MATERNAL HEALTH: COST ANALYSIS OF INTRODUCING THE UMBIFLOW VELOCITY DOPPLER SYSTEM AT PRIMARY HEALTH LEVEL. A PILOT STUDY CONDUCTED AT KRAAIFONTEIN COMMUNITY HEALTH CENTRE AND DURBANVILLE DAY CLINIC

By

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PREAMBLE

I. DECLARATION

I, Plaxcedes Chiwire, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

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II. THESIS ABSTRACT

Background:

A South African report, Saving Babies 2010-2011, reports 32,178 still births in a 2 year period of January 2010 to December 2011 within the 94% of the total hospitals who provide data to a Perinatal Problem Identification programme (PPIP). In order to deal with perinatal mortality, specifically Intra-Uterine Growth there is needed to equip the primary health care (PHC) with technology for monitoring. An instrument called the Umbiflow Doppler ultrasound machine has been developed and there is need to test its economic impact in the PHC.

Methods:

A cross- sectional analytical study was conducted in the Tygerberg Eastern Health District of the Metro Region of Western Cape, South Africa at two primary health care (PHC) facilities, one secondary level hospital, and one tertiary hospital namely Kraaifontein Community Health Centre (CHC), Durbanville Day Clinic, Karl Bremmer District Hospital, and Tygerberg Hospital respectively.

The aim of the research was to conduct a cost analysis in the introduction of an Umbiflow Doppler machine in the primary health care with the major goal being to reduce the number of perinatal deaths in the public health system.

A societal perspective was adopted. The cost analysis study was carried out on the already approved sample size of 139 patients stemming from the Umbiflow Clinical study. The inclusion criteria for patient participation was poor SF growth and late bookers >28 weeks attending Kraaifontein Community Health Care Centre and Durbanville Clinic for antenatal services.

The data collection instruments comprised of two questionnaires. The first questionnaire was for patient costing and the second for facility costing. Physical observation was used to calculate the staff time per general patient (one who does not need a Doppler) at the primary health level. The extra staff

time for a Doppler needing patient was attained from the Umbiflow system which captures time stamps automatically and uploads the information to a central server. The average time needed for a Doppler was validated in the facility questionnaire.

Results:

The average cost was higher for secondary hospital visit for Doppler screening (R194.77) compared to R73.62 for a visit to the primary health care. From the health system perspective, the cost was 722.28 rands and 6709.78 rands in the primary health care setting and hospital respectively. Doppler screening strategy in hospital level proved less costly than clinic based Doppler strategy,

Having adjusted for inflation and annualised and discounted the costs at the 3%, the average unit cost per patient at the PHC level was estimated to be ZAR 49.62, at the secondary level ZAR 36.27 and at the tertiary level ZAR 18.26.

The low unit cost estimates at the secondary and tertiary institutions were mostly affected by the extremely high number of referral patients attended to at Tygerberg in comparison to Karl Bremmer and Kraaifontein/Durbanville PHCs i.e. economies of scale. However, the total costs are extremely higher at secondary and tertiary hospitals

From the health care provider perspective only, then the hospital Doppler intervention is less costtly, highlighting the impact social costs have on an economic evaluation.

Conclusions:

The study findings show how less costly it is to adopt the portable, easy-to use, Umbiflow Doppler ultra-sound machine to reduce patient and health provider costs. It would also ensure patients do not abscond from referrals due to financial costs. Adopting a policy that can see wider implementation of the Umbiflow would be the first step to reducing the high rate of perinatal deaths and ensure favourable fetal outcomes.

III. ACKNOWLEDGEMENTS

Many thanks to the CSIR and Medical Research Council for funding the research. Special thanks to Dr. Olufunke. Alaba for guiding the economic research as well as the Umbiflow clinical research team which included Dr. Josef Madunda, Dr. Stefan , Sister Marvina Johnson and Rita van Rooyen

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1. RESEARCH PROTOCOL

1.0 Introduction

The study focus was on introduction of technologies that help in diagnosing fetus intrauterine growth retardation (IUGR) due to placental insufficiency i.e. the placenta's inability to provide sufficient blood flow for the fetus to continue growing relative to the standard growth curve which may result in death of the fetus if no treatment measures are taken i.e. perinatal mortality (Calhoun Rice, 2012). Perinatal mortality (PNMR) accounts for deaths during the period before the child is born (Stillbirths) and the first week of birth. It is calculated as the number of perinatal deaths per 1000 total births. (World Health Organisation, 2013) South Africa's definition of perinatal mortality differed from that of World Health organisation before 2005.

Improvement of maternal health and reduction of child mortality form Goal 4 and 5 of the Millennium Development Goals (MDGs) advocated by signatories to the United Nations in 2000, South Africa included (World Health Organisation, 2014). To achieve these goals it is critical that the mother and the fetus obtain medical monitoring during the 40-42 weeks pregnancy period to avoid disability or death of the child or the mother.

In South Africa perinatal period began at 28 weeks Gestational age at 1000g to day 28 days after delivery. World Health Organisation (WHO) perinatal period began at 22 (154 days) weeks Gestational age to day 7 (World Health Organisation, 2013). However, South Africa's PNMR since 2005 has adapted the WHO definition of PNMR (Health Systems Trust, 2013). At what cost will the introduction of the technology will the perinatal deaths avoided, and if so what magnitude of the perinatal deaths could be avoided is an important area of assessment in the study.

It is during this period that a fetus may fail to develop or suffers slow growth as a result of several clinical factors and maternal lifestyle habits (Mook-Kanamori et al., 2010). In case of death occurring during that period, it is recorded with the hope that answers as to the cause may be obtained. A South African report, Saving Babies 2010-2011 (Pattinson, 2013), reports 32,178 still births in a 2

year period of January 2010 to December 2011 within the 94% of the total hospitals who provide data to a Perinatal Problem Identification programme (PPIP)(Chopra et al., 2009).

The PPIP has been instrumental in auditing the perinatal, neonatal and maternal mortality in South Africa and is supported by the District Health Information System (DHIS) used by the department of health to collect statistics from all public institutions in the country (South Africa Medical Research Council, 2014). Apart from relying on information from the DHIS, the South African government has ventured on different programmes to help in improving the maternal and child mortality in the country.

One such programme is the African Union led project called The Campaign on Accelerated Reduction of Maternal Mortality in Africa (CARMMA) meant to reduce maternal, new-born and child mortality in Africa (African Union, 2012). The key issues rally upon sharing information on how to reduce mortality amongst the latter, continue, and introduce best practices and increase resources as well as political commitment in maternal health (African Union, 2012).

In essence, the pillars of CARMMA build upon the six building blocks of health systems strengthening namely, "service delivery; health workforce; information; medical products, vaccines and technologies; financing; and leadership and governance (stewardship)."(World Health Organisation 2007) If the 32,178 still births in South Africa are to be reduced and the MDG goals are to be attained, the aforementioned pillars will need rigorous strengthening.

Health care financing is a key component of health systems strengthening. Who pays for health care is a determinant that can strengthen or cripple the system. It affects utilisation of health care services. In South Africa, user fees were abolished to allow for more expecting mothers to access health care, resulting in a 4.6% average increase in booked deliveries (Jo Borghi, Ensor, Somanathan, Lissner, & Mills, 2006).

However, it resulted in high maternal mortality due the failure of the increase in patient load not matching the staff as well as the facilities available to cater for the patients. Proponents of Health Care strengthening advocate for increased financial incentives and infrastructural and technological additions and improvements to offset the increased patient burden which leaves the staff overworked and disgruntled resulting in low quality of service provision (Jo Borghi et al., 2006; Gilson & McIntyre, 2005; Gilson, 1997).

The introduction of technology into the PHC to assist human capital is seen as strengthening the Technology pillar of health systems. However, technological innovations are not always cheap and are usually confined to the secondary and tertiary institutions. Less costly technology in the clinics and community health centres (CHC) is likely to reduce hospital admissions by 44 %, caesarean sections due to foetal distress by 52% and possibly avert 20% of induced labour (Council for Scientific and Industrial Research, 2013).

There is a continuous quest for improved efficiency and equity in the health system, especially when an innovation is about to be introduced in a resource constraint setting. The costing of health services has been used to understand and monitor health care costs at the national level costs right down to facility level. Costing of health activities falls under the umbrella subject of Economic Evaluation.

Economic evaluation is an accepted method for the appraisal of health care programmes. It is one of the tools available to assist in choosing efficient alternatives from an array of alternatives that will maximize the use of resources. Economic evaluation may be defined as 'the comparative analysis of alternative courses of action in terms of both their costs and consequences' (Drummond et al., 1987).

The economic evaluation methods include Cost Minimisation Analysis, Cost-Benefit Analysis (CBA), cost utility (CUA), Cost Effectiveness Analysis (CEA) , and Budget Impact Analysis(BIA) (Haute Autorite de Sante 2012; Drummond et al., 2005; Torrance & Stoddart n.d.).

Economic Evaluation has been essential in budgeting for health care services, understanding the efficiencies and inefficiencies of the health care system. Importantly, costing of programmes helps management in deciding whether a programme should be implemented or cancelled given the start-up costs or incremental costs to the health system. The same applies for maternal health care costing.

a) Statement of the problem

Worldwide, perinatal mortality is assumed to reach 3.3 million per annum, with 6 out of 10 being stillbirths (World Health Organisation 2006). The developing countries account for 90% of worldwide PNMR statistics (World Health Organisation, 2006). The sub-Saharan African region has a perinatal mortality rate of 56 per 1,000 births (Chinkhumba et al., 2007).

According to statistics from WHO, South Africa has a maternal mortality ratio of 310 deaths per 100 000 lives births. The infant (under-1) mortality rate in 2010 was 41 deaths per 1 000 live births, while the under-5 mortality rate was 57 per 1 000 live births (South Africa Info. 2013). Such statistics have compelled national departments of health to require that all expecting mothers be monitored during the 9 month period, the full duration of conception to child birth.

In 2008/09 the National average PNMR 31.4/1000, with the Western Cape Province having the lowest (26.3/1000) and Free State the highest of 37.9/1000 (Health Systems Trust, 2008). In 2011, South Africa was reported to have 61 stillbirths per day and was ranked 176 out of 193 in terms of stillbirths (Times Live-SAPA, 2011). Factors attributing to perinatal death include intrauterine growth restriction, infections, and birth trauma, maternal disease, antepartum haemorrhage, intrapartum hypoxia, and spontaneous pre-term labour, fetal abnormalities whilst 38% of the still births are unexplainable (Health Systems Trust 2011).

Maternal disease may include HIV AIDs, Tuberculosis and effects from smoking amongst others (Health Systems Trust, 2011). Socio-economic factors also add to poor perinatal outcomes, e.g. poor maternal education, poor fed mothers may lead to low birth weight of the fetus or child (Ezechi & David 2010).

Conclusions regarding quality and availability of antenatal (during pregnancy) and intrapartum (during labour) care can be deduced from the stats above. In comparison to the developed countries, these statistics paint a gory picture of maternal health care in South Africa.

In order to avert unnecessary maternal and child mortality, South African government has had to concentrate on strengthening the health system pillars and shifting resources to primary health care (PHC) which is the first port of call for any pregnant woman. The National Strategic Plan for Maternal, New-born, Child and Women's Health (MNCWH) and Nutrition in South Africa 2012 – 2016 feeds into the PHC reengineering reinforcing the provision of community based MNCWH (South Africa's Department of Health, 2012).

Primary health care institutions are usually under resourced and face financial and technical problems. As part of the monitoring intrauterine growth of a fetus, measurements of the symphysis fundal (SF) are done by tape measure and plotted against a fetal growth chart (National Collaborating Centre for Women's and Children's Health, 2008). If the fetus has small gestational age (SGA), precautionary measures to avoid death or disability to the fetus may be taken in form of different treatment regimens depending on the cause(RC Pattinson, 2007).

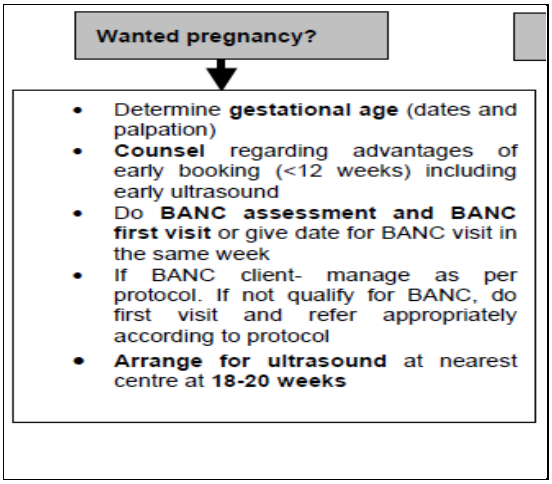
Due to technological innovations, the ultrasound machines have been used to check for low symphysis fundal. However, in developing countries where the 3D ultrasound machines are mostly found in the secondary level hospitals and not in the clinics, monitoring is restricted to tape measurements of the SF by the nurses. Consequently, issues of misdiagnosis of IUGR and SGA are rife and are only confirmed at the secondary level institutions. If a false positive occurs, there patient would have had to incur extra transport, time costs and lost

incomes whilst attending the referral which would later prove to be false. Secondly, the health system at secondary level incurs extra costs in evaluating the patient who in actual fact has no low SF as noted initially at the lower level hospital through tape measure usage (Dowie 2008).

i) South Africa's maternal health care protocol

In South Africa, the protocol to follow when a woman tests positive for pregnancy, assuming the baby is wanted is noted in the Basic Antenatal Care handbook. It states that a woman's ANC should begin during the first visit to the hospital (Pattinson, 2007). This may be in order to confirm pregnancy or when one already knows they are pregnant and are seeking ANC. Below is a table that shows the steps to be taken when a pregnancy is to be carried to full term.

Figure 1: Steps to be followed at first visit to the clinic



Source: Pattison (2007)

From there onwards the fetus growth is monitored by using a tape measure to measure the SF (Pattinson, 2007). In the South African Health system the SF growth measurement is administered by the nurses in the public hospital setting whilst in the private sector, the gynaecologist has the responsibility (Cronjé, Bam, & Muir, 1993b). In most cases the ultrasound is used as a secondary option to validate the results of tape measure monitoring.

The high powered ultrasound machines are normally situated at higher level hospital facilities, not at lower level primary care such as community health

centres and clinics. It therefore means when a patient is found to be at risk of low SF, they are referred to the higher level hospital for a Doppler ultrasound, which is conducted by a trained sonographer on a high powered ultrasound machine (Pattinson, 2007). The Doppler evaluation may confirm the low SF or may prove that there is no low SF growth.

Due to the complicated nature of evaluating fetal growth, there have been instances of false diagnosis noted as 2.5 times for every correct diagnosis (Cnattingius, Axelsson, & Lindmark, 1985) whilst some have noted 5% false negatives (National Collaborating Centre for Women's and Children's Health, 2008).

In the case of a referred patient being found to normal or not risky SF the patient is referred back to the community health centre or clinic for continuous monitoring for the rest of the pregnancy duration (Pattinson, 2007). It is essential to determine the costs incurred by the patients and the health care system in relation to the referral process to allow for reprioritisation of service provision which allows for efficiency and cost minimisation.

b) **Theoretical and empirical literature**

Several studies have been conducted to assess the effectiveness of intrauterine growth retardation monitoring with regards to finding clinical solutions in order to reduce perinatal mortality or morbidity (Henderson & Martin, 2000). Most of the studies compare the different strategies of monitoring IUGR and SGA against no monitoring at all.

The study samples include women with high risk pregnancies stemming from previous still births, hypertension, diabetes and those who would have been noted to have IUGR. However, most studies concentrate on the second trimester more than the first, limiting the range of assessing effectiveness of monitoring from early on in the pregnancy.

The monitoring strategies in most of the studies include monitoring of Body Mass index (Haws et al., 2009), SF measurement by tape measure and Doppler

ultrasound (Henderson & Martin, 2000; Marsál, 1994; Stampalija, Gml, & Alfirevic, 2010). Ultrasound screening is considered to provide more information regarding SGA and IUGR than the BMI and tape measure strategies allowing for much more accurate diagnosis (Henderson & Martin, 2000).

Some studies note there are a value in monitoring high risk pregnancies especially those with suspected placental dysfunction using the Doppler ultrasound (Haws et al., 2009; Henderson & Martin, 2000; Marsál, 1994).

However, a Cochrane review of Randomised and quasi-randomised controlled trials of Doppler ultrasound versus no Doppler ultrasound revealed that there was no evidence of the mother or fetus benefiting whether the Doppler was performed or not on second trimester women in two of the studies reviewed. They however, recommended that more reviews be done on first trimester women (Stampalija et al., 2010) as they could be a potentially opposite result.

Consequently, 16 studies reviewed collectively suggest that perinatal mortality can be reduced by 29% [RR 0.71, 95% CI 0.52-0.98] if Doppler monitoring is used together with other appropriate interventions. Despite the result, the data was not statistically significant. Below is a section on the history of Doppler ultrasound monitoring.

i) Fetus intrauterine growth retardation (IUGR) monitoring with Ultrasound

Amongst the technology that has been used to help human capital assess the health status of a fetus is the Doppler ultrasound machine. Over centuries, medical companies such as General Electric, Toshiba amongst others have competed in the production of new technologies that would, “protect fragile lives and promote growth and development (G.E. Healthcare, 2014).

To fulfil the goal of giving peace of mind to the parents, the ultrasound including Doppler machines have evolved from 2D imagin,3D and now 4D imaging and is expected to evolve over time. The Doppler is a machine that uses sound waves to measure blood flow in the blood vessels. It is used to evaluate different

medical conditions such as strokes, pulmonary embolism, and deep vein thrombosis amongst others. In the case of pregnant women, it is used to check the blood flow through the umbilical cord to the placenta, of which supplies nutrients to the fetus. This is referred to as the Doppler ultrasound. A knob called a transducer is placed on the stomach above the blood vessels and it, "sends, and receives sounds that are amplified through a microphone.

The sound waves bounce off solid objects, including blood cells. The movement of blood cells causes a change in pitch of the reflected sound waves (called the Doppler Effect). If there is no blood flow, the pitch does not change. Information from the reflected sound waves can be processed by a computer to provide graphs or pictures that represent the flow of blood through the blood vessels." (WebMD, 2014)

The family of Doppler machines comprises of four types namely the "Bedside" or continuous wave, Duplex, Colour, and Power Doppler's. All the Doppler's produce sound waves which provide information on the blood flow. However the unlike the duplex, colour and power Doppler the continuous wave Doppler is portable and does not produce a picture and relies on the doctor/nurse's listening skills.

