CUA and CBA require monetary valuations of health outcomes, some authors (Phelps & Mushlin, 1991 in Drummond, 2003) have argued that their techniques are nearly equivalent. However, in contrast, it has been argued that the basic foundation of CBA is in the principles of welfare economics where the relevant sources of values are believed to be individual consumers (Drummond et al. 2003).

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<sup>26</sup> Utility indices can also accommodate states that are considered worse than death, which are represented by utility weights less than zero. See, e.g. Drummond et al. (2003).

### **4.5.3 Cost–benefit analysis**

CBA is based on the principle that resources dedicated to a given program could have been put to an alternative use. A sacrifice is involved and the decision rule of CBA is to pursue only those policies where the value of the benefit is at least as great as the value of the sacrifice. CBA includes all costs (benefits), irrespective of who bears (accrues) them, on the potential Pareto principle: if net benefit is positive, it is possible to compensate the losers and still leave society better off. Therefore, a program passes or fails the cost benefit test according to whether it could make society better or worse off (Drummond et al. 2003; Johannesson & Jönsson, 1991; 1982; Mishan, 1988).

CBA addresses both technical and allocative efficiency concerns in the production of health gains. It can be used to compare programs across sectors — housing, education, transport, and health, for instance. By comparing the monetary valuations of benefits and opportunity costs, in principle, CBA can be used to determine the optimal size of each sector to the point that no further wellbeing gains can be achieved from shifting resources between sectors (Drummond et al. 2001).

For an illustration we can consider a health care intervention that is a clinical gait analysis and represents it by subscript  $G$ . The intervention has benefits,  $B_G$ , and

costs  $C_G$ . It would be worth having a gait analysis if the benefits exceeded that of the costs:

$$B_G > C_G \quad (4.6)$$

Equation (4.6) shows the basic cost-benefit criterion. This determines whether a particular type of health care intervention should be undertaken, or not. In certain instances, even if the costs are greater than benefits, governments in order to meet social or political obligation often ignore the decisions based on these economic evaluation concepts. Furthermore, when budgets are constrained not all projects for which (4.6) is true may be undertaken, in reality.

The CBA approach can also be thought of dealing with the final result of health care intervention (patient satisfaction). Before arriving at the end result, there is an intermediate stage, which transforms the treatment from an input to an output that can be represented by  $G$ . In this case  $E$  is referred to as the effect of the treatment. In the gait example the effect could be pain relief from muscular injury. Benefits in such case could be calculated by placing a monetary value on the effect that is:  $B_G = P_G * E_G$ . Where  $P$  is the willingness to pay per unit of effect. Therefore, equation (4.6) becomes:

$$P_G * E_G > C_G \quad (4.7)$$

By rearranging equation (4.7) and dividing both sides by  $C_G$ , we get the requirement that benefit-cost ratio (BCR) must exceed unity:

$$\frac{P_G * E_G}{C_G} > 1 \quad (4.8)$$

When budget constraints are imposed, the viability of alternatives must be considered. In the case of this research an alternative to 3DGA (2<sup>nd</sup> generation) is the current method (1<sup>st</sup> generation) of observation and treatment. Let us represent benefits as  $B_T$  (equal to  $P_T * E_T$ ) and costs as  $C_T$ . In such situations, it is not sufficient to have a benefit-cost ratio greater than unity. The BCR must also be greater than the benefit-cost ratio of the alternative program. That is:

$$\frac{P_G * E_G}{C_G} > \frac{P_T * E_T}{C_T} \quad (4.9)$$

Equation (4.9) shows that if one spends on treatment G, there is more benefit per dollar spent on costs than with the alternative use of funds.

CBA has not been used as frequently as CEA and CUA in the health sector because of the difficulty in obtaining acceptable monetary valuations for health outcomes and, in particular, lives, since the latter have been a controversial issue in the economic evaluation literature (Drummond et al., 2003; Johannesson &

Jönsson, 1991). As a result, three valuation methods have been employed in CBA studies in order to assign a dollar value to health outcomes:

- the human capital approach;
- the revealed preference approach; and
- the stated preference of willingness-to-pay approach.

#### **4.5.3.1 *Human capital approach***

Until the early 1990s, the HCA was the most commonly used measure for evaluating health technologies (Johannesson & Jönsson, 1991). It is measured in terms of the present value of the individual's expected lifetime earnings, in the same way that productive capital is commonly valued. This means that the value of preventing someone's death or injury is equal to the gain in the present value of his or her future earnings. This approach is simple and requires relatively few data to implement.

Mishan (1988) points out that the HCA is not consistent with the principles of WE due to the following reasons: (1) it discriminates against less productive people, particularly those disadvantaged due to race and education attainment; (2) it assigns very small values to the health of poor people and those that are not in the labour force; and (3) the focus on productive value is too narrow, ignoring an

individual's value to family, friends, and the community (see also Drummond et al., 2003; Jönsson, 1976).

Koopmanschap *et al.* (1995) introduced an alternative approach to HCA called the "friction cost method" (FCM) for measuring indirect costs in economic appraisal of health care programs. The author's argued, based on a study in the Netherlands in 1988 and 1990 using the FCM and the HCA, that FCM takes into account several economic circumstances and reduces the estimated production losses substantially as compared with estimates based on the HCA.

The shortcomings of the HCA, thus, had led to the development of CEA and CUA. Although these were important steps forward, it was not free of problems and did not answer questions from a societal perspective (Johannesson, 1996; Johannesson & Jönsson, 1991). Despite the shortcomings of the HCA, some economists have argued that it still serves as a lower bound measure of benefits (Berger et al., 1987).

#### **4.5.3.2 Revealed preference approach**

The revealed preference approach was most commonly used in the labour market. It requires observing actual decisions by individuals in hazardous jobs and the wage rates that they require to accept the job (wage-risk trade-offs). While the revealed preference approach is consistent with the WE framework,

which is based on individual preferences regarding the value of increased (decreased) health risk such as injury at work, as a trade-off against increased (decreased) income, McKie *et al.* (1998) state that it is problematic to extrapolate the value of life from the context of a low risk of death. The contexts of low and high risks of death may be extremely different, and affect individuals' preferences in different ways. The authors conclude that willingness-to pay techniques based on a simple extrapolation of the value of human life are flawed and at best measure the value of life contaminated by the value of risk.

A more fundamental concern is that the wage-risk trade-offs made by individuals may not be sound due to the imperfections in the labour market and the limitations in how individuals perceive occupational risks. Viscusi (1992), in "Fatal Tradeoffs", shows the tradeoffs individuals make when they make safety and health risk decisions and the errors that can be involved in those tradeoffs.

#### **4.5.3.3 Stated preference (contingent valuation) approach**

Monetary valuations of outcomes in CBA have mostly been based on WTP techniques. This approach uses an individual's *stated preferences* rather than *revealed preferences* to determine the relative values of program outcomes and is often referred as contingent valuation (CV) approach. Johannesson (1996) refers to stated preferences as responses to hypothetical questions about willingness to pay. In CV studies, respondents are required to think about the

contingency of actual market existing from a program or health benefit and to reveal the maximum they would be willing to pay for such program or benefit (Drummond et al. 2003). CV studies for non-marketed goods such as health have been widely accepted as a measure of consumer surplus which forms the basis of a CBA.

Johannesson & Jönsson (1991) in a study on the application of CV methods using CBA in health economics and comparing it with existing methods of HCA, CEA and CUA concluded that existing methods had several weaknesses. This made CV method an appropriate method to achieve acceptable response rate in the study. The weaknesses of CV methods with respect to measuring willingness to pay using survey methods were considered no more troublesome than those associated with measuring utility or quality of life in CUA.

#### **4.6 Stages in Economic Evaluation**

A full economic evaluation consists of identifying, measuring, valuing and comparing the costs and consequences of the alternatives being considered. Simply, it is conducted in the following four stages (Drummond et al. 2003) and details of which are discussed in chapter 5:

- defining the study question and perspective;
- identifying and measuring costs and benefits;

- analysing the costs and benefits; and
- applying a decision rule.

#### ***4.6.1 Defining the study question and perspective***

An economic evaluation study has a research question to address, which identifies a specific set of health programs for comparison, including the option of “doing nothing” or the current baseline program (Boardman et al., 2001). An example of a study question would be, “Is there a variability of gait analysis in patients with cerebral palsy at different centers?” The study perspective — that is, the decision making context of the study — has implications for which costs and consequences are considered and what decision rules are used in economic evaluation. Study perspectives include the service provider (like the hospital), the patient, the government, the third party payer or the society (i.e. all the cost and consequences of a health care program to all members of a society).<sup>27</sup> However, as was emphasised earlier, a truly economic study accounts for all individuals who are affected by a resource allocation decision, not just the perspective of a subset.

