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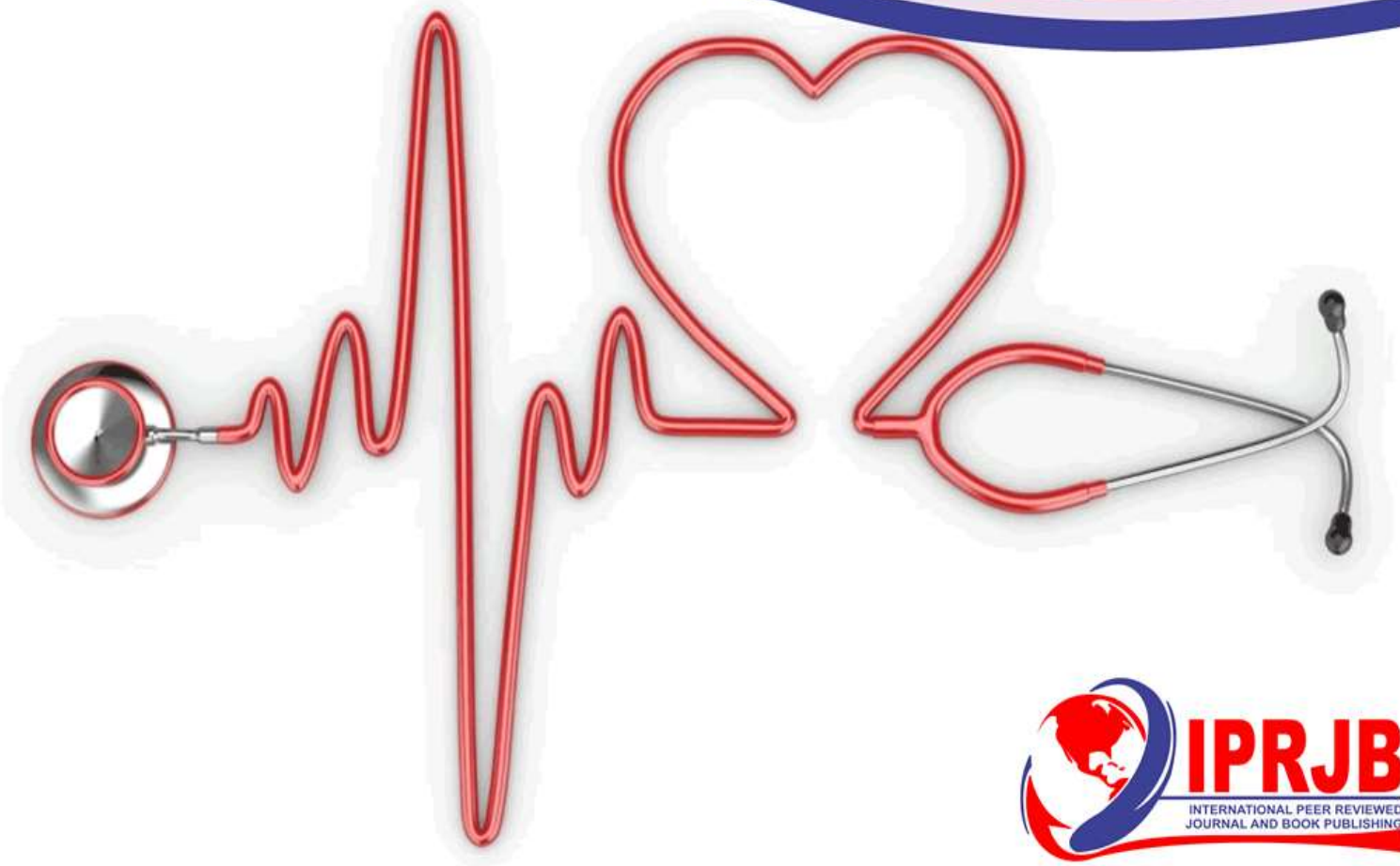

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Effect of Antenatal Digital Risk Assessment on Women's Perceptions of Maternal Referral System Functionality in Siaya County, Kenya: A Randomized Controlled Trial

Christabel Wesonga[1*]
[1]Department of Health Systems Management, Kenya Methodist University, Kenya
Wanja Tenambergen[1]
Department of Health Systems Management, Kenya Methodist University, Kenya
Job Mapesa[2]
[2]Department of Public Health, Human Nutrition and Dietetics, Kenya Methodist University, Kenya

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Abstract

Purpose: Over the past two decades, global maternal mortality has decreased by 34%, from 339 to 223 deaths per 100,000 live births. However, the rate of decline has slowed, and remains insufficient to achieve the Sustainable Development Goal (SDG) 3.1. This study aims to evaluate the effectiveness of a digital antenatal risk stratification tool in improving the functionality of maternal referral systems in selected healthcare facilities, with the goal of enhancing maternal and neonatal health outcomes.

Methodology: A randomized controlled trial (RCT) was conducted in level 4 healthcare facilities. Eligible pregnant women were randomized into an intervention group or a standard of care group with an equal sample size of 175 in each group. Modified Coopland's Scoring System was employed to categorize maternal risk levels. Descriptive and inferential statistical analysis to summarize the data. Multivariable logistic regression was employed to evaluate the impact of the intervention on the functionality of a referral system controlling sociodemographic outcomes and mode of delivery.

