

Viability of Point of Care Ultrasound screening in Primary Health Care Setting: A Kenyan Experience

**Matiang'i M^{1*}, Ngunju P¹, Koen J², Kiilu C¹, Romy H³, Heteyey A³ Hangelbroek M³,
Opanga Y¹, Ndoria S⁴**

¹Amref International University (AMIU)

²Philips Foundation

³ Amref Flying Doctors in the Netherlands

⁴ Venture Sage Consultants

*Corresponding author, mobile contact: +254 723 727 325; Email:
miconyiego@gmail.com/micyiego@yahoo.com/Micah.Matiangi@amref.ac.ke

ABSTRACT

The limited number of sonographers in developing countries and high cost of conventional obstetric ultrasound screening services has led to only 6.9 percent of pregnant women accessing the service in rural areas. It is a World Health Organization (WHO) requirement to have pregnant women access obstetric ultrasound screening before 24 weeks gestation. This led to Amref International University piloting a business model that can make point of care obstetric ultrasound screening (POCUS) affordable and sustainable. One-year post intervention, an evaluation survey got conducted in the project sites in two pilot counties in Kenya (Kajiado and Kisii counties) to establish the viability of the entrepreneurship driven implementation of POCUS. Two stage cluster sampling was employed with mixed methods of data collection. A sample of 33 Midwives and 196 women of reproductive age from the pilot sites participated in the evaluation. The survey findings were that midst the COVID-19 pandemic, a total of 1250 pregnant women were screened in one year at a fee of USD 5 per scan. Among those interviewed, 168 (85.7%) of the women confirmed the service was affordable and easily accessible. It emerged that 85 (43.4%) of the respondents were screened by midwives in local health centres. Notably, 180 (91%) of the women interviewed recommended scaling up of the service and 32 (96%) of the midwives reported that the continuous coaching from radiographers enhanced skills acquisition. Despite the marginal negative net present value of cash flows, the impact generated by the project was of high significance. The conclusion drawn was that the business model is viable from implementation perspective since it demonstrated the potential to reach a Break-Even Point (BEP) at a modest of 1833 ultrasound scans per year. The project has potential for further buy-in by Primary health care professionals having accorded them a gross margin of 60% with a probable increase to 80% in subsequent years. Further, Obstetric Ultrasound screening services can be provided sustainably at low cost by trained Primary Health Care Workers (PHCWs). Financial viability of the POCUS is subject to increasing pregnant women's access to POCUS.

Key Words: *Point of Care Ultrasonography Screening (POCUS), Midwives, Antenatal care, Business Model*

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1.0 Introduction

Given the financial constraints developing countries' health systems are facing in financing provision of universal PHC services, self-sustaining social enterprises provides an opportunity to help increase access to health care in lower levels of the health system. The barriers of digital health literacy and internet connectivity in PHC settings notwithstanding, digital health provides an opportunity to improve quality, efficiency and effectiveness of care (Geronimo et al, 2020). The Midwives ultrasound project in 2 pilot counties in Kenya was therefore designed to explore the feasible business model for implementing the mobile digital ultrasound screening service in resource constrained settings. Portable ultrasound technology is increasingly becoming popular in Low, Middle Income Countries (LMICs) due to its affordability, user-friendliness, and adaptability to the harsh and restrictive conditions in the poor-resource settings (Stanton.,2013).

Therefore, multilateral and bilateral organizations as well as private donors, are keen to comprehensively assess the feasibility of introducing POCUS in LMIC settings before appropriating funds for larger scale interventions. To enable all pregnant women access obstetric ultrasound screening before 24 weeks gestation, there is need for more affordable and self-sustaining interventions, knowing that ultrasound screening is generally regarded as safe and affordable (Kongnyuy and van den Broek, 2007). Early ultrasound screening for pregnant women also has the potential to save perinatal care costs by detecting abnormalities early in pregnancy (Groen et al, 2011). Papp and Fekete support routine ultrasound screening on the basis that 85 to 90% of congenital malformations occur without maternal or family antecedents and therefore, selective ultrasound screening may miss a lot of cases that cannot be deducted based on previous medical history (Papp and Fekete, 2003).

