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Effects of a clinical decision support algorithm on malaria testing and treatment among febrile children in Tanzania: Findings from a mixed-methods cluster-randomized trial (DYNAMIC study)

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Abstract

Background

Effective malaria case management relies on consistent testing and appropriate treatment of febrile children. Yet adherence to these practices remains suboptimal in many endemic settings. Digital clinical decision support algorithms (CDSAs) such as ePOCT+ have been proposed to improve clinical guideline adherence.

Methods

This study presents a pre-specified secondary outcome analysis from the DYNAMIC cluster-randomized trial in Tanzania, evaluating the impact of the ePOCT+ CDSA on malaria case management (testing and treatment) among febrile children aged 2 months to 14 years in 40 primary health facilities. Quantitative data were analyzed using generalized linear mixed models, and where appropriate, Poisson regression models with a log link and robust standard errors. Qualitative interviews were conducted with healthcare providers in 15 purposively selected health facilities.

Results

Malaria testing was performed in 89.0% (8,931/10,037) of febrile children in the ePOCT + arm versus 71.9% (6,780/9,431) in routine care (adjusted risk ratio [aRR] 1.33; 95% Confidence Interval [CI]I 1.06–1.67). This effect was substantially larger in facilities with low malaria test positivity rates (< 5%; aRR 2.31, 95% CI 1.83–3.87) than in those with higher positivity rates (≥ 5%; aRR 1.09, 95% CI 1.03–1.15), suggesting ePOCT + may be particularly valuable where providers might otherwise deprioritize testing due to perceived low risk. Nearly all malaria-positive children received appropriate treatment in both arms (99.6% ePOCT + vs. 95.0% control). No significant difference was observed in inappropriate antimalarial prescriptions among malaria-negative or untested patients. Qualitative findings revealed barriers to testing, including rapid diagnostic test stockouts, staff shortages, low perceived local malaria risk, and caregiver refusal.

Conclusions

Implementation of ePOCT+ significantly increased malaria testing among febrile children, particularly in low-transmission settings, but did not change treatment practices, which were already largely appropriate. While CDSAs may standardize diagnostic practices and enhance adherence to testing guidelines, sustained impact requires addressing systemic constraints, including specific guidance and training for low-endemicity areas, improved supply chains, and sufficient human resources.

Trial registration

ClinicalTrials.gov identifier NCT05144763, 30.11.2021

BACKGROUND

The global burden of malaria, particularly in low- and middle-income countries (LMICs), remains a critical concern, despite sustained international efforts and substantial gains in reducing malaria incidence and mortality over the past two decades. According to the World Malaria Report 2025, the estimated number of malaria cases increased from 230 million in 2015 to 282 million in 2024, while malaria-related deaths increased from 578,000 to 610,000 during the same period [1]. The WHO African Region bore the greatest burden of malaria, accounting for approximately 94% of global malaria cases and 95% of malaria-related deaths in 2024 [1]. Among malaria-related deaths in the region, approximately 75% occurred among children under the age of five [1]; however, school-aged children (5–16 years) declined from 21.6% in 2015 to 11.3% in 2023, with children aged 9–14 years at higher risk of infection than younger school-aged children [2]. Children aged 10–14 years are classified as early (or "young") adolescents according to WHO age-band definitions; for readability, we use the term "children" throughout this manuscript to refer to the full study population aged 2 months to 14 years, unless otherwise specified. Similar epidemiological trends have been observed in Tanzania, which has one of the highest caseloads of malaria globally, with 9.4 million cases in 2024 [1]. However, Tanzania has observed a reduction in malaria prevalence among children aged 6 to 59 months, with the prevalence decreasing from 14% in 2015–2016 to approximately 8% in 2022[3].

Appropriate case management to accurately diagnose and treat malaria is fundamental to decreasing the burden of malaria globally. The malaria case management cascade involves testing all febrile children in endemic settings and prescribing antimalarial medications only to positive cases according to body weight and age [4]. It has been reported in several studies that healthcare providers attending suspected cases of malaria do not adhere to the proposed guidance, leading to poor-quality case management [5–10]. Some febrile patients, including children in high-endemic areas, are not tested for malaria [5, 11, 12]; some tested for malaria with negative results still receive antimalarials [13–18]; some still receive antimalarials without being tested[13, 14] and some patients with positive malaria results are not prescribed antimalarials [19].