Findings: The median age was 26 years (IQR:23-31) in the controls and 25 (22-29) in the intervention group (p-value=0.039). SVD was the most common mode of delivery in both groups. Significant higher proportion of participants reported adequate human resource support during referral in intervention group as compared to the standard of care group (p-value < 0.001). Overall, 27.7% reported the system as function, all of whom were in the intervention group. Functionality of the referral system was associated with assignment to the intervention group, household monthly income of KES 10,000-50,0000 and delivery through caesarean section.

Unique Contribution to Theory, Practice and Policy: Digital interventions can strengthen maternal referral systems by facilitating timely and appropriate referral of high-risk pregnancies, which suggest that establishing a national digital referral coordination framework to enable real-time tracking and accountability and integrating risk stratification tools into routine antenatal care protocols could improve perceived quality of the referral system within Siaya county.

Keywords: *Functionality, Maternal, Referral System, Kenya, Digital Health, Risk Stratification, Antenatal Care*

JEL Codes: *I11,I15,I10*

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INTRODUCTION

Despite a global reduction of 38% in the Maternal Mortality Ratio (MMR) from the years 2000 to 2017, approximately 810 women still died globally in 2017 due to pregnancy-related complications. Furthermore, approximately 2 million stillbirths occurred worldwide in 2019, despite a 35% reduction in stillbirths since the year 2000 (Hug et al., 2021). Sub-Saharan Africa (SSA) bears the highest burden of maternal deaths and stillbirths, accounting for 66% and 40%, respectively. These figures are 89 and 36 times higher than those in European countries (Hug et al., 2021; World Health Organization (WHO), 2019) . This disparity is largely attributed to inequalities in access to high-quality healthcare services, fluctuating poverty levels, and disparities in educational attainment between the regions (Meh et al., 2019; Tesema et al., 2020).

Approximately 25% of maternal deaths occur during pregnancy influenced by factors such as unsafe abortion, violence, and regional disease burdens (Bwana et al., 2019). The most likely cause of these maternal deaths are clinical such as hypertension (including pre-eclampsia and eclampsia) and antepartum hemorrhage, which are often associated with inadequate prenatal care (Medjedovic et al., 2023) and health system which includes delays in recognizing obstetric danger signs, poor access to transport, and health system inefficiencies in maternal care continue to contribute to high maternal and perinatal mortality (Orwa et al., 2020; Shah et al., 2020).

In the 1990s, the World Health Organization (WHO) established Focused Antenatal Care (FANC) model, targeting at least four ANC contacts with the skilled health provider during prenatal period (ANC4+). These recommendations were updated in 2016 to include eight antenatal visits, with the goal of improving the healthcare experience and minimize poor pregnancy outcomes especially in low-middle income countries (Macharia et al., 2022). The key services provided during these visits included, screening of complications (such as anemia, abnormal lie, hypertension, diabetes, syphilis, tuberculosis, and malaria), provision of preventive interventions (such as tetanus immunization and insecticide-treated bed nets); counselling about diet, hygiene, HIV status, birth, emergency preparedness, and care and feeding of babies, and classification of women based on their risk of delivery complications (Halle-Ekane et al., 2015; Tunçalp et al., 2017). Despite the deployment of FANC to replace traditional ANC as a strategy to reduce MMR, Kenya continues to report high maternal morbidity and mortality compared to other nations (Orangi et al., 2021).

In Siaya County, maternal deaths could be stemming from inadequate ANC, delayed referrals, due to ineffective risk stratification. Despite improvements in ANC attendance nationally, many women in Siaya initiate care late in the third trimester and do not complete the recommended four ANC visits. Moreover, delays in recognizing obstetric danger signs, poor access to transport, and systemic inefficiencies in maternal care continue to contribute to high maternal and perinatal mortality (Alhassan et al., 2024; Umutesi et al., 2021) .

Early antenatal risk stratification effectively identifies high-risk pregnancies and implements timely interventions including referrals to high level facility to continue with care, thereby reducing complications and improving outcomes for both mothers and newborns (Johnson et al., 2024; Souza et al., 2024). By providing early information on pregnancy risk, this approach supports informed decisions, allowing low risk women to continue routine care at their usual facilities, while those at medium or high risk are referred for additional assessments, treatments, and/or specialized delivery arrangements at higher level facilities. Early antenatal

risk assessment relies on detailed history taking (obstetric, medical, and surgical history), systematic physical examinations, diagnostic tests, and imaging (Fente et al., 2023; Pallepogula et al., 2022). This approach assumes that factors associated with adverse outcomes at the population level can accurately predict risk for individual women, which practice requires risk measures with high sensitivity tests and minimal false negatives (Cooper et al., 2025).

In October 2023, the president of Kenya enacted four bills related to health that were aimed at the realization of the Universal Health Coverage (UHC). One of the bills was the Digital Health Bill, of 2023 (which would later become the "Digital Health Act, 2023"). The bill was meant to the information related to health and health system "provide the foundation for decision making by integrating a system that will collect, collate, store, manage, analyze, synthesize, and transmit the patient's/client's electronic health record and use health and health-related data for operational management or system supporting health care policy decisions" the Act also proposes among others the establishment of a digital health agency that will be tasked with developing, operationalizing and maintaining a comprehensive integrated health system. The agency will also be responsible for establishing health facilities registries and promoting best practices for digital health while ensuring data portability and integration with the health information systems. The Act also covers the provision of e-health services which will make healthcare more accessible, especially in rural areas (The Digital Health Bill, 2023, 2023).

