

Digital health and entrepreneurship in Primary Health Care settings – Kenya’s experience

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Abstract

Background

The limited number of sonographers in developing countries and high cost of conventional obstetric ultrasound screening services in high level facilities led to only 6.9% of pregnant women accessing the service in rural areas. However, Point of Care Ultrasound (POCUS) services in Primary Health Care (PHC) settings has shown the potential to enable developing countries implement the WHO requirement of pregnant women accessing obstetric ultrasound screening before 24 weeks gestation. Through POCUS, life threatening complications can be easily identified and managed on time thus reversing the Maternal Mortality trends in developing countries. Given the ease to learn and use POCUS technology, there is an opportunity to train selected PHC health professionals to offer the service at an affordable cost that supports routine acquisition of essential ultrasound screening supplies and entrepreneurial incentivisation of the care providers. The aim of this paper is to document viability of POCUS in a PHC setting of a developing country.

Methods

One year post intervention, an evaluation survey got conducted in the project sites that spanned across two pilot counties in Kenya (Kajiado and Kisii) on viability of the entrepreneur driven implementation of POCUS services. The sample size was calculated using the formula to estimate the difference in proportions between two independent populations and sampling was done using two stage

cluster sampling method. The survey adopted mixed methods in data collection. A sample of 33 Midwives who had been trained to offer the service and 196 women from Community Health Units (CHUs) surrounding the pilot health facilities took part in the study. Facility record reviews on the project also provided additional sources of information.

Findings

Despite the COVID-19 pandemic that limited pregnant women's utilization of ANC services, the trained midwives had screened a total of 1250 pregnant women in one year at a fee of USD 5 for each scan. 168 (85.7%) of the women confirmed the service was affordable and easily accessible in the local facilities. 85 (43.4%) of the women confirmed they were screened by midwives in local public primary health care facility and 28 (84.8%) of the midwives reported to have had sustainable acquisition of essential supplies needed for the service in addition to the performance-based incentive/token received from the intervention. Notably, 180 (91%) of the women interviewed recommended scaling up of the service. On effectiveness of the POCUS training, 32 (96%) of the midwives reported that the continuous mentorship and coaching by TOTs (radiographers) post the electronic and face to face training enhanced acquisition of knowledge and skills for the project.

Although the project realised a marginal negative net present value of cash flows, the impact generated was of high significance. The project was viable from implementation perspective since it demonstrated the potential to reach a Break Even Point (BEP) at a modest of 1833 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.

Conclusion

Obstetric Ultrasound screening services can be provided at lower levels of health system 1,2,3 by nurses and midwives among other PHC health professionals who are well trained. The POCUS services can be offered at an affordable and cost to keep the service delivery viable or sustainable in limited resources settings. Financial viability of the POCUS is subject to increasing the number of women accessing the service.

Key words: Point of Care Ultrasonography Screening (POCUS), Midwives, Antenatal, Primary Health Care settings, Business Model

Introduction

Given the financial constraints developing countries' health systems are facing in financing provision of 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). Multilateral and bilateral organizations as well as private donors, therefore, are keen to comprehensively assess the feasibility of introducing POCUS in these 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).

Intervention

Upon approval of the project and training curricula by the relevant professional regulatory bodies in Kenya, the pilot project got initiated in two counties to assess midwives' uptake of basic obstetric ultrasound screening skills and women's utilisation of Point of Care Ultrasound Screening Services (POCUS) in selected ten (10) Primary Health Care (PHC) facilities also referred to as 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 make impression of 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 sustainably available, mothers were required to pay USD 5 per screening session to meet operational costs for consumables, incentivise the service providers through a performance-based approach and maintain the equipment whenever they broke down. Within the first one-year 1250 women were screened by the PHC midwives. The fee charged was electronically paid to a centralised collection account then disbursed to the midwives on a monthly basis.

