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Abstract

South Africa had a stillbirth rate of 16.4/1000 in 2019. Umbiflow is a sophisticated portable continuous wave Doppler device with bidirectional indication of blood flow velocity in the umbilical cord. Umbiflow clinical trial results have indicated that several stillbirths were avoided by screening pregnant women classed as low risk.

The study aimed to describe the perceptions of health professionals on the Umbiflow screening tool. The objectives were to explore the health professionals' perceptions on the usability, acceptability and the perceived challenges with implementation of Umbiflow. A qualitative descriptive study design was adopted, and purposive and snowball sampling was used to select 13 health professionals in two sites. Thematic data analysis was conducted. Ethics approval and permissions were obtained from the UWC Biomedical Research Ethics Committee, and respective provincial health departments. Informed consent from participants was obtained voluntarily. Data was transcribed verbatim and stored on a USB and will be destroyed in five years.

The main finding is that though low ANC prioritization and barriers to ANC access were identified the perceptions on usability of the Umbiflow are positive. The study recommends hiring sufficient staff and providing adequate training on Umbiflow. Other considerations include manufacturers provide after sales training to health workers and health departments to have an adequate health budget to ensure access to Umbiflow.

Declaration

I declare that **Perceptions of health professionals using the Umbiflow portable continuous wave Doppler in two (2) urban hospitals in South Africa** is my own work, that it has not been submitted for any degree or examination at any other university, and that all sources I have used or quoted have been indicated and acknowledged by complete references.

Earl Jason Prinsloo

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Abbreviations

ANC	Antenatal Care
BANC	Basic Antenatal Care
BANC Plus	Basic Antenatal Care Plus
BMREC	Biomedical Research Ethics Committee
CHNs	Community Health Nurses
COVID-19	Coronavirus Disease 2019
FGR	Fetal Growth Restriction
LMICs	Low- and Middle-Income Countries
NDOH	National Department of Health
NGO	Non-Governmental Organization
PHC	Primary Health Care
SAMRC	South African Medical Research Council
SDG	Sustainable Development Goal
WHO	World Health Organization

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Chapter 1: Introduction

1.1 Background

Sustainable Development Goal (SDG) 3.2 aims to end preventable deaths of newborns and children under five (5) years of age by 2030 (WHO, 2015). The neonatal period begins at birth and ends at 28 days of life (Pathirana et al., 2016). UNICEF (2016) defines the under-five mortality rate as the probability of a child dying between birth and before the fifth birthday. Therefore, all countries aim to reduce neonatal mortality to at least 12/1000 live births, and under-five mortality to at least 25/1000 live births (WHO, 2015). Currently the average global neonatal and under-five mortality rates are 17 and 37 per 1000, respectively (UNICEF, 2020). The World Health Organization (WHO) reports that in 2019 an estimated 5.9 million deaths under the age of five occurred globally, of which 2.5 million occurred in the first month of life (WHO, 2020). UNICEF (2020) have reported global estimates for the neonatal mortality rate as 11 for 2018, 10.8 for 2019 and 10.6/1000 for 2020, respectively. Although the under-five mortality rate is below the global average, it remains unacceptably high at 34.532.2/1000 (UNICEF, 2020).

Perinatal mortality can be defined as the number of fetal deaths past 22 completed weeks of pregnancy, plus the number of deaths among live-born children up to seven completed days of life, per 1000 total births (Wingate et al., 2017). The perinatal period begins at 22 weeks of gestation for stillbirths and ends on the seventh completed day of life for early neonatal deaths (WHO, 2006). The main factors which contribute to perinatal mortality include preterm birth, low-birth weight, fetal growth restriction and congenital abnormalities (Unterscheider, 2014). However, a large number of stillbirths remain unexplained (Nkosi et al., 2019). UNICEF (2020) reports the following: An estimated 2 million babies were stillborn globally in 2019, with an estimated median of 13.87/1000. Sub-Saharan Africa has a stillbirth rate of 21.7/1000, significantly higher than the

global average. The neonatal mortality rate remains significantly high at 27/1000 for sub-Saharan Africa.

According to the United Nations, at least 56 countries, particularly in Africa and areas affected by conflict, will have to increase, to more than double the present progress, to reach the sustainable development goal 3.2 targets to reduce infant mortality (United Nations, 2019). The top 25% of countries with the highest stillbirth rates are all LMICs, with the greatest burden being sub-Saharan Africa and South Asia (United Nations Inter-Agency Group for Child Mortality Estimation, 2020). South Africa had a stillbirth rate of 16.4/1000 in 2019 (United Nations Inter-Agency Group for Child Mortality Estimation, 2020).

Antenatal care in South Africa is discussed in the following section, in relation to the WHO guidelines on the Basic Antenatal Care, which later became the Basic Antenatal Care Plus guidelines.

1.1.1 Antenatal care in South Africa

In 2007, the National Department of Health (NDOH) advised that all health facilities providing antenatal care (ANC) services had to adopt the Basic Antenatal Care (BANC) approach by the end of 2008 (Pattinson et al., 2019). The BANC approach was introduced as a quality improvement strategy based on the principle that good-quality ANC could reduce maternal and perinatal mortalities. Thus, aiming to achieve Millennium Development Goals 4 and 5, the BANC approach was introduced in the primary health care (PHC) clinics (Patience et al., 2016). It was simplified to the bare minimum so that ANC services were provided by every midwife based at PHC level. There is a focus on early attendance by all pregnant women and limiting the total number of ANC visits to a minimum of four or five visits per pregnancy for low-risk women (Patience et al., 2016).

However, the BANC model was still not preventing stillbirths (Pattinson et al., 2019). Based on local findings and global evidence, the NDOH adopted the Basic Antenatal Care Plus (BANC Plus) guidelines for antenatal care, and at-scale implementation started in April 2017. The BANC Plus model has eight (8) ANC visits in total (Pattinson et al., 2019). The new ANC package emphasizes the importance of having the first visit as early as possible, with the next visit scheduled at 20 weeks gestation. Thereafter, repeat visits at 26, 30 and 34 weeks; and every two weeks until delivery.

Inadequate ANC in low-resource settings may compromise the development of the foetus, as placental insufficiency may not have been identified during routine care (WHO, 2016a). As a result, causal pathways for stillbirth frequently involve impaired placental function, either with fetal growth restriction preterm labour, or both (Colella et al., 2018). Oxygen and nutrients supplied to the foetus, via the uterine and umbilical arteries, has a direct impact on fetal development. If compromised, this can lead to intrauterine growth restriction, which refers to abnormally slow growth of a foetus, and is associated with an increased risk of illness and death during the perinatal period (Sharma et al., 2016).

1.1.2 The Umbiflow™ screening device for placental insufficiency

Umbiflow is a sophisticated portable continuous wave Doppler device with bidirectional indication of blood flow velocity in the umbilical cord, developed by the South African Medical Research Council (SAMRC) and the Council for Scientific and Industrial Research (CSIR) (SAMRC, 2019). This type of ultrasound Doppler technology allows health care practitioners to assess placental function, i.e., the ability to supply sufficient oxygen and nutrition to the foetus. The screening tool measurement is used to recommend specialist intervention should the foetus be discovered to be

at high risk. Umbiflow was specifically designed for use by nursing staff and midwives at PHC facilities and antenatal clinics, including remote and low-resource settings (Nkosi et al., 2019). It offers an affordable, easy-to-use solution to screen all pregnant women for placental function and identify those at potential risk of stillbirth for further testing and intervention (SAMRC, 2019).

Clinical trial which were carried out around the Mamelodi area in Pretoria, South Africa results from between 1 June 2015 and 31 July 2017 indicated that a number of perinatal deaths were avoided by screening pregnant women classed as having low-risk pregnancies (Nkosi et al., 2019). Nkosi et al. (2019: 347) provides information on the results:

> *"An Umbiflow RI [resistance index] was performed in 2 868 women, and pregnancy outcome was available for 2 539 fetuses (88.5%); 297 fetuses (11.7%) were regarded as at high risk. AEDF [absent end-diastolic flow] was found in 1.5% of the population screened with an outcome. There were 29 perinatal deaths in the Umbiflow group (low risk n=18, high risk n=11). The perinatal mortality rate for 12 168 women attending the Community Health Centres [CHCs]and the antenatal clinics draining to the CHCs who did not have an RI was 21.3/1 000 births, significantly higher than that in the Umbiflow group (11.4/1 000 births) (risk ratio 0.58, 95% confidence interval 0.42 - 0.81)."*

A pilot study entitled *"The prevalence of abnormal Doppler's of the umbilical artery in a low-risk pregnant population in South Africa"* has since been conducted in nine (9) sites in South Africa (Hlongwane et al., 2021). The project has also been extended to five (5) African countries as Umbiflow International (University of Pretoria, 2021). It was therefore necessary to explore the perceptions of health professionals on Umbiflow, as this has not yet been found in the literature.

