# Systematic Review and Meta-analysis of Diagnostic Accuracy of Mobilelinked Point-of-Care Diagnostics in Sub-Saharan Africa

Ernest Osei<sup>1</sup>, Sphamandla Josias Nkambule<sup>1,3</sup>, Portia Nelisiwe Vezi<sup>1</sup>, Tivani P. Mashamba-Thompson<sup>1,2</sup>

<sup>1</sup>Discipline of Public Health Medicine, School of Nursing and Public Health, University of KwaZulu-Natal, Durban, South Africa

<sup>2</sup>Faculty of Health Sciences, University of Pretoria, Prinshof Campus, Pretoria, South Africa

<sup>3</sup>Centre for Health Policy, University of Witwatersrand, Gauteng, South Africa

Corresponding Author: Ernest Osei

Address: 2<sup>nd</sup> Floor of George Campbell Building, Department of Public Health Medicine, University of

KwaZulu-Natal, Howard College Campus, Durban, 4001, South Africa

Email address: ernestosei56@gmail.com

Tel: +233242012953

The email address of co-authors

Portia Nelisiwe Vezi (mgabadeli999@gmail.com)

Sphamandla Josias Nkambule (210501689@stu.ukzn.ac.za)

Tivani P. Mashamba-Thompson (tivani.mashamba-thompson@up.ac.za/Mashamba-Thompson@ukzn.ac.za)

#### Abstract

Mobile health devices are emerging applications that could help deliver point-of-care (POC) diagnosis, particularly in settings with limited laboratory infrastructure, such as sub-Saharan Africa (SSA). The advent of coronavirus has resulted in an increased deployment and use of mHealth-linked POC diagnostics in SSA. We performed a systematic review and meta-analysis to evaluate the accuracy of mobile-linked point-of-care diagnostics in SSA. Our systematic review and meta-analysis were guided by the Preferred Reporting Items requirements for Systematic Reviews and Meta-Analysis (PRISMA). We exhaustively searched PubMed, Science Direct, Google Scholar, MEDLINE, and CINAHL with full-text via EBSCOhost databases from mHealth inception to March 2021. The statistical analyses were conducted using OpenMeta-Analyst software. All 11 included studies were considered for the metaanalysis. The included studies focused on malaria infections, Schistosoma haematobium, Schistosoma mansoni, soil-transmitted helminths, and trichuris trichiura. The pooled summary of sensitivity and specificity estimates were moderate compared to the gold reference standard. The overall pooled estimates of sensitivity, specificity, positive likelihood ratio, negative likelihood ratio and diagnostic odds ratio of mobile-linked POC diagnostic devices were as follows: 0.499 (95% CI: 0.458-0.541); 0.535 (95% CI: 0.401-0.663); 0.952 (95% CI: 0.60-1.324); 1.381 (95% CI: 0.391-4.879); and 0.944 (95% CI: 0.579-1.538), respectively. Evidence shows that mobile-linked POC diagnostics' diagnostic accuracy is presently moderate in detecting infections in sub-Saharan Africa. Future research is recommended to evaluate mHealth devices' diagnostics with excellent sensitivities and specificities in diagnosing diseases in this setting.

Prospero registration: CRD 42020155041

Keywords: mHealth devices; diagnosis; accuracy; sensitivity; specificity; sub-Saharan Africa

#### 1. Introduction

Currently, sub-Saharan Africa (SSA) bears the highest disease burden worldwide (13). The high rate of infectious diseases, high recurrence of epidemics, increasing growth of chronic diseases, weak healthcare systems, insufficient funds to support healthcare, inadequately skilled health professionals, and poor healthcare infrastructure pose a significant challenge in improving healthcare provision SSA (13-15). Most patients or people have no access or limited access to healthcare clinics and even essential healthcare services (13). With these challenges, digital health such as mobile health (mHealth) applications have demonstrated their potentials in screening and testing communicable and non-communicable diseases at point-of-care diagnostics globally, including SSA (4, 16-18). mHealth technology is considered one of the emerging diagnostic tools or recognized as an enabling technology for disease diagnosis (1-4). In this study, we defined mHealth as the use of mobile health devices such as smartphones, tablets, and others as diagnostic tools to diagnose or detect existing disease conditions of patients.

The current global outbreak of the novel Coronavirus infections has overstretched many healthcare systems, and its implications are still unfolding. With the considerably increasing number of cases and limited available resources, there is a growing need for deployment and scalable solutions such as digital health technologies, including mHealth applications, to monitor and manage the pandemic (3-5). A recent study in the USA shows mHealth applications' use to screen healthcare workers for COVID-19 symptoms to control this disease's spread (3). Other studies conducted in the USA, Canada, and Taiwan have also demonstrated the use mHealth applications for preliminary screening and early detection of possible COVID-19 infected persons and accelerating linkage to care (2, 6, 7).