Method

To assess the entrepreneurial viability of the midwives' ultrasound project after the one year of a feasibility study amidst the COVID-19 pandemic, a cross-sectional survey design was adopted which employed a stratified random sampling and mixed methods in data collection. Purposive sampling was used for the other data collection techniques such as 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. ANC records in the facilities provided corroborative evidence for those screened. The evaluation sought feedback from the project beneficiaries (mothers and pregnant women), the implementers (i.e., midwives), and the key project stakeholders. The Utilization Focused Evaluation (UFE) Framework was adopted in the participatory data collection approaches adopted. To assess Viability of the pilot project, the evaluation focused on a five-point criteria; relevance, **efficiency, effectiveness, impact, and sustainability.**

Data collection

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 analyzed thematically using the five evaluation criteria. Reporting and data dissemination was done as per Amref's dissemination plan incorporating ethical consideration measures by ESRC. Covid-19 restriction measures were put in place during the evaluation exercise, trainings, and feedback workshops.

Data Management and Analysis

The data and information collected was coded, cleaned, entered analysis software, triangulated, and analyzed 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

Ethics

Authorization for data collection was obtained from the relevant administrative authorities in Kajiado and Kisii Counties in Kenya. Oral and written informed consent was the foundation for the participation of eligible midwives. 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.

Limitations and Delimitations

People in primary health care settings sometimes face language barrier challenges but enumerators were selected on the basis of being able to speak local languages in addition to the two national languages

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%) the midwives interviewed concurred that POCUS had made referral services easier because the midwife is able to identify early those cases that definitely need referral. Before then, referrals from PHC settings were made only out a high suspicion index.

They further opined that the portable 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.

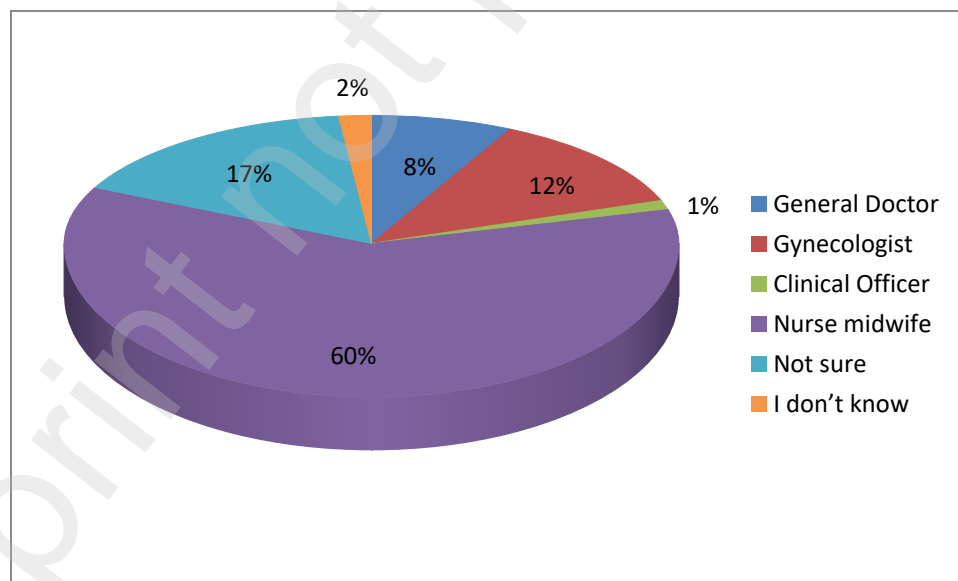


Fig 1: who performed the POCUS service to the pregnant women

Further to this all the 33 midwives interviewed proposed to have the POCUS service scaled up to other counties 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
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>Key Resources</u> <ul style="list-style-type: none"> • POCUS portable technology • Trained TOTs • Trained Nurse midwives • Health centres and Dispensaries (public/ private) 	<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 • Increased capacity for PHC health care workers (midwives etc.) • UHC/ Household income enhancement/saving. 	Midwives trained to provide the OUSS (Obstetric Ultrasound services) Midwives perform OUS on expectant mothers for a fee. <u>Channels</u> <ul style="list-style-type: none"> • Services offered at health facilities. • Midwives enrolled into the Programme • Expectant mothers reached through health facilities. 	i) Midwives ii) Expectant mothers in need of Obstetric Ultrasound services.
<u>Cost Structure</u> i) <u>Establishment or set up Expenses:</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. 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 iii) <u>Variable costs:</u> These are costs that vary depending on the number of scans produced. They include consumable and incentives.			<u>Revenue Streams</u> Ksh500 paid per POCUS by the beneficiary (The expectant Mother). The fee is gradually increased to Ksh 1,000.	

