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Limited Obstetrics Ultrasound in Primary Healthcare Delivery; Outputs for Strategic Considerations: A Review of Pilot Study in Gauteng Province, South Africa

Tshililo Mashamba[1, *], Akpan Eyo[2], Sikhonjiwe Masilela[3], Anele Busakwe[4], Olakunle Towobola[1]

[1]Department of Obstetrics and Gynaecology, Sefako Makgatho University Pretoria, South Africa

[2]Primary and Referral Care Africa, General Electric International Operation Nigeria, Lagos, Nigeria

[3]Maternal Neonatal Child Adolescent Youth Women's Health Integrated School Health Programme and Nutrition, Gauteng, South Africa

[4]Prestige Health Technologies (PTY) Ltd, Johannesburg, South Africa

Email address:

tjmashamba@yahoo.com (T. Mashamba)
*Corresponding author

Abstract: In South Africa, midwives in primary healthcare setting are first responders to majority of the expectant mothers in the community. These pregnant mothers should benefit from at least one ultrasound in their pregnancy according to the WHO recommendation. However, these midwifes are not equipped to provide such limited obstetrics ultrasound services essential to accurately date the pregnancy, identify normal pregnancy and refer unsuspecting mothers in a timely manner following abnormality detected on ultrasound. The Advanced Midwifes could accurately diagnose morbidity related complications (for which ultrasound is perceived as the gold standard), they were trained to identify - placenta previa, breech presentation, intrauterine foetal demise and miscarriages, abnormal amniotic fluid levels, cervical incompetence, ectopic pregnancy, abnormal foetal growth and selected gross foetal anomalies. The Advanced Midwifes were accurately able to date the pregnancy on women who access the service did not know their last menstrual period (LMP) and on those who could recall their LMP had a significant disparity between gestational age by LMP and by composite ultrasound age (CUA). Limited obstetric ultrasound gestational age determination by advanced midwives was useful in not only assessing gestational age but also in identifying abnormalities associated with the pregnancies.

Keywords: Ultrasound, Advance Midwives, Primary Healthcare, Gestational Age, Limited Obstetrics

1. Introduction

The effectiveness of routine ultrasound in antenatal care (ANC) in the primary healthcare setting is still not well understood. Some International Health Organisations, Ministries of Health and Public Healthcare Practitioners agree that routine ultrasound during antenatal care visit can improve pregnancy outcomes primarily through reliable estimation of gestational age of the pregnancy, early detection of pregnancy complications in unsuspecting clinical scenarios and appropriate referrals to secondary healthcare providers [7, 9]. The utilization of ultrasound services at the primary care level has unequivocally shown to be an incentive driving two important outputs. First, increasing the health seeking behaviour amongst expectant mothers - evidenced by changing antenatal ANC attendance, skill birth attendance (SBA), and facility-based delivery [16]. Second, improvement in providers' clinical decision-making behaviour in appropriate referral because of improved diagnostic point of care diagnostic capability, both of which result in increased utilization of the ANC service. The policy of at least one routine ultrasound out of the eight ANC visits recommended by the World health organisation (WHO 2018), the International Federation of Gynaecology and Obstetrics (FIGO 2014) and endorsed in the guidelines for

maternity care in South Africa (2015) is an enabler.

Recent global steady decline in Maternal Mortality Ratio (MMR) has inadvertently imposed a philosophical dichotomy to PHC Interventions, broadly into interventions that can improve pregnancy experience via improvement in personalised care and conventional community focused intervention aimed at reducing impact of various on composite health outcomes like Maternal Mortality Ratio deployed at scale like preventive vaccines and nutritional care. While the former is arguably consistent with expectations in developed economy, developing economies like South Africa's, integrate community focused interventions within its strategic health plan (SADHS 2016) to improve pregnancy outcomes. Routine utilization of ultrasound during ANC by all mothers satisfy both objectives of improving personalised care and as a community focused preventive care through early detection of complications and timely referral.