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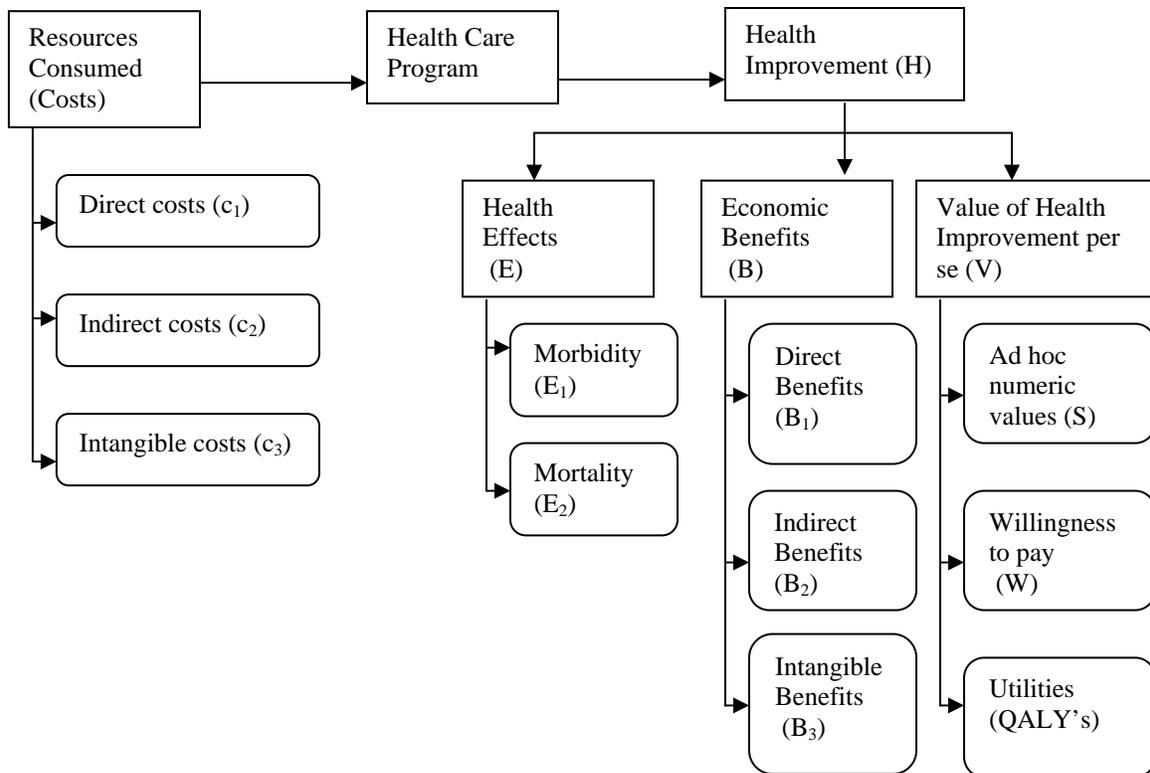
<sup>27</sup> While it may be difficult to consider all costs and consequences to every member of the society, it is important to recognise the need for capturing such information when it comes to the use of scarce resources.

#### **4.6.2 Identifying and measuring costs and benefits**

Depending on the study perspective, relevant cost items include the costs borne by governments, individuals, firms, and so on. Similarly, benefits may be identified relating to changes in the quality of life for patients and their families, and resources saved due to a particular intervention (Drummond et al. 2003). As shown in figure 4, three categories of cost are identified. Direct costs ( $c_1$ ) which relates to the cost of Physicians' time, hospitals, drugs and other health care costs; indirect costs ( $c_2$ ) which relates to the cost of lost production and the intangible costs ( $c_3$ ) which relates to the monetary value of pain, grief and suffering of the patient and family.

Health improvements can be measured in a number of different ways. The health effect (E) is a measurement of the units that are natural to the program or disease, e.g. cases prevented, life years gained etc. Direct benefits ( $B_1$ ) are the savings in health care costs because the program makes people healthier and uses fewer health care resources. Indirect benefits ( $B_2$ ) are the production gains to society because more people are well, and able to return to work. One can measure the value to the patient, family or society of the health improvement itself, regardless of any economic consequences using ad hoc numeric scales (S), willingness to pay (W) and QALYs based on utility measurement (Torrance, 1986). The willingness to pay concept will only be discussed in this paper.

**Figure 4: Components of economic appraisal**



Source: Torrance (1986), figure 1, pp. 2

#### **4.6.2.1 Willingness to pay**

The utility of an individual depends on the consumption of private (non-health) goods and the health of the individual (equation 4.1). The health of the individual is assumed to be exogenous meaning that the possibility of an individual to produce health is not included. A utility maximising individual will thus have the following function subject to his/her budget constraint  $Y-PC=0$ ., where  $P$  is price of non health good and  $Y$  income after tax (all the cost of health are assumed to

be covered by tax). The utility for an individual can therefore be rewritten as a function of income and price of non health goods (Johannesson, 1996):

$$V=V(Y,P,H) \tag{4.10}$$

This indirect utility function is used to define monetary measures of health changes. It is thus possible to define WTP and WTA for a health change by holding either the utility level before the change in health or after the change in health respectively.<sup>28</sup>

Using equations and graphical representation the WTP concept can be shown. For example a drug (Botox) is introduced which improves the health status of an individual from spasticity (HS) to full health (H\*). The WTP of botox can be defined as:

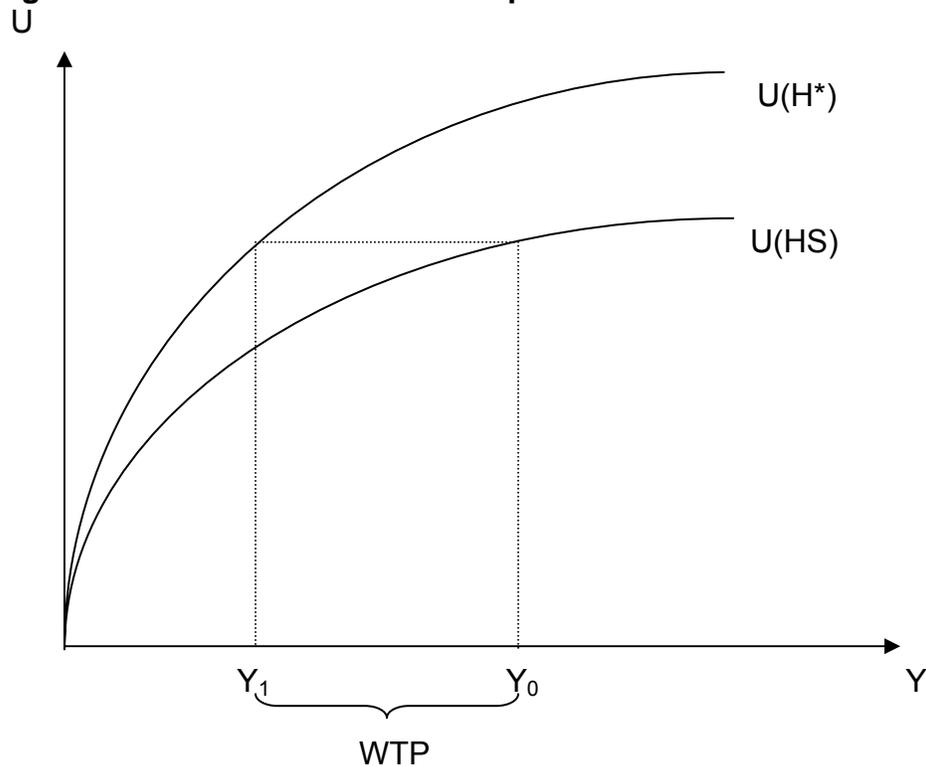
$$V(Y-WTP,P,H^*) = V(Y,P,HS) \tag{4.11}$$

The WTP is the amount of money, if paid, keeps an individual at the initial utility level (say the utility level with spasticity). Using the graph, the WTP is illustrated as follows (figure 5 below).

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<sup>28</sup> WTP and WTA measures can be defined by using equivalent variation method or compensating variation method. In this paper we will use the compensating variation definitions of WTP and WTA since it follows the market analogy where individuals are compensated for giving something up and paid to receive something.

**Figure 5 : The WTP for a health improvement**



Source: (Johannesson, 1996. Figure 1, pp. 27)

The initial health state with spasticity with an income is  $Y_0$ . To define WTP, income in the healthy state which leads to same utility as income in  $Y_0$  is determined. The income is  $Y_1$  and the WTP is the difference between  $Y_0$  and  $Y_1$ .

A similar illustration is made for the definition of the WTA for a deterioration of health. For instance, analysing the consequences of withdrawing the drug, (botox as in above example), from the patient. The equation would thus read as follows:

$$V(Y+WTP, P, HS) = V(Y, P, H^*) \quad (4.12)$$

The WTA is the difference between  $Y_1$  and  $Y_0$ . For further reference on graphical representation of WTA and marginal WTP see Johannesson, (1996).

Johansson (1995) showed that the WTP (WTA) can be converted to the change in utility by multiplying the WTP (WTA) by the marginal utility of income. This would mean that the WTP or WTA will always have the same sign as the change in utility as long as the marginal utility of income is positive.<sup>29</sup> Generally, in the literature there is wide use of WTP measure as compared to WTA and there are citations of large differences between the amounts (Johannesson, 1996) even though, in theory, WTP ought to equal WTA for a given change in entitlement.

There are also discussions on the size of the WTP for total change in health, prices and income. Often comparisons are made with two or more initial health states with one final health state. Johansson (1995) makes reference on the ranking properties of WTP. These measures could also be extended to a more realistic case with risks of different health state (including death), where individuals are paying for decreased risk of morbidity and mortality.

This section has only considered the private WTP on improving one's health. This is basically built on the assumption that the individual is only concerned with his/her own well-being. In the health field individuals may even value other

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<sup>29</sup>This will always be true for an individual who would like to have higher income that is non satiated individuals.

individuals' health, i.e. caring externalities, for e.g. (Culyer, 1991) may exist. For the purpose of this study, WTP will not be considered to measure cost and benefits of CGA. However, in instances where CGA was performed for family assurance only, the willingness to pay using the stated preference approach will be used.

### ***4.6.3 Analysis of costs and benefits***

In CBA, costs and consequences of alternative programs need to be compared directly. Since comparisons of programs are made at a particular point in time (usually the present), the timing of program costs and consequences which do not occur in the present time also needs to be taken into consideration. The current recommendation is to use a discount rate of 3% or 5% as the base case scenario (Drummond & McGuire 2001), although other rates are defensible on theoretical grounds (see, e.g. Mishan, 1988). In order to determine the extent to which the choice of discount rate impacts on the results the sensitivity analysis included a discount rate of 0%, 3% and 5% for both treatment and intervention costs will be applied. A further discussion on these issues is made in the next chapter.

