The Utilization of Health Care Services by Children with Foetal Alcohol Syndrome in the Western Cape, South Africa

Sarah Credé
Student number: MGHSAR001
BSc Physiotherapy
MPH Candidate, University of Cape Town

Supervisor: Prof. Leslie London
Co-supervisor: Dr Edina Sinanovic

Dissertation submitted in partial fulfilment of the requirements for the degree of Master of Public Health, School of Public Health and Family Medicine, University of Cape Town, 28 June 2010

Declaration of plagiarism

I, Sarah Crede, hereby declare that the work on this dissertation thesis is based on my own original research and has not, in whole or in part, been submitted towards another degree at this university or elsewhere.

The University of Cape Town is empowered to reproduce either the whole or any portion of the contents for purposes of research.

_____
Sarah Crede

_____
Date

Acknowledgements

I would like to acknowledge the advice and assistance of my supervisors Prof.Leslie London and Dr Edina Sinanovic in the production of this mini-dissertation.

TABLE OF CONTENTS

PART A: PROTOCOL

1. Introduction

Foetal Alcohol Syndrome (FAS) is a serious public health concern in the Western Cape. However, the burden that this condition places on the health care systems in this region is poorly understood. The research proposed here will evaluate the utilization of health care services by children with FAS and Partial Foetal Alcohol Spectrum Disorders (PFAS) in Cape Town. In addition this study will identify factors that are correlated with increased utilization of health care.

1.1 Problem identification

Foetal Alcohol Syndrome, resulting from prenatal alcohol exposure, is a major public health concern in South Africa. The rates of this Syndrome in the Western Cape are much higher than those reported elsewhere in the world. Children with FAS often require medical attention at birth, as low birth weight is common to many of these children. The use of medical services for these children continues as they age because of the need for surgical correction of birth defects, such as oral clefts and cardiac defects. In addition, services are required to manage developmental and cognitive impairment in children with FAS and to provide support for their families. Although it is widely accepted that FAS is of serious public health concern in South Africa, little is known about the utilization of health care services by children with FAS. This information is necessary to understand the direct and indirect costs associated with health care utilization with a view to ensuring that these systems are adequately funded and the appropriate prevention programs are instituted.

1.2 Rationale and motivation

The rates of FAS in the Western Cape exceed reported rates from other high risk settings in first world populations and have been identified as evidence of a major public health problem, which needs to be addressed (Rosenthal *et al*., 2005). May *et al*., 2000, reported rates of FAS in a community in the Western Cape annually as being 40.5-46.4/1000 (i.e. for every 1000 live births it is estimated that 40.5 - 46.4 will be FAS infants). This study involved active case ascertainment from a cohort of first grade children (*ibid*.). When FAS was measured in the same community five years later this estimate increased to 65.2-74.2/1000 (Viljoen *et al*., 2005). Although both studies focused on FAS, in the latter study by Viljoen *et al*., 2005, a spectrum of severity was noted in diagnosing FAS thus the increased incidence noted may partly be explained by the inclusion of children with both FAS and FASD. While, more recently, May *et al*., 2007, found the prevalence rates of FAS among a third cohort of children being studied to be 68.0– 89.2 per 1000. By comparison in the United States, a developed country, the rates of FAS during the 1980s -1990s was 0.5 to 2/1000 live births (May and Gossage, 2001). It is clearly a matter of concern for public health not only that these rates are considered globally to be very high but also that they are increasing.

Populations with low socio-economic status, in both developed (Abel, 1995) and developing countries (May *et al*., 2000) have been seen to be at high risk for having children with FAS. Abel (1995) further identified ethnicity to be a determinant in the incidence of FAS. In Native American and African-American populations, characterized by low socio-economic status in the United States, the incidence of FAS was ten times higher than that observed in Caucasian populations (*ibid.*). May and Gossage, 2001, state that older mothers, or those who have had numerous previous pregnancies are at increased risk of alcohol use.

Other social and environmental factors that are reported by these authors to increase the risk of alcohol consumption during pregnancy include unemployment, adverse social conditions, smoking or depression (*ibid.*).

The consequences of FAS that result from prenatal exposure to alcohol (May *et al*., 2007) are life-long. Foetal Alcohol Syndrome is entirely preventable (Klug & Burd, 2003) which highlights the need for appropriate prevention programs in the Western Cape.

The presentation of effects in children with FAS can vary across a spectrum of physical and cognitive disabilities from mild to severe (Bertrand *et al*., 2005). While some of the physical manifestations of FAS may be obvious at birth and signal the need for life-long care, many of the cognitive and developmental deficits only present as the child ages. It is believed that FAS is the most common non-hereditary cause of mental retardation, which is a severe cognitive disability (May and Gossage, 2001). Foetal Alcohol Syndrome (considered to be the more severe end of the spectrum) presents with a characteristic triad of signs: facial dysmorphology; prenatal or post natal developmental delay; and altered central nervous system function (Bertrand *et al*., 2005). Infants who present with lesser degrees of physical anomalies or developmental deficits, but who have clear manifestations of prenatal alcohol exposure, are often termed as having foetal alcohol spectrum disorders (FASD), which may include conditions previously described as partial foetal alcohol syndrome (PFAS); alcohol related birth defects (ARBD) or alcohol related neuro-developmental disorder (*ibid.*).

The findings of May *et al.,* 2007, also indicate that mothers to whom children with FAS were born were more likely to be farm labourers than were the mothers of children who did not have a diagnosis of FAS.

This pattern of children with FAS being more likely to be born to rural farm labourers is likely to be the legacy of the „dop' system, where farm labourers received part of their payment in the form of alcohol.[1] This payment system of providing wages in the form of alcohol is unique to the Western Cape agricultural sector and has resulted in widespread alcohol abuse in this region (London, 2000). The „dop' system is now illegal, although some reports from farm workers suggest that similar systems were still being practiced in the late 1990's (London, 2000). The legacy of the effects of the „dop' system are still visible in the characteristic heavy drinking that still takes place in the Western Cape (May *et al*., 2005). In addition London, 2000, believes that the „dop' system has contributed to a culture of alcohol consumption that can be seen not only on the farms where it was initially introduced but also in the region as a whole. The high rates of FAS in the Western Cape provide further evidence that heavy drinking is still common.

1.3 Health care costs of FAS

The health care needs of often underweight children with FAS may begin as soon as they are born. Surgical interventions may be needed to correct major birth defects and medical interventions may be required to manage cognitive impairment and mental retardation as the child ages.

The prevalence of FAS in South African communities has been shown to be very high and the subsequent contribution of FAS to the burden of disease in South Africa is large. In estimating the burden of disease that is attributable to alcohol in South Africa in 2000 as part of the Comparative Risk Assessment for South Africa it was found that 5.5% of disability-adjusted life years (DALYs) could be attributed to FAS (Schneider *et al*., 2007).

[1] *Dop* is an informal Afrikaans term used to describe a tot or small drink (usually alcoholic).

In terms of alcohol attributable disability (Years of life lived with a disability YLDs), FAS was estimated to be the third largest contributor (18.1%) (*ibid*.). Although theses results show the considerable burden that alcohol abuse places on the health care system in South Africa the methodology used in this study is likely to have underestimated the true burden of alcohol related birth defects (ARBD); as children with a diagnosis of ARBD and alcohol-related neuro-developmental disorder (ARND) were excluded from this study. Not only is the true burden of alcohol related birth defects unknown but the economic burden that FAS and FASD conditions places on health care systems has not been quantified.

Studies conducted in the United States of America have estimated the burden that the annual costs of caring for children with FAS places on its health care systems. Although these estimates vary greatly, partly due to the cost components and partly due to the differing incidence of FAS in different communities, each clearly indicates the substantial economic costs of this condition. In 1987 the annual medical costs in America for managing the manifestations of FAS was estimated at $321 million per year (Abel and Sokol, 1987). More recently Abel and Sokol, 1991, estimate that the annual costs related to FAS amount to $74.6 million, significantly less than the previous estimate. Annual cost estimates have also been reported by Lupton *et al*., 2004, to vary substantially from $75 million in 1984 to an exceptionally high $4.0 billion in 1998.

Klug and Burd, 2003, found that the annual health care costs for a child with FAS were substantially more than those for a non-FAS child, the difference being estimated at $500. The average annual cost for a child with FAS was found to be $2,842 (*ibid*.). This finding indicates that if one case of FAS was prevented per year, for each of the subsequent 10 years, the resultant savings would be $128,810 in that ten year period (*ibid.*).

Many of these studies have estimated the costs only for patients with FAS, which is the most severe end of the spectrum. These estimates are therefore likely to underestimate the true burden that the full spectrum of alcohol related birth disorders places on health care systems (Stade *et al*., 2007). Having accurate estimates of the economic costs of providing health care services for persons with FAS is essential in order to fund these services appropriately and to further identify areas on which public health prevention should be focused (Lupton *et al.,* 2004).

The economic burden to the health care systems of managing children with FAS can be seen to vary considerably. However, FAS does not only have economic implications for state and private health systems but also to the families of children with FAS. A cross-sectional study conducted in Canada estimated that the direct and indirect annual costs at the patient level were $14,342 per child (Stade *et al*., 2006). This amounted to a total annual cost of $344,208,000 for the 1 to 21 year olds that were studied (*ibid.)*. Significant determinants of these costs were found to be the severity of FASD, the child's age and the area in which the child lived (*ibid.*). Stade *et al*., 2006, found that the greatest percentage (32.6%) of the direct cost of caring for a child with FASD was from education in the form of home schooling, special schooling and residential programs. Other components of the total cost of caring for a child with FASD included medical treatment (30.3%) and social services (21.9%) (*ibid*.). The costs for social services were calculated by summing the costs of respite care, foster care and legal services (*ibid*.). Stade *et al*., 2006 also included costs incurred due to children's externalizing behaviours in the form of violent acts and stealing.

The impact of child's age on the cost of managing FAS was found by Stade *et al.,* 2006, to reflect the differing need for health care and other services (e.g. specialized education) at different stages in a child's development.

The cost for the age category 6-15 years was found to be significantly more than other ages this, the authors believe, is a result of the need for special education as well as specialized medical services amongst this age grouping (*ibid*.). It is not surprising that children with FAS and FASD have differing needs at different ages as many of the cognitive and developmental deficits only become apparent as the child ages. Low birth weight is a physical characteristic of many of these children that will predict medical costs early in a child's life. In addition severe physical defects are also more likely to require surgical correction in the early stages of a child's life. It can be seen that identifying factors that are associated with increased health care utilization may provide the required information to target prevention strategies in this region. Further more determining the cost-components of the direct and indirect costs of caring for a child with FAS and other FASDs will enable policy makers to allocate health care resources appropriately and to provide necessary support to families of children with FAS/ FASDs.

In conclusion, then, studies conducted in other countries have shown the high economic burden that FAS places on the health care systems as well as the direct and indirect costs to the families of children with FAS . These findings suggest that equivalent health care systems and families in South Africa may be burdened to a similar extent. As the prevalence rates of FAS are much higher in the Western Cape than anywhere else in the world, health care systems seem likely to be carrying an economic burden that is proportionally greater than those seen in the United States.

Understanding the average utilization of health care by persons with ARBDs and specifically those with FAS, as well as the direct and indirect costs to families, would be an important public health finding which could be used to ensure that health systems are adequately funded and the appropriate support is available to families.

It is clear that in South Africa we need to understand the utilization of health care services as well as the associated economic costs of managing a child with FAS. Without this knowledge it is difficult to advocate for appropriate funding or to motivate prevention programs designed to minimize the burden of this preventable condition.

1.4 Research Aim:

The aim of this project is to estimate the utilization of health care services by children with FAS and PFAS, factors associated with utilization, as well as the economic costs of health care use to the families of children with FAS/ PFAS.

1.5 Research Objectives:

1. To describe the types of health care services in Cape Town being used by children with FAS/ PFAS.

2. To estimate the frequency of utilization of health care services in Cape Town by children with Foetal Alcohol Spectrum Disorders and in particular those with Foetal Alcohol Syndrome and Partial Foetal Alcohol Syndrome.

3. To estimate the direct and indirect costs to the family of a child with FAS/ PFAS associated with utilization of health care services for their child with FAS/ PFAS.

4. To identify variables that are associated with increased frequency of health care utilization by families with FAS/ PFAS children.

1.6 Potential Impact

Findings from this research will create a better understanding of the burden of FAS on the Western Cape health care system. This study will provide a description of the type of health care use and the frequency of use by children with FAS/ PFAS which will aid in ensuring that the appropriate services are available to these children and that these services are appropriately resourced. In addition this study will also provide an estimate of the direct and indirect health care costs to a family in caring for a child with FAS/ PFAS. This information will increase our understanding of the burden that this condition places on these families. Results from this study have the potential to aid policy makers to improve prevention programs aimed at decreasing the economic burden of FAS on the Cape Town health care services.

1.7 Potential Outcomes

This research will be presented as a requirement for the Masters of Public Health at the University of Cape Town, South Africa. This study is also a sub-study that will comprise part of a project undertaken by South African institutions (Universities of Pretoria and Cape Town) in collaboration with the Centre for Diseases Control in the USA. Findings of this project will be submitted to scientific peer-reviewed journals; a project report will be submitted to the Department of Health; and a Briefing document will be prepared for the Parliamentary Portfolio Committee on Health. In addition, reports from this project will be sent to policy makers including the Ministry of Social Development in South Africa.

2. Methods

2.1 Definition of terms

Foetal Alcohol Syndrome (FAS) is a syndrome characterized by multiple system involvement including physical dysmorphology, cognitive deficits and central nervous system dysfunction. Diagnosis of FAS should be made if documentation exists of: 1) all three dysmorphic facial features (i.e., smooth philtrum, thin vermillion border, and small palpebral fissures); 2) prenatal or postnatal growth deficit in height or weight; and 3) Central Nervous System abnormality (Bertrand *et al.*, 2005).

Foetal Alcohol Spectrum Disorder (FASD) includes the spectrum of effects that can occur in a person whose mother drank alcohol during pregnancy, including physical, mental, behavioral, and learning disabilities, with possible lifelong implications (Bertrand *et al*., 2005).

Partial Foetal Alcohol Syndrome (PFAS) refers to a lesser FASD in which a child presents with characteristic facial dysmorphic features but with fewer abnormalities in growth or central nervous system structure and function than a child with FAS (Hoyme *et al*., 2005).

Family refers to the group of individuals living together in one household who provide care for the child with FAS/ PFAS.

2.2 Study Design

This research will be based on quantitative, cross-sectional data collected via face-to-face survey interviews with caregivers of children with FAS and PFAS.

2.3 Setting

The high rates of FAS in the Western Cape, South Africa, make it an ideal region to study the utilization of health care services for children with FAS. Furthermore, despite having the highest rates of FAS in South Africa, there is a dearth of research on this topic in the region. In addition this study will be the first to look at health care utilization and its associated costs in this region.

Within the Western Cape this study will be conducted at the Child and Family Unit and the Developmental Clinic at Red Cross Children's Hospital in Cape Town and at the Paediatric Out-Patient departments at Tygerberg and Paarl Hospitals. Red Cross Children's and Tygerberg hospitals are tertiary health care centres that service areas within and around Cape Town. As these services are tertiary care centres it is anticipated that children with severe FAS, who have entered the health care system, will receive treatment here. The Child and Family Unit at Red Cross Children's hospital provides outpatient assessment and treatment for children <12 years of age and their families who have emotional, behavioural or psychiatric problems. The Developmental Clinic sees children 0- 7 years of age with developmental problems.

Paarl Hospital is situated in the Cape Winelands, a high FAS prevalence area (May *et al*., 2007). Due to the high prevalence of FAS in the region it is anticipated that many children with FAS/ PFAS who require health care but who do not currently require specialized services of a tertiary hospital will be seen at this facility.

As FAS is the most common non-hereditary cause of mental retardation (May and Gossage, 2001) it is anticipated that many of these children and their families will be seeking assistance at these units.

2.4 Study Population:

Primary care givers of children (<12years) with a documented medical diagnosis of FAS/ PFAS who, in the twelve months prior to the commencement of the study, attended the Child and Family Unit or the Developmental Clinic at Red Cross Children's hospital or the Paediatric Out-Patient department at either Tygerberg or Paarl hospitals, in the Western Cape, South Africa.

2.5 Sample size

50 care givers will be invited to participate in the study.

This study is primarily a costing study. Therefore the accepted norm of a sample of 50 participants as used by health economists in costing studies will be used[2]. To establish the statistical power that a sample size of 50 will provide a further calculation was done.

It is estimated that children who do not have a diagnosis of FAS/ PFAS visit public health care facilities on average 2.57 times per year[3]. It has been assumed children with FAS/ PFAS, due to their health care needs, visit health care facilities twice as often as non-FAS children (5 annual visits). Using a standard deviation of 2 and α=0.05 a sample size of 50 provides >90% power.

[2] Personal communication, Dr Edina Sinanovic, Health Economics Unit, University of Cape Town.
[3] Personal communication, Dr Alaba, Health Economics Unit, June 2010, based on an unpublished data set from the SACBIA (South African Consortium for Benefit Incidence Analysis) survey, conducted in 2008.

2.6 Sampling

Potential participants will be identified through review of hospital records for patients being treated at the Child and Family Unit; the Developmental clinic or Paediatric Out-Patient department at the respective hospital sites.

The primary care giver of all children (0-12 years) who have a diagnosis of FAS/ PFAS documented in their medical notes will be identified as potential participants. These care givers will therefore form the sampling frame. From this sampling frame a method of random sampling, using a table of random numbers, will identify 60 of these children's care givers to participate in the study. A rough estimate of 20% non-response has been factored into the sample size.

Tracing patients is difficult in South Africa. This is often due to poorly kept patient records. To assist in tracing all potential participants' only children who have attended the clinics in the twelve months prior to the commencement of the study will be chosen. It is assumed that these children are more likely to have up to date contact information and may have follow up clinic dates assigned to them.

Having identified children with FAS/ PFAS, the parents (biological, adoptive or foster) or the primary care giver for the children will be contacted and invited to participate in the study. If any parent refuses to participate the next medical record with a documented diagnosis of FAS/ PFAS will be identified. For those parents who verbally consent to participation in the study a date and time for an interview will be set. If parents of the identified children can not be contacted, and they have a documented follow up appointment in their medical file it will be arranged that on this day I am at the hospital to try and meet with the parent and conduct the interview or to set up an interview time should they be willing to participate.

All interviews will be undertaken in the paediatric out-patient departments at each of the respective hospitals by a trained interviewer, in the language of the participants.

2.7 Measurement

Record review

Initial record review will be conducted to obtain information regarding the child's diagnosis (FAS/ PFAS) as documented in the medical notes. Further information obtained from the medical records will include: the child's date of birth, child's gender, physical address and the child's home language. Medical information regarding child's birth weight, previous surgery, admission to hospital in the previous six months and other visits to hospital (other than admission) will be collected. The type of services visited at Red Cross Children's hospital/ Tygerberg hospital/ Paarl hospital in the previous six months will also be obtained from this record review. This information will be discarded if the primary care giver refuses to participate in the study or is not contactable. The information collected for those children whose care giver agrees to participate will assist in validating the information obtained through the interviews with the child's care giver.

Instrument

A questionnaire will be used to collect information regarding the quantity of health care services utilized and the types of services utilized by the parents for the care of their children with FAS. This questionnaire has been designed by me with assistance from the Health Economics Unit at the University of Cape Town.

This questionnaire consists of items to measure the type of health care facilities used and the frequency of use during a six month period. Questions regarding the direct medical costs incurred by a family in caring for a child with FAS/ PFAS, including hospital admission, health professional services, medication and transport costs will also be asked. These costs will be the fee that the family pays for the health service which will differ from the cost to the health care service in providing this service. Further questions will be asked regarding indirect costs to the families of children with FAS incurred in utilizing health care service. These indirect costs will include opportunity costs such as time spent travelling to and from the health centre, waiting time at the health centre, consultation time and time spent looking after a sick child away from work.

This questionnaire will also include questions regarding receipt of welfare grants and the type of grant received. Further questions regarding schooling and costs incurred through antisocial behaviour and the need for support services will also be asked. Like the questions asked regarding health care service utilization these questions will ask about the types of services used the frequency of use and the direct and indirect costs incurred in utilizing these services. The interview will consist of a structured questionnaire incorporating both open and closed ended questions.

Questions will be restricted to a reliable duration of recall, such as 6 months for remembering a hospitalization, a visit to a health care profession or clinic. Questions regarding surgical intervention will be asked for the child's entire life. The unit cost for each of these services paid by the parent will also be obtained to estimate the total expenditure on health care services. These questions will be piloted with the families of ten children who do not have FAS who are attending the Child and Family Unit at Red Cross Hospital. Where the questions are found to be poorly understood new questions will be developed and re-piloted.

Interviewers fluent in Afrikaans and Xhosa, the two predominant languages spoken in the Western Cape, will conduct interviews when required. Questionnaires have been translated and back translated into Afrikaans and Xhosa. During interviewer training the translation of the questionnaires will be verified and it will be ensured that the interviewer has an accurate interpretation of each question. To control for possible inter-observer variation all questionnaires and interviews will be standardized. Training sessions with all interviewers will also help to control for this potential variation.

All interviews will be conducted at the Child and Family Unit at Red Cross Children's hospital or at the Paediatric out-patient department at Tygerberg or Paarl hospitals. Prior to the start of the interview written informed consent will be obtained from the participant. The questions will be asked by a trained interviewer. Answers to the questions will be documented directly on the interview form. On completion of the interview all forms will be collected and stored and will not be available to third parties.