1.2 Problem statement

According to Nkosi et al. (2019), the largest category of perinatal deaths in South Africa remains unexplained stillbirths, where women were generally regarded as having healthy, low-risk pregnancies. Therefore, innovative methods are required to detect foetuses at risk of stillbirth or early neonatal death. The utility of the Umbiflow device has been shown to directly prevent stillbirths (Nkosi et al., 2019). The use of Doppler ultrasound to measure umbilical cord blood flow has been reported in literature to reduce the perinatal mortality rate amongst a population of high-risk pregnancies by an average of 38% (Theron & Pattinson, 2018). Although device efficacy may have been demonstrated in larger quantitative clinical trials, the studies did not describe the perceptions of health professionals on the Umbiflow device. The healthcare professional perceptions are important to explore, because it provides direct insight on the acceptability, feasibility and anticipated challenges with Umbiflow. The potential benefits of the Umbiflow device includes early detection of pregnancy complications for early intervention, reduced pressure on the health system caused by unnecessary referrals to hospitals for Doppler scans, and reduced burden on patients to pay transport costs for these unnecessary referrals (Nkosi et al., 2019; Hlongwane, et al., 2021).

Following the introduction and problem description is a literature review that describes the available literature and illustrates gaps which this study will fill. The methodological approach used to conduct this study follows, which includes a description of the study design, aim and objectives, study sample and the data analysis method. The rigour and ethical considerations are elaborated in the methodology chapter as well. Thereafter, the results of the data collected from study participants are discussed and presented in various themes. This is followed by an in-depth

discussion where results are compared to available literature. Based on the discussion, the conclusion is presented, and recommendations made.

Chapter 2: Literature Review

2.1 Introduction

While reviewing the published literature, four themes have been identified which are relevant to the Umbiflow device prior to national rollout in South Africa. The four themes are: (a) maternal health and ANC coverage, (b) value proposition of novel technologies, (c) factors influencing acceptability of novel technologies, and (d) barriers to national implementation. Maternal health and ANC coverage must be explored in-depth to establish an understanding around the importance of access to technologies, the need for novel medical device technology, its affordability and acceptability by both health professionals and patients, the quality of the device, and why it is important to meet regulatory standards. The value proposition discusses how Umbiflow has the potential to reduce costs for the health system and patients and to prevent possible perinatal deaths. Reducing waiting times and unnecessary patient referrals, and reducing travel costs are described. In reviewing literature on the factors which influence acceptability, it is discussed along three topics. Firstly, procurement, which relates to how provincial and national departments of health award bids to suppliers of medical devices. Health worker perspectives are reviewed to identify how health professionals have reviewed and accepted or rejected medical device technology. Similarly, patient perspectives are evaluated as the services of novel medical device technology directly affect them.

2.2 Maternal Health and Antenatal Care Coverage

Adequate access to antenatal care (ANC) is required to reduce mortality rates, and to achieve the SDG 3.2 by 2030 (Moller et al., 2017). Rural, low-income areas are more precarious than urban cities, due to higher levels of poverty and may not have better access than urban areas, to ANC

services in South Africa (Atkinson, 2014). Umbiflow was designed to be used in low-income areas with poor access to ANC services (SAMRC, 2019).

2.2.1 Access to technologies for quality antenatal care

Pattinson et al. (2019) state that improving antenatal and intrapartum care are imperative aspects for increasing child survival; and for this to be achieved, challenges have identified with achieving increased ANC visits, creating next-level expertise and access for high-risk women, and detecting and managing placental insufficiencies. A systematic review conducted by Haddad et al. (2019) on mHealth platforms for improving clinical ANC concluded that applications which had great potential for improving ANC, were mostly unavailable for free download, and access was restricted. Betran et al. (2018) aimed to evaluate whether a supply chain strategy based on the provision of medical supply kits could improve quality of care in pregnant women in Mozambique. It was concluded that a supply chain strategy that resolves stockouts at point of care can result in an improvement in quality during ANC visits, in comparison with the routine Mozambican national process for procurement and distribution of supplies. There is concern that too few visits result in missed opportunities to detect and treat asymptomatic pregnancy complications (Hofmeyr, 2015).

The WHO (2016b) guidelines state that accurate low-cost methods for detecting abnormal growth are desirable due to ultrasounds being resource-intensive and not widely available in LMICs. The only way to determine fetal growth restriction at PHC level is to measure the symphysis fundus height (Nkosi et al., 2019). Hlongwane et al. (2021) report that the prevalence of abnormal resistance index and absent end-diastolic flow in a screened low-risk population of 7088 women across nine sites in South Africa were 919 (13.0%) and 87 (1.2%), respectively, which is ten times

higher than previously recorded in high-income countries. These results warrant continuous wave Doppler ultrasound screening of the low-risk pregnant population in South Africa.

2.2.2 Characteristics of successful products

To increase access, the technology must be feasible. The Program for Appropriate Technology in Health (PATH) identifies three characteristics which make a product successful: *accessibility, affordability, and high quality* (PATH, 2018). Medical devices must therefore exist in a health ecosystem, buyers must be able to afford it, quality must be maintained throughout the supply chain and it must address an immediate need. These are the requirements to improve ANC quality of care through novel technologies. In line with the requirements mentioned by PATH, the following section will illustrate the characteristics of Umbiflow. These characteristics will unpack the accessibility, affordability, and quality.

Umbiflow accessibility

Despite most of the global population living and being treated in LMICs, over 80% of the medical devices market share is within high-resource settings, who often does not understand the context of LMICs in terms of accessibility (Piaggio et al., 2021). The Umbiflow device was designed and manufactured locally, can be used in low-resource settings as it only requires a laptop and appropriate software, and easily is accessible for those who attend PHC facilities in low-resource areas (SAMRC, 2019). Umbiflow Doppler technology has also reduced unnecessary referrals to specialized care by 55%, which is generally less accessible by those who live in remote areas away from these specialized services (Mufenda et al., 2015).

Umbiflow affordability

The use of low-cost ultrasound technology in LMICs has been growing in low-resource settings, and WHO recognizes the need for this growth in order to meet their requirements for PHC settings (Stewart et al., 2020). Umbiflow contributes to this by being a low-cost device, with locally-sourced components, which eliminates import costs and fluctuating forex rates (SAMRC, 2019).

Umbiflow quality

Measuring user requirements during medical device development will result in successful, high-quality products, which will improve effectiveness, patient safety and reduce the costs related to product recalls for necessary modifications (Martin et al., 2006). An ISO 13485 has been implemented at the CSIR and the process to obtain a European Conformity (CE) Mark for Umbiflow is near completion (Personal Communication, 2020). CE Mark certification is an expensive, and lengthy process and may impact negatively on the cost per unit. This challenge will be mitigated by acquiring additional funding sources to subsidize costs to ensure that low-resource areas can afford the device, resulting in improved access and health outcomes. For optimal quality, further research is required to better comprehend the requirements for manufacturers within the medical devices sector and new, adaptive methods are required to fully realize the user involvement (Money et al., 2011).

2.3 Value Proposition of perceptions on Novel Technologies

The value proposition of perceptions on novel medical device technologies are broken down in the subsection below. These are namely the perceptions on stakeholder value, current guidelines, and patient-centric value added.

2.3.1 Stakeholder value

Different perspectives and values pursued by various stakeholders on medical devices poses potential difficulty to the medical device industry, because it can cause deviations to a single outcome, therefore the viewpoints of the public must be considered through an evaluation framework (Park et al., 2019). The use of Umbiflow for widespread screening of low-risk pregnancies for impaired placental function, especially in LMICs, offers a very clear benefit in directly reducing the perinatal mortality rate (Nkosi et al., 2019).