We defined disease diagnosis as the process of identifying a health condition, disorder, or problem by a systematic analysis of a patient's background or history, examining the signs or symptoms, evaluating the research or test results, and investigating the probable causes (8). The diagnosis of disease conditions can be performed accurately or inaccurately by health professionals, patients, and any other relevant person. In this study, diagnostic accuracy can generally be defined as the authentic results that contain both true positive (sensitivity) and true negative (specificity) of a disease condition in a population (9). Diagnostic accuracy can further be described as a test's ability to discriminate between the target disease condition and health (10). Mobile health technology could be defined as using mHealth devices such as simple mobile phones, smartphones, tablets, and others to provide actual results that include sensitivity, specificity, and predictive values of a target disease condition and health situations (11).

Our scoping review aimed at mapping evidence on mHealth applications to diagnose diseases and support treatment procedures by healthcare workers in sub-Saharan Africa (12). The results showed that mHealth applications are available and utilized to support healthcare services by health professionals. The results demonstrated that mHealth applications are being used for diagnosing certain disease conditions in sub-Saharan Africa. The results further indicated that mHealth applications are being utilized to manage HIV, TB, cancer, and hypertension cases in sub-Saharan Africa (12). In recent times, mobile health devices are being used to provide accurate and rapid diagnosis of diseases at POC diagnostics, which is critical in promptly providing effective and life-saving treatments (13-16). Other studies have also demonstrated that access to a simple mHealth device at POC diagnostics can potentially transform individuals' health behavior and improve people's preventive interventions in hard-to-reach communities (17, 18). Similar studies revealed that mHealth devices had been used in resource-

poor settings at POC diagnostics to detect recent infectious Ebola, Severe Acute Respiratory Syndrome (SARS), and Zika viruses to help in the early treatment of such cases (19-22). Although the advent of mobile-linked diagnostics at point-of-care in resource-limited settings helps improve access to healthcare and reduce healthcare inequalities (13, 14), there is limited evidence on their diagnostic accuracy. Therefore, we performed this systematic review and meta-analysis to evaluate mobile-linked POCdiagnostics' accuracy in sub-Saharan Africa (SSA).

#### 2. Materials and Methods

The review followed the Preferred Reporting Items requirements for Systematic Reviews and Meta-Analysis (PRISMA) (23). The Population, Intervention, Comparison, and Outcome (PICO) framework for determining the primary research question eligibility (Table 1) was followed.

The primary research question was: What is the evidence on the diagnostic accuracy of mobile-linked POC diagnostics' in sub-Saharan Africa?

**Table 1:** PICO framework for determining the eligibility of the research question

Determinants	Description						
P-Population	Diseases such as communicable and non-						
	communicable ones						
I-Intervention Type of mobile-linked POC diagno							
C-Comparison	Other forms of diagnostic devices						
O-Outcome	Diagnostic accuracy is defined as the actual results that contain both true positive						
	(sensitivity) and true negative (specificity) of						
	a disease condition in a population (24).						

## 2.1. Search strategy

An electronic search was carried out to identify all relevant published descriptive quantitative studies, randomized controlled trials, non-randomized controlled trials, and mixed-method studies to answer the review question. The search strategy included all relevant quantitative studies published from the inception of mHealth technology to March 2021 to show the patterns of reports on the diagnostic accuracy of mobile-linked POC diagnostics in sub-Saharan Africa. As part of our search criteria, database searches were conducted from mHealth technology inception to July 2019. They were updated in March 2021 using PubMed, Science Direct, Google Scholar, MEDLINE, and CINAHL with full text via EBSCOhost databases. Reference lists of all included studies eligible for inclusion were also searched for relevant potential articles. Boolean terms (AND, OR) and MeSH (Medical Subject Headings) terms which formed part of the search strategy, were used. The keywords used for the search included: "mHealth technologies", "mHealth apps", "mHealth devices", "point of care diagnostics", "diagnostic", "accuracy", "sensitivity", "specificity", "health workers" and "sub-Saharan Africa" (Additional file 1). Limitations such as date and language during the search were removed to capture all the necessary literature on mobile-linked POC diagnostics' diagnostic accuracy in SSA.

## 2.2. Study selection

Following databases search for all the relevant studies, the principal investigator (EO) initially screened all titles of articles identified via the search strategy. All the eligible study titles were then exported to an Endnote X9 library specifically designed for this review. All duplicates identified were deleted, and the Endnote library was shared with the review team for abstract screening, which EO and PNV performed in parallel. All discrepancies between the reviewer's results following abstract screening were resolved through discussion until consensus was reached. Included studies following abstract screening were included in full article screening, which was performed by two reviewers EO and PNV, independently in parallel. TPM-T, a third reviewer, was invited to resolve all the discrepancies in screeners' results following the full-text screening. The screening was guided by the eligibility criteria presented below:

## 2.3. Eligibility criteria

To ensure that all relevant evidence sources were identified and selected for our review, the study selection process was guided by the eligibility criteria specified under the inclusion and exclusion criteria. The origins of evidence included information from published primary studies that reported mobile-linked POC diagnostics' diagnostic accuracy.