Digital clinical decision support algorithms (CDSAs) for children have shown improvements in the adherence of healthcare providers to clinical guidelines, better clinical outcomes, and reductions of unnecessary prescriptions of antibiotics [20–24]. Such CDSAs combine patients' demographic and clinical information with clinical protocols or guidelines to assist healthcare workers in making diagnosis and treatment decisions. While some studies have demonstrated improvements in malaria case management through CDSAs [25, 26], others have shown conflicting results [27, 28], suggesting that efficacy is highly dependent on implementation context, user experience, and integration with routine health system workflows. However, the existing evidence base remains critically limited: few randomized trials, most studies are short-term pilots conducted in controlled settings, overwhelmingly focus on children under five years of age, and lack data from high-burden East African primary care contexts.

To address these gaps, the present pre-specified analysis of secondary outcomes from a cluster-randomized trial [22] aims to assess the effectiveness of ePOCT+, a digital CDSA, in improving the management cascade of suspected malaria cases among febrile children aged 2 months to 14 years attending primary care facilities in Tanzania. To better understand factors influencing malaria testing decisions, we also analysed qualitative data from in-depth interviews with healthcare providers that explored malaria testing practices and their perceptions of the CDSA.

METHODS

Study design and setting

The present study (part of the Tanzanian DYNAMIC project[22]) used a sequential explanatory mixed-method approach to compare the effectiveness of a digital intervention on case management of malaria to routine care. The

quantitative part was a pre-specified secondary outcome analysis of an open-label, parallel group, pragmatic cluster randomized trial called Dynamic CDSA to manage sick children in Tanzania (DYNAMIC-TZ) with a registration number NCT05144763 (the unit of randomization being the health facility) [22, 29]. The qualitative part consisted of in-depth interviews with healthcare providers to explore their perceptions of malaria testing decision-making while using the ePOCT+ digital tool.

The study was conducted in primary-level healthcare facilities, including health centers and dispensaries, in the Morogoro and Mbeya regions of Tanzania. Malaria incidence varies across the study districts: in 2023, Mbeya District Council (DC) and Mbeya City Council (CC) had fewer than 50 cases per 1,000 people; Ifakara Town Council (TC) and Mlimba DC had between 50 and 100 cases per 1,000, while Ulanga DC had more than 100 cases per 1,000 [30].

National policy on malaria testing and treatment [31] requires that all suspected malaria cases be confirmed through microscopy or malaria rapid diagnostic tests (mRDTs) before treatment starts. The target is for at least 80% of children with fever to seek treatment and be tested for malaria within 24 hours. Malaria testing and treatment are free for children under five, pregnant women, and the elderly (60 years and above).

Most healthcare providers in these dispensaries and health centers are clinical officers with three years of training, nurses with certificate or diploma qualifications, and medical attendants [32].

Participants of the quantitative study

The inclusion criteria for clusters (health facilities) have been described elsewhere [22]. In brief, government-operated and government-designated dispensaries and health centers, situated within the geographical jurisdictions of the Mlimba, Ifakara, and Ulanga districts in the Morogoro Region, as well as the Mbeya Rural District and Mbeya City Council in the Mbeya Region, were enrolled. In addition, inclusion required an average weekly attendance of at least 20 children aged 2 months to 5 years. Facilities classified as secondary or tertiary level were excluded. Forty health facilities meeting inclusion criteria were included in the main trial.

For the present analysis, patients were eligible for inclusion if they were aged 2 months to 14 years and presented for a new consultation with an acute illness that included a reported fever by caregiver, measured temperature equal to or above 37.5°C, or the child felt hot to a healthcare provider when temperature was not measured. Patients were not eligible if they came for scheduled consultations related to chronic illnesses, such as HIV, tuberculosis (TB), or malnutrition, or if they were seeking routine preventive care, including growth monitoring, vitamin supplementation, deworming, or vaccinations. Additionally, if the guardian was unavailable, unable, or unwilling to provide informed consent, the patient was not included. Older children were allowed to provide consent if an adult observer was present during the consent process.

Intervention

The intervention consisted of a tablet-based CDSA that guided clinicians through the consultation step-by-step, leading to suggested diagnoses, treatment, and management. It also included additional point-of-care diagnostic tools, including C-reactive protein tests, hemoglobin measurement devices with cuvettes, and pulse oximeters. Healthcare providers working in intervention health facilities underwent refresher training on the Integrated Management of Childhood Illness (IMCI), specific training on the use of the CDSA and point-of-care tests, and received regular mentorship and supervision from the study team [22]. In addition, healthcare providers received

regular audits and feedback[33, 34] through a digital dashboard displaying near-real-time quality-of-care indicators (Supplementary figures S1, S2, and S3). Further details of the intervention have been described elsewhere [22].