2.0 Intervention

Upon approval of the venture type of project by the relevant professional regulatory bodies in Kenya, the feasibility study got initiated in two pilot counties to assess if there is an entrepreneurship opportunity in deploying of Point of Care Ultrasound Screening Services (POCUS) among Primary Health Care Workers (PHWs) particularly midwives from ten (10) Primary Health Care (PHC) sites or business units. A total of forty-five (45) midwives got trained both physically and electronically (on-line) using standardised e-Learning content) on how to offer the service and interpret the images seen during the screening procedure. Professional Radiographers were trained by Sonographers to play the role of TOTs in mentoring and coaching the selected midwives in the project for a period of 3 months. The mentorship and coaching were tapered with time to allow the midwives develop a level of autonomy and reduce on remote consultations. To make the service accessible and affordable, mothers were required to pay USD 5 per screening session to meet operational costs for consumables, performance-based service provider's incentive and equipment maintenance. Despite the aversiveness to health facilities generated by the COVID-19 pandemic, a total of 1250 women were screened by midwives within the first one year. The fee charged was electronically paid to a centralised collection account then disbursed to the midwives on a monthly basis.

3.0 Methods

To assess the entrepreneurial viability of the midwives' ultrasound project, a cross-sectional survey was adopted which employed stratified random sampling and mixed methods in data collection. Purposive sampling was used to identify subjects for key informant interviews (KIIs). The two pilot counties were the first stratum, while the community units around the 10 pilot sites were the

second stratum. Antenatal Care (ANC) records in the facilities provided corroborative evidence for those who received the ultrasound screening services. The evaluation sought feedback from the project beneficiaries (mothers and pregnant women), the implementers (midwives), and the key project stakeholders. The Utilization Focused Evaluation (UFE) Framework was adopted in the participatory data collection approaches. To assess Viability of the pilot project, the evaluation focused on five-point criteria; relevance, efficiency, effectiveness, impact, and sustainability.

Structured and semi-structured interviews were conducted. Quantitative data was collected using KoBo toolbox uploaded on the enumerators' Android phones and later exported to SPSS for analysis. Quantitative data was analysed thematically using the five evaluation criteria. The data and information collected was coded, cleaned, entered analysis software, triangulated, and analysed using both qualitative and quantitative analyses on the thematic areas and variables. The Quantitative analysis was done using descriptive and inferential statistics. Qualitative analysis was done by framework Analysis centered on thematic areas focusing on Narrative analysis and where possible interpretative phenomenological analysis, grounded theory; discourse analysis and conversation analysis using Software program NVivo. To ensure compliance with ethical practices guiding scientific surveys, authorization for data collection was obtained from the relevant administrative authorities at the county level. Oral and written informed consent was the foundation for the participation of eligible respondents. The participants were informed that they could withdraw their participation at any time during the research process. To ensure confidentiality, anonymity was observed during interviews. To overcome the language barrier challenges facing respondents in primary health care setting, enumerators were selected on the basis of being able to speak local languages in addition to the two national languages.

4.0 Results

It emerged that out of the 45 registered midwives trained on POCUS at the beginning of the project, 28 (85%) were actively offering the mobile service within their community facilities at the conclusion of the pilot phase of the project although the numbers they were reaching had significantly reduced due to the COVID-19 pandemic that limited interaction between households and health care providers. Their TOTs who got interviewed as Key informants expressed confidence in their skills mastery which was much achieved through a 3 months period of phased hands on coaching and mentorship. Majority, 189(96.4%) of the ANC Mothers interviewed from the pilot sites had attained full awareness on availability of the service in their community facilities and they knew the benefits and cost of the service per screening. For instance, 158(80.6%) of the ANC mothers knew that the ultrasound scan is able to determine gestation of a pregnancy and rule out presence of foetal abnormalities. On referral and access to ultrasound services, 32(96.7%) of the midwives interviewed concurred that POCUS had made referral services easier because the midwife is able to identify cases that need referral early enough. Before then, referrals from PHC settings were made only out a high suspicion index.