Site Preparation

Prior to commencement of the study and following ethics approval permission will be sought from the Western Cape Provincial department of health to conduct the study at each of the sites. In addition ethics approval will be sought from the Stellenbosch University ethics committee as Tygerberg hospital falls under their supervision. The medical manager at each of the hospital facilities will also be approached for permission to conduct research at the respective hospital facility.

Following permission the doctor in charge of the respective clinic facilities will be informed of the study, its aims, objectives and methods. In addition a presentation will be offered to the staff working at these clinics.

Secondary information

Secondary data regarding the costs of various health care services in South Africa, available from the Health Economics Unit at the University of Cape Town will also be utilized. This data includes the cost for clinic visits at the primary, secondary and tertiary level of care depending on the type of visit, either acute or chronic. The cost of caring for a child with FAS/ PFAS from the perspective of the health services will be estimated through the use of this data. Information obtained from the interviews regarding the frequency of use for each type of service will be multiplied by the cost of providing each service to estimate the total cost to the health care service in a six month period.

3. Data management and analysis

Data collection will be undertaken by trained interviewers and I will oversee the data collection from these interviews. All data entry will be undertaken by myself. Data will be entered into Microsoft excel spread sheets and then transferred to STATA 10 (StataCorp, 2007). Twenty percent of the surveys will be randomly selected and the data recaptured for quality control purposes.

Raw data from this study will be analyzed using STATA 10 (StataCorp, 2007) and for health care costs Microsoft Excel will be used.

Initial data exploration will include graphical representation of data collected. Numerical data will be explored through histograms and box plots and categorical data through bar graphs. Summary statistics will be calculated regarding participants' demographic variables as well as the demographic variables of their caregiver.

For demographic variables that are categorical the frequency and percentage of study subjects classified into a given category will be calculated. These categorical variables are listed in Tables 1 and 2. For numerical variables the mean and standard deviation will be calculated and in the case of non-normally distributed data the median and ranges. The number of visits made by a child to the Child and Family unit at Red Cross Children's Hospital or the paediatric out-patient clinic at Tygerberg or Paarl hospitals will be dichotomized into low versus high number of visits. Four or less visits to the unit in the previous year will be classified as low use and 5 or more visits will be classified as high use. The age of the child will be dichotomized into a younger age category, 5 years or younger, and an older age category for caregivers 6 years or older. The age of the caregiver will also be dichotomized into a younger age category, 30 years or younger, and an older age category for caregivers 31 years or older.

Health care utilization will be tabulated by the average number of visits made to each type of service in a twelve month period for each age category (Table 3). Frequency of visits to the different levels of health care services as well as the type of service will be numerical, count data.

More specifically, analysis of this data will include T-tests to compare the mean number of visits to hospital for the two categories of child's age. These visits will include both visits for FAS related health care needs and visits that are unrelated. In addition T-tests to compare the mean total number of visits to all health care facilities between the two age categories will be conducted. If the data do not meet the assumptions for the T-test, normal data distribution, the Wilcoxon Rank Sum test will be used to test the null hypothesis that the two age categories have equal median number of visits per year.

These tests will reveal if there are significant differences in health care utilization and level of care between the different age categories.

In addition to better understand the possible relationships between the dependent variable (number of visits to a health care facility) and explanatory variables Chi-squared statistics will be used to assess the relationship between univariate categorical risk factors and the number of visits, stratified by the child's diagnosis FAS/ PFAS. These categorical risk factors will include the child's gender; employment status of the parent (employed/ unemployed) and whether or not the household receives any government grants. For numeric variables box plots will be created between these variables and health service use. The direct and indirect costs for children with FAS will be compared to those of children with PFAS. In addition the predictors for these two outcomes will be compared.

Table 1: Summary statistics of child's demographic information

Demographic information		Frequency	Percentage
Gender (n=):	Male Female		
Age (n=) Mean age	0-5 years 6-12 years		
Diagnosis	FAS PFAS		
Relationship to parent	Biological Adoptive Foster		
School grade	Not attending school Preschool Grade 1 Grade 2 Grade 3 Grade 4 Grade 5 Grade 6 Grade 7		

Table 2: Summary statistics of demographic information of the care giver

Demographic information		Frequency	Percentage
Gender (n=):	Male Female		
Age (n=)	<20years 20-30 30-40 40-50 50-60 Younger age <30 years Older age 31 years or older		
Relationship to child	Biological Adoptive Foster Step parent Primary care giver		
Employment situation	Employed full-time Employed part-time Self-employed full-time Self-employed part-time Pensioner Not working at all Other		
Average monthly household income	R		
Education of care giver	No schooling Sub A/sub B/grade 1/grade 2/grade 3 Grade 4 Grade 5 Grade 6 Grade 7 Grade 8 Grade 9 Grade 10 Grade 11 Grade 12 Diploma/certificate with Grade 11 or lower Diploma/certificate with Grade 12 Degree		
Medical Insurance cover	Yes No		
Receiving grant	Yes No		
Type of grant received	Disability grant Child support grant Foster-care grant Child dependency grant		

Table 3: Utilization of health care service by level of service use for children 0-5 years

Level of service	Average number of visits in 6 months	Average direct cost per visit	Average indirect costs per visit
Traditional healer			
Private Doctor			
Day Hospital			
Government hospital			
Hospitalization			
Private hospital			

A logistic regression analysis will be conducted to model the effect of the different risk factors on the high versus low number of visits to hospital. The number of visits will be dichotomized into low number of visits versus high number of visits across the median that is found in initial data exploration. Separate models will be created for children with a diagnosis of FAS and those diagnosed with PFAS. Explanatory variables will include: child's age; child's sex; time in months since diagnosis; time taken to get from home to health care facility; mode of transport used to get to health facility; household income; age of care giver; sex of care giver; education of care giver; employment status of care giver; relationship of care giver to child and household size and whether or not anyone in the household of the child with FAS/ PFAS receives any form of government welfare grant. Odds Ratios with their corresponding 95% confidence intervals will be used to measure the effect of each risk factor on the dependent variable.

The cost of utilization of health care services for each family will be calculated by multiplying the cost per visit (direct and indirect) by the number of visits made for each kind of service used. The total cumulative costs will be the sum of all the service costs in the twelve month period. The average cost for health care service use will be calculated from the total costs of each family divided by the number of families interviewed. Direct costs and indirect costs that will be estimated for each visit to a health care facility are listed in Table 4.

In addition the costs to the health care service in managing children with FAS/ PFAS will also be calculated. It is anticipated that the costs to the health care service will far outweigh the costs to the family of children with FAS/ PFAS. Finally the total cost will be calculated as the sum of direct and indirect costs to the family and the cost to the health care services.

Table 4: Components of the direct and indirect cost to be measured

Direct costs	Indirect Costs
• Cost for service (e.g. user fee) • Any other medical expenses resulting from visit (e.g. drugs, medical supplies) • Travelling costs	• Travelling time to and from health care facility • Waiting time at health care facility • Duration of consultation • Time spent looking after sick child (away from work)

Opportunity costs will be estimated using the information elicited regarding the total time spent visiting health care facilities and caring for the child with FAS/ PFAS over the six month period. This will be converted to the number of working hours lost and then multiplied by the parent's average hourly wage. If the parent is unemployed the wage will be taken as an entry level labourer's salary as this time also equates to opportunity costs in the unemployed.

A linear regression analysis will be conducted to identify significant determinants of total annual cost per child, controlling for explanatory variables. If the outcome variable (annual cost per child) is found to be non-normally distributed a log transformation will be conducted prior to regression to transform this variable to a normal distribution. Explanatory variables used in this analysis will include: age of child, child's diagnosis (FAS versus PFAS), hospital that the child attends, child's sex, age of caregiver, employment status of caregiver (employed versus unemployed), relationship of caregiver to child (biological versus non-biological), whether or not the household receives social support grants and whether or not the household receives social support grants specifically for the child with FAS/ PFAS.

4. Logistics and time schedule

Table 5: Time table

Month	Anticipated progress
September 2008	15 September: submit draft proposal
January 2009	Submit proposal for ethics approval 8th January
February 2009	Literature review
March 2009	Identify potential study participants and contact participants
April 2009	Begin interviews with study participants at Red Cross
May 2009	Interviews with study participants at Red Cross
June 2009	Interviews with study participants at Red Cross
July 2009	Interviews with study participants at Red Cross
August 2009	Interviews with study participants at Red Cross
September 2009	Submit proposal for Provincial ethics approval for Paarl Hospital
October 2009	Interviews with study participants at Paarl Hospital
November 2009	Interviews with study participants at Paarl Hospital
December 2009	Interviews with study participants at Paarl Hospital
January 2010	Submit proposal to Stellenbosch University for ethics approval for Tygerberg Hospital Interviews with study participants at Paarl & Tygerberg Hospital
February 2010	Interviews with study participants at Paarl & Tygerberg Hospital
March 2010	Data analysis
April 2010	Write up
June 2010	Submit MPH thesis

This study is part of a larger project funded by the National Research Foundation (PI: Prof L London, Fund 443296) and linked to a collaborative FAS prevention programme associated with the University of Pretoria, the Medical Research Council and the Centers for Diseases Control in the USA. The study will commence once ethical approval has been obtained from the University of Cape Town Health Science Faculty Human Research Ethics Committee and the Western Cape Department of Health. It is anticipated that the thesis will be completed by June 2010, so I can graduate from the MPH program in December 2010.

5. Resources

Table 6: Budget

Line Item	Anticipated costs	Total
1. Personnel 1.1 MPH student bursary 1.2 Fieldworker (x1) R75x 40 interviews of 1 hour 1.3 Fieldworker training R75 x 2hours	 R 4 000 R 3 000 R 150	**R 7150**
2. Supplies 2.1 Questionnaires (x60) (21 pages at 40c/page) 2.2 Consent forms (x60) at 40c	 R 504 R 24	**R 528**
3. Travel 3.1 Use of private vehicle (R2.40/Km x 1000km)	R2400	**R 2400**
4. Participant Costs 4.1 supermarket shopping vouchers (R50 x 60) 4.2 travel costs (R40 per person x 60)	 R 3000 R 2400	**R 5400**
Total Budget:		**R 15478.00**

This study is funded by the NRF. To complete this study a bursary has been awarded to the MPH student who will be conducting the research. Further funding is available to cover costs incurred during the study.

- It has been estimated that 40 of the 60 interviews will require a fieldworker who is fluent in either Xhosa or Afrikaans and two hours of training will be needed with this fieldworker.

- All photocopying has been estimated at 40c per page and it is anticipated that the questionnaire will consist of 21 pages of questions.

- Travel costs include petrol costs and wear and tear for use of a private vehicle at the University of Cape Town standard rate.

- Participant costs include travel costs which have been estimated at R40 for each participant. Each participant will also be given a R50 supermarket shopping voucher as remuneration for their time. An additional ten supermarket shopping vouchers have been included in the budget for the 10 interviewees interviewed in the pilot study.

6. Ethical considerations

Ethics approval will be obtained from the University of Cape Town Health Science Faculty Human Research Ethics Committee and the University of Stellenbosch and the Western Cape Department of Health prior to commencement of the study.

Permission to conduct this research at Red Cross Children's hospital, Tygerberg hospital and Paarl hospital will be sought from the medical superintendents at these sites.

Informed consent

Special care will be taken to ensure that consent obtained from each study participant is clearly understood (i.e. informed consent obtained.) Consent forms will be translated into the main languages of the region (Xhosa, Afrikaans and English) and will include information regarding the purpose of the study; requirements of the participant and potential risks and benefits of being involved in the study. These consent forms will aim to emphasize the key issues of the study as simply as possible. A trained fieldworker will be available to read the informed consent to the study participant, if necessary, and will be available to clarify any misunderstandings. Once the field worker is satisfied that informed consent has been obtained he/she will, with the participant, be required to sign the informed consent document.

A copy of the informed consent form will be given to the participant. The field workers will be responsible for ensuring that the consent obtained is fully understood.

Avoiding harm

Care will be taken to ensure the safety of the field workers. To this end the questionnaires will be conducted at the hospital sites.

As this is a survey, participants should not come under any direct harm from the study. However issues regarding FAS and finances may be very personal and sensitive to the participants. Interviewers will be trained to be sensitive in their methods of interview. If it becomes evident that a respondent requires emotional support the interviewer will have access to trained counsellors to whom the respondent can be referred. In the instance where a child is identified as being in need of medical care or social assistance these children will be referred back to the paediatric department at the respective hospital facility which will follow these patients up.

To avoid study participants potentially being stigmatized due to the sensitivity of the subject special care will be taken to ensure confidentiality of the participants. Surveys will be conducted in an area away from other people, where the participant feels comfortable.

The field worker's contact information will also be given to the participant. If questions should arise regarding the research the participant will be able to contact the fieldworker.

Participation

Individuals are free to refuse participation in the study and this will be explained to them by the fieldworker. Study participants are also free to withdraw at any stage during the interview. Refusal to participate in the study will in no way affect the care and services provided to these families at the out-patient departments.

Participant requirements

After providing consent to be part of the study, participants will be required to be present for an interview which should take 1 hour of their time. Interviews will take place at the Child and Family unit at Red Cross hospital or at the paediatric Out-patient departments at Tygerberg and Paarl hospitals.

Benefits

The benefits will be increased knowledge about health care utilization and the associated costs of utilizing such services for children with FAS, which may help in ensuring that health care facilities are appropriately funded and that the required services are available for children with FAS. Study participants will be remunerated for the time given to participating in this study with a supermarket shopping voucher to the value of R 50. Participants will also be remunerated for the transport costs to attend the interview.

Confidentiality and anonymity

Field workers will be required to sign a confidentiality statement in which they will not be permitted to link information provided by the participant with the participant's name. The field worker will be responsible for explaining to the participant that all answers will be treated confidentially.

Particular efforts will be made to ensure that participants remain anonymous. Each participant will be assigned a random number which will be documented on the form. Thus the participant will not be identifiable to third parties

Finally every attempt will be made in the statistical analysis of the data collected to ensure that the information obtained from the study participants is not misinterpreted.

7. Limitations

The sample size that is to be used in this study is small which may reduce the statistical precision of some of the results. The sample size is based on the accepted norm for costing studies used by health economists. The sample size is also small to ensure that this study can be completed within a year.

8. References

Abel, E.L. and Sokol, R.J., 1987. Incidence of fetal alcohol syndrome and economic impact of FAS-related anomalies. *Drug Alcohol Depend.* 19(1): 51-70

Abel, E.L. and Sokol, R.J., 1991. A revised estimate of the economic impact of fetal alcohol syndrome. *Recent Dec Alcohol*. 9: 117-125

Abel, E.L., 1995. An update on incidence of FAS: FAS is not an equal opportunity birth defect. *Neurotoxico Teratol*. 17(4): 437-43

Bertrand, J., Floyd, R.L. and Weber M.K., 2005. Guidelines for Identifying and Referring Persons with Fetal Alcohol Syndrome. *MMWR Recomm Rep.* 28;54 (RR-11): 1-14

Declaration of Helsinki., 2008, Available at: http://www.wma.net/en/20activities/10ethics/10helsinki/index.html Accessed on: 07/01/09

Hoyme, H.E., May, P.A., Kalberg, W.O., Kodituwakku, P., Gossage, J.P., Trujillo, P.M., Buckley, D.G., Miller, J.H., Aragon, A.S., Khaole, N., Viljoen, D.L., Lyons Jones, K., and Robinson, L.K., 2005. A Practical Clinical Approach to Diagnosis of Fetal Alcohol Spectrum Disorders: Clarification of the 1996 Institute of Medicine Criteria. *Pediatrics*. 115: 39-47

Klug, M.G. and Burd, L., 2003. Fetal alcohol syndrome prevention: annual and cumulative cost savings. *Neurotoxicology and Teratology.* 25: 763–765

London, L., 2000. Alcohol consumption amongst South African farm workers: a challenge for post-apartheid health sector transformation. *Drug and Alcohol Dependence*. 59; 199–206

Lupton, C., Burd, L. and Harwood, R., 2004. Cost of fetal alcohol spectrum disorders. *Am J Med Genet C Semin Med Genet.* 127c(1):42-50

May, P.A., Brooke, L., Gossage, J.P., Croxford, J., Adnams, C., Jones, K.L., Robinson, L. and Viljoen D., 2000. Epidemiology of Foetal Alcohol Syndrome in a South African community in the Western Cape Province. *Am J Public Health*. 90(12): 1905-12

May, P.A. and Gossage, J.P. ,2001. Estimating the Prevalence of foetal alcohol syndrome: A summary. *Alcohol Res. Health.* 25:159-176

May, P.A., Gossage, P., Brooke, L.E., Snell, C.L., Marais, A-S., Hendricks, L.S., Croxford, J.A. and Viljoen, D.L., 2005. Maternal Risk Factors for Fetal Alcohol Syndrome in the Western Cape Province of South Africa: A Population-Based Study. *American Journal of Public Health.* 95(7): 1190-1199

May,P.A., Gossage, J.P., Marais, A.S., Adams, C.M., Home, H.E., Jones, K.L., Robinson, L.K., Kale, N.C., Snell, C., Kullberg, W.O., Hendricks, L., Brooke, L., Stellavato, C. and Viljoen, D., 2007. The epidemiology of fetal alcohol syndrome and partial FAS in a South African Community. *Drug Alcohol Depend.* 88: 259-71

Rosenthal, J., Christianson, A. and Cordero, J., 2005. Fetal Alcohol Syndrome prevention in South Africa and other low-resource countries. *Am J Publ Health.* 95:1099 -1101

Schneider, M., Norman, R., Parry, C.D.L., Bradshaw, D. and Plüddemann, A., 2007. Estimating the burden of alcohol abuse in South Africa in 2000. Methodological Note. Cape Town: South African Medical Research Council.

Stade, B., Ungar, W.J., Stevens, B., Beyen, J. and Koren, G., 2006. The burden of prenatal exposure to alcohol: measurement of cost. *JFAS Int.* 4:e5: 1-14

Stade, B., Ungar, W.J., Stevens, B., Beyen, J., and Koren, G., 2007. Cost of fetal alcohol spectrum disorder in Canada. *Can Fam Physician*. 53(8): 1303-1304

StataCorp. 2007. *Stata Statistical Software: Release 10*. College Station, TX: StataCorp LP.

Viljoen, D., Cossage, J.P., Brooke, B.S., Adnams, C.M., Jones, K.L., Robinson, L.K., Hoyme, E., Snell, C., Khaole, N.C.O., Kodituwakku, P., Asante, K.O., Findlay, R.F., Quinton, B., Marais, A-S., Kalberg, M.A. and May, P.A., 2005. Fetal Alcohol Syndrome Epidemiology in a South African Community: A Second Study of a Very High Prevalence Area. *J Stud Alcohol.* 66(5): 593–604

PART B: LITERATURE REVIEW

1. Objectives of literature review

1. To describe the prevalence of Foetal Alcohol Syndrome (FAS) and other Foetal Alcohol Spectrum Disorders (FASD) in South Africa as reported in past and current studies.
2. To summarize findings of past and current research that reports on

2.1 The risk factors for FAS/ FASD

2.2 The effects of FAS/ FASD

3. To identify and summarize literature that reports on the health care costs associated with caring for a child with FAS/ FASD.
4. To describe previous findings that relate to the components of costs incurred through caring for children with FAS/ FASD.

2. Literature search strategy

International literature was searched in order to provide background information regarding Foetal Alcohol Syndrome, the prevalence of the syndrome in South Africa and risk factors for the syndrome. In addition, information regarding the costs related to Foetal Alcohol Syndrome was sought through review of key literature. To obtain this literature an initial search of Pubmed was conducted. The terms used in this search strategy included: “Foetal alcohol syndrome AND South Africa”; “Foetal alcohol spectrum disorder”; “Foetal alcohol syndrome AND costs” “Alcohol related birth defects” and “Partial foetal alcohol syndrome”. These searches were limited to studies of humans.

The UNICEF report “Fetal Alcohol Spectrum Disorder in South Africa: Situational and Gap Analysis” as well as the MRC Burden of Disease Reports were used.

Further literature was obtained through references cited in the articles found in this initial search.

3. Summary of literature

Foetal Alcohol Syndrome is a major public health concern in South Africa. The consequences of FAS that result from prenatal exposure to alcohol (May *et al*., 2007) are life-long. Foetal Alcohol Syndrome is an entirely preventable condition (Klug and Burd, 2003) which highlights the need for appropriate prevention programs in South Africa and, in particular, in the Western Cape.

The presentation of effects in children with FAS can vary across a spectrum of physical and cognitive disabilities that range from mild to severe (Bertrand *et al*., 2005). While some of the physical manifestations of FAS may be obvious at birth and signal the need for life-long care, many of the cognitive and developmental deficits only present as the child ages. It is believed that FAS is the most common non-hereditary cause of mental retardation, which is a severe cognitive disability (May and Gossage, 2001). Foetal Alcohol Syndrome (considered to be the more severe end of the FAS-FASD spectrum) presents with a characteristic triad of signs which includes: facial dysmorphology; prenatal or post natal developmental delay; and altered central nervous system function (Bertrand *et al*., 2005). Infants who present with lesser degrees of physical anomalies or developmental deficits, but who have clear manifestations of prenatal alcohol exposure, are often termed as having foetal alcohol spectrum disorders (FASD), which may include conditions previously described as partial foetal alcohol syndrome (PFAS), alcohol related neuro-developmental disorder (ARND) or alcohol related birth defects (ARBD) or (*ibid.*).