Integrating digital antenatal risk stratification (ARS) into the referral system may strengthen functionality by enhancing coordination, streamlining decision-making, and improving the allocation of healthcare resources, particularly by reducing delays in maternal and newborn care. However, the extent to which digital ARS influences the functionality of referral system remains underexplored particularly in regions where referral systems are weak and where primary care clinics are far from higher-level facilities which is a common characteristic of settings with high maternal and newborn mortality. The study aims to investigate the impact of digital ARS on the functionality of maternal referral system in Siaya County. By providing context-specific evidence-based insights, this research seeks to inform policy and practice to improve referral system performance and maternal health outcomes in Siaya County, Kenya.

In Siaya County, maternal referral systems rely on paper-based risk assessment tools that are prone to delays, illegibility, loss of records, and lack of real-time communication between primary facilities and referral hospitals. These systemic friction points contribute to delayed or inappropriate referrals for high-risk pregnancies, undermining efforts to reduce maternal and neonatal mortality. While digital health interventions have shown promise in improving health system efficiency, evidence on whether a digital antenatal risk stratification tool can outperform existing paper-based methods in improving referral system functionality remains limited. This study aims to evaluate the effectiveness of a digital antenatal risk stratification tool compared to standard paper-based risk assessment in improving the functionality of maternal referral systems in selected healthcare facilities in Siaya County.

This study is grounded in the World Health Organization Health Systems Framework, which conceptualizes a health system through six core building blocks: service delivery, health workforce, health information systems, access to essential medicines and technologies, health financing, and leadership and governance. The framework provides a comprehensive lens for evaluating how a digital antenatal risk stratification tool may influence referral decision-making, particularly through its integration into service delivery and health information

systems. By applying this framework, the study aims to assess not only the clinical outcomes of the intervention but also its broader implications for health system performance and referral efficiency.

METHODOLOGY

Study Setting and Design

This study was conducted in Siaya County which is located between latitude 0° 26' to 0° 18' north and longitude 33° 58' east to 34° 33' west. The County consists of six sub-counties: Alego, Usonga, Bondo, Ugenya, Ugunja, Gem, and Rarieda. Siaya County with 220 health facilities comprising of 11 sub-county referral and teaching hospitals (level 4), 50 health centers (level 3), and 159 dispensaries (level 2). All the health facilities provide Basic Emergency Obstetric and Newborn Care services and Child Health services. The 11 level 4 health facilities are additionally designated as comprehensive emergency obstetric care services offering specialized care and management for high-risk pregnancies and serving as referral hubs for lower-level health facilities (dispensaries and health centers). According to the Kenya 2019 census, Siaya County has a total population of 993,183, with 53% female and 47% male. The county's average fertility rate is 4.6, and 99.1% of pregnant women have access to skilled antenatal services. The Kenya Demographic and Health Survey (KDHS) report of 2022 indicates that 84.4% of deliveries take place at health facilities, and 65.1% of pregnant women complete the recommended four ANC visits.

The study employed a randomized control trial (RCT) design where participants in the intervention group were assessed for referral decision guided by digital antenatal risk stratification tool while in the control group, the referral decision followed the standard of care protocol. The pregnant women were individually randomized in a 1:1 allocation ratio to either the intervention or control group.

Randomization Procedure

Randomization was performed by an independent statistician not involved in participant recruitment or outcome assessment. A computer-generated random allocation sequence was created using a 1:1 allocation ratio with randomly permuted block sizes of 4 and 6 to ensure balance between groups. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes. Following enrollment and baseline assessment, the next envelope was opened to reveal group assignment. Outcome assessors were blinded to group allocation, though blinding of participants and healthcare providers was not feasible due to the nature of the intervention.

Population and Sampling

Eligible participants were adult pregnant women of at least 30 weeks gestational age and residents of Siaya County. Women presenting with life threatening obstetric complications or were too ill to provide their own consent for study participation were excluded. The study was conducted in high volume sub-county referral and teaching hospitals (level 4 health facilities) to evaluate the impact of the digital antenatal risk stratification tool compared with the existing referral framework.

The study used a two-stage random sampling selection process. In the initial selection, 4 out of 11 hospitals were randomly selected using lottery methods in collaboration with sub-county health management teams from the six sub-counties. Second stage involved random allocation of women to either intervention or control arm using ballot method within the selected health

facilities. The ANC clinic registers served as the sampling frame, from which participants were drawn. The sample size selected from each hospital was proportional to its average monthly ANC attendance to ensure representativeness.

Sample Size Determination

To determine the appropriate sample size for the study with 1:1 allocation ratio, Fleiss method for comparing two proportions with a two-sided test was used (Chow et al., 2017). The study assumed a two-sided confidence level of 95%, a statistical power of 80%, a minimum detectable absolute difference between intervention and control group of 15% and allowing for a 10% loss to follow up. The minimum sample size required was 345, which was rounded up to 350 participants. Pregnant women were proportionally recruited depending on the monthly attendance in each facility.

Data Collection

The data were collected using a structured questionnaire administered to antenatal care (ANC) women by the trained research assistants. Data collected included demographic characteristics (age in years, education level, monthly household income in Kenyan shillings, and parity), functionality of referral system, human resource capacity, and client's health literacy. Marital status was categorized as single, married, separated and those who prefer not to answer, occupation as unemployed, employed, self-employed and students, level of education categorized into primary, secondary, tertiary and other levels of education, monthly household income in Kenya shillings (< 5,000, 5,000 -10,000,10,000-50,000 and > 50,000), number of pregnancies (first time, 2-3,4-5, and > 5) and obstetrics outcome which includes mode of delivery classified as SVD and CS and outcome of pregnancy (full term, low birth weight, stillbirths and maternal mortality). Questions on digital infrastructure were asked to the intervention group only. Women in the intervention group were assessed for risk stratification electronically using modified Cooplands risk scoring system (Pillai & Mohan, 2021).