#### **4.6.4 Decision rules**

A core decision rule typically uses outcome–cost ratios to rank the health programs under consideration (Drummond and McGuire, 2001). Refer to table 1 on the selection criteria for projects evaluated under the four methods of economic evaluation. Other relevant decision criteria include distribution of health benefits and the practicality of health programs. For instance, consideration may be given to whether older patients should be favoured over the young, or whether existing infrastructure is capable of supporting any change to existing services.

We can make decisions whether to accept or reject a project by looking at the marginal cost and marginal benefits of a program. Figure 6 shows the relationship between social benefits (B), social costs (C) and social gain (G). Welfare is maximised where the difference (B) and (C) is greatest ( $X_0$ ).<sup>30</sup>

Figure 7 shows the relationship between marginal benefit (B) and marginal cost (C) at different resource inputs. It is the marginal benefit and costs which determines the amount of resources to be used in a program and not the total cost and benefits. If resources are increased above  $X_0$  more costs are added than benefits. If the resource input is increased to the point where total benefits equal total cost (figure 6), then there is a social loss by the shaded area as

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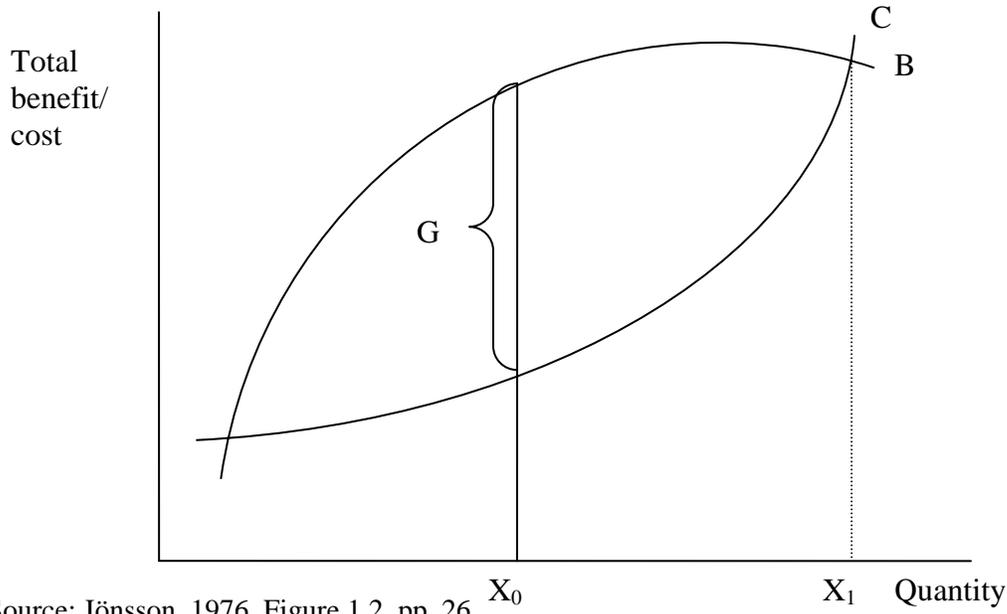
<sup>30</sup> It is assumed that social benefit increases when the resource input and the production of good increases. It is also assumed that benefits will increase at a decreasing rate and costs will rise at an increasing rate as production grows.

shown in figure 7. Therefore, in order to answer resource allocation questions it is important to look at the marginal cost and benefits and not its total costs.

## **4.7 Conclusion**

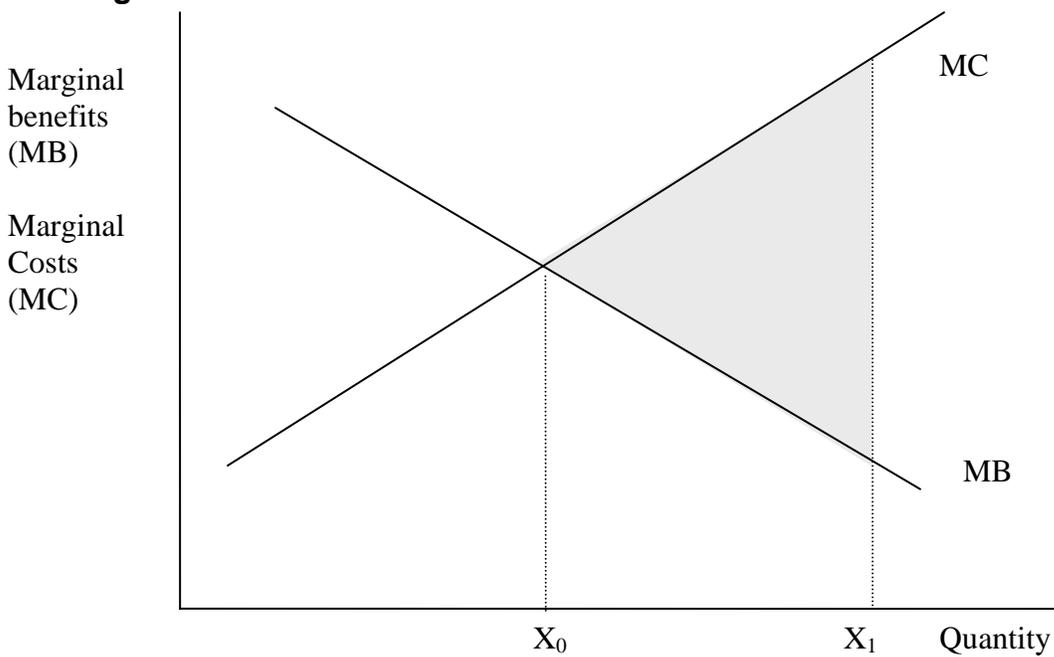
This chapter relates to chapter 3 on the theoretical underpinnings of CBA and welfare economics. While it is seen that there may be difficulties in measuring health benefits in relation to welfare economics criteria, these difficulties are no different to those of other economic evaluations techniques. A CBA thus is still considered to be the appropriate tool to measure social welfare.

**Figure 6: Relationship between production volume and total benefit and total costs**



Source: Jönsson, 1976. Figure 1.2, pp. 26

**Figure 7: Relationship between production volume and marginal benefit and marginal costs**



Source: Source: Jönsson, 1976. Figure 1.2, pp. 26

# CHAPTER FIVE

## DATA AND METHODOLOGY

### 5.1 Introduction

In chapter 4, the basic components of an economic evaluation were discussed. Although there are various tools and components to measuring the benefits and costs in a CBA, this research will specifically focus on the costs and benefits of the changes in treatment options and associated costs to parents and families. This approach is motivated by the relatively short time available for this study. However, if a partial CBA of this kind produces a positive NPV, there may be little need for a more intensive approach. In this study most of the costs are captured, while only a subset of benefits is measured. Thus a positive NPV would likely be larger with greater benefit measurement.

In order to conduct this study, various requirements and procedures had to be met. Firstly, an ethical clearance was required from Queensland Health and the University of Queensland. These clearances were acquired prior to the commencement of study. Secondly, the source for data was identified; patients and their parents were contacted for their consent to participate in the study based on the inclusion and exclusion criteria. Thirdly, the cost benefit framework was set up and due to time limitations the author had specified the scenarios to

include in the survey. The fourth stage included the development of the scenarios into questionnaires and the collection of data. Finally, the fifth phase included modelling the data and developing and simulating the model.

## **5.2 Ethical requirements**

Prior to conducting this study ethical clearance was sought from the Royal Children's Hospital & Health Services District Ethics Committee of the Queensland Health. Approval to conduct research was granted on 16<sup>th</sup> May 2005. Clearance was also sought from the University of Queensland's School of Economics Ethics Committee and was granted approval on 20<sup>th</sup> May 2005. An executive approval was also sought and obtained from the district manager of the Royal Children's Hospital and Health Services District.

The parents/guardians of all children who were assessed by the QCGL were given an information sheet that contained all relevant details of the research. These included explaining details of the procedures proposed, including the anticipated length of time it would take, and an indication of any discomfort or possible risks that could be expected. It was explained to the parents that the only test to be undertaken was 3D Gait Analysis. Although the purpose of this research is to improve the quality and capacity of future gait analysis, it was explained that this was a research project and not a treatment program, and thus the child's involvement may not be of any benefit to the child or the parent.

Finally the confidentiality of the report was ensured with no effect on the future treatment of the child should they withdraw during the course of the research. An information sheet was also prepared for the child that contained same information in simpler terms. A consent form was then signed by both the parent/guardian and child.

### **5.3 Sources of Data**

Three sources of data were combined for information in the analysis.

#### **5.3.1 Children**

Children ages 6-11 (inclusive) who have been assessed at the QCGL during the period 1 October, 2004 to 31 May, 2005 were included in this study. The usual inclusion criteria for each child who underwent a 3D Gait analysis were applied for this study. These were the ability to understand instructions at the gait lab, cooperate for two hours, have a minimum height of 100cm, functional and consistent gait pattern, and required to walk for a minimum distance of 100 metres for gait and 500 metres for energy assessment. Children who did not meet the above criteria and children whose parents did not consent to their involvement in the study were excluded from the research. Based on the inclusion and exclusion criteria we had 15 willing subjects.

Each child was assessed at the same time of day by the same assessors to minimise any order effects at the follow up assessment. Gait data were collected and processed using the Motion Analysis Corporation 3D Gait Analysis (3DGA) equipment. Markers were placed on the body and viewed by eight visible infra-red cameras, to provide a 3 dimensional model of the child, in real time. There were three force plates in the floor which measured forces exerted by the body and which allowed clinicians to determine the direction and size of the forces on each joint during walking (gait). The data were then analysed by the multi-disciplinary team at the QCGL.