3.1 Prevalence rates of FAS and FASD

The rates of FAS in the Western Cape exceed reported rates from other high risk settings in first world populations and have been identified as evidence of a major public health problem, which needs to be addressed (Rosenthal *et al*., 2005). May *et al*., 2000, reported rates of FAS in a community in the Western Cape annually as being 40.5-46.4/1000 (i.e. for every 1000 live births it is estimated that 40.5 - 46.4 will be FAS infants). This study involved active case ascertainment from a cohort of first grade children (*ibid*.). When FAS was measured in the same community five years later this estimate increased to 65.2-74.2/1000 (Viljoen *et al*., 2005). Although both studies focused on FAS, in the latter study by Viljoen *et al*., 2005, a spectrum of severity was noted in diagnosing FAS; thus the increased incidence noted may partly be explained by the inclusion of children with both FAS and FASD. While, more recently, May *et al*., 2007, found the prevalence rates of FAS among a third cohort of first grade children being studied to be 68.0– 89.2 per 1000. By comparison in the United States, a developed country, the rates of FAS during the 1980s -1990s were 0.5 to 2/1000 live births (May and Gossage, 2001).

A study looking at the prevalence of FAS among first grade scholars at four schools in Gauteng was conducted to establish whether the high rates of FAS in South Africa are exclusive to the wine producing regions of the Western Cape (Viljoen and Craig, 2003). The median prevalence of FAS among these school pupils was found to be 19/1000 which indicates that this public health problem is not only evident in the Western Cape but in other South African provinces too (*ibid*.). The finding that FAS is a widespread problem in South Africa is reiterated in findings from a study in the Northern Cape Province.

In this study of Grade one children in two towns in the Northern Cape (De Aar and Upington) the prevalence of FAS/ Partial Foetal Alcohol Syndrome (PFAS) was found to be 119.4/1000 in De Aar and 74.7/1000 in Upington (Urban *et al*., 2008). The rates reported from De Aar are the highest rates reported for the prevalence of Foetal Alcohol Syndrome combined with Partial Foetal Alcohol Syndrome in the world.

Reports show that over time in specific communities differing rates of FAS have been reported, these are likely to be the result of different approaches used in case ascertainment within these areas. May *et al*., 2009 report that globally three methods of case ascertainment have been used: surveillance, clinic-based studies, and active case ascertainment. From a summary of studies using these methods it was found that passive surveillance methods yielded the lowest prevalence rates while clinic-based and active case ascertainment yielded the highest rates of FAS. This suggests that many previous studies may have under-identified cases of FAS (May *et al*., 2009). School children can be seen to be representative of the local population and May *et al*., 2009, believe that in-school studies provide better prevalence estimates of FAS than any other method of case ascertainment as more cases are identified when clinicians assess children in the schools.

Using prevalence rates from nine in-school studies conducted in South Africa, Italy and the United States of America May *et al*., 2009 averaged the rates for FASD in each of these three countries. The prevalence of FASD was found to be highest in South Africa with an average of 72.3 per 1,000 children (*ibid*.). The mean in Italy was 35.7 per 1,000 which, while lower than South Africa, was found to be higher than the mean rate of FASD in the USA at 16.5 per 1,000 (May *et al*., 2009). The average rates for FASD in South Africa do not differ greatly from those previously reported as it is in South Africa that the most extensive in-school studies have been carried out and the previous estimates were based on these findings.

What these findings do suggest is that studies from elsewhere in the world have previously underestimated the prevalence of FASD as a consequence of the methodology being used.

Looking at the rates of FAS and FASD in South Africa it can be seen that the FAS rates far exceed those reported in other countries while the FASD rates as reported by May *et al*., 2009 are only two to four times higher than those reported in Italy and the USA. The ratio of children with FAS: PFAS were found to vary greatly between the three countries studied. In South Africa the ratio was 3.1 FAS case for every PFAS case; in Italy 0.22 FAS case to every PFAS case and in the USA the ratio of FAS to PFAS was 0.44 (May *et al*., 2009). There are various plausible reasons for the discrepancies seen. Firstly differing methodology used in case-ascertainment in previous studies in the different countries will have led to differing prevalence estimates of FAS and PFAS. Some prevalence studies focused on the prevalence of FAS alone and the prevalence of FASD was not estimated (*ibid*.) possibly because diagnosing the more severe end of the spectrum of disorders is much easier, thus under diagnosing the full spectrum of the disorder. More recently it has been found that in some studies increasing numbers of PFAS compared to FAS children have been identified as a result of more sensitive and specific tests being applied to children with FASD (Kodituwakku *et al*., 2006). Furthermore, May and colleagues, 2009, believe that in South Africa the ratio of FAS to FASD is much higher due to the high levels of maternal risk factors such as low socio-economic status and binge drinking in the communities studied. In contrast, the risk factors are less intense in more developed countries and as a result there are more children born with PFAS as a ratio to FAS (May et *al*., 2007).

Thus while the rate of FAS may be much higher in South Africa than in other countries the improved methods of case-ascertainment and detection suggest that the less severe end of the spectrum of alcohol related birth defects is far more common world wide than the rates of FAS alone indicate.

It is clearly a matter of concern for public health in South Africa that, despite evidence of previous underestimations from elsewhere in the world, the rates of FASD in South Africa can be considered globally to be very high. In addition, over time the rates of FAS/ FASD in South Africa appear to have increased.

3.2 Maternal risk factors for having a child with FAS or a FASD

Populations with low socio-economic status, in both developed (Abel, 1995) and developing countries (May *et al*., 2000) have been seen to be at high risk for having children with FAS. Abel, 1995, further identified ethnicity to be a determinant in the incidence of FAS. In Native American and African-American populations, characterized by low socioeconomic status, in the United States the incidence of FAS was ten times higher than that observed in predominantly middle/upper class Caucasian populations (*ibid.*). May and Gossage, 2001, state that older mothers, or those who have had numerous previous pregnancies are at increased risk of alcohol use. Other social and environmental factors that are reported by these authors to increase the risk of alcohol consumption during pregnancy include unemployment, adverse social conditions, smoking and depression (*ibid.*).

The findings of May *et al.,* 2007, also indicate that mothers to whom children with FAS were born in South Africa were more likely than the mothers of non-FAS children to be farm labourers. This pattern of children with FAS being more likely to be born to farm labourers is likely to be the legacy of the „dop' system, where farm labourers received part of their payment in the form of alcohol.[4] This payment system of providing wages in the form of alcohol in the Western Cape agricultural sector has resulted in widespread alcohol abuse in this region (London, 2000). The „dop' system is now illegal, although some reports from farm workers suggest that similar systems were still being practiced in the late 1990's (London, 2000). The legacy of the effects of the „dop' system are still visible in the characteristic heavy drinking that still takes place in the Western Cape (May *et al*., 2005). In addition London, 2000, believes that the „dop' system has contributed to a culture of alcohol consumption that can be seen not only on the farms where it was initially introduced but also in the region as a whole. In 1993, nearly 20% of farm workers, working in the deciduous fruit industry, who were interviewed, reported that the DOP system was being practiced on the farms on which they work providing evidence that this form of payment was not limited to wine-producing farms (London, 2000). The high rates of FAS in the Western Cape provide further evidence that heavy drinking is still common. Morojele *et al*., 2010, provide additional evidence that heavy drinking is still common in that one in five women of child-bearing age in the rural areas of the Western Cape were found to be at risk of an alcohol-exposed pregnancy as a result of currently using alcohol.

[4] *Dop* is an informal Afrikaans term used to describe a tot or small drink (usually alcoholic).

3.3 Health care needs of children with FAS/ FASD

The health care needs of children with FAS and FASD may begin as soon as they are born. Medical or surgical interventions may be needed to manage or correct cardiac anomalies of which the rate of comorbid Congenital Heart Defects (CHD) and FASD has been estimated at 28.6% (Burd *et al*., 2007). In addition medical interventions may be required to manage cognitive impairment and mental retardation as the child ages.

The prevalence of FAS in South African communities has been shown to be very high and the subsequent contribution of FAS to the burden of disease in South Africa is large. In estimating the burden of disease that is attributable to alcohol in South Africa in 2000 as part of the Comparative Risk Assessment for South Africa it was found that 5.5% of disability-adjusted life years (DALYs) could be attributed to FAS (Schneider *et al*., 2007). In terms of alcohol attributable disability (Years of Life lived with a Disability -YLDs), FAS was estimated to be the third largest contributor (18.1%) (*ibid*.). Although theses results show the considerable burden that alcohol abuse places on the health care system in South Africa the methodology used in this study is likely to have underestimated the true burden of alcohol related birth defects (ARBD); as children with a diagnosis of ARBD and alcohol-related neuro-developmental disorder (ARND) were excluded from this study. Not only is the true burden of alcohol related birth defects unknown but the economic burden that FAS and FASD conditions places on health care systems has not been quantified.

3.4 Health care costs

Studies conducted in the USA have estimated the burden that the annual costs of caring for children with FAS places on its health care systems. Although these estimates vary greatly, partly due to the cost components and partly due to the differing incidence of FAS in different communities, each clearly indicates the substantial economic costs of this condition. A summary of the following cost estimates are presented in Table 1. In 1987 the annual medical cost in the USA of managing the manifestations of FAS was estimated at $321 million per year (Abel and Sokol, 1987). Using an incidence rate of 1.9 FAS births per 1000 live births Rice *et al*., 1991, estimated that from the perspective of health care services the annual economic cost of FAS was $1.6 billion. A subsequent article by Abel and Sokol, 1991, estimated that the annual costs related to FAS amount to $ 74.6 million, based on an incidence rate of 0.33 FAS births per 1000 live births, significantly lower than their previous estimate. The authors believe that nearly 77% of this cost is due to the supervised residential care required for FAS children with cognitive disabilities (*ibid*.). In reviewing the literature on the major components of cost for individuals with FAS Lupton *et al*., 2004, reported that the annual cost estimates in the United States were seen to vary substantially from $75 million in 1984 to an exceptionally high $4.0 billion in 1998.

Klug and Burd, 2003, found that the annual health care costs for a child with FAS were substantially more than those for a child without a diagnosis of FAS, the difference being estimated at $500. The average annual cost for a child with FAS was found to be $2,842 (*ibid*.). Many of these studies have estimated the costs only for patients with FAS, which is the most severe end of the spectrum. These estimates are therefore likely to underestimate the true burden that the full spectrum of alcohol related birth disorders places on health care systems (Stade *et al*., 2007).

Having accurate estimates of the economic costs of providing health care services for persons with FAS is essential in order to fund these services appropriately and to further identify areas on which public health prevention should be focused (Lupton *et al.,* 2004).

The economic burden to the health care systems of managing children with FAS can be seen to vary considerably. However, FAS does not only have economic implications for state and private health systems but also to the families of children with FAS. A cross-sectional study conducted in Canada estimated that the direct and indirect annual costs at the patient level were $14,342 per child (Stade *et al*., 2006). Using a conservative FAS incidence rate of 3/1000 the total annual cost to the Canadian society in caring for children with FAS aged 1- 21 years amounted to $344,208,000 (95 % CI $ 311, 664, 000; $ 376, 752, 000) (*ibid.)*. Significant determinants of these costs were found to be the severity of FASD, the child's age and the area in which the child lived (*ibid.*). Stade *et al*., 2006, found that the greatest percentage (32.6%) of the direct cost of caring for a child with FASD was from education in the form of home schooling, special schooling and residential programs. Other components of the total cost of caring for a child with FASD included medical treatment (30.3%) and social services (21.9%) (*ibid*.). The costs for social services were calculated by summing the costs of respite care, foster care and legal services (*ibid*.). Stade *et al*., 2006 also included costs incurred due to children's externalizing behaviours in the form of violent acts and stealing.

The impact of a child's age on the cost of managing FAS was found by Stade *et al.,* 2006, to reflect the differing need for health care and other services (e.g. specialized education) at different stages in a child's development. The cost for the age category 6-15 years was found to be significantly more than other ages.

This, the authors believe, is a result of the need for special education as well as specialized medical services amongst this age grouping (*ibid*.). It is not surprising that children with FAS and FASD have differing needs at different ages as many of the cognitive and developmental deficits only become apparent as the child ages. Low birth weight is a physical characteristic of many of these children that will predict medical costs early in a child's life. In addition severe physical anomalies are also more likely to require surgical correction in the early stages of a child's life.

Stade *et al*., 2009, recently revised their previous estimate of the direct and indirect costs associated with FASD at the individual level in order to overcome limitations of their past findings. This recent study included children from the day of birth as well as adults beyond the age of 21 years and added the costs incurred through institutionalization of children with FASD. The same Health Services Utilization Inventory as used in the first study was adapted for this second study to include additional questions related to costs incurred during infancy and adulthood, as well as the costs of living in an institution (*ibid*). Compared to the initial estimate of $14,342 the annual costs of caring for a person with FASD at the patient-level increased to $21,642 (95% CI, $19,842; $24,041) (*ibid*.). In this revised estimate medical services made up the greatest component of the total costs (35%) with educational costs being the second largest contributor to the total costs (28%) (*ibid*.). The mean adjusted annual costs per individual in the youngest age category (0-3 years) (Mean $30,222) was found to be greater than the other age categories studied (Stade *et al*., 2009). This, the authors believe, reflects the need for hospitalization of neonates and the use of specialized health care professionals in infancy (*ibid*.).

Thanh and Jonsson, 2009, estimated both the annual long-term and short-term economic costs of caring for a child with FASD in Alberta, Canada. The annual long-term costs were calculated from the societal perspective and equalled the lifetime costs associated with the care of a child with FASD multiplied by the number of FASD children born each year (Thanh and Jonsson, 2009). The short-term costs refer to the costs incurred by those currently living with FASD (*ibid*.). With the lifetime cost of caring for a child with FASD estimated to be $1.1 million the annual long-term costs were estimated to rise from $130 to $400 million each year for this Canadian community (*ibid*.). Of these long-term costs 30% are due to medical expenses (*ibid*.). The short-term costs which include costs incurred through special education, health care services, judicial systems and specialized residential care were estimated to be $48- $143 million (*ibid*.).

In conclusion, then, studies conducted in other countries have shown the high economic burden that FAS places on the health care systems as well as the direct and indirect costs to the families of children with FAS. These findings suggest that equivalent health care systems and families in South Africa may be burdened to a similar extent. As the prevalence rates of FAS are much higher in the Western Cape than anywhere else in the world, health care systems seem likely to be carrying an economic burden that is proportionally greater than that seen in the United States. However, as the standard of health care in South Africa is seen to be lower than that in developed countries and children are not entering the health care system as a result there may not be as much cost as would be expected with the high prevalence rates.

Table 1 Summary of costing studies conducted in the United States and Canada

Source of estimate	Design	FAS/ FASD	Country	Incidence rate per 1000 live births	Estimated Cost per child	Estimated Total Annual Cost	% contributed by sub components
Abel & Sokol, 1987	From perspective of Health service. Incidence based of prospective and retrospective data Age 1- 21 years	FAS	United States	1.9	*Not calculated*	$ 321 million	11% Institutionalization due to Cognitive disability Other components of cost: medical expenses due to Low birth weight & surgical repair of physical anomalies
Rice *et al*., 1991	Use of Survey data: cost of treatment and care patients < 21 years. Residential care all ages.	FAS	United States	1.9	*Not calculated*	$ 1.6 billion	80% cost of residential care for patients > 21 years Other components of cost: Medical care for FAS related birth defects; care resulting from Cognitive disability
Abel & Sokol, 1991	Prospectively gathered data Age 1-21 years	FAS	United States	0.33	*Not calculated*	$ 74.6 million	77% supervised residential care due to cognitive disability 23% Medical services
Klug and Burd, 2003	Data from North Dakota Health Claims Database Age 0-21 years	FAS	United States	*Not stated*	$ 2,842	*Not calculated*	*Not stated*
Stade *et al*., 2006	Cross- sectional Participants selected from parent support groups of children with FASD Age 1-21 years	FASD	Canada	1-6	$ 14,342 ($ 12,986; $ 15,698)	$ 344,208,000 ($ 311,664,000; 376,752,000)	32.6% Education 30.3% Medical services 21.9% Social services 7.1% Out-of-pocket 8.1% productivity loss
Stade *et al*., 2009	Prospective Cross-sectional. Participants selected from parent support agencies. Birth to 53 years.	FASD	Canada	1/ 100	$ 21, 642 ($ 19,842; $ 24,041)	$5.3 billion (95% CI $4.12 billion; $6.4 billion)	35% medical 28 % education
Thanh and Jonsson, 2009	Estimated annual short-term and long-term economic costs of FASD	FASD	Alberta, Canada	3-9	$15,812	Short-term costs $48-$143 million Long-term economic costs rises $130-$400 each year	33% Education 30% Medical 19% cost to family 18% social services, productivity losses & externalizing behaviours

4. Frame work for health care costing

Accurate health care costing is necessary to assist policy makers in appropriately allocating resources within the health care system (Mogyorosy and Smith, 2005; McGuire, 2001). Furthermore having costing data on specific illnesses can help in prioritizing health care expenditure. This is especially pertinent in areas where public health care resources are scarce with many diseases burdening the health care system. The main aims of any costing analysis should be to identify all the inputs into the health care process of interest and to quantify these to enable a monetary value to be placed on the service offered (WHO, 1994).

There are various perspectives from which and cost evaluation can be undertaken: societal, provider or patient. In looking at costs from the provider's perspective only the costs incurred in providing the service are estimated (Floyd, 1999). The patient's perspective will estimate costs borne by patients such as: travel costs, health service fees, or lost income due to time away from work (*ibid*.). The societal perspective, in comparison, includes all costs incurred from both the provider and patient's perspectives (*ibid*.).

Mogyorosy and Smith, 2005, found through their review of literature that there is a general consensus in the accounting and economic literature regarding the basic principles of costing. It is believed that when costing the following steps should be followed:

a) formation of a well-defined problems which includes the objectives of costing as well as the time horizon,
b) the description of the health service (cost object),
c) identification of all resources used to deliver the service,
d) measurement of resource utilization, and

e) attaching a monetary value to this resource use (*ibid*.).

Clearly defining the problem is important in determining which services are measured as well as identifying which costs are to be included in the analysis. In addition identifying the time horizon will determine what cost should be included in the study as well as assisting with determining costs which are variable over time (*ibid*).

A clear and detailed description of the services that are to be included in the costing analysis is necessary in order to ensure that costs measured for particular services (e.g. GP visits) are comparable with other like visits (*ibid*.). Furthermore by providing a detailed description of the services offered will enable the findings of the costing analysis to be compared to other studies that used the same description of services.

Data collection on health service utilization is often done retrospectively using a structured questionnaire (*ibid*.). Myogyorosy and Smith, 2005, state that one of the benefits of this type of data collection is that it is particularly useful in situations where patients used many different types of services over a particular time period.

In order to quantify the costs identified it is necessary to a) measure the quantity of the resource used b) assign a unit cost to this resource use (Drummond *et al*., 2005). The market price for these items is usually assigned to the resource use and for non-market related costs e.g. patient time the market related wage rates may be used (Drummond *et al*., 2005.).

5. Identification of gaps or needs for further research

In South Africa there are no published studies that report on the health care costs of caring for a child with FAS/ PFAS. Quantifying the health care costs associated with caring for children with FAS/ PFAS is important in understanding the total economic burden associated with this condition.

While health care costs are only one component of these costs, previous studies have shown that as much as 35% of total costs were incurred in medical services (Stade *et al*., 2009). Thus further research that quantifies the health care costs of caring for a child with FAS/ PFAS is needed.

Understanding the average utilization of health care by persons with ARBD and specifically those with FAS, as well as the direct and indirect costs to families, would be an important public health finding which could be used to ensure that health systems are adequately funded and the appropriate support is available to families. It is clear that in South Africa we need to understand the utilization of health care services as well as the associated economic costs of managing a child with FAS/ PFAS. Without this knowledge it is difficult to advocate for appropriate funding or to motivate prevention programs designed to minimize the burden of this preventable condition. Therefore the findings of research into the economic costs associated with medical care for children with FAS/ PFAS need to be further translated into policy documents.

It can be seen that identifying factors that are associated with increased health care utilization may provide the required information to target prevention strategies in this region. Furthermore determining the cost-components of the direct and indirect costs of caring for a child with FAS/ PFAS will enable policy makers to allocate health care resources appropriately and to provide necessary support to families of children with FAS/ PFAS. In addition quantification of the costs of FAS/ PFAS to society should give impetus to the urgent need for policy interventions that would address the abuse of alcohol in general, and by women of child-bearing age in particular, in the Western Cape.

6. Implications of the literature for this study

This study is the first to cost health care utilization by children with FAS/ PFAS in the Western Cape. While the prevalence of this condition has been estimated and the burden of the condition appears significant in this region, quantifying the cost of providing children with FAS/ PFAS health care is vital in ensuring that the health care services are appropriately funded. Providing a quantification of this cost will also equip public health practitioners and policy makers with evidence to advocate for appropriate prevention programs. By gathering data on all levels of health care used as well as on both public and private facility use this will provide a good reflection of which types of facilities are in greatest need and thus enable funds to be appropriately distributed.

The study sample only includes children who have already entered the health care system at a secondary or tertiary level hospital which can be seen as a potential weakness. By only including children in the health care system it is likely that the health care costs of many children with FAS/ PFAS who do not require the services of a secondary or tertiary hospital will not be included. However, by including patients from multiple hospital sites this is likely to make the results more generalizable to children with FAS/ PFAS who are attending health care facilities.