The Duplex Doppler produces a picture and the sound is reflect on a graph whist the Colour Doppler produces a picture as well as, "sounds into colours that are overlaid on the image of the blood vessel and that represent the speed and direction of blood flow through the vessel". (WebMD, 2014) Power Doppler is the most sophisticated of them all and it is used in the evaluation of vessels found in more solid organs. The Duplex, Colour and Power Doppler machines are mostly found in the secondary institutions in South Africa. An example of the continuous wave Doppler is an Umbiflow Doppler. It is discussed in detail in the next section.

ii) **The Umbiflow Doppler Machine**

The Council for Scientific and Industrial Research (CSIR) commissioned project has been instrumental in the testing of a miniature ultrasound Doppler machine

developed by Jeremy Wallis, South African Medical Research Council, CSIR and funded by the South African National Research Foundation for use in the lower level facilities (Council for Scientific and Industrial Research, 2003). The Umbiflow Doppler machine is meant for patients who do not present as high risk at the initial visits but with further monitoring are then suspected to have IUGR (Council for Scientific and Industrial Research, 2003). It is similar to the ultrasound machines used at tertiary hospitals but does not contain imagery of the womb. It is in the family of the continuous wave Doppler and, "uses continuous-waveform ultrasound to detect the blood flow within the umbilical cord of a fetus.

By using the Doppler Effect, the velocity of the blood flow can be determined, and from this an assessment is made on the ability of the placenta to supply sufficient oxygen and nutrition to the growing fetus."(Council for Scientific and Industrial Research, 2013) The Umbiflow Doppler which is used in conjunction with a computer and does not need a trained and experienced sonographer and can be operated by trained midwives and nurses.

A similar Pentium 3 PC based Umbiflow Doppler was used at Tygerberg hospital in the Western Cape Province (South Africa) for at least 5 years and placed in 2 community health care centres for trial purposes between the years 2002 and 2004 (Hugo, Grove, & Odendaal, 2007) as part of the primary health care reengineering programme.

The description of how the Umbiflow works by the manufactures is noted as follows,

"*Umbiflow consists of a self-contained software programme and a vascular transducer in the form of a hand-held probe that plugs into the USB port of a computer (desktop, notebook, or tablet). The USB port provides power to the probe and facilitates the signal transfer to a software application. The software processes the Doppler ultrasound signals to generate a high quality waveform depiction of the umbilical blood flow, and automatically calculates the so-called "resistance index" (RI) which can be directly linked to the functioning of the placenta. The blood flow umbilical cord is also audible in the loudspeakers and a*

digital interface allows the user to print the test results. Umbiflow is connected via the mobile network, and allows for remote expert monitoring so that centrally located obstetricians."(Council for Scientific and Industrial Research, 2003)

The study revealed the Umbiflow Doppler test run on the Pentium 3 PC which produced a normal flow velocity waveform was less likely to be followed by perinatal deaths (Hugo et al., 2007). However, no full economic impact study was done i.e. of the health system and from the patient perspective.

Figure 2: The Umbiflow ultrasound Doppler machine

Source: Council for Scientific and Industrial Research 2013

iii) Costing Models

The costing of health services has been used to understand and monitor health care costs at the national level costs right down to facility level. Costing of health activities falls under the umbrella subject of Economic evaluation. The subject sub-categorises economic evaluation into cost minimisation, cost utility, cost effectiveness, cost benefit and cost analysis (Drummond, Sculpher, & Hons, 2005; Haute Autorite de Sante, 2012; Torrance & Stoddart, n.d.). This has been essential in budgeting for health care services, understanding the efficiencies and inefficiencies of the health care system.

Importantly, costing of programmes helps management in deciding whether a programme should be implemented or cancelled given the start-up costs or incremental costs to the health system. The same applies for maternal health care costing. There is an urgency to save funds whilst continuing to provide quality maternal health care, thus the need to find out at what cost the

programme can be implemented and the incremental costs of adding a service in a facility. The cost effectiveness studies around the issue of stepping up maternal health care are mostly concentrated in developing countries where 98% of the worldwide perinatal deaths occur (Bhutta, Yakoob, Lawn & Rizvi, 2011).

A study of maternal health care costs in 3 countries namely Malawi, Uganda and Ghana assessed the different facility costs to help ascertain any need for management restructuring for improvement of maternal health services (Levin et al., 2003). The costing study of maternal health care in Blantyre district, Malawi revealed the complexities of different facility arrangements. The costs at public hospitals were noted to be higher than those at mission hospitals, an inverse to most studies which found mission hospitals to be less costly. Like South Africa, Ghana offers free ANC. In a cross sectional study which followed a step-down allocation approach, the average cost per ANC visit in Ghana from the health care perspective was US$18 (Dalaba et al., 2013).

In the case of facilities offering intense basic and advanced care to pregnant women, with a 99% coverage approximation, there is likelihood that 45% of 3 million still births in the 3rd trimester recorded annually worldwide (Robert Pattinson, Kerber, Buchmann, & Friberg, 2011), 54% of maternal deaths (Bhutta et al., 2011), and 43% of the Neonatal deaths could be deterred in 68 priority countries of which South Africa is included (Robert Pattinson et al., 2011).

The cost as deduced from the Lives Saved Tool for the preferred outcome would amount to between $0.96 $US 2,32 per pregnant woman monitored using ingredients costing of recurrent costs only, i.e. not capital costs included. A primary costing conducted at Liverpool Women's Hospital regarding ultrasounds on pregnant women revealed a cost of ultrasound for growth abnormalities to be approximately £15.71 (£13.58–£17.84) whilst for fetal well-being scan cost £15.46 (£11.67–£21.16) (Henderson & Martin, 2000).

A review of Popline, Medline and donor websites databases reviewed that they were not many cost effectiveness, cost utility, cost benefit and cost analysis in

the field of maternal health (Josephine Borghi, n.d.). A few that could be found are listed in Table 1.

Table 1: Studies on Cost of Antenatal Care (US$)

Country	Public Hospital		Public Health centre		Private maternity home[a]	At home (MC)
	Average cost (AC)	Marginal cost (%AC)	Average cost	Marginal cost (%AC)	Average cost	
Bolivia (secondary)[c]	7.03 (incl. Lab on 1st visit)	NA	7.13	NA	NA	NA
Bolivia tertiary level	13.87 (incl. lab on 1st visit)	NA	NA	NA	NA	NA
Mexico	NA	NA	7.47[c] 4.74[a]	NA	NA	NA
Ecuador[e]	NA	NA	3.48	NA	NA	NA
Uganda public	4.18[a] 2.60[f]	1.48[a] (35) 1.25 (55)[f]	2.21[a]	1.03[a] (47)	1.39/3.42 (0.71/3.01)	NA
Uganda mission[a]	5.20	4.10 (79)	6.43	1.60 (25)	NA	NA
Malawi public[a]	5.48	4.44 (81)	3.23	2.18(67)	NA	NA
Malawi mission[a]	5.77	5.08 (88)	4.18	2.94 (70)	NA	NA
Ghana public[a]	5.45	2.59 (48)	3.17	1.94 (61)	3.02 (1.13)	NA
Ghana mission[a]	2.97	2.09 (70)	4.03	2.37 (9)	NA	NA
Argentina[g]	28.75 (24.40; 42.51)	7.90 (27)	33.46 (26.44; 31.06)	1.65 (5)	NA	NA
Cuba[h]	12.15 (8.85; 15.46)	4.15 (34)	NA	NA	NA	NA
Thailand[i]	6.20 (5.33; 7.06)	1.46 (24)	NA	NA	NA	NA
South Africa[j]	9.05 (7.47; 10.62)	0.95 (10)	7.24 (5.78; 8.70)	0.42 (6)	NA	NA
Bangladesh[k]	NA	NA	17.83-92.74 per QALY gained or 30.12-78.29 per QALY gained	NA	NA	NA
Grenada[l]	NA	NA	25.13-29.92	NA	NA	NA
The Gambia[m]	NA	NA	21.32; 9.93	NA	NA	NA
India[n]	NA	NA		NA	NA	4.63 (0.14)
Indonesia[o]	NA	NA	0.82-0.91	NA	NA	NA

Source: Borghi (n.d.)

The cost for South Africa listed in the table above was for the year 2000 (Jinabhai et al., 2000) and there don't seem to be any studies accessible on the public domain going forth.

1.1 Rationale of the Study

Given the discussion above, it is imperative that a study be carried out that sheds more light on the introduction of low cost technology which is also clinically effective in monitoring pregnancies and reduce unwarranted referrals to secondary and tertiary level of care hospitals. The purpose of the study is therefore to present a cost analysis of introducing the technology.

The Umbiflow Doppler wave machine discussed in the literature review is one such machine and considering a randomised control study (Cnattingius et al. 1985; Council for Scientific and Industrial Research, 2013; Cronjé, Bam, & Muir, 1993a; Haute Autorite de Sante, 2012) on it has proven it clinically effective, the economic impact needs to be proven and well documented before the decision to introduce the machinery in the primary health care level is taken.

The system can be manufactured at low cost and is easy-to-use so that only little training is required in order to obtain a Doppler measurement. The Umbiflow

software has since been upgraded and is being used in conjunction with a notebook (laptop) making it much more user friendly. Consequently, Umbiflow was specifically designed for use by nursing staff and midwives at primary health care facilities and antenatal clinics in remote settings where patients face long distances to a referral facility (Council for Scientific and Industrial Research, 2003).

One of the benefits of Umbiflow is that reduces "costs associated with secondary level tests that require specialised medical staff involvement" (Council for Scientific and Industrial Research, 2003). Estimates for standalone ultrasound equipment have been pegged at ZAR 200,000 with high-end equipment costing approximately ZAR 1.5 million (Council for Scientific and Industrial Research, 2013), too expensive to allow for the same specialised equipment to be placed at primary health care level.

The Umbiflow is produced at much lower costs (Council for Scientific and Industrial Research, 2013). It is essential to determine the true economic impact from the health and the social perspective if Umbiflow Doppler machine is to be permanently introduced in the primary health care level in South Africa's' public healthcare system.

1.2 Study Purpose and Objectives

The study purpose is to determine the economic impact of introducing an Umbiflow Doppler machine at the primary care level. The Objectives of the study are as follows:

- To determine the cost of introducing a continuous-wave Doppler analyser (Umbiflow Intervention) at primary antenatal care facilities
- To determine the average cost per patient to the secondary level hospital from the patient's perspective
- To determine the average cost per patient referral for a Doppler to the secondary level hospital from the health system perspective

1.3 Methods

Study design, Population sampling and Sample size

Umbiflow intervention programme

The study is cross- sectional analytical study. A societal perspective was taken in order to include not only the cost to the health sector but also the patient (Drummond et al., 2005; Guide, 2012; Tan-torres, 1981; Torrance & Stoddart, n.d.). It is more beneficial to include the patient perspective which gives a broad view on society's welfare which helps in policy decision making (Byford & Raftery, 1998).

The Economic Impact study was carried out on the already approved sample size of 139 patients stemming from the Clinical study. The 139 patient stems from the sample size calculation by Dr. Justin Harvey at Stellenbosch University. The inclusion criteria for patient participation is poor SF growth and late bookers >28 weeks attending Kraaifontein Community Health Care Centre and Durbanville Clinic for antenatal services. Based on that statistically established that 139 patients will fulfil the ethics approved inclusion criteria.

1.4 Measurements

a) Instruments

The data collection instruments comprised of two questionnaires. The first questionnaire was for patient costing and the second for facility costing. The first section captured demographic information, followed by socio-economic information, patient direct and indirect costs, and lastly guardian costs. The interviewer relied more on recall by the patient on their expenditure.

The facility costing relied on interviews of the staff at the different level facilities using a standard questionnaire. The first section of the facility costs questionnaire captures the general facility information such as name of facility, level of facility, opening times etc. This is followed by staff time for Doppler administering, equipment and furniture, building, and training costs.

Physical observation was used to calculate the staff time per general patient (one who does not need a Doppler) at the primary health level. The extra staff time for a Doppler needing patient will be attained from the Umbiflow system

which captures time stamps automatically and uploads the information to a central server. The average time needed for a Doppler was validated in the facility questionnaire.

1.5 Analysis Plan

a) Data Management

The hard copies of questionnaires are stored in a locked compartment and will be kept for the next 2 years after completion in which case they will be destroyed. Access to the questionnaires is limited to the researcher, supervisor, and the clinical research team put together by mHealth Inc.

b) Data Analysis

A societal perspective was adopted in the cost analysis. The costs were divided into 2 categories namely health systems and patient costs. The costs were calculated in Rand value, the South African currency at the year 2013 prices. Data was entered and summarised in the Microsoft excel for health care facilities. Microsoft excel was used to analyse the data. The Doppler ultrasound administering to a patient at different levels of care was be costed.

Health Systems Costs

The costs assessed encompassed the referral to secondary and tertiary institutions as well as implementing Umbiflow at primary health care level. The direct health system costs included recurrent costs of administering a Doppler were included in the analysis and where costs are shared, proportional allocation was used for calculations . These include consumables during patient assessment and staff costs. Overhead costs for Tygerberg and Karl Bremmer Hospitals, were not - included since they are an inherent part of the hospital programme and did not change due to the implementation of a Doppler programme.

The same applied to the clinics though it was clear the electricity bill for the clinic was affected assuming full implementation of the Doppler wave ultrasound or the 3D ultrasound at clinic level. Therefore, the electricity overhead costs were included in the primary health care level facility costing as

noted by Drummond, during a societal perspective costing, it is important to be weary of some costs causing measurement challenges when they do not have a major impact on the study results (Drummond et al., 2005).

Training costs for the staff administering were included. Training was considered a future investment and was discounted with 5%, 3% and 0% for comparison purposes. Capital costs were annualised to ascertain the cost in the year of assessment given they were used over a longer period of time.

The rate at which to discount cost has always controversial but there is a general consensus amongst economic evaluators. The French use the a social discount rate of at 4% as of 2005, assuming the time horizon is less than 30 years, reducing up to 2% thereafter (Haute Autorite de Sante, 2012). In a review of 147 economic evaluation studies conducted by the University of York the most commonly used rates for health costs were 3% and 5%, whilst some studies used 0% (Smith & Gravelle, n.d.).

Using the 3%-5% annual rate since it has been used in most of the published material gave room for referencing and comparison (Drummond 2005). The costs were discounted at 3% annually. Sensitivity analysis was done on the discount rate using 0% and 5%.
Costs of referral to the regional hospital (Karl Bremmer Hospital) or tertiary hospital (Tygerberg Hospital) for a Doppler will be assessed

$$PV = \sum_{t=0}^{T} \frac{Cost}{(1+r)^t}$$

PV = the present value; t = the period in which the costs occur; r i=the discount rate.

Patient Costs

The patient direct costs calculated included transport costs, food costs, and any payment for child care during the referral visit. Indirect costs included, opportunity cost of the referral, lost productivity which could be measured in terms of wages lost. This followed the economic evaluation method of the human capital and the friction costs method (Haute Autorite de Sante, 2012). Human capital entailed giving value to potential productivity loss whilst the

friction costs method calculated the loss of production due to absence at work (Haute Autorite de Sante, 2012).

Below is a table showing the cost parameters that were included in analysis.

Table 2: Categories of Cost Parameters

Cost Category	Type of cost	Components	Description
Direct Costs	**Provider costs**	**Recurrent costs**	
		Consumables	wipes, gel
		Staff	nursing, synographer staff
		Overheads	
		Rental	
		Capital costs	
		Equipment	knob, beds, chairs, ultrasound , computer
		Training	facilitator, writing materials, training materials
		Building	
	Patient Costs	Transport	public taxi , public taxi or bus, private car
		Food	
		Child care	creche
		Gaurdian	
Indirect cost	**Patient Costs**	Loss of Productivity	

Outcomes expected included the

- Average cost per patient /referral
- Average Health system cost per patient/referral
- Costs for introduction of Umbiflow Doppler Wave ultrasound in the primary health level
- Cost of introducing a 3D Doppler ultrasound machine in the primary health sector

1.6 Ethics

1. **Research Study proposal approval**

This proposal was submitted to the Human Research Ethics committee at the University of Cape Town. It should be noted that the clinical and economic impact research protocol of the Umbiflow Blood Flow Velocity Doppler System has been submitted to the CSIR and Stellenbosch for approval and was accepted. It was then forwarded to the Western Cape Department of health and was also

approved. The approvals have been added in the appendix section. The study adhered to the Declaration of Helsinki principles.

Informed consent

A Standard English consent form was developed for the clinical study and the same participants were interviewed for the economic impact assessment of the Umbiflow study. Consent was obtained from the patients using the standard form which has also been translated into Xhosa and Afrikaans. The participants voluntarily participated in the study and are allowed to withdrawal from participating at any point in time without explaining why. The participants were made aware of the reason of the economic impact research and the implications to the health system as well as to themselves.

2. **Participant confidentiality**

In order to protect the participants, special identifiers in form of unique numbers were used for each participant on the questionnaire. Only the research team had access to information on the questionnaires or any other information relating to the patients. Contact with the patients was only restricted to the research team.

3. **Risks and Benefits of participation**

Participation in the economic impact assessment has no risk whatsoever. It did no bodily harm to the participant or their pregnancy. The possible benefit derived from the study was to show the extent to which time and money is saved for the patient in case the Umbiflow is introduced at the primary health care level.

1.7 Stakeholder and Reporting

a) **Stakeholders**

- The parties that were affected by information provided by the study were :
- Pregnant women
- Council for Scientific and Industrial Research (CSIR)Provincial Health Department
- Medical Research Council
- Stellenbosch University
- South African National and Provincial Health Departments
- South African Health Care Facilities

- University of Cape Town

b) **Reporting**

The outcome of the study was disseminated to the stakeholders in the form of a report. The findings was also be presented at a Maternal Health Conference 2015. Participants also received the outcomes translated into layman's language in English, Afrikaans, and Xhosa in the form of a pamphlet.

1.7 Logistics

The duration of the research is expected to be 7 months as shown in the timetable below. Since the research is desktop based there were no costs involved.

a. Timetable

		Feb-14	Mar-14	Apr-14	May-14	Jun-14	Jul-14	Aug-14
Activity	**Method/Tools**							
Literature Review		x x x x						
Review of protocol/tools		x						
Review of financial records (comparator Umbiflow)	clinic level	x x						
Review of financial records (comparator duplex mode sonar)	higher level care	x x						
Review time and motion study (nursing/operator staff)	system time stamps		x x					
Data entry and analysis patient	questionnaires		x x x x	x				
Data entry and analysis nurse/operator	questionnaires		x	x				
Data entry and analysis study nurse	questionnaires			x				
Data entry and analysis health systems	records/research			x x				
Final data analysis for results section					x x x x			
Write-up						x x x x	x x x x	
Report								x
Paper and dissemination of findings								x x

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1.9 Protocol Appendices

Appendix A: Information and consent Form

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

- **TITLE OF THE RESEARCH PROJECT: Doppler field study**

- **PRINCIPAL INVESTIGATOR:**
- Dr Josef Mufenda

- **ADDRESS:**
- Department of Obstetrics and Gynaecology
- TYGERBERG HOSPITAL

- **CONTACT NUMBER: 24 hour emergency number 021 938 4707**

- You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

- This study has been approved by the **Health Research Ethics Committee at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

- **What is this research study all about?**

- This study is done to test a special, portable sonar machine called a Doppler device. Doppler tests, when indicated, are usually done at a large hospital as the machines are very big. This means that women have to travel on their own expenses to the hospital if a Doppler test is needed. For this field study, a smaller (portable) version of the same device will be tested to see if it can save women the expenses of travelling to another unit to have the test done.
- You have been selected for the study today as the sister examining your baby suspects that the baby may not be growing well. There could be several reasons for that, the most common one being a normal baby that is just smaller than other babies at this time.
- A Doppler test can distinguish between normal, but small babies and babies that are small due to specific problems, such as poor growth.
- This test is usually done at Karl Bremer or Tygerberg hospital, but for the study today we will do the same test on the smaller, mobile device, and the result will immediately be available. Nine out of ten times the baby will be normal, so you will know that good news within a few minutes.