2.3.2 Value proposition and current guidelines

In South Africa, current guidelines suggest that all pregnant women should preferably have access to one basic obstetric ultrasound examination at 18 – 20 weeks gestation (NDOH, 2015). Level 1 scans are conducted by accredited ultrasonographers at district level in South Africa, as per the National Department of Health Maternity Guidelines (NDOH, 2015). Level 1 scans entail multiple images being taken of the developing foetus, uterus, amniotic fluid and placenta, which are reviewed by a medical professional, who may request a more detailed, Level 2 Doppler ultrasound to detect fetal anomalies (Kaiser Permanente, 2018). Level 1 scans confirm the following: an intra-uterine pregnancy, fetal viability, the number of foetuses, the basic gestational age, the location of the placenta, and the amniotic fluid volume (Ulrich & Dewald, 2021). Level 1 scans are not expected to detect most serious fetal anomalies; hence this scan is currently only suitable for patients at a low-risk for fetal anomalies. Due to capacity constraints with accredited ultrasonographers, therefore, radiographers or trained midwives who have completed a basic ultrasound course, may also perform Level 1 scans (Kim et al., 2018). In South Africa, there are many unnecessary referrals for Doppler ultrasounds, which burdens the pregnant mother with

additional transport costs and extended waiting times at public hospitals, and also burdens the provincial health departments' limited resources (Nkosi et al., 2019)

2.3.3 Patient-centric value added

Routine conventional ultrasound does not reduce perinatal mortality or morbidity in LMICs (Goldenberg et al., 2018). The value the Umbiflow technology adds is to detect previously undiagnosed growth restricted babies that could benefit from intervention to prevent stillbirths or development issues in early infancy. It further offers the opportunity to identify issues at the PHC level at low cost, thereby both preventing unnecessary referrals and identifying potential high-risk cases that would otherwise have been missed by routine ANC screening and care (Nkosi et al., 2019).

Furthermore, routine ANC is very poor at detecting fetal growth restriction (FGR) (Figueras & Gardosi, 2011). The specific additions offered by Umbiflow include immediate diagnosis of abnormal Doppler at PHC level, avoiding unnecessary referrals and enhancing detection of placental insufficiency and FGR, which are causes of stillbirths. Benefits to higher care levels and patients include reduced hospital admissions and associated costs to the provincial departments of health (Nkosi et al., 2019).

Healthcare professionals may be potentially empowered by learning how to conduct diagnostic measurements that previously required a specialist. The perspectives of health workers on this valued skills development is yet to be explored. Drummond et al. (2013) report that it can be argued that there are other interest groups which include the general public and health care workers whose input must be considered in relation to the value added by novel health technologies.

2.4 Factors Influencing Acceptability of Novel Technologies

The factors which influence the acceptability of novel technologies are discussed in this section. These factors may also influence the acceptability of Umbiflow prior to national rollout in South Africa and have been identified as procurement, health worker and patient perspectives, and market-entry barriers for Umbiflow.

2.4.1 Procurement of medical devices

Health technology in South Africa has evolved over the last two decades and is constantly challenged by the introduction of rapidly changing technologies into the market (Govender et al., 2011). Tendering (Procurement) was written into the South African National Constitution in paragraph 217 (South African Government, 1996). Out of this, the Preferential Procurement Policy Framework Act (Act 5 of 2000) was produced to regulate the procurement process in the country (National Department of Treasury, 1999). The stages of evaluation in the tendering process focus on having registration with the South African Health Products Regulatory Authority's ISO 13485, competency, and Broad-Based Black Economic Empowerment score, as well as being registered on the Central Supplier Database. For Umbiflow to fulfill tender requirements, clinical trial results play an important role in proving the need, informed by both clinical trial results and the general acceptability by health professionals. This study will assist in additional background information on the perspectives of health professionals on acceptability of Umbiflow, should these perspectives be researched by national or provincial government officials prior to awarding a bid, or adding the device to the essential equipment list.

2.4.2 Health worker and patient perspectives

Several health worker acceptability barriers were identified which prevent results of user research being linked to development, as certain user and technological aspects of development were seen as separate work streams during the development process (Martin & Barnett, 2012). It is reported that a range of informal and formal organizational processes exist that can affect the uptake of user data during medical device development and that adopting a formal decision-making process can assist manufacturers during development, resulting in a higher quality product (WHO & World Bank Group, 2018).

Sekhon et al. (2017) identifies a model known as the Theoretical Framework for Acceptability (TFA) consisting of seven component structures: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy. However, there are no known examples of acceptability studies which fulfill these criteria.

An evaluation qualitatively assessed the feasibility, usability, and acceptability of a mobile Client Data Application for maternal, neonatal, and child client data management by community health nurses (CHNs) in rural Ghana (Rothstein et al., 2016). This app enabled CHNs to enter, summarize, and query client data. Reminders for clients were also sent via the app and provided a mechanism to report level of care to district officers. Results indicated high acceptability due to the app's capacity to facilitate client follow-up, data reporting, and decision-making (Rothstein et al., 2016). Despite acceptability, the feasibility and usability of the application were hindered by high client volumes, staff shortages, and software and device challenges.

Existing technology already allows for establishing patient empowerment, but a change in attitude by health professionals, policy makers and patients is required to influence patient acceptability

(Akeel & Mundy, 2019). While mobile health technology initiatives aim to give patients more medical information and empower them over their medical treatments, not enough is known on how medical device technology relates to health worker acceptability in the maternal health space (WHO & World Bank Group, 2018). Safi et al. (2018) reported that the acceptance of novel digital solutions and innovative medical technology by patients and professionals rely on comprehension of their anxieties and feelings of insecurity; and that the process will take time as individuals accept change at different rates.

2.5 Barriers to national implementation

Potential barriers to national rollout in South Africa have been identified as market entry barriers, public sector entry pathways, and healthcare worker acceptability and training. These are further discussed in the subsections below.

2.5.1 Market Entry Barriers for Umbiflow

Bergsland et al. (2014) identified the following barriers which affect market entry for medical devices in New Zealand: medical practice patterns and education, market size and penetration, research and development (R&D) and device failures, regulatory limitations and approval processes, patent limitations, and publication issues, reimbursements, pricing, and payments; and ethical considerations. Although South Africa does not necessarily have the same challenges as New Zealand, similar barriers have been identified by funders, manufacturers, and distributors for Umbiflow (PATH, 2018).

2.5.2 Public Sector entry pathways

The WHO estimates that 70% of medical equipment from developed nations does not work in emerging markets, due to pricing, market size, a lack of spare parts, and a lack of reliable power

and water (Malkin, 2014). Securing contracts within the provincial or national departments of health in South Africa remains an ongoing barrier, as these factors are taken into account during the bidding process (National Department of Treasury, 1999).

Considering emerging tender irregularities which have become evident in South Africa, it has become increasingly difficult to secure contracts as suppliers of the departments of health (Business Tech, 2021). A requirement for submitting a bid during the public tender application process is to include the price per unit (National Department of Treasury, 1999), which has not yet been finalized for Umbiflow. It also remains uncertain whether government will have sufficient budget to purchase Umbiflow once a price is finalized. Having better insight into perceptions on this device will aid in demonstrating a potential need for it, which supports the case for a competitive bid.

2.5.3 Health care worker acceptability and training

Unlike Doppler ultrasound devices that are operated by qualified ultrasonographers, the continuous-wave Doppler ultrasound as performed by Umbiflow only requires two days of training with lay health care workers to operate (Mufenda et al., 2015)). To empower health workers through novel technologies, governments need to provide foundations for trustworthy, ethical, and human-centered transformation to ensure support among health workers (Kruk et al., 2018). The acceptance and use of novel medical devices by health workers in their work settings remain to be seen. McDonald et al. (2019) estimates that 40-70% of donated medical devices are not functional or appropriate, amongst others because of a lack staff training. Although training is provided by the manufacturer of the Umbiflow device, once it has been distributed beyond the borders of South Africa, it is unknown whether ministries of health will support training activities with their available resources.

2.5.4 Efficient distribution channels

A stable supply system for medical devices requires stability and opportunities for trade fairness through increased transparency (Lee et al., 2018). The absence of a reliable supply chain in the public health sector may result in service delivery failure and/or a shortage in essential equipment or medicine (Maphumulo & Bhengu, 2019). If health facilities in South Africa experience a shortage in essential equipment, it may result in patients not having their health needs met, which could have dire consequences (NDOH, 2020). The CSIR, who are the developers of Umbiflow, have identified one distributor who will ensure that supply is adequate within South Africa and neighboring countries; however, a reliable distribution channel must be established beyond Africa.

2.6 Conclusion

There are multiple dimensions that need to be considered before novel medical devices that address maternal and child health challenges can be considered for national rollout. A multisectoral approach is required indefinitely and stakeholders must have a working understanding of their respective roles in the process. ANC visit adherence and early booking remain a challenge needed to be solved within South Africa. In doing so, fetal anomalies can be addressed sooner by appropriate intervention strategies, which are readily available by expert health professionals. Significant decreases in stillbirths among those who were in the Umbiflow group have been cited in clinical trials. In addition to Level 1 scans as per the appropriate guidelines, Umbiflow scans have reduced unnecessary referrals. In terms of factors influencing acceptability, further investigation is required to establish how it will be procured or be generally accepted by health workers. Finally, the barriers to national implementation must be explored as relevant literature for low- and middle-countries is limited. With most novel medical devices developed and exported from high-income countries, there is an increased need for an understanding of the local context

in South Africa. The health professional perspectives are a much-needed complement to insights on requirements and the way forward for addressing the problem of unexplained stillbirths in the country.