When healthcare workers at the primary healthcare level accurately perform obstetrics ultrasound routinely, pregnancies will be dated accurately, potentially leading to improvement in planned delivery, and ultrasound detectable pregnancy related complications will be identified earlier. The more ultrasounds they perform the more their skills improve. Uncertainty about gestational age leads to either premature delivery or prolong pregnancy with associated complications. Miniaturization and the introduction of affordable battery powered portable ultrasound like the General Electric's Vscan Access handheld ultrasound machine, implementation of task sharing policies and role extension, improved accessibility to remote tele-mentoring and supervision, affordable price point per product and improvement in social immersion capabilities at the primary healthcare level are identified extrinsic enablers driving these benefits and change in healthcare investment behaviour. This article is a report of our evaluation findings during the 12-month pilot period where trained Advance Midwifes provided ultrasound services in 35 Midwife-Obstetric Units across the Gauteng Province of South Africa.

2. Materials and Methods

A retrospective descriptive evaluation of the recorded data for the total number of patients who received ultrasound scan assessment performed by advance midwifes during the expectant mothers' antenatal clinic was carried out. Data was aggregated and analysed.

Study population: The Tshwane Health District has an estimated population of 2.9 million persons of which 50% are females and greater than 35% of them are in their reproductive age. Only 15% of this population leaves at distances greater than 10km from a Primary Health Care (PHC) facility with its corresponding travel time been more than 1 hour to the health facility. Approximately 45% resides within less than 5km radius to a PHC facility. The total female fertility rate is 2.9 per woman and according to the SADHS (2016), 94% and 74% of all women received care from skilled provider at least once and up

to four times during their last pregnancy respectively. Although female contraceptive use has declined over the last two decades, 65% of the population at reproductive age confirm their use of a modern contraceptive method.

2.1. Participants and the Intervention

Ten (n=10) trained Advance Midwifes (ADM), performed limited obstetric ultrasound (LOU) in a community outreach model, in day clinics including primary health facility other than the facility of their primary employment. A total of 35 health facilities, 10 Midwife-Obstetric Units (MOU) and 15 Community Health Centres (CHC), supported in the Tshwane Health District of Gauteng Province were assessed over an eight-month period starting from March 2017.

Routine antenatal ultrasound was provided by 10 Advanced Midwifes who had completed the three (3) months Limited Obstetrics Ultrasound Training (LOUT) organised by General Electric Primary and Referral Care Division. The competency expectation post-training included: (i) completions of ultrasound assessment of a pregnant mother according to the LOUT Protocol, (ii) accurate dating of pregnancy using appropriate sonobiometric parameters, (iii) identification of gross pregnancy/foetal complications and (iv) implementing appropriate follow up action based on ultrasound findings and primary referral to the higher level of healthcare. The ADM scanned patients of all trimesters and their primary objectives while performing LOUT were: pregnancy dating and foetal weight assessment using foetal growth curve, determine number of foetuses, confirm the presence of foetal heartbeat, determine foetal presentation, determine the cervical length, determine if the placenta was clear off the internal cervical is, determine amniotic fluid volume using deepest vertical pocket and identify any gross anomalies. For first trimester scans, ADM had to confirm location of gestational sac, date the pregnancy and determine the regularity of the gestational sac. Based on the ultrasound findings, the ADM corresponding actions were limited continuing in-facility care (no action), recall patient for a follow-up scan, and to refer the expectant mothers to a higher level of healthcare. The reason for referral was limited to mother's preference, the need for a second opinion scan when midwifes were unsure of the scans, and further management because of facility limitation to handle the identified complication.