They further opined that the portable or mobile ultrasound screening had reduced the distance pregnant women previously travelled (50-70km) to access the service at high level public and private facilities at a higher cost (USD 25-35). From the FGD sessions held with mothers who had benefited from the service, it emerged that they found the cost affordable that they could raise the fee required from a day's sales of basic items such as vegetables. The women further applauded flexibility of the service, the short time the procedure took, proximity of service providers to their households, immediate access to real time results and the initiation of immediate care in cases where complications were detected. A key informant from one of the pilot sites singled out two

cases they had referred on time; one had an Intra-uterine Fetal Death (IUFD) and the other one had a low-lying placenta.

The project midwives appreciated the cost friendly nature of the service, its flexibility given that at times they could extend their services (using portable technology) to Service delivery points that had a need within the radius of the pilot sites. POCUS technology also the reduced the paperwork involved in generation of reports and made it easy to transfer or share imaging information with a remotely located TOT or consultant. Majority, 189(96.4%) of the women interviewed accepted the ultrasound screening services offered by midwives in their PHC facilities and also expressed willingness to continue paying for them. Although, sometimes community members don't easily distinguish cadres of service provides, 118 (60%) of the women intimated that at the facility they were screened by midwives (fig 1). The 33 midwives interviewed also appreciated the financial incentive they received from the service but proposed to have the service cost increased to USD 8 (Ksh 800) since government referral facilities were charging a minimum of USD 10-15 lately excluding transport and other miscellaneous costs mothers incurred travelling there. During the baseline survey 32% of the 366 women who had been interviewed had expressed willingness to pay USD 10 for the service considering it had potential to help them save on their travel expenses to referral hospitals.

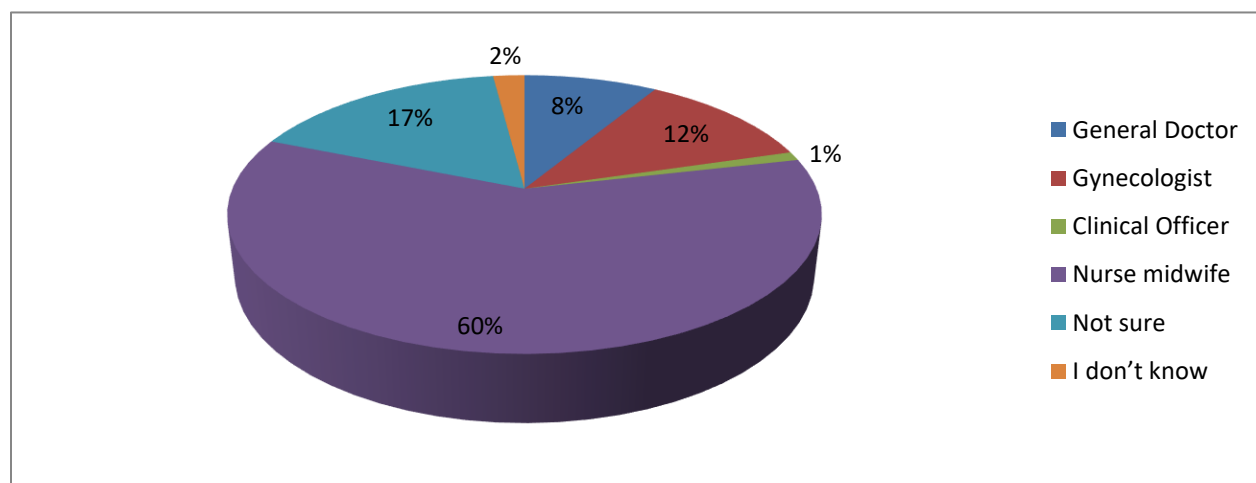


Figure 1: Who performed the POCUS service to the pregnant women

Further to this all the 33 midwives interviewed proposed to have the POCUS service scaled up to other counties in Kenya where MNCH indicators were wanting. To scale up the intervention the midwives proposed various strategies to be considered (Table 1) which included the need to formally adopt a national policy on task sharing in obstetric ultrasound screening services so as to enable all pregnant women access routine ultrasound screening services as recommended by WHO.