Chapter 3: Methodology

3.1 Study Design

Qualitative descriptive research studies seek to discover and understand a phenomenon, a process, or the perspectives and worldviews of the people involved (Bradshaw et al., 2017). Therefore, to gain the perspectives of medical doctors, nurses (all levels), advanced midwives and antenatal care practitioners on Umbiflow, a qualitative descriptive study was used for the purposes of this research.

3.2 Study aims and objectives

3.2.1 Aim

To describe the perceptions of health professionals on the Umbiflow screening tool used in two urban hospitals.

3.2.2 Objectives

- To explore the health professionals' perceptions on the usability of the screening tool in two urban hospitals
- To describe the acceptability of the screening tool by health professionals in two urban hospitals
- To describe the perceptions on the challenges with the implementation of Umbiflow screening anticipated by health professionals in two urban hospitals

3.3 Study Setting

3.3.1 Facility A – Upington, Northern Cape

Upington, in the Northern Cape Province has an area of 577.87 km² with a population of 57 220. Seventy-eight percent (78%) of the population are Coloured, 13% white and 7% Black African.

Afrikaans is the predominant language with 94% of the population who speak it as a primary or second language (Statistics South Africa, 2011). Facility A is a regional hospital with 327 beds and is the referral hospital for the western side of the Northern Cape. This includes both rural and urban areas. It serves as a level-one facility to all residents in the Dawid Kruiper local municipality area (including the Kalahari region) and provides services to in-patients and outpatients which are ideally referred from a community health centre or a PHC clinic. It is also a level-two, referral facility with specialist and sub-specialist services provided for residents of the !Kheis, Nama Khoi, Hantam, and Kai !Garib local municipalities.

The hospital has 24-hour health services in the following disciplines: paediatrics, obstetrics and gynaecology, general surgery, internal medicine, and trauma and emergency services. The hospital is also the first level of care for all maternity cases, normal and abnormal, within the municipality area excluding the Kalahari region where normal vaginal deliveries are performed. Kakamas hospital in the Kai !Garib municipality does not perform Caesarean sections, which compromises quality maternal and child health care and overburdens the provincial services with an added unplanned cost implication. (Northern Cape Department of Health, 2018).

3.3.2 Facility B – Welkom, Free State

Welkom, in the Free State Province, has an area of 167.55 km² with a population of 64 130. The most spoken languages are Afrikaans (38%), Sesotho (33%), English (11%) and isiXhosa (9%). In terms of demographics, 61% are Black African, 27% White, and 11% Coloured (Statistics South Africa, 2011). Facility B, which is situated in Welkom, offers free services to pregnant and breastfeeding women, as well as children under the age of six years from surrounding rural and urban areas. Specialist services include: 24-hour casualty service, maternity, obstetrics and gynaecology, paediatrics as well as outpatient services, amongst others.

3.3.3 Clinical trial

This study follows a clinical trial that was conducted in the two settings described in sections 3.3.1 and 3.3.2. According to Nkosi et al. (2019) the following inclusion and exclusion criteria were reported for the clinical trial:

Inclusion criteria

For pregnant women to have been included in the clinical trial, the following criteria must have been met: singleton pregnancy, gestation of 28-32 weeks, low, medium or high-risk. Low-risk pregnancies were followed up at local clinics for delivery. Medium to high-risk pregnancies were referred to hospitals.

Exclusion criteria

Women were excluded from the clinical trial if they were not pregnant or pregnant with multiple gestation. In addition to this, women were excluded if they were earlier than 28, or later than 32 weeks, respectively.

3.4 Study Population

The study population selected to participate were staff from both facilities A and B, comprising of professional (registered) nurses advanced midwives, ultrasonographers and medical officers who have been informed and orientated on the use of Umbiflow within their respective facilities.

3.5 Sampling

Purposive sampling is widely used in qualitative research for the identification and selection of information-rich cases related to the area of interest (Palinkas et al., 2015). Purposive sampling was therefore the methodology best suited for selecting participants for this particular study design that included interviews (Robson & McCartan, 2016). In this study, the purposive sample was

complemented by snowball sampling. Snowball sampling is when the researcher identifies one of more individuals from the population of interest and after they had been interviewed, they refer the researcher to other members of the same population to be interviewed (Robson & McCartan, 2016). Healthcare professionals, who had been informed on the uses of Umbiflow, were sampled for study participation. The total study sample was thirteen (13) health professionals. Six (6) participants were selected from Facility A and seven (7) from Facility B.

3.5.1 Inclusion criteria

For a health professional to be included in the sample, they must have been orientated and informed on the uses of Umbiflow. Participants will be included if they have used the Umbiflow or having knowledge about its uses. Having knowledge of the Umbiflow can include where: information on Umbiflow have been shared with participants in meetings, formal training, information leaflets, or demonstration videos. Study participants may be employed by the Department of Health or a non-governmental organization (NGO), and must be based at Facility A or B.

3.5.2 Exclusion criteria

Health professionals were excluded from the sample if they had not been informed on the uses of Umbiflow via meetings, formal training, information leaflets, or demonstration videos. Therefore, not having used the device or not having knowledge on its uses will exclude participants from this study.

3.6 Data collection

The key heads of departments (HODs) who were involved in the Umbiflow clinical trial were contacted by the researcher and asked to provide the names and contact numbers of potential participants. These participants consisted of midwives, advanced midwives, professional and

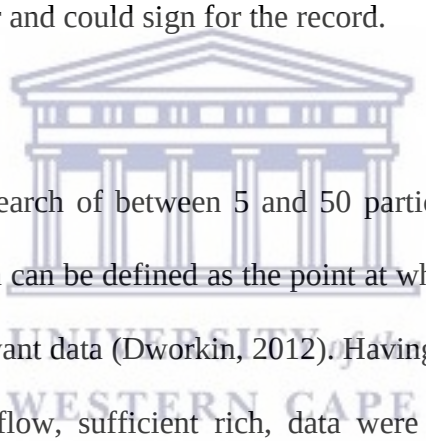
registered nurses, as well as specialists in obstetrics and gynaecology. They were contacted, and the purpose of the study was explained, and voluntary consent was gained for interviews. Dates and times for interviews were arranged via WhatsApp as this was the best platform to contact staff. Ten (10) of 13 participants were interviewed whilst at their place of work and three (3) were connected to their Bluetooth car system while driving between facilities. Follow-up interviews were not necessary, albeit participants had availed themselves for further assistance. The initial list of participants provided by the HODs had not been sufficient, therefore snowball sampling was used for recruiting fellow colleagues recommended by the original participants. Eight [8] participants were provided from the HOD's list and five [5] participants were included as a result of snowball sampling.

Due to COVID-19 safety protocols and national lockdown restrictions imposed by the Ministerial Advisory Committee of South Africa, no face-to-face data collection occurred, and all interviews were conducted via telephone. All interviews were audio recorded and transcribed verbatim. Arrangements were made by the researcher for participants to make use of an available office space in the facility to ensure privacy. In the event where no office space was available, participants were asked to do the interview from their private residences, at their most convenient time. However, although three interviews had been scheduled from participants' homes, they were conducted while driving due to unforeseen work circumstances.

A semi-structured interview guide (Appendix A) was used to collect data during all the interviews (Robson & McCartan, 2016). Semi-structured interviews typically consist of a dialogue between the researcher and participant, which is guided by a flexible interview protocol and has follow-up questions, probes and comments, designed to collect open-ended data, to explore thoughts, feelings and beliefs on a specific topic (DeJonckheere & Vaughn, 2019). Interviews were conducted in

English or Afrikaans, the languages in which the researcher was proficient. Given that all participants were health professionals, a working proficiency of English exists. All participants were, however, asked if they were comfortable with being interviewed in English or Afrikaans. For Facility A, two (2) out of six (6) interviews were conducted in English and four (4) in Afrikaans. The Afrikaans transcripts were translated to English. For Facility B, all seven (7) interviews were completed in English

Participant information sheets and consent forms were distributed via e-mail. Consent for interviews were gained verbally on interview recordings and electronically where the participant had access to a laptop and printer and could sign for the record.