2.2. Data Collection

Within the eight months of evaluation, the 10 ADM were able to scan a total of 8215 patients unaided. After each scan, the ADM had to log her entry into the Ultrasound Scan Logbooks. The scan log entry was tested and verified and approved for use by the Gauteng Department of Health assigned team of clinicians from obstetrics and gynaecology faculty. Three categories of entry were recorded into the scan logbooks: (i). Information provided by patient; whether the patient knew her LMP, how many ultrasounds had been performed during the index pregnancy. (ii) information

elicited by the ADM; ultrasound findings, follow up action, patient trimester and (iii) machine generated information: Gestational age (GA) estimation by LMP, GA estimation by composite ultrasound, biometric parameter measurements for BPD, FL, HC, CRL, AC. An in-depth interview was performed with all ADM to further understand certain trends with the data and further understand the context.

2.3. Data Analysis

Data generated from the study were verified and the clean-up data were extracted from the scan logbooks into a Statistical Package for Social Sciences software programme (SPSS; IBM, USA) for analysis. The effective sample size was determined independently for each parameter analysed. Statistical analysis and the results are presented as percentages and charts.

3. Results

Gestational Age (GA) determination, patient recollection of LMP vs access to ultrasound dating:

7500 patients logbooks were reviewed for their knowledge of their last menstrual period (LMP). Figure 1 shows 26% (n=1950) of pregnant mothers could not recall their LMP. An additional 23% (n=1276) out of 74% of patient who knew their LMP, had a significant (>3weeks; range 2 - 16weeks) disparity between GA by composite ultrasound assessment (CUA) and the GA determined by LMP. Regardless of this disparity, all gestational ages were confirmed by CUA and appropriate case management actions were taken accordingly.
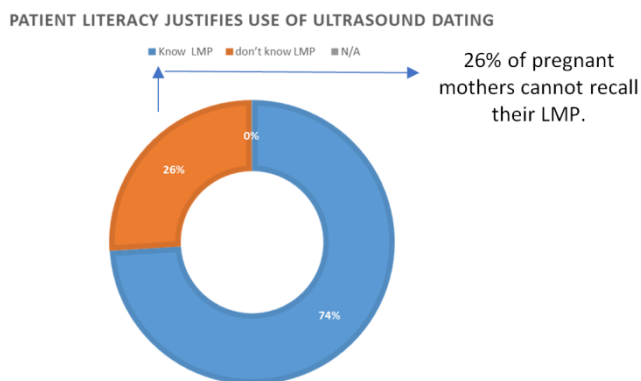

Figure 1. *Remembrance of LMP.*

3.1. Access to Ultrasound

Figure 2 shows that 97% of the pregnant mothers (n=7275) had access to ultrasound for the first time in the index pregnancy, all scans were performed within the healthcare facility. Only 3% (n=225) of the women had received previous ultrasound scan other than the scan in the present study. There was no significant change throughout the eight months of this study in this distribution or access pattern as shown in Figure 3. In Figure 4, the pattern of distribution of ultrasound access is similar to the pattern of ANC attendance

with 15%, 60% and 25% for first, second and third trimester respectively. Ultrasound access for earlier booking (i.e. < 20weeks) was 73% (n=5475). There was a marginal increase in antenatal attendance especially in the third trimester at the end of the study as shown in figure 5.

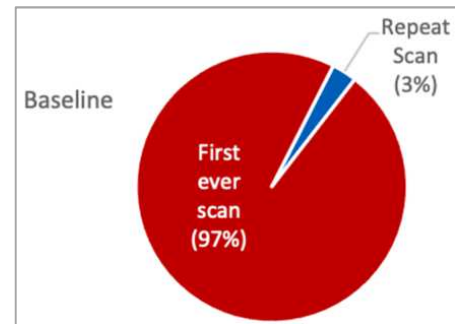### 3.2. Distribution of ANC Attendance and Access to Ultrasound
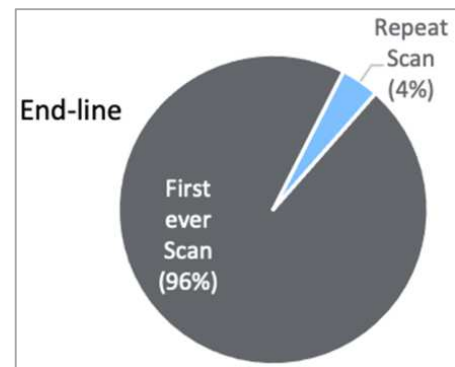