To assess the functionality of the referral system in antenatal care, which is the outcome of interest, we constructed a composite binary variable. A respondent was coded as "1" (functional referral system) if she met all of the following criteria: she had ever been referred for antenatal care; reported that there was coordination during the referral (rated as good or very good); received care in a timely manner; was able to communicate effectively during the referral; received the necessary information; felt that the management of her case was good or very good; rated the overall organization of the referral system positively (good, very good, or excellent); and found that there was a clear structure in the referral process (good or very good). Respondents who did not meet all these conditions were coded as "0" (non-functional referral system). The indicators align with the World Health Organization Quality of care domains and referral system guidelines in which failure of any core component compromises overall referral functionality (Tunçalp et al., 2015; West et al., 2021).

A Human Resource adequacy score (HR_score) was computed from six items assessing patient perceptions of staffing support. Five Likert-scale items on staff guidance, follow-up access, staff knowledge, staff availability, and staff understanding were dichotomized ('Agree'/'Strongly Agree' = 1), combined with a direct binary assessment of adequate human resources. The sum of scores ranged 0–6, with scores ≥4 classified as adequate overall human resource support. The choice of the cut-off, though not used in any of the literatures but aligns with common practice of dichotomizing multi-item scales using a substantive majority criterion (Streiner et al., 2024).

Pretesting was conducted to assess the clarity, feasibility, and reliability of the study tools and procedures before full-scale implementation of the study. The pretesting was conducted in one healthcare facility which was not part of the actual interviews. The questionnaires were validated with experts in the maternal and newborn experts before the pretesting and start of the actual study implementation.

Data Management and Analysis

Data were collected electronically using REDCap with inbuilt data validation to ensure accuracy and completeness. The system was password-protected to avoid unauthorized access of the data. Data cleaning was conducted to check for missing values, outliers, and inconsistencies. Descriptive statistics including median and interquartile range were used to summarize continuous outcomes, while frequencies and percentages were used to summarize categorical variables. Chi-square or Fisher's tests were used to compare categorical variables, and Wilcoxon rank sum tests to compare continuous variables. A multivariable logistic regression model was used to assess the association between the functionality of maternal referral system and intervention, adjusting for sociodemographic characteristics and obstetrics outcomes. All analysis were conducted using RStudio Version 4.5.1 and p-value < 0.05 were set as level of significance.

Ethical Considerations

Ethical approval was sought from the Kenya Methodist University (KeMU) Ethics Review Committee and research permit from Kenya National Commission of Science Technology and Innovation (NACOSTI). Additionally, approval was obtained from the Siaya County Health Department to ensure alignment with county-level healthcare policies and regulations. Further, authorization was obtained from the hospital management of the participating healthcare facilities to conduct the study within their premises. All participants were consented before the start of the data collection process by appending signatures or thumb print on the informed consent forms. The study followed the ethical guidelines of the approval institutions throughout.

RESULTS

Baseline Characteristics

A total of 350 participants were included in the study, with an equal number randomized to the cases and controls. The median age was 26.0 years (IQR: 22.0-30.0), and majority (n=268 ;76.6%) were married. Most participants were unemployed (n=149; 42.6%), with education levels mainly secondary (n=201; 57.4%), and tertiary (n=111; 31.7%). One hundred and twenty-four (35.4%) had household incomes less than KES 5,000 per month, and 120 (34.3%) reported monthly household income between KES 5,000 and KES 10,000. There were significant differences in age (p-value=0.039) and monthly household income (p-value=0.041) between the standard of care and intervention groups (Table 1).

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Table 1: Baseline Characteristics of the Population

Characteristic	Overall N = 350	*Randomization Group* Standard of care N = 175[1]	Intervention N = 175[1]	p-value[2]
Name of the facility, n (%)				0.64
Ambira	86 (24.6)	38 (21.7)	48 (27.4)	
Bondo	88 (25.1)	47 (26.9)	41 (23.4)	
Siaya	87 (24.9)	45 (25.7)	42 (24.0)	
Yala	89 (25.4)	45 (25.7)	44 (25.1)	
Age in years, Median (IQR)	26.0 (22.0 – 30.0)	26.0 (23.0 – 31.0)	25.0 (22.0 – 29.0)	0.039
Marital status, n (%)				0.12
Single	79 (22.6)	34 (19.4)	45 (25.7)	
Married	268 (76.6)	140 (80.0)	128 (73.1)	
Separated	1 (0.3)	1 (0.6)	0 (0.0)	
Don't prefer to answer	2 (0.6)	0 (0.0)	2 (1.1)	
Occupation, n (%)				0.49
Unemployed	149 (42.6)	72 (41.1)	77 (44.0)	
Employed	65 (18.6)	32 (18.3)	33 (18.9)	
Self employed	115 (32.9)	63 (36.0)	52 (29.7)	
Student	21 (6.0)	8 (4.6)	13 (7.4)	
Level of education, n (%)				0.19
Primary School	36 (10.3)	22 (12.6)	14 (8.0)	
Secondary School	201 (57.4)	101 (57.7)	100 (57.1)	
Tertiary Education	111 (31.7)	50 (28.6)	61 (34.9)	
Other	2 (0.6)	2 (1.1)	0 (0.0)	
Household income in a month, n (%)				0.041
< KES 5,000	124 (35.4)	59 (33.7)	65 (37.1)	
KES 5,000-10,000	120 (34.3)	59 (33.7)	61 (34.9)	
KES 10,000-50,000	97 (27.7)	56 (32.0)	41 (23.4)	
KES >50,000	9 (2.6)	1 (0.6)	8 (4.6)	
Number of pregnancies, n (%)				0.23
First-time Pregnant	113 (32.3)	51 (29.1)	62 (35.4)	
2-3 Pregnancies	175 (50.0)	86 (49.1)	89 (50.9)	
4-5 Pregnancies	50 (14.3)	31 (17.7)	19 (10.9)	
More than 5 Pregnancies	12 (3.4)	7 (4.0)	5 (2.9)	