3.6.1 Data saturation

A sample size in qualitative research of between 5 and 50 participants is considered adequate (Dworkin, 2012). Data saturation can be defined as the point at which the data collection process no longer offers any new or relevant data (Dworkin, 2012). Having had 13 participants who were informed on the uses of Umbiflow, sufficient rich, data were provided, which has become saturated, with participant's responses. There was no need for follow-up interviews as data saturation had been reached.

3.7 Data Analysis

The interviews were audio recorded, and the recordings were transferred to a USB flash drive. The researcher transcribed all the interviews verbatim and the Afrikaans transcripts were then translated to English. A master copy of the original transcripts is kept on a USB stick to ensure that the data source within the context of the transcript was accurate.

The thematic coding analysis approach described by Gibbs (2007) was used to analyze the data: familiarization, coding, identifying themes, defining, and naming themes and eventually integrating and interpretation. The researcher read the English transcripts repeatedly to become familiar with the data. ATLAS.ti 9, which is the latest version, was then used for thematic analysis. The researcher coded sections of texts that expressed a specific perspective, concept or behaviour, highlighted the sections on the transcripts and added a descriptive code. Similar codes were categorized together to identify themes and patterns emerging from these categories. Following on this process, the researcher reviewed the revised or new themes to ensure that they could be found in the data. New themes were grouped together and named, providing overarching themes that describe the main idea of the grouped themes. Meanings were derived from the themes and allowed for interpretation of data to draw conclusions from it, and provide insights on the research question.

3.8 Rigour

Qualitative researchers use various strategies to ensure validity and truthfulness of data (Robson & McCartan, 2016). Rigour was achieved by ensuring that participating staff were appropriately qualified, experienced, or orientated on the Umbiflow device. To achieve trustworthiness, qualitative researchers must demonstrate that data collection was conducted in a precise, consistent and exhaustive manner, disclosing the methods of collection with adequate detail to enable readers to determine that the process was credible (Nowell et al., 2017). This was achieved by purposive and snowball sampling which has been shown to increase credibility, trustworthiness and confirmability of the information gathered (Forero et al., 2018). Triangulation of data is a validity procedure whereby researchers search for convergence among multiple sources of information to form emerging themes in a study (Creswell & Miller, 2000).

The different health professional categories provided multiple data sources that could be triangulated. Confirmability was ensured by the richness of the data where the interpretations were securely based in the data enhancing the confirmability of the conclusions (Forero et al., 2018). In addition to this, an audit trail was kept of the raw data, transcripts, and records of decision processes in the reflexive journal.

A conflict of interest that must be declared is that the researcher is employed by the SAMRC, who has been the funder of the initial clinical trial on Umbiflow. The researcher also received a bursary to complete his Master's in Public Health from the SAMRC. However, the research does not directly benefit the SAMRC. No participants received any compensation for their participation or benefitted personally, or financially from the rollout of the Umbiflow device.

3.9 Ethical considerations

Ethical approval was obtained from the University of the Western Cape's Biomedical Research Ethics Committee (BMREC). In addition to BMREC, permissions were requested from the Northern Cape and Free State Departments of Health via the National Health Research Database. Thereafter, the chief executive officers of the respective hospitals were approached for permission to conduct interviews.

During the invitation to participants to be part of the study, the researcher explained the purpose of the study to participants. The participant information sheet explained the aim and objectives of the study and requested their informed consent to take part in the study. Consent forms were signed by four participants and returned to the researcher via e-mail and consent was obtained verbally at the start of each interview with the remaining 9 participants.

The researcher explained that participation is voluntary, and that a participant may withdraw at any time without any repercussions. The participant was informed that confidentially would be maintained by the researcher and that the collected information would be stored on a USB data drive that would be destroyed after five years. The researcher did not mention the participant's name on any of the interview recordings.

Participant names and the names of other people referred to in the interviews were replaced with pseudonyms in the interview transcripts. Codes for pseudonyms are kept in a file on the researcher's laptop which is password protected Names of participants will be replaced with pseudonyms in the transcripts. The hard copies of the transcripts are stored with the USB flash drive in a locked safe only accessible to the researcher. The computer and files on the computer remain password protected. The password is only known to the researcher. After five years, the hard copies will be shredded and the information on the USB and hard drive of the computer will be permanently deleted.

The researcher complied with the requirements of the Protection of Personal Information Act (POPIA) in collecting, processing and distributing personal information. The researcher further agreed to take appropriate measures to safeguard information collected, to maintain the confidentiality of personal information and to prevent access by persons other than the researcher.

With any human interaction there is a potential for discomfort. Should a situation arise where discomfort was experienced, participants were informed that they may terminate the interview and the participant would be referred to the social worker on duty at the health facility. A possible risk was that participants might feel that their performance was being judged. Should this occur, the researcher would reaffirm the aim and purpose of the study, reassuring the participant that measuring performance was not the objective of the study.

3.10 Study Limitations

The study population initially were only those who have used the Umbiflow during the clinical trial but because a number of the participants declined to participate the study population was expanded to include those who either had knowledge of or experience the use of the Umbiflow device. A limitation of the study is that a few of the already small number of initial study population who were the nurses who participated in the clinical trial declined participation, but the research study gained rich descriptive data on using the Umbiflow.

Chapter 4: Results

This chapter outlines research findings of the semi-structured interviews with healthcare professions from facilities A and B combined. Participant demographic information is provided for age, ethnicity, gender and job title.

4.1 Participant demographics

Two public health facilities were included in this study and 13 participants were interviewed, six (6) based at Facility A and seven (7) at Facility B. Twelve females and one male were interviewed and their ages ranged from 38 to 60 years. Table 1 summarises the demographic profile of the research participants.

Table 1: Participant demographics

	Age	Ethnicity	Gender	Job title
Participant 1	38	Black	Male	Medical Officer OB/GYN, obstetrics and gynaecology
Participant 2	60	Black	Female	Advanced Midwife
Participant 3	41	Coloured	Female	Advanced Midwife
Participant 4	42	Coloured	Female	Professional Nurse
Participant 5	39	Coloured	Female	Professional Nurse
Participant 6	55	White	Female	Medical Doctor
Participant 7	57	Black	Female	Professional Nurse
Participant 8	Unknown	Black	Female	Head of Department OB/GYN
Participant 9	53	Black	Female	Deputy Director Clinical Specialist Midwife
Participant 10	56	Black	Female	Advanced midwife: labour ward manager
Participant 11	47	Black	Female	Advanced midwife: operational manager
Participant 12	40	Black	Female	Advanced Midwife
Participant 13	58	Black	Female	Advanced ANC practitioner

4.2 Themes and subthemes

After using a thematic analysis approach, a few key themes and subthemes emerged. ANC prioritization of pregnant women within the surround areas of the two hospitals were discussed with all participants. Data analyses have presented subthemes on poor adherence, teenage pregnancy shame and misinformation among pregnant women who access services at the two hospitals.

The theme of barriers to antenatal care access emerged from study participants. Subthemes related to these barriers were identified and are related to patient attitudes towards their pregnancy, transport barriers and working schedules not allowing for access to services during the week.

The third theme relates to the perceptions of participants on novel device technology have produced subthemes which are related to the need for Umbiflow at the PHC level, as well as questioning the available resources to operationalize this device.

The fourth theme describes the acceptability of the use of the Umbiflow device according to participants. Subthemes relate to the challenging the status quo, apprehensiveness by staff, equipment supply shortages the benefits to the National Department of Health.

The fifth and final theme discusses the anticipated challenges with the national rollout of Umbiflow screening in all PHC facilities. Related subthemes discuss training, a lack of support by the national department of health, and procurement concerns. In addition to this, staff resource concerns are discussed and the likelihood of being overburdened by adding additional duties to their daily routine.

4.2.1 Prioritization of antenatal care

Participants have illustrated specific concern for patient attitudes towards their pregnancy.

> *"It's really a[n] I don't care attitude, because distance isn't a problem here because we have mobile clinics that go out to where people are. The issue is that patients don't want to take responsibility." (P5)*

Skepticism exists among participants on whether pregnant women prioritize their pregnancy.

> *"I don't think they prioritize their pregnancy at all. I know I shouldn't generalize, but there are always a high number of late bookings…" (P1)*

Participants raised their concerns with the ANC late bookings as missed opportunities.

> *"…due to late bookings, they miss the opportunity for early intervention as complications could have been identified early on. It is very important to intervene as early as possible and late bookings do not help the situation." (P1)*

Participants have noted that a small proportion of monthly deliveries have not attended ANC.