Figure 2. *Ultrasound in pregnancy at enrolment.*

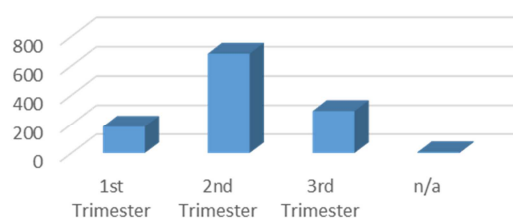
Figure 3. *Ultrasound at end of study.*

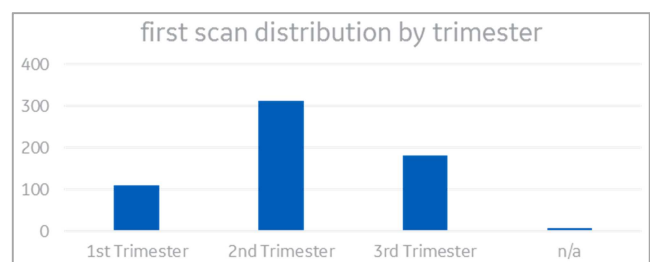**Figure 4.** *Pattern of ANC attendance.*

Figure 5. *Patient attendance distribution by trimester.*

3.3. Distribution of Ultrasound Anomaly Detected

3.3.1. Profile of Pregnancy Risk Category of Expectant Mothers

Figure 6 shows that only 11% (n=825) of patients who utilised the ultrasound services had a high-risk indication for their pregnancy. Of this high-risk category, 70% (n=577) of these mothers were referred because of suspected anomalies aiding a change in clinical management decision. The referral for asymptomatic expectant mothers who utilised the service as part of their routine ANC check is 15% (n=888) as indicated in figure 7.
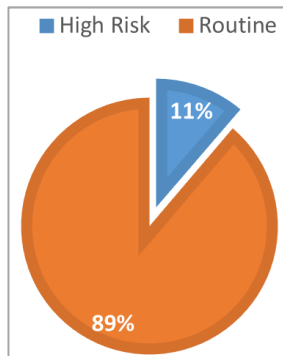
Figure 7. *Routine vs high risk referral.*
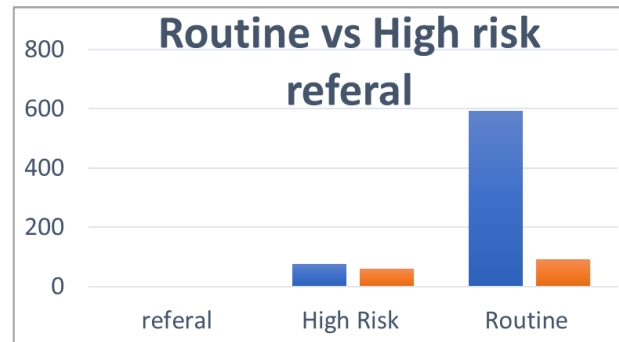
Figure 6. *Risk categorization.*