[1]Median (IQR) or Frequency (%)
[2]Pearson's Chi-squared test; Wilcoxon rank sum test; Fisher's exact test

Referral System

Perceptions of participants on the indicators of maternal referral system functionality are presented in Table 2. Of the participants referred, a total of 80.9%(n=283) strongly agreed that there was coordination in the referral system, while the remaining 19.1% (n=67) disagreed (2.9%; n=10) or agreed (16.3%; n=57) with the perception. Fewer than one-third of the participants 24.6% (n=86) reported receiving timely and appropriate care at the referral facility, and just over half felt they could communicate clearly with the staffs (51.1%; n=179) or clearly received information on follow-up or referrals steps (56.0%; n=196) and there was a clear referral protocol in place (53.4% ;n=187). A hundred and eighty-four (52.6%) of the participants agreed that the management was supportive in addressing any issues, however, only 8.9% (n=31) strongly agreed with this perception. Despite these deficiencies in the

process, majority (n=200;57.1%) reported the overall experience of organization of services at the referral facility was very good with only three of the participants reporting poor services. Overall, the intervention group reported significantly better experiences across most domains, including system coordination (p=0.009), communication clarity (p<0.001), information receipt (p<0.001), management support (p<0.001), protocol clarity (p<0.001), and overall experience (p=0.007) than the standard of care group. There was a significant difference in the primary outcome functionality of maternal referral system between the two groups as none of the participants in the Control group rated the referral system as functional compared to 55.4% (n=97) in the intervention group (< 0.001).

Table 2: Functionality of the Maternal Referral System in Siaya County

Indicators of functionality	Overall N = 350	Randomization Group		p-value[1]
		Standard of care N = 175	Intervention N = 175	
There was coordination, n (%)				0.009
Disagree	10 (2.9)	9 (5.1)	1 (0.6)	
Agree	57 (16.3)	22 (12.6)	35 (20.0)	
Strongly agree	283 (80.9)	144 (82.3)	139 (79.4)	
Did you receive timely and appropriate care, n (%)	86 (24.6)	40 (22.9)	46 (26.3)	0.46
Were you able to communicate clearly with the staff, n (%)	179 (51.1)	54 (30.9)	125 (71.4)	<0.001
Did you receive information on the steps for follow-up or referrals clearly?, n (%)	196 (56.0)	56 (32.0)	140 (80.0)	<0.001
management was supportive in addressing any issues, n (%)				<0.001
Strongly disagree	8 (2.3)	8 (4.6)	0 (0.0)	
Disagree	127 (36.3)	96 (54.9)	31 (17.7)	
Agree	184 (52.6)	62 (35.4)	122 (69.7)	
Strongly agree	31 (8.9)	9 (5.1)	22 (12.6)	
The overall experience of organization of services at this facility, n (%)				0.007
Poor	3 (0.9)	3 (1.7)	0 (0.0)	
Fair	21 (6.0)	15 (8.6)	6 (3.4)	
Good	71 (20.3)	42 (24.0)	29 (16.6)	
very good	200 (57.1)	95 (54.3)	105 (60.0)	
Excellent	55 (15.7)	20 (11.4)	35 (20.0)	
There was a clear structure or protocol followed for referral process, n (%)				<0.001
Strongly disagree	7 (2.0)	6 (3.4)	1 (0.6)	
Disagree	134 (38.3)	123 (70.3)	11 (6.3)	
Agree	187 (53.4)	42 (24.0)	145 (82.9)	
Strongly agree	22 (6.3)	4 (2.3)	18 (10.3)	
Functionality of a referral system, n (%)	97 (27.7)	0 (0.0)	97 (55.4)	<0.001

[1]Pearson's Chi-squared test; Fisher's exact test

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www.iprjb.org

Digital Infrastructure

Among the participants in the intervention group (N=175), 84.0% (n=147) reported being informed about the digital risk stratification (DARS) tool at the facility of services and 86.3% (n=151) were educated on how it could improve pregnancy outcomes. There was a positive perception of DARS with 90.3% (n=158) perceived that it would improve care and referral process, and 98.9% (n=173) agreed or strongly agreed that it made them feel safer knowing their risk was assessed digitally. Majority of the participants (97.1%;n=170) had the perception that the staff understood the tool's functionality, and 74.9% (n=131) reported adequate staffing for its utilization. There were, however, technical issues such as problems with laptops, application functionality, internet access, or data transfer reported during the referral process. Only two participants disagreed that they felt safer knowing their risk levels had been assessed (Table 3).