#### 2.3.1. Inclusion criteria

The following criteria were used:

- Articles that presented evidence on Health Professionals using mHealth devices at POC diagnostics.
- Articles that presented evidence on diseases diagnosed at POC diagnostics.
- Articles that reported evidence on mHealth devices such as smartphones, tablets, and others for POC diagnostics.
- Studies that published evidence on other diagnostic tools linked to POC diagnostics.
- Studies reported mHealth interventions such as voice calls, text messages, mobile apps, and multimedia messaging.
- Articles published on the diagnostic accuracy of mobile-linked POC diagnostics.
- Articles that presented evidence from sub-Saharan Africa.

## 2.3.2. Exclusion criteria

The following were excluded:

- Studies that presented evidence of patients using mHealth devices at POC diagnostics.
- Studies reported evidence on using mHealth devices for diagnosing injuries such as burns, cuts, and others.
- Articles that reported evidence on typical diagnostic devices.
- Articles published on mHealth devices support treatment in appointment reminders, medication and treatment compliance, and others.

- Studies that showed evidence on mHealth for disease surveillance.
- Articles that showed evidence on mHealth for medical education.
- Studies published evidence on using mHealth for communication purposes.
- Articles that published evidence outside sub-Saharan Africa

#### 2.4. Data Extraction

We designed a data extraction tool specifically for this review to extract all the relevant data from the included primary studies. The data for the analysis extracted from the included primary studies were in two sections: basic information and the primary study outcomes. The first section had the name of the author(s), date of publication, the aim of the study, country of research, study design, geographical settings, study setting, study population, sample size, type of mobile-linked POC diagnostics, nature of mHealth intervention, key findings, most significant outcomes of the study and conclusions. The second section also included true positive values, false-positive values, true negative values, false negative values, sensitivity, specificity from each of the included primary studies, and a 2 x 2 table was constructed. EO and TPM-T independently conducted the included studies' data extraction using the designed standard data extraction tool. A discussion resolved discrepancies between the reviewers' responses until a consensus was reached.

## 2.5. Assessment of methodological quality

Quality Assessment of Diagnostic Accuracy Studies 2 (QUADAS-2) tool was employed to assess the quality of all the included primary studies (25). Quadas-2 is a well-structured tool recommended by the Cochrane Collaboration for determining diagnostic accuracy studies by evaluating them under four main domains: patient selection, index test, reference standard, and flow and timing (25). The included primary studies' risk of bias was comprehensively assessed independently by two reviewers (EO and TPM-T). All the disagreements in their assessment were resolved via a discussion.

### 2.6. Data Analysis

The meta-analysis of diagnostic accuracy was considered for studies whose sensitivity and specificity had been evaluated. Statistical analyses were all performed using the R-based software Open Meta-Analyst (26). A random-effects model (DerSimonian-Laird) was used to calculate the pooled sensitivity, specificity, and diagnostic odds ratio (DOR) with a 95% confidence interval (CI). A summary receiver operating characteristic curve (ROC) was constructed by plotting the individual and summary points of sensitivity and specificity to determine mobile devices' overall diagnostic accuracy. Heterogeneity among the included primary studies was determined using I² statistics where a score of 25% indicates low, a score of 50% represents moderate, and a score of 75% means high levels of heterogeneity (27). A p-value of < 0.05 was employed to demonstrate a statistically significant association in all the analyses.

## 3. Results

## 3.1. Search

A total of 29,976 articles were identified from the combined search. Seven hundred and forty-eight articles were eligible from the database search. One hundred and eight-six duplicates were removed, leaving behind five hundred and sixty-two articles suitable for abstract screening. A total of four hundred and ninety-nine articles were excluded following the abstract screening. Sixty-three articles were eligible for full-text screening. Fifty-two of them were excluded, as illustrated in Figure 1, showing the PRISMA flow chart of literature search and selection of studies. Finally, eleven articles were included for data extraction, which further underwent quantitative meta-analysis.