3.3.2. Anomaly Distribution

First, second and third scans where performed. An anomaly was defined by conditions detected only by ultrasound that necessitated an action as an adjunct to change clinical management outcome decision including referral, second opinion review, clinical case follow up as at the time of scan. Figure 8 is an anomaly distribution table that shows a wide range of pregnancy condition detected by the ADM. Foetal malpresentation, multiple pregnancy and low-lying placenta where the commonest anomaly detected. Consistent with the pattern of ANC attendance, we observed that 60% of complication was identified early < 28 weeks of gestation.
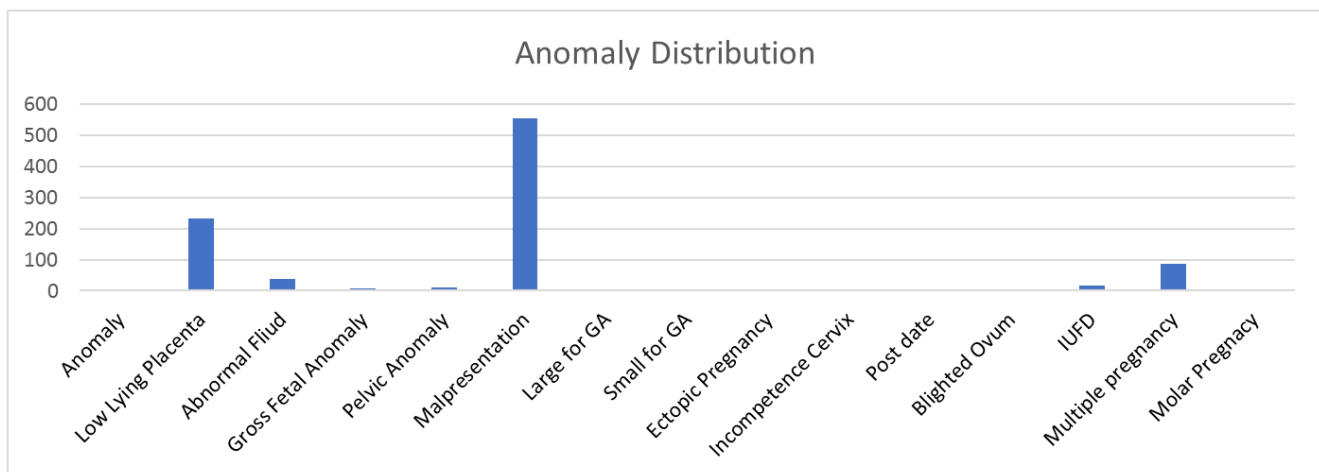
Figure 8. *Anomaly Distribution.*

3.4. Change in Clinical Management Decision by ADM; Patient and Case Referral

Observed difference in referral pattern between the CHC and MOU is shown in figure 9 and figure 10 respectively. This arguably is consistent with the facility functional setup, CHC has the expanded CEMoNC capability to take deliveries while the MOU's are BEMoNC day facility and do not deliver babies, allowing for more necessary referral. A 3% increase overall referral out based on ultrasound findings for both facility type combined was observed eight months after the implementation of the program as shown in figures 11 and 12.
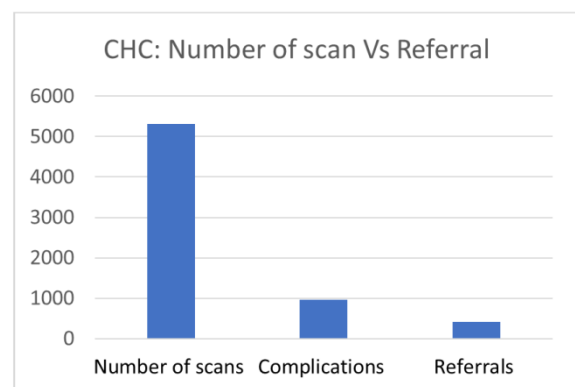
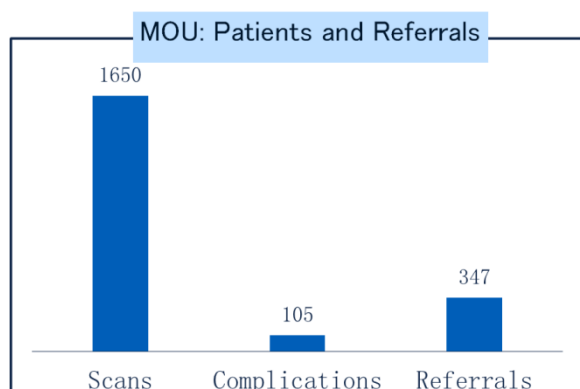**Figure 9.** *CHC: Number of scan vs Referral.*
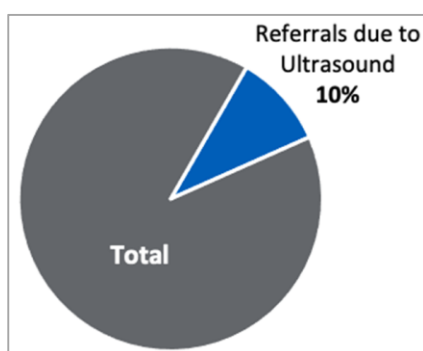
Figure 10. MOU: Patients and Referrals.