A baseline questionnaire was administered to the parents/guardians of patients. This questionnaire included items on patient demographics, disability history, initial and current symptoms, any treatment received to date and compensation status. Information was requested on employment status and weekly income along with (compensated and/or uncompensated) time lost from paid employment and unpaid duties (e.g. home duties). In order to minimise the non-response bias associated with the survey, parents and children were assured that their responses would not affect the management of the child. They were assured that only the outcome of the gait analysis would be reviewed in the light of the initial recommendation of the specialist. Questions assessing the time spent and costs incurred by them immediately after their initial consultation and after the first return visit to hospital were also recorded.

The time taken for each patient's gait analysis was extracted from the records of the gait laboratory. The records clearly showed the number of visits made, the duration of analysis, and time spent by each specialist on a particular case. General hospital records were used for the time taken to conduct a particular surgical procedure. Physician consultation hours were extracted from the patient's hospital records. These data ensured that deficiencies in data collection were minimised.

Unit prices were used to estimate the total and marginal costs and benefits associated with the analysis and the subsequent (actual and hypothetical) treatment pathways and their consequences. Market prices were used for all of the identified resource items, i.e. it was assumed that market prices are indicative of (short-run) opportunity costs.

### **5.3.2 Physicians**

The medical staffs involved in the study were subsequently interviewed in order to obtain quantitative data on the costs and benefits of 3DGA. Six physicians who currently make referrals to the QCGL were approached for inclusion and panel members at the QCGL assisted in encouraging their colleagues to participate.

More specifically, clinical advice was sought from treating medical consultants, prior to the conduct of gait analysis. Details were sought on the diagnosis, differential diagnoses (where applicable) and proposed intervention(s) and treatment pathways that were recommended for subjects in the absence of further diagnostic information becoming available. Then, in the light of the results of 3DGA, the same clinical experts were asked to provide another assessment and recommend an appropriate clinical treatment pathway. These pre- and post-gait-analysis assessments and clinical decisions were compared and the costs and consequences of the gait analyses were estimated with reference to direct clinical costs. It is to be noted that, in this research, there was no direct contact with patients in the study and no changes were sought to clinical procedures.

In order to help ensure that the participating physicians gave true responses, we presented the questionnaire after the examinations were conducted. Since the examination reports of individual patients are discussed with a group of physicians, the chance of reporting bias was reduced. To minimise non-response, the questionnaire was kept well focused and as brief as possible.

Standard economic techniques were then applied, informed by expert medical opinion, to estimate the costs and consequences of treatment pathways with and without the use of clinical gait analysis. The primary costs and consequences of interest in this preliminary study were those direct costs associated with the different clinical treatment pathways that arose in the absence (presence) of gait

analysis results in the diagnostic process. Relevant costs include the costs (and costs averted) of the physician, nurses, technicians, costs of using the gait lab and the hospital facilities. Fixed and variable costs were measured.

The cost of a GP visit varies depending on the complexity of the problem and the duration of the consultation. It will be assumed that the initial GP visit requires slightly more time than the follow-up visits. Based on the November 2004 Medicare Benefits Schedule (MBS) the initial consultation costs \$35.50 (for long consultation. That is, greater than 25 minutes but no more than 45 minutes) and the remainder \$14.10 (for short consultation. That is greater than 5 minutes but less than 25 minutes). (Australian Government Department of Health and Ageing, 2004).

### ***5.3.3 Gait Laboratory***

The cost data on the gait analysis was obtained from the QCGL. Based on the current estimates, the cost of a gait analysis is estimated to be \$1,680 per patient. These costs are based on labour and maintenance costs of motion analysis equipment (\$261,780 per year). A further calculation to this was made and which included rental costs of 220 m<sup>2</sup> area, cleaning, electricity and air conditioning. Cleaning costs \$36 per m<sup>2</sup> and electricity costs \$5,280 per year. Since specific data could not be obtained for air conditioning we have included this as a package with rental costs. Data was obtained from real estate agents on

market rates per square meter for commercial property (hospitals) and which ranged between \$250 and \$350 per annum. \$300 was taken as the base case for the analysis.

#### **5.4 The cost benefit framework**

While conducting this study, the Drummond checklist for assessing economic evaluation was used as the basic criteria set for the cost-benefit analysis (Drummond et al., 2003, pp. 28-29). The key requirements are as follows:

##### *Step 1: Question and perspective*

The purpose of this study was to conduct an economic evaluation of alternative means of treating gait. More specifically, the answer to the following was sought: “which method of treating cerebral palsy (clinical gait analysis or current method of observation) maximises the difference between social benefits and social costs?” The technique of cost-benefit analysis was employed to answer this question.

The study considers an alternative which is clinical gait analysis (2<sup>nd</sup> generation) as compared to the current method (1<sup>st</sup> generation) of gait analysis. The viewpoint for this study is societal and it takes into account the costs of clinical gait analysis, health care costs and expenditure by the government and

patients out of pocket expenses. A cost benefit analysis takes into account all the costs and consequences from a societal viewpoint no matter whom they accrue. For the purpose of this study such a perspective is not feasible as time constraints limited the ability to extrapolate such data. Thus, although this study is concerned with social costs and benefits, the CBA is partial in its scope.

### *Step 2: Description of alternatives*

A CBA is designed to compare the costs and consequences of two or more alternatives. Often, new programs are compared with a do-nothing alternative. For instance, conducting a clinical gait analysis as compared to no analysis for gait related disorder patients. However, with gait related disorders there are basically two approaches. One consists of the 1<sup>st</sup> generation method of observation and basic x-rays and the other using 3D gait laboratories (2<sup>nd</sup> generation). In this study 2<sup>nd</sup> generation method is compared with the 1<sup>st</sup> generation method.

### *Step 3: Establishing the effectiveness of the program*

The effectiveness of clinical gait analysis is still under debate. As was discussed in chapter 2, there is a considerable body of literature on the usefulness of gait analysis and its ability to change treatment options. However, the actual benefits from these changes to treatment options have not been well documented. Its

increasing use by most physicians may, however, provide some indication of its perceived effectiveness.

*Step 4: Identification of costs and consequences*

In this analysis the direct health care costs associated with the intervention (1<sup>st</sup> and 2<sup>nd</sup> generation of gait analysis) and some indirect costs are included. On subjects' entry into the study, baseline data on the number of visits made, the analyses conducted, consultations with physicians (in hours, by clinician type), information on initial decision and decision taken after analysis were ascertained. Details on the type of medical intervention for both options were acquired and appropriate costs were assigned. An estimate of the cost of both procedures was ascertained using hospital cost data for each intervention type.

The main categories of costs were identified. These included in-hospital and some out-of-hospital health sector costs and resources used by the patient and their families. In this study, a measure of outcomes was confined to measures of improvements in clinical treatment and their related costs and benefits.<sup>31</sup> The duration of this study imposed a constraint on our ability to collect other measures of meaningful outcomes such as actual functional improvement. In

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31 In a detailed economic evaluation costs common to both programs needs to be included due to the reason that these costs would be used later to contemplate broader comparison. As such all the costs of the program have to be included.

subsequent work, the collection of such outcome data would enhance the economic evaluation.

Costs within the health sector (program costs) include the costs of physician time, nurses, technicians and the variable costs of using the gait lab and the hospital facilities. Specialist referrals (e.g., physiotherapy), tests (pathology), and investigations ordered (e.g., X-rays, MRI scans, and CT scans) were all included as costs. Patient and family costs included all the necessary care facilities at home, the time spent looking after the patient by family members, and time spent travelling to and from hospital and gait lab. Resources used from other sectors were not measured for this preliminary study. With cases of CP, there is very little chance of death with the relevant surgical interventions. For simplicity, we have assumed zero related mortality risks. Morbidity costs were also not included given that measuring health changes in the time frame available was not feasible. Furthermore, measuring improvements in health status would require patients to be monitored over a longer time period and this is outside the scope of this study. All costs are expressed in Australian dollars and discounted at a continuous annual rate of 3%.

The indirect health costs such as those attributed to pain, suffering, anxiety, lost production due to sickness and premature death were not measured for this study. Other costs that are not included are the costs after the treatment has taken effect. These would include side effects, nursing costs, hospitalisation,

rehabilitation costs, allied health service costs and the cost of additional medical aids etc.

In addition to the preceding sources of data, the study also employed administrative data on the costs incurred by Queensland Health to operate the QCGL. Such costs included the costs of consumables and labour.

*Step 5: Measuring costs and consequences*

It is appropriate, once the cost categories have been identified, that the individual items are then measured (quantities) and valued (prices, opportunity costs). The records from the gait laboratory showed the number of visits made, the duration of analysis, and time spent by each specialist on a particular case. Physician consultation hours were extracted from the patient's hospital records.

An important cost component is that of health care inputs. The estimation of these health care inputs was conducted in two steps. The first step was to estimate the quantity of inputs used and the second step was to estimate the unit cost of each input used. Unit costs were multiplied by the quantities of inputs used to produce the cost of the input. An example of a health input cost is the number of hours of physician time (quantity) and the cost of physician time (dollars per hour). These costs however, in practice, could be further classified as time of the physician, time of nurse and administrative costs, with the appropriate

unit costs. The cost of the physician and all associated costs that occurred at the surgery including referrals for initial recommendation were recorded.

For each comparison group and type of surgery, the following parameters were computed: the incidence of diagnosis and treatment recommendation before gait laboratory data review, incidence of no change in diagnosis and treatment recommendation after gait laboratory data review, the incidence of changes in diagnosis and treatment recommendation after gait laboratory data review, incidence of change for more or less surgery, the percentage of change relative to incidence of recommendation, the percentage more surgery in relation to number of changes, and the percentage less surgery in relation to number of changes. AR-DRG 4.2 (2002-03) hospital cost data for each surgical procedure were used to evaluate the impact on the overall cost associated with different sets of surgical recommendations.<sup>32</sup>

The cost data on the gait analysis was obtained from the QCGL with added information on rent, cleaning, electricity and air conditioning. The initial cost data (cost per patient) provided information only on human capital and the motion analysis equipment.