Table 1: Scale up strategies proposed by the project midwives

Response	Frequency	Percentage (%)
Train more midwives and nurses to offer the service	17	36.9
Increase the number of POCUS technologies in communities	9	19.6
Community sensitization/ awareness to increase utilization	7	15.4

Response	Frequency	Percentage (%)
Local governments to co-fund replenishing of consumables	3	6.6
Provide OUSS in outreach services in the communities	2	4.4
Train more PHC health workers under a national task sharing policy	2	4.4
Increase community awareness to increase utilisation	1	2.1
Cost reduction to increase access	1	2.1
National government to own the portable POCUS services through formal legislation	2	4.3
Make the service free with co-funding from local governments so as to increase access	1	2.1
Integrate POCUS with routine ANC services	1	2.1
Total	46	100

To assess the financial viability (sustainability of the project), further analysis was carried out factoring various cost drivers and the existing income streams from the project within the one-year feasibility study period and a 5-year projection based on the business modelling canvas in Fig 2.

Midwives Obstetric Ultrasonography Project Cost Analysis Canvas				
<u>Key Partners</u>	<u>Key activities</u>	<u>Value proposition</u>	<u>Customer Relationships</u>	<u>Customer Segments</u>
i) Phillips Foundation. ii) Amref international University iii) Ministry of Health and Regulatory bodies iv) Lead nurses	i) Training of TOTs ii) Training of Nurse midwives of PHC health care workers. iii) Mentorship Programme. iv) POCUS screening	<u>Commercial Proposition:</u> Affordable & Accessible Point of Care Ultrasound Screening. <u>Impact proposition.</u> <ul style="list-style-type: none"> Reduction in pregnancy complications 	Midwives trained to provide the OUSS (Obstetric Ultrasound services) Midwives perform OUS on expectant mothers for a fee.	i) Midwives ii) Expectant mothers in need of Obstetric Ultrasound services.

	<p><u>Key Resources</u></p> <ul style="list-style-type: none"> ● POCUS portable technology ● Trained TOTs ● Trained Nurse midwives ● Health centres and Dispensaries (public/ private) 	<ul style="list-style-type: none"> ● Increased capacity for PHC health care workers (midwives etc.) ● UHC/ Household income enhancement/saving. 	<p><u>Channels</u></p> <ul style="list-style-type: none"> ● Services offered at health facilities. ● Midwives enrolled into the Programme ● Expectant mothers reached through health facilities. 	
<p><u>Cost Structure</u></p> <p>i) <u>Establishment or set up Expenses (CAPEX):</u> these are costs associated with the setting up of the business unit. They include costs of equipment, technology, licenses, and basic training that must be in place to produce the POCUS. This is a long-term investment. They are one off costs for the entire PLC. Study costs are included.</p> <p>ii) <u>Fixed costs:</u> These are costs that are related to production of the scan but not variable to the number of scans performed</p> <p>iii) <u>Variable costs:</u> These are costs that vary depending on the number of scans produced. They include consumable and incentives.</p>		<p><u>Revenue Streams</u></p> <p>Ksh500 paid per POCUS by the beneficiary (The expectant Mother). The fee is gradually increased to Ksh 1,000.</p>		
<p><u>Impacts and measurements.</u></p> <ul style="list-style-type: none"> i) Capacity building of the beneficiaries, ii) Routine uptake of OUS, iii) Sustainability of the business model iv) Adoption of PHC digital solutions 				

Figure 2: Project business modelling Canvas

To evaluate the financial sustainability, first the project got analysed from a commercial outlook to establish whether the model could make positive cash flows by its operations and also establish whether the resultant cumulative cash flows over the project lifeline will pay back the initial project establishment cost. Going by the nature of the model, which is a social enterprise model both internal funding and external funding were considered.