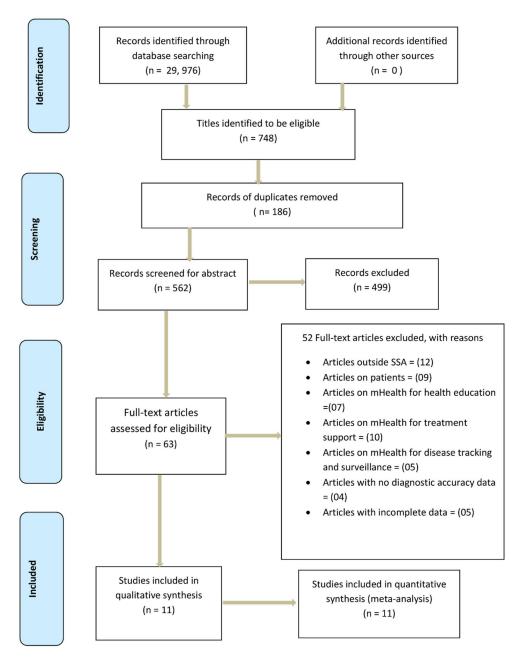


Figure 1: PRISMA flow chart showing literature search and selection of studies

## 3.2. Characteristics of the Included articles

Table 2 illustrates the characteristics of the included studies. A total of eleven articles were reviewed, and all underwent meta-analysis. Three of the included articles were conducted in Côte d'Ivoire (28-30), two in Ghana (31, 32), two in Uganda (33, 34), two in Sudan (35, 36), one in Tanzania (37), and one in Ethiopia (38). Sample sizes ranged from 50-1530 persons. Out of eleven studies, only one employed cohort study (30) and ten used cross-sectional studies (28, 29, 31-38), and one cohort study (30). All the included primary studies presented findings on the diagnostic accuracy of mobile-linked POC diagnostics in SSA. In terms of geographical settings, eight of the included studies were conducted in rural locations (28-32, 37, 38), whiles three were conducted in urban settings (33, 35, 36). All the 11 included studies were conducted in English language from 2010-2017. All the 11 included studies reported on only the diagnostic accuracy of mobile-linked POC diagnostic devices.

**Table 2:** Characteristics of the included studies

Author and date	Country of study	Aim of the study	Geographical setting (urban/semi- urban/rural)	Study setting	Study design	Study population (diseases)	Type of mHealth devices	Other diagnostic devices (Gold standard)	Sample size
Coulibaly et al., 2016a (29)	Côte d'Ivoire	To compare the accuracy of mobile phone and handheld devices to light microscopy to diagnose Schistosoma haematobium, S. mansoni, and intestinal protozoa infections in a community-based survey	Rural	Grand Moutcho community	Cross- sectional survey	Schistosoma haematobium  Schistosoma mansoni, and  Intestinal Protozoa Infections	Newton Nm1 reversed lens CellScope	Olympus CX21 microscope	226
Coulibaly et al., 2016b (39)	Côte d'Ivoire	To evaluate the "real-world" diagnostic operating characteristics of a handheld light microscope with mobile phone attachment integrated into a community-based screening program for malaria in rural Côte d'Ivoire	Rural	Grand Moutcho community	Cross- sectional survey	Malaria (Plasmodium falciparum)	Newton Nm1	Olympus CX22 microscope	223
Bogoch et al., 2014 (30)	Côte d'Ivoire	To examine the utility of a novel commercial, portable light microscope and a simple mobile phone microscope to	Rural	Azaguié Makouguié	Cohort study	Schistosoma mansoni, Schistosoma haematobium &	iPhone add- on, Newton Nm1	Olympus CX21 microscope	180

Bogoch et	Ghana	diagnose S. mansoni, S. haematobium, and soil-transmitted helminths.	Rural	Sorodofo-	Cross-	Soil- transmitted helminths	Novel	Olympus CX21	60
al., 2017 (32)	Citatia	performance of the handheld microscope in the diagnosis of Schistosoma.	Traita.	Abaasa Village	sectional survey	haematobium	Mobile phone microscope	microscope	
Sousa- Figueiredo et al., 2010 (34)	Uganda	To assess the diagnostic performance of the CyScope and the lateral-flow Paracheck-Pf test as RDTs for malaria in children under five and women	Rural	Bugoigo, Walukuba, Piida, Bugoto, Bukoba, Lwanika	Cross- sectional survey	Malaria (Plasmodium spp)	CyScope	Thick Giemsa Smear	1530
Bogoch et al., 2013 (37)	Tanzania	To compare the diagnostic accuracy of our mobile phone microscope with conventional light microscopy	Rural	Pemba Island	Cross- sectional survey	Trichuris trichiura	iPhone add- on	Olympus CX21 microscope	199
Stothard et al., 2014 (33)	Uganda	To assess the diagnostic performance of Newton Nm1 microscope towards malaria microscopy	Urban	Kampala	Cross- sectional study	Malaria (Plasmodium spp)	Newton Nm1	Olympus CX22 microscope	50
Birhanie et al., 2015 (38)	Ethiopia	To assess the diagnostic performance of Partec rapid malaria test regarding light microscopy for the	Rural	Gendewuha health center	Cross- sectional study	Malaria (Plasmodium spp)	CyScope	Thick Giemsa Smear	180