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<sup>32</sup> While general hospital records could be used for time taken to conduct a particular surgical procedure and its costs we used Australia's Public Sector Round 7 (2002-03) hospital cost data (AR-DRG 4.2).

The impact of a treatment also leads to changes in the behaviour of an individual which will also eventually have resource consequences. For instance, an introduction of a treatment may lead to reduced time and use of resources needed for health production. However, given time constraints, it was not possible to collect data on behavioural changes since individuals were required to be followed up after the treatment. Also, in certain instances, difficulties would arise while allocating consumption to health input or consumption of non-health goods.

Data on the quantities of these inputs were estimated from the analysis of patient records and a questionnaire to physician (physician visits, nurse visits, lab tests and drugs used) and via a questionnaire to patients/parents (number of trips, working time for relatives and parents). With respect to transportation costs, we accounted for the use of different modes of transportation including public and private vehicle use and parking costs (where relevant).

When calculating program costs in health care, an important issue to consider is the problem of joint costs. These may arise when a patient is treated for more than one health problem at the same time and the treatment cost for different diseases cannot be separated. Some arbitrary assumptions could be made on allocating costs by half to each of the two diseases. In the case of this analysis we have assumed that there are no joint costs at the hospital. It is assumed that the treatment program utilises the facilities when they are not otherwise in use

(excess capacity) and the opportunity cost is zero. This assumption is considered to be reasonable as we are considering 3DGA of a particular disorder only and are considering the treatment of that disorder.

#### *Step 6: Valuing costs and consequences*

In determining the value of health inputs, market prices were used for all of the identified resource items. The equipment costs both at the hospital and gait lab employed current market prices although, in theory, these prices could deviate from true opportunity costs if markets (e.g. medical labour markets) fail. Non-market resources such as volunteer time and patient/family leisure time are often measured using the unskilled wage rate and market wage rate respectively. However, the market value of leisure time is subject to controversy and, in this primary analysis, it was decided to assign a zero value to lost leisure time. The impact of this assumption will be dealt with in the sensitivity analysis.

#### *Step 7: Allowing for uncertainty*

A sensitivity analysis is an important component of an economic evaluation. Its purpose is to assess the effects of uncertainty about the model parameters on the outcomes modelled. This determines the robustness of the results. A sensitivity analysis involves varying the key assumptions and re-estimating the costs and benefits. In this study the discount rate of costs are varied (see table 2 below).

**Table 2: Range of values included in the sensitivity analysis**

Variables	Base Case	Sensitivity analysis range
<b>Cost</b>		
Gait lab rent per m <sup>2</sup>	\$3,00	\$2,50-\$3,50
Post gait cost	\$1,930	Increase by 5%-20%
Discount rate	3%	0%-15%

The current recommendation is to use a discount rate of 3% or 5% as the base case scenario (Drummond, O'Brien, Stoddart, & Torrance, 1997). While it was discussed earlier in chapter 3 on the debate of using various discount rates (e.g. Mishan, 1975), for consistency with modern practice in health economics the main analysis employs the three percent rate of discount. In order to determine the extent to which the choice of discount rate impacts on the results the sensitivity analysis included a discount rate of 0%, 3%, 5% and 15% for both treatment and intervention costs.

*Step 8: Results, discussion and conclusion*

The results, discussion and conclusion are discussed in chapters six and seven. A discussion on the feasibility of adopting the clinical gait analysis prior to any surgical intervention is also included in chapter six.

## **5.5 Modelling**

After collating data and assigning specific costs to the treatment chosen by the physicians and tabulating patient data, the data were entered into the Microsoft Excel program. The costs and benefits of clinical gait analysis were determined using the Microsoft Excel program. The software program, @RISK<sup>®</sup> version 4.5 Professional was used for simulation and sensitivity analyses (Palisade Corporation, 2002). Modelling is frequently done in economic evaluations to explore the effect of varying key parameters used in the model. In order to conduct risk analysis all the possible values of risky variables were identified and their possible values were determined.

## **5.6 Bootstrapping**

Sensitivity analysis was conducted to examine the robustness of the estimated result over a range of alternative values for the uncertain parameters. This method is widely recommended in the economic evaluation of health care programs (included as one of the ten checklists by Drummond et al., 2003). Kuntz & Weinstein (2001) have identified four main sources of uncertainty: methodological; sampling variation or parameter uncertainty; extrapolation or modelling uncertainty; and, generalisability/transferability.

There are, however, limitations with sensitivity analysis such as: biasness in selection of variables by the analyst; the interpretation of the results is subjective and is not subject to specific standards or guidelines on the acceptable level of variation of assumption; and the variation of uncertain parameters one at a time carries the risk that interactions between parameters may not be captured. Due to the limitations of traditional sensitivity analysis the development of what is called probabilistic sensitivity analysis by Monte Carlo simulation methods has been developed (Drummond et al. 2003).

For every marginal cost and benefits calculated from the raw data 2,000 iterations was performed using @Risk<sup>®</sup>. For each of the iterations the costs and benefits were recalculated using different randomly selected sets of values from the probability distributions in the model. Effectively all possible combination of input values was tested to simulate all possible outcomes.

## **5.7 Conclusion**

The focus of this chapter outlines the methods used to generate the data used in the study. The method used was via a questionnaire and extraction of data from patient medical records. Although there are various costs and consequences associated with a health care intervention, justifications were made if certain measurements were excluded from the analysis.

The sampling process resulted in a good response rate: the response rate was approximately 70%, and this is considered to be sufficient in most of the economic and sampling literature. Although the sample itself is quite small, the use of bootstrapping methods to perform Monte Carlo simulation overcomes this problem to some extent. The results of the analysis are presented in chapter six.

# CHAPTER SIX

## RESULTS AND DISCUSSIONS

### 6.1 Introduction

In the previous chapter the description of information requirements for an economic evaluation identified two basic cost components: (i) the costs associated with the treatment and (ii) the costs incurred by the patient.

Since this study specifically focused on the costs and benefits of the changes in treatment options, the results may not be as conclusive as those of a full cost benefit analysis might have produced. However, due to well-specified method of data collection, a 67% response rate and unbiased reports, we are still confident that these results are novel and well informed for future work on the costs and benefits of clinical gait analysis.

### 6.2 Response rate

*Physicians*

Of the ten respondents, six either had their treatment options changed or deferred, three had no changes but wanted confirmation and one had CGA to assure family of the initial diagnosis by the physician.

The response rates of specific questions are shown in table 3. Altogether ten (out of 15) patient responses were received from three (out of six) physicians. The response rate (67 percent) of patient and 50 percent physician is considered satisfactory with respect to the short timeframe for the survey. However, there are concerns with the actual non-response to some important questions.

**Table 3: Physician response rate and usable responses**

Question	Response rate % of population	Item non-response % of response rate	Usable responses % of population
Patient information	67	15	65
Referrals, tests, investigations ordered/undertaken	67	0	67
The Problems and the management (pre-gait analysis)	45	40	40
New problems and the management (post-gait analysis)	53	20	47
General information	67	50	33

The patient information section required information on the reasons for referrals to specialists and the date of first visit and date referred to gait lab. The response rate for this section was good, except for the date of visit question. This is likely

to be due to the reason that many of these patients may have been ill for a long period of time and practitioners may have been unwilling to search their file notes to provide this level of detail. This question was also not being captured in the patient questionnaire. Such questions, however, could be important to gauge the importance of a particular disorder and the use of gait laboratory. A longer interval would suggest the continuous monitoring by the physician to recommend an appropriate treatment. The cost incurred in this interval could be an essential element of cost averted by the gait lab. However, such conclusions are not feasible at this stage.

With regard to referrals to other specialists, pathology, x-ray and other tests conducted, none of the specialists considered referrals to other specialists. The most common tests conducted were simple x-rays. The analysis by the physician prior to gait analysis and after gait analysis was completed by all physicians for all patients. However, there were difficulties in obtaining actual treatment pathways as they were not detailed enough (often too vague) to determine the precise treatment pathways. Physicians were contacted again to specify the actual treatment pathway. The general information question was not useful in the analysis as most tests (e.g. MRI, pathology etc.) were not used.

### *Patients*

The patient response rate was quite low in the survey (55%). Patient information is considered important in measuring costs incurred prior to and after CGA. However, some missing data was extracted or imputed from patient medical records and from physician's notes. In instances where the patient or their proxies (e.g. parents) required gait analysis for assurance despite the physician's recommendation, their willingness to pay was ascertained. Parents were asked questions as to how much they were willing to pay for a given treatment. These values were changed until they were indifferent and their WTP was determined. The average cost, which includes physician, travel and investigation costs, of diagnosis prior to gait analysis was approximately \$304.

### **6.3 Cost of 3DGA**

The average cost for a 3DGA is estimated to be approximately \$1,280 per patient per case (excluding fixed costs). The average cost of gait analysis increases to \$2,125 when all fixed costs are taken into consideration. The average labour cost for a 3DGA is \$1,006. This cost, which includes the analysis of *temporospatial*, *kinematics*, *kinetics* and *electromyography*, is an estimate for one condition only. If analysis is required for more than one condition, then the above rate is multiplied by the number of conditions analysed. Table 4 below shows the change in average cost per patient as the number of patients analysed per year increases.

**Table 4: Cost of Gait analysis per patient<sup>33</sup>**

Number of patients per year	Fixed costs <sup>34</sup>	Non labour variable costs <sup>35</sup>	Labour <sup>36</sup>	Total
130	\$1,167	\$368	\$1,006	\$2,541
144	\$1,057	\$335	\$1,006	\$2,399
158	\$957	\$305	\$1,006	\$2,270
175	\$867	\$278	\$1,006	\$2,152
193	\$785	\$254	\$1,006	\$2,046
235	\$711	\$232	\$1,006	\$1,950
193	\$644	\$212	\$1,006	\$1,863
260	\$584	\$194	\$1,006	\$1,784
Average	\$847	\$273	\$1,006	\$2,125

Currently, the gait laboratory analyses 130 patients (2.5 per week) per year. However, with the current technology and yearly funding, these could be increased to 260 patients (5 patients per week) per year. Excess capacity currently exists and therefore fixed and variable costs decline as the number of patients increases. Labour cost remains constant between 130 and 260 patients since no increase in labour is required when an additional patient is analysed.