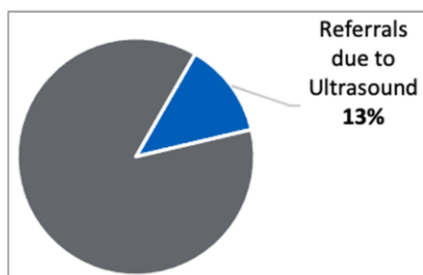*Figure 11.* Referrals at enrolment.

Figure 12. Referrals at completion.

4. Discussion

Pregnancy complications related to length of gestation and fetal weight significantly and consistently contribute to reported perinatal mortality in South Africa (Statistics South Africa, 2016). Overt reliance on LMP in the absence of accurate ultrasound dating in primary health centers leading to incorrect estimation of gestational age, is a predisposing risk contributor to this trend. This also increases incidence where the foetus is delivered too early if the gestational age is overestimated or too late if the gestational age is underestimated by an unsuspecting healthcare provider. We show that 50% of GA determined by LMP among study population of women was unreliable. This agrees with the findings from a multicounty study by Rada, Gamper et al [13], and the report of the study conducted in California by Wegienka and Day [20]. Such findings were not expected from the Gauteng Province (South Africa) – being a sub-metropolis and having a higher level of female literacy.

However the LMP recall by women of reproductive age has been reported not to correlate with their education status [20]. Qualitative insights from the ADM (providers) reveals that most mothers' reliance on contraceptive methods the SADHS keep contraceptive coverage at 58.3%, while the use of male contraceptive methods has increased since 1988 to its current level of 18% [16] against the background of reported high contraceptive failure [4] is likely responsible for the trend of poor recollection of LMP and consequently poor gestational dating. It is our conviction that the two factors of high contraceptive failure, poor and unreliable reliance on LMP are likely to have a causal association for inaccurate GA determination.

By simply been available within the health facility offering ANC services, we observed access to first ultrasound at 97%, 25% of whom are already in their third trimester, consistently over the entire 8-month study period. Through an informal focus group discussion with community members, we infer firstly, that there is good community acceptance and that the mothers perceive ultrasound as an additional benefit to their pregnancy. Secondly, it suggests a change in the providers ultrasound prescription behaviour derived from their perceived usefulness of their newly acquired ultrasound service to influence clinical decision making as suggested by Kimberly [7]. We did not evaluate the effect of the ultrasound service on ANC service primarily because the facility outreach component where the ADM travelled to a health facility other than their own and patient were booked to receive their ultrasound altered the facility ANC workflow. The participating facility was either an MOU or a CHC. However, [10, 16] in their well-structured study demonstrate a positive association between ultrasound and ANC indices, including indirect benefit like uptake of malaria test for pregnant women.

Improving availability and access to ultrasound for pregnancy care at the Primary Health Care level should be deliberately planned, implemented and improved. We introduce a mixed approach method combining facility-based ultrasound service delivery, a component where women access ultrasound in the health facility, and a facility outreach model where the ADM maintain a booking schedule in health facility other than their own on a fixed routine. Chamber and Boothe [3] argue that health administrations aiming to institutionalize facility outreach and community-based model should put in place policy guidance, primarily to account for inappropriate utilizations of scanning services. Such administrations should also have a clear clinical justification, action guidelines to avoid over treatment and have a patient care guideline to manage anxiety and a referral framework for altered case management. Few studies have reported the Community Outreach Model as a means to improve access to diagnostic services not necessarily to demonstrate comparative effectiveness of one model over the in-facility model [3, 14, 19]. A baseline survey determination of community ultrasound access and accessibility matched against maternal health outcomes would substantiate the true value of a chosen model. However our decision to adopt an

outreach model was intended to overcome access barriers dictated primarily by socio-economic constraints so that patients do not need to travel more than 15km to access the ultrasound service. In addition, we worked closely with the GDoH to ensure that the right protective policy framework and logistics were available.