- **Why have you been invited to participate?**

- We ask all women who has a baby who seems to be growing slowly to participate. This is part of routine management and you would have been asked to go to Karl Bremer hospital in any case for the same test.

- **What will your responsibilities be?**

- You must attend the clinic regularly on your appointment dates. All the visits will be part of routine care and you must try to do everything that is required for the best interest of your baby (for example live healthy, do not drink alcohol or smoke, make sure your baby is kicking regularly).

- **Will you benefit from taking part in this research?**

- The benefit from this study is for you and for future patients. You will receive the best care we can give. Instead of having to travel to another clinic or hospital, you

can have the test at your own clinic and you will know if everything is all right immediately.

- **Are there in risks involved in your taking part in this research?**

- Every pregnancy can have some complications, but by taking part in this study there are no bigger chance for complications than if you do not take part. In that case you will still have to go for the Doppler test at Karl Bremer hospital. If you do not go for the Doppler test, we will not know if the baby is having problems or not. There is a small risk that you will receive news that the baby is not growing well and will then be referred to Tygerberg Hospital. This may upset you when you learn the news, but we will be there to support you.

- **If you do not agree to take part, what alternatives do you have?**

- The alternative management will still be the same as before, except that you will be referred to another hospital for the test, and will then be managed according to that result. If normal, you will be referred back to Kraaifontein.

- **Who will have access to your medical records?**

- Only the doctors and nurses treating your pregnancy and delivery, as with any delivery at Kraaifontein MOU, Karl Bremer Hospital or TYGERBERG HOSPITAL.

- **Will you be paid to take part in this study and are there any costs involved?**

- No. Antenatal care and delivery is free at this hospital if you do not have a good income and the number of visits is the same as for any other high risk pregnancy.

- **Is there anything else that you should know or do?**
- You can contact the doctor on call at TYGERBERG HOSPITAL tel 0219384707 if you have any further queries or encounter any problems.

- You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.
- You will receive a copy of this information and consent form for your own records.

- **Declaration by participant**

- By signing below, I …….. agree to take part in a research study entitled DOPPLER FIELD STUDY.

- **I declare that:**
- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

- Signed at (*place*) …….. on (*date*) …….. 2005.

- ……
- **Signature of participant** **Signature of witness**

Appendix B: Patient Questionnaire

DD/MM/YY

RESEARCH QUESTIONNAIRE for :

Astudy of the economic impact and to establish a cost-benefit analysis ofFetal Umbilical Blood Flow Velocity Doppler System at Kraaifontein CHC, and Durbanville Day Clinic

Umbiflow is a sophisticated but easy-to-use Doppler with bi-directional indication of blood flow velocity in the umbilical cord. This type of continuous-wave ultrasound Doppler technology allows health care practitioners to assess placental function, in essence its ability to supply sufficient oxygen and nutrition to the growing fetus. The Doppler measurement is used to recommend specialist intervention should the fetus be at risk. The project was motivated by the status quo in South Africa is which Doppler interventions are only available at higher levels of care, and thus require patient referral, and potentially presenting avoidable cost and burden to both the health care system and the patient. Umbiflow was specifically designed for use by nursing staff and midwives at primary health care facilities and antenatal clinics in remote settings where patients face long distances to a referral facility.

The Umbiflow field trial consists of two parts and two phases namely to investigate clinical significance and is administered by a competent clinical study team and to study economic impact and to establish a cost-benefit analysis.

My name is (name). The organization I am working for, (name of organization), is interested in the costs that people face when they are seeking health care. Therefore, we would like to inquire how much money and time people spend on healthcare and more specifically on trips for antenatal visits and when referred for a Doppler to Karl Bremmers Hospital and Tygerberg Hospital from Kraaifontein Community Health Centre and Durbanville Clinic. It is important for you to understand that your participation in this study is completely voluntary. We would be really grateful if you would agree to participate in this study, but do feel free to refuse. If you refuse, there will be no consequence for you and you will receive whatever care and treatment you need at the health facility as usual. If you decline to participate you will not lose any benefit that you are entitled to such as receiving care and support that is provided at the clinic. If you choose to participate in this study you need to know that you may withdraw from the study at any stage without giving any explanation for your withdrawal. Your answers will be kept confidential. At some point I will ask you about your personal income and the income of your household. We will NOT provide this information to any tax or welfare authorities, also not after the end of the study. This survey will take about 30 minutes.

Do you have any questions? Do you want to participate? (Circle) Yes / No
If Yes: Thank you!
If No: Is there a reason why not?
1. Language not good enough 2. Time constraint 3. Not comfortable 4. Unspecified

Date 12/04/2014 **PID** 13609392

DD/MM/YY

OFFICIAL USE ONLY				
Patient ID	Date of interview (dd/mm/yy)	Name of PHC centre attended by patient (Kraaifontein or Durbanville day clinic)	Place of Interview (household or facility name)	Interviewer Name
			home	
Category of Facility *(Circle the appropriate one)*	Primary Health Care Centre	District/Provincially Aided Hospitals	Tertiary Hospital	
Interviewee	1. Same as patient 2. Guardian 3. Other			

DEMOGRAPHIC INFORMATION		
In the following questions, you may be asked to select a response from the provided options. Please indicate your response by placing a tick [√], circling or writing in the appropriate box.		
1.	How old were you on your last birthday?	
2.	Marital Status	1. Married 2. Single 3. Have a live in partner 4. Have a partner who does not reside in same house

Date 12/04/2014 **PID** 13609392

DD/MM/YY

Socioeconomic information, direct costs and Indirect costs incurred during visits to the clinic and Hospital

Circle most appropriate

3. Who is the primary income earner in the household?

1. Patient 2. Wife/mother 3. Husband/father 4. Extended family 5. Son/daughter
6. partner

What is the highest level of education of .....:

4. The patient?

1. Not attended/illiterate 2. primary 3. secondary 4.graduate/certificate 5. Other

5. Primary income earner?

1. Not attended/illiterate 2. primary 3. secondary 4.graduate/certificate 5. other

6. Head of household?

1. Not attended/illiterate 2. primary 3. secondary 4.graduate/certificate 5. primary income earner = head of hh

7. Spouse of head of household?

1. Not attended/illiterate 2. primary 3. secondary 4.graduate/certificate 5. other

8. Are you formally Employed? *Name all options first*	1. Yes, formal work *(go to 11)* 2. No, informal work *(go to 11)* 3. On sick leave *(go to 9)* 4. School, university (go to 14) 5. Retired *(go to 14)* 6. Combination (specify, go to 14)

Date 12/04/2014 **PID** 13609392

DD/MM/YY

	7. Patient does not work

9.Is the reason for Not Working related to the Pregnancy? 1. Yes 2. No

10. If Yes: **When was the last time you were working? .....**

11. How are you usually paid?
1. cash2. in kind 3. cash and in kind 4. not paid 5. bank transferred salary 6. other

12. What is your usual estimated personal take home earning per week? (includes welfare, disability, or other social support):

1. Under R300 per week 2. R301to R400 per week 3. R401-R500 per week 4. More than R500 per week 5. Don't earn

13. What is your estimated personal take home earning per month NOW? (includes welfare, disability, or other social support)
1. Under R300 per week 2. R301to R400 per week 3. R401-R500 per week 4. More than R500 per week 5. Don't earn
14. What is your weekly allowance?

If informal work
15. How many hours do you work on average per day? ..... Hours

16. How much are you paid per hour? R.....

17. How many hours did you work on the day you were referred to the hospital for a Doppler per day? ..... Hours

18. Is the change related to the appointment for referral for the doppler? 1. Yes 2. No

19. Did someone do the work (not related to child care) you were supposed to do on that day? 1. Yes 2. No
If yes go to 36

20. What relation is the person who worked on your behalf?

1. daughter 2. son 3. spouse 4. friend 5. nobody 6. other family

21. Did you pay them for the service?1. Yes 2. No

b)If you paid for the service, how much money did you pay? (State amount) R.....

22. Did you pay for child care while attending your visit at the referral clinic? If so, did you pay for child-care?

1. Yes 2. No

23. How much did you pay for child care? R.....

Date 12/04/2014 **PID** 13609392

DD/MM/YY

24. What mode of transport do you use to get to the clinic (Kraainfortein or Durbanville)?

1. bus 2. Private car 3. paid meter taxi 4. Walk 5. Public transport- train

26. How far is the clinic (Kraaifontein) from your house? Patient unsure so she gave us address to check- .....

25. How long (time) does it take you to get to the clinic (Kraaifontein)from your home? .....min

26. How much do you pay for transport to and from the clinic (Kraaifontein)?R.....

27. What mode of transport do you use to get to the hospital (Karl Bremmer) for the referral visit?

1. bus 2. Private car 3. paid meter taxi 4. Walk 5.public transport-taxi

28. How far is the hospital (Karl Bremmer) from your house? Patient unsure

29. How long (time) does it take you to get to the Hospital (Karl Bremmer) from your home? 45min

30. How much do you pay for transport to and from the Hospital (Karl Bremmer or Tygerberg) for referral visit?R...

31. How much time did you spend at the hospital on the referral visit (waiting time for presenting and procedure time)?

.....hrs

32. **Did you buy any food or drinks during referral visit?**1. Yes 2. No

b) If yes, How much did it cost? R....

Guardian Costs

33. a) Does any family/friend accompany you to any visits
1. Yes 2. No

b) *If YES,* **on which visits has your family/friend accompanied you and how much did he or she spent on each visit?**

Record PHC visits and referral visits separately
Complete at data entry:

Visit to PHC costs per visit: Transport _____ Food _____
Visit to referral hospital per visit: Transport _____ Food _____

Total Guardian PHC visit cost:
Total Guardian Referral visit cost :

How many hours do your guardian work on average per day? ..... Hours

Date 12/04/2014 **PID** 13609392

DD/MM/YY

34. How many hours did the guardian work on the day you were referred to the hospital for a Doppler per day? .....Hours

35. Is the change related to the appointment for referral for the doppler? 1. Yes 2. No

36. Did someone do the work (not related to child care) on your guardians behalf on the day of the referral visit? 1. Yes 2. No

37. Did you pay them for the service?1. Yes 2. No

38.If your guardian paid for the service, how much money did they pay? (State amount) R.....

39. Did your guardian pay for child care while attending your visit at the referral hospital? If so, did you pay for child-care?

(State amount) R .....

Comments by Interviewer:

Signature by Interviewer:.....

Appendix C: Facility Costing Questionnaire

1.0	General Information			
1.)	Were there any specific issues or events which prevented the facility from delivering its desired level of doppler services?			
			RECORD RESPONSE	Notes / comments
1.01	Type of health facility	Tertiary 1 Regional 2 Community Health Centre 3 Clinic 4		
1.02	How many health posts does this facility support	Number		
1.03	What is the ownership of the facility?	Government 1 Private		
1.04	What type of area is the facility located in?	Rural 1 Urban 2		
1.05	What year did the facility open?	*Example: 1941*		
1.06	When was the last major renovation in last 3 years?	a. Month b. Year		
1.07	What time does patrient care start and end?	07:30hrs to 16:00hrs 1 Open 24hrs a day (doesn't close) 2		
1.08	How does the facility provide antenatal services?	At the facility 1 Outreach 2 All of the above 3		
1.09	How many times a week are antenatal sessions provided?	Number		
1.10	What time do the antenatal visits start and end?	EXAMPLE: IF STARTS AT 7 AM, RECORD 0700 IF IT ENDS AT 7PM, RECORD 1900		
1.11	How often are outreach activities scheduled per month	Number of visits per month If no outreach enter 999		
1.12	How many zones are supported by this facility?			
1.13	What is the number of pregnant women in the catchment population of the facility in 2013?			
1.14	How many staff work in the antenatal clinic/ward?			

2	Staff Time for Doppler Administering

1.) In your opinion, do staff involved in the doppler programme have any spare or non-productive time?

(Also indicate non-productive time caused by situations not controllable by the staff)

2.) Other than normal staff time, do health workers spend overtime or use their off-days to conduct doppler services?

3.) Do you engage retired nurses or other health workers on contract to conduct doppler services.
If YES, record the number of hours and activities supported in the table below.

4.) To calculate staff time allocation to the activity , record the method of allocating time if applicable, e.g. # of dopplers done / total antenatal visits attendances or similar

	INTERVIEWER: List all health staff by position working in the facility that spend time on doppler administering etc. Include retired or par- time staff who assist in this activity	Civil servant (SALARY SCALE) **(PLEASE REFER TO PREVIOUS MONTH)**	Number of years in position	How many days per week does a member of staff usually work at this health facility?	How many hours per week does a member of staff usually work at this health facility?	What portion of these hours is spent on doppler related activities?
2.0	***Staff Time for doppler administering***	**2.01**	**2.02**	**2.03**	**2.04**	**2.05**
	Position			**DAYS/WEEK**	**HOURS/WK**	**HOURS/WK**
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						

3	*Equipment and Furniture*	*Brand name*	Capacity	Number Used	Useful Life	Current age of item	% Used for doppler	Replacement Price
Instruction: **On this sheet record all equipment being used during a doppler. This should include equipment partly used for doppler**								
	Doppler machine							
	Lap Top Computer							
	Printer							
	Speakers							
	Tables							
	Chairs							
	Cabinet							
	Bench							
	Lamp							
	Bed							
	Printer							

4	Building						
			Kraaifotein	Durbanville	Karl Bremmer	Tygerberg	Comments
4.01	What is the approximate area of the Health Centre?	Sq Meters					
4.01	What is the approximate area of the room(s) where the doppler is administered?	Sq Meters					
4.01	Are these rooms used exclusively for where the doppler is administered?	Yes/No					
4.01	If No, what percent of facility working time are these rooms used for where the doppler is administered?	% time					
4.01	What is the approximate area of the room(s) where the doppler machine is stored (if different from above)?	Sq Meters					
4.01	Are these rooms used exclusively for the doppler storage?	Yes/No					
4.01	If No, what percent of facility working time are these rooms used for doppler machine storage? (In the case of storage this could be % of available shelf space / floor area?)	% time					
4.01	What is the approximate area of the room(s) where doppler supplies and safety boxes are stored (if different from above)?	Sq Meters					
4.01	Are these rooms used exclusively for doppler supply storage?	Yes/No					
4.01	If No, what percent of facility working time are these rooms used for doppler supply storage?	% time					

5	*TRAINING COSTS*									

Additional remarks: Provide additional information for the folowing questions

1.) **How are staff selected for training and what category of staff are provided with doppler training?**

2.) **For those training expenses not paid for by the facility, please indicate where the expenses are incurred and managed.**

3.) **How is training initiated and by whom? Does the facilities request training or is it all arranged by the district / province / national?**

	TRAINING COSTS	5.01	5.02	5.03	5.04	5.05	5.06	5.07	5.08	Comments
		How many staff have received training related to the following?	How many training sessions by type were done?	Were any of these training events held for the first time? Yes=1, No=2	What was the average duration of the training (in days)?	What was the per diem per day for training?	What did the facility pay for organizing the events ? Put 00000 if no expenditure.	What were the expenditures made for printing and stationery ? Put 00000 if no expenditure.	What was the total expenditure made for training ? Put 00000 if no expenditure.	
A	Doppler administering									
B	Record-keeping and data for a doppler									
C	Other (specify_____)									

Appendix D: Western Cape Department of Health Approval

Western Cape Government
Health

STRATEGY & HEALTH SUPPORT
healthres@pgwc.gov.za
tel: +27 21 483 9907; fax: +27 21 483 9895
1st Floor, Norton Rose House,, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za

REFERENCE: RP 008/2013
ENQUIRIES: Ms Charlene Roderick

PO Box 19125
Tygerberg
7505

For attention: Dr J Mufenda, Dr S Gebhardtr

Re: Umbiflow Field trial

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.
Please contact the following people to assist you with any further enquiries in accessing the following sites:

Karl Bremer Hospital **Dr F Patel Tel.: (021) 918-1337 (Secretary)**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final report within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (healthres@pgwc.gov.za).
3. The reference number above should be quoted in all future correspondence.

We look forward to hearing from you.

Yours sincerely

DR NT Naledi
DIRECTOR: HEALTH IMPACT ASSESSMENT
DATE: 14/03/2013
CC **DR L BITALO** **DIRECTOR: NORTHERN / TYGERBERG**

Page 1of 1

Appendix E: Stellenbosch Research Ethics Committee Approval

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Approval Notice
Response to Modifications- (New Application)

23-Dec-2012
Mufenda, Josef J
Stellenbosch, WC

Ethics Refernce #: S12/10/263
Title: Umbiflow field study

Dear Dr Josef Mufenda,

The **Response to Modifications -** *(New Application)* received on **10-Dec-2012**, was reviewed by Health Research Ethics Committee 2 via Committee Review procedures on **13-Dec-2012** and has been approved.
Please note the following information about your approved research protocol:

Protocol Approval Period: **13-Dec-2012 -13-Dec-2013**

Present Committee Members:
Blaauw, Renee R
Barsdorf, Nicola
De Roubaix, Malcolm JAM
Moller, Marlo M
Willett, David DWE
Verster, Gerrit GC
Edwards, C E
Rohland, Elvira EL
Botha, Matthys MH
Davids, Mertrude MA
Fernandez, Pedro PW
Weber, Franklin CFS

Please remember to use your **protocol number** (**S12/10/263**) on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:
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 for an external audit.
Translation of the consent document to the language 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).

Provincial and City of Cape Town Approval

Please note that for research at a 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 Helene 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.

We wish you the best as you conduct your research.
For standard HREC forms and documents please visit: www.sun.ac.za/rds

If you have any questions or need further assistance, please contact the HREC office at 0219389207.

Appendix F: Council for Scientific and Industrial Research (CSIR) Research Ethics Committee Approval

CSIR Research Ethics Committee
PO Box 395 Pretoria 0001 South Africa
Tel: +27 12 841 4060
Fax: +27 12 841 2476
Email:R&DEthics@csir.co.za

18 March 2013

Dear: Ms Rita van Rooyen

Approval of Protocol: **Umbiflow Field Study**.

This is to confirm that your Protocol reviewed by the CSIR REC has been approved. The reference number of this research project is REF: 59/2013.