Healthcare providers from routine health facilities received IMCI refresher training and used the electronic case report form (eCRF) for routine data collection, but did not have access to the CDSA. They also received training and supportive supervision to use the eCRF. Both arms received quarterly supervision from the District Health Management Team (DHMT) to ensure availability of supplies.

Outcomes of the quantitative study

The pre-specified outcomes for the present analysis include: 1) the proportion of febrile children for whom clinicians requested a malaria test; 2) the proportion of children with positive malaria test results for whom antimalarial medications were prescribed; 3) the proportion of children with negative malaria test results for whom antimalarial medications were still prescribed; and 4) the proportion of children not tested for malaria for whom presumptive antimalarial medications were appropriately prescribed [29]. The presence of fever, malaria test result, and the treatment prescribed were documented by the healthcare providers within the ePOCT+ CDSA during the consultations in intervention health facilities and in the eCRF in control facilities. In control facilities, data were sometimes documented in paper logs, and then entered in the eCRF after the consultation.

Randomization

Forty health facilities (24 in the Morogoro region and 16 in the Mbeya region) were randomly selected from all eligible health facilities in the participating councils [22]. A larger number of facilities were included in Morogoro to allow assessment of whether the effect of the intervention varies by the level of malaria transmission. Four health centres per region were included, while the other facilities were dispensaries.

The healthcare facilities (clusters) were then randomly assigned in a 1:1 ratio to either use ePOCT+ (intervention group) or to provide routine care (control group). The randomization process was divided into strata based on the council, type of health facility (health center or dispensary), and attendance rate. A statistician who was not affiliated with the study was responsible for conducting the computer-generated sampling and randomization.

Statistical methods for the quantitative analysis

All available medical cases with completed clinical information in the tablet-based application (i.e., cases completed using the CDSA in the intervention arm and cases for which clinicians filled the eCRF in the control arm) were analyzed in this secondary analysis. While the primary trial analysis followed the intention-to-treat principle [22], the present secondary analysis was restricted to the per-protocol population, defined as children whose providers completed the consultation using ePOCT + in intervention facilities and children with completed eCRFs in control facilities. Cases with missing data related to malaria testing or treatment were excluded. The primary statistical analysis was carried out using a generalized linear mixed model (GLMM) with a random intercept at the facility level to account for clustering, while adjusting for council as a fixed effect [35]. Additional fixed effects included age, sex, mobile phone ownership (used as a proxy for socioeconomic status), presenting complaint (gastrointestinal, respiratory, skin), facility type (dispensary or health centre), and facility monthly attendance rate. A random-effects structure was used at the health facility level to account for unmeasured heterogeneity of the intervention effect [36]. Confounding by cluster was addressed by separating within- and between-cluster effects using a partitioning method [37, 38].

To assess the impact of the intervention at the population level (i.e., the population-averaged effect), the two marginal probabilities in the exposed and unexposed children were computed by marginalization of the estimated conditional probabilities [39, 40]. Based on these marginal probabilities, the marginal relative risk was computed. For the low-prevalence outcomes (treatment in negative and no-test patients), we employed modified Poisson regression with robust standard errors clustered by facility [41, 42]. Given that models containing the full covariate set were unstable, a consequence of collinearity between facility-level covariates and health facility council, we fitted a parsimonious model adjusting only for intervention arm and council to obtain stable risk ratio estimates.

Post-hoc subgroup analyses examined malaria testing rates among febrile children stratified by council and by health facility malaria positivity level (low: <5% test positivity; high: ≥5%). For prevalence subgroups, we used the same mixed-effect logistic regression model with a random intercept for health facility and within-between (Mundlak) partitioning of patient-level covariates as in the main analysis, adjusting for council, age, sex, phone ownership, symptoms, facility type, and patient volume. For council-specific subgroups, the full mixed-effects model with a random intercept could not be reliably estimated due to the limited number of health facilities per council (7–9 facilities), resulting in a singular fit [43, 44]. We therefore used standard logistic regression (GLM) without random effects, adjusting for the same covariates except council (which is constant within each stratum). This approach is supported by simulation studies showing that when mixed models fail or are singular, switching to a fixed-effects model yields similar type I error rates and power, and that mixed models provide similar estimates to logistic regression when the proportion of small clusters is limited [45, 46]. Risk ratios and 95% confidence intervals for council models were derived from predicted probabilities. All models accounted for the clustered nature of the data either via random intercept (prevalence models) or by stratification (council models) (48,49). All analyses were done using R statistical software version 2026.05.0 + 218 and Stata version 20.