Children need a documented medical diagnosis of FAS/ PFAS to be included in this study. In South Africa there are many problems with accurately diagnosing FAS/ PFAS and specialist multi-disciplinary teams are often needed to provide an accurate diagnosis (Rendall-Mkosi *et al*., 2008). While the diagnosis of FAS/ PFAS is often made on clinical suspicion it is possible that many FAS/ PFAS children are not being diagnosed at the primary health care centres and thus are not being referred for the support they require at the secondary or tertiary level health care facilities (*ibid*.).

Thus it is possible that many children who utilize primary level facilities for their alcohol related birth conditions have not been included in this study as they have not received a diagnosis and thus have not entered the secondary or tertiary hospital facilities.

Children from the age of 0-12 are to be included in the sample. This age range was chosen as children older than 12 years are not seen in the paediatric departments at the respective hospital facilities. By allowing children under 1 year of age to be included in the study this will enable an accurate quantification of costs borne during infancy as the result of FAS/ PFAS to be calculated. On the other hand the health care costs of children with FAS/ PFAS are likely to continue beyond the age of 12 years and these will not be calculated in this study. Thus the true burden of caring for FAS/ PFAS patients as they age will remain unknown and further research will be required to establish this.

There are numerous other costs that are incurred in looking after a child with FAS/ PFAS for example: the need for special education, which has been shown to be one of the major components of cost burden in Canada (Stade *et al*., 2006; Stade *et al*., 2009; Thanh and Jonsson, 2009), and the costs of institutionalization. As the focus of this study is on the health care costs of children with FAS/ PFAS these additional costs to society will not be calculated. Thus the true total cost to society in caring for children with FAS is likely to be much higher than found in this study and further research will be needed to establish the total cost to society.

7. References

Abel, E.L. and Sokol, R.J., 1987. Incidence of fetal alcohol syndrome and economic impact of FAS-related anomalies. *Drug Alcohol Depend.* 19(1): 51-70

Abel, E.L. and Sokol, R.J., 1991. A revised conservative estimate of the incidence of FAS and its economic impacts. *Alcohol Clin Exp Res*. 15(3): 514-524

Abel, E.L., 1995. An update on incidence of FAS: FAS is not an equal opportunity birth defect. *Neurotoxico Teratol*. 17(4): 437-43

Bertrand, J., Floyd, R.L. and Weber M.K., 2005. Guidelines for Identifying and Referring Persons with Fetal Alcohol Syndrome. *MMWR Recomm Rep.* 28; 54 (RR-11): 1-14

Burd, L., Deal, E., Rios, R., Adickes E., Wynne, J. and Klug, M.G., 2007. Congenital Heart Defects and Fetal Alcohol Spectrum Disorders. *Congenit Heart Dis.* 2: 250-255

Drummond, M.F., Sculpher, M.J., Torrance, G.W., O'Brien, B. and Stoddart, G.L., 2005. Methods for the Economic Evaluation of Health Care Programmes, Third Edition, Oxford University Press, Oxford.

Floyd, K., 1999. Generic protocols for cost and cost-effectiveness analysis for tuberculosis diagnosis and treatment services. World Health Organization, Geneva.

Klug, M.G. and Burd, L., 2003. Fetal alcohol syndrome prevention: annual and cumulative cost savings. *Neurotoxicology and Teratology*. 25: 763–765

Kodituwakku, P., Coriale, G., Fiorentino, D., Aragón, A.S., Kalberg, W.O., Buckley, D., Gossage, J.P., Ceccanti, M. and May, P.A., 2006. Neurobehavioural Characteristics of Children with Fetal Alcohol Specturm Disorders in Communities from Italy: Preliminary Results. *Alcoholism: Clinical and Experimental Research.* 30(9): 1551-1561

London, L., 2000. Alcohol consumption amongst South African farm workers: a challenge for post-apartheid health sector transformation. *Drug and Alcohol Dependence*. 59; 199–206

Lupton, C., Burd, L. and Harwood, R., 2004. Cost of fetal alcohol spectrum disorders. *Am J Med Genet C Semin Med Genet.* 127c(1):42-50

May, P.A., Brooke, L., Gossage, J.P., Croxford, J., Adnams, C., Jones, K.L., Robinson, L. and Viljoen D., 2000. Epidemiology of Foetal Alcohol Syndrome in a South African community in the Western Cape Province. *Am J Public Health*. 90(12): 1905-12

May, P.A. and Gossage, J.P., 2001. Estimating the Prevalence of foetal alcohol syndrome: A summary. *Alcohol Res. Health.* 25:159-176

May, P.A., Gossage, P., Brooke, L.E., Snell, C.L., Marais, A-S., Hendricks, L.S., Croxford, J.A. and Viljoen, D.L., 2005. Maternal Risk Factors for Fetal Alcohol Syndrome in the Western Cape Province of South Africa: A Population-Based Study. *Am J of Public Health;* 95(7): 1190-1199

May,P.A., Gossage, J.P., Marais, A.S., Adams, C.M., Home, H.E., Jones, K.L., Robinson, L.K., Kale, N.C., Snell, C., Kullberg, W.O., Hendricks, L., Brooke, L., Stellavato, C. and Viljoen, D., 2007. The epidemiology of fetal alcohol syndrome and partial FAS in a South African Community. *Drug Alcohol Depend*. 88: 259-71

May, P.A., Gossage, J.P., Kalberg, W.O., Robinson, L.K., Buckley, D., Manning, M. and Hoyme, E., 2009. Prevalence and Epidemiologic Characteristics of FASD from Various Research Methods with and Emphasis on Recent In-School Studies. *Developmental disabilities research reviews*. 15: 176-192

McGuire, A., 2001. Theroretical concepts in the economic evaluation of health care. In: Drummond, M. and McGuire, A. (Eds.), Economic evaluation in health care. Oxford, pp.1 -21

Mogyorosy, Z. and Smith, P., 2005. The main methodological issues in costing health care services: A literature review. CHE Research Paper 7, University of York. Available at: http://www.york.ac.uk/inst/che/publications/publicationsbyyear.htm#2005

Morojele, N.K., London, L., Olorunju, S.A, Matjila, M.j., Davids, A.S. and Rendall-Mkosi, K.M., 2010. Predictors of risk of alcohol-exposed pregnancies among women in an urban and a rural area of South Africa. *Social Science & Medicine.* 70: 534-542

Rendall-Mkosi, K., London, L., Adnams, C., Morojele, N., McLoughlin, J. and Goldstone, C., 2008. Fetal Alcohol Spectrum Disorder in South Africa: Situational and Gap Analysis. UNICEF, Pretoria.

Rice, D.P., Kelman, S. and Miller, L.S., 1991. Estimates of economic Costs of Alcohol and Drug Abuse and Mental Illness, 1985 and 1988. *Public Health Reports*. 106: 307-316

Rosenthal, J., Christianson, A. and Cordero, J., 2005. Fetal Alcohol Syndrome prevention in South Africa and other low-resource countries. *Am J Publ Health.* 95:1099 -1101

Schneider, M., Norman, R., Parry, C.D.L., Bradshaw, D. and Plüddemann, A., 2007. Estimating the burden of alcohol abuse in South Africa in 2000. Methodological Note. Cape Town: South African Medical Research Council.

Stade, B., Ungar, W.J., Stevens, B., Beyen, J. and Koren, G., 2006. The burden of prenatal exposure to alcohol: measurement of cost. *JFAS Int.* 4:e5: 1-14

Stade, B., Ungar, W.J., Stevens, B., Beyen, J., and Koren, G., 2007. Cost of fetal alcohol spectrum disorder in Canada. *Can Fam Physician*. 53(8): 1303-1304

Stade, B., Alie, A., Bennett, D., Campbell, D., Johnston, M., Lens, C., Tran, S. and Koren, G., 2009. The burden of prenatal exposure to alcohol: revised measurement of cost. *Can J Clin Pharmacol*. Vol 16(1): e91-e102

Thanh, N.Z. and Jonsson, E., 2009. Costs of fetal alcohol spectrum disorder in Alberta, Canada. *Can J Clin Pharmacol*. Vol 16(1): e80-e90

Urban, M., Chersich, M.F., Fourie, L-A., Chetty, C., Olivier, L. and Viljoen, D., 2008. Fetal alcohol syndrome among Grade 1 school children in Northern Cape Province: Prevalence and risk factors. *South African Medical Journal*. 98: 877-882

Viljoen, D. and Craig, P., 2003. Fetal Alcohol Syndrome – South Africa, 2001. *Morbidity and Mortality Weekly Report*. 52, 660-662

Viljoen, D., Cossage, J.P., Brooke, B.S., Adnams, C.M., Jones, K.L., Robinson, L.K., Hoyme, E., Snell, C., Khaole, N.C.O., Kodituwakku, P., Asante, K.O., Findlay, R.F., Quinton, B., Marais, A-S., Kalberg, M.A. and May, P.A., 2005. Fetal Alcohol Syndrome Epidemiology in a South African Community: A Second Study of a Very High Prevalence Area. *J Stud Alcohol*. 66(5): 593–604

World Health Organization (WHO)., 1994. Creese, A. and Parker, D. (Eds). Cost analysis in primary health care: A training manual for programme managers. World Health Organization, Geneva.

PART C: MANUSCRIPT

Journal: Drug and Alcohol Dependence

ABSTRACT

The rates of Foetal Alcohol Syndrome (FAS) and Partial Foetal Alcohol Spectrum (PFAS) in South Africa are the highest reported worldwide. There is a paucity of research examining the health care costs of caring for children with FAS or PFAS in this country.

A cross-sectional analytical study was conducted using an interviewer-administered questionnaire among caregivers of children (0-12 years) with FAS/ PFAS in the Western Cape to estimate the utilization of health care services; the annual direct and indirect health care costs per child as well as the total cost to society for providing health care services to children with FAS/ PFAS. It was found that the median number of annual visits to public health care facilities per child was 8 (IQR 4 to 14). The total average annual cost per child was $1039.38 (95% CI: $ 808.68; $1270.07) and the total annual societal cost for the Western Cape was $70,960,053.68 (95% CI: $5,528,895.48; $86,709,971.13). Caregivers in receipt of a social support grant reported spending significantly less on health care for a child with FAS/ PFAS (Fisher's exact p=0.004). These study results confirm the significant burden of FAS/ PFAS on the Western Cape economy and the health care system which has significant implications for FAS prevention.

Key words: Foetal Alcohol Syndrome, Partial Foetal Alcohol Syndrome, Foetal Alchol Spectrum Disorder, Cost, Western Cape, South Africa

1. INTRODUCTION

Foetal Alcohol Syndrome (FAS), which results from prenatal exposure to alcohol, is a major public health concern in South Africa. While FAS is the most severe diagnosis that a child whose mother drank alcohol during pregnancy can receive, the presentation of effects in children can vary across a spectrum of physical and cognitive disabilities (Centres for Disease Control and Prevention, 2005). Foetal Alcohol Spectrum Disorders (FASD) is the term used to describe the spectrum of effects that can result in persons whose mothers drank alcohol during pregnancy (Centres for Disease Control and Prevention, 2005). Partial Foetal Alcohol Syndrome (PFAS) refers to a lesser FASD in which a child presents with characteristic facial dysmorphic features but with fewer abnormalities in growth or central nervous system structure and function than a child with FAS (Hoyme *et al*., 2005).

The rates of FAS in the Western Cape province of South Africa are amongst the highest reported in the world. In 2000 it was estimated, in one high-risk community in the Western Cape, that the rates of FAS were 40.5-46.4/1000 (May *et al*., 2000). Two later studies, conducted in the same area, estimated slightly higher rates of FAS of 65.2-74.2/1000 (Viljoen *et al*., 2005) and 68-89.2/1000 (May *et al*., 2007). The reason for the higher incidence may be, in part, due to the inclusion of FASD diagnoses in the latter two studies. By comparison, in the United States, a developed country, the rates of FAS during the 1980s -1990s were 0.5 to 2/1000 live births (May and Gossage, 2001).

Using prevalence rates from nine in-school studies conducted in South Africa, Italy and the USA, May *et al*., 2009 averaged the rates for FASD in each of these three countries. The prevalence of FASD was found to be highest in South Africa with an

average of 72.3 FASD children per 1,000 children. The mean in Italy was 35.7 per 1,000 which, while lower than South Africa, was found to be higher than the mean rate of FASD in the USA at 16.5 per 1000 (May *et al*., 2009).

Looking at the rates of FAS and FASD in South Africa it can be seen that the FAS rates far exceed those reported in other countries while the FASD rates as reported by May *et al*., 2009 are only two to four times higher than those reported in Italy and the USA. Uncertainty exists regarding the exact relationship of FAS to FASD globally which may result from: differing methodology used in case ascertainment; a study focus on FAS versus FASD (May *et al*., 2009); the sensitivity and specificity of diagnostic tools used (Kodituwakku *et al*., 2006) as well as differences in the profiles of co-morbid risk factors in the participants studied (May *et al*., 2009). However, what remains clear is that South Africa is the world leader in the rates of FAS or FASD.

Not only are the high rates of FASD in South Africa startling, but the fact that the estimated FAS rates in South Africa are significantly higher than in developed countries is a matter of concern for public health. Although the rates of FASD in South Africa are a major public health concern, little is known about the utilization of health care services by children with FAS/ FASD and no information exists regarding the costs associated with health care utilization amongst children affected by FASD in South Africa. As the true rates of FAS and FASD remain uncertain, establishing the burden in terms of health care and health care costs presents a major challenge.

The health care needs of children with FASD extend through multiple medical disciplines. Specialist interventions may be needed to correct physical defects and manage cognitive impairment and developmental delay (Stratton *et al*., 1996). In addition, managing behavioural issues may require the services of psychiatrists and

psychologists who in collaboration with speech and occupational therapists may assist with educational needs (Stratton *et al*., 1996).

Although the economic costs of FASD have not been documented in South Africa, studies conducted in the United States of America clearly indicate the substantial economic costs of this condition. Abel and Sokol, 1987, estimated the annual medical costs in the US for managing the manifestation of FAS to be $321 million. This cost estimate was derived using an incidence rate of 1.9 FAS children per 1,000 live births (Abel and Sokol, 1987). Using this incidence rate of 1.9/ 1,000 Rice *et al*., 1991, estimated that from the perspective of health care services the annual cost of FAS was $1.6 billion. Using an incidence rate of 0.33/ 1,000 derived from prospective data, which yields lower incidence rates than retrospective data, Abel and Sokol, 1991, estimated that the annual costs related to FAS amount to $74.6 million. A study conducted in North Dakota, USA, found that the annual health care costs for a child with FAS were substantially more than those for a non-FAS child, the difference being estimated at $500 (Klug and Burd, 2003).

Although these cost estimates can be seen to vary greatly, partly due to the differing incidence rates of FAS used and partly due to the difference in cost components, each clearly indicates the sizeable economic burden of this condition on the health care system. Foetal alcohol spectrum disorders not only have economic implications for the health care systems but also to the families of children with the syndrome. Stade *et al*., 2006, estimated that the direct and indirect annual costs to each family were $14,342 per child (1-21years). Of the total direct costs calculated by Stade *et al*., 2006, the greatest percentage (32.6%) was incurred as a result of the need for special schooling, home schooling and residential programs. Another large component of these costs (30.3%) was spent on medical treatment for children with FASD (Stade *et al*., 2006). Stade *et al*., 2009, calculated revised cost estimates at

the patient level in an attempt to overcome some of the limitations reported in their previous study by including infants from the day of birth and adults beyond the age of 21 years. The results show that the adjusted annual costs associated with FASD at the patient level increased using this methodology to $21,642 (Stade *et al*., 2009). In this study the greatest percentage of costs was incurred on medical services (35%) (Stade *et al*., 2009).

From a societal perspective, Thanh and Jonsson, 2009, estimated both the annual long-term and short-term economic costs of FASD in Alberta, Canada. The long-term costs were calculated by multiplying the lifetime cost of caring for a child with FASD by the number of children born with FASD each year. The long-term costs for FASD were calculated to rise $130-$400 million each year, of which 30% would be due to medical costs (Thanh and Jonsson, 2009). Using a FASD incidence of 3-9/1000, the annual short term costs of FASD in Alberta were found to range from $48-$143 million; again medical expenses were only one component of these costs.

While some of the more recent studies have included children with a spectrum of alcohol related disorders, many of the costing studies are limited to children with FAS only. Therefore the cost estimates derived from these studies are likely to underestimate the true economic burden to society that results from prenatal exposure to alcohol.

The objectives of this research are to estimate the utilization of health care services in the Western Cape by children with FAS/ PFAS and to estimate the annual direct and indirect costs per child with FAS/ PFAS that results from making use of health care services, as well as the total cost to society for providing health care services for children with FAS/ PFAS. The lack of existing costing data from the government

hospital system has prevented the additional health care costs relating to surgical interventions from being included in this cost estimate.

2. METHODS

2.1 Study design and setting

A quantitative, cross-sectional research design was used in this study. Data were collected via face-to-face interviews. This study was conducted in the Western Cape province of South Africa. Within the Western Cape the study was conducted at two tertiary level hospitals – Red Cross Children's Hospital and Tygerberg Hospital – and at Paarl Provincial hospital, which is a secondary level hospital.

2.2 Sample

Potential participants were identified through review of hospital records at the Paediatric departments at the three hospitals. Both Red Cross Children's and Tygerberg hospitals service areas within and around Cape Town. As both of these hospitals are tertiary health care centres it was anticipated that children with FAS/ PFAS who had entered the health care system requiring specialist treatment would be receiving treatment there. Paarl hospital is situated in the rural Cape Winelands, a high FAS prevalence area (May *et al*., 2007). Due to the high prevalence of FAS in the region, it was anticipated that many children with FAS/ PFAS who required health care but who did not currently require specialized services of a tertiary centre would be being treated at this facility.

To be eligible for the study the child needed a documented medical diagnosis of FAS/ PFAS and needed to have attended an out-patient clinic at one of the three hospitals' facilities within the twelve months prior to the commencement of the study. Potential participants were excluded if the primary care giver was younger than 18 years of age. In addition, children who reside in children's homes were excluded as it was believed that the health care expenditure patterns of these institutions might differ from the general population.

The study sample included primary care givers of children (0-12 years) for whom there was a documented medical diagnosis of FAS/ PFAS. Eighty-nine children were identified, of whom only 49 had contactable addresses. Forty-four care givers, who met the inclusion criteria and were traceable through the contact details documented in their child's medical records, agreed to participate in this study. Interviews with participants were conducted between August 2009 and March 2010

2.3 Data collection

A questionnaire was used to collect data regarding the types of health care services utilized; the frequency of utilization; and the costs associated with the use of these facilities for the care of children with FAS/ PFAS.

The questionnaire also included questions about the type of health care facilities used and the frequency of use during the six months prior to the interview. Questions were asked regarding the direct medical costs paid by the family, including: hospital admission, health professional service fee, and medication and transport costs. In addition, questions were asked regarding the indirect costs to the families incurred through health care utilization for the child with FAS/ PFAS.

These opportunity costs included time spent travelling to and from the health centre, waiting time at the health facility, and consultation time with the health care professional, as well as time spent away from work looking after a sick child. Questions regarding health care service use were asked for the previous 6 months, while questions regarding surgery covered the child's entire life.

2.4 Data analysis

Statistical analysis of data was conducted using STATA 10 (StataCorp, 2007). For estimating health care costs, Microsoft Excel was used. All estimated costs were converted to US Dollars at the average exchange rate of US Dollar to South African Rand for 2009 of $1 = R8.4076 (Standard Bank, 2009).

To estimate the direct patient costs associated with health care utilization for each family, the unit price for each item, paid by the participant, was multiplied by the number of visits made to each service within a six month period. In calculating transport costs in the instance where a participant used his or her own car the current rate for travel reimbursement ($0.35 /km), as prescribed by the South African Minister of Finance, was used (South African Revenue Service, 2009).

In estimating the indirect costs, participants were asked to report their monthly income within a $119 interval and the median was used in calculating potential loss of earnings. Hourly wages were calculated assuming that there are twenty-two eight-hour working days per month, which totals 176 working hours per month for full-time workers and 88 for part-time workers. For participants who were unemployed, pensioners, or those who refused to state their monthly income, the minimum hourly

rate for a domestic worker in South Africa ($0.82) was used (South Africa, Department of Labour, 2009).

The potential loss of earnings was calculated by multiplying the time spent using health care facilities and looking after a sick child by the hourly income of each participant, and then multiplying this by the number of visits made during a six month period.

The total cost at the patient level (direct and indirect) was calculated by summing the costs for each child over a six month period by level of care. The average cost per visit for health care service use was calculated as the total of direct and/or indirect costs associated with health care use divided by the number of visits made to that type of facility over a six month period.

The cost to the health care service in managing children with FAS/ PFAS was estimated using the estimates of Unit Costs for Patient Services for South Africa (WHO, 2005). These estimates were inflated to 2009 costs using 2005 as the base year and inflating the rates as follows: 2006 – 4.7%; 2007–7.1%; 2008–11.5% and 2009–5.8%, as indicated by data from Statistics South Africa (Statistics South Africa, 2010). These calculated costs are presented in Table 1. These costs were multiplied by the number of visits to, or in-patient days at, each type of health care facility in six months.