This approval is granted under the condition that:

1. The researcher remains within the procedures and protocols indicated in the proposal, as well as the additions made to the procedures and protocols as indicated in the responses submitted to the questions of the REC, particularly in terms of any undertakings made and guarantees given.
2. The researcher notes that the research must be submitted again for ethical clearance if there is substantial departure from the existing proposal.
3. The researcher remains within the parameters of any applicable national legislation, institutional guidelines and scientific standards relevant to the specific field of research.
4. This approval is valid for one calendar year from the date of this letter.
5. The researcher submit bi-annual progress reports to the REC
6. The researcher immediately alert the REC of any adverse events that have occurred during the course of the study, as well as the actions that were taken to immediately respond to these events.
7. The researcher alert the REC of any new or unexpected ethical issues that emerged during the course of the study, and how these ethical issues were addressed. If unsure how to respond to these unexpected or new ethical issues as they emerge, the researcher should immediately consult with the REC for advice.
8. The researcher submit a short report to the REC on completion of the research in which it is indicated (i) that the research has been completed; (ii) if any new or unexpected ethical issues emerged during the course of the study; and if so, (iii) how these ethical issues were addressed.

We wish you all of the best with your research project.

Kind regards

Dr Mongezi Mdhluli

(CSIR REC Chair)

Dr Sandile Ncanana

(CSIR REC Secretariat)

2. LITERATURE REVIEW

The literature review section will review theoretical and empirical literature. The key words used in literature search included, perinatal mortality, maternal mortality, Doppler ultrasound, symphysis fundal (SF), fetal growth chart and gestational age (SGA). The search yielded 160 publications. However, not all of them met the criteria required. The criteria were to include articles which included costing information in the area of maternal health. Most of the articles were limited to clinical information only without and economic information on introduction of technologies in the health system. A 106 articles were then used as part of this literature review.

2.1 Introduction

There is an urgency to save funds whilst continuing to provide quality maternal health care, thus the need to find out at what cost the programme can be implemented and the incremental costs of adding a service in a facility. The cost effectiveness studies around the issue of stepping up maternal health care are mostly concentrated in developing countries where 98% of the worldwide perinatal deaths occur (Bhutta et al., 2011).

Improvement of maternal health and reduction of child mortality form Goal 4 and 5 of the Millennium Development Goals (MDGs) advocated by signatories to the United Nations in 2000, South Africa (SA) included (World Health Organisation, 2014). To achieve these goals it is critical that the mother and the fetus obtain medical monitoring during the 40-42 weeks pregnancy period to avoid disability or death of the child or the mother (Patterson, 2007). It is during this period that a fetus may fail to develop or suffer slow growth as a result of several clinical factors and maternal lifestyle habits (Mook-Kanamori et al., 2010).

A South African report, Saving Babies 2010-2011, reports 32,178 still births in a 2 year period of January 2010 to December 2011 within the 94% of the total hospitals who provide data to a Perinatal Problem Identification programme (PPIP)(South Africa Medical Research Council, 2014). The PPIP has been instrumental in auditing the perinatal, neonatal and maternal mortality in South

Africa and is supported by the District Health Information system (DHIS) used by the department of health to collect statistics from all public institutions in the country (South Africa Medical Research Council, 2014).

Apart from relying on information from the DHIS, the South African government has ventured on different programmes to help in improving the maternal and child mortality in the country. One such programme is the African Union led project called The Campaign on Accelerated Reduction of Maternal Mortality in Africa (CARMMA) meant to reduce maternal, new-born and child mortality in Africa (African Union, 2012).

The key issues rally upon sharing information on how to reduce mortality amongst the latter, continue, and introduce best practices and increase resources as well as political commitment in maternal health. In essence, the pillars of CARMMA build upon the six pillars of health systems strengthening namely, "service delivery; health workforce; information; medical products, vaccines and technologies; financing; and leadership and governance (stewardship)." (World Health Organisation, 2007) If the 32,178 still births in South Africa are to be reduced and the MDG goals are to be attained, the aforementioned pillars will need rigorous strengthening.

The introduction of technology into the PHC to assist human capital is seen as strengthening the Technology pillar of health systems. However, technological innovations are not always cheap and are usually confined to the secondary and tertiary institutions. Less costly technology in the clinics and community health centres (CHC) is likely to reduce hospital admissions by 44 %, caesarean sections due to foetal distress by 52% and possibly avert 20% of induced labour (Council for Scientific and Industrial Research, 2013).

2.1.1 South Africa Maternal Health

Neonatal mortality background

Worldwide, perinatal mortality is assumed to reach 3.3 million per annum, with 6 out of 10 being stillbirths (World Health Organisation, 2006). The developing

countries account for 90% of worldwide PNMR statistics (World Health Organisation, 2006). According to statistics from WHO, South Africa has a maternal mortality ratio of 310 deaths per 100 000 lives births. The infant (under-1) mortality rate in 2010 was 41 deaths per 1 000 live births, while the under-5 mortality rate was 57 per 1 000 live births (South Africa Information, 2013).

National departments of health require that all expecting mothers be monitored during the 9 month period, the full duration of conception to child birth. In 2008/09 the National average Perinatal Mortality Rate (PNMR) was 31.4/1000, with the Western Cape Province having the lowest (26.3/1000) and Free State the highest of 37.9/1000 (Health Systems Trust, 2008). In 2011, South Africa was reported to have 61 stillbirths per day and was ranked 176 out of 193 in terms of stillbirths (Times Live-SAPA, 2011). The table below gives a summary of births and deaths per level of care in South Africa during the years 2010-2011.

Table 3: South African Birth and Deaths per Level of Care 2010-2012

	Community Health Centres	District Hospitals	Regional Hospitals	Provincial Tertiary Hospitals	National Central Hospitals	Total
	500 grams +					
Total births	209096	548976	350838	99257	116399	1324566
Liveborn	207400	536883	341165	95956	111409	1292813
Survivor	207067	530229	336075	93746	108414	1275531
Early Neonatal Death	305	6257	4184	1765	2378	14889
Still Birth	1696	12093	9673	3813	4990	32265
Perinatal deaths	2001	18350	13857	5578	7368	47154
	1000 grams+					
Total births	207017	544480	345277	96871	112216	1305861
Liveborn	206791	534580	338236	94478	109019	1283104
Survivor	207067	529358	334816	93024	107144	1271409
Early Neonatal Death	205	4895	2747	1110	1425	10382
Still Birth	1219	9900	7041	2749	3197	24106
Perinatal deaths	1424	14795	9788	3859	4622	34488

Source: Pattison (2013)

Factors being attributing to perinatal death include intrauterine growth retardation, infections, and birth trauma, maternal disease, antepartum haemorrhage, intrapartum hypoxia, and spontaneous preterm labour, fetal abnormalities whilst 38% of the still births are unexplainable (Health Systems

Trust, 2011). Maternal disease may include HIV AIDs, Tuberculosis and effects from smoking amongst others (Health Systems Trust, 2011). Unexplained deaths are the highest amongst all causes or perinatal and still births in South Africa for babies weighing below 1000g.

Socio-economic factors also add to poor perinatal outcomes, e.g. poor maternal education, poor fed mothers may lead to low birth weight of the fetus or child (Ezechi & David, 2010). Conclusions regarding quality and availability of antenatal (during pregnancy) and intrapartum (during labour) care can be deduced from the stats above. In comparison to the developed countries, these statistics paint a gory picture of maternal health care in South Africa. Below is a table that shows how much of the perinatal, stillborn, and early neonatal deaths are unexplained, caused by intrauterine growth retardation (IUGR).

Table 4: The primary obstetric causes of death per level of care for babies 500g or more

Perinatal deaths	Community Health Centres	District Hospitals	Regional Hospitals	Provincial Tertiary Hospitals	National Central Hospitals
Unexplained intrauterine death	3.18	9.09	9.39	13.74	9.02
Intrauterine growth retardation	0.28	0.38	0.91	0.54	1.07
Still Births					
Unexplained intrauterine death	3.17	9.05	9.36	13.51	8.99
Intrauterine growth retardation	0.25	0.3	0.78	0.4	0.93
Early neonatal deaths					
Intrauterine growth retardation	0.03	0.08	0.13	0.15	0.14

Source: Saving Babies 2010-2011

In order to avert unnecessary maternal and child mortality, South African government has had to concentrate on strengthening the health system pillars and shifting resources to primary health care (PHC) which is the first port of call for any pregnant woman. The National Strategic Plan for Maternal, New-born, Child and Women's Health (MNCWH) and Nutrition in South Africa 2012 – 2016 feeds into the PHC reengineering reinforcing the provision of community based MNCWH (South Africa's Department of Health, 2012).

As part of the monitoring intrauterine growth of a fetus, measurements of the symphysis fundal (SF) are done by tape measure and plotted against a fetal growth chart (National Collaborating Centre for Women's and Children's Health, 2008). If the fetus has small gestational age (SGA), precautionary measures to avoid death or disability to the fetus may be taken in form of different treatment regimens depending on the cause. Due to technological innovations, the ultrasound machines have been used to check for low symphysis fundal. However, in developing countries where the 3D ultrasound machines are mostly found in the secondary level hospitals and not in the clinics, monitoring is restricted to tape measurements of the SF by the nurses.

Consequently, issues of misdiagnosis of IUGR and SGA are rife and are only confirmed at the secondary level institutions. If a false positive occurs, the patient would have had to incur extra transport, time costs, and lost incomes whilst attending the referral which would later prove to be false. Secondly, the health system at secondary level incurs extra costs in evaluating the patient who in actual fact has no low SF as noted initially at the lower level hospital through tape measure usage.

2.1.2 Innovative technologies and maternal and child health

The development of medical equipment has been central to fighting disease. The same applies to maternal and child health. Over the years new technologies have been developed to improve the outcomes of treating a patient. In Africa, maternal health has suffered greatly due to poor economies and non-functioning health systems. C.M. Morel et al., (2005) notes that,

"Improving the health of the poorest people in the developing world depends on the development of many varieties of health innovations, such as new drugs, vaccines, devices, and diagnostic tools, as well as new techniques in process engineering and manufacturing, management approaches, software, and policies in health systems and services." (Morel et al., 2005)

The screening of expectant mothers and need for prompt identification of those at risk or with abnormalities has led to increased technological innovations and

increased referrals to higher level hospitals equipped to handle the major complications. One of these technological innovations to detect IUGR is the Doppler ultrasound machine.

The Doppler ultrasound technology analyses blood flow and wave forms to measure blood flow in the blood vessels. It is a non-invasive measurement which reduces the incidence of costly invasive procedure which may prove unnecessary. It has been hailed for providing medical solutions through the mapping of blood flow in two dimensional forms and of recent years in three and four dimensional forms (3D and 4D imaging) which are expected to evolve over time (WebMD 2014).

The maternal Doppler ultra-sound is an innovation from the broader technologies of Dopplers which has led to the discovery of new clinical applications (Sigel 1998). Because Doppler technology deals with measuring and sensing blood flow in the vascular system, it is used to evaluate different medical conditions such as strokes, pulmonary embolism, and deep vein thrombosis amongst others.

In the case of pregnant women, it is used to check the blood flow through the umbilical cord to the placenta, of which supplies nutrients to the fetus (WebMD 2014). A knob called a transducer is placed on the stomach above the blood vessels and it, "sends, and receives sounds that are amplified through a microphone. The sound waves bounce off solid objects, including blood cells. The movement of blood cells causes a change in pitch of the reflected sound waves (called the Doppler Effect). If there is no blood flow, the pitch does not change. Information from the reflected sound waves can be processed by a computer to provide graphs or pictures that represent the flow of blood through the blood vessels."(WebMD 2014)

The family of Doppler machines comprises of four types namely the "Bedside" or continuous wave, Duplex, Colour, and Power Doppler's. All the Doppler's produce sound waves which provide information on the blood flow. However unlike the duplex, colour, and power Doppler the Bedside Doppler is portable

and does not produce blood vessel pictures or those of surrounding organs and relies on the doctor/nurse's listening skills (WebMD 2014).

The Duplex Doppler produces a picture and the sound is reflect on a graph whist the Colour Doppler produces a picture as well as, "sounds into colours that are overlaid on the image of the blood vessel and that represent the speed and direction of blood flow through the vessel". (WebMD 2014) Power Doppler is the most sophisticated of them all and it is used in the evaluation of vessels found in more solid organs. The Duplex, Colour, and Power Doppler machines are mostly found in the secondary institutions in South Africa. An example of the continuous wave Doppler is the Umbiflow Doppler Machine. It is discussed in detail in the next section.

2.1.3 The Umbiflow Doppler Machine

The Council for Scientific and Industrial Research (CSIR) commissioned project has been instrumental in the testing of a miniature ultrasound Doppler machine developed by Jeremy Wallis, South African Medical Research Council, CSIR and funded by the South African National Research Foundation for use in the lower level facilities (CSIR 2003).

The Umbiflow Doppler machine is meant for patients who do not present as high risk at the initial visits but with further monitoring are then suspected to have IUGR (CSIR 2003). It is similar to the ultrasound machines used at tertiary hospitals but does not contain imagery of the womb. It is in the family of the continuous wave Doppler and, "uses continuous-waveform ultrasound to detect the blood flow within the umbilical cord of a fetus.

By using the Doppler Effect, the velocity of the blood flow can be determined, and from this an assessment is made on the ability of the placenta to supply sufficient oxygen and nutrition to the growing fetus."(CSIR 2013) The Umbiflow Doppler which is used in conjunction with a computer based does not need a trained and experienced sonographer and can be operated by trained midwives and nurses.

A similar Pentium 3 PC based Umbiflow Doppler was used at Tygerberg hospital in the Western Cape Province (South Africa) for at least 5 years and placed in 2 community health care centres for trial purposes between the years 2002 and 2004[1] (Hugo et al., 2007) as part of the primary health care reengineering programme.

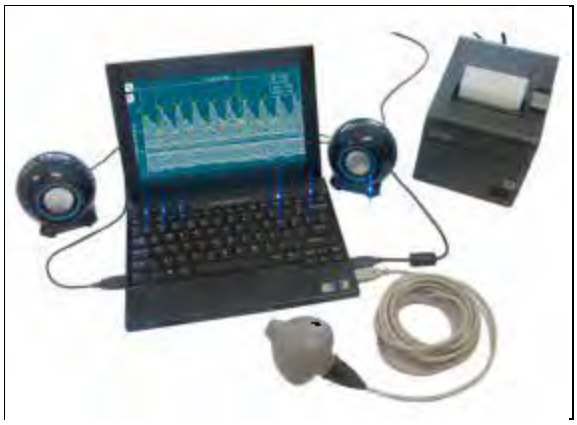
The description of how the Umbiflow works by the manufactures is noted as follows,

"*Umbiflow consists of a self-contained software programme and a vascular transducer in the form of a hand-held probe that plugs into the USB port of a computer (desktop, notebook, or tablet). The USB port provides power to the probe and facilitates the signal transfer to a software application. The software processes the Doppler ultrasound signals to generate a high quality waveform depiction of the umbilical blood flow, and automatically calculates the so-called "resistance index" (RI) which can be directly linked to the functioning of the placenta. The blood flow umbilical cord is also audible in the loudspeakers and a digital interface allows the user to print the test results. Umbiflow is connected via the mobile network, and allows for remote expert monitoring so that centrally located obstetricians*."(CSIR 2003)

The study revealed the Umbiflow Doppler test runs on the Pentium 3 PC which produced a normal flow velocity waveform was less likely to be followed by perinatal deaths (Hugo et al. 2007). However, no full economic impact study was done i.e. of the health system and from the patient perspective.

[1] Communiqué with Sr. Theron the Sonographer at Tygerberg Hospital on 13 December 2013.

Figure 3: The Umbiflow ultrasound Doppler machine



Source: Council for Scientific and Industrial Research 2013

Health care is a dominant economic and political issue in many economically developing and even developed nations. Most of these nations have experienced rapid increases in their healthcare spending over recent years. This challenge creates a continuing quest for reaching better health system efficiency, equity as well as quality and safety. It is therefore essential that all the budgeting and programme planning be costed beforehand. As noted by Henderson, 2002 economic costing of ultrasound scans are very sparse.

2.2 Costing

Cost Effectiveness Analysis (CEA)

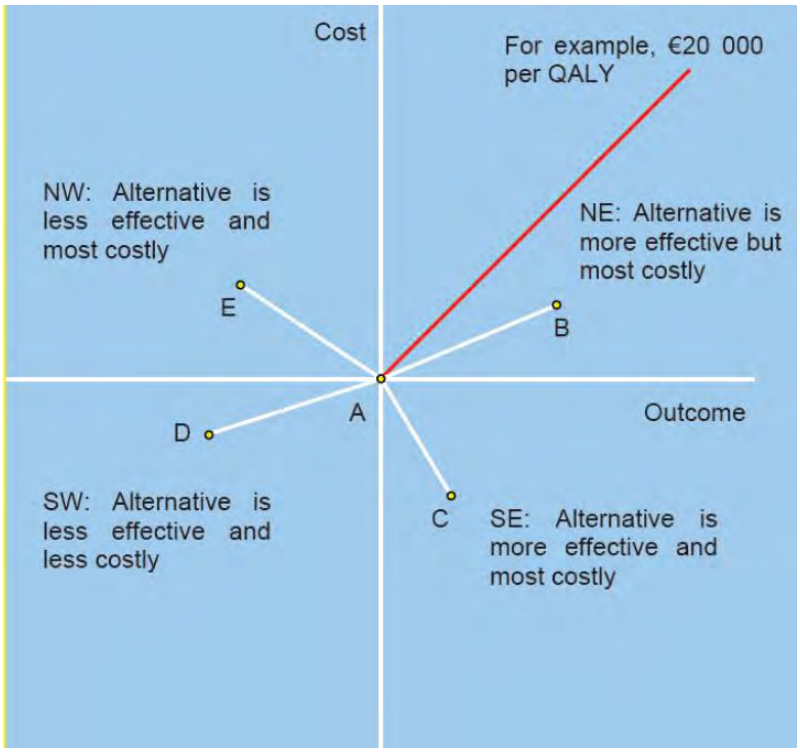
Cost Effectiveness Analysis (CEA) concentrates on evaluation costs against outcomes/benefits when implementing a programme. The outcomes of the programmes should however be the same e.g. life years saved. The outcomes are not measured in monetary terms. Cost effectiveness studies assess different strategies, i.e. the current strategy and an alternative and in some cases 3 or more alternatives in order to find the best alternative and efficient way of implementation of the programme or screening in this study (Drummond 1987).

Drummond notes that CEA is measured as a ratio i.e. the Incremental Cost Effectiveness Ratio (ICER) as noted below

$\frac{\$CostA - \$CostB}{EffectA - EffectB}$

Below is a depiction of CEA Decision Plane as noted by Drummond (1987)

Figure 4: CEA Decision Plane



Source: Drummond (1987)

Furthermore CEA is divided in three categories, namely Ex-post, Ex-ante, and Intermediary evaluation (European Commision n.d.). Ex-ante evaluations are defined as those that support decision making through strategy choice. Ex-post evaluation is done once an evaluation has already been carried out and there is need to measure the programmes economic efficiency.

Intermediary evaluations are an update of the ex-ante's outcomes and inform the choice of which strategies should continue or be slatted. CEA however has its own limitations which include its inability to evaluate programmes with different outcomes (Drummond et al. 2005). Secondly, it is meant for programmes whose costs and outcomes are easily identifiable (European Commision n.d.).

Thirdly, there is debate amongst economists on which costs to include and how they should be valued e.g. in terms of lost productivity time, care giver time and extended costs for life years gained due to intervention success (World Health Organisation 2003).