Impacts and measurements.

- i) Capacity building of the beneficiaries,
- ii) Routine uptake of OUS,
- iii) Sustainability of the business model
- iv) Adoption of PHC digital solutions

Fig 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 OUS that should be conducted per year to just cater for fixed and variable costs of delivering OUS for the entire project.

Table 2: Break -Even Analysis

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

The BEP based on the current project fees and costs is at 1,834 scans. 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 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
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.

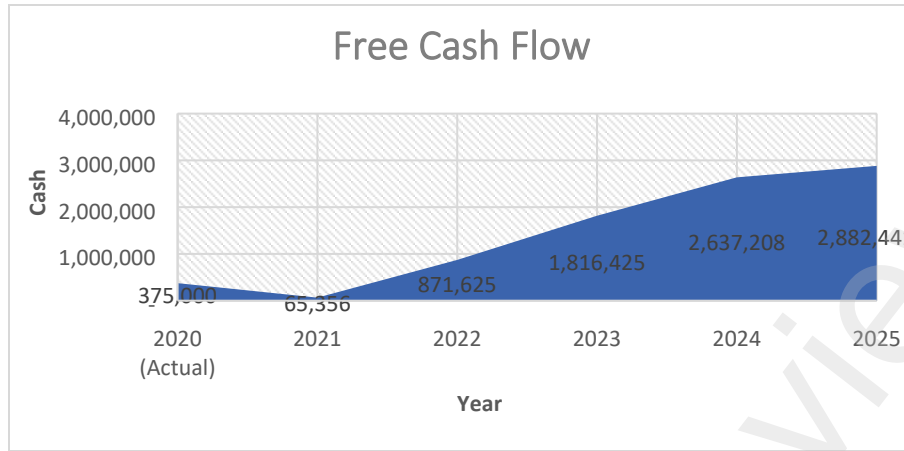


Fig 3: Project cash flow analysis

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.

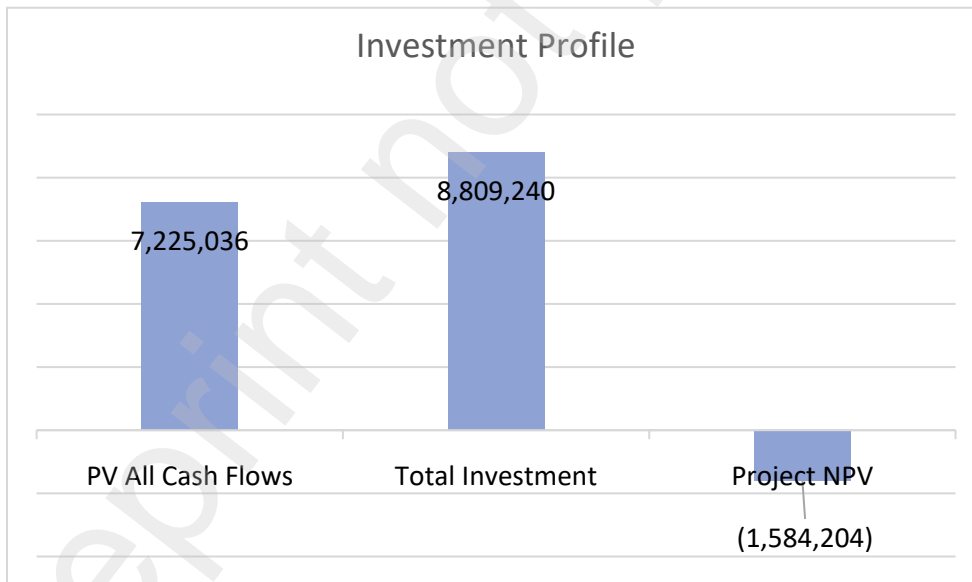


Figure 4: Project Net Present value

Present Value of the future cash flows 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 Kshs