Qualitative study

Study population and sampling

Semi-structured interviews were conducted with healthcare providers to explore their experience and perception of the ePOCT+ tool, with this analysis focused on data related to malaria testing practices. Interviews were conducted during Phase 2 of the DYNAMIC project. Following completion of the cluster-randomized trial (Phase 1), ePOCT + was rolled out to all remaining study facilities, so that all 60 facilities, the 40 original trial facilities plus 20 additional facilities added at the end of Phase 1, were using ePOCT + at the time of data collection and were eligible for inclusion.

From this pool of 60 facilities, 15 were purposively selected from the outset using a maximum-variation sampling approach to ensure diversity across three characteristics: patient load, ePOCT+ uptake, and geographic setting (rural, peri-urban, urban). Patient load was derived from six months of DHIS2 outpatient data on under-five attendances preceding data collection, and classified as low, medium, or high using the thresholds defined in Table 4. ePOCT+ uptake was derived from medAL-monitor usage data over the same period: for the original 40 trial facilities, uptake was calculated from data collected during the trial itself; for the 20 facilities added after the trial, uptake was calculated from their corresponding usage data following ePOCT+ implementation. Thirteen facilities in Morogoro region were excluded from the sampling frame because the interviewer (LL) had prior professional relationships with staff there that could have influenced participants' responses.

At each selected facility, one healthcare provider who had used ePOCT+ with at least 25 patients per month was recruited; where more than one provider met this criterion, one was selected at random.

Data collection

Interviews were scheduled by calling facility in-charges to arrange dates with potentially eligible providers; in-charges were involved only in scheduling logistics and did not select which provider to approach. Eligible providers were then approached directly by the research team, informed that participation was voluntary and independent of their facility leadership's role in scheduling, and provided written informed consent before participation. All approached providers agreed to participate.

LL, a male Tanzanian physician and doctoral candidate, conducted all interviews in person in Kiswahili; interviews were conducted in private rooms within health facilities and were audio-recorded. No other person was near the interview room during the interviews. Each interview lasted 60–90 minutes, with questions related to malaria testing lasting 15 minutes on average. Prior to data collection, the interview guide was pilot-tested with healthcare providers using ePOCT+, and adjustments were made to make the questions clear.

Data analysis

The Framework method[47] was used for the analysis. An independent qualitative researcher with a master's degree in public health and over 10 years of qualitative research experience transcribed and translated all interviews verbatim into English. LL reviewed the first four transcripts for quality control and provided feedback for improvement; back-translation was not performed, but LL checked all transcriptions and translations against the original audio recordings, making corrections so that the English versions accurately reflected the participants' intended meaning.

A deductive code tree was developed based on the semi-structured interview guide. The first two transcripts were independently coded by LL and LFB; results were compared, with 78% agreement between coders, and differences resolved through discussion, refining code definitions for clarity. LL then coded and indexed the remaining transcripts, and the final coding matrix was reviewed by LFB and RT. LL led the final interpretation, which was shared with and discussed among the wider research team. Coding and indexing were conducted using MaxQDA 24 (v24.5.1).

Quotes are contextualized throughout using the council-level malaria test positivity rate (MTPR), based on data from the cluster randomized trial period (December 1, 2021 to October 31, 2022).

Ethical considerations

This study received ethical approval from the Ifakara Health Institute ethical committee (IHI/IRB/No: 11-2020), the Mbeya Medical Research Ethics Committee (SZEC-2439/R.A/V.1/65), the National Institute for Medical Research Ethics Committee (NIMR/HQ/R.8a/Vol. IX/3486 and NIMR/ HQ/R.8a/Vol. IX/3583) in Tanzania, as well as the cantonal ethics review board of Vaud (CER-VD 2020–02800) in Switzerland. Consent was sought and documented from all caregivers of the children participating in the cluster-randomized trial. A study assistant, upon identifying children who met the inclusion criteria, explained the study and permitted caregivers to ask questions for clarification. Assent was obtained from older children who visited the health facility alone but always in the presence of a witness. For the qualitative interviews with healthcare providers, information regarding the interview was provided, and they signed a consent form before the interview. We also obtained verbal consent for audio recording. All audio files and transcripts were encrypted.