Table 3: Digital Infrastructure

Indicators	N = 175
Have you been informed about the digital antenatal risk stratification (DARS) tool at this facility?, n (%)	147 (84.0)
Was the staffing adequate to allow the utilization of DARS?, n (%)	131 (74.9)
The staff understood the functionality of DARS tool and they were not struggling, n (%)	
Disagree	5 (2.9)
Agree	122 (69.7)
Strongly agree	48 (27.4)
Have you been educated about how digital antenatal risk stratification can improve your pregnancy outcomes?, n (%)	151 (86.3)
Do you feel that digital antenatal risk stratification will improve the care and referral process?, n (%)	158 (90.3)
The digital antenatal risk stratification tool had a positive impact on the referral process, n (%)	
Strongly disagree	0 (0.0)
Disagree	7 (4.0)
Agree	90 (51.4)
Strongly agree	78 (44.6)
Were there any technical issues (e.g., adequate laptops, functional app, internet access, data transfer) during your referral process?, n (%)	56 (32.0)
I feel safer knowing my risk level has been assessed digitally, n (%)	
Disagree	2 (1.1)
Agree	78 (44.6)
Strongly agree	95 (54.3)

Human Resource Capacity

There were mixed experiences regarding human resource support during the referral process with significant differences favoring the intervention group. Most of the participants agreed that health professionals involved in their care seemed supportive in guiding through the referral process (n=216; 61.7%), while 39 (11.1%) strongly agreed, a substantial minority of the participants 27.2% (n=95) disagreed or strongly disagreed with the statement.

In contrast, the majority (n=286; 81.7%) of the participants strongly agreed that they were able to access follow-up services of check-ups after referral and 54 (15.4%) agreed. Nearly all

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www.iprjb.org

participants (97.4%) felt that healthcare staff had adequate knowledge during antenatal care, with 53.7%; n=188) agreeing and 43.7%; n=153 strongly agreeing and an overwhelming majority (97.2%) reported being able to access follow-up services after referral (81.7% strongly agreed, n=286; 15.4% agreed, n=54).

Most participants agreed that the staff were available when they needed assistance with their referral (66.9%; n=234), 15.7% (n=55) strongly agreed, however 17.4%; (n=61) of the participants disagreed with the statement. Based on the composite human resources score, 89.4% (n=313) of the participants were classified as having adequate overall human resource support during the referral services. None of the participants in the intervention groups strongly disagreed that healthcare professionals involved in their care seemed supportive in guiding them through the referral process. Higher proportions agreed or strongly agreed with the statement among the intervention compared to the Control group (p-value < 0.001). The trend was similar when participants were assessed on healthcare staff availability when in need of assistance with the referral services (p-value=0.009). The composite measure of adequate human resource support showed high overall adequacy (89.4%, n=313), but intervention group participants reported significantly higher adequacy (97.7% vs 81.1%; p-value < 0.001).

Table 4: Human Resource Capacity

Indicators	Overall	Randomization Group		p-value[2]
		Control	Intervention	
	N = 350	N = 175[1]	N = 175[1]	
The healthcare professionals involved in your care seemed supportive in guiding you through the referral process, n (%)				<0.001
Strongly disagree	8 (2.3)	8 (4.6)	0 (0.0)	
Disagree	87 (24.9)	67 (38.3)	20 (11.4)	
Agree	216 (61.7)	86 (49.1)	130 (74.3)	
Strongly agree	39 (11.1)	14 (8.0)	25 (14.3)	
You were able to access follow-up services or check-ups after your referral - (call the patients), n (%)				0.77
Strongly disagree	5 (1.4)	3 (1.7)	2 (1.1)	
Disagree	5 (1.4)	2 (1.1)	3 (1.7)	
Agree	54 (15.4)	30 (17.1)	24 (13.7)	
Strongly agree	286 (81.7)	140 (80.0)	146 (83.4)	
I felt that the healthcare staff had adequate knowledge to assist me during my antenatal care, n (%)				0.25
Disagree	9 (2.6)	7 (4.0)	2 (1.1)	
Agree	188 (53.7)	94 (53.7)	94 (53.7)	
Strongly agree	153 (43.7)	74 (42.3)	79 (45.1)	
Healthcare staff were available when I needed assistance with my referral., n (%)				0.009
Disagree	61 (17.4)	41 (23.4)	20 (11.4)	
Agree	234 (66.9)	111 (63.4)	123 (70.3)	
Strongly agree	55 (15.7)	23 (13.1)	32 (18.3)	
Adequate Human Resource support, n (%)	313 (89.4)	142 (81.1)	171 (97.7)	<0.001

[1]Frequency (%)

[2]Fisher's exact test; Pearson's Chi-squared test

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Client's Health Literacy

Clients' health literacy and seeking behavior are shown in Table 5 with almost all women (98.9%; n=346) attended ANC services once per month, 70.3% (n=246) had been informed about their antenatal risk status, and 78.3% (n=274) understood the importance of antenatal risk stratification. A total of 48.3% (n=169) of mothers initiated their ANC visit within the recommended first trimester (by 12 weeks). This included four participants in 0-4 weeks and 47.1% (n=165) at 5-12 weeks. Another 40.6% (n=142) participants initiated their ANC visit between 13-24 weeks of their pregnancy (second trimester), 38 (10.9%) in the 25-34 weeks of pregnancy and only one woman attended the first ANC visit above 33 weeks of their pregnancy (late second or third trimester). Overall, communication about referrals was largely effective as 84.9% (n=297) of the participants found the information provided about their referral to be very clear, while additional 7.4% (n=26) found the information extremely clear. There was significant difference in participants reporting being informed about their antenatal risk status during their ANC visits (p-value < 0.001), those who reported having understood the importance of antenatal risk stratification in their pregnancy care (p-value < 0.001), and rating of the clarity of information provided about their referral (p-value < 0.001) between both groups.