Hassan et al., 2010 (36)	Sudan	diagnosis of malaria in Northwest Ethiopia To examine the specificity and sensitivity of CyScope microscope in compared to the gold standard of light microscopy	Urban	Sinnar hospital	Cross- sectional study	Malaria (Plasmodium falciparum)	CyScope	Thick Giemsa Smear	293
Hassan et al., 2011 (35)	Sudan	To compare the performance of CyScope fluorescence microscope with the Giemsa-stained light microscopy for the diagnosis of malaria among pregnant women	Urban	Medani Maternity hospital	Cross- sectional study	Malaria (Plasmodium falciparum)	CyScope	Thick Giemsa Smear	128
Nkrumah et al., 2011 (31)	Ghana	To compare two the novel Partec Rapid Malaria Test and the Binax Now Malaria Rapid Diagnostic Test with the conventional Giemsa stain microscopy for malaria diagnosis in children at the clinical laboratory of a health facility in a rural endemic area of Ghana	Rural	Agogo Presbyterian hospital	Cross- sectional survey	Malaria (Plasmodium falciparum)	CyScope	Thick Giemsa Smear	263

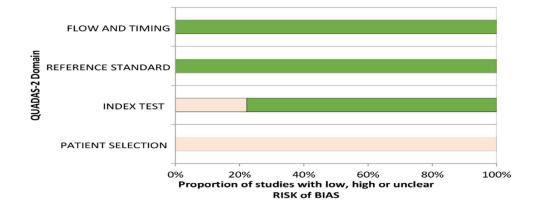
## 3.3. Assessment of risk and applicability

Table 3 shows the risk of bias and applicability concern assessment of the included studies using the QUADAS-2 tool. The results illustrate a range of findings in the included studies that employed QUADAS-2 as the quality assessment tool (25). Participants' enrolment in all the included studies was not a random sampling technique regarding the patient selection domain but rather a convenience approach. Even though it is highly possible that the convenience sampling technique could introduce a high-risk bias, it is unlikely to affect the diagnostic accuracy of mHealth devices. The reference standard domain was found to be at low risk of bias across all the included studies. This may contribute to the diagnostic accuracy of mHealth devices for the detection of diseases. All the included studies were at low risk of bias in the flow and timing domain. However, all the studies included were at high risk of bias under the patient selection. Concerning the applicability assessment, nine of the included studies were at low risk of bias (39-41, 43-45, 47, 48), while two were found to be a high risk of bias (31, 35). Figure 2 displays the graphical results of the included studies from the QUADAS-2 assessment tool.

**Table 3:** Summary of methodological quality assessed with the QUADAS-2

	RISK C	OF BIAS			APPLICABILITY CONCERNS				
Author and year of publication	PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD	FLOW AND TIMING	PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD		
Bogoch et al., 2014	8	8	©	©	<b>©</b>	©	©		
Coulibaly et al., 2016a	8	8	©	©	©	©	©		
Coulibaly et al., 2016b	8	8	©	©	©	©	©		
Bogoch et al., 2017	8	<b>©</b>	©	©	<b>©</b>	©	<b>©</b>		
Stothard et al., 2014	8	©	<u>©</u>	<u> </u>	©	©	©		
Bogoch et al., 2013	<b>⊗</b>	©	©	©	<u>©</u>	<u> </u>	©		
Sousa- Figueiredo et al., 2010	8	©	©	©	©	©	©		
Birhanie et al., 2015	8	©	©	©	©	©	©		
Hassan et al., 2010	8	©	©	©	©	©	©		
Hassan et al., 2011	8	<b>©</b>	<u>©</u>	<u> </u>	<b>©</b>	©	8		





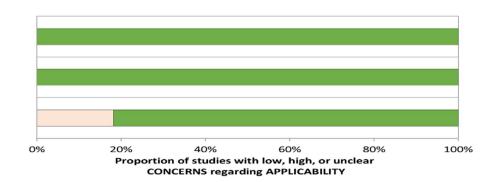


Figure 2: QUADAS-2 assessments of included studies

## 3.4. Diagnostic accuracy of mobile-linked diagnostic devices

Table 4 illustrates true-positive, false-negative, false-positive, true-negative results and their corresponding sensitivity and specificity values for mobile-linked POC diagnostic devices for detecting disease conditions. The summary estimates of sensitivity and specificity of mobile-linked devices were 0.499 (95% CI: 0.458-0.541) and 0.535 (95%CI: 0.401-0.663), respectively (Figure 3). The pooled estimates of specificity and sensitivity are statistically significant at the meta-analysis. The individual pooled and summary estimates of sensitivity and specificity at the 95% CI region for all the included studies of mobile-linked POC diagnostic devices are presented in an ROC graph (Figure 4). The overall pooled estimates of the positive likelihood ratio (PLR) and negative likelihood ratio (NLR) were 0.952 (95%CI: 0.60-1.324) and 1.381 (95%CI: 0.391-4.879), respectively (Figure 5). Heterogeneity was determined as statistically insignificant as I<sup>2</sup> = 35.6% (p = 0.098) for the degree of inconsistency. The ROC curve analysis demonstrated a significantly moderate diagnostic performance of the mobile-linked POC diagnostic devices. The diagnostic odds ratio (DOR) for mobile-linked POC diagnostic devices' accuracy was found to be OR = 0.944 (95% CI:

0.579-1.538) (Figure 6). Hence, the overall effect estimate of the study at the meta-analysis is statistically insignificant.