The project financials outcomes for the first year (historical) were analysed first then using key lessons from both the financial performance and other outcomes corrective measure were proposed. Thereafter the most plausible scenario based on corrective measures was used to project for the rest of the project life. The financial analysis considered the project in its entirety including all the locations, trained midwives and all scans done during the feasibility study period. Also considered were the financial benefits to the individual midwife whose motivation is a crucial element in sustaining or scaling up of the project.

Internal funding of the project was achieved through the revenues generated by the POCUS end user fees. Sustainability from this perspective means that the revenues generated should cater for the successful running of the project after initial set up. Since cash generated internally is taken up by the implementers (midwives and the health facilities), the capability to generate internal revenue directly reflects on the willingness of the midwives and the pregnant women to take up the project.

First, Break Even Point analysis (Table 2) was carried out to identify the number of paid for ultrasound scans that should be conducted to just cater for fixed and variable costs of delivering the services sustainably in the 10 pilot sites per year.

Table 2: Break -Even Analysis

BEP	
Total Fixed Costs*	Ksh 550,000.00
Total variable Costs Per OUS	Ksh 200.00
Unit Price per Scan	Ksh 500.00
BEP (Number of POCUS scans)	1,833.33 units

**Represent total fixed costs for operating 10 sites of the POCUS project in terms of depreciation and maintenance costs after initial investment. Not dependent on number of scans per month. Investment costs totalling to Kshs 8,809,240 not included in the BEP calculation but was used in calculating investment payback period, IRR or their ROI.*

The BEP calculation got based on the current project fees and costs as well the targeted output of 1,834 scans in the first year. Given that 1,250 scans were undertaken in the year under evaluation, a 46.7 % shortfall was experienced probably due to the COVID-19 pandemic otherwise there was a high possibility of meeting the target. In the background of lower demand associated with COVID 19, the BEP is projected to be achievable in the next 1 year based on the total addressable market and the corrective measures considered in the analysis in Table 3 scenario.

Table 3: BEP considering probable value adding corrective measures

	Scenario 1	Scenario 2	Scenario 3
	50% Increase in OUS fees	20% Decrease in Variable costs	60% increase in OUS fees & 50% in Variable costs
Total Fixed Costs (Ksh)	550,000	550,000	550,000
Total variable Costs Per Scan (Ksh)	200	160	300

	Scenario 1	Scenario 2	Scenario 3
	50% Increase in OUS fees	20% Decrease in Variable costs	60% increase in OUS fees & 50% in Variable costs
Unit Price per Scan (Ksh)	800	500	800
BEP (Number of scans)	1,000.00	1,618	1,222

Considering the scenario 1 in Table 3, whereby charges per scan are increased by 60% to reach Ksh 800 the breakeven point is at 1,000 scans is considered plausible from the fact that a normal scan costs up to Ksh 1,500 albeit with limited accessibility within the target market. Scenario 2 in Table 3 has a marginal effect on the BEP yet with reduced motivation to the midwives or compromise to the quality of the POCUS service. Scenario 3 is recommended since an increase in the variable costs which would include motivation to the mentors (Radiologists) coupled with an increased margin for the midwives will motivate the growth of POCUS numbers. Consequently, the scenario is adapted in making growth projections of the model in 2022, with gradual increase thereafter to reach Kshs 1,000 by 2025.

On cash flow, the project generated positive cash flows of Kshs 375,000 in the first year, thereby being able to cater for its running costs. With projected growth in revenues in the next 5 years it will realize total positive cash flow of Kshs 8,648,056 which gives a total present value of Kshs 6,850,035.61. Provision for depreciation of the POCUS mobile/portable technology machines is a key element of the costs which though affecting profitability does not influence cash flows.