<sup>33</sup> Figures are rounded to the nearest dollar.

<sup>34</sup> Fixed costs include cost of hardware and building cost.

<sup>35</sup> Non labour variable cost includes equipment maintenance and electricity.

<sup>36</sup> Labour costs include time spent by each gait staff.

Using annual average geometric growth the numbers of patients were evenly distributed over seven years as these could vary in any given year.<sup>37</sup> It is expected that patient numbers will increase over coming years. A seven year period is taken in this project since the 3DGA equipment lifespan is seven years.

#### **6.4 Scenarios used in the analysis**

Various scenarios are used in the analysis of the marginal costs and benefits of clinical gait analysis. In calculating the NPV and BCR four different scenarios are taken. The results are summarised in table 5 below.

Scenarios 1 and 2 assume that there are no fixed costs. It is also assumed that the capital equipment (3DGA equipment and building) are already in place and these costs are treated as sunk cost in the analysis. Scenario 1 considers a worst case situation in which there will be only 130 patients every year over the seven year period. Scenario 2 considers the marginal costs and benefits with patient numbers increasing (annual average geometric growth) over the seven years. Likewise, Scenarios 3 and 4 take the same approach to Scenario 1 and 2 but includes all costs (fixed and variable). Since capital costs consist of 40% of the overall gait analysis cost it was important to measure its impact on the NPV.

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<sup>37</sup> An even growth of patients over a seven year period (lifespan of capital) was used in the analysis to show the impact on costs and benefits and NPV. This was more appropriate rather than using only minimum (130) or maximum (260) patents per year. Number of patients with given initial resources could be any where between 130 and 260.

As shown in table 5, there is a positive NPV and a BCR greater than 1 for all the scenarios. Even with high discount rates (15%), except for scenario 3, the NPV is greater than \$700,000. This indicates that the benefits of clinical gait analysis outweigh its costs.

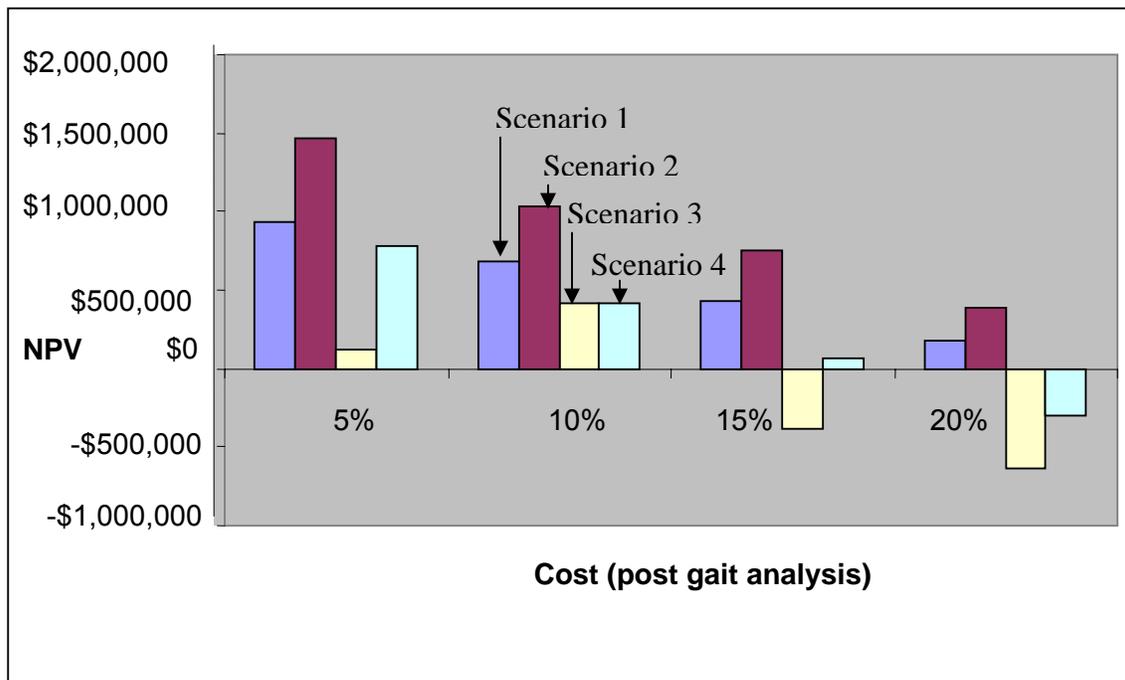
**Table 5: NPV and BCR of Four Volume-Based Scenarios**

Discount rate	3 percent	5 percent	10 percent	15 percent
<b>Scenario 1: Variable cost with n=130</b>				
NPV	\$1,181,037	\$1,108,526	\$958,582	\$842,933
BCR	1.75			
<b>Scenario 2: Variable cost with n=130-260</b>				
NPV	\$1,828,019	\$1,695,723	\$1,425,165	\$1,219,857
BCR	1.87			
<b>Scenario 3: Total cost with n=130</b>				
NPV	\$369,841	\$347,134	\$300,179	\$263,964
BCR	1.15			
<b>Scenario 4: Total cost with n=130-260</b>				
NPV	\$1,139,381	\$1,045,564	\$855,146	\$712,288
BCR	1.42			

In this analysis the treatment costs generated by the physician's treatment prior to gait analysis was well established. National hospital cost data were used for specific procedures prescribed by the physician. The costs of scanning (e.g. CT scan) and other diagnostic testing were obtained from the MBS. However, the

data obtained for changes in treatment options after gait analysis was insufficient as patients required follow-ups for more than 18 months. More accurate figures on the number of physiotherapy and drugs were required. While estimates were made from physicians and physiotherapists it was thought best to see the impact of increased cost of post gait analysis on the NPV.

**Figure 8: Changes in NPV with percentage increase in costs after gait analysis**



After CGA most physicians opted for an alternative treatment pathway. These alternative treatment pathways also incurred costs which were not well captured during the study, as these treatments would have occurred over a longer duration. As shown in figure 8, a 5%, 10%, 15% and 20% increase in cost as a result of changes in treatment option, NPV was positive for all Scenarios at 5%

and 10%. Scenario 3, which include all costs and 130 patients, had negative NPV at 15% and 20%. Scenario 4 had a negative NPV at 20% increase in costs.

A reduction in building rental from \$300 to \$250 per square meter per annum increased the NPV in all the four scenarios. An increase in building rental to \$350 per square meter per annum still had a positive NPV and BCR greater than one for all scenarios with the various discount rates.

## **6.5 Monte Carlo Simulation**

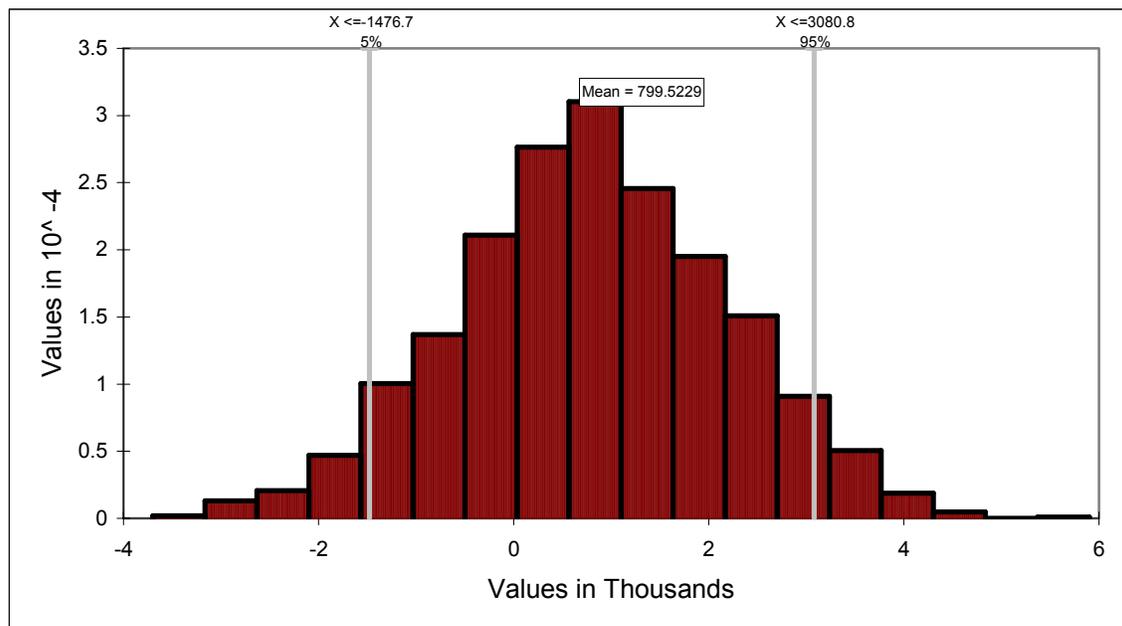
### ***6.5.1 Distribution of average net benefits***

Given the small number of observations the question of validity arises. In order to strengthen the results from the raw data @Risk<sup>®</sup> software was used to undertake a simulation, known as *Monte Carlo* analysis. The costs and benefits are recalculated over and over again, each time using different, randomly chosen, set of values. The random selection of values is based on the characteristics of each input variable's probability distribution. @Risk randomly sample values of the uncertain variables from its specified probability distributions in order to calculate the NPV using sample values. This process is repeated many times (iterations). The program than assembles all saved results presenting them as a probability distribution (Campbell & Brown, 2003).