8,743,515 against a total investment of Kshs 8,809,240. The project realizes 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 as detailed in section 4.6. 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: This occurs mostly because of 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 increases of up to Kshs 1,000 in 2024 -2025 to support financial sustainability; this is considered to still be competitive given the inflation 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 stand 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

	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	Lower uptake of OUS.	Expanded training and sensitization programmes to the target group.

benefits leading to negative attitude by some MOH staff on midwife's empowerment to provide OUSS.		
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Discussion

In Sub-Saharan Africa many digital health solutions have been piloted in health sector with little attention to understand the processes that underpin efforts to scale up and sustain the digital health solutions (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. 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)

In Universal Health Coverage (UHC) digital health is a means to an end. Primary health care digital health solutions can help accelerate achievement of SDG target 3.8. Technology has 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. The opportunities that digital health solutions are opening notwithstanding, there is need to ensure all interventions are people centred; personalised and participatory health care (Wilson et al,2021). Point of Care Ultrasound screening services have shown such a potential.

Low resource settings countries including Kenya are yet to reap from the opportunities digital health brings to the community as a result of weak infrastructure, limited awareness and knowledge on digital health, unstable power supply and limited internet connectivity (Olushayo et al, 2019).

Point of Care Ultrasound Screening (POCUS) technology, is one of those digital health solutions with potential for entrepreneurial venture through delivery of low-cost services in underserved settings.

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 (county governments) to implement the Managed Equipment Services (MES) in Kenya. As a

result, private sector continues to be the main diagnostics service provider albeit the exorbitant charges it costs. The Midwives ultrasound project has revealed that, if well trained, the Primary health care workers can execute some of the essential obstetric ultrasound screening services in hard to reach areas to improve on pregnancy health outcomes.

When maternity services are offered for free, it automatically increases utilization without necessarily guaranteeing improved quality of care and sustained consumption of targeted services (Mukabana and Wambui, 2016). Therefore, 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 sonographers in low resource settings, implementing Point of Focus Ultrasonography (POCUS) through other middle level care givers is now more feasible. The Midwives project in Kenya has demonstrated that it is possible to sustainably deploy HRH incentivization models on Point of Care Ultrasound Screenings (POCUS) as a critical decision-making tool in low resource settings.

Conclusion

Point of Care Ultrasound Screening (POCUS) does improve pregnancy care. It is possible to deploy digital health led entrepreneurial ventures in PHC settings to improve access and quality of care among the hard to reach populations. Wide stakeholder involvement in such ventures is a critical driver of success.

Recommendations

- i. There is need for a clear policy framework on how to implement POCUS in primary health settings
- ii. Basic medical imaging training should be included in the curriculum for training middle level health care professionals who end up serving in 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. Standardising a national or regional continuing professional development course on obstetric ultrasound screening for PHCWs will enhance fast acquisition of skills
- vi. Stakeholders need to explore cheaper financing options to enable many PHC facilities acquire POCUS technology.

Acknowledgments

We would like to thank our respondents, Kajiado County, Kisii County and the research assistants who made this study a success.

Funding

We acknowledge the financial support received from Phillips Foundation supported by Phillips Health Care Solutions. Particularly we acknowledge the programmatic support from Joosse Koen, Ties Kroezen, June Omollo, Ephantus Muriithi and Christine Apimo.

Conflict of interest

The authors declare no conflict of interests

Authors' contributions

Matiang'i M designed, coordinated and oversaw the study, Ngunju P supervised implementation and data collection, Kiilu C digitised and piloted data collection tools while Omogi J drafted the first manuscript while Romy and Marianne contributed a lot of programmatic ideas during project implementation. All authors read and approved the manuscript.

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