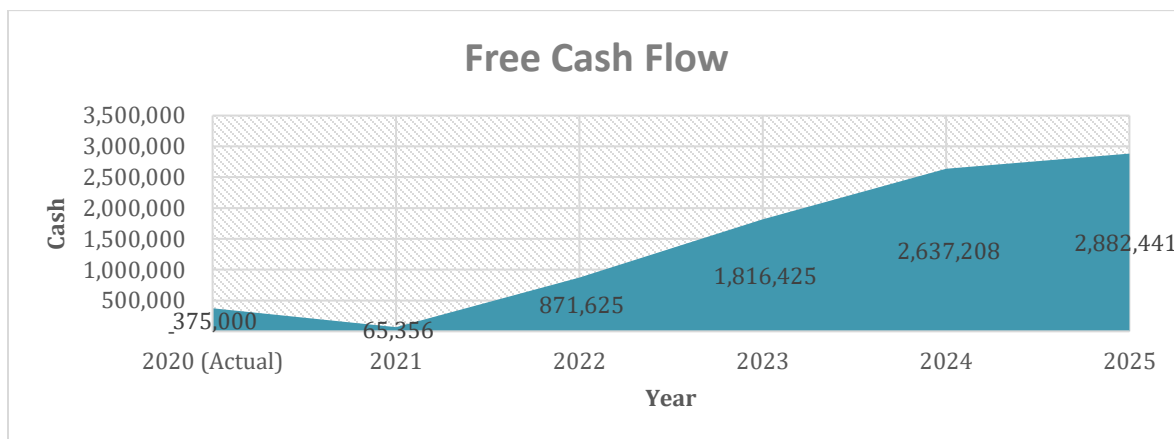


Figure 3: Project cash flow analysis

On external funding Viability, the sustainability of the model is dependent on buy-in for long term funding by public and/or non-profit institutions. Sustainability means that the project is attractive or viable for funding to cater for establishment costs which include purchase of probes, software, licensing, and initial training. To evaluate the attractiveness, we assess the financial return on investment and the non-financial return.

On financial Return on Investment (ROI), the financial ROI is incorporated (fig 4) on the assumption that the financial benefit or loss made, though not directly recouped by the project funder represents the financial benefit realized by the project and passed over to those executing

the POCUS services (the midwives). This as well speaks to motivation and retention of the midwives.