Cost Minimisation Analysis

In comparison a cost minimisation analysis determines the minimal cost to implement a programme assuming the available input costs only whilst assuming outcomes of alternative strategies to be equal Baghbanian & Esmaeili (2012). This is different from CEA and CUA which notes the difference in outcomes. The weakness is the assumptions that the outcomes/outputs are equal which does not reflect real life.

Cost Benefit Analysis

Like the other economic evaluations, cost benefit analysis includes monetary measurements but measures the outcomes differently. An example is that of using willingness to pay as a proxy for benefits/outcomes. This implies putting monetary value on pain suffering and life is usually disliked by society and considered unreliable due to varying ways people's perception of their health weights in terms of money. (Drummond 1987, Brown et al., 1998).

Ratios are calculated when doing a cost benefit analysis and the strategy with a higher cost benefit or net present value or net benefit ratio is the most cost effective (Baghbanian & Esmaeili 2012).

Cost Utility analysis

Cost Utility analysis is often used interchangeably with cost effectiveness analysis. However, there is a major difference in that CUA allows for different outcomes for comparability therefore one can analyse programmes with different outcomes. CUA measurement unit on outcomes include Quality Adjusted Life Years (QALYs) and Disability Adjusted Life Years (DALYs) which group the outcomes and make it possible for comparison (Baghbanian & Esmaeili 2012). Most cost utility studies measure quality adjusted life years (QALYs).

CUA requires some common outcome measures that can incorporate quantity and quality of life changes. Such measures can be seen as measures of utility (or value of health) to individuals. This means strong assumptions have to be made with regards to methods of measuring the health related quality of life. The Euroqol is a popular method which had been used to date (EuroQol Research Foundation 2014). It consists of different weighting measurements such as the EQ-5D-5L and the EQ-5D-3L value sets. These are currently available for the following countries: Denmark, France, Germany, Japan, the Netherlands, Spain, Thailand, UK, US and Zimbabwe (EuroQol Research Foundation 2014). Using the same valuations for different countries may result in inaccurate or unreliable cost utility measurements.

An example is that of comparing a Tuberculosis (TB) treatment programme, Antiretroviral Treatment (ART) and a Cancer Programme. The one with the least cost and the highest outcomes is the most cost effective option to use.

Table 5: Types of Economic Evaluation Studies and their Valuation of costs and consequences

Methods	Measurement and Valuation of Costs in Both Alternatives, Dollars	Identification of Outcomes	Measurement and Valuation of Outcomes	Summary Measure
Cost-Minimisation Analysis				
In a CMA, the consequences of two or more interventions being compared are equivalent. The analysis therefore focuses on costs alone, and the cheapest option is chosen.	Monetary Units	None	None; only inputs are compared; outputs are assumed to be equal, which is rarely so	Dollars (difference in cost between alternatives)
Cost-Effectiveness Analysis				
An economic analysis to compare interventions that have a common health outcome; it attempts to measure a clinical output, such reduction in blood pressure, or quality of life.	Monetary Units		natural effects, physical units or clinical outcome (e.g. life years gained, reduction in blood pressure, cases of ventilator-acquired pneumonia avoided)	Cost-effectiveness ratio (eg, dollars per life year gained)
Cost-Utility Analysis				
Often interventions impact both on quality and quantity of life. A CUA can be used where outcomes are valued on individual preferences (QALYs Gained).	Monetary Units	Single or multiple effects, not necessarily common to both alternatives	Health state values what is so called health years (e.g. healthy years or quality adjusted life-years gained)	Cost-utility ratio (eg, cost per QALY)
Cost-benefit analysis				
In a CBA, attempts are made to value all the costs and consequences of an intervention in monetary terms. If the benefits are less than the costs then the intervention is acceptable.	Monetary Units (Dollars)	Single or multiple effects, not necessarily common to both alternatives	Monetary Units (Dollars)	Net gain or loss in dollars
Cost-consequence analysis				

Source: Baghbanian & Esmaeili (2012)

Budget impact analysis

Budget impact analysis is an extension of costing. It introduces a fixed or non-fixed amount of resources which needs to be adhered to deciding which alternative strategy to take when choosing programmes. The budget is usually designated to a certain programme or services e.g. Antiretroviral Treatment (ART). With the ART budget the chosen strategies give 2 or more treatment paths should absorb the given budget.

However, most cost evaluations are done on a fixed budget which tends to result in suboptimal decision making. It is important to include costs that are outside the budget given their potential to destabilise the stipulated budget of that period. Policy making depends on being given all the facts and not half of the story.

2.2.1 Theoretical Literature Review of Costing

It is imperative to note that accounting and economic literature generally agree on the basic principles of costing. Generally, the costing exercise begins with conceptualization of a clearly identified decision problem. This process also includes the definition of the objectives of costing, the costing perspective to be used, as well as the time-frame (Mogyorosy and Smith 2005)

It is also important to identify all the requisite resource items, and justify their omission from the cost calculation. In addition, measurability or ease of observation should not be solutions for resource identification (Brouwer 2001). There is need to include even those difficult to measure resources and find a way to measure them if they add value to the research. Over-inclusion and over-exclusion can be a problem (Byford 2003).

2.2.1.2 The Economic definition of cost and differentiations

The backbone of economics is the scarcity of resources in a given environment which results in decisions having to be made on what is to be forgone to achieve the intended alternative (Investopedia 2015). Because we leave in a monetary

economy where goods and services are traded using money, financial costs are a form of monetary measurement.

In Economics, costs include all the financial costs, costs of donated goods or in-kind services, and all opportunity costs. The online business dictionary states that economic costs consist of the opportunity costa and the accounting costs which are cash involved. The economic cost concept can be extended to health.

There is increasing research interest on the impact of medical costs on households (WHO 2004). It has been observed that individual illness has significant, largely negative, implications for other household members (Sauerbon 1996). The discipline of health economics explores the costs to the health system and to the patients seeking health care including the opportunity costs of being ill.

Thus, costs are generally divided into three categories: direct, indirect, and intangible costs (McIntosh 1996). Direct costs are those costs for which direct payments are made and include medical costs that are mainly borne by the health-care sector, and non-medical costs such as transportation and home modifications, which are incurred by the patients and their families, while indirect costs pertain to those for which no actual payments are made but for which resources are lost (Leardini et al 2002). These are often classified as either morbidity or mortality costs and thus, the conceptualization of costs depends on the costing perspective (Wolfe et al., 2005).

Intangible costs refer to costs that are difficult to measure such as pain, discomfort that emanates from sickness and treatment. They cannot be easily quantified as they are not actual resources. They are however, ways of valuing intangible costs such as willingness to pay (how much is one willing to pay to eradicate the pain or feel comfortable) and quality of life measurement (IQWiG, 2009). These methods are meant to convert non-marketed goods and services into economic costs (World Health Organization 2009).

2.2.1.3 Costing perspectives

From whose perspective an economic evaluation is being conducted detects the types of costs that should be taken into account, e.g. have implications on whether direct non-medical costs should be taken into account (Jegers2002). Furthermore, the perspective will also determine whether productivity costs should or should not be taken into account, as well as whether service providers' overheads should be added to direct medical costs or not (Payne 2002).

In costing perspective, the productivity loss for health providers is limited to those who pay for sick leave and pay health insurance, patient perspective is limited to patients' loss of income and sick leave paid for by the employer (Lensberg et al. 2013).

Since healthcare economic evaluation is conceptually based on welfare economics, it has therefore been argued that economic evaluations should adopt a societal perspective to be able to evaluate the impact on society as a whole (Byford & Raftery 1998, Byford 1998). A societal perspective costing includes all parties affected by the intervention i.e. health providers and the patients as well as the community and takes into account all the outcomes and costs regardless of who experiences them (Gold, 1996). Table 6 shows the inclusion and exclusion of costs by perspectives (Luce 1996):

Table 6: Inclusion and exclusion of costs by perspectives

	Perspectives			
Cost elements	**Societal**	**Public purchaser**	**Private purchaser**	**Provider**
Health service costs	All	Covered expenses	Covered expenses	Expenses of provided services
Productivity costs	Included	Excluded	Excluded	None
Informal carers	Included	Excluded	Excluded	Excluded
Transportation	All	If any paid	If any paid	Excluded
Other non health service costs	All	If any paid	If any paid	Excluded
Sick leave	Administration costs only	If any paid + administration costs	If any paid + administration costs	Excluded
Disability benefits / pensions	Administration costs only	If any paid + administration costs	If any paid + administration costs	Excluded

Source: Luce 1996

In general, identifying and valuing all the costs from a societal perspective can be challenging but analysts should do their best to identify measure and value resource use where it is possible in an economically feasible way (Green 1999). During a societal perspective costing, it is important to be weary of some costs causing measurement challenges when they do not have a major impact on the study results such as calculating building costs in a scale up programme (Drummond et al., 2005).

However, there has been a decrease in economic evaluations from the societal perspective with most studies focusing on the provider perspective (Johannesson, 1995). The reason for most scholars concentrating on provider perspective is the popularity in measuring/assessing relative efficiency of alternative health care (European School of Health Economics - HEPaMI 2009). It has been argued that adopting a patient perspective for an economic evaluation may create a bias towards the social benefits of health care (European School of Health Economics - HEPaMI 2009). Some scholars note that

if economist value health benefits from a social perspective therefore so should the costs related to offering health care(European School of Health Economics - HEPaMI 2009).

2.2.1.4 Costing Methodology: Micro costing versus Gross-Costing

The approaches to resource consumption measurement vary widely and may be determined by the aim of the cost analysis and by the availability of data. On one hand, there is the direct measurement of patient-specific resource utilisation, commonly called micro-costing, activity based costing or the bottom-up approach (Smith 2003).

While on the other hand, is the estimation of resource utilisation and costs by assigning a national average figure on non-patient specific bases such as using Diagnostic Related Groups (DRGs), or Healthcare Resource Groups (HRGs) based on national or regional administrative databases; commonly known as the gross-costing or top-down method (Brouwer 2001). The choice between micro-costing and gross-costing approaches has consequences for the identification of resource items and the measurement of resource utilisation (Smith 2003).

In gross costing, health services are divided into large components intermediate products and these large cost items have to be identified (Brouwer 2001). Thus, gross-costing can be simple and transparent (Luce 1996). The result may be externally valid, and may be able to tackle regional or institutional variability. In addition, cross costing is usually faster and cheaper than micro-costing, but may be less accurate, because relatively large resource units are measured (Smith 2003). Less precise costing, however, could negatively affect decisions related to patient care as well as health policy (Luce 1996).

On the other hand, in micro-costing, a very detailed service delivery process is established and all the relevant resource items identified and measured separately (Brouwer 2001). Micro-costing frequently use measurement techniques developed by other industries, such as time and motion studies in which the production function is broken down into discrete activities which are

analysed separately (Smith 2003). Therefore, micro-costing could be more reliable and precise, but it could be expensive and may not always be practical (Brouwer 2001). However, it may be the preferred method when gross costing is a poor estimate of resource utilisation (Luce 1996). A decision on the precision of resource utilisation measurement can be influenced by the possible impact of uncertainty the particular resource utilisation could have on the decision (Drummond 2005). It should however be noted that the end user of the economic evaluation results may influence the type of costing carried out.

2.2.1.5 Measuring the Resource Utilisation of each cost element

There are several ways to calculate unit costs, although most methods follow the full absorption cost principles (Zimmerman 2003). This means that all costs, both direct and indirect, relating to the provision of a particular service is included in the cost calculation (Brouwer 2001). There is a consensus about the fundamental principles of cost allocation (Green 1999).

Ideally, costs should be traced directly in an economically feasible way (Wolfe et al., 2005). In essence, indirect costs should be allocated to service areas based on actual utilisation or cause-and-effect bases (Mogyorosy and Smith 2005). Drummond divides the costs incurred during screening in the health care, patient and family costs and other sectors.

2.2.1.6 Costs from the provider (Health systems) perspective

A provider (health systems) perspective relates to the costs incurred by the health sector in the quest for delivering health care to the public. The costs are from the provider of health care perspective, i.e. incurred by the provider. These are divided into direct and indirect costs. Below is further explanation on direct and indirect costs

Direct costs incurred by the health system

Direct cost incurred by the health system can be materials, labour, or expenses (Zimmerman 2003). Thus, the direct costs incurred by the health system include overheads, capital costs, and equipment (Johnston 2001). Hence, depending on the essential infrastructural requirements, health system services can be divided into two major subcategories, namely, facility-based services and

peripatetic services (Beecham 1995). Furthermore, they can be divided into patient related costs and non-patients costs/ programme costs (Benjamin et al., 2003).

In a discussion about rapidly rising healthcare costs, inevitable attention turns to the pricing of medical services and products. While current prices may preserve incentives for innovation and reflect investments in research and development (Jayadev and Stiglitz, 2009), these prices may also reflect market asymmetries in information and monopoly power (Dafny, 2009; Pauly and Burns, 2008).

In practice, identifying most of the direct costs incurred by the health system is generally straightforward and easy, although some of them can be a little bit problematic, and a few of them very difficult (Zimmerman 2003). For instance, some of the overhead costs, such as training costs, supervision costs, and administrative overheads are frequently omitted from the cost calculation (Johnston 2001). Likewise, the identification of joint costs is crucial, but challenging (Yazbeck 2001).

The concept of capturing direct costs incurred by the health system means that all the relevant resources used are taken into account during the cost calculation (Beecham 2005). This is essential for accurate cost calculation, although, in practice, it could be very challenging (Smith 2003). For instance, a doctor treat several patients in the intensive care unit, therefore it is necessary to apportion a doctor's salary between patients to estimate the real as well as correct costs of the treatment of a patient in the intensive care unit (Bean 1996).

Discounting and annualisation of direct costs

Training is considered a future investment and is discounted and annualised accordingly. Capital costs are annualised to ascertain the cost in the year of assessment given they will be used over a longer period of time.

The formula used to acquire the present value is as follows;

$$PV = \sum_{t=0}^{T} \frac{Cost}{(1+r)^t}$$ *PV* = the present value; t = the period in which the costs occur; *r* i=the discount rate.

The rate at which to discount costs is controversial but there is a general consensus amongst economic evaluators.

The French use the a social discount rate of at 4% as of 2005, assuming the time horizon is less than 30 years, reducing up to 2% thereafter (Haute Autorite de Sante 2012). In a review of 147 economic evaluation studies conducted by the University of York the most commonly used rates for health costs were 3% and 5%, whilst some studies used 0% (Smith & Gravelle n.d.). Using the 3%-5% annual rate since it has been used in most of the published material will give room for referencing and comparison (Drummond 2005).

Indirect costs to the health system

On the other hand, indirect costs to the health system have no direct relationship to the cost object; therefore, they cannot be traced to the cost object easily or in an economically feasible way (Yazbeck 2001). Indirect cost to the health system may include materials, labour, or expenses. For instance, the cost of catering or cleaning in a hospital, as well as the cost of clinical audit, is classified as indirect costs of health services (Smith 2003).

In addition, the cost of cleaning personnel or security is usually classified as indirect labour costs to the health system (Wolfe et al 2005). The costs of materials used to clean the wards are also classified as indirect material costs to the health system (Zimmerman 2003).

2.2.1.7 Costs from the Patient perspective

A patient perspective relates to the costs incurred by the patient and the family in the quest to get treatment from the health care sector. These are divided into direct and indirect costs and intangible costs. Below is further explanation on patient direct and indirect costs.

Direct costs incurred by the Patients

Direct costs are incurred by the patients as a consequence of out of pocket payments paid for seeking treatment at a health care facility, purchasing of drugs and transportation to the health care facility (Segel 2006). The patient direct costs include transport costs, food costs, and any payment for child care during the referral visit. Economists generally agree on how to measure direct costs of patients as they are easily quantifiable. However, indirect costs incurred by patients whilst seeking treatment are debatable in terms of measurability.

Indirect costs to the Patients

Indirect costs include time costs, opportunity cost of the referral, lost productivity which could be measured in terms of wages lost. More explicitly they consist of the opportunity cost of time lost due to morbidity (Zimmerman 2003), loss of productive time as a result of seeking health care services, which is inclusive of the time spent in hospital; time spent queuing at the hospital and the time travelling to and from the hospital (Segal J, 2006). These factors affect the patient attendance for a screening, monitoring, and referral.

The human capital theory is the most commonly used method for valuing productivity costs and it is based on neoclassical economic theory, which states that profit-maximizing firms employ workers up to the point where their marginal contribution to production equals their gross wage (Merkesdal et al., 2001). Economic evaluation method is informed by the human capital and the friction costs methods (Haute Autorite de Sante 2012). Human capital entails giving value to potential productivity loss whilst the friction costs method calculates the loss of production due to absence at work (Haute Autorite de Sante 2012).

The productivity of individual workers is a critical factor of workplace productivity, and is directly affected by an illness (Escorpizo et al., 2007). Worker productivity is generally classified as either absenteeism or presenteeism (Brouwer 2001). Absenteeism is defined as productivity loss due to health-related absence from work, and includes sick days, personal time off, and time taken as short or long-term sick leave (Kessler 2008).

Methodological concerns of indirect costs quantification

A variety of studies have used the human capital theory to estimate productivity loss by multiplying the cumulative number of missed workdays by a daily salary (Verstappen et al., 2005). The ethics associated with the use of individualized wages has been questioned as this approach leads to the identification of patients with lower incomes, and a preference for treating patients with higher incomes (McIntosh 1996).

In addition to productivity losses arising from gainful employment, housewives, retired people, and students also incur substantial productivity losses called Household productivity costs (Verstappen et al., 2005). Household productivity costs have been found to account for up to 88% of total productivity costs, suggesting that loss of household productivity might actually exceed that of paid productivity (Koopmanschap and Rutten 1996).

The productivity loss for health providers is limited to those who pay for sick leave and pay health insurance, patient perspective is limited to patients' loss of income and sick leave paid for by the employer (Lensberg et al., 2013). Collection of information is usually done collecting official attendance records from the employer or relying on the workers noting how many days they spend at work, However it's been noted that relying on employee self-reporting of absenteeism may result in overestimating costs (Lensberg et al., 2013).

Debates on indirect costs measurements

Significant debate exists not only around the issue of whether indirect costs should be taken into account in an economic evaluation, but also on the proper way to estimate these costs (Zimmerman 2003). The United Kingdom's National

health Institute and Personal Social Services does not allow for the inclusion of productivity costs in its economic evaluation (Lensberg et al., 2013).

However, Canada and Australia allow the inclusion as long as they are evaluated separately (Lensberg et al., 2013). The Swedish and Dutch allow for the inclusion of costs related to production loss. The Swedish recommend the use of the Human Capital method, whilst the Dutch, Australians, and Canadians recommend the use of the friction cost method (Lensberg et al., 2013). The friction cost method was therefore proposed as an alternative approach to the human-capital theory (Koopmanschap & Rutten 1996).