Table 5: Clients' Health Literacy

Characteristic	Overall N = 350	Randomization Group		p-value[2]
		Control N = 175[1]	Intervention N = 175[1]	
How often do you attend antenatal care (ANC) services? n (%)				>0.99
Once per month	346 (98.9)	173 (98.9)	173 (98.9)	
Once every 2 months	4 (1.1)	2 (1.1)	2 (1.1)	
Have you been informed about your antenatal risk status during your ANC visits?, n (%)	246 (70.3)	99 (56.6)	147 (84.0)	<0.001
Do you understand the importance of antenatal risk stratification in your pregnancy care?, n (%)	274 (78.3)	123 (70.3)	151 (86.3)	<0.001
How far along in your pregnancy were you when you first started ANC visits? (weeks), n (%)				0.89
0-4 week	4 (1.1)	2 (1.1)	2 (1.1)	
5-12 weeks	165 (47.1)	82 (46.9)	83 (47.4)	
13-24 weeks	142 (40.6)	74 (42.3)	68 (38.9)	
25-32 weeks	38 (10.9)	17 (9.7)	21 (12.0)	
>33 weeks	1 (0.3)	0 (0.0)	1 (0.6)	
How would you rate the referral ?, n (%)				<0.001
Not clear	1 (0.3)	0 (0.0)	1 (0.6)	
Moderately clear	26 (7.4)	1 (0.6)	25 (14.3)	
Very clear	297 (84.9)	174 (99.4)	123 (70.3)	
Extremely clear	26 (7.4)	0 (0.0)	26 (14.9)	

[1]Frequency (%)

[2]Fisher's exact test; Pearson's Chi-squared test

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Participants Obstetrics History

In terms of obstetrics history, half of the participants (n=175; 50.0%) had experienced 2-3 previous pregnancies, while 113 (32.3%) were first-time mothers. Almost all deliveries were Spontaneous Vaginal Delivery (SVD) (n=302; 86.3%), while 334 (95.4%) were full-term. There were 3.7% (n=13) low birthweight infants, two stillbirths and one maternal mortality in the study population.

Table 6: Patient Obstetrics Outcome

Characteristic	Overall N = 350	*Randomization Group* Standard of care N = 175[1]	Intervention N = 175[1]	p-value[2]
Mode of delivery, n (%)				0.35
SVD	302 (86.3)	148 (84.6)	154 (88.0)	
C-section	48 (13.7)	27 (15.4)	21 (12.0)	
Outcome of full term infant, n (%)				0.71
Full term infant	334 (95.4)	165 (94.3)	169 (96.6)	
Low birth weight	13 (3.7)	8 (4.6)	5 (2.9)	
Still Birth	2 (0.6)	1 (0.6)	1 (0.6)	
Maternal mortality	1 (0.3)	1 (0.6)	0 (0.0)	

[1]Frequency (%)
[2]Pearson's Chi-squared test; Fisher's exact test

Factors Associated with Functionality of a Maternal Referral System

In the univariable analysis, the intervention group, having household monthly income between KES 10,000 and 50,000 and delivery by C-section were significantly associated with the functionality of maternal referral system. The same variables remained significant even after adjusting for all other variables in the multivariable analysis with all the variables showing an increased odd of functionality. In the multivariable analysis, the odds of functionality of maternal referral system was 18.15 times higher among the cases compared to the control group (AOR: 18.15; 95%CI (9.70-36.26); p-value < 0.001), that of those from household with monthly income between KES 10,000 and 50,000 were 5.98 times higher than those who earn less than KES 5,000 (AOR:5.98; 95%CI:2.61-14.40) and 4.03 times higher among those who delivered through C-section compared to those who delivered through SVD (AOR: 4.03;95%CI:1.82-9.29) (Table 7).

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Table 7: Factors Associated With the Functionality of a Referral System

Variable	Category	Non-functional	Functional	OR (univariable)	AOR (multivariable)
Randomization	Control	147 (84.0)	28 (16.0)	-	-
	Intervention	65 (37.1)	110 (62.9)	8.88 (5.42-14.97, p<0.001)	18.15 (9.70-36.26, p<0.001)
Age (years)	Mean (SD)	26.2 (5.2)	27.0 (6.2)	1.03 (0.99-1.07, p=0.184)	0.99 (0.91-1.06, p=0.705)
Household income per month	< KES 5,000	81 (65.3)	43 (34.7)	-	-
	KES 5,000-10,000	82 (68.3)	38 (31.7)	0.87 (0.51-1.49, p=0.618)	0.94 (0.48-1.86, p=0.857)
	KES 10,000-50,000	45 (46.4)	52 (53.6)	2.18 (1.27-3.77, p=0.005)	5.98 (2.61-14.40, p<0.001)
	KES >50,000	4 (44.4)	5 (55.6)	2.35 (0.59-9.95, p=0.219)	2.24 (0.43-12.79, p=0.341)
Gravida	First-time Pregnant	67 (59.3)	46 (40.7)	-	-
	2-3 Pregnancies	115 (65.7)	60 (34.3)	0.76 (0.47-1.24, p=0.270)	0.50 (0.24-1.03, p=0.063)
	4-5 Pregnancies	23 (46.0)	27 (54.0)	1.71 (0.88-3.37, p=0.117)	2.33 (0.75-7.39, p=0.145)
	More than 5 Pregnancies	7 (58.3)	5 (41.7)	1.04 (0.29-3.46, p=0.949)	1.03 (0.15-7.18, p=0.972)
Mode of delivery	SVD	191 (63.2)	111 (36.8)	-	-
	C-section	21 (43.8)	27 (56.2)	2.21 (1.20-4.14, p=0.012)	4.03 (1.82-9.29, p=0.001)