TABLE 1: Unit cost for patient services by level of care for 2009*

Level of care	Cost per bed day	Cost per out-patient visit
Tertiary hospital	$ 251.14	$ 96.80
Secondary hospital	$ 128.88	$ 65.44
Primary level clinic	N/A	$ 46.13

*Source: WHO (2005) "Estimates of Unit Costs for Patient Services for South Africa" adjusted for inflation.

Finally, the cost incurred by society in providing health care for children with FAS/ PFAS was calculated by adding the health service costs and the total cost to the patient across all levels of care. Costs based on 6 months recall were extrapolated to a one year period. The average cost per child with FAS/ PFAS was calculated by dividing the total cost by the number of participants interviewed (n=44).

To establish significant determinants of the total annual cost per child for health care service use at the family level as well as the determinants of total number of annual visits to health care services, bivariate comparisons using α^2 tests were conducted. The total annual cost per child for health care service use was dichotomized across the median ($99.08) and the total number of annual visits to health care facilities was dichotomized across the mean (low number of annual visits <5 and high number of annual visits ≥5). In addition, a linear regression analysis was conducted to identify significant determinants of total annual cost per child, controlling for explanatory variables. A log transformation was conducted on the variable "total annual cost per child" prior to regression to transform this variable to a normal distribution. Explanatory variables used in this analysis included: age of child, child's sex, child's diagnosis (FAS/ PFAS), hospital at which child received care, age of caregiver, employment status of caregiver, relationship of caregiver to child (biological or non-biological), whether or not the household received social support grants and whether or not the household received social support grants specifically for the child with FAS/ PFAS.

The additional cost to the South African Government incurred through social support grants received for the child with FAS/ PFAS was calculated by summing the monthly cost of each type of grant received and then multiplying this by 12 for a total annual cost. Three types of social service grants received for the care of the child with FAS/ PFAS were reported, and the monthly payment of these was taken as the amount

payable as at 01 October 2009: Child support grant (unconditional cash transfer for poverty alleviation) $28.55/ month; Foster-care grant $80.88/ month and the care-dependency (child disability) grant $120.13/ month (South Africa, Department of Social Services, 2009).

To compare the utilization rates for health care facilities of children with FAS/ PFAS found in this study with non-FAS/ PFAS children a normative rate was used. The normative rate used indicates that children without a diagnosis of FAS/ PFAS visit public health care facilities on average 2.57 times per year (personal communication, Dr Alaba, Health Economics Unit, June 2010, based on an unpublished data set from the South African Consortium for Benefit Incidence Analysis (SACBIA) survey, conducted in 2008).

2.5 Ethics

The research was approved by the Health Science Faculty Human Research Ethics Committees of the Universities of Cape Town (010/2009) and Stellenbosch (N10/02/033) as well as by the Western Cape Department of Health (19/18/RP85/2009).

The study was conducted in adherence to the declaration of Helsinki of the 25th World Medical Assembly and all caregivers participated on the basis of written informed consent.

3. RESULTS

3.1 Sample

Across the three study sites 89 children were identified as having a diagnosis of FAS/ PFAS who had attended the Paediatric department at each of the respective sites in the 12 months prior to study commencement. Of these children 4 were excluded as they reside in children's homes. One caregiver refused to participate, while 44 agreed. The other 40 potential participants were not traceable via the contact details left at the hospital. Forty four caregivers participated in the study. Tables 2 and 3 present the characteristics of the children and caregivers respectively.

In this study sample 77% of the children had a diagnosis of FAS while the remaining 23% were assessed as having PFAS. Of the 16 children who were not currently attending school one child was over 7 years (the statutory age at which children in South Africa start school). Five children were currently attending special schools, two of which did not have grades.

TABLE 2: Summary characteristics of children with FAS/ PFAS

Characteristics		*Number (n=44)*	%
Sex	**Male** **Female**	21 23	47.73% 52.27%
Diagnosis	**FAS** **PFAS**	34 10	77.27% 22.73%
Age	**0-5 years** **6-12 years** **Mean age ± Standard deviation**	16 28 6.32 ± 2.75	36.36% 63.64%
Relationship to parent	**Biological** **Adoptive** **Foster** **Legal guardian**	21 2 13 8	47.73% 4.55% 29.55% 18.18%
Current school grade	**No schooling** **Preschool** **Grade1** **Grade 2** **Grade 3** **Grade 4** **Special school no grades**	16 10 11 4 0 1 2	36.36% 22.73% 25% 9.09% 0% 2.27% 4.55%
Site of interview	**Red Cross Children's Hospital** **Tygerberg Hospital** **Paarl Hospital**	21 5 18	47.73% 11.36% 40.91%

TABLE 3: Summary characteristics of primary care giver

CHARACTERISTIC		*Number (n=44)*	*%*
Sex	**Male**	1	2.27%
	Female	43	97.73%
Age	**<=30 years**	16	36.36%
	>30 years	28	63.64%
	Mean age ± standard deviation	44.14 ± 11.82	
Employment status	**Unemployed/ pensioner**	30	68.18%
	Employed	14	31.82%
Average monthly household income	**$ 0 - $119**	7	17.50%
	$119 - $237.88	15	37.50%
	$237.89 - $356.82	6	15%
N=40*	**$356.83 - $475.76**	3	7.50%
	$475.77 - $564.70	4	10%
	$564.71 - $713.64	1	2.50%
	$713.65 – $832.58	2	5%
	> $832.58	2	5%
Highest level of education	**Grade 1 to Grade 7**	20	45.45%
	Grade 8 to Grade 12	21	47.73%
	Diploma/ certificate with Grade 11 or lower	2	4.55%
	Diploma or certificate with Grade 12	0	0%
	Degree	1	2.27%
Home language	**Afrikaans**	31	70.45%
	English	10	22.73%
	Xhosa	3	6.82%
Medical Insurance	**Yes**	2	4.55%

*4 participants refused to answer

Table 4 presents the Social Support grants received per household. Of the caregivers interviewed, 72.73% were receiving a social support grant for the child with FAS/ PFAS in their care.

TABLE 4: Social Support Grants received per household

CHARACTERISTIC		*Number (n=44)*	*%*
Household receives social support grants	Yes	38	86.36%
Total number of social support grants received per household	0	6	13.64%
	1	30	68.18%
	2	6	13.64%
	3	2	4.55%
Families receiving social support grants for FAS/ PFAS child	Yes	32	72.73%
Type of social support grant received for FAS/ PFAS child	Child support grant	24	54.55%
	Foster care grant	7	15.91%
	Care-dependency grant	1	2.27%

3.2 Health care utilization and associated costs

The utilization of health care services, by level and type of service, for the children with FAS/ PFAS is presented in Table 5 along with the average costs to provider, family and society (sum of provider and family costs) associated with this utilization. The median number of annual visits to all public health care facilities per child was found to be 8 (IQR 4 to 14). In addition, those children with a diagnosis of FAS were found to visit government health care facilities 1.6 times more frequently than children with PFAS, average 8 times a year (95% CI: 6; 14) versus 5 (95% CI: 2; 8) annual visits, respectively. Using probabilities based on a Poisson distribution the utilization rates for children with FAS/ PFAS (average 8 annual visits) were found to be significantly higher than the average 2.57 visits made by a non-FAS/ PFAS child (p=0.0081). While the average 8 visits made by a child with FAS was found to be significantly more than a non-FAS child (p=0.0081), the utilization rate for a child with PFAS (5 annual visits) was not found to differ significantly from the average number of visits made by a non-PFAS child (p=0.1).

Table 6 presents the average annual cost per child with FAS/ PFAS incurred by the Department of Health, by caregivers, and by Social Services. The total societal cost incurred equals the sum of all three costs above. This total average annual cost per child with FAS/ PFAS, excluding additional costs incurred through social security grants, is $1039.38. Including social support grants the average annual cost per child increases to $1413.39.

Of the total cost to society, 85.98% is paid by the state (59.52% by the Department of Health for medical services and 26.46% by the Department of Social Services through social support grants).

TABLE 5: Utilization and total cost of health care services by level of service use for children with FAS/ PFAS in 12 months (n=44)

		COST TO PROVIDER	*COST TO FAMILY*			*SOCIETAL COST*	
Level of service	**Total utilization* 12 months**	**Average cost to provider per visit****	**Average cost to family per visit*****	**Average direct cost to family per visit**	**Average indirect cost to family per visit**	**Total cost in 12 months**	**Average cost per visit********
Government Hospitalization (days)	48 (in-patient days)	$ 208.48 (per day)	$ 8.04 (per day)	$ 6.18 (per day)	$ 1.86 (per day)	$ 10,392.72	$ 216.51 (per day)
Government hospital Out-Patient Department	236	$ 80.03	$ 8.42	$ 4.40	$ 4.02	$ 20,874.25	$ 88.45
Government clinic/ Community health centre	158	$ 51.39	$ 10.36	$ 2.77	$ 7.59	$ 9,756.27	$ 61.75
Private hospital	2	N/A	$ 76.93	$ 67.55	$ 9.38	$ 153.86	$ 76.93
Private Doctor	40	N/A	$ 39.01	$ 29.37	$ 14.99	$ 1,774.44	$ 39.01
Traditional healer	6	N/A	$ 20.03	$ 19.82	$ 0.20	$ 120.17	$ 20.03

* Utilization indicates total number of in-patient days when a child was hospitalized or total number of visits made to health care service.
** Average cost to provider was based on the estimates of Unit Costs for Patient Services for South Africa (WHO, 2005) summed for the total number of in-patient days or visits made to the provider divided by the total number of in-patient days or visits
***Average cost to family per visit was calculated as the sum of the direct and indirect costs to the families for use of that type of health care divided by the total number of visits
**** Average cost to society per visit was calculated as the sum of the average costs to the provider and family per visit

TABLE 6: Average Annual Cost (% of total) of FAS/ PFAS per case over 12 months (n=44)

Average Provider costs (Department of Health)		
Hospitalization		
Government hospital	$ 227.43 (21.88%)	
Private hospital	N/A	
Out-Patient department visits	$ 429.28 (41.30%)	
Primary level clinic visits	$ 184.54 (17.75%)	
Private doctor visits	N/A	
Traditional healer visits	N/A	
Total cost to provider per patient	**$ 841.25 (59.52%)**	
	Direct cost	**Indirect cost**
Average Patient Costs		
Hospitalization		
Government hospital	$ 6.74 (0.65%)	$ 2.03 (0.19%)
Private hospital	$ 3.07 (0.30%)	$ 0.43 (0.04%)
Out-Patient department visits	$ 23.59 (2.27%)	$ 21.55 (2.07%)
Primary level clinic visits	$ 9.95 (0.96%)	$ 27.24 (2.62%)
Private doctor visits	$ 26.70 (2.57%)	$ 13.63 (1.31%)
Traditional healer visits	$2.70 (0.26%)	$ 0.03 (<0.01%)
Days off caring for ill child	N/A	$ 60.47 (5.82%)
Total cost to patient	**$ 198.13 (14.02%)**	
TOTAL SOCIETAL COSTS FOR HEALTH CARE SERVICE USE	**$1039.38**	
Average Cost to social services		
Child support grant	$ 186.84	
Foster care grant	$ 154.41	
Care-dependency grant	$ 32.76	
Total cost to social services	**$ 374.01 (26.46%)**	
TOTAL SOCIETAL COST INCLUDING COST TO SOCIAL SERVICES	**$ 1413.39**	

In this study it was found that thirty-four children visited government hospital out-patient departments while twenty-six children received health care services at government clinics in the six months preceding the interview. Table 7 shows the types of health care practitioners seen at these facilities and the number of children who made visits to each of these practitioners at their most recent visit to the government hospital or clinic.

TABLE 7: Type of health care practitioner seen at Government hospital and clinic

Health care practitioner seen	Government Hospital Out-patient department N= 34		Government clinic N= 26	
	Number of visits	*%*	*Number of visits*	*%*
Doctor	28	82.4%	16	61.5%
Nurse	9	26.5%	18	69.2%
Occupational therapist	3	8.8%	0	0%
Dietician	1	3.0%	0	0%
Speech therapist	4	12.0%	0	0%
Dentist	1	3.0%	1	3.8%
Psychologist	1	3.0%	1	3.8%
Social worker	2	6.0%	2	7.7%

3.3 Determinants of cost and utilization

On bivariate comparisons, the only variable found to be significantly associated with the total cost of caring for a child with FAS/ PFAS was whether or not the caregiver received a social support grant for the child (Fisher's exact p=0.004). The total cost of health care was lower for those families who received social support grants for the child with FAS/ PFAS (average cost $ 38.44; n=32) than for those who did not receive such grants (average cost $104.66; n=12). Families receiving child related grants visited health care facilities less frequently than those who did not receive child related grants (median 8 versus 15 visits, respectively; Fisher's exact p=0.006). A linear regression analysis for predictors of total cost of caring for a child with FAS/ PFAS, controlling for confounding, provided estimates consistent with the bivariate

analysis. Only receipt of a grant was significantly associated with total cost (β estimate = -0.392, p=0.004).

3.4 Cost to the Western Cape province

Although this study was not designed to estimate the average annual cost at the population level in the Western Cape, some exploratory extrapolation to estimate the full extent of the burden that this condition places on this region seems important. The lower-end estimate of prevalence of FAS/ PFAS in the Western Cape, as reported by May *et al*. in 2007, was 68 FAS/ PFAS children per 1000. The mid-year population estimate for 2009 is that there are approximately 1,506,000 children under 14 years of age living in the Western Cape (Statistics South Africa, 2009). This means that, at a conservative estimate, that there are 102,408 children with FAS/ PFAS living in the Western Cape region. The average annual cost to society of providing health care for a child with FAS/ PFAS has been found to be $1039.38 (95% CI: $ 808.68; $1270.07). Thus a conservative estimate of the annual societal cost to the Western Cape region, assuming similar utilization patterns by children in the community, is $106,440,080.5 (95% CI: $82,815,204.39; $130,064,956.7).

Because all children utilize health care services, not all of this total cost can be attributed to FAS/ PFAS. As stated previously, the findings of this study suggest that children with FAS/ PFAS are utilizing health care services 3 times more than non-FAS/ PFAS children. It seems reasonable, then, to assume that two-thirds of this total cost is due to the additional health care needs of children with FAS/ PFAS. Therefore the cost due to FAS/ PFAS in the Western Cape is estimated to be $70,960,053.68 (95% CI: $ 55,210,136.26; $86,709,971.13) annually.

Two sensitivity analyses were conducted to assess whether the total societal cost would differ if the underlying assumptions of this first analysis changed. The assumptions and results are presented in Table 8. In the first sensitivity analysis, a lower estimate was assumed for children in the community with FAS/ PFAS (i.e. not the selected population recruited through hospital sampling) based on twice, rather than three times, the number of annual visits to health care facilities compared to non-FAS/ PFAS children. The average annual cost to society incurred due to FAS/ PFAS under these assumptions was found to be $53,220,040.26 (95% CI: $41,407,602.19; $65,032,478.35).

The second sensitivity analysis was conducted to assess whether the total societal cost would differ if children with FAS (comprising 77% of the sample) and PFAS (comprising 23% of the sample) were not treated as having equivalent utilization in cost estimates. Thus the health care costs of FAS and PFAS were costed separately and their costs weighted by the respective prevalence of these conditions. The average annual cost per child with FAS $1072.82 (95% CI: $1006.68; $1138.96) and average annual cost per child with PFAS $873.16 (95% CI: $785.62; $ 960.69) as calculated in this study were used in this sensitivity analysis. The prevalence of FAS in a typical community in the Western Cape was taken as 51.3/1000 and PFAS 16.8/1000 (May *et al*., 2009). Extrapolating this data the total annual societal cost to the Western Cape was found to be $104,975,378.00 (95% CI: $97,650,705.14; $118,247,021.10) of which $69,983,585.34 (95% CI: $65,100,470.09; $74,866,680.54) can be attributed to FAS/ PFAS.

TABLE 8: Sensitivity analyses

	Assumptions		Outcomes		
Scenario	**Prevalence**	**Utilization rates**	**Average cost per FAS child**	**Average cost per PFAS child**	**Total societal cost (95% CI) attributable to FAS/PFAS**
Baseline *	Prev. FAS/FASD = 68/1000	FAS/ PFAS=8 Non FAS/PFAS=2.57**	$ 1039.38	$ 1039.38	$ 70,960,053.68 ($ 55,210,136.26; $86,709,971.13)
1	Prev. FAS/FASD = 68/1000	FAS/PFAS=5 Non FAS/PFAS=2.57**	$ 1039.38	$ 1039.38	$ 53,220,040.26 ($ 41,407,602.19; $ 65,032,478.35)
2	Prev. FAS = 51.3/ 1000 Prev. PFAS = 16.8/ 1000	FAS = 8 PFAS = 5 Non FAS/PFAS=2.57**	$ 1072.82	$ 873.16	$ 69,983,585.34 ($ 65,100,470.09; $ 74,866,680.54)

* Baseline results as presented in Table 6

** Utilization rates non-FAS/ PFAS children in general population: 2.57 visits annually (personal communication, Dr Alaba, Health Economics Unit, University of Cape Town, June 2010, based on an unpublished data set from the South African Consortium for Benefit Incidence Analysis (SACBIA) survey, conducted in 2008)

4. DISCUSSION

This study has confirmed the significant burden that foetal alcohol syndrome (and partial foetal alcohol syndrome) places on the health care system, as well as the financial burden to society in caring for children with this disorder.

4.1 Health care utilization

The average utilization of health care services was found to be 8 annual visits across all public sector facilities. This number is far greater than the estimated average 2.57 annual visits made by all children across all public health care facilities. While all children can be expected to need health care services for common childhood illnesses, the fact that children with FAS/ PFAS are utilizing health care services on average 3 times more than other children indicates the significant burden this condition is placing on the health services.

It is unsurprising to find that children with FAS visit government health care facilities more often than children with PFAS. The diagnosis of FAS is reserved for children who present with a characteristic triad of signs including: facial dysmorphology; prenatal or postnatal developmental delay; and altered central nervous system function (Centers for Disease Control and Prevention, 2005). These children are accordingly considered to have the more severe end of the spectrum of alcohol related birth disorders. It can therefore be anticipated that these children will require health care services more than children with lesser degrees of physical anomalies or developmental problems. The difference in average number of visits between FAS and PFAS children is quite small however, (on average visits were 1.6 times higher), which attests to the growing body of information that children with PFAS who do not

present with the full-blown diagnostic manifestations of FAS may still present with significant neurobehavioural problems.

Selectively including children who have already entered the health care system at a secondary or tertiary hospital may have led to selection bias and decreased the difference; as all the identified health care needs of children with FAS and PFAS are addressed once in the system.

The findings clearly show that children with FAS/ PFAS, in this study, utilize public health care facilities far more than privately run facilities. Private hospitals and traditional healers were each only used by one family for the care of their child with FAS/ PFAS, while 8 families visited private doctors. As only two families have medical insurance cover and 86% of households receive a form of social support grant, indicative of low household income, these findings are unsurprising in this population. Health care services are also free in public facilities for children under 6 and for those who are in foster care; in addition, health care is fully subsidised for individuals receiving social support grants (South Africa, Department of Health, 2002). This means that for the majority of families public health care facilities provide the only affordable health care option.

The findings of this study show that the health care needs of children with FAS and PFAS extend through multiple medical disciplines. It is unsurprising to find that 82.4% of children who have attended out-patient departments in the previous six months have seen a doctor at their most recent visit as these children are often followed up regularly by medical doctors. Allied health practitioners such as occupational therapists, dieticians and speech therapists are often not based at government clinics, which would explain the lack of visits made to these practitioners at government clinics. However, it does appear that only a few children are using the

services of occupational therapists, speech therapists and psychologists which is surprising in view of the neurodevelopmental problems that children with FAS and PFAS suffer. The results from this study may underestimate the use of these health care practitioners as some of these therapy services are offered in the school setting and questions regarding this were not asked. It is of concern that only 6% of children who attended out-patient clinics and 7.7% attending primary health care services were seen by a social worker. In the case of FAS and PFAS, where there has clearly been abuse of alcohol by the mother during pregnancy, it might have been assumed that more children and their families would be receiving assistance and support for the home environment.

4.2 Health care costs

The average annual health care cost from the societal perspective in providing health care for a child with FAS/ PFAS in the Western Cape was $1,039.38. A striking 80.94% of the annual costs associated with caring for such children were incurred by the Department of Health. This provides further evidence of the substantial burden that this entirely preventable condition is placing on an already over-burdened health care system.

The burden of caring for children with FAS/ PFAS is also heavy on the caregivers of these children, with 14.02% of the total costs being borne by these caregivers. This cost of caring for the health needs of their child with FAS/ PFAS represented 8.33% of the total annual household income reported by the families. The single largest contributor to the cost (30.52%) for the care givers can be seen to come from loss of earnings through days taken off work to care for their ill children.

At the population level, it is staggering that annually $70,960,053.68 (95% CI: $55,210,136.26; $86,709,971.13) is estimated to be spent on managing the health care needs of children with FAS/ PFAS. This estimate amounts to 5% of the Western Cape Department of Health's $1,422,863,005.00 budget for 2010/11 (Western Cape Provincial Treasury, 2010) having to be spent on providing health care for children with FAS/ PFAS. In a region with a high burden of morbidity and mortality resulting from HIV and tuberculosis, other chronic diseases, maternal and child mortality, as well as violence (Abdool Karim *et al*., 2009; Mayosi *et al*., 2009; Chopra *et al*., 2009; Seedat *et al*., 2009), it is of concern that such a significant portion of the Provincial Health Budget is being consumed by a condition which is entirely preventable.