Using the raw data (marginal benefits, marginal costs, and net benefits) 2000 iterations were made. The raw data included all costs (fixed and variable) and an average of 130 and 260 patients. The results of the iterations are shown in figures 9 and 10 below.

Figure 9 shows that 90% of the net benefits are between negative \$1477 and \$3080. To see what percentage of the net benefits were between zero dollars and \$3080, the x1 line to the left of the graph was shifted to zero. The results showed that 67% of the range of benefits was between zero dollars and \$3080.

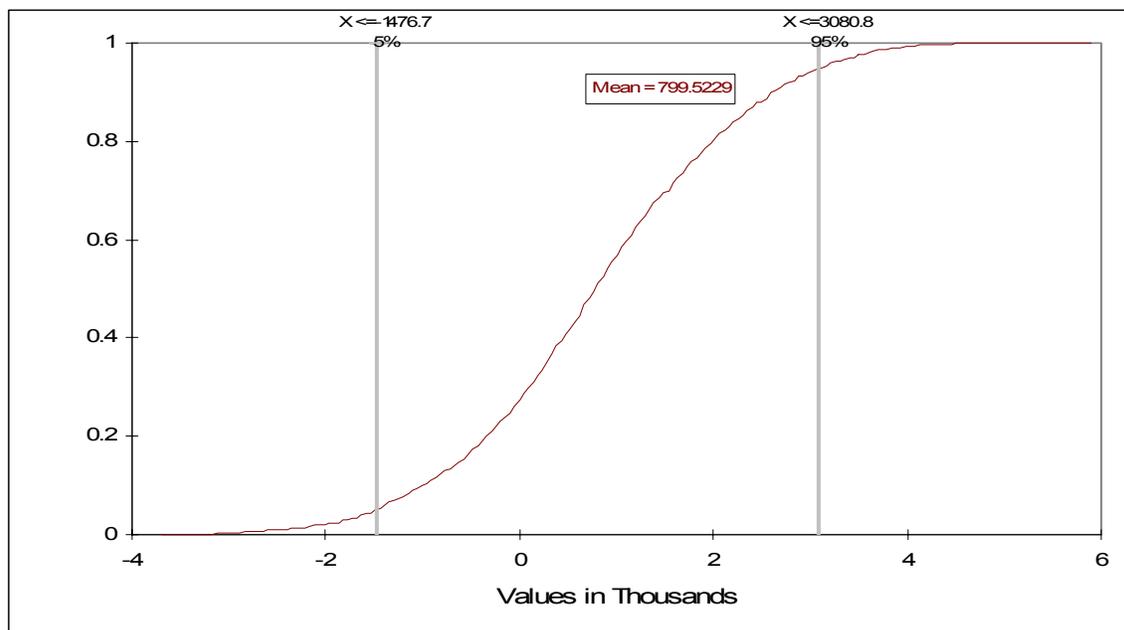
**Figure 9: Estimated distribution of average net benefit**



Alternatively, the above could be presented using the cumulative probability distribution. The vertical axis is scaled from 0 to 1 showing the cumulative probability up to the corresponding net benefit value on the horizontal axis (figure

10). The cumulative distribution indicates what the probability is of the net benefits lying below (or above) a certain value. For example, there is 22% chance that the net benefits will fall below zero dollars and 78% chance that it will be above. Similarly, there is 50% chance that the net benefits fall below \$1000 and 50% chance that they will fall above \$1000.

**Figure 10: Estimated cumulative distribution of average net benefit**

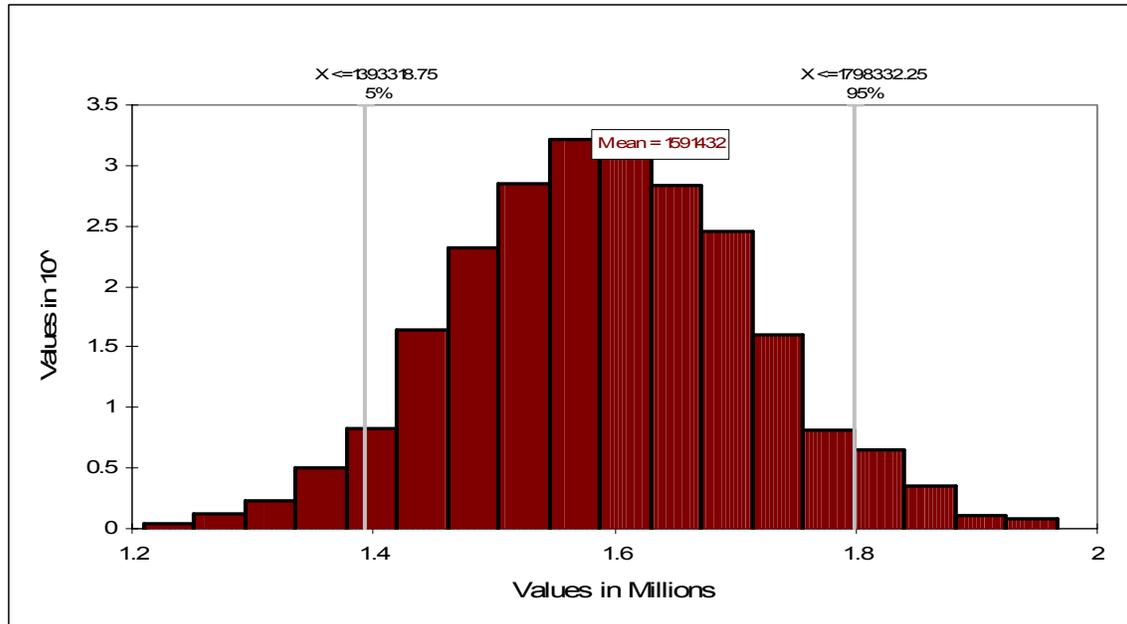


### **6.5.2 Distribution of NPV**

In the survey it was earlier discussed that only limited benefits were measured and this could have implications for the results. However, in the above analysis the average net benefit itself suggested that benefits outweigh costs. Since costs were also subject to uncertainty these were also varied in a sensitivity analysis.

As such, for the purpose of this exercise, a different probability distribution was used to characterise the random variables and the probability distribution of NPV was calculated.

**Figure 11: Estimated distribution of NPV for scenario 2**

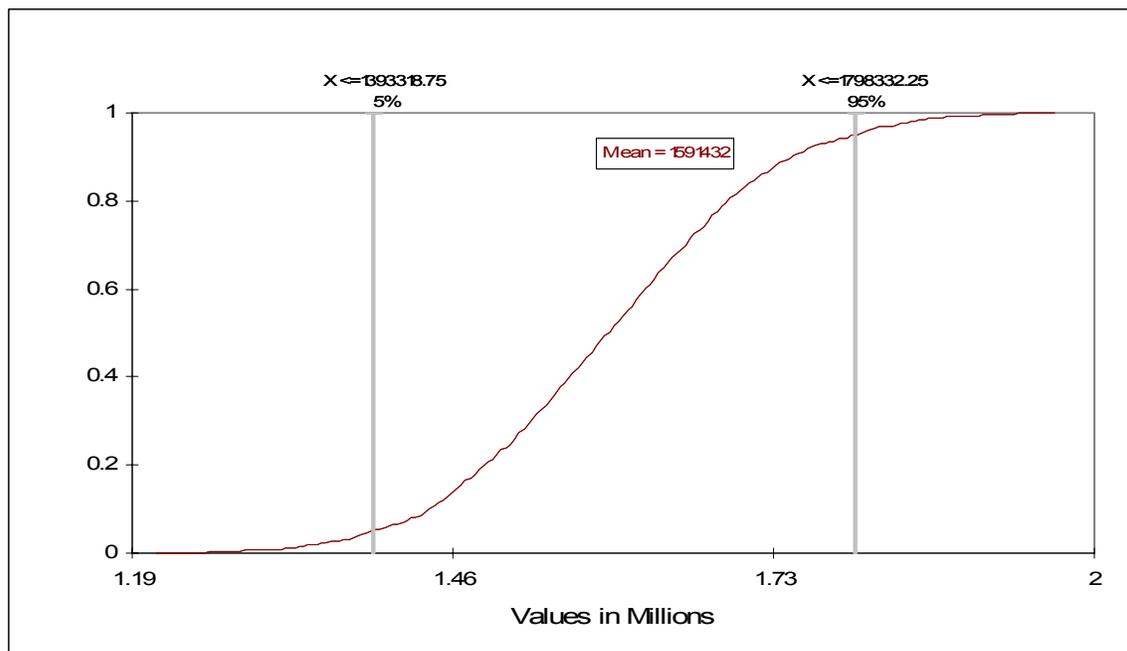


There was uncertainty underlying the costs of CGA such as underestimating future treatment costs following recommendations by the QCGL. Using scenarios 2 and 4, which includes all costs, the following results, presented in the forms of a histogram and cumulative distribution were obtained. Using the “*riskuniform*” function minimum and maximum values (\$218,000 and \$392,000) were used to characterise the costs for scenario 2.<sup>38</sup>

<sup>38</sup> A *UNIFORM* function was used to define a range of values, minimum and maximum which has equal probability of occurrence (Campbell & Brown, 2003).

From figure 11 it is evident that 90% of the NPV estimates fall between \$1.4 million and \$1.8 million. This is consistent with the findings of the initial analysis (table 5) where the NPV was \$1.8 million. The minimum, maximum and mean values are \$1.21 million, \$1.59 million and \$1.97 million, respectively, with a standard deviation of \$0.12 million. The cumulative distribution of the NPV (figure 12) shows that 15% of the NPV is less than \$1.46 million and 90% of the NPV is less than \$1.75 million.