RESULTS

Baseline characteristics of participants and health facilities (quantitative study)

Among the 40 included health facilities, 24 were located in the Morogoro region and 16 in the Mbeya region. Data were collected from December 1, 2021, to October 31, 2022, covering 44,306 consultations: 23,593 in the ePOCT + arm and 20,713 in the routine care arm.

For the present analysis, 13,556 children (of whom 11,746 were non-febrile cases) and 11,282 children (of whom 10,237 were non-febrile cases) were excluded from the intervention and control arms, respectively (Fig. 1). The final population analysed consisted of 10,037 patients in the intervention arm and 9,431 in the control arm.

In general, baseline characteristics were similar between the two arms. Females accounted for slightly more than 50% of participants, with the vast majority of children in both arms being under five years of age (Table 1). The median age was 682 days in the intervention arm and 635 days in the routine care arm. More children in the intervention (38.0%) than in the control (14.5%) arm had their axillary temperature measured due to the use of the CDSA, which recommended the measurement of vital signs.

Table 1
Baseline characteristics of the participants and health facilities involved in the study.

Characteristic	**Intervention (*n* = 10037)**	**Control (*n* = 9431)**
Sex: Females, %, (*n)*	51.7 (5190)	50.6 (4769)
Age group, % (n)		
2 to 59 months	85.9 (8621)	85.0 (8020)
5 years to < 15 years	14.1(1416)	15.0 (1411)
Age in days, median (IQR)	682 (321,1322)	635 (300,1278)
Mobile phone availability, % (n)	81.0 (8129)	79.2 (7473)
Children with measured axillary temperature > = 37.5°C % (n)	38.0 (3817)	14.5 (1371)
Children with history of fever, % (n)	95.2 (9553)	99.1 (9342)
Children with fever detected through touch, % (n)	2.0 (200)	0.1 (10)
Children with respiratory complaints, % (n)	49.7 (4987)	54.7 (5158)
Children with gastrointestinal complaints, % (n)	23.3 (2338)	19.8 (1863)
Children with skin complaints, % (n)	5.7 (572)	5.2 (494)
Children with ear, nose and throat complaints, % (n)	2.2 (221)	1.5 (144)
Children with genitourinary complaints, % (n)	1.1 (115)	3.2 (299)
Number of participants per month per health facility from each council, median (IQR)		
Mbeya city council	152 (127,348)	255(149,255)
Mbeya district council	56 (43,96)	67 (40,91)
Ifakara town council	198 (198,212)	136 (68,216)
Mlimba district council	135 (115,199)	163 (128,163)
Ulanga district council	105 (88,118)	144 (73,144)
Health facility type, *n*		
Morogoro region		
Dispensaries	10	10
Health centres	2	2
Mbeya region		
Dispensaries	6	6
Health centres	2	2

Table 2
Comparison of malaria management outcomes in health facilities using ePOCT+ (intervention) and routine care (control)

Outcome measures	ePOCT+ n/N (%)	Routine care n/N (%)	Unadjusted Risk Ratio (95% CI)	Unadjusted p-value	Adjusted Risk Ratio (95% CI)	Adjusted p- value	Intracluster correlation (ICC)
Febrile children tested for malaria[a]	8931/10037 (89.0%)	6780/9431 (71.9%)	1.24 (1.22,1.26)	< 0.001	1.33 (1.06,1.67)	0.014	0.27
Febrile children with positive malaria test receiving antimalarial treatment[a]	1615/1622 (99.6%)	1541/1622 (95.0%)	1.05 (1.04,1.06)	< 0.001	1.04 (0.99, 1.09)	0.155	0.00
Febrile children with negative malaria test receiving antimalarial treatment[b]	47/7309 (0.6%)	25/5158 (0.5%)	1.82 (1.32,2.51)	< 0.001	1.65 (0.73,3.74)	0.229	N/A
Febrile children not tested for malaria receiving presumptive antimalarial treatment[b]	63/1106 (5.7%)	31/2651 (1.2%)	4.87 (3.19,7.45)	< 0.001	1.47 (0.42,5.12)	0.550	N/A

[a]Mixed-effects logistic regression model adjusted for council, age, sex, phone ownership, patient volume, health facility type, and presenting symptoms as fixed effects, and health facility as a mixed effect.