Table 4: Diagnostic accuracy of mobile-linked POC diagnostic devices

Author	Mobile phone microscope/ CyScope  Author, Disease Sensitivity Specificity PPV NPV TP FP TN FN											
date	Disease	_	(95% CI)	1		I		(95%	1			
uate		(95% CI)	(95% CI)	(95% CI)	(95% CI)	(95% CI)	(95% CI)	(95% CI)	(95% CI)			
Coulibaly	Schistosoma	50.0	99.5	85.7	97.3	51.0	0.5	0.51	50			
-		50.0				51.0	0.5	0.51	50			
et al.,	mansoni	(25.4-74.6)	(97.0-100)	(42.0-	(93.9-							
2016a	6.1.1	25.6	100	99.2)	98.9)	66.2	0.0	0.0	64.4			
	Schistosoma	35.6	100	100	70.1	66.2	0.0	0.0	64.4			
	haematobium	(25.9-46.4)	(96.6-100)	(86.7-	(63.1-							
<b>D</b> 1 1	6.1.1	60.2/60.4	64.2	100)	76.3)	22.2	25.7	26.2	24.0			
Bogoch et	Schistosoma	68.2 (60.1-	64.3	95.4	15.8	32.2	35.7	36.2	31.8			
al., 2014a	mansoni	75·5)	(35·1–	(89.5–	(7.5–							
			87·2)	98.5)	27.9)							
	Trichuris	30.8 (19.9–	71.0	40.8	61.2	71.5	29.0	29.0	69.2			
	trichiura	43·4)	(61.1–	(27.0–	(51.7-							
			79-6)	55·8)	70·1)							
Bogoch et	Trichuris	54.4(46.3-	63.4 (46.9-	85.1	26.5	46.4	36.6	37.2	45.6			
al., 2013	trichiura	62.3)	77.4)	(76.4-	(18.4-							
		,	,	91.2)	36.6)							
Bogoch et	Schistosoma	72.1 (56.1–	100.0	100.0	57.1	28.3	0.0	0.0	27.9			
al., 2017	haematobium	84.2	(75.9–	(86.3–	(37.4–							
			100.0)	100.0)	75.0)							
Coulibaly	Malaria	80.2 (73.1-	100 (92.6–	100	65.6	20.0	0.0	0.0	19.8			
et al.,		85.9)	100.0),	(96.4-	(54.9–							
2016b				100.0)	74.9)							
Sousa-	Malaria	86.7	38.8	32.8	89.4	13.3	61.2	62.8	13.3			
Figueiredo	Iviaiaiia	(79.3 -	(33.6 -	(27.7 -	(83.4 -	13.3	01.2	02.8	13.3			
et al.,		92.2)	44.1)	38.3)	93.8)							
2010		92.2)	44.1)	30.3)	93.0)							
2010												
Stothard	Malaria	02 5 /70 6	100 (82.4-	100	90.5	6.5	0.0	0.0	6.5			
et al.,		93.5 (78.6-		(88.1-	(69.6-							
2014		99.2)	100)	100)	98.8)							
Birhanie	Malaria	93.8 (87.1-	97.0./70.7	86.4	94.6	6.3	12.1	12.2	6.2			
et al.,		100)	87.9 (79.7-	(77.2-	(88.7-							
2015			96.1)	95.5)	100)							
Hassan et	Malaria	98.2 (90.6-	00.2/05.7	93.3	99.6	1.8	1.7	1.72	1.8			
al., 2010		100)	98.3 (95.7-	(83.8-	(97.6-							
•		,	99.5)	98.2)	100)							
Hassan et	Malaria	97.6 (92.2-	89.1 (77.5-	94.1	95.3	2.43	10.9	98.2	2.4			
al., 2011		99.6)	95.9)	(87.4-	(85.4-							
,		,	,	97.8)	99.2)							
Nkrumah	Malaria	100 (96.6-		96.4	100	0.0	2.6	2.63	0.0			
et al.,		100 (55.5	97.4 (93.6-	(91-	(97.6-							
			99.3)	1 (31-								