In extrapolating the total cost to society in the Western Cape it might be argued that the economic burden could have been over-estimated, since many children with FAS/ PFAS in the community may not access health care services and thus, by foregoing care, are not burdening society through their health care needs. However, the sensitivity analysis that was conducted assuming more modest elevations in the number of annual health care visits for children with FAS/ PFAS did not substantially change the original calculation. In addition, even if the extrapolation does over-estimate costs because the assumed utilization rates are too high, the methods used in this calculation err on the side of underestimation in that the lower end of the estimated range of FAS/ PFAS prevalence, as reported by May *et al*. in 2009, was used, and thus there may be an additional 21 children with FAS/ PFAS per 1000 whose health care costs have not been included in this conservative estimate.

Furthermore, a decision was taken to exclude children currently living in children's homes as these facilities may have different health care utilization patterns than the

general population. These may have been children with more severe disabilities and their exclusion may have led to a lower cost estimate.

4.3 The additional cost of social support grants

A further burden on society is the added cost of social support grants for these children living with FAS/ PFAS, of whom nearly 73% are receiving some form of grant. The additional burden to society of these social support grants is, on average, $374.01 per child living with FAS/ PFAS per year. While many of these families may still receive social support in the form of child support grants, even if the child has not had a diagnosis of FAS/ PFAS, it is to be hoped that through appropriate prevention of FAS/ PFAS, these children would be less likely to need foster care and hence foster care grants. In addition, had the FAS/ PFAS been prevented it would again be reasonable to hope that these children would not have suffered permanent or severe disabilities, and in turn would no longer qualify for care-dependency grants.

Families who received social support grants for the care of their children with FAS/ PFAS were found to visit health care facilities less frequently, and thus the total societal cost of these children was found to be less than that of families who did not receive grants. This finding may appear counter-intuitive as it might be anticipated that children living in a household with low income who qualify for social support grants would be more likely to be of poor health and thus access health care services more frequently than children whose families do not qualify for social support grants. However, a number of factors may plausibly explain this seemingly contradictory finding. Firstly, it was found that 66% of those receiving child related grants were children older than 6 years, who had probably been in the health care system over a significant period of time and had thus received the necessary support and services to manage their chronic conditions outside of health care facilities, minimising their need for health care services at the time the survey was undertaken.

In addition, children younger than 6 years old who had higher needs for specialized services might not have been in the health care system long enough to have accessed social support grants. Moreover, it might be argued that, as household income increases with the receipt of support grants, families are better able to take care of their children, and thus these children may not become acutely ill as often and not require medical services as frequently.

Furthermore, as the means-tested income threshold in South Africa necessary to qualify for a social support grant is low, this finding may also indicate that families that do not qualify for a grant because they earn over the income threshold may still not have sufficient funds to be able to care for their children with FAS/ PFAS, and thus receipt of government grants may confer improved health. This notion is supported by evidence of significantly increased growth in height in children who have received the child support grant over a period of time during early life, compared to children from similar socio-economic backgrounds who have not received the grant (Agüero *et al*., 2006).

4.4 Limitations

An additional health care cost to society, which has not be quantified in this study, is the cost incurred through surgical procedures required by children with FAS/ PFAS. Fifteen of the children in this study have undergone surgery at some point in their lives, many of whom have had repeat surgical procedures, including the following: heart surgery, eye surgery, cleft pallet repair, tonsillectomy, adenoidectomy, grommets and hernia repairs. The costs of these surgical procedures were not available and thus the total societal cost of caring for these children, who often require surgical correction of birth defects, is likely to have been underestimated.

This study only included children up to the age of 12 years, and the cost of caring for children with FAS/ PFAS beyond 12 years has not been calculated. It is likely that the health care costs of caring for individuals with FAS/ PFAS extend beyond the age of 12 years. These costs need to be quantified in order fully to appreciate the burden of this lifelong condition.

The sample used in this study included only caregivers who were traceable through contact details registered at each of the respective hospitals. This may have introduced some selection bias. However, the sample included participants from multiple hospital sites, thereby including children from various areas in and around Cape Town. The heterogeneity of the sample suggests that the participants in the study were typical of children attending health care facilities in the Western Cape. It is noteworthy in this regard that the difficulties experienced in tracing patients were similar at each of the three hospital sites.

The focus of this study has been on the utilization and associated costs of health care use, and for this reason other significant costs related to the care of children with FAS/ PFAS, such as specialized schooling, which has been shown to be one of the major components of cost burden in Canada (Stade *et al*., 2006; Stade *et al*., 2009; Thanh and Jonsson, 2009) or the cost of institutionalization, were not included. As 11% (n=5) of the children included in this study were attending a special school and 20% (n=9) were found to have previously failed a school grade the cost of specialized schooling is likely to be high. Thus the total cost to society of the care of children with FAS/ PFAS would be substantially higher were the educational care burden to be included.

5. CONCLUSION

These findings, which probably represent a minimum cost, clearly indicate the significant financial burden that foetal alcohol spectrum disorders place on the Western Cape economy. The quantification of this cost provides necessary evidence for policy makers and health care providers to recognise the impact of prenatal exposure to alcohol and in turn initiate preventive interventions that address FAS. It is to be hoped that the incidence of FAS/ PFAS would be significantly reduced through the creation and dissemination of comprehensive prevention strategies (Rendall-Mkosi *et al*., 2008), and that this in turn would reduce the burden placed on both the health care system and on society by this entirely preventable condition. Reducing the cost of FAS/ PFAS to the Western Cape Government would in turn allow financial resources to be directed to other health care needs. These findings also provide a description of the types of health services utilized by children with FAS/ PFAS. This should assist the Department of Health to allocate resources in such a way as to ensure that these children's needs are addressed.

The finding that receipt of social support grants predicts lower health care costs has important implications for social policy. Although further research is needed, if indeed receipt of social grants does confer improved health, in that families are able to take better care of their children with FAS/ PFAS, this would suggest that social policy should encourage those in need to access grants. This would in turn decrease some of the burden placed on the health care system.

6. REFERENCES

Abdool Karim, S.S., Churchyard, G.J., Abdool Karim, Q., Lawn S.D., 2009. HIV infection and tuberculosis in South Africa: an urgent need to escalate the public health response. *The Lancet*. 374 (9693): 921-933

Abel, E.L. and Sokol, R.J., 1987. Incidence of Fetal alcohol syndrome and economic impact of FAS-related anomalies. *Drug Alcohol Depend*. 19(1): 51-70

Abel, E.L. and Sokol, R.J., 1991. A revised estimate of the economic impact of Fetal Alcohol Syndrome. *Recent Dec Alcohol.* 9: 117-125

Agüero, J.M., Carter, M.R. and Woolard, I. 2006. The Impact of Unconditional Cash Transfers on Nutrition: The South African Child Support Grant. Center for Global Development. Available at: http://www.cgdev.org/doc/events/11.07.06/unconditional%20cash%20transfers.pdf

Centers for Disease Control and Prevention., 2005. Guidelines for identifying and referring persons with fetal alcohol syndrome. *Morbidity and Mortality Weekly Report* 2005. 54(No. RR-11): 1 -14

Chopra, M., Daviaud, E., Pattinson, R., Fonn, S. and Lawn, J.E., 2009. Saving the lives of South Africa's mothers, babies, and children: can the health system deliver? *The Lancet*. 374(9692): 835-846

Declaration of Helsinki., 2008, Available at: http://www.wma.net/en/20activities/10ethics/10helsinki/index.html. Accessed on: 07/01/09

Hoyme, H.E., May, P.A., Kalberg, W.O., Kodituwakku, P., Gossage, J.P., Trujillo, P.M., Buckley, D.G., Miller, J.H., Aragon, A.S., Khaole, N., Viljoen, D.L., Lyons Jones, K., and Robinson, L.K., 2005. A Practical Clinical Approach to Diagnosis of Fetal Alcohol Spectrum Disorders: Clarification of the 1996 Institute of Medicine Criteria. *Pediatrics*. 115: 39-47

Johannesburg Stock Exchange., 2010, Exchange Rate. Available at: http://www.jse.co.za/Home.aspx. Accessed on: 23/06/10

Klug, M.G. and Burd, L., 2003. Fetal alcohol syndrome prevention: annual and cumulative cost savings. *Neurotoxicology and Teratology*. 25(6): 763-765

Kodituwakku, P., Coriale, G., Fiorentino, D., Aragón, A.S., Kalberg, W.O., Buckley, D., Gossage, J.P., Ceccanti, M. and May, P.A., 2006. Neurobehavioural Characteristics of Children with Fetal Alcohol Specturm Disorders in Communities from Italy: Preliminary Results. *Alcoholism: Clinical and Experimental Research*. 30(9): 1551-1561

May, P.A., Brooke, L., Gossage, J.P., Croxford, J., Adnams, C., Jones, K.L., Robinson, L. and Viljoen D., 2000. Epidemiology of Fetal Alcohol Syndrome in a South African community in the Western Cape Province. *Am J Public Health*. 90(12): 1905-12

May, P.A. and Gossage, J.P., 2001. Estimating the Prevalence of foetal alcohol syndrome: A summary. *Alcohol Res. Health.* 25:159-176

May, P.A., Gossage, J.P., Marais, A.S., Adams, C.M., Home, H.E., Jones, K.L., Robinson, L.K., Kale, N.C., Snell, C., Kullberg, W.O., Hendricks, L., Brooke, L., Stellavato, C. and Viljoen, D., 2007. The epidemiology of fetal alcohol syndrome and partial FAS in a South African Community. *Drug Alcohol Depend*. 88: 259-71

May, P.A., Gossage, J.P., Kalberg, W.O., Robinson, L.K., Buckley, D., Manning, M. and Hoyme, E., 2009. Prevalence and Epidemiologic Characteristics of FASD from Various Research Methods with and Emphasis on Recent In-School Studies. *Developmental Disabilities Research Reviews*. 15: 176-192

Mayosi, B.M., Flisher, A.J., Lalloo, U.G., Sitas, F., Tollman, S.M. and Bradshaw, D., 2009. The burden of non-communicable diseases in South Africa. *The Lancet*, 374 (9693): 934-947

Rendall-Mkosi, K., London, L., Adnams, C., Morojele, N., McLoughlin, J. and Goldstone, C., 2008. Fetal Alcohol Spectrum Disorder in South Africa: Situational and Gap Analysis. UNICEF, Pretoria.

Rice, D.P., Kelman, S. and Miller, L.S., 1991. Estimates of Economic Costs of Alcohol and Drug Abuse and Mental Illness, 1985 and 1988. *Public Health Reports*. 106: 307-316

Seedat, M., Van Niekerk, A., Jewkes, R., Suffla, S., Ratele, K., 2009. Violence and injuries in South Africa: prioritising an agenda for prevention. *The Lancet*, 374 (9694): 1011-1022

South Africa, Department of Health., 2002. Explanation of the Current Policy Regarding the Classification of Patients for the Determination of Fees. Available at: http://www.doh.gov.za/programmes/upfs/docs/annexureH.pdf. Accessed on 22/04/2010

South Africa, Department of Labour., 2009. What domestic workers and their employers should know about minimum wages and conditions of employment. Available at: http://www.uif.gov.za. Accessed on 20/01/2010

South Africa, Department of Social Services., 2009. You and Your Grants 2009/10. Available at: http://www.sassa.gov.za. Accessed on 31/03/2010

South African Revenue Service., 2009. Prescribed rate per kilometre. Available at: http://www.sars.gov.za/home.asp?pid=3784 Accessed on: 10/01/2010

Stade, B., Ungar, W.J., Stevens, B., Beyene, J. and Koren, G., 2006. The burden of prenatal exposure to alcohol: measurement of cost. *JFAS Int*. 4:e5: 1-14

Stade, B., Ali, A., Bennett, D., Campbell, D., Johnston, M., Lens, C., Tran, S. and Koren, G., 2009. The burden of prenatal exposure to alcohol: revised measurement of cost. *Can J Clin Pharmacol*. Vol 16(1): e91-e102

Standard Bank., 2009. Rand/ Dollar Exchange Rate. Available at: www.ed.standardbank.co.za/ExchangeM.html. Accessed on: 16/07/2010

StataCorp., 2007, *Stata Statistical Software: Release 10*. College Station, TX: StataCorp LP.

Statistics South Africa., 2009. Mid-year population estimates 2009. Available at: www.statssa.gov.z/publications/P0302/P03022009.pdf. Accessed on 19/04/2010

Statistics South Africa., 2010. Consumer Price Index History. Pretoria: Statistics South Africa

Stratton, K., Howe, C.J., Battaglia, F.C., 1996. Fetal alcohol syndrome: diagnosis, epidemiology, prevention, and treatment. Washington, DC: National Academy Press

Thanh, N.X. and Jonsson, E., 2009. Costs of Fetal Alcohol Spectrum Disorder in Alberta, Canada. *Can J Clin Pharmacol*. Vol 16(1): e80-e90

Viljoen, D., Cossage, J.P., Brooke, B.S., Adnams, C.M., Jones, K.L., Robinson, L.K., Hoyme, E., Snell, C., Khaole, N.C.O., Kodituwakku, P., Asante, K.O., Findlay, R.F., Quinton, B., Marais, A-S., Kalberg, M.A. and May, P.A., 2005. Fetal Alcohol Syndrome Epidemiology in a South African Community: A Second Study of a Very High Prevalence Area. *J Stud Alcohol*. 66(5): 593–604

Western Cape Provincial Treasury., 2010, Budget Overview of Provincial Expenditure 2010. Available at: http://www.capegateway.gov.za/eng/pubs/budgets/

World Health Organization (WHO)., 2005, Estimates of Unit Costs for Patient Services for South Africa. Available at: www.who.int/choice/costs/unit_costs/en/. Accessed on: 26/01/10

PART D: INFORMED CONSENT, QUESTIONNAIRE & DATA CAPTURE FORMS

1. CONSENT FORM

Hello, my name is _____ and I work for the University of Cape Town. I am approaching you to ask you if you would be willing to participate in a research study.

What is the purpose of the study?
The University of Cape Town, is doing research to estimate how much people use health services in the Western Cape for children with Foetal Alcohol Syndrome or FAS. We would like to find out what health care services you use for your child <name>, how often you use these services and what they cost. That is how much money families spend taking their children to the doctor, hospital or clinic and other health services. The questionnaire asks about your child and your child's health as well as questions about how much money you spend taking your child to health care facilities. We hope that the results from this study will help us better understand how much it costs you and your family and the health care services to look after a child with FAS.

What are the possible benefits of participating?
There will be no direct benefit to you; however the information we obtain from this study will give policy makers a better understanding of the costs of looking after a child with FAS. What you have to say could play an important role in ensuring that health care services have enough money to look after children with FAS and in helping to create better preventative public health programs. Your travel costs to attend the interview will be reimbursed and for the time that you spend being interviewed you will be given a supermarket shopping voucher.

What are the possible drawbacks or discomforts in participating?
This is only a survey so there is nothing painful or dangerous about participation; however you will be asked questions about your child's health and about money which may be very personal. Some people may find it difficult to discuss these matters.

Do I have to participate?
Your participation in this study is completely voluntary. Should you agree to participate you are required to sign this form. You are free to withdraw from the study at any stage and this will in no way affect your child's treatment at this clinic. If you agree to participate the interview should take approximately one hour.

What will happen to me if I participate?
Information regarding your child's health and the money that you spend on health care will be recorded and treated confidentially. This means that the information that you give will not be given to anyone without your permission, and when we draw up the report, no-one will be able to link any information in the report to you or your child.

Contact details. If you have any questions about this interview contact:

Professor Marc Blockman (Head of Health Sciences Faculty Human Research Ethics Committee)
Tel: 021- 406 6338 or
e-mail: mblockman@uctgsh1.uct.ac.za

Sarah Crede (Principle Investigator)
Tel 071 264 0911
e-mail sarahcrede@gmail.com
This study has been reviewed and approved by the University of Cape Town ethics committee.
I,…… (name of respondent in block letters) have read and understood all the information given to me about my participation in this study and I was given the opportunity to discuss it and ask questions. I volunteer to take part in this study. I have received a copy of this consent form.

_____ _____
Signature of respondent **Date**

Interviewer/ fieldworker: I have:

Explained the nature and purpose of the study to the respondent	N	Y
Handed over a copy of the consent form	N	Y

_____ _____
Signature of the interviewer **Date**

2. QUESTIONNAIRE

Utilization of health care services by children with Foetal Alcohol Syndrome

Participant Identification (ID) number: ☐☐

Patient's folder number: ☐☐☐☐☐☐☐☐

Site where interview was conducted: _____

Date of Interview: Day ☐☐ Month ☐☐ Year ☐☐

Name of Interviewer: _____

SECTION 1: Information about child with FAS/ PFAS

READ: "Firstly I would like to ask you some questions about your child that you bring to the *Child and Family unit at Red Cross Children's Hospital/ Out Patient department at Tygerberg or Paarl hospital"*

101. Is the child male or female?

Male	0
Female	1

102. How old will this child be **at his/her next birthday**? (If it is a baby, put 1)

[____|____] enter age in years

103. What is the diagnosis of the child?

Foetal Alcohol Syndrome (FAS)	1
Partial Foetal Alcohol Syndrome (PFAS)	2
Don't know	88

104. What is your relationship to the child?

Biological parent	1
Adoptive parent	2
Foster parent	3
Step parent	4
Other (specify)……	5

105. Does your child go to school?

No	0
Yes	1

IF NO SKIP TO SECTION 2
IF YES..

106. In what grade is your child at school?

No schooling	0
Preschool	1
Grade 1	2
Grade 2	3
Grade 3	4
Grade 4	5
Grade 5	6
Grade 6	7
Grade 7	8
Other (specify)……..	9

107. Has your child failed a grade at school?

No	0
Yes	1

IF NO SKIP TO QUESTION 109

IF YES.. FOR EACH TIME THAT THEY FAILED

108. Please list the grade that the child failed and how many times the child failed this grade

	Grade the child failed	Number of times this grade was failed
1		
2		
3		
4		

109. Has your child's teacher ever reported any problems with your child at school?

No	0
Yes	1

IF NO SKIP TO SECTION 2
IF YES..

110. Which of the following best describes the problem/s reported by the teacher?
Read responses. (Can be more than one)

Learning difficulty	1
Behavioural problem (e.g. fighting, not co-operating, aggressive, can't sit still in class)	2
Medical problem (e.g. sick often, hearing problem, poor vision)	3
Other (specify)……	4

111. Does your child receive any special services for the problems reported by their teachers?
(These services may include extra lessons, counseling)

No	0
Yes	1

IF NO SKIP TO SECTION 2
IF YES..

112. If yes please list what these special services are

	Service
1.	
2.	
3.	
4.	

SECTION 2. Information about the caregiver

READ: "Now I would like to ask you some questions about yourself"

201. Gender of caregiver

Male	0
Female	1

202. How old will you be on your **next birthday**? [____|____] enter age in years

203. What is your residential address?_____
_____
_____

204. Which of the following would best describe your employment situation?

Not working at all	0
Employed full-time	1
Employed part-time	2
Self-employed full-time	3
Self-employed part-time	4
Pensioner	5
Other (specify) ……..	6

205. Can you briefly describe what work you do?

Not working: (unemployed or house wife)	0
Not working: Retired/pensioner	1
Not working: Disabled	2
Not working: Currently looking for work	3
General labourer/contract worker	4
Domestic work for others	5
Child minder	6
Services (hotel, cafe, shop)	7
Professional (teacher, nurse)	8
Student	9
Clerk/administrator	10
Other (specify)……..	11

206. What was the highest standard/ grade you passed at school?

No schooling	0
Sub A/sub B/grade 1/grade 2/grade 3	1
Grade 4/ Standard 2	2
Grade 5/ Standard 3	3
Grade 6/ Standard 4	4
Grade 7/ Standard 5	5
Grade 8/ Standard 6	6
Grade 9/ Standard 7	7
Grade 10/ Standard 8	8
Grade 11/ Standard 9	9
Grade 12/ Standard 10	10
Diploma/certificate with Grade 11 or lower	11
Diploma/certificate with Grade 12	12
Degree	13
Other (specify).....	14

207. What is the average monthly income of your household? (A household includes everyone who eats and sleeps in the house for at least 15 days of each month and income includes: all wages, grants, pensions and remittances earned by everyone in the household).

(**Indicate if patient does not want to answer, must ask question even if they say they are unemployed)**

Under R500	01
R501-R1000	02
R1001-R1500	03
R1501-R2000	04
R2001-R3000	05
R3001-R4000	06
R4001-R5000	07
R5001-R6000	08
R6001-R7000	09
R7001-R8000	10
R8001-R9000	11
R9001-R10000	12
R 10000 –R20 000	13
> R20 000	14
Don't know	88
Refuse to answer	98

208. Do you or anyone in your household receive any pension, disability grant or other type of grant from the government? **(May be more than one)**

No	0
Yes (Pension)	1
Yes (Disability grant)	2
Yes (Child support grant)	3
Yes (Foster care grant)	4
Yes (Child dependency grant)	5
Other (specify).....	6

IF NO SKIP TO QUESTION 210
IF YES..

209. How did you get access to the government grant?

Applied to social services	1
Referred by social worker	2
Referred by hospital/ doctor	3
Other (specify)……..	4

210. Do you have any form of medical scheme or Medical Aid cover? (Any scheme that helps you pay for health care services or medicine)

No	0
Yes	1

SECTION 3: Questions about Health care utilization

READ: "Now I would like to ask you some questions about your visit to *Red Cross Children's Hospital today/Tygerberg or Paarl Hospital today*."