> *"Out of 400 I'd say 15 - 25 deliveries did not attend ANC. This is more or less the same every month when I pull stats from the register." (P7)*

Superstition has been sighted as a contributing factor to late booking and causing a lack of accessing ANC services.

> *"A big problem is superstition…the mother or grandma says they should not book too early. Some believe it is bad luck to book too early." (P8)*

Teenage pregnancies have been cited as a small number of monthly bookings who enroll after 20 weeks gestation.

"…nine times out of ten patients always turn up before 20 weeks, but, let's say the other 10% turn up one month before they must come to give birth. These are mainly school girls. It is not good for mothers to book after 20 weeks because there can be many issues that they don't know they have" (P4)

Participants have noted that shame associated with teenage pregnancies contribute to late bookings.

"I think that young girls are embarrassed and are scared of their parents or elders. That is why most young girls hide or are ashamed of the pregnancy. They are very scared that they are going to be put out of the house." (P6)

It is believed that women in the district do not make full use of adequate, free, PHC services.

"Services are available for all, and services are free, but they don't want to make use of these services and book themselves early, or even come for all their visits." (P4)

Participants are concerned that adherence to ANC services are poor as a result of patient attitudes.

"Many jobs give patients the day off and clinics are close enough to their house, so, no one has an excuse not to attend ANC. I think that they just don't want to listen" (P2)

Participants have raised concerns about unregistered patients who go directly to hospitals to give birth.

"Some [participants] don't attend [ANC] at all, whether it is planned or unplanned pregnancies. They come to the hospital ready to give birth, but there's no record of them. Then if anything happens to them, then we are in trouble. You never know what can be wrong with them because they never had any care before." (P4)

The importance of having ANC educational information available to patients has been viewed as the reason for a slight improvement in early bookings.

> *"I don't think the situation [late bookings] is as bad as it used to be because lately it is improving, especially those who book early. Maybe the pamphlets at the clinic are helping to raise awareness." (P5)*

One participant has noted migration as one of the reasons for not booking early.

> *"…some come from Lesotho and Eastern Cape but since COVID, not as much. Hopefully we won't get so much more late bookings from there now. Maybe it helps a little bit." (P10)*

Pregnant women who appear not to prioritize their pregnancy have a unique set of challenges which may prevent them from accessing these ANC services in the district. These are discussed in greater detail in the next section.

4.2.2 Barriers to antenatal care access

A multitude of factors, some related to client prioritization of ANC discussed above, may create a barrier to accessing ANC services.

> *"A lack of patient responsibility, and accountability exists among patients to prioritize antenatal care. There may be some challenges with transport for those who live in rural areas, so it is very difficult for them to attend their visits. You know everything is far from each other here. A lack of education on the importance of antenatal care also is one other challenge that needs to be addressed." (P1)*

Access to ANC services are hindered by employed patients not getting paid for hours missed at work, as reported by participants.

"Women who are employed struggle to get the day off to go to the clinic. I think it is a 'no work, no pay' situation, and women can't afford to take leave for one day. This means they will get paid less at the end of the week because they not paid for off days." (P8)

It has been noted that clinic operational hours may be a challenge to employed patients.

"Employed patients find accessing services a challenge because the clinic is only open from Monday to Friday, 7 'o clock until 4 'o clock in the afternoon. There's no bookings done on a Saturday." (P9).

Ill-health posing a challenge to ANC services is a data outlier. Existing chronic conditions may exacerbate pregnancy complications.

"Co-morbidities such as hypertension and diabetes are prevalent and poor quality of life may prevent women from seeking ANC services for their pregnancy as they simply do not feel well. That being said, it places patients at a greater risk for pre-eclampsia and this is why it is so important to book early." (P1)

Participants have noted that existing transport from rural areas are unreliable for patients, and because of this, women do not attend all ANC visits.

"They don't attend follow-up visits, because the farmer may not drive to town on their dates. This is their only transport they have as it is too expensive to take a taxi for them. So, they have to depend on the farmer." (P5)

Relationships and interactions with healthcare professions play an important role in patients accessing ANC.

"...I think that the reason why women stop coming to the clinic is that most are discouraged with the treatment from nurses or healthcare workers. Sometimes they misunderstand us and think that we are being rude. Then they stop coming to the clinic for their other visits. This can be a big problem." (P8)

Participants report that a lack of education and information are contributing factors to patients not accessing ANC.

"There is often a shortage of pregnancy information leaflets at the facility. These leaflets have very important information on pregnancy and early bookings. Most of the patients are not educated so these leaflets really help them to understand" (P13)

Extended patient waiting times remain a discouraging factor to patients. Participants note that the problem extends nationwide.

"...It is very discouraging when there are full clinics and they don't get helped on the same day. It discourages them from returning. Long waiting times has always been an issue in South Africa because the clinics are too full, and we don't have enough nurses to help patients faster. (P12)"

Participants note that false claims of not being aware of the pregnancy, prevent patients from accessing services.

"Some women claim they didn't know they were pregnant. But I don't know how true it is. As a woman, we know our bodies and can tell when something is different. I feel like it is just fear, negative attitudes and a lack of information on the importance of antenatal care that stops patients from accessing care." (P10)

4.2.3 Perceptions on novel device technology

Participants note that Umbiflow clinical trials and how effective it has been in the early identification of pregnancy complications, attributes to positive expectations on novel device implementation.

> *"Umbiflow is a great idea. It picks up many issues in pregnancy and allows for early intervention. During clinical trials so many stillbirths were prevented, and this really makes us as health professionals excited to welcome new technology into our facilities." (P1).*

Participants have confirmed that sufficient equipment and staff exist in hospitals; there are resource shortages across the district.

> *"Many patients do not receive an ultrasound at their local clinic and there is potential to miss complications which could have been addressed early enough. Hospitals have enough equipment and the ultrasonographers to do scans, but in the district there are challenges." (P7)*

Participants have confirmed there is a need for novel device technology at PHC level to address the problem with unexplained stillbirths. The Umbiflow clinical trial has revealed noticeable decreases in the stillbirth rate.

> *"Umbiflow has caused the stillbirth rate to decrease. In the clinical trial here, there have been a few issues that would not have been picked up if it wasn't for Umbiflow. It is definitely a good idea to have it available in all clinics. I think at hospitals there is enough equipment but Umbiflow will be very useful at PHC level." (P11)*

It has been indicated that since the clinical trial has ended, the stillbirth rate had started increasing, and there is a growing concern about this.

"There was a 50% reduction in stillbirths during the clinical trial, however since the end of the trial the stillbirth rate started increasing again. The main challenge is the unknown causes of stillbirth and Umbiflow is very important in identifying patients who are at risk" (P10)

Participants view Umbiflow as being especially important for women with co-morbidities and a history of pregnancy complications:

"Patients who present with co-morbidities such as hypertension and diabetes are at greater risk for pregnancy complications and it is so important to have Umbiflow in our clinics, especially for women who have pre-eclampsia." (P12)

Considering the profoundly expressed need for novel technology to address the stillbirth rate, a broader discussion was required around its acceptability among health professionals.

4.2.4 Perceptions on acceptability of Umbiflow

Previous clinical trial results have created positive reactions among participants to novel medical device technologies and unlearn the status quo.

"I think it is time for the older generation to learn about new technology and how it will benefit the stillbirth rate and antenatal entirely. We are so used to doing things in a certain way. We are excited to have Umbiflow in all clinics in South Africa." (P9)

Health professionals are presented with an opportunity to acquire newly learned skills in terms of operating Umbiflow and data interpretation, according to participants.

"It is very easy to use and a part of improving primary health care services where advanced midwives can learn new skills." (P13)

Participants have expressed concern about the adaptability of healthcare professionals, and the need for adequate training on Umbiflow.

> *"Hopefully we will learn this quickly. We definitely need training, and how to interpret data is needed at grassroots level to address complications early on. I'm also concerned that it will be used a lot in the beginning, but you know how people are, they go back to the way they have always done things." (P11).*

Participants have stated that they cannot rely on patients to adhere to scan appointments with Umbiflow.

> *"Even if we have Umbiflow, there is uncertainty with how patients will react to it. We don't know if they are going to be willing or keep appointment dates for scans. We obviously can't force them. The problem is still that patients don't want to come book early and if patients were to wait that long it may be too late for intervention. (P3)"*

A shortage of ultrasound equipment in the district creates a need for novel device technology, according to participants. The ease-of-use of Umbiflow is anticipated to improve PHC services at a faster rate.