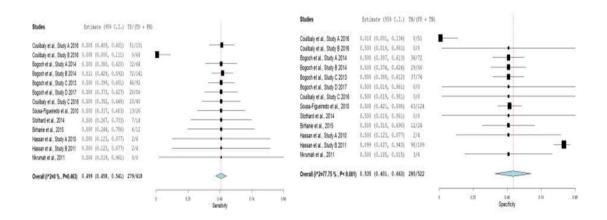


Figure 3: Forest plots of pooled sensitivity and specificity estimates for all included studies of mobile-linked diagnostic devices

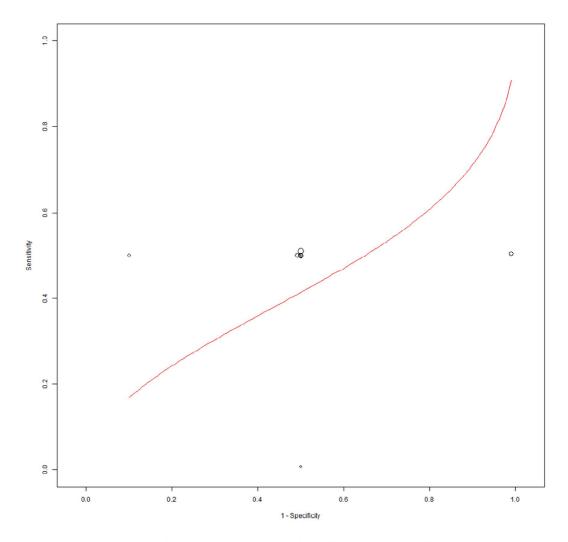


Figure 4: ROC graph of the included studies of mobile-linked POC diagnostic devices

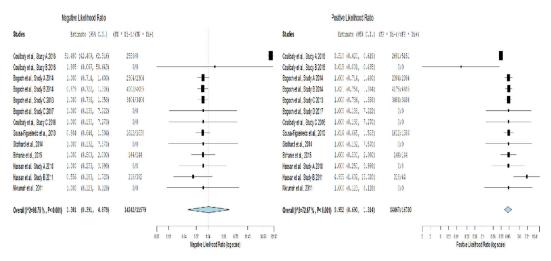
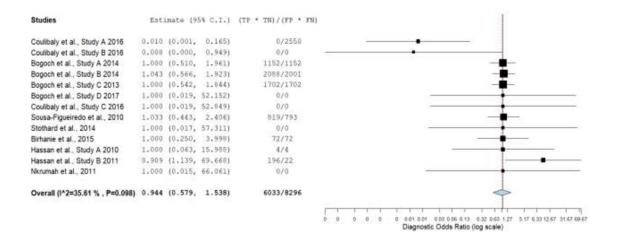


Figure 5: Negative likelihood ratio and positive likelihood ratio of the included studies of the mobile-linked POC diagnostic devices



**Figure 6:** Diagnostic odds ratio forest plot of the included studies of mobile-linked diagnostic devices

## 4. DISCUSSION

The evidence available from this study showed a moderate diagnostic accuracy of mobile-linked POC diagnostics in sub-Saharan Africa. This systematic review's objective was to evaluate the diagnostic accuracy of mobile-linked POC diagnostics in SSA. We found that mobile-linked POC diagnostics' overall sensitivity for disease detections was 49.9%, and specificity was 53.5%. The meta-analysis results indicate a moderate diagnostic accuracy of mobile-linked POC diagnostic for disease detections in SSA. The ROC curve also confirms the average diagnostic performance of these mobile-linked POC diagnostic devices. This means that mobile-linked POC diagnostics have less sensitivity and specificity abilities than the cut-off value of the gold standard described by the World Health Organization (WHO) (40). We performed a sub-group analysis of the included studies to determine the rate of sensitivities and specificities of similar disease outcomes. A cursory examination of seven included studies that

used mobile-linked POC diagnostic devices to detect malaria infections found moderate sensitivity and specificity estimates 0.500 (95% CI: 0.352-0.648) and 0.500 (95% CI: 0.019-0.981) compared to the cut-off value of the standard gold light microscope described as an effective diagnostic tool (40).

The results also show that two studies that used mobile-linked POC diagnostic devices to detect Schistosoma mansoni found an average sensitivity estimate of 0.500 (95% CI: 0.380-0.620) and a low specificity estimate of 0.010 (95% CI: 0.001-0.136) compared to the gold standard conventional light microscope (40). Again, the results demonstrate that mobile-linked POC diagnostic devices for detecting Schistosoma haematobium infections found a low sensitivity estimate of 0.008 (95% CI: 0.409-0.601) and an average specificity estimate of 0.500 (95% CI: 0.019-0.981) compared to the gold standard conventional light microscope (40). Additionally, the results indicate that two studies that used mobile-linked POC diagnostic devices to diagnose trichuris trichiura infections found moderate sensitivity and specificity estimates of 0.511 (95% CI: 0.429-0.592) and 0.500 (95% CI: 0.388-0.612) compared to the gold standard light microscope (40). These mobile-linked POC diagnostic devices providing moderate sensitivity and specificity estimates prove that such devices are below the cut-off point compared with the gold standard light microscope that is considered an effective diagnostic tool. The moderate diagnostic abilities of mobile-linked POC diagnostic devices for infectious and non-infectious diseases could also be attributed to the first-generation mobile phone microscopes employed by most of the included studies.