301. How long did it take you to get to the hospital today?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

302. How did you get to the hospital today?

Walk	1
Own car	2
Taxi	3
Train	4
Bus	5
Other (specify)	6

IF OWN CAR SKIP TO QUESTION 304

303. How much did you pay for transport to get to the hospital today?
R_____

SKIP TO QUESTION 305

304. Approximately, how many kilometres did you do from home to the hospital **and back**? _____km

305. Did you have to take time off work for this visit?

No	0
Yes	1

306. How much time did you take off? _____hours

307. Did you have to ask someone to take care of other children at home while you came here?

No	0
Yes	1

IF NO SKIP TO QUESTION 310
IF YES..

308. Did you have to pay this person?

No	0
Yes	1

309. How much did you pay this person? R_____

READ: "I would now like to ask you some questions that relate to the health care services that you use for your child."

310. Has your child ever had surgery?

No	0
Yes	1
Don't know	88

IF NO OR UNSURE PLEASE SKIP TO QUESTION 312

If YES for each time he/she had surgery…

311. Please list for each surgical procedure that your child has had

	What was the surgery for?	Age of the child when this surgery was performed.
1		
2		
3		
4		

Hospitalization

READ: "I would now like to ask you some questions about other visits to hospital in the last 6 months."

312. Has your child been admitted to **ANY** hospital in the last 6 months? (This means that the child spent at least one night in the hospital)

No	0
Yes	1

IF NO PLEASE SKIP TO SECTION 4

If yes please ask the following questions...

313. For each admission to hospital in the last six months please can you tell me…At which hospital was your child admitted and how many days was your child in hospital?

PROBE: "Were there any other times your child was admitted to hospital in the last six months?"

	Which hospital?	How many days was your child in hospital?
1.		
2.		
3		
4.		

READ: "Now I would like you to think about the LAST time that your child was admitted to hospital"

314. Which hospital was your child in? _____

315. Who paid for this hospitalization?

Self or family member	1
State	2
Medical aid	3
Other (specify)….....	4
Don't know	88

316. How much did you pay for your child's last hospitalization? R_____

317. Were there any other medical costs that you had to pay at this last visit? (Includes medicine and medical supplies)

No	0
Yes	1

318. How much did these cost you? R_____

319. How long did it take you to get to the hospital from your home?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

320. How did you get to the hospital?

Walk	1
Own car	2
Taxi	3
Train	4
Bus	5
Other (specify)…….	6

IF OWN CAR SKIP TO QUESTION 322

321. How much did you pay for transport? R_____

SKIP TO QUESTION 323

322. Approximately, how many kilometres did you do from home to the hospital **and back**? _____km

323. Did you have to take time off work to care for your child during this hospitalization?

No	0
Yes	1

324. How much time did you take off? _____hours

325. Did you have to ask someone to take care of other children at home while your child was in hospital?

No	0
Yes	1

IF NO SKIP TO SECTION 4
IF YES...

326. Did you have to pay this person?

No	0
Yes	1

327. How much did you pay this person? R_____

SECTION 4: Government Hospital Out-patient visits

READ: "Now I would like to ask you some questions about the OUT-PATIENT visits you have made to government hospitals in the last 6 months. This does not include visits to the Day Hospital"

401. During the last 6 months have you visited an out-patient clinic at a government hospital for your child? (This is not the times when your child stayed in the hospital but may include out-patient visits, emergency services and collection of medication)

No	0
Yes	1

IF NO PLEASE SKIP TO SECTION 5
If YES...

402. How many times in the last 6 months have you taken your child to the out-patient clinic?

Once	1
Twice	2
Three times	3
Four times	4
Other (specify)……..	5

READ: "The <u>LAST</u> time the child was taken to the government hospital for an out-patient visit."

403. On your last visit to the government hospital out-patient department who was your child seen by? **(Can be more than one)**

Doctor	1
Nurse	2
Social worker	3
Occupational therapist	4
Physiotherapist	5
Dietician	6
Psychologist	7
Speech therapist	8
Dentist	9
Other (specify)…..……	10
Don't know	88

404. How long did you wait to be seen at the out-patient clinic at the government hospital?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

405. How long was the consultation with the person you took your child to?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

406. Who paid for this visit?

Self or family member	1
State	2
Medical aid	3
Other …….	4
Don't know	88

407. How much did you pay for this visit? R_____

408. Were there any other medical costs that you had to pay at this last visit to the out-patient department? (Includes medicine and medical supplies)

No	0
Yes	1

IF NO SKIP TO QUESTION 410
IF YES...

409. How much did you pay for these? R_____

410. How long did it take you to get to the out-patient clinic at the government hospital from your home?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

411. How did you get to the out-patient clinic at the hospital?

Walk	1
Own car	2
Taxi	3
Train	4
Bus	5
Other (specify)……..	6

IF OWN CAR SKIP TO QUESTION 413

412. How much did you pay for transport to get to the hospital?
R_____

SKIP TO QUESTION 414

413. Approximately, how many kilometres did you do from home to the hospital **and back?** _____ km

414. Did you have to take time off work for this visit?

No	0
Yes	1

IF NO SKIP TO QUESTION 416
IF YES...

415. How much time did you take off? _____hours

416. Did you have to ask someone to take care of other children at home while your child was in hospital?

No	0
Yes	1

IF NO SKIP TO SECTION 5
IF YES...

417. Did you have to pay this person?

No	0
Yes	1

418. How much did you pay this person? R_____

SECTION 5: Health care utilization -Private hospital

READ: "Now I would like to ask you some questions about using PRIVATE hospitals for your child."

501. During the last 6 months have you visited a private hospital for your child?

No	0
Yes	1

IF NO PLEASE SKIP TO SECTION 6
IF YES...

502. How many times in the last 6 months have you taken your child to the private hospital?

Once	1
Twice	2
Three times	3
Four times	4
Other (specify)……	5

READ: "Now I would like you to think about the LAST time the child was taken to the private hospital"

503. On your last visit to the private hospital who was your child seen by? (Can be more than one)

Doctor	1
Nurse	2
Social worker	3
Occupational therapist	4
Physiotherapist	5
Dietician	6
Psychologist	7
Speech therapist/ Audiologist	8
Dentist	9
Other (specify)……	10
Don't know	88

504. How long did you wait to be seen at the private hospital?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

505. How long was the consultation with the person you took your child to?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

506. Who paid for this visit?

Self or family member	1
State	2
Medical aid	3
Other	4
Don't know	88

507. How much did you pay the private hospital for this visit? R_____

508. Were there any other medical costs that you had to pay at this last visit? (Includes medicine and medical supplies)

No	0
Yes	1

IF NO SKIP TO QUESTION 510
IF YES...

509. How much did these cost you? R_____

510. How long did it take you to get to the private hospital from your home?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

511. How did you get to the private hospital?

Walk	1
Own car	2
Taxi	3
Train	4
Bus	5
Other (specify)……..	6

IF OWN CAR SKIP TO QUESTION 513

512. How much did you pay for transport to get to the private hospital? R_____

SKIP TO QUESTION 514

513. Approximately, how many kilometres did you do from home to the private hospital **and back?** _____ km

514. Did you have to take time off work for this visit?

No	0
Yes	1

IF NO SKIP TO QUESTION 516
IF YES...

515. How much time did you take off? _____ hours

516. Did you have to ask someone to take care of other children at home while your child was in hospital?

No	0
Yes	1

IF NO SKIP TO SECTION 6
IF YES…

517. Did you have to pay this person?

No	0
Yes	1

IF NO SKIP TO SECTION 6
IF YES…

518. How much did you pay this person? R_____

SECTION 6: Day Hospital/ Clinic- Primary level services

READ: "Now I would like to ask you some questions about your visits to the government clinic or day hospital for your child."

601. During the last 6 months have you visited a day hospital for your child?

No	0
Yes	1

IF NO PLEASE SKIP TO SECTION 7
IF YES...

602. How many times in the last 6 months have you taken your child to the day hospital?

Once	1
Twice	2
Three times	3
Four times	4
Other (specify)…….	5

READ: "Now I would like you to think about the LAST time you took your child to the day hospital."

603. Which day hospital did you visit _____

604. On your last visit to the day hospital who was your child seen by? (Can have more than one)

Doctor	1
Nurse	2
Social worker	3
Occupational therapist	4
Physiotherapist	5
Dietician	6
Psychologist	7
Speech therapist	8
Dentist	9
Other (specify)……..…….	10

605. How long did you wait to be seen at the day hospital?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

606. How long was the consultation with the person you took your child to?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

607. Who paid for this visit?

Self or family member	1
State	2
Medical aid	3
Other (specify)……	4
Don't know	88

608. How much did you pay the day hospital on this visit? R_____

609. Were there any other medical costs that you had to pay at this last visit? (Includes medicine and medical supplies)

No	0
Yes	1

IF NO SKIP TO QUESTION 611
IF YES…

610. How much did these cost you? R_____

611. How long did it take you to get to the day hospital from your home?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

612. How did you get to the day hospital?

Walk	1
Own car	2
Taxi	3
Train	4
Bus	5
Other (specify)……..	6

IF OWN CAR SKIP TO QUESTION 614

613. How much did you pay for transport to get to the day hospital?
R_____

SKIP TO QUESTION 615

614. Approximately, how many kilometres did you do from home to the day hospital **and back?** _____km

615. Did you have to take time off work for this visit?

No	0
Yes	1

IF NO SKIP TO QUESTION 617
IF YES…

616. How much time did you take off? _____hours

617. Did you have to ask someone to take care of other children at home while your child was in hospital?

No	0
Yes	1

IF NO SKIP TO SECTION 7
IF YES...

618. Did you have to pay this person?

No	0
Yes	1

619. How much did you pay this person? R_____

SECTION 7: Private Doctor (GP)

READ: "Now I would like to ask you some questions about visiting a <u>private</u> doctor (GP)"

701. During the last 6 months have you visited a private doctor for your child?

No	0
Yes	1

IF NO PLEASE SKIP TO SECTION 8
IF YES...

702. How many times in the last 6 months have you taken your child to a private doctor?

Once	1
Twice	2
Three times	3
Four times	4
Other……..	5

READ: "Now I would like you to think about the <u>LAST</u> time the child was taken to the private GP"

703. How long did you wait to be seen by the private doctor?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

704. How long was the consultation with the private doctor?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

705. Who paid for this visit?

Self or family member	1
State	2
Medical aid	3
Other (specify)……..	4
Don't know	88

706. How much did you pay the private doctor for this visit? R_____

707. Were there any other medical costs that you had to pay at this last visit? (Includes medicine and medical supplies)

No	0
Yes	1

IF NO SKIP TO QUESTION 709
IF YES…

708. How much did these cost you? R_____

709. How long did it take you to get to the private doctor from your home?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

710. How did you get to the private doctor?

Walk	1
Own car	2
Taxi	3
Train	4
Bus	5
Other (specify)…….	6

IF OWN CAR SKIP TO QUESTION 712

711. How much did you pay for transport to get to the private doctor? R_____

SKIP TO QUESTION 713

712. Approximately, how many kilometres did you do from home to the private doctor **and back?** _____km

713. Did you have to take time off work for this visit?

No	0
Yes	1

IF NO SKIP TO QUESTION 715
IF YES…

714. How much time did you take off? _____hours

715. Did you have to ask someone to take care of other children at home while your child was in hospital?

No	0
Yes	1

IF NO SKIP TO SECTION 8
IF YES…

716. Did you have to pay this person?

No	0
Yes	1

717. How much did you pay this person? R_____

SECTION 8: Health care utilization-Traditional healer

READ: "Now I would like to ask you some questions about visiting a Traditional Healer"

801. During the last 6 months have you visited a traditional healer for your child?

No	0
Yes	1

IF NO SKIP TO SECTION 9
IF YES...

802. How many times in the last 6 months have you taken your child to a traditional healer?

Once	1
Twice	2
Three times	3
Four times	4
Other (specify)……..……..	5

READ: "Now I would like you to think about the <u>LAST</u> time the child was taken to the traditional healer."

803. How long did you wait to be seen at the traditional healer?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

804. How long was the consultation with the traditional healer?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

805. Who paid for this visit?

Self or family member	1
State	2
Medical aid	3
Other (specify)……	4
Don't know	88

806. How much did you pay the traditional healer for this visit? R_____

807. Were there any other medical costs that you had to pay at this last visit? (Includes medicine and medical supplies, medical devices)

No	0
Yes	1

IF NO SKIP TO QUESTION 809
IF YES..

808. How much did these cost you? R_____

809. How long did it take you to get to the traditional healer from your home?

Up to 30 minutes	1
31-60 minutes	2
61-90 minutes	3
91-120 minutes	4
>120 minutes	5

810. How did you get to the traditional healer?

Walk	1
Own car	2
Taxi	3
Train	4
Bus	5
Other (specify)…….	6

IF OWN CAR SKIP TO QUESTION 812

811. How much did you pay for transport to get to the traditional healer? R_____

SKIP TO QUESTION 813

812. Approximately, how many kilometres did you do from home to the traditional healer **and back?** _____km

813. Did you have to take time off work for this visit?

No	0
Yes	1

IF NO SKIP TO QUESTION 815
IF YES...

814. How much time did you take off? _____hours

815. Did you have to ask someone to take care of other children at home while your child was in hospital?

No	0
Yes	1

IF NO SKIP TO SECTION 9
IF YES...

816. Did you have to pay this person?

No	0
Yes	1

817. How much did you pay this person? R_____

SECTION 9: Other questions

READ: "Finally I would like to ask you some questions about the time you spent caring for your child in the last 6 months."

901. In the last 6 months have you taken any time off work to stay at home and look after your sick child?

No	0
Yes	1

IF NO SKIP TO QUESTION 904

IF YES..

902. How many days have you taken off work? _____days

903. Did you get paid for these days?

No	0
Yes	1

904. Has your child ever been admitted into custodial care or to a long term institution?

No	0
Yes	1

IF NO SKIP TO END

IF YES..

905. For each time that your child was admitted into supervised care or to an institution please list

	Name of institution	Duration of admission	How much did this admission cost you?
1			
2			
3			
4			

READ: "We have come to the close of this interview. Thank you for your time. The information you have shared has been very helpful. I assure you that we will protect private information to the best of our ability."

3. DATA CAPTURE FORM

1. Folder number ☐☐☐☐☐☐☐

2. Physical Address of Child _____
_____
_____

3. Contact number _____

4. Home Language

English	
Afrikaans	
Xhosa	
Other ……	

5. Child's Gender:

Male	
Female	

6. Child's Date of Birth: Day ☐☐ Month ☐☐ Year ☐☐

7. Medical scheme cover:

No	
Yes	
No information	

Medical information

8. Child's Diagnosis

Foetal Alcohol Syndrome (FAS)	
Partial Foetal Alcohol Syndrome (PFAS)	

9. Birth weight: _____

10. Previous surgery at Red Cross Children's / Tygerberg/ Paarl hospital

	Date	Surgical Procedure
1.		
2.		
3.		
4.		
5.		
6.		
7.		

11. Admission to Red Cross Children's/ Tygerberg/ Paarl hospital in previous six months

	Admission Date	Discharge Date	Ward	Reason for admission
1.				
2.				
3.				
4.				
5.				
6.				
7.				

12. Visits to Red Cross Children's/ Tygerberg/ Paarl hospital other than admission in previous six months

	Date	Clinic visited	Who was child seen by
1.			
2.			
3.			
4.			
5.			
6.			
7.			

12. Admission to hospitals OTHER than Red Cross Children's/ Tygerberg/ Paarl hospital in previous six months

	Hospital admitted to	Admission Date	Discharge Date	Reason for admission
1.				
2.				
3.				
4.				
5.				
6.				
7.				

APPENDICIES

Appendix 1:

Drug and Alcohol Dependence

An International Journal on Biomedical and Psychosocial Approaches

Guide for Authors

Available at:
http://www.elsevier.com/wps/find/journaldescription.cws_home/506052/authorinstructions

An International Journal on Biomedical and Psychosocial Approaches
Sponsored by the College on Problems of Drug Dependence

Drug and Alcohol Dependence is an international journal devoted to publishing original research, scholarly reviews, commentaries, and policy analyses in the area of drug, alcohol and tobacco use and dependence. It is sponsored by the College on Problems of Drug Dependence (CPDD), the oldest scientific organization in the United States concerned with research on addiction. The goal of its editors is to promote mutual understanding of the many facets of drug abuse to the benefit of all investigators involved in drug and alcohol research, and to facilitate the transfer of scientific findings to successful treatment and prevention practices. Drug and Alcohol Dependence is currently being distributed to all the members of CPDD.

Submission of Manuscripts

All submissions to Drug and Alcohol Dependence are made online. Before beginning the submission process, authors are advised to read these instructions carefully and prepare the following separate files in advance: 1) Abstract 2) Manuscript text including a title page, abstract, references and figure legends, 3) tables (if any), 4) graphics files of figures (if any), 5)author disclosure statements (NEW! -see below) and 6) supplementary material for viewing with the online version of the journal (if any). Although it is possible to perform the submission in several steps, authors will find it easier to have all of the needed documents ready before they begin the process so it can be completed in one session.

By accessing the online submission system at http://ees.elsevier.com/dad authors will be guided stepwise through the creation and uploading of the various files. Authors will be requested to direct the manuscripts to the most appropriate Section/Category of research to assist in editor assignment, to provide some Key Words to assist with indexing the article as well as to select one or more scientific Classifications which will be used by the editor to identify reviewers with the appropriate expertise. There is a section for Editor Comments where authors are invited to direct comments to the editors or suggest possible reviewers (please also provide e-mail adresses) for their paper. If the paper has been invited to be part of a special issue of the journal, this issue can be selected during the Section/Category step.

Once the uploading is done, the system automatically generates an electronic (PDF) proof, which is then used for reviewing. The submitting author will be required to view this PDF and approve it for release to the journal office.

All correspondence, including the Editor's decision and request for revisions, will be processed through the system and will reach the corresponding author by e-mail. Once a manuscript has successfully been submitted, authors may track the status of their manuscript using the online submission system (details will be provided by e-mail).

For further details on how to submit online, please refer to the online Tutorial for Authors which can be accessed on the submission page. Authors may send technical queries concerning the submission process to the Author Support Team at esubmissionsupport@elsevier.com. Alternatively, contact the Central Editorial Office for the journal at dad@vcu.edu.

Elsevier also provides 24/7 Telephone Support for:

The Americas: +1 888 834 7287
Asia & Pacific: +81 3 5561 5032
Europe & the rest of the world: +353 61 709 190

Preparation of manuscripts

Manuscripts should be written in English. Drug and Alcohol Dependence is an international journal. Authors should avoid overly parochial national or regional perspectives. Addressing a geographically, politically, and culturally diverse readership will enhance the impact of your paper.

Types of Papers

Full-length Reports reporting original results of research within the field of drug, alcohol and tobacco use and dependence.

Review Articles of specialized topics within the scope of the journal. Typically, these are critical reviews of a field of research.

Short Communications reporting on research that has progressed to the stage where a preliminary publication is appropriate. The maximum length allowed will be 2000 words plus references and illustrations. There should be not more than 2 illustrations (figure or tables).

Commentaries express points of view on scientific matters or published papers. Typically, commentaries are solicited by the editors, but authors who wish to submit commentaries are advised to contact the editor-in-chief to discuss the suitability of the proposed paper. The journal does not publish letters to the editor, individual case studies or book reviews.

Manuscript submission requirements

The online manuscript submission system will guide you when and how to submit the following required items:

1) There should be a **title page** which provides a title and **addresses** (including postal codes) **for all of the authors** as they should appear in the publication and full **contact details for the corresponding author** (address with postal codes and countries, phone, FAX and E-mail).

2) An **abstract** with a 200-word summary (250-word maximum). Abstracts can be either unstructured or structured with specific sections describing the background, methods, results and conclusions.

3) 3-6 **key words or phrases** for indexing placed on the bottom of the abstract page.

4) The body of research reports will generally include introduction, methods, results and discussion sections. Further subheadings are acceptable. Review papers should also use section headings and subheadings. Sections should be numbered using the 1., 1.1, 1.1.1, 2., 2.1 etc. system. Extensive use of footnoting is not encouraged.

5) References should be assembled beginning on a separate sheet. Within the text they should be referred to by author surname and year. When referring to a work by more than two authors, the name of the first author should be given followed by et al. Examples of the correct format for citation within the text are (Jessor and Jessor, 1977; Smith and Davis, 1975) and (Chutuape et al., 2001). Citations to organization reports should spell out the name of the organization (National Institute on Drug Abuse, 2005). Personal communications and papers submitted for publication should be so indicated and appear with the source or author's name(s) in the text in parentheses. In the References section of the manuscript, they should be listed alphabetically by first author surname and must consist of names and initials of all authors, year, title of paper, abbreviated title of journal, volume number and first and last page numbers of the paper. Abbreviations of journal titles should conform to those used by Index Medicus (http://www.nlm.nih.gov/tsd/serials/lji.html). References to journals, books, chapters and reports should be in accord with the following examples:

Chutuape, M.A., Katz, E.C., Stitzer, M.L., 2001. Methods for enhancing transition of substance dependent patients from inpatient to outpatient treatment. Drug Alcohol Depend. 61, 137-143.

Jessor, R., Jessor, S.L., 1977. Problem Behaviour and Psychosocial Development: A Longitudinal Study of Youth. Academic Press, New York. National Institute on Drug Abuse, 2005. Epidemiologic Trends in Drug Abuse. Vol. 1: Proceedings of the Community Epidemiology Work Group. Highlights and Executive Summary. NIH Publication No. 07-5879A. U.S. Department of Health and Human Services, Washington, DC.