An out-referral of 15% for unsuspecting and asymptomatic patients who attended routine ANC, is an interesting finding. Partly because it elucidates the value of the service to influence a change in patient care management plan for patients in the routine category. There exist contradicting views if this translate into benefit to the mother and child from an outcome perspective, for example Bricker and his team reporting in the Cochrane's review [1] argue for a no overall outcomes benefit of routine ultrasound performed in low risk mothers, especially in late pregnancy. Patients with multiple pregnancies and placenta previa may missed if asymptomatic, which at least one ultrasound policy will identify such patients. A clinical high-risk pregnancy was defined in line with WHO [21] maternal outcome guidelines. The value of ultrasound is not limited to symptomatology management of high-risk mothers, [they are, as of necessity, referred either way from the primary healthcare level using clinical matrix] but in asymptomatic pregnant women, who present for routine ultrasound. Increasing demand for ultrasound examinations from pregnant women needs to be balanced with medical indication and health benefits. Up to 70% of ultrasound findings that warrant a change in patient care management decision were observed amongst clinical high-risk patients; of whom foetal well-being assessment was vital, given the maternal status.

The ADM were trained to identify a wide range of first, second and third trimester anomalies as shown in Figure 7. These essentially influence the change in patient care management plan. Adhoc ultrasound training programs in resource constraint settings consistently show that midwifes can identify these anomalies [16] with safe and clinically acceptable level of accuracy. Malpresentation, low lying placenta and multiple pregnancy were the highest anomalies identified. This is consistent with our expectation since greater than 80% of the patients scanned were in their 2nd trimester. Our training for the ADM enabled them to suspect ectopic pregnancy, identify absence of fetal heartbeat in the first trimester, anembryonic gestations, molar pregnancy and abnormal pelvic fluid collections. From a practice competency and skills enhancement standpoint, given the low utilization of ultrasound by patients in their first trimester (15%) most probably due to socio-cultural factors, it is important to ensure that ADM ability to identify first trimester anomalies is consistently audited and remains acceptable for sensitivity and specificity. The change in patient care decision making was limited to follow up management of the patients within the same healthcare facility due to ultrasound finding and patients referred out due to ultrasound finding to a secondary healthcare facility for further management.

The action pattern varied depending on if the health facility was an MOU or a CHC. Several published findings have demonstrated beneficial change in clinical management plan potentially influencing the outcome of the pregnancy and maternal indices. Kimberley 2010, Kotler & Moore 2008, Stein et al 2008 and Shah et al 2009, have reported a 17%, 62%, 22% and 43% change in clinical decision making in their studies respectively. All studies were focused on non-physician care management in primary health facilities except for Kotlyar & Moore [8] whose targeted providers where medical residents in secondary facility. Kotlyar & Moore [8] further broadened their definition for change in care management to include any change in medication, referral for surgery and change in management plan the patient received. Hence, these may be responsible for the high percentages observed in their study. We demonstrate in the present study that change in a case management and referral out due to ultrasound finding is closely associated with the health provision delivered in the facility. MOU's are 24-hour healthcare facilities providing maternity [Comprehensive Emergency Obstetrics and Newborn Care (CEMoNC)] services linked to CHC providing day routine ANC services. The primary difference being in the intrinsic latitude of case management capability of each facility by design. In Figure 9, only 50% of complications detected by ultrasound were referred. This was so because most identified complications were adequately managed within the healthcare facility. CHC without MOU attached being day clinics would refer all complications regardless. Patient preference and the facility limitation to take delivery, also suggested that third trimester pregnancies with normal scans were equally referred out. It will be interesting to find out if a clinical protocol only, without ultrasound, will generate a similar referral pattern when compared to having a clinical protocol plus ultrasound in a controlled assessment. The referral behaviour within the health facility is not obviously defined by ultrasound findings alone, cultural perception, administrative constrains, availability of skill and consumables and public perception of quality of healthcare service provided are reported factors that influence referral pattern.