> *"It is very easy to use and will form part of improving PHC services. We have a shortage of equipment in many of the clinics in the district, especially ultrasound equipment and that is why Umbiflow will be good to have. So many patients don't get scans and it will actually be nice to give them that." (P7)*

A small number of participants have expressed that they are apprehensive about Umbiflow. This can be attributed to a lack of direct experience and understanding the device.

"It is difficult to say as only one nurse was assigned at our facility. However, no problems or complaints were reported as far as I know. I don't know enough about the results of Umbiflow to actually say if nurses will accept it or not." (P13)

Participants have noted that pre-requisites on training resources and additional staff must be met. There is a call to the National Department of Health to support this.

"As long as proper training is done on Umbiflow and the Department of Health provides dedicated staff and financial resources, there should not be a problem with accepting this new device. You see, the problem is that we are always rotating duties and already have our hands full, so there is always a bit of concern when they add to our workload" (P8)

Negative feelings have been expressed from a co-worker during clinical trials. The participant states that a lack of understanding has resulted in this.

"…When I was busy with the scans I always used to get very negative vibes from a fellow colleague. Maybe it is because she didn't understand what we were trying to do. She even said that she believes doctors should be doing these scans. I think so many people are just negative and resistant to change." (P7)

Participants believe that Umbiflow will save the patient and the department of health money.

"If we have Umbiflow then we won't have to refer patients so far away to hospitals for scans that they won't need. Because if Umbiflow can show that they are low-risk then they won't have to pay money for a taxi to town. And we need it in the clinics so they [patients] can be referred to high risk [hospital] if they are high-risk. Remember that hospitals are also very full and the department also spends a lot of money on Doppler scans for every patient." (P2)

Participants believe that Umbiflow will make a significant difference at PHC level and will directly reduce stillbirths.

We have seen the number of stillbirths decrease after Umbiflow was here. This is why I have no hesitation that it will directly reduce stillbirths here. Especially at primary health care level, I think it will really have significant impact. (P6)

Participants confirm that acceptability is centered around the early-identification of fetal anomalies offered by Umbiflow.

"From what I heard, patients were screened between 28 - 32 weeks to identify issues early on. This is good, because once they are at the hospital, it will be too late then. Umbiflow lets you see early on if there are any issues" (P3)

4.2.5 Perceptions on the potential challenges with the implementation of Umbiflow screening

Participants have noted that there are anticipated challenges with adequate staffing to perform Umbiflow screening.

Us as midwives are already overburdened by the high number of patients, and it is a concern to find dedicated staff who will be available every day to do screening with Umbiflow. This is the challenge in most clinics in the district. Because of staff shortage, we must rotate duties almost every day and it is unknown how this challenge will be sorted out. Adding Umbiflow to our duties will just make more work for us. I think that they must hire more staff who can only work with Umbiflow. (P2)

Concerns have been raised in terms of adequate training required prior to Umbiflow rollout.

"Staff need training, but there is a shortage of staff, and it's difficult to coordinate everyone in one setting. We will need training before Umbiflow is rolled out and nurses don't know if it is offered with the device and who is going to pay for it." (P1)

Participants have voiced concern regarding a lack of support from the department of health, and national treasury.

> *"National and provincial budgets are set annually, at the beginning of each year. This is a challenge because what if treasury does not prioritize Umbiflow or support it financially?" (P8)*

Day to day activities place strain on staff and an additional task without job promotion or being compensated, lowers morale.

> *"We have a shortage of staff, so it is going to be a challenge to take on more work. Every day we are already overworked and if some staff have to do extra work then I think they will complain. I really hope that they can hire more staff for Umbiflow, then it will be fine for everyone." (P4)*

Change management, training and access, were sighted as areas which may require attention prior to rollout.

> *"Training and education is needed among staff as many find it hard to adjust to new technology. It is necessary to explain the importance of the role which new technology will play to improve the situation of stillbirths. There are so many patients who do not have access to this type of technology, and it needs to happen soon." (P9)*

Mobile clinic staff requires training on Umbiflow, to optimize efficacy.

> *"Mobile clinic staff also need training because they go out into the location and farms. Many of the patients in rural areas are forgotten and if we have trained mobile clinic midwives it can really make a difference." (P9)*

A small number of participants express concern for how Umbiflow will be procured nationally and if a reliable supply chain will exist.

"I hope that Umbiflow will be procured properly and that there won't be any supply chain problems along the way." (P4).

Chapter 5: Discussion

There are four five key findings from the results that have been described according to the perceptions of healthcare professionals. Data collected from participants on ANC prioritization, barriers to ANC access, perceptions of Umbiflow as novel technology and its acceptability as screening device, and the anticipated challenges with implementation, are discussed in relation to findings in the available literature.

5.1 Prioritization of antenatal care

The study's findings highlighted the perception of healthcare professionals that some patients did not consider ANC a priority. In a case study in Johannesburg, ANC attendance rates were 5% lower than national levels, and especially low among adolescents, owing to stigma when seeking care (Gumede et al., 2017). Participants from this study reported from both one facility that shame and fear among adolescents discouraged pregnancy disclosure and enrollment for ANC, therefore providing the impression of low ANC prioritization. Current findings from participants revealed a similar trend of low ANC prioritization in rural and urban areas in the respective catchment population of the two study facilities. A study from a rural area in Mbombela, Mpumalanga reports that pregnant women's attitudes towards their ANC prioritization are shaped by their previous experiences with ANC services, interaction with clinical staff and their awareness and acceptability of the pregnancy (Drigo et al., 2020). Jinga et al. (2019) report on a study of 10 healthcare providers at MOU's and PHC's in Gauteng that women who had had previous pregnancies and who were aware of the various pregnancy stages still neglected to initiate ANC early.

A study from the Eastern Cape Province by Kaswa et al. (2018) reports that beliefs, knowledge and perceptions that manifest as superstition with regard to ANC services outweigh perceived benefits of early ANC bookings. In the current study superstition was also related to late bookings.

Participants in this study identified various barriers to ANC access that are discussed in the following section.

5.2 Barriers to antenatal care access

Participants stated that long patient waiting times at PHC facilities influences access to ANC negatively. Baron and Kaura (2021) report on long waiting times at PHC facilities in the Western Cape Province because of staff, patient, communication, infrastructural and equipment factors. This might result in some patients not being able to access ANC on the same day as their appointment.

Another factor influencing access to ANC is the fear to disclose pregnancy by adolescents. This is concurred by Kaswa et al. (2018) who found that a small number of participants in the Eastern Cape had admitted that the failure to disclose their pregnancy to their parents was cited as a factor which hindered access to ANC services. In this study participants revealed that social and cultural belief systems associated with superstition influenced pregnant women's access to ANC. Similarly, Sibiya et al. (2018) reported that social and cultural beliefs are challenges that delay patients from seeking care and utilizing ANC services to its full capacity.

In addition, Nyathi et al. (2017) reports a lack of transport, high transport costs, and long distances as factors which hinder patients from accessing ANC. However, participants in this study did not cite transport as a factor, as mobile clinic services were available to patients. The study was about health workers' perspectives and not patients' perspectives.

Participants in this study reported a shortage of ultrasound equipment. Furthermore, Moyimane et al. (2019) found a critical shortage of medical equipment, and the low-quality and poor maintenance of existing equipment impact negatively on care at hospitals.

Participant perceptions of Umbiflow are discussed in the next section.

5.3 Perceptions on novel device technology

Participants in this study indicated that there was a need for Umbiflow to improve the stillbirth rate. Manderson and Ross (2020) report that pre-natal monitoring with available technology is assumed to be beneficial in reducing stillbirth and increasing chances of survival.

This study's findings reported equipment shortages in clinics. Access to routine ultrasounds and quality care in LMICs has been reported as poor (Mueller et al., 2021). The integration of Umbiflow into ANC visits has been reported by this study's participants as being potentially well-accepted at PHC level. A study on point-of-care sexually transmitted infection screening integrated into ANC first visits in 3 clinics in Tswane district have indicated a 97.3% acceptability rate by pregnant women (Morikawa et al., 2018).

Participants of this study referred to the successful clinical trial with Umbiflow that illustrated a significant decrease in the stillbirth rate. Nkosi et al. (2019) reported that screening low-risk women resulted in absent-end diastolic flow which is 10 times higher in the group which had not been screened with Umbiflow.

Study participants indicated that certain prerequisites must be met for Umbiflow™ to be accepted by healthcare workers. These will be discussed in the section to follow.