[b]Simplified modified Poisson adjusted for council only.

ICC is reported only for outcomes modelled with mixed-effects logistic regression (rows a), as the Poisson models with robust standard errors do not estimate cluster-level variance components.

Malaria testing among febrile children

A significantly higher number of febrile children were tested for malaria in facilities using ePOCT+ than in control facilities: 89.0% (8,931/10,037) in intervention, compared to 71.9% (6,780/9,431) in routine care health facilities [unadjusted relative risk (RR) 1.24; 95% CI 1.22 to 1.26 and adjusted RR (aRR) 1.33; 95% CI 1.06 to 1.67] (Table 2, Fig. 2).

Footnote: Febrile children: *Number/proportion of children with fever in intervention and control arm.* Tested for malaria: *Number/proportion of febrile children tested for malaria using mRDT or blood slide (BS).* Positive malaria test:

Number/proportion of febrile children found to be malaria positive with mRDT and/or blood slide (BS). Malaria treatment if positive: *Number/proportion of febrile children found to be malaria positive and have received antimalarials.*

Among patients tested, malaria positivity rate was 18.2% in ePOCT+ healthcare facilities and 23.9% in routine healthcare facilities. Post-hoc exploratory subgroup analyses examined malaria testing among febrile children by council and by health facility malaria test positivity rate (MTPR) (Table 3; Supplementary figure S4). When stratified by health facility MTPR, the intervention significantly improved malaria testing in both low-and high-prevalence settings (aRR = 2.31, 95% CI 1.83–3.87 and aRR = 1.09, 95% CI 1.03–1.15, respectively). The larger effect in low-prevalence facilities reflects the much lower baseline testing rate in the control group (46.6% vs 85.8% in high-prevalence facilities), which provided greater possibility for improvement. A similar effect was seen when examining geographical subgroups, where again larger effects were observed in councils with lower MTPR and baseline testing rate. The strongest effect was observed in Mbeya District Council (aRR 2.18, 95% CI 2.11–2.25), followed by Ifakara Town Council (aRR 1.58, 95% CI 1.56–1.60) and Mbeya City Council (aRR 1.43, 95% CI 1.39–1.48). A more modest effect was observed in Mlimba District Council (aRR 1.05, 95% CI 1.05–1.05), while no evidence of an intervention effect was observed in Ulanga District Council (aRR 0.95, 95% CI 0.95–0.96). These findings indicate that the intervention was effective across different epidemiological settings, with the greatest absolute gains observed in areas with lower baseline testing coverage.

On further exploration (Fig. 3), the relationship between MTPR and the proportion of febrile children tested varied across health facilities and study arms. In the intervention health facilities, testing rates were generally high, even when the MTPR was low, and the correlation between testing rate and MTPR was thus moderate (Spearman's rho = 0.64). In contrast, in routine care health facilities, testing rates increased more sharply with rising MTPR, showing a stronger correlation (Spearman's rho = 0.88).

Table 3
Post-hoc subgroup analyses of malaria testing by council and malaria test positivity rate (MTPR)

Subgroup	**ePOCT + n/N (%)**	**Control n/N (%)**	***Adjusted Risk Ratio (95% CI)**	**Council MTPR[a] n/N (%)**
By council				
Mbeya DC	642/759 (84.6%)	436/1122 (38.9%)	2.18 (2.11,2.25)	15/1078 (1.4%)
Ifakara TC	2789/3063 (91.1%)	829/1440 (57.6%)	1.58 (1.56,1.60)	200/3618 (5.5%)
Mbeya CC	922/1333 (69.2%)	966/2001 (48.3%)	1.43 (1.39,1.48)	32/1888 (1.7%)
Mlimba DC	1805/1895 (95.3%)	2635/2903 (90.8%)	1.05 (1.05,1.05)	1084/4440 (24.4%)
Ulanga DC	2773/2987 (92.8%)	1914/1965 (97.4%)	0.95 (0.95,0.96)	1913/4687 (40.8%)
By health facility Malaria test positivity rate (MTPR) level				
Low positivity rate (< 5%)	3634/4423 (82.2%)	1566/3357 (46.6%)	2.31(1.83,3.87)	-
High positivity rate (> = 5%)	5297/5614 (94.4%)	5214/6074 (85.8%)	1.09 (1.03,1.15)	-

[*]Council subgroups: GLM (no random effects) due to singular fits with 7–9 health facilities per council; RR and CI derived from predicted probabilities. ICC not applicable for council models. Prevalence subgroups: GLMM with random intercept and within-between portioning, same as main analysis.