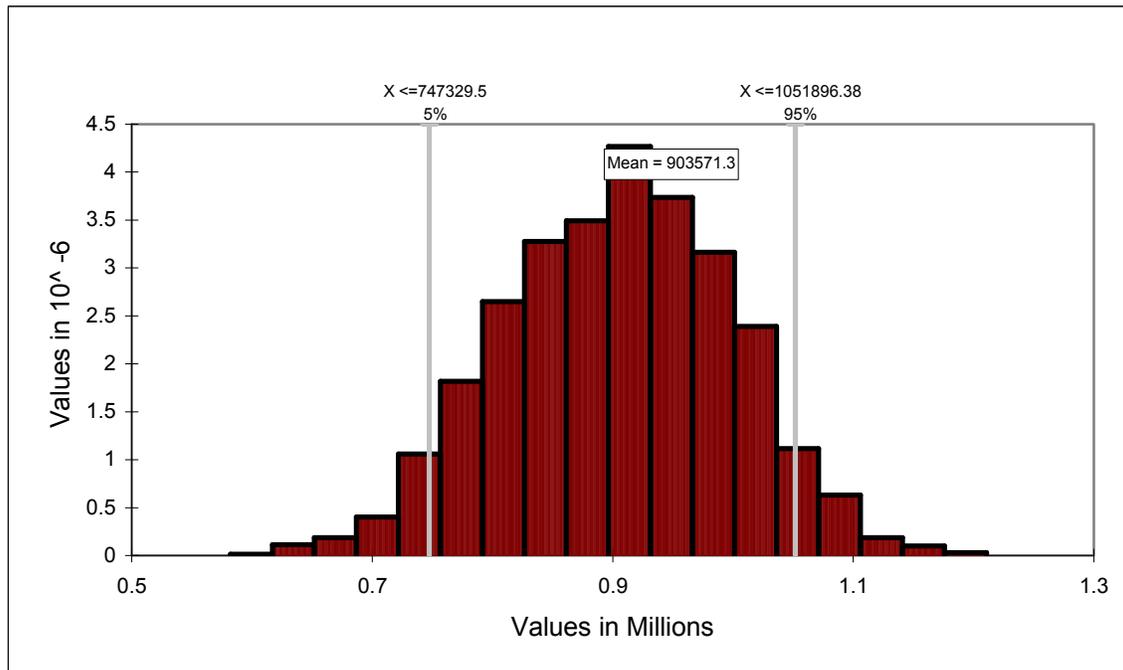
**Figure 12: Estimated cumulative distribution of the NPV for scenario 2**



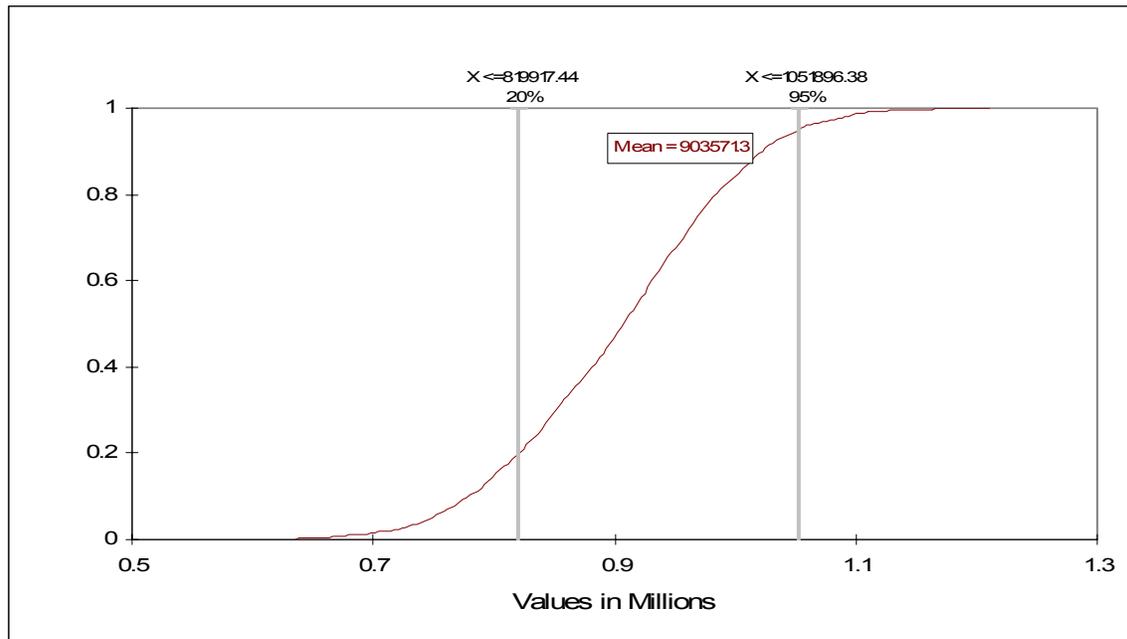
Scenario 4, which includes all costs, results in 90% of NPV results falling between \$0.75 million and \$1.05 million. This is again consistent with the initial results obtained in table 5 at the 3% discount rate. The minimum, maximum and mean values are \$0.58 million, \$1.2 million and \$0.9 million, respectively, with a

standard deviation of \$0.094 million. The cumulative distribution of the NPV shows that 20% of the NPV is less than \$0.8 million and 46% of the population has NPV less than \$0.9 million.

**Figure 13: Estimated distribution of the NPV for scenario 4**



**Figure 14: Cumulative distribution for NPV of scenario 4**



## 6.6 Conclusion

The results from the analysis suggest that despite measuring only a subset of benefits of CGA, the NPV is generally positive. This is also true when costs are varied by even 20 percent. A worst case scenario (3) that included all costs and a minimum number of patients (130) estimate also produced a positive NPV at the 5% and 10% rates of discount. Bootstrapping techniques produced showed similar results even when costs were varied in a sensitivity analysis.

# CHAPTER SEVEN

## CONCLUSION

### 7.1 Introduction

The purpose of this thesis was to conduct an economic evaluation of alternative means of treating gait. More specifically, the answer to the following question was sought: “which method of treating *cerebral palsy* (1<sup>st</sup> generation or 2<sup>nd</sup> generation) maximises the difference between social benefits and social costs?” The technique of CBA was employed to answer this question. Children between ages 6 and 11 were used in the survey and 6 physicians making referrals to the gait laboratory were approached to provide clinical input.

### 7.2 Main findings

The main finding from the research is that greater benefits than costs are associated with treating patients using the 2<sup>nd</sup> generation technology, 3DGA. Using the raw data from the survey and the various simulation scenarios, it can be concluded that the benefits of CGA probably outweigh its costs. The four scenarios included in the analysis had the following features: (1) minimum cost of treating gait, assuming no fixed cost, and 130 patients; (2) minimum cost and 260 patients; (3) all costs and 130 patients; and (4) all costs and 260 patients. In

all the cases, the NPV was positive at lower discount rates. Scenario 3 had a negative NPV above 10% increase in costs at all discount rates. Using sensitivity analysis and increasing costs for rental and post gait costs by 20%, similar results were obtained with Scenario four having a negative NPV for all discount rates (below -\$350,000).

While a negative NPV normally suggests that a project is not worth considering, in this analysis it is suggested that these negative values are marginal given that all benefits were not captured in the analysis. The benefits of not having surgery and having casting instead will likely have much higher benefits than the cost of initial change in treatment options. The pain and suffering, the time taken for healing and any after effects of inappropriate surgery can be very substantial but, for pragmatic reasons, were not measured for this study. Counting these as benefits of CGA would undoubtedly produce a NPV positive for all scenarios even at considerably high discount rates. The assumption that was responsible for a negative NPV was the assumption of a minimal patient load for the QCGL. This suggests that, in order to have positive NPV without measuring more benefits, the number of patients would have to be greater than 130 per annum.

Using the @Risk program and performing 2000 iterations of the marginal benefits and costs, it can be concluded that that with a larger sample size benefits would still likely be greater than costs.

### **7.3 Strengths**

The main advantage of this study is that it is the first step in identifying the costs and benefits of CGA. Established methods of economic evaluation, where theoretical basis is provided by welfare economics, were applied for this study. Furthermore, since data collection for this study was time-intensive and the resulting sample size was small, appropriate simulation techniques were applied. These, along with an application of other forms of sensitivity analysis (e.g. changes in assumptions about the discount rate, patient volume, and costs) provide some confidence in the results reported herein.

### **7.4 Limitations**

As with any modelling exercise, the main limitation of this model is that it necessarily simplifies reality. This study considers only the direct health care costs and a subset of total benefits. As such there is still some uncertainty surrounding the parameters of the model. In order to conduct a more extensive assessment of costs and benefits of CGA, a larger group of patients and physicians would need to be studied. In this study we did not consider following up patients after their treatment. Such follow-ups could be important for the accurate measurement of the future benefits and costs of a program.

In order to analyse the effects of clinical gait analysis, it is important to select study groups that are treated with recommendations from CGA and those that are not. However, there are obvious ethical problems that are implied by conducting such given the invasive procedures (such as surgery) that could be involved and also the potential for care to be withheld.

## **7.5 Recommendations**

Whilst it is shown that CGA plays an important role in decision making for physicians, its actual costs and benefits require further research. At this stage it cannot be asserted with complete confidence that the benefits of using a gait laboratory outweigh the costs, although the results do suggest this is probably the case. While most costs have been captured, benefits of such analysis require a longer period of time for their measurement.

This research also showed that the capacity utilisation of the gait lab is an important economic consideration, due to its capital – intensity. This result suggests that, in relatively small cities, such as Brisbane, it would likely be impossible to operate more than one economically viable gait laboratory.

This research is a first step in measuring the costs and benefits of CGA. More resources and time are required for a more complete analysis of the costs and benefits of CGA. A further matter for consideration, in future studies, is how to

value the information CGA provides when physicians use it as a diagnostic tool. This is an especially challenging question to answer, empirically, in those cases where CGA simply provides a confirmation of the physician's intended diagnosis and treatment plan.

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