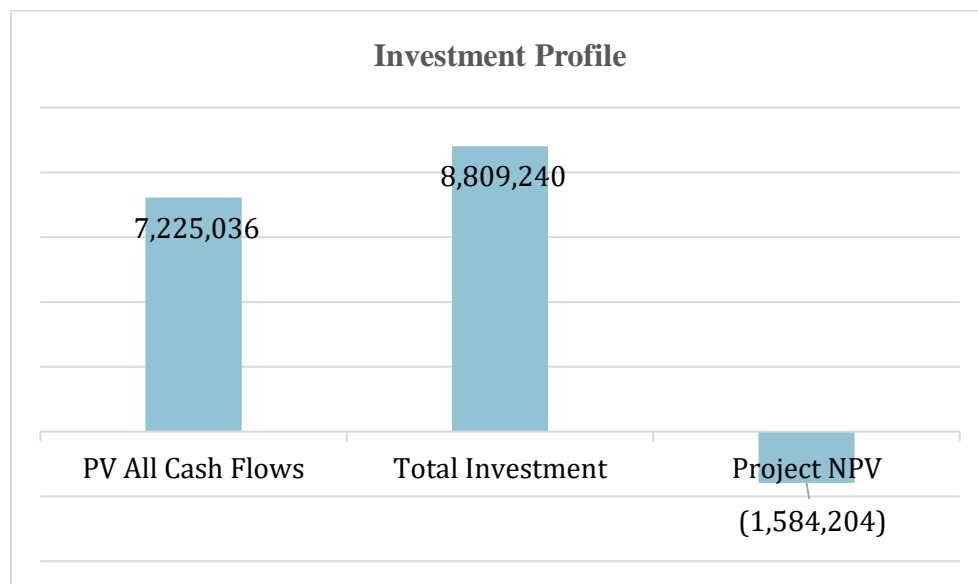


Figure 4: Project Net Present value

Present Value of the future cash flows of the entire project at a discount rate of 5% (equivalent to inflation) is Kshs 8,809,240 which added to the actual income received in 2020 gives total present value of Ksh. 8,743,515 against a total investment of Kshs. 8,809,240. The entire project realized net present value of Kshs (1,584,209). On impact returns, the midwives' business model gives rise to numerous social and health benefits which are long term in nature. In brief these includes, reducing the 3 delays (Ds) that cause maternal neonatal morbidity and mortality, awareness creation on locally available POCUS to the community, increased household incomes for both the mothers and the midwives as a result of the economic opportunity accorded to the mothers. The easy access to POCUS services within a short distance implies that mothers have more time to engage in other economic activities with potential to generate more income. The positive impact of the project is considered adequate to enhance the marginal financial NPV. This is on the premise that prospective investors are concerned with both the impact returns and the financial returns thereby presenting an investable case. The fee charged currently has been established as affordable to the mothers given the ease of access and lower cost compared to those by normal scans which cost Kshs 1,500 on the minimum. The projected increase of screening costs up to Ksh 1,000 in 2024 -2025 to support financial sustainability; is still considered competitive given the inflation rates with time. Incentives provided by the project translated into an increase of income for the nurse midwives who provided the service. The gross margins enjoyed by midwives for 2020 stood at 60% and can be enhanced up to 84% by 2025 to offer the motivation for increased engagement including promotion. Additional budget for refresher training and promotion of community support is a probable cost that if projected in the business model has potential to enable boosting of the number of scans done by the midwives for sustainability. With the BEP within achievable range and projected positive cash flows the business model for the midwives implementing PHC digital solutions driven entrepreneurship is viable to support continued running and replicating of the project. The models' financial NPV though marginally negative is strongly boosted by significant long-term externalities realized by the project. This

presents a strong case for buy in to external funders to fund initial set up of the project. The implementation model already has a buy in from both mothers and midwives, therefore the number of scans provided is expected to grow exponentially with time to a period of 6 years. Notably, if some of the challenges that emerged during implementation (Table 4) are sufficiently addressed the midwives' ultrasound PHC business model's sustainability and scalability is likely to improve even more.

Table 4: Challenges that potentially affected the business model

Challenges	Effect On sustainability	Mitigation
Drop out of Trained midwives	Increased per unit cost of training. Lower number of OUS and revenues.	Better incentivization through margins and Larger number of trainees for economies of scale in training.
Misunderstanding of Task/role shifting and its benefits leading to negative attitude by some MOH staff on midwife's empowerment to provide OUSS.	Lower uptake of OUS.	Expanded training and sensitization programmes to the target group.

5.0 Discussion, Conclusions and Recommendations

5.1 Discussion

Social enterprises have the potential to increase access to health services in Primary Health Care (PHC) settings but little is known on impact metrics and financial sustainability (Lokman and Chahine 2021). The POCUS entrepreneurship social enterprise project explored financial sustainability through differential pricing that involved reduced cost of service in remote areas hoping to benefit from economies of scale (high-volume low-cost work stream). The challenge facing entrepreneurship in health ecosystem is that it is not part of the core training in health training institutions (Suryavanshi, 2020) and most of the social entrepreneurs in health do focus mostly on curative services with little attention on preventive care. The midwives ultrasound project is one of those that focused on preventive care. There is a paradigm shift to PHC innovations taking form of wearable technology that documents patient experiences or websites that allow patients to access their own lab work. There is also the need for integrated data solutions in the PHC social enterprising space.

Health reforms are now becoming necessary considering the emerging convergence of communicable and non-communicable diseases in developing countries. Primary Health Care (PHC) workers who include nurses and midwives can have value adding trainings with enhanced scope of practice under task sharing (Wilson et al., 2012) to address the emerging needs. This can involve governments embracing social entrepreneurial or intrapreneurial roles in low resource settings so that the Primary Health Care Workers (PHCWs) in that space are motivated to perform the extra roles and responsibilities to enhance improved health outcomes through increased access to Universal Health Coverage.