[a]MTPR = Malaria Test Positivity Rate

Malaria treatment in patients according to malaria test result

Among children who tested positive for malaria, no difference in receiving an antimalarial prescription was observed between facilities using ePOCT + and routine care: 99.6% (1,615/1,622) in intervention and 95.0% (1,541/1,622) in routine care facilities (aRR = 1.04, 95% CI 0.99–1.09, p = 0.155) (Table 2, Fig. 2). Among patients with a negative malaria test, the proportion who still received antimalarials was also similar: 0.6% (47/7309) in the intervention and 0.5% (25/5158) in the control health facilities (aRR 1.65, 95% CI 0.73–3.74; p = 0.229) (Table 2). Among febrile children who were not tested for malaria, the proportion who received a presumptive antimalarial treatment was very low in both arms: 5.7% (63/1,106) in intervention and 1.2% (31/2,651) in routine care facilities (aRR = 1.47, 95% CI 0.42–5.12, p = 0.55) (Table 2). Stepwise adjustment (Supplementary table S1) revealed that the crude RR of 4.87 was attenuated to 1.47 after controlling for health facility council, indicating that geographic variation in baseline presumptive treatment practices was the main confounder. Further adjustment for patient-level covariates (sex, phone ownership, symptoms, and age) produced negligible additional change (aRR = 1.13, p = 0.80)

Qualitative results: Reasons for not testing for malaria

Socio-demographic background of healthcare providers

The qualitative interviews involved 15 healthcare providers from 15 primary healthcare facilities using ePOCT+. Of these, ten facilities had also participated in the quantitative (Cluster Randomized Trial) study, while five were enrolled only in the follow-up study. Participant characteristics are summarized in Table 4, while de-identified participant-level details, including study-phase participation, are provided in Supplementary Table S2. Council-level malaria test positivity rate (MTPR) is reported alongside each participant quote throughout this section, as providers' reasoning about testing frequently referenced the perceived local prevalence of malaria; reporting MTPR allows the reader to assess these accounts against the actual transmission context of each provider's catchment area.

Table 4
Characteristics of qualitative interview participants (n = 15)

Characteristic	n (%) or range
Total participants	15
Sex – Female	8 (53%)
Sex – Male	7 (47%)
Age (years), range	26–43
Professional cadre	
Clinical officer	10 (67%)
Medical officer	1 (7%)
Registered nurse (diploma)	1 (7%)
Enrolled nurse (certificate)	3 (20%)
Total work experience (years), range	1–13
Experience at current facility (years), range	0.25–11
Facility type	
Dispensary	12 (80%)
Health centre	3 (20%)
Leadership (in-charge) role	8 (53%)
Council malaria test positivity rate (MTPR)	
High MTPR council	3 (20%)
Low MTPR council	12 (80%)
Facility location	
Rural	8 (53%)
Peri-urban	2 (13%)
Urban	5 (33%)
ePOCT+ tool uptake[a]	
Low	6 (40%)
Medium	5 (33%)
High	4 (27%)
Patient load[b]	
Low	4 (27%)
Medium	4 (27%)
High	7 (47%)

[a] *Tool uptake categorised as low (< 50%), medium (50–70%), or high (≥ 70%) of eligible under-five consultations managed using e-POCT+, based on facility-level usage data.*

[b] *Patient load categorised as low (< 45), medium (45–100), or high (> 100) average under-five attendances per month.*

Despite Tanzanian national guidelines recommending universal malaria testing for febrile children, 1106 (11%) of the children in the intervention arm were not tested. During the interviews, healthcare providers revealed their reasons for not conducting a malaria test in some children. These reasons are categorized below, ordered from most to least frequently cited across the 15 interviews.