A study conducted in some low-and middle-income countries found the use of mobile phone fluorescence microscopy for detecting waterborne pathogen with an accuracy of 95%, which is not consistent with our study results (41). Similar studies conducted in Finland and New Zealand illustrated that mobile phone microscopes exhibited high sensitivity for detecting *soil-transmitted helminths and Schistosoma*, which do not agree with our study results (42, 43). Luis Rosado et al. carried out another study in Portugal where mobile phone microscope indicated higher sensitivity and specificity for diagnosing malaria infections at variance with this study's results (44). A survey conducted in the USA by Paul Slusarewicz et al. revealed that mobile phone microscopes detected parasite eggs in mammalian faeces with high sensitivity and specificity, which disagrees with this study's findings (45). A study conducted in Sweden revealed that mobile phone microscopes could be used extensively for clinical diagnostics when their sensitivities reach or exceed the 80% threshold (42). Studies conducted in the USA have demonstrated that mobile handheld devices had a high diagnostic accuracy at POC diagnostics for detecting coronary stenosis and other disease conditions (16, 46).

This review study included studies carried out in different geographical settings, giving an exhaustive overview of mobile-linked POC diagnostic devices' diagnostic accuracy in SSA. Date and language limitations were removed from this review study to capture all the essential literature on mobile-linked POC diagnostic devices' diagnostic accuracy in SSA. Nonetheless, a piece of evidence on mobile-linked POC diagnostic devices' diagnostic accuracy in SSA may have existed under different contexts that were not included in the study. This review was limited to studies that used quantitative methods since this study focused on the diagnostic accuracy of mobile-linked POC diagnostic devices in SSA. The systematic review was also limited to studies carried out in SSA and could not be made to represent the entire world.

The results illustrate that most of the studies were conducted in rural settings where there is no access or little access to standard laboratory facilities. This will benefit such rural inhabitants in improving their health conditions if these activities are often conducted in such areas. The study results provide a moderate diagnostic yield of disease conditions and may not encourage

healthcare professionals to rely on such devices to support healthcare provision continually. This means that more technologically advanced mobile-linked POC diagnostic devices and well-validated with excellent sensitivities and specificities should be made available to these healthcare professionals and other users.

The results suggest that most of the studies that used first-generation mobile phones attached to microscopes provided a modest diagnostic yield of infectious and non-infectious diseases in resource-poor settings. We recommend future research on using low-cost technologically advanced mobile phone microscopes at POC in resource-constrained settings that may improve their diagnostic capabilities. The results also indicate that mobile-linked POC diagnostic devices' diagnostic accuracy in detecting infectious and non-infectious diseases was found only in six SSA countries. We, therefore, encourage more countries in SSA to employ these mobile-linked POC diagnostic devices to assist in diagnosing a lot more infectious and non-infectious diseases, especially in remote areas.

#### 5. Conclusion

Mobile-linked POC diagnostic devices can improve healthcare provision quality in clinical and public health care to diagnose diseases in resource-constrained SSA areas. Current devices have been integrated slowly in routine clinical practice with innovations such as mobile phone microscopes, machine learning, computer vision, and others that could assist in automatic or instant diagnoses of diseases. The study results illustrate that mobile-linked POC diagnostic devices provided an average diagnostic yield in detecting infectious and non-infectious diseases in SSA. The study results further demonstrate that the first-generation mobile phones employed contributed to moderate sensitivities and specificities in diagnosing infections in low-resourced SSA settings. Hence, we recommend that a lot more primary research be carried out in SSA with mobile-linked POC diagnostic devices advanced technologically and well-validated to provide sensitivities and specificities estimates to reach or exceed the 80% threshold. We also recommend that more mHealth diagnostics evaluation studies use refined mHealth devices with excellent sensitivities and specificities to diagnose existing diseases in sub-Saharan Africa.

## Additional file 1: Results from the initial database search

#### **Author contributions**

EO and TPM-T conceptualized and designed the study. EO, PNV, and TPM-T contributed to the abstract, full article screening, and the included studies' quality assessment. NSJ performed the meta-analysis and assisted in the interpretation of the results. EO prepared the draft of the study, TPM-T reviewed the draft critically. EO prepared the final draft, and all authors approved it.

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The authors declare no conflict of interest.

### Additional information

No additional information is available for this paper.

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