According to the friction cost approach, productivity losses still occur but are confined to the period until a previously unemployed individual is able to replace the absent worker (Escorpizo et al., 2007). Since the amount of production lost as a result of a disease depends on the time organizations need to restore the initial production levels, it is argued that the friction cost method provides a more realistic picture of productivity loss occurring to a society with an increasing number of health economists arguing that this method reflects societal productivity costs most accurately (Backman 2004)

The Human capital and Grossman theorem

Production within an economy is known to be made possible by the following components; capital (machinery and other equipment's), buildings, and land (Singh 2014). Most importantly humans are responsible for putting these components together for production to be successful.

The Human Capital theory assumes that humans should be equated to capital since they also help in the production of goods and services. Because there is time involved, humans can allocate their time to production, labour, or leisure. In the event of sickness, the time has to be altered involuntarily to accommodate health seeking (Howitt 2005). Poor economic growth in developing has been attributed to poor health due to HIV/AIDS, malaria, Tuberculosis amongst others.

Investment in human capital is assumed to help increase production and an employer may do so by providing education, training, and sick leave to the employees who alters the time for labour and leisure. As noted above, to estimate productivity lost, the cumulative number of missed workdays is multiplied by a daily salary i.e. Human Capital theory uses wages as a proxy to employee output.

The Grossman theory is an extension to the Human Capital Theory which values human capital for its future earning potential only. The Grossman theory states that one should invest in health to avoid early death. This stems from what Grossman terms the realisation that ill health results in loss of productivity in supply of labour as well as the realisation that though consumers pay for services in health care, they in actual fact pay for good health. He goes on to distinguish between consumption of health and investment for Health. Consumption is noted to provide direct utility to the individual who can choose to seek treatment or not. Lack of health is a disutility and this is presented in a utility function as noted below.

$$\int_0^T U(C,H)e^{-pt}dt$$

C represents the consumption and *H* the stock of the individual's health. Utility of C and H are assumed positive though diminishing form time 0 to time *T* (Laporte 2014).

Grossman (1972) disputes Malthusian theory that noted any increase in income increased the chances of a healthy being since they have more money at their disposal for nutritional foods and health care access (Grossman 1972). Grossman notes that in developed countries, Malthusian Theory does not hold true due to fluctuations in income making an individual vulnerable to mortality and morbidity.

The Grossman theory has faced several criticisms. Galata et al (2012) argues it does connect current health behaviour with the patient's history and it ignores the fact that a lower socio-economic status results in a decline in health status. Zweifel (2012) notes that it ignores the fact that humans don't live forever, assumes positive health outcomes if there is an investment in health which does not hold true in real life and (Laporte 2014). More so, it does not take into account individuals who have suffered a major health illness.

The friction cost method on the other hand uses replacement cost of the employee as a proxy to output in calculation production loss. The replacement costs include advertising for a replacement worker, recruiting, and training him. It has been criticised for being cumbersome and needing too much information in comparison to the Human capital cost method proponents (Laporte 2014).

The next section reviews the empirical findings with respect to the monitoring IUGR and SGA as well as relevant costing studies which add value to our study.

2.2.2 Empirical Literature Review

2.2.2.1 Costs from a health systems perspective

A review of Popline, Medline and donor websites databases reviewed that they were not many cost effectiveness, cost utility, cost benefit and cost analysis in the field of maternal health (Borghi n.d.); and the introduction of new technology into the healthcare system, specifically ultrasound machines (Henderson 2002). There were more clinical studies but were not followed up by the economic evaluation (Borghi n.d.). Below is a review of the few that were available.

2.2.2.2 Costing methods

As noted in the theoretical literature, the type of costing method determines the information that will be used in the costing exercise. This will ultimately affect the outcome under review e.g. the average cost per patient.

A costing analysis study whose main objective was to estimate the, "distribution of costs incurred on the Primary Health Centre, by service provided at a primary health care centre, Chhainsa in Haryana, revealed that 11% (US$ 2668) of the total costs incurred during a 1 year period were attributable to maternal care i.e. Indian rupee 127 average cost per patient (approximately ZAR 23) (Anand et. Al., 1995). No economic costs (outcomes/benefit measurements) were included which may undermine the results for their lack of showing the true economic cost and exploration of the societal perspective.

In a cross sectional study using a step-down allocation approach which included both capital and recurrent costs, the average cost per ANC visit in Ghana from the health care perspective was US$18 (Dalaba et al., 2013). Like South Africa, Ghana offers free Antenatal Care (ANC). The amount may be deemed inaccurate due to the use of step-down approach in which cost data was extracted from the health centre budget and the ANC component allocated as per usage i.e. did not reflect the actual ingredients[2] used in ANC. Average costs of operating an ANC were approximately US$23,063, which were considered high due to the lack of

[2] Costing ingredients are resources required for an intervention to occur

utilisation of services. It is critical to distinguish whether the unit costs are high due to under or over utilisation of services. This is because it affects the efficiency ratings of the health care centre.

A cost effectiveness study of one-stage ultrasound screening in pregnancy in the Helsinki ultrasound trial by Leivo et al (1996) included the lack of utilisation of facilities in their study by representing them as negative costs in their model. The results of the Helsinki Random Controlled Trial revealed the unit cost of an ultrasound to be $102 when positive costs were assessed. The avoidable cost of a perinatal death due to ultrasound monitoring was US$21 938. Having combined the negative costs and positive costs the cost saving to the health care system amounted to US$ 17.

Ultimately, One-stage second-trimester ultrasound screening with more time spend during the ultrasound administering examination was noted to be cost effective due to the inclusion of the significant costs and effects.

2.2.2.3 Direct and Indirect costs to the health system

The inclusion of recurrent costs and capital costs has its own strengths and weakness. Whether it is ideal to exclude certain cost items depends on the perspective of the study, the outcome required, if it is incremental costing or scale up costing amongst other things.

In some studies, overhead costs, such as training costs, supervision costs, and administrative overheads are frequently omitted or included from the cost calculation (Johnston 2001) as well as capital costs such as buildings, vehicles, technological equipment. Below are examples of the aforementioned studies.

Table 7: Economic evaluation studies and their costing ingredients

Authors	Title of paper	Location	Cost year	Methodology	Costing Ingredients						
					Staff	Drugs	Labs	Overheads	Patient costs	Above faility costs	Other
Janson J (2012)	Costs and process of in-patient tuberculosis management at a central academic hospital cape town	South Africa	2009	Gross Costing at the Academic Unit for Infection Prevention and Control (UIPC),at the University of Stellenbosch, Western Cape	x	x	x	x			
McConnel C et al (2002)	The cost of a rapid-test VCT clinic in South Africa	South Africa	2003	Gross Cosing ; An urban, church-based, non-profit organisation that offers rapid-test VCT services in KwaZulu-Natal, South Africa	x			x			
Desmond C and Boyce G (2004)	Assessing the cost of pilot site in Eastern Cape	South Africa	2003	Activity based costing in Rural Eastern Cape at 3 clinics and 1 hospital based clinic	x	x	x	x			
Basset I. V et al (2014)	Mobile HIV Screening in Cape Town, South Africa: Clinical Impact, Cost and Cost-Effectiveness	South Africa	2012	Ingredients Costing, Setting is a Cape Town community with a mobile VCT unit	x		x	x			
Meyer-Rath G (2013)	Rates and Cost of Hospitalization Before and After Initiation of Antiretroviral Therapy in Urban and Rural Settings in South Africa	South Africa	2009	Study conducted at Empilweni Services and Research Unit (ESRU)							Patient day equivalent rate

NB: X shows the ingredient was included.

Source: Authors compilation

The objective of Kranzer et al.,(2012) was to analyse the cost of, "adding TB screening using sputum induction to the existing mobile HIV testing service," (Kranzer et al. 2012) i.e. an incremental costs analysis which focused only on financial costs. Economic costs were excluded. It was a provider based study therefore did not include any patient costs.

Capital costs for equipment and transport were considered, annualised, and discounted at 6% whilst recurrent costs such as staff, consumables, laboratory tests, office rent, and overhead were also included. Time and motion studies were done to determine staff costs and apportioned appropriately with time spend on patients. It would have been interesting to include patient costs in order to understand the cohort's economic and financial costs towards TB screening as well as obtain a social cost of the programme.

A cohort study to ascertain the cost of hospitalisation before and after antiretroviral initiation, used the patient per day rate (PDE) which is predetermined by public hospitals' districts (Meyer-Rath et al., 2013). It was calculated by dividing the total expenditure of the hospital for the financial year with the number of patient visits. This however, may result in inaccurate estimates because it assumed the rate was not far removed from that of HIV patients which maybe the case. They do however give a justification of their decision to use PDE.

Desmond (2004)'s cross sectional - costing exercise of the national PMTCT protocol was conducted in four pilot sites across South Africa (Desmond et al., 2004). The costing ingredients included staff, drugs, facility (e.g. renovations of the buildings), baby formula, and training costs. Interesting, is the inclusion of training costs which they discounted and annualised for 5 years whilst the start-up building costs life years were set at 15years.

Like South Africa, Ghana offers free ANC. A cross sectional cost analysis study in Ghana whose objective was to cost maternal health services in Selected Primary Care Centres included vehicle costs in the capital cost list (Dalaba et al., 2013). It followed a step-down allocation approach, and the average cost per ANC visit in Ghana from the health care perspective was US$18 (Dalaba et al., 2013). The exclusion could have attributed to the increased unit costs given that the annualised costs of owning the vehicle would be higher with less utilisation by patients.

A modelling study by Patterson (2011) which sought to calculate the cost of scale-up of care for mothers and babies at the health-system level to prevent stillbirths. The Lives Saved Tool's resulted noted the preferred outcome to be between $0.96 $US 2,32 per pregnant woman monitored using ingredients costing of recurrent costs only, i.e. no capital costs was included (Pattinson et al. 2011). The exclusion of capital in the costing is a great limitation to the study as equipment such as ultrasound imaging is an essential part in determining the possible outcomes of the fetus. Possibly, lack of cost of the equipment may have resulted in the impossibility of calculating capital costs. They may also have

been deemed as causing measurement challenges as noted by Drummond (2005).

In some cases, including all types of costs gives the opportunity to identify cost pushers or cost saving areas. A cohort study at Liverpool Women's Hospital whose objective was to detect fetal abnormalities by routine ultrasound and the related costs conducted a cost effectiveness study (Henderson & Martin 2000). Primary costing included staff, equipment, disposables, and capital costs.

The study revealed the underutilisation of equipment but a need for extra staff due to increase routine scans. In the second phase of the study more staff was employed to help with the routine scanning and no equipment was purchased. The cost of introducing routine scanning was costed to be equivalent to £16 per pregnant woman. The cost of ultrasound for growth abnormalities to be approximately £15.71 (£13.58–£17.84) whilst for fetal well-being scan cost £15.46 (£11.67–£21.16) (Henderson & Martin 2000).

On the other hand, hospital costs were estimated to be 11% of the recurrent costs and these were apportioned to the programme. Such apportionment risk a danger of underestimating or over estimating the overheads costs of the programme and in-turn bias the final unit cost for the evaluation. Time taken per scan was recorded on diaries and training times were also captured. Staff costs were calculated by apportioning time spent by each staff member of ultra-sounding duties to their salaries. Average time spend on clerical duties during scanning was 5 minutes whilst average time for conducting the anomalies scan was an average of 15 to 20 minutes which is not different from the Long and Sprigg (1998) study.

However, there was no mention of training being discounted costs which weakens the study in terms of accounting for future benefits from training the staff. This is the recommended way by most health economists and is meant to give a true reflection of staff costs. Interesting is the addition of 6% onto capital as a return of investment on top of the 7% straight line depreciation and discount rate.

Type *of Hospital and location's effects on direct and indirect costs*

Location and level of hospital is a key factor in costing exercises. They are differences in cost within the different levels of the public hospitals. Some items are donated to the hospitals and have to be costed using either health market prices instead of actual purchase prices. This may inflate the cost. In most developing countries, mission hospitals receive donated goods.

A costing study of maternal health care in Blantyre district, Malawi revealed the complexities of different facility arrangements (Levin et al., 1999). The costs at public hospitals were noted to be higher than those at mission hospitals, an inverse to most studies which found mission hospitals to be less costly. Public hospitals had unfair advantage of having highly qualified staff and more support staff which meant higher staff costs.

However, drugs were much cheaper at public hospitals to due to subsidising by government. Referral hospitals also saw more patients resulting in higher unit cost. Overall, the cost of ANC ranged between US$5.00 to US$6.00. Furthermore, the use of more drugs at the hospitals increased the costs at in comparison to the public health centres (Clinics). It notes that the different facilities, drugs, and supplies constituted the bulk of the costs whilst in comparison to other services indirect costs were lower for ANC.

Overstaffing and underutilisation are some of the key factors that affect the calculation of unit costs rendering them high or low. The unit costs emanating from these studies are used in resource allocation and it is important that they be as accurate as possible. It is not clear cut to state that a low/high unit cost is the best to show efficiency of a clinic or hospital. It may be due to overstaffing or good delivery of services which may be requiring more items As noted in the Ghana study (Dalaba et al., 2013), underutilisation resulted in high unit costs.

A cost analysis of maternal health care in the South of Tanzania showed gross underutilisation of clinics resulting in higher unit costs in comparison to hospitals i.e. cost of normal virginal delivery was US$6.30 in a hospital and

US$12.30 in a clinic. Cost of consultation for ANC was relatively low at US$2.50 (von Both et al. 2008). Sensitivity analysis has been conducted on utilisation in several studies to check how increase or decrease in utilisation of facilities or service affects the costs or cost effectiveness. Such results are important in optimal decision making.

2.2.2.4 Costs from the patient perspective

Patients incur costs in seeking treatment and these are divided into direct and indirect cost as noted in the theoretical literature review. The direct costs are further divided into the medical and non-medical expenditure. The medical expenditure includes consultation fees, payments for drugs and investigations whilst non-medical costs include transport, food, guardian, and lodgings.

These are termed household costs and the family needs to manage these and avoid not falling into the poverty trap where one finds it difficult to escape poverty. Failure to manage health costs results in patients seeking alternative treatment or deciding to go untreated as noted by the Model of Patient Pathway to Treatment Conceptual Framework (Walter et al., 2012)

The cost of screening affects the attendance by a patient. In a household study in Nepal, to ascertain the cost of illness (maternal health), the cost of a home delivery ranged from US$5.43 to US$11.63 with the help of a friend/relative or health worker respectively. In comparison the cost of a normal delivery at the hospital cost the family US$8.97 whilst a caesarean section cost US$150 and above depending on possible complications. With the inclusion of opportunity costs and transport costs the normal delivery at the hospital amounted to US$70 and above.

In the study conducted in London on cost implications of introducing a telecardiology service for fetal ultrasound screening, London women incurred an average of £37 in comparison to £5.50 for the telemedicine referrals (Dowie et al. 2008). The costs were collected through postal surveys. In some instances, postal surveys are deemed not very reliable due to low response rates.

However, patient interviews are always marred by recall bias considering the time lost between interview date and date of clinic or hospital visit.

There has been a great debate in including opportunity costs in the final patient cost due to the difficulty and non- standardised way of measuring that aspect of the study. Torgerson, Donaldson, and Reid (1994) assessed the differences between private and societal opportunity costs and concluded that the private opportunity costs were a more reliable predictor of the demand for screening services. As noted in the Nepalese study, there is an increase from US5.43 or US$11.63 to US$70 when the opportunity costs and transport costs are included which is quite significant. However, to gather the true economic costs it is essential to include opportunity costs as per the Human Capital and Grossman theorems.

2.2.3 Effectiveness of Monitoring IUGR and SGA

Several studies have been conducted to assess the clinical effectiveness of intrauterine growth retardation monitoring with regards to finding clinical solutions in order to reduce perinatal mortality or morbidity (Henderson & Martin 2000) . Most of the studies compare the different strategies of monitoring IUGR and SGA against no monitoring at all. The study samples include women with high risk pregnancies stemming from previous still births, hypertension, diabetes and those who would have been noted to have IUGR.

However, most studies concentrate on the second trimester more than the first, limiting the range of assessing effectiveness of monitoring from early on in the pregnancy. The monitoring strategies in most of the studies include monitoring of Body Mass index (Haws et al., 2009), SF measurement by tape measure and Doppler ultrasound (Henderson & Martin 2000; Marsál 1994; Stampalija et al., 2010). Ultrasound screening is considered to provide more information regarding SGA and IUGR than the BMI and tape measure strategies allowing for much more accurate diagnosis (Henderson & Martin 2000).

Some studies noted there is a value in monitoring high risk pregnancies especially those with suspected placental dysfunction using the Doppler ultrasound (Henderson & Martin 2000; Haws et al., 2009; Marsál 1994). However, a Cochrane review of Randomised and quasi-randomised controlled trials of Doppler ultrasound versus no Doppler ultrasound revealed that there was no evidence of the mother or fetus benefiting whether the Doppler was performed or not on second trimester women in two of the studies reviewed. They however, recommended that more reviews be done on first trimester women (Stampalija et al., 2010) as they could be a potentially opposite result.

Consequently, 16 studies reviewed collectively suggest that perinatal mortality can be reduced by 29% [RR 0.71, 95% CI 0.52-0.98] if Doppler monitoring is used together with other appropriate interventions. Despite the result, the data was not statistically significant.

Waitzman (1998) noted there was uncertain social benefits to routine screening for fetal anomalies with the benefit to cost ratio ranging from 0.33 to 3 (Waitzman et al., 1998) . Mores studies in this area would provide more insight in the area of monitoring IUGR and SGA especially by ultrasound and tape measure.

2.2.3.1 Studies on Introducing Ultrasound in Low Resource Settings

Tape measures and ultrasound machines are used to monitor IUGR and SGA. A systematic review by Harris and Marks (2009) revealed that there are not many studies dealing with the introduction of compact ultrasound in low resource settings, namely developing countries. In their findings they note that evidence based analysis in those areas has been hampered by the lack of useful information on perinatal and maternal morbidity and mortality as well as lack of effectiveness studies on the compact ultrasound in comparison to full sized unmovable ultrasounds. They recommend such studies be carried out. This particular study follows the recommendation by Harris and Marks.

A study conducted in Tanzania's Lugufu refugee camp between 2005 and 2007 revealed that it was feasible to introduce a portable ultrasound unit in a low resource setting (Adler et al., 2008). Out of the female cohort, for 24.1% of the total were pregnancy related exams. A study in a Ghana also revealed the feasibility of a portable ultrasound in 2 different settings, i.e. 2 primary care sites and 2 hospitals (Spencer and Aldler, 2008). 29% of the cases were related to abdominal, pelvic, and genitourinary. In the hospital setting the range of ultrasound examinations was much wider, showing how an ultrasound machine is of multiple uses similar to the full sized ultrasound machines in the secondary and tertiary hospitals in our study. It alluded to the issue of using an allocative factor to apportion the costs related to the type of examination performed by the ultrasound machine.

Kongnyuy et al., (2007) notes the importance of not only training doctors to use ultrasound in obstetrics but to also train midwives (Kongnyuy & van den Broek 2007). Task shifting from sonographers, to nursing staff was noted as an option in the studies regarding introducing portable ultrasounds in low resource settings (Adler et al., 2008).