In Sub-Saharan Africa many Primary Health Care (PHC) digital health solutions have been piloted with little attention to understanding the processes that underpin efforts to scale up and sustain them. (Swartz et al,2021). In the new digital era, smartphones, telemedicine, virtual reality among other technological advances are gradually but surely becoming part of routine health care practices. In this fast-evolving digital health ecosystem, there is need to pursue development of bankable and sustainable entrepreneurial solutions around technology for PHC services delivery. Digital health for PHC has inherent capabilities to improve the quality of care and enhance health financing with better health outcomes at lower costs of service delivery (Wulfovich and Meyers, 2020)

To reduce inequality on accessing PHC services, attain health related SDGs and Universal health coverage, significant gains can be made through PHC innovations (Islam, 2021). Convergence of science and technology has made it possible to characterise diseases and other health states with precision especially in underserved settings (Sanjeev et al.,2016); Primary health care digital innovations have the potential to change how services are delivered where physical infrastructure is limited; digital innovations have potential to increase the number of people reached in hard to reach areas, carry out data analytics for better health outcomes, enhance service coverage and reduce the cost of care among the vulnerable in need of health care. Primary Health Care innovations have capacity to address the challenges facing health systems in low- and middle-income countries (More,2019); high cost of care, low quality of services, poor infrastructure and limited access to experts among others. The opportunities digital health solutions bring along notwithstanding, there is need to ensure all interventions are people centred; personalised and participatory health care (Wilson et al,2021). Entrepreneurship driven Point of Care Ultrasound screening services (POCUS) in selected PHC sites in Kenya has shown such a potential.

It is unfortunate that low resource countries are yet to reap from the entrepreneurship opportunities digital health brings due to weak infrastructure especially on internet connectivity, limited public awareness, limited knowledge and expertise among care providers (Olushayo et al, 2019). According to Lassi et al (2016), limited technology, lack of expert staff in areas of radiography and ultrasonography in primary health care settings, has grossly affected the health devolved units (refer Kenya's county governments) to implement the Managed Equipment Services (MES). As a result, private sector continues to be the main diagnostics service provider albeit the high costs of their services. The Midwives ultrasound project has revealed that, if well trained, the Primary health care workers can execute some of the essential digital driven screening or diagnostic services in hard to reach areas to improve the vulnerable populations' health outcomes.

Many developing countries are adopting free maternity care policies that do not necessarily guarantee improved quality of care and sustained consumption of targeted services (Mukabana and Wambui, 2016). To achieve quality maternal and neonatal care in low- and middle-income countries, there is need to address both Human Resource for Health (HRH) motivation and availability of the right equipment for services delivery. Given the shortage of expert service providers in PHC settings coupled with limited infrastructure, Primary health care digital solutions have the capability to bridge the gap.

5.2 Conclusion

Social entrepreneurship on Point of Care Ultrasound Screening (POCUS) does contribute to affordable and sustainable access to quality pregnancy care. It is possible to sustainably deploy affordable obstetric ultrasound screening services in rural settings through Primary Health Care Workers (PHCWs)

5.3 Recommendations

- i. There is need for a clear national policy framework on how to implement task sharing on PHC digital health solutions e.g. POCUS
- ii. Basic medical imaging training should be included in the curriculum for training middle level health care professionals who end up serving in primary health care settings
- iii. Further simplification of imaging technology training is needed to enable PHC professionals offer the service in hard to reach areas.
- iv. Considering the many emerging digital health solutions for PHC, more research is needed to assess the role of digital interdependence on pregnancy outcomes
- v. There is need for standardised training resources to support skills acquisition among PHC service providers on POCUS.
- vi. Stakeholders need to explore cheaper financing options to enable many PHC facilities acquire POCUS technology.

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