Discussion

In this study, we aim to evaluate the impact of digital ARS on the functionality of referral systems in the four sub-county referral and teaching health facilities. Less than half of the women attending ANC classified the referral system as function with significant difference between the intervention and control groups. The low proportion of participants reporting the system as function is an indication of weak link within the health system in this setting. The criteria for referral are supposed to be purely medical, and objective, in the interest of the woman which appears to be straightforward, however, this study have found the referral

systems to be dysfunctional especially among the control group which may results in too few referrals or patients come too late to receive treatment. Other studies have been conducted in different settings highlighting human resources, the professional environment, patients and families, and community support as central to effective maternal health systems (Sastrawan et al., 2025).

The participants in the intervention group perceived the referral system to be effective in coordination, communication, explaining the referral procedures and clarity in the follow-up protocol as compared to the group in the standard approach of referral which aligns with some of the necessary qualities of a functional referral system (Harahap et al., 2019). An effective referral system is crucial for reducing maternal morbidity and mortality by ensuring timely access to higher-level healthcare facilities and is one of the necessary elements of successful Safe Motherhood programmes (Oduro-Mensah et al., 2021). Technological interventions has been used to improve health service delivery in maternal and newborn heath (Nigussie et al., 2021) and integrating the intervention within the current referral system is likely to further improve the maternal and newborn health outcomes in this setting.

Despite fewer Women in the intervention groups classified the system as functional, none was in the control group. Consequently, the use of digital ARS (intervention group) was associated with the functionality of referral system with higher odds among the intervention group as compared with the standard of care group. Similarly, women who delivered by caesarean section were more likely to report the referral system as functional, likely reflecting successful referral and access to definitive obstetric care. Proper use of digital system helps in identification of conditions associated with referral before onset of labor and delivery, thus, prevents Maternal and child deaths through timely, evidence-based and cost-effective interventions (Sultana et al., 2025). The digital tool appears to address the First Delay (delay in deciding to seek care) by enabling more accurate and timely risk stratification at the point of antenatal care, facilitating earlier identification of high-risk pregnancies. The tool also addresses the Second Delay (delay in reaching care) by improving communication and coordination between referring and receiving facilities, as evidenced by the significantly higher proportion of intervention group participants reporting adequate human resource support during referral. The absence of any control group participants meeting the functionality criteria suggests that the paper-based system fails to consistently address either delay, resulting in fragmented referral pathways.

Strengths and Limitations

This is the first kind of study to be conducted on the effect of the technology of the functionality of maternal referral system in this setting. The study randomized participants into standard of care and intervention groups which control other factors that might have confounded the results in addition to the regression analysis conducted. The study acknowledged few limitations such as the use of cross-sectional research design which could not allow for the follow-up of these women on their perceptions in the previous or subsequent pregnancies. Secondly, omission of some of important variables that could influence the association between functionality and intervention such as human resource capacity, client's literacy, infrastructures (supply of medicines and equipment). Third, we were unable to follow those referred women to their respective health facilities and the quality of care they received in those facilities. Analyzing the links between the referral and receiving facilities would give further insight into the functioning of the network. Lastly, the study included only level 4 health facilities leaving out

other levels which might have more information on the functionality of the maternal referral systems in this setting. Further studies with large sample size incorporating facilities at all levels are recommended. This will be valuable to see how our findings generalize to different levels of health facilities.

Due to individual randomization occurring within shared clinical spaces, there was a risk of contamination, whereby healthcare workers could inadvertently apply the digital tool to control group participants or alter their referral behavior across study arms. This limitation was acknowledged, and efforts were made to minimize contamination through standardized training and clear separation of study protocols.

Conclusion

The functionality of referral system depends on the patients' perception at the facility of care, confidence in the staff and capacity of receiving health facility, and the efficiency of health system. Barriers to referrals can limit patients' ability to receive appropriate care in a timely manner and lead to inefficiency in maternal and neonatal referrals. The use of digital technology was effective in improving the referral system through enhanced coordination, communication, and follow-up protocol. Referral functionality was significantly associated with the intervention group, household monthly income and CS as mode of delivery. Integrating digital system is likely to strengthen maternal and newborns referral processes and should be encouraged, particularly in low- and middle-income countries with high maternal mortality, to improve perceived quality of the referral process. The findings suggest that establishing a national digital referral coordination framework to enable real-time tracking and accountability and integrating risk stratification tools into routine antenatal care protocols could improve perceived quality of the referral system within Siaya county.

What is already known on this topic:

- Digital health tools offer promising individual-level strategies to complement care provided during pregnancy.
- Integration of digital health tools in Maternal and Newborn Healthcare has been shown to promote positive health behaviors and care seeking.
- Key factors influencing the quality of referral systems include timely assessment, rapid decision-making and effective communication with the clients and between healthcare facilities.

What this study adds:

- Use of digital technology within referral systems contributes to improved functionality of maternal referral pathways.
- Early detection of high-risk pregnant women and timely referral through digital platforms enhance health system responsiveness.
- Digital referral systems improve coordination, communication, and follow-up during antenatal period.

Competing Interest

None of the authors declared any competing interest

Author's Contribution

CW and WT conceived the study and designed the methodology. CW drafted the initial version of the manuscript. WT and JM supervised all stages of the study. All authors critically reviewed and revised the manuscript, contributed to the final version, and approved the submitted manuscript.

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