The World Health Organisation provides guidelines of training sonographers and general practitioners (Kurjak & Breyer 1986). A study in a rural setting in Rwanda, ultrasound training on maternal health was offered to the local physicians and the quality assessment showed 96% accuracy. The Ghana study mentioned above used a skilled radiologist.

2.3 Lessons and Gaps derived from the literature

The literature review identified gaps in terms of maternal costs within South Africa. The cost for antenatal care in public health care centres in South Africa of US$7.24 ($5.78-$8.70) noted in Jinabhai et al was for the year 2000 (Borghi (n.d.)), and there don't seem to be any studies accessible on the public domain going forth. It is interesting that with all the talk of reaching the millennium goal on child and maternal health, no one has bothered to come with a cost covering the 9 month pregnancy period or a simple visit cost for the patient. It has been

widely published that financial constraints on the patients result in most of them not attending antenatal care.

However, not much effort has been done to cost a financial burden per visit to the ANC. The economic impact on the introduction of the Umbiflow machine into the primary health care intends to calculate the cost per visit to the ANC and to a referral for further monitoring.

More so, there have been limited studies on the cost effectiveness of an introduction of a new machine for maternal care. As noted in the previous section, clinical effectiveness studies have been done on introduction of ultrasounds including portable ones in low resource settings. A literature search for similar cost studies yielded no study. A systematic review by Harris and Marks (2009) revealed that there are not many costing studies dealing with the introduction of compact ultrasound in low resource settings (Harris & Marks 2009).

Most studies evaluated clinical effectiveness but did not explore the economic impact. The Umbiflow study aims to cover part of this gap. It will also provide comparative material in case of similar studies in the future. To our knowledge, this will be the first detailed costing study of an antenatal technology intervention programme in South Africa context, and though a pilot study, it will provide strong insights into possibilities of benefits of introducing a reasonable cheaper technology in low resource setting that could improve antenatal outcomes.

Given the fact that the evidence in the current study on cost effectiveness of the introducing the Umbiflow is from a pilot study with limited population study group which also lacks a proper comparison group, a full economic evaluation of antenatal procedure as well as the introduction of the personal computer (PC)-based, continuous-wave Doppler machine (the Umbiflow® machine in the primary health care setting should be undertaken to provide a full picture of health benefits as well as costs.

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3 JOURNAL ARTICLE

MATERNAL HEALTH: COST ANALYSIS OF INTRODUCING THE UMBIFLOW VELOCITY DOPPLER SYSTEM AT PRIMARY HEALTH LEVEL. A PILOT STUDY CONDUCTED AT KRAAIFONTEIN COMMUNITY HEALTH CENTRE AND DURBANVILLE DAY CLINIC

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Abstract

Background
Umbiflow is a sophisticated but easy-to-use Doppler with bi-directional indication of blood flow velocity in the umbilical cord. The Doppler measurement is used to recommend specialist intervention should the fetus be at risk. The project was motivated by the status quo in South Africa is which Doppler interventions are only available at higher levels of care, and thus require patient referral.

Study Objective
The objective was to study the costs associated with using an Umbiflow Doppler analyser at primary antenatal care facilities from a societal perspective.

Methods
A pilot study was carried out on a cohort of 131 pregnant women with suspected low Symphysis Fundus. A retrospective cost analysis was conducted on 41 out of the 66 pregnant women, referred to a higher level hospital from Kraaifontein and Durbanville Clinics, between April 2013 and March 2014 using structured questionnaires. Health provider and societal cost perspective were adopted. The costs were calculated in 2013 Rand value.

Results
The average cost was higher for secondary hospital visit for Doppler screening (R194.77) compared to R73.62 for a visit to the primary health care. From the health system perspective, the cost was 722.28 rands and 6709.78 rands in the primary health care setting and hospital respectively. Doppler screening strategy in hospital level proved less cost-effective than clinic based Doppler strategy,

Conclusions
The evidence provided strong insights into benefits of introducing a reasonable cheaper technology in low resource setting that could improve antenatal outcomes.

Keywords: Umbiflow Doppler, Intrauterine growth restriction (IUGR), Symphysis Fundus, portable ultrasound, perinatal mortality rate Cost analysis

3.1 Background and Setting
The study focus was on introduction of technologies that help in diagnosing fetus intrauterine growth retardation (IUGR) due to placental insufficiency i.e. the placenta's inability to provide sufficient blood flow for the fetus to continue growing relative to the standard growth curve which may result in death of the fetus if no treatment measures are taken i.e. perinatal mortality (Calhoun Rice, 2012). Perinatal mortality (PNMR) accounts for deaths during the period before the child is born (Stillbirths) and the first week of birth. It is calculated as the number of perinatal deaths per 1000 total births. (World Health Organisation, 2013) South Africa's definition of perinatal mortality differed from that of World Health organisation before 2005.

Improvement of maternal health and reduction of child mortality form Goal 4 and 5 of the Millennium Development Goals (MDGs) advocated by signatories to the United Nations in 2000, South Africa included (World Health Organisation, 2014). To achieve these goals it is critical that the mother and the fetus obtain medical monitoring during the 40-42 weeks pregnancy period to avoid disability or death of the child or the mother. It is during this period that a fetus may fail to develop or suffers slow growth as a result of several clinical factors and maternal lifestyle habits (Mook-Kanamori et al., 2010). A South African report, Saving Babies 2010-2011 (Pattinson, 2013) , reported 32,178 still births in a 2 year period of January 2010 to December 2011 within the 94% of the total hospitals who provide data to a Perinatal Problem Identification programme (PPIP)((MRC 2014)

Fetal growth assessment is an important part of positive maternal outcome and the early detection of intrauterine growth restriction (IUGR). In South Africa, the protocol to follow when a woman tests positive for pregnancy, assuming the baby is wanted is noted in the Basic Antenatal Care (BANC) handbook (RC Pattinson, 2007). A woman's antenatal care (ANC) should begin during the first visit to the hospital to confirm pregnancy. From there onwards the fetus growth is monitored by nurses using a tape measure to measure the symphysis-fundal (SF) (Cronjé, Bam, & Muir, 1993b). The status quo of suspected cases of IUGR using the tape-rule measurement of SF height is an upward referral to the higher level care for Doppler ultrasound. As a result of the subjective referral, a number of cases are sent back to the primary health care (PHC) due to false alarm (false diagnosis noted as 2.5 times for every correct diagnosis or in some cases 5%) and thus both the health care system and the patients are exposed to avoidable cost and burden (Cnattingius 1985 & NCCWCH 2008).

The introduction of technology into the PHC to assist human capital is seen as strengthening the Technology pillar of health systems. However, technological innovations are not always cheap and are usually confined to the secondary and tertiary institutions. Less costly technology in the clinics and community health centres (CHC) is likely to reduce hospital admissions by 44 %, caesarean sections due to foetal distress by 52% and possibly avert 20% of induced labour (CSIR, 2013). The study focus is on introduction of relatively cheap technology that could help in diagnosing IUGR due to placental insufficiency (Calhoun Rice, 2012).

The Council for Scientific and Industrial Research (CSIR) commissioned project has been instrumental in the testing of a miniature mobile ultrasound Doppler machine developed by Jeremy Wallis, Medical Research Council, CSIR and funded by the South African National Research Foundation for use in the lower level facilities (CSIR, 2003). It is meant for patients who do not present as high risk at the initial visits but with further monitoring are then suspected to have IUGR (CSIR, 2003). It is a miniature, portable ultrasound machine which doesn't contain imagery of the womb. It uses continuous-waveform ultrasound to detect the blood flow within the umbilical cord of a fetus in conjunction with a computer/ laptop and does not need a trained and experienced sonographer (CSIR, 2003). It can be operated by trained midwives and nurses. A previous clinical study revealed the Umbiflow Doppler test run on the Pentium 3 PC which produced a normal flow velocity waveform was less likely to be followed by perinatal deaths (Hugo et al., 2007). However, no full cost analysis study was done i.e. from the health system and the patient perspective.

3.2 Methodology

3.2.1 Ethics Approval

Ethical approval was provided by the University of Cape Town, Stellenbosch University, and the Western Cape Department of Health Research Ethics Committee. Only the research team had access to patient data and codes were used as individual identifiers for anonymity.

3.2.2 Setting

The study was conducted in the Tygerberg Eastern Health District of the Metro Region of Western Cape, South Africa at two primary health care facilities, one secondary level hospital, and one tertiary hospital namely Kraaifontein Community Health Centre (CHC), Durbanville Day Clinic, Karl Bremmer District Hospital, and Tygerberg Hospital respectively. The hospitals are all public institutions funded by the Western Cape Department of Health (WCDOH), one of South Africa's 9 provinces. The patients presenting at Karl Bremmer and Tygerberg hospitals are referred from Kraaifontein and Durbanville clinics i.e. they form part of their catchment area. The pilot project was conducted during the period July 2013-March 2014. The clinical study included an economics impact analysis of introducing the Umbiflow Doppler machine into the primary health sector, the results of which are reported in this report. The cohort of the clinical study was 139 patient stems from the sample size calculation by Dr. Justin Harvey at Stellenbosch University for the Umbiflow clinical study. The inclusion criteria for patient participation is poor SF growth and late bookers >28 weeks attending Kraaifontein Community Health Care Centre and Durbanville Clinic for antenatal services. All patients who met the criteria of suspected IUGR from Kraaifontein CHC and Durbanville clinic following an Umbiflow medium and high risk result were referred to Karl Bremmer or Tygerberg depending on case severity for further confirmation of the Doppler results.

3.3 Costing Approach

A societal perspective was adopted in the cost analysis. The costs were divided into two categories namely health systems and patient costs. The costs were calculated in Rand value, the South African currency at the year 2013 prices. Microsoft excel was used to analyse the data. The Doppler ultrasound administering to a patient at different levels of care will be costed.

3.3.1 Patient costs

The patient costs were collected through structured questionnaire and reflects a bottom up approach. To avoid recall bias, the team made an effort to interview the patients within the month of referral. Out of the 139, 66 had clear referral information and 41 were successfully interviewed for the economic study. The reminder either refused to be interviewed, or were not reachable on their phones or addresses due to either wrong telephone numbers supplied, or having moved from their original addresses. It was also difficult to identify some addresses due to the haphazard town planning of the suburbs.

The patient direct costs, included travel costs, refreshment costs, and any payment for child care substitute during the primary health care centers and referral visit; all reported in Rands .

The reported time to travel and the waiting time were calculated for PHC visits and referral visits (hospital visits). Patient costs categories that were collected in the

analysis included direct costs (travel costs and refreshments i.e. snacks and drinks) and indirect costs (travel time to the clinic and waiting time at the clinic). The indirect cost is therefore, the productive time lost or forgone income by not only the patients but also the caregivers is estimated. In order to quantify the time loss, the lost hours are monetized by multiplying the total number of hours lost by average hourly wage. However, the use of general average wage or an average wage of people with same characteristics as been accepted as proxy (Zhang et al., 2011). **Due to the fact that over 75% of the patients were unemployed or with irregular jobs, with little education, the national minimum wage of domestic workers in 2013 (9.63rands per hour) was used as a proxy**

3.3.2 Health Systems Costs

Incremental costs were assessed from the perspective of the health system in relation to introducing the Umbiflow Doppler ultrasound machine into the primary health care level. The costs assessed encompassed the health system related costs due to referral of patients to secondary and tertiary institutions.

3.3.2.1 Consumables and Overhead Costs

Micro-costing was constituted in collecting the direct costs. The direct health system costs included recurrent costs of administering a Doppler namely consumables during patient assessment and staff costs. There was no drug costs included since the radiology department is not a drug administering department. Most overhead costs are not affected in case of introduction of the Umbiflow Doppler machine into the primary health care since the existing maternity rooms will be used for the examinations and their maintenance is already included on the clinic budgets. Despite the electricity bill for the clinics' likely increase in the instance of full implementation of the Umbiflow Doppler machine or the Complex fixed ultrasound machine at clinic level, it was impossible to determine the voltage used by the machines since these are lumped onto the whole clinic or hospital electricity bill. This resulted in the exclusion of the electricity costs in the calculations.

3.3.2.2 Capital costs

Capital costs and useful life years were obtained from the facilities procurement departments. The original costs of the products were provided and these were converted to 2013 prices. Capital costs were discounted and annualised at 3% which is a standard foe World Health Organisation whilst sensitivity analysis was done at 0% and at 5% annually in order to give room for referencing and comparison (Drummond 2005, World Health Organisation, 2005). Equipment and furniture was apportioned depending on time the capital and the number of patients was used on Doppler related activities vis-a-vis other diagnostic services offered by the same machine. The Umbiflow programme is viewed to be a scaling up programme with an assumption that the existing buildings will be used in implementing the project; therefore buildings were excluded from cost calculations.

Training costs for the staff administering were included. These were costs incurred for training the nurses in using Doppler machines at the primary health care level. The useful years for training were 30 years (Wondering, Reinhold & Black, 2005). The same discounts rates as for capital were used given that training is considered a future investment.

3.3.2.3 Personnel costs

In order to ascertain the personnel costs interviews with Nurses, sonographers and personnel involved in the pilot project were conducted in which their government salary grades and the actual amounts were provided. These were confirmed by the DOH from the WCDOH. Based on the time spent by the different staff administering Doppler at the primary health care level, the proportion of their salary was allocated to human resources cost of conducting a Doppler to obtain a personnel cost per month. The Umbiflow computer captured every Doppler administered onto an online server, capturing the actual time spent per patient. However, out of the 139 cohort, only 131 time records were found in the time sheet. The average time per patient for administering a Doppler on an Umbiflow machine was 4.4 minutes, using the 131 cohort. However, at the tertiary and secondary hospitals, the online capturing of each activity was not available therefore an average of 5 minutes per Doppler was used. Information was obtained from key staff at the hospitals through an interview schedule, and the data captured into excel. Their responses could not be validated through a time and motion study, and hence may have over or under estimated the portion of their time applied to Doppler administering .The limitation of this strategy is the difference in patients' weight, fetus gestation age amongst others which determines the time taken per patient. Therefore, stamping an average may not be the most accurate option.

3.4 Results

3.4.1 Patient Costs Results

Demography

The patients interviewed were 41 with an average age of 26 years; the youngest 18 and oldest 38 years. 34.2% were married, 19.5 lived with their partners whilst 46.3% were single and resided mostly with their parents. 78.1% formed the informal employment/unemployed group. 21.9 % were employed but mostly as domestic workers. In terms of education level, 17% (7 people) attained primary education whilst 68% (28 people) and 15% (6 people) had secondary and graduate education respectively.

Referrals

The current antenatal procedure is that pregnant women with observed low SF are referred to the secondary institution for ultrasound test. In cases where the fetus was not in danger, the women were sent back to the clinic otherwise they are retained in the hospital. In this study, cases that were referred back to the primary health care were called 'avoidable visits' while the cases retained in the tertiary were called 'unavoidable cases'. Out of the 41 women interviewed, 31.7% (13) were 'avoidable cases'; 61% (25) were 'unavoidable cases' and 7.3% (3) couldn't go for their referral appointment because of financial constraints.

Costs

Although, all the patients had travel time to the primary health care but not all had travel cost and refreshments. Only 58.5% had travel expenses to the PHC with an average transport cost of R28.45. The average time of 0.8hrs was spent by all participants to the primary health care facilities**. Table 8** reflects the return cost for travel expenses as mentioned by the participants. The opportunity cost was calculated by multiplying the time with the proxy hourly rate of R9.63.

Table 8: Costs incurred by Patients whilst visiting the Primary Health Care Centre

Direct costs				Indirect/opportunity costs	
Travel cost (n)		Refreshments		Travel time (n)	
Patients	Caregiver	Patients	Caregiver	Patients	
R28.45 (24)	R16.00 (2)	0	R12.50 (2)	0.80hrs (41)	R 7.71

Source: calculated by authors

Table 9 below contains the average breakdown of the patient costs by those who went for the Doppler referral appointment in the secondary hospital. As expected, the patients experienced higher direct and indirect costs for referral experience as they do need to travel far and also wait for treatment much longer. The average travel cost for the patients and those that accompanied them was R38.25 and R50.20 respectively while the average travel time for the patients alone was 1hr 41 minutes, translating into R16.21. The average waiting time in the hospital was over 5 hours in all cases. This indicates the increase in financial burden on patients who need not go for Doppler referral.

Table 9: Costs incurred by Patients whilst visiting the Secondary Hospital on referral

Visits	Direct cost				Indirect cost/opportunity cost			
	Travel cost		Refreshments		Travel time		Waiting time	
	Patients	Caregivers	Patients	Caregivers	Patients		Patients	
All visits	R38.25 (33)	R50.20 (9)	R26.45 (29)	R11.83 (12)	1hr 41mins (37)	R 16.21	5hrs 23mins (33)	R 51.83
Avoidable visits	R47.41 (11)	R67 (2)	R24.63 (8)	R25.67 (3)	2hr 15mins (13)	R 21.66	5hrs 25mins (11)	R 52.15
Unavoidable visits	R33.68 (22)	R45.43 (7)	R27.14 (21)	R27.44 (9)	1hr 23mins (24)	R 13.31	5hrs 23mins (22)	R 51.83

Table 10 contains the total costs (sum of direct and indirect costs) represented as the average costs per patient visit for Doppler screening. As can be observed, the average cost is higher for tertiary visit for Doppler (R194.77) compared to R73.62 for a visit to the primary health care. The referral cost was further divided into avoidable and unavoidable visits for Doppler screening and this indicated that average cost per avoidable Doppler visit was higher compared to the unavoidable visit.

Table 10: Patient Perspective costing summary

From the perspective of the patients	Primary health care	Referral (ALL)	Avoidable	Unavoidable
Transport expenses for monitoring and referral	44.45	88.45	114.41	79.11
Time taken for return trip	7.71	16.21	21.66	13.31
Waiting time	8.96	51.83	52.15	51.83
Money spent on food and refreshments	12.5	38.28	50.3	54.58
Total Average cost	**73.62**	**194.77**	**238.52**	**198.83**

The prospective total patient cost for all the 139 cohort was 9108.67 rands in the PHC and 19846.42 rands in the secondary hospital. The cost indicated that primary health care visit is far cheaper than for a secondary level visit.

3.4.2 Health Systems Costs Results

The model included personnel, consumables, and capital and equipment costs. At the primary level only professional based nurses work there whilst the secondary and tertiary hospitals have sonographers for the ultrasound Doppler administering rendering the costs higher for higher level institutions. The nurses on the Umbiflow project were not only stationed in the maternity unit. They were moved around to perform services in accordance to clinic regulations, resulting in new nurses having to be trained mid-project. The primary health care institutions have lower patient volumes in comparison to the higher levels i.e. an average of 15 patients for Doppler.

However, the Karl Bremmer which is a referral district hospital had an average of 185 patients per month, most of the patients coming from several community health centers and Clinics. It had 2 sonographers employed to administer Doppler and other radiology activities. Tygerberg had an average of 445 Doppler patients per month with 1 sonographer who was highly qualified in comparison to the other levels, thereby rendering her unit cost more. These numbers affected the costs of consumables used at the relevant institutions.