Smith, S.G., Davis, W.M., 1975. A method for chronic intravenous drug administration in the rat. In: Ehrenpreis, S., Neidle, A. (Eds.), Methods in Narcotics Research. Marcel Dekker, New York, pp. 3-21.

To cite material on the internet, the authors (if known) or organization, title of the page and the URL should be provided along with an [accessed on [date]] to indicate a date on which the cited material was present. Only internet pages of a relatively permanent nature should be cited (e.g. reports, data bases, electronic journals).

6) Figure legends (descriptive captions) should be numbered consecutively and typed on a separate page as a text file and included as part of the manuscript, not placed within the graphics file of the illustration. If there is more than one figure, the legends should be placed together on one page (or more if necessary).

7) Tables should be prepared as text files and are to be numbered consecutively (Table 1, Table 2, etc.) and uploaded as a step in the submission process. The captions go above the body of the Table and are left justified; Tables are read from the top down, consistent with others in this journal.

8) Figures of good quality should be submitted online as a separate file. The lettering should be large enough to permit photographic reduction. Simple black on white reproduces best, so avoid shading in the background and the use of 3D and other enhancements. If possible, place the key to the symbols or lines within the axes of the graph. Do not place the legend within the graphics file, as this is printed below the image by the publisher. If there are more than one panel in the figure, please assemble the panels as you would like them to appear in the journal within a single graphics file. Please refer to the generic Elsevier artwork instructions available in the "Author Information" menu on http://ees.elsevier.com/dad/

NOTE: **Tables and figures** should be so constructed that they, together with their captions and legends, will be intelligible with minimal reference to the text. Clinical Trials

9) *Drug and Alcohol Dependence* endorses the policy of the International Committee of Medical Journal Editors (guidelines available at www.icmje.org) on the **registration of clinical trials.** The ICMJE defines a clinical trial "as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like." Any trial that started recruiting on or after 1 July 2005 should be registered in a publicly owned, publicly accessible registry and should satisfy a minimal standard dataset. Please include the trial identification number within the manuscript. Should the ms be accepted, trials registered in www.clinicaltrials.gov will be hyperlinked in the online version of papers. There will be considerable flexibility in this policy during the first years of its implementation, so authors should not be discouraged from submitting reports of unregistered but well designed and conducted trials initiated after July 2005 without first contacting the editors.

Reporting Guidelines for Specific Study Designs

Reports of clinical trials are not always optimal and the editors of DAD encourage prospective authors to familiarise themselves with guidelines for reporting essential elements for the relevant study design. For reports of randomized controlled trials authors should refer to the CONSORT statement http://www.consort-statement.org/. The CONSORT guidelines provide a set of recommendations comprising a list of items to report and a patient flow diagram. Reporting guidelines have also been developed for a number of other study designs:

Initiative	Type of study	Source
CONSORT	randomized controlled trials	http://www.consort-statement.org
STARD	studies of diagnostic accuracy	http://www.consort-statement.org/stardstatement.htm
QUOROM	systematic reviews and meta-analyses	http://www.consort-statement.org/Initiatives/MOOSE/moose.pdf
STROBE	observational studies in epidemiology	http://www.strobe-statement.org
MOOSE	meta-analyses of observational studies in epidemiology	http://www.consort-statement.org/Initiatives/MOOSE/moose.pdf

Prior Publication of Results
The editors of *Drug and Alcohol Dependence* believe that interpretation of trial results and discussion of their clinical relevance are best suited to a peer-reviewed journal; however, we support disclosure of non-peer reviewed study results in publicly accessible databases, subject to their presentation in a 'dispassionate' format. Should you be considering disclosure of your results in a results database, please indicate which database and the timeframe of disclosure in the accompanying submission letter (and include a copy of the results as they are planned to be disclosed). Presentation of results in abstract, poster or oral presentation at a clinical or scientific meeting does not count as prior publication.

10) Author Disclosures - *NEW!!* As is widely acknowledged within medical publishing, the integrity of articles published in Drug and Alcohol Dependence depends in part on how well the Journal handles author disclosure. As described in detail below, authors are requested to provide three mandatory and one optional author disclosure sections; please do not include them in the manuscripts. The author disclosures will be automatically incorporated in the PDF builder of the online submission system. These statements will appear in the journal article if the paper is accepted. It is highly recommended that authors prepare these author disclosures prior to going online to submit the paper.

Sequence should be **Role of Funding Source** (required; default text "Nothing declared"), **Contributors** (should always state something when more than 1 author), **Conflict of Interest** (required; default text "No conflict declared") and **Acknowledgements** (optional).

The four statements should not be numbered
Headings should be in bold
No white space between the heading and the text
Same font size as the references

Role of Funding Source (mandatory)
Authors are kindly requested to identify who provided financial support for the conduct of the research and/or preparation of the manuscript and to briefly describe the role of the sponsor(s), if any, in study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the paper for publication. If the funding source(s) had no such involvement, authors should so state.

eg, Funding for this study was provided by NIMH Grant XXXXXXX; the NIMH had no further role in study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the paper for publication.

Contributors (mandatory)
Authors are required to declare their individual contribution to the manuscript under a subheading Contributors. All authors must have materially participated in the research and/or manuscript preparation, so roles for all authors should be described. The statement that all authors have approved the final manuscript should be true and included in the disclosure.

eg, Authors X and Y designed the study and wrote the protocol. Author Z managed the literature searches and summaries of previous related work . Authors X and Z undertook the statistical analysis, and author W wrote the first draft of the manuscript. All authors contributed to and have approved the final manuscript.

Conflict of Interest (mandatory)
The third aspect of the Journal's new policy concerns Conflict of Interest. ALL authors are requested to disclose any actual or potential conflict of interest including any financial, personal or other relationships with other people or organizations within three (3) years of beginning the work submitted that could inappropriately influence, or be perceived to influence, their work.

Examples of potential conflicts of interest which should be disclosed include employment, consultancies, stock ownership (except for personal investment purposes equal to the lesser of one percent (1%) or USD 5000), honoraria, paid expert testimony, patent applications, registrations, and grants. If there are no conflicts of interest, authors should state that there are none.

eg, Author Y owns shares in pharma company A. Author X and Z have consulted for pharma company B. All other authors declare that they have no conflicts of interest.

Acknowledgements (optional)
Finally, the Journal will publish Acknowledgements, in a separate section, and not as a footnote on the title page. If there are no acknowledgements there would be no heading or default language.

eg, We thank Mr A, who kindly provided the data necessary for our analysis, and Ms B, who assisted with the preparation and proof-reading of the manuscript.

11) Supplementary material (when applicable). Elsevier now also accepts electronic supplementary material to support and enhance your scientific research. Supplementary files will be published online with the electronic version of your article in Elsevier web products, including ScienceDirect: http://www.sciencedirect.com.

NOTE: Your published article will be assigned a digital object identifier (DOI) which is used to cite and link to the electronic documents. The DOI consists of a unique alpha-numeric character string which is assigned to a document by the publisher upon the initial electronic publication. The DOI will never change. Therefore, it is an ideal medium for citing a document, particularly Articles in Press because they have not yet received their full bibliographic information. The DOI can also be used to create an URL hyperlink to supplementary material associated to an article.

When you use the DOI to create URL hyperlinks to documents on the web, they are guaranteed never to change.

Readers will complete the following steps to view the supplementary material for your paper:

1. Open the following DOI site with a browser: http://dx.doi.org
2. Enter the entire DOI citation in the text box provided, and then click Go.

The article or supplementary material that matches the DOI citation appears in the browser window.

The DOI scheme is administered by the International DOI Foundation. Many of the world's leading learned publishers have come together to build a DOI-based article linking scheme known as *CrossRef*.

The article in the journal must be complete and fully comprehensible without reference to the Supplementary Material. The purpose of Supplementary Material is to provide additional and usually more detailed information for readers who are particularly interested in the study. Supplementary Material is not an integral part of a published paper; the suitability of the Supplementary Material is assessed by the editor but it is not subject to the peer review procedure as applied to articles in the journal. Supplementary Material may either accompany the first version of a manuscript submitted to the journal or in response to a request from an editor.

Scope of Supplementary material . Several types of material may be included in Supplementary Material. These may include more detailed tables of demographic data and of results and statistical analyses. In other cases, Supplementary Material provides an opportunity for authors to publish questionnaires used for data collection that are too long for inclusion in the journal article. Additional and more detailed figures and photographs, including colour pictures, can be reproduced in this way.

There is also a possibility of supplying audio and video files as Supplementary Material; in such cases, authors are advised to seek the advice of the Editor before preparing the material.

Format for submission . Supplementary Material should begin with a statement of the Title and Authors of an article exactly as they appear in the main manuscript, followed by the statement "This material supplements but does not replace the content of the peer-reviewed paper published in Drug and Alcohol Dependence". Authors should ensure that the journal article contains at least one footnote referring to the Supplementary Material.

The text of the Supplementary Material should to the extent possible be styled according to the usual format of the journal. However, when the intention is to display materials in an existing format (e.g. a questionnaire or psychological test materials), they may be reproduced without change.

Word-processor or rtf files for widely-used computer systems are acceptable. Word-processor files may include graphics. Separate graphic items may also be submitted in standard file formats such as metafiles, bitmaps, jpg or gif. Scanned images are acceptable but image sizes, colour depth and resolution should be adjusted to the minimum necessary to convey the required information at high quality. Files should not be submitted in proprietary formats that cannot be read without special software. At this time only media that can be read by Windows systems can be accepted.

Supplementary Material relating to a particular article may be submitted as more than one file. However, if a large number of files are submitted, editors may request they be combined into a smaller number of larger files. Editorial offices will convert all submitted files to pdf format; all Supplementary Material for any one article will be incorporated into one pdf file.

There is at present no specific limit on the file sizes for Supplementary Material but editors reserve the right to refuse excessively large files or material that they consider unsuitable for any other reason.

Colour reproduction

Drug and Alcohol Dependence is included in a new initiative from Elsevier: 'Colourful e-Products'. Through this initiative, figures that appear in black & white in print can appear in colour, online, in ScienceDirect at http://www.sciencedirect.com. There is no extra charge for authors who participate.

For colour reproduction in print, you will receive information regarding the costs from Elsevier after receipt of your accepted article. Please indicate your preference for colour in print or on the Web only.

Because of technical complications which can arise by converting colour figures to "grey scale" (for the printed version should you not opt for colour in print) please submit in addition usable black and white versions of all the colour illustrations. For further information on the preparation of electronic artwork, please see the "Author Information" menu at http://ees.elsevier.com/dad/

Ethics of experimentation

The journal and CPDD are committed to the protection of animal and human research subjects and ethical practices in science publishing. Studies submitted to Drug and Alcohol Dependence must have been conducted in accordance with the Declaration of Helsinki and according to requirements of all applicable local and international standards. An example of a widely accepted standard for research subject protection is the Guide for the Care and Use of Laboratory Subjects as adopted and promulgated by the US National Institutes of Health. Studies that entail pain or distress will be assessed in terms of the balance between the distress inflicted and the likelihood of benefit, and must be of such a nature that their objectives could not have been achieved by using less stressful procedures. All authors must conform to the highest standards of ethical conduct in the submission of accurate data, acknowledging the work of others, and divulging potential conflicts of interests. Policies on the handling of evidence for scientific misconduct can be obtained from the editors.

Copyright transfer

Upon acceptance of an article, you will be asked to transfer copyright (for more information on copyright see right hand menu "Author Information" at http://ees.elsevier.com/dad). This transfer will ensure the widest possible dissemination of information. If excerpts from other copyrighted works are included in the submission, the author(s) must obtain written permission from the copyright owners and credit the source(s) in the article. Elsevier has pre-printed forms for use by authors in these cases: contact Elsevier's Rights Department, Philadelphia, PA, USA: phone (+1) 215 238 7869, fax (+1) 215 238 2239, e-mail

healthpermissions@elsevier.com

Requests for materials from other Elsevier publications may also be completed on-line via the Elsevier homepage http://www.elsevier.com/locate/permissions.

Proofs

One set of proofs will be sent to the corresponding author. A form with queries from the copyeditor may accompany your proofs. Please answer all queries and make any corrections within 2 days of receipt. No alteration of the substance of the text, tables or figures will be allowed at this stage. Should there be no corrections, please confirm this.

Elsevier will do everything possible to get your article corrected and published as quickly and accurate as possible. In order to do this we need your help. When you receive the (PDF) proof of your article for correction it is important to ensure that all of your corrections are sent back to us in one communication. Subsequent corrections will not be possible, so please ensure your first sending is complete.

Tracking Accepted Manuscripts

After acceptance of your article by the journal, and following receipt of the files at Elsevier, authors can keep track of the progress of their accepted article, and set up e-mail alerts informing them of changes in their manuscript's status using the 'Track Your Paper' feature of Elsevier's Author Gateway (http://authors.elsevier.com/TrackPaper.html). You will receive a unique reference code together with the acknowledgement e-mail from Elsevier sent upon receipt of your manuscript files in the Elsevier production system.

Authors in Japan please note

Upon request, Elsevier will provide authors with a list of people who can check and improve the English of their paper (before submission). Please contact our Tokyo office: Elsevier Japan, 4F Higashi-Azabu, 1-Chome Bldg, 1-9-15 Higashi-Azabu, Minato-ku, Tokyo 106-0044, Japan, Phone: (03)-5561-5032; Fax: (03)-5561-5045; e-mail: jp.info@elsevier.com

Reprints

The corresponding author, at no cost, will be provided with a PDF file of the article via e-mail. The PDF file is a watermarked version of the published article and includes a cover sheet with the journal cover image and a disclaimer outlining the terms and conditions of use.

Appendix 2:

UNIVERSITY OF CAPE TOWN

Health Sciences Faculty
Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
e-mail: sumayah.ariefdien@uct.ac.za

03 February 2010

REC REF: 010/2009

Mrs SH Crede
School of Public Health & Family Medicine

Dear Ms Crede

PROJECT TITLE:. UTILIZATION OF HEALTH CARE SERVICES BY CHILDREN WITH FOETAL ALCOHOL SYNDROME.

Thank you for your submissions.

1.Your request to amend the study to include children attending Tygerberg hospital is granted. However, you will need to obtain permission from the medical superintendent at Tygerberg Hospital to use their site for recruitment.
2.Approval for this study is extended for a **further 12 months until 10 February 2011.**

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

pp

sAriefdien

UNIVERSITY OF CAPE TOWN

Health Sciences Faculty
Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
e-mail: sumayah.ariefdien@uct.ac.za

03 September 2009

REC REF: 010/2009

Mrs S Crede
Public Health & Family Medicine

Dear Mrs Crede

PROJECT TITLE: UTILIZATION OF HEALTH CARE SERVICES BY CHILDREN WITH FOETAL ALCOHOL SYNDROME.

Thank you for your letter to the Research Ethics Committee.

'Approval is granted for the inclusion of Paarl Hospital as an additional site for this study. This approval is conditional on hospital management giving permission for the research to take place at Paarl Hospital.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

Yours sincerely

Lesley Henley

PP **PROFESSOR M BLOCKMAN**
CHAIRPERSON, HSF HUMAN ETHICS

sAriefdien

Verwysing
Reference
Isalathiso 19/18/RP85/2009

Navrae
Enquiries
Imibuzo Dr N Peer

Telefoon
Telephone
Ifowuni 021 483 6858

Departement van Gesondheid
Department of Health
iSebe lezeMpilo

Women's Health Research Unit
School of Public Health and Family Medicine
Falmouth Building, entrance 5, level 3
Health Sciences Faculty
Anzio Road
University of Cape Town
7925

FAX: 021 – 406 6788

Dear Ms S Crede

RE: Utilization of Health Care Services by Children with Foetal Alcohol Syndrome

Thank you for submitting your proposal to undertake the above mentioned study. We are pleased to inform you that the department has granted you approval for your research.

Yours Sincerely

DR J CUPIDO
DEPUTY-DIRECTOR GENERAL
DISTRICT HEALTH SERVICES AND PROGRAMME
DATE: 23/10/2009

CC: DR B Kruger

Superintendent: Paarl Hospital

Dorpstraat 4
Posbus 2060
KAAPSTAD
8000

4 Dorp Street
PO Box 2060
CAPE TOWN
8000

Departement van Gesondheid

Department of Health

iSebe IezewMpilo

Verwysing: **Reference:**	**RESEARCH**	**Telefoon:** **Telephone:** **Ifowuni:**	**(021) 658 5383**
Navrae: **Enquiries:**	**Dr. T. Blake**	**Fax:**	**(021) 658 5166**
Datum: **Date:**	**3 March 2009**	**Email:**	**Tblake@pgwc.gov.za**

Sarah Crede
Women's Health Research Unit
Public Health and Family Medicine
Room 3.36
Observatory, 7925

Dear Ms Crede

RESEARCH PROJECT: Utilization of Health Care Services by Children with Foetal Alcohol Syndrome

Permission is hereby granted to conduct the above-mentioned research at Red Cross War Memorial Children's Hospital.

Kindly inform the Child and Family Unit of your starting date and how you will interact with staff and parents.

Yours sincerely,

Dr. T. Blake
Senior Medical Superintendent

Red Cross War Memorial Children's Hospital
Klipfontein Road / Private Bag
RONDEBOSCH
7700 / 7701

Rooikruis Oorlogsgedenk Kinderhospitaal
Klipfonteinweg / Privaatsak
RONDEBOSCH
7700 / 7701

11 February 2010

MAILED

Mrs S Crede
Department of Public Health and Family Medicine
University of Cape Town
Observatory
Cape Town
7925

Dear Mrs Crede

"Utilization of health care services by children with foetal alcohol syndrome."

ETHICS REFERENCE NO: N10/02/033

RE : APPROVAL

It is a pleasure to inform you that a review panel of the Health Research Ethics Committee has approved the above-mentioned project on 10 February 2010, including the ethical aspects involved, for a period of one year from this date.

This project is therefore now registered and you can proceed with the work. Please quote the above-mentioned project number in ALL future correspondence. You may start with the project. Notwithstanding this approval, the Committee can request that work on this project be halted temporarily in anticipation of more information that they might deem necessary to make their final decision.

Please note a template of the progress report is obtainable on www.sun.ac.za/rds and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly and subjected to an external audit.

Translations of the consent document in the languages applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372
Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Please note that for research at primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Hélène Visser at City Health (Helene.Visser@capetown.gov.za Tel: +27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

Approval Date: 10 February 2010

Expiry Date: 10 February 2011

Yours faithfully

MRS MERTRUDE DAVIDS
RESEARCH DEVELOPMENT AND SUPPORT
Tel: 021 938 9207 / E-mail: mertrude@sun.ac.za
Fax: 021 931 3352

Departement van Gesondheid
Department of Health
iSebe lezeMpilo

Verwysing
Reference
Isalathiso

Navrae
Enquiries
Imibuzo

Dr M.A. Mukosi

Telefoon
Telephone
Ifowuni

021-938 5966

Tygerberg Akademiese Hospitaal en
Mitchellsplein & Tygerberg Mondgesondheidsentrums

Tygerberg Academic Hospital and
Mitchells Plain & Tygerberg Oral Health Centres

Isibhedlele Sase Tygerberg Kwakunye Ne
Mitchells Plain Neziko Lamazinyo Lase Tygerberg

Privaatsak X3/ Private Bag X3
Tygerberg, 7505

Date: 1st February 2010

Ref: Your Research / Clinical trial No 010/2009 : Utilization of health care services by children with foetal alcohol syndrome.

Dear Ms Crede

PERMISSION TO CONDUCT YOUR RESEARCH/CLINICAL TRIAL AT TYGERBERG HOSPITAL

In accordance with the Provincial Research policy and Tygerberg Hospital Notice No. 40/2009, permission is hereby granted for you to conduct the above-mentioned research/clinical trial here at Tygerberg Hospital.

DR PTA CARTER
CHIEF DIRECTOR : TYGERBERG HOSPITAL
SH Crede

UNIVERSITY OF CAPE TOWN

Health Sciences Faculty
Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
e-mail: sumayah.ariefdien@uct.ac.za

14 January 2009

REC REF: 010/2009

Ms SH Crede
Department of Public Health

Dear Ms Crede

PROJECT TITLE: UTILIZATION OF HEALTH CARE SERVICES BY CHILDREN WITH FOETAL ALCOHOL SYNDROME.

Thank you for submitting this excellently prepared protocol.

It is a pleasure to inform you that the Ethics Committee has **formally approved** the above-mentioned study.

Approval is granted for one year till the 16th January 2010.

Please submit an annual progress report if the research continues beyond the expiry date. Please submit a brief summary of findings if you complete the study within the approval period so that we can close our file.

There are a few minor points to consider which relate to the consent form. It would be helpful to include the anticipated length of the interviews (+- one hour). This is especially important if a parent and child have been brought to hospital by the hospital transport services. Please could you also include the contact details for Professor Marc Blockman, chairperson of the Human Research Ethics Committee in case parents have any questions or concerns about their rights and welfare as research participants.

There is a minor typo in the consent form: to discuss these matter (not "theses").

An application form to conduct research at Red Cross Children's Hospital is attached. It is advisable to carry the Ethics Approval letter with you when doing the research on the hospital premises as the staff are authorised to question any researchers who conduct research in the clinics and wards.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

lemjedi

Yours sincerely

pp **PROFESSOR M BLOCKMAN**
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

The Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

lemjedi