5.4 Perceptions on health worker acceptability of Umbiflow as a novel medical device

These study participants reported significant workload challenges in terms of being under strain with exiting daily activities, and there are concerns that there may not be sufficient staff for additional tasks brought about by Umbiflow. In addition, participants have raised concerns centered around the hiring of dedicated staff to operate Umbiflow. These reported challenges are supported by Maphumulo and Bhengu's (2017) review findings that despite the adoption of quality improvement programmes in the public health sector, there had not been an improvement in quality-of-care health service delivery in South Africa. Prolonged waiting times due to staff shortages posed as one of the contributing factors.

Study participants' references to frustration among staff being overwhelmed by the number of patients and patients dealing with prolonged waiting times are an indication of a more profound root cause. Naicker et al. (2009) reports that there are two doctors and eleven nurses per 10 000 patients in sub-Saharan Africa, as compared to 32 doctors and 78 nurses per 10 000 patients in North America. This illustrates a problem which exists beyond the South African context.

5.5 Potential challenges with the implementation of Umbiflow screening

Study participants displayed concerns on the training of Umbiflow. More specifically, the availability of existing staff, appointing new staff and training resources were mentioned as areas of concern. South Africa provides public health services to 13 718 people per clinic on average, which exceeds the WHO recommendations of 10 000 per clinic (Monareng et al., 2019). It was also unknown who would train staff and whether they would be burdened with additional duties. Bronsoler et al. (2020) reported on evidence of a positive effect on productivity on health care workers after new technology had been introduced. A systematic review by Winters et al., 2019 revealed training gaps in the areas of peer learning and supervision for training community health

workers in LMICs. This reveals an opportunity for healthcare workers to be trained and upskilled as part of the Umbiflow implementation. Shah et al., (2015) identified a lack of training as a primary barrier to regular use of ultrasonography for different purposes in developing countries and recommended further research on best practices for training methods to enhance ultrasound use in low-resource settings. Equipment maintenance and cost challenges were also highlighted as important factors.

In a systematic review of 287 studies reporting original or novel applications of ultrasound use in LMICs, 70% of studies originated from Southeast Asia and sub-Saharan Africa. The highest innovative ultrasound use emanated from sub-Saharan Africa (Stewart et al., 2020).

Supply chain concerns raised by a small number of participants are supported by other literature. The procurement of essential equipment in South Africa needs to be effectively managed by the National Department of Health to ensure accessibility and availability of essential medicines and equipment (Modisakeng et al., 2020).

Chapter 6: Conclusion and Recommendations

6.1 Conclusion

In conclusion, this study built on previous findings on the effectiveness of the Umbiflow screening tool effective in reducing the stillbirth rate that continues to pose a challenge in the two study districts. Although there is no clear evidence on how the usability of Umbiflow will help to improve the prioritizations of ANC, it will aid in the skills development of healthcare workers. Patients who book late will not change their behaviour by simply introducing them to Umbiflow. Although demonstrated efficacy exists, the low prioritization of ANC by patients will remain, irrespective of life-saving novel medical devices introduced at PHC level.

Looking at the perceptions on the acceptability of Umbiflow no healthcare professional in the study objected to it, although some expressed their unfamiliarity with the device. Despite high acceptability there are concerns on the number of available staff and how current roles would be managed if the implementation of Umbiflow is added to the nursing tasks. Despite a positive reception of Umbiflow by study participants, convincing the National Department of Health to add it to the essential equipment list still remains a barrier.

Challenges regarding the provision of adequate staff to operate the Umbiflow device remain an open question. In addition, change management poses a challenge. This will require a complex process of unlearning the status quo and introducing a new screening method among seasoned healthcare workers. The profoundly rooted issue of extended patient waiting times and healthcare workers being overwhelmed continue to pose a challenge. These issues will likely remain, despite the implementation of Umbiflow, as patients must firstly prioritize their pregnancy, book early, be attended to on the same day and be adequately cared for by competent and focused staff, who are not overwhelmed by the health system.

6.2 Recommendations

6.2.1 Prioritization of antenatal care

There is a need to establish educational campaigns within communities in addressing the issue of late bookings. This can be done via local newsletters, radio, and roadshows. Communities must be engaged via community leaders who have the most influence in their respective district. The engagement between health and educational professionals with communities could occur at local community planning meetings. This could be done with the support of the Departments of Health, Social Development and Education, who would provide staff resources in the planning, designing, implementation and monitoring of interventions.

6.2.2 Access barriers to ANC services

As illustrated earlier, staff shortages lead to extended patient waiting times which may contribute to late booking or non-adherence to all appointments. A recommendation to the National Department of Health is to prioritize appointing of more ANC staff. Furthermore, NGOs should train community members on the importance of ANC access and attending all appointments throughout the ante- and postnatal phases of pregnancy and childbirth.

6.2.3 Anticipated Challenges with Umbiflow

The appointment of additional staff in public health facilities in South Africa is required to reverse the extensive burden of work. However, it is uncertain if there is capacity for Umbiflow training. It is therefore recommended that new staff be appointed. Despite the resource challenges, it is recommended that training resources also be provided by NGOs and stakeholders involved in the

previous clinical trials. National Treasury would not need include Umbiflow devices as a line item, if manufacturers could provide the equipment at no cost for the state. As part of a complete package, when Umbiflow is purchased by health facilities, after-sales services should include training and maintenance. With these recommendations, together with timeous application for and provision of equipment, expected challenges could be managed.

6.2.4 Umbiflow implementation prerequisites

Based on the results of data collected from participants in this study, a list of Umbiflow requirements need to be fulfilled if it is to be accepted as a novel device to use in the public health sector:

- Appoint additional nursing staff on all levels (professional and enrolled nurses and advanced midwives)
- Train newly-appointed and current staff on Umbiflow
- Make a training budget available to upskill dedicated Umbiflow staff to a level of competency
- Ensure that the appointed Umbiflow manufacturer provides after-sales services, inclusive of training and maintenance
- Review policies and make appropriate amendments should there be any identified areas in legislation that require change in relation to access to Umbiflow

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Appendix A: Interview Guide Questions

1. Could you kindly state for the record, that you are participating in this study willingly?
2. What is your job title?
3. What is your age?
4. What is your gender?
5. How long have you been working at this hospital?
    - Can you describe your work experience?
    - What you do on a daily basis?
6. In your opinion, do pregnant women in this area prioritize their antenatal care?
    - What do you think are the challenges women face with antenatal care?
7. How were you introduced to the Umbiflow device?
    - What was your experience with the training on the device?
    - Do you feel comfortable and confident using the device?
    - How would you describe access to the device in the facility?
    - What are your general opinions about the device?
8. Do you think Umbiflow will help to decrease the stillbirth rate?
    - Why do think that?
    - What, in your opinion, what works best about the design of the device and software?
    - What does not work well with the Umbiflow device?
    - If so, how can this be improved?
9. What are the challenges with the using the device?
10. Do you think that it can be used nationally at all health facilities?
    - In your opinion, how will this device save the health system money?

- Do you anticipate any challenges or obstacles with a national rollout implementing the device?

11. Do you have any final comments?

Afrikaans

Leidende onderhoud vrae

1. Vir die rekord, kan u asseblief verklaar dat u vrywillig aan die studie deelneem?
2. Wat is u werkstitel?
3. Wat is u ouderdom?
4. Wat is u geslag?
5. Hoe lank werk u al by die hospitaal?
    - Kan u, u werkservaring beskryf?
    - Wat doen u op n daaglikse basis?
6. In u opinie, prioritiseer swanger vroue hul voorgeboorte sorg?
    - Wat dink u is die uitdagings wat vrouens mee sukkel in verband met voorgeboorte sorg?
7. Hoe was u aan die Umbiflow toestel bekend gestel?
    - Wat was u ervaring met die opleiding ten opsigte van die gebruik van die toestel?
    - Voel u gemaklik en vol vertroue met die gebruik van die toestel?
    - Hoe sou u toegang tot die toestel in die fasiliteit beskryf?
    - Wat is u algemene opinie van die toestel?
8. Dink u dat Umbiflow die stilgeborte koers sal help afbring?
    - Waarom dink u so?

- In u opinie, wat werk die beste omtrent die ontwerp van die toestel en die sagteware?
- Wat werk nie so goed met die Umbiflow toestel nie?
- Hoe kan die toestel verbeter word?

9. Wat is die uitdagings met die gebruik van die toestel?
10. Dink u die toestel sal nasionaal by alle gesondheidsorg fasiliteite gebruik kan word?
    - In u opinie, hoe sal die toestel die gesondheidsorg sisteem geld spaar?
    - Voorspel u enige uitdagings of struikelblokke met n nasionale implementering van die toestel?
11. Het u enige finale kommentaar?