At end line, there was a 3% increase in referral out due to ultrasound findings, as shown in Figure 12. This simply was due to increase utilization of the service; hence more complications were identified. We associate all referrals due to ultrasound findings as a positive output. During clinical protocol development and implementation, it is important to include measures that mitigate excessive referrals, thereby justifying responsible use of ultrasound at this level of care. Also, it is important to state that out-referrals must be matched with a corresponding effective communication protocol or communication policy framework which protect the pregnant woman by ensuring that she reaches and receives immediate management of the identified complication otherwise it does not translate to positive outcomes neither does it justify the dictum 'reducing unnecessary referral'. This is also consistent with the recent assertion by Franklin and his co-authors, [5]. We did not

compare facility referral out before introduction of ultrasound and at specified timelines post-introduction of ultrasound longitudinally, while accounting for other extraneous variables as well. Our programme allows for qualitative assessment into the referral made by the ADM. Back referral from the secondary facility was frequently reported by the providers at the referral facility, most probably due to their perceived confidence on the ADM's competence given their newly attained competency level. This happened in the first few months of the Project and a stakeholder's advocacy involving providers (physicians and nurses and midwifes) at the referral facility was implemented to resolve this trend. Back referral is a phenomenon which counters the intended effect on clinical patient outcomes by hindering the referred patient to receive healthcare with the deserving urgency. It must be taken into consideration and device appropriate supporting practice and policy frameworks, wherever task shifting, and role extension framework is implemented.

5. Conclusion

We conclude that ultrasound at the primary healthcare facilities will reduce anomalies associated with length of gestational age and foetal weight estimation. However, until this becomes widely devolved, overt reliance on LMP which is shown to be inaccurate in 50% of the time should raise sufficient clinical suspicion when the provider develops a care plan. At the primary health care centre, ultrasound will induce a change in care management for the pregnant woman, especially in clinically unsuspecting and asymptomatic women and providers should anticipate and put in place a clear framework for referral out due to ultrasound findings. In addition, a plan needs to be in place to counter back referral from the referral facility especially if the service is newly introduced and provided by midwifes or other healthcare workers other than physician. It is the GDoH intension to improve lateral capacity of the midwives and the primary healthcare facility by enabling ADM to provide LOU as a strategy to improving maternal and new born health indices. This ultrasound-based initiative delivered by ADM should be replicated by other provinces in SA and in other countries because of its positive outputs to improve personalise care for the pregnant mother and its preventive attribute to inform clinicians to take appropriate patient care management decision. The only outstanding important issue is encouraging community to book antenatal care early so that ultrasound could be performed early in pregnancy.

Abbreviation

AC	Abdominal Circumference
ADM	Advance Midwifes / Advanced Diploma in Midwifery
ANC	Antenatal Care
BEmONC	Basic Emergency Obstetrics Newborn Care

BPD	Biparietal Diameter
CEmONC	Comprehensive Emergency Obstetrics Newborn Care
CHC	Community Health Centre
CRL	Crown Rump Length
CUA	Composite Ultrasound Age
FL	Femur Length
GDOH	Gauteng Department of Health
HC	Head Circumference
IDI	In-depth Interview
LMP	Last Menstrual Period
LOU	Limited Obstetrics Ultrasound
LOUT	Limited Obstetric Ultrasound Training
MMR	Maternal Mortality Rate
MOU	Midwife-Obstetric Unit
NNS	Neonatal Nursing Sciences
PHC	Primary Health Care
SADHS	South African Demographic Health Survey
WHO	World Health Organisation

Acknowledgements and Declaration

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