Furthermore in terms of capital costs, Karl Bremmer had 2 ultrasound machines, with the Mindray being a new acquisition (2013 cost of R297 000) which costs 7 times more than the Toshiba acquire in 2012 (R41 750). The Mindray DC6 is a high powered Doppler ultrasound machine with colour imaging. The Soner Acer at Tygerberg cost R135 000 in 2012. Unlike the Umbiflow Doppler machine, the Xario, Mindray and Soner Acer Doppler ultrasound machines are more expensive and not portable. Though the Xario is movable within the hospital it is not easily portable in comparison to the Umbiflow. In terms of bringing Doppler portable ultra-sounding to the primary level, the Umbiflow machine proves more versatile and less costly especially if when used for outreach clinic programmes. The Umbiflow machine costs ZAR 20,000. The specialised beds (Metron and Sonar couch) used at Karl Bremmer and Tygerberg hospitals also proved costly compared to the standard

examination bed at the PHC level. The same applied to the specialised chair at the secondary level hospital (Salli chair) whose purchase price was R6000.

Having adjusted for inflation and annualised and discounted the costs at the 3%, the average unit cost per patient at the PHC level was estimated to be R49.62, at the secondary level R36.27 and at the tertiary level R18.26. The low unit cost estimates at the secondary and tertiary institutions were mostly affected by the extremely high number of referral patients attended to at Tygerberg in comparison to Karl Bremmer and Kraaifontein/Durbanville PHCs i.e. economies of scale. However, the total costs are extremely higher at secondary and tertiary hospitals, See Table 11. Adding the provider and patient monthly total cost, the societal costs to the PHC and secondary hospital amounts to 9 830.95 rands and 26 556.20 rands i.e. for secondary hospitals its approximately 3 times more than the PHC.

Table 11: Average unit costs per patient for Doppler administering (3% discount rate; ZAR in 2013 Value)

	Kraaifontein and Durbanville		**Karl bremmer**		**Tygerberg**	
	Total costs	*Cost profile*	*Total costs*	*Cost profile*	*Total costs*	*Cost profile*
Recurrent costs						
Personnel	224.25	31%	4 598.72	68.54%	6 412.02	79%
Consumables	140.27	19%	1 422.54	21%	727.20	9%
Total recurrent costs	***364.52***	**50%**	***6 021.26***	**90%**	***7 139.22***	**88%**
Capital costs						
Furniture and Equipment	298.39	41%	580.78	8.66%	881.90	11%
Training	59.36	8%	107.74	2%	107.74	1%
Total capital costs	***357.76***	**50%**	***688.52***	**10.26%**	***989.64***	**12%**
Total monthly cost	**722.28**	**100%**	**6 709.78**	**100.00%**	**8 128.85**	**100%**
Average unit cost per patient	***49.62***		***36.27***		***18.26***	
Average monthly doppler patients per facility	**15**		**185**		**445**	

**Average monthly Doppler patient of Kraaifontein and Durbanville calculated using 131 cohorts*

3.4.2.1 Sensitivity analysis

The sensitivity analysis is used to test the changes that may occur due to changes in the basic assumptions used to generate the initial results. Sensitivity analysis was conducted (using a baseline of 3%) at 0% discount rate and 5% on the capital costs including training to check the robustness of the health systems costs. In all cases the costs proved to be robust. Assuming a 100% increase in Doppler's needed for the women attending all levels of hospitals, the average health system costs will decrease drastically as shown in Table 14 below:

Table 14: Sensitivity analysis on Average unit costs per patient for Doppler administering (ZAR in 2013 Value)

	PHC (Kraaifontein and Durbanville)	Secondary (Karl Bremmer)	Tertiary (Tygerberg)
BASELINE VALUE	49.62	36.27	18.26
3% Discount rate on training only	47.89	35.81	17.85
3% Discount rate on capital only	48.21	36.07	18.17
Discount rate 0% (both capital and training)	33.74	35.61	17.77
Discount rate 5% (both capital and training)	37.21	36.76	18.63
Number of Dopplers Administered +100%	24.81	18.13	9.13

3.5 Discussion and conclusion

This study explored the cost of the introduction of the personal computer (PC)-based, continuous-wave Doppler machine (the Umbiflow® machine) in to the primary health care facilities for routine antenatal screening. The use of personal computer (PC)-based, continuous-wave Doppler machine has been shown to improve the management of pregnancies with fetal growth restriction (Odendaal & Theron 2008) and therefore, the machine can be considered effective. Our study results show that screening with Umbiflow will improve the management of pregnant women in PHC by reducing the cost burden of avoidable referral and lowering the burden on secondary level health system, and reducing the ANC default rates.

A study by Abrahams et al, 2001 on the health seeking behavior of pregnant women in Cape Town showed that antenatal care attendance was influenced by transport cost among other barriers (Abrahams et al., 2001). National MNCH mortality audit data showed that the majority of child and maternal mortality deaths were linked to avoidable factors such as poor use of health care facilities by patients and transport (Chopra et al., 2009). It was therefore not surprising that some pregnant women did not attend their referral appointment due to financial constraints and therefore lost to follow up. Therefore, the DOH should consider introducing the Umbiflow Doppler in the PHC to avoid referrals.

The secondary hospital-based Doppler strategy proved to be more costly than the clinic based Doppler strategy to successfully screen and retain a patient. This was due to extra resources required when operating a high powered Doppler machine specifically the sonographers. The World Health Organisation provides guidelines of training sonographers and general practitioners (Kurjak & Breyer, 1986). Kongnyuy et al., (2007) noted the importance of not only training doctors to use ultrasound in obstetrics but to also mid-wives (Kongnyuy & van den Broek, 2007). Task shifting

from sonographers, to nursing staff has been noted as an option and this study used nurses in operating the Umbiflow thereby reducing operational costs. Ultimately the Umbiflow machine proved less costly more so if placed in a PHC.

Limitations

While considerable efforts were taken to make this study as accurate and relevant as possible, certain limitations arose which impacted the methodology used and how the results from the study can be interpreted and compared. A literature search for similar cost studies yielded no study. A systematic review by Harris and Marks (2009) revealed that there are not many costing studies dealing with the introduction of compact ultrasound in low resource settings (Harris & Marks, 2009). To our knowledge, this is the first detailed costing study of an antenatal technology intervention programme in South Africa context, and though a pilot study, it provided strong insights into possibilities of benefits of introducing a reasonable cheaper technology in low resource setting that could improve antenatal outcomes.

The limitations also include the small sample size and the inelegant CEA study design. Given the fact that the evidence in this study is from a pilot study with limited population study group which also lacks a proper comparison group, a full economic evaluation of antenatal procedure as well as the introduction of the personal computer (PC)-based, continuous-wave Doppler machine (the Umbiflow® machine in the primary health care setting should be undertaken to provide a full picture of health benefits as well as costs.

3.6 Competing Interests

There was no conflict of interest for the Author

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4. Policy Brief

MATERNAL HEALTH: COST ANALYSIS OF INTRODUCING THE UMBIFLOW VELOCITY DOPPLER SYSTEM AT PRIMARY HEALTH LEVEL. A PILOT STUDY CONDUCTED AT KRAAIFONTEIN COMMUNITY HEALTH CENTRE AND DURBANVILLE DAY CLINIC

Author: Plaxcedes Chiwire, University of Cape Town, January 2015.

Introduction

The study focus was on introduction of technologies that help in diagnosing fetus intrauterine growth retardation (IUGR) due to placental insufficiency i.e. the placenta's inability to provide sufficient blood flow for the fetus to continue growing relative to the standard growth curve which may result in death of the fetus if no treatment measures are taken i.e. perinatal mortality (Calhoun Rice, 2012). Perinatal mortality (PNMR) accounts for deaths during the period before the child is born (Stillbirths) and the first week of birth. It is calculated as the number of perinatal deaths per 1000 total births. (World Health Organisation, 2013) South Africa's definition of perinatal mortality differed from that of World Health organisation before 2005.

Improvement of maternal health and reduction of child mortality form Goal 4 and 5 of the Millennium Development Goals (MDGs) advocated by signatories to the United Nations in 2000, South Africa included[4]. To achieve these goals it is critical that the mother and the fetus obtain medical monitoring during the 40-42 weeks pregnancy period to avoid disability or death of the child or the mother. It is during this period that a fetus may fail to develop or suffers slow growth as a result of several clinical factors and maternal lifestyle habits[5]. In case of death occurring during that period, it is recorded with the hope that answers as to the cause may be obtained.

[4] World Health Organisation, (2014). WHO _ Millennium Development Goals 4 and 5. Available at: http://www.who.int/pmnch/about/about_mdgs/en/index.html [Accessed on 15 January 2014]

[5] Mook-Kanamori, D. et al., (2010). Risk factors and outcomes associated with first-trimester. The Journal of the American Medical Association, 303(6), pp.527–34

Worldwide, perinatal mortality is assumed to reach 3.3 million per annum, with 6 out of 10 being stillbirths[6]. The developing countries account for 90% of worldwide perinatal mortality rate (PNMR) statistics[7] . According to statistics from World Health Organisation, South Africa has a maternal mortality ratio of 310 deaths per 100 000 lives births. The infant (under-1) mortality rate in 2010 was 41 deaths per 1 000 live births, while the under-5 mortality rate was 57 per 1 000 live births[8]. A South African report, Saving Babies 2010-2011, reports 32,178 still births in a 2 year period of January 2010 to December 2011 within the 94% of the total hospitals who provide data to a Perinatal Problem Identification programme (PPIP)[9].

The national departments of health to require that all expecting mothers be monitored during the 9 month period, the full duration of conception to child birth. In 2008/09 the National average PNMR 31.4/1000, with the Western Cape Province having the lowest (26.3/1000) and Free State the highest of 37.9/1000[10]. In 2011, South Africa was reported to have 61 stillbirths per day and was ranked 176 out of 193 in terms of stillbirths[11]. The table below gives a summary of births and deaths per level of care in South Africa during the years 2010-2011

6 World Health Organisation, (2006). Neonatal and Perinatal Mortality: country, regional and global estimates. Available at: http://whqlibdoc.who.int/publications/2006/9241563206_eng.pdf [Accessed 12 January 2014].

7 Ibid.

8 South Africa Info., (2013). Health Care in South Africa. Available at: http://www.southafrica.info/about/health/health.htm#spend [Accessed on 31 January 2014].

9 Chopra, M. et al., (2009). Saving the lives of South Africa's mothers, babies, and children: can the health system deliver? Lancet, 374(9692), pp.835–46. Available at: http://www.ncbi.nlm.nih.gov/pubmed/19709729 [Accessed on 1 October 2014]

10 Health Systems Trust, 2013. South Africa's Perinatal Mortality Rate- Health statistics. Available at: http://indicators.hst.org.za/healthstats/75/data/eth [Accessed on 1 February 2013].

11 Times Live-SAPA. (15 April 2011). SA experiences 60 stillbirths a day -. *Times Live*. Available at http://www.timeslive.co.za/local/2011/04/15/sa-experiences-60-stillbirths-a-day [Accessed on 28 January 2014]

Table 8: South African Birth and Deaths per Level of Care 2010-2012

	Community Health Centres	District Hospitals	Regional Hospitals	Provincial Tertiary Hospitals	National Central Hospitals	Total
	500 grams +					
Total births	209096	548976	350838	99257	116399	1324566
Liveborn	207400	536883	341165	95956	111409	1292813
Survivor	207067	530229	336075	93746	108414	1275531
Early Neonatal Death	305	6257	4184	1765	2378	14889
Still Birth	1696	12093	9673	3813	4990	32265
Perinatal deaths	2001	18350	13857	5578	7368	47154
	1000 grams+					
Total births	207017	544480	345277	96871	112216	1305861
Liveborn	206791	534580	338236	94478	109019	1283104
Survivor	207067	529358	334816	93024	107144	1271409
Early Neonatal Death	205	4895	2747	1110	1425	10382
Still Birth	1219	9900	7041	2749	3197	24106
Perinatal deaths	1424	14795	9788	3859	4622	34488

Source: Saving Babies 2010-2011

Factors attributing to perinatal death include intrauterine growth restriction, infections, and birth trauma, maternal disease, antepartum haemorrhage, intrapartum hypoxia, and spontaneous preterm labour, fetal abnormalities whilst 38% of the still births are unexplainable[12]. Maternal disease may include HIV/AIDs, Tuberculosis, and effects from smoking amongst others[13]. Unexplained deaths are the highest amongst all causes or perinatal and still births in South Africa for babies weighing below 1000g.

The policy brief reports the findings of a study conducted in the Tygerberg Eastern Health District of the Metro Region of Western Cape, South Africa at two primary health care (PHC) facilities, one secondary level hospital, and one tertiary hospital namely Kraaifontein Community Health Centre (CHC), Durbanville Day Clinic, Karl Bremmer District Hospital, and Tygerberg Hospital respectively. The hospitals are all public institutions funded by the Western Cape Department of Health (WCDOH), one of South Africa's nine provinces. The study was funded by the Medical Research Council and the Council for Scientific and Industrial Research. The aim of the research was to conduct an economic

[12] Health Systems Trust, (2011). Saving Mothers and Babies_ Perinatal mortality. Available at: http://www.slideshare.net/oerafrica/saving-mothers-and-babies-perinatal-mortality [Accessed on 14 February 2014].

[13] Health Systems Trust, (2013). South Africa's Perinatal Mortality Rate- Health statistics. Available at: http://indicators.hst.org.za/healthstats/75/data/eth [Accessed on 1 February 2013].

impact in the introduction of an Umbiflow Doppler machine in the primary health care with the major goal being to reduce the number of perinatal deaths in the public health system.

Research Objective

The study determined the cost of introducing a continuous-wave Doppler analyser (Umbiflow Intervention) at primary antenatal care facilities; average cost per patient to the secondary level hospital from the patient's perspective and the average cost per patient referral for a Doppler to the secondary level hospital from the health system perspective

Methods

A cross- sectional analytical study was conducted from the societal perspective. The Economic Impact study will be carried out on the already approved sample size of 139 patients stemming from the Umbiflow Clinical study. The inclusion criteria for patient participation is poor SF growth and late bookers >28 weeks attending Kraaifontein Community Health Care Centre and Durbanville Clinic for antenatal services.

The data collection instruments comprised of two questionnaires. The first questionnaire was for patient costing and the second for facility costing. Physical observation was used to calculate the staff time per general patient (one who does not need a Doppler) at the primary health level. The extra staff time for a Doppler needing patient will be attained from the Umbiflow system which captures time stamps automatically and uploads the information to a central server. The average time needed for a Doppler was validated in the facility questionnaire.

Findings

- An average transport cost of ZAR 28.45. The average time of 0.8hrs was spent by all participants to the primary health care facilities. The opportunity cost was calculated by multiplying the time with the proxy hourly rate of R9.63.
- As expected, the patients experienced higher direct and indirect costs for referral to secondary hospital due to long distance travel and long waiting

time before being attended to. The average travel cost for the patients and those that accompanied them was ZAR 38 and ZAR 50.20 respectively while the average travel time for the patients alone was 1hr 41 minutes. The average waiting time in the secondary hospital was over 5 hours

- The prospective total patient costs for the 139 cohort was ZAR 9108.67 in the PHC and 19846.42 rands in the secondary hospital.
- The PHC had lower patient volumes in comparison to the higher levels i.e. an average of 15 patients per month for Doppler. However, the Karl Bremmer which is a referral district hospital had an average of 185 patients per month, most of the patients coming from several CHC and Clinics. Tygerberg had an average of 445 Doppler patients per month
- Having adjusted for inflation and annualised and discounted the costs at the 3%, the average unit cost per patient at the PHC level was estimated to be ZAR 49.62, at the secondary level ZAR 36.27 and at the tertiary level ZAR 18.26. The low unit cost estimates at the secondary and tertiary institutions were mostly affected by the extremely high number of referral patients attended to at Tygerberg in comparison to Karl Bremmer and Kraaifontein/Durbanville PHCs i.e. economies of scale. However, the total costs are extremely higher at secondary and tertiary hospitals

Table 9 : Average unit costs per patient for Doppler administering (3% discount rate; ZAR in 2013 Value)

	Kraaifontein and Durbanville		**Karl bremmer**		**Tygerberg**	
	Total costs	*Cost profile*	*Total costs*	*Cost profile*	*Total costs*	*Cost profile*
Recurrent costs						
Personnel	224.25	31%	4 598.72	68.54%	6 412.02	79%
Consumables	140.27	19%	1 422.54	21%	727.20	9%
Total recurrent costs	***364.52***	**50%**	***6 021.26***	**90%**	***7 139.22***	**88%**
Capital costs						
Furniture and Equipment	298.39	41%	580.78	8.66%	881.90	11%
Training	59.36	8%	107.74	2%	107.74	1%
Total capital costs	***357.76***	**50%**	***688.52***	**10.26%**	***989.64***	**12%**
Total monthly cost	**722.28**	**100%**	**6 709.78**	**100.00%**	**8 128.85**	**100%**
Average unit cost per patient	***49.62***		***36.27***		***18.26***	
Average monthly doppler patients per facility	**15**		**185**		**445**	

- Assuming we cost the research protocol as per the Western Cape Department of Health which does not include Doppler testing on 1st bookers the cost for PHC would be very high i.e. 240 rands average unit cost per patient due to the low number in follow up patients referred for Doppler testing per month
- Assuming a 100% increase in Doppler's needed for the women attending all levels of hospitals, the average health system costs will decrease drastically as shown

The Implication of the Findings on Policy.

- Patients who are from a poor background are incurring catastrophic costs in seeking Antenatal Care especially during referrals to secondary care if found to need extra monitoring. Some even abscond from referral visits.
- The waiting times at both PHC and secondary care for ANC and Doppler ultrasound are long. This is due to the high numbers of patients in the PHC and Secondary Hospitals. Interventions to reduce waiting time need to be put in place.
- There is a possible reduction of referrals with the introduction of the Umbiflow Doppler ultrasound Machine at the PHC level.
- Costs carried by the health system for avoidable referrals are huge and can be reduced by introducing an intervention at the PHC level. This means reviewing the Basic Antenatal Care Handbook which stipulates the protocol for ANC in the public Hospitals

Recommendation

- It is recommended that the Umbiflow ultrasound machine be introduced on a wider scale in PHC as a form of reducing referrals for Doppler to Secondary and tertiary care hospitals. Training of nursing staff on a wider scale should also be implemented if Umbiflow ultra sounding is to be introduced in the PHC for the same reason.
- Alternatively, the department of health could bring the higher powered ultrasound machines into the PHC for Doppler ultra-sounding but this would not be cost effective as noted by the research finding.

Conclusion

South Africa is experiencing a perinatal mortality crisis, which is testing its health system. In order to curtail these problem new cheaper technologies can be introduced at primary health care level, the first port of ANC. In so doing, the study findings show how cost effective it is to adopt one those technologies, i.e. the portable, easy-to use, Umbiflow Doppler ultra-sound machine to reduce patient and health provider costs. It would also ensure patients do not abscond from referrals due to financial costs. Adopting a policy that can see wider implementation of the Umbiflow would be the first step to reducing the high rate of perinatal deaths and ensure favourable fetal outcomes.

5. Appendices

Appendix A: Social Science and Medicine Author Guidelines

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