1. Contextual risk perceptions: "There's no malaria here"

Providers based their diagnostic decisions on the perceived low malaria prevalence in their catchment areas, particularly in colder, highland regions like Mbeya, especially when patients have not travelled outside the district. This perception often overrode tool guidance, leading to deprioritized testing. Some providers felt that the tool pushed them to test: *"Sometimes you just test because the tool told you to, but you already know there's no malaria here."* (Female, 35, Enrolled Nurse, Council MTPR = 1.4%)

However, this perception was not present in all participants. Some providers, even in those areas considered low risk for malaria, reported actual encounters with confirmed malaria cases, often unexpectedly. One provider described a specific moment that changed her own practice: *"At first, I would say, 'Oh, it's just a fever from a cold,' but sometimes they come back with malaria. I was shocked. I realized I shouldn't be judging through eyes... so now, I send many of them to test."* (Female, 35, Clinical Officer, Council MTPR = 1.7%; this provider's account is discussed further in section 4 below, as it also illustrates a shift in clinical reasoning over time). Another healthcare provider echoed this concern about the diagnostic value of testing regardless of perceived prevalence: *"Out of maybe 50 patients, two actually have malaria. This suggestion is crucial. Without the tablet, I might have treated the child for vomiting and fever and missed the malaria diagnosis."* (Female, 26, Clinical Officer, Council MTPR = 1.7%)

2. Systemic supply issues: "You cannot test what you do not have"

A critical malaria testing barrier, frequently cited in interviews, was the stockout of mRDT kits. Healthcare providers reported that despite the clear protocol mandate for testing, the absence of kits often rendered compliance impossible. Some facilities had developed coping strategies for stockouts, but when supplies were unreliable, providers reported testing selectively rather than universally. For instance, one clinical officer said, *"Sometimes, facilities run out of test supplies, not just ours but everywhere... You might call nearby facilities, and they say, 'We don't have supplies.'"* (Female, 30 yrs old, Council MTPR = 24.4%). This was echoed by another clinical officer, *"You might find that the tests are out of stock... So, it means you end up treating the patient without testing for malaria."* (Male, 31 yrs old, Council MTPR = 1.4%)

In some cases, even when stock was available, providers implicitly triaged patients for testing based on perceived risk or limited resources. *"You'll have a large number using test kits, they'll run out while there are other people who must be tested, for example pregnant women... you reduce the frequency of testing others even if the tablet has told you to."* (Female, 32, Registered Nurse, Council MTPR = 1.7%)

3. Human resource limitations: "The lab gets closed"

Shortage of staff and high workloads emerged as critical structural barriers. The healthcare providers described some scenarios where the absence of laboratory personnel, time pressure, or even fatigue led to skipping tests when

indicated by ePOCT+: *“If someone has been working since morning and a client comes at 3:40 PM… they might feel the need to wrap up and rest.”* (Female, 29, Clinical Officer, Council MTPR = 1.4%). Another provider said: *“The lab technician is gone... who else will test? It means the lab gets closed.”* (Female, 35, Clinical Officer, Council MTPR = 1.7%). This led to a clear sense of task prioritization and informal decision-making emerging from necessity, as described by another provider: *“The pressure to manage a large number of patients... essential steps may be compromised. This can lead to skipping necessary tests.”* (Male, 32, Medical Officer, Council MTPR = 1.7%). These findings highlight how limited human resources indirectly shape diagnostic decisions through implicit rationing and the mental shortcuts needed to cope with workload.

4. Clinical rationalization and cognitive shortcuts: "I shouldn't be judging through eyes"

Healthcare providers described cognitive processes that led to bypassing mRDTs, ranging from anchoring on presenting symptoms to overconfidence in visual assessment or recent negative test results. Such reasoning reflected clinical pragmatism but also introduced potential diagnostic blind spots. Some providers described how a presenting complaint could lead colleagues to assume malaria was unlikely without testing. One enrolled nurse explained this pattern in general terms: *"someone might think, 'Ah, this person just has a cough, or a cold'... they might say, 'This is just a cough.' So, they might not test for malaria, and that could also be a reason"* (Female, 29, Enrolled Nurse, Council MTPR = 1.4%).

As introduced in section 2 above, one provider (Female, 35, Clinical Officer, Council MTPR = 1.7%) described a specific moment that changed her own practice, moving from visual/symptom-based judgement toward more consistent testing after being surprised by an unexpected positive result. Prior recent testing was another factor that led to refusal to re-test, despite ePOCT+ prompts: *“You might see a mother coming this week with her child, and you test the child for malaria; the following week she says she’s returning because the child is still feverish, when you enter the temperature again it tells you to test for malaria again. So what is the need to test for malaria when I tested her last week? So I refuse and continue maybe with other management.”* (Female, 32, Registered Nurse, Council MTPR = 1.7%). These behaviours illustrate how participants adapt to specific clinical situations, sometimes reinforcing visual/symptom-based judgement and sometimes, as with the provider referenced above, prompting self-correction toward greater reliance on testing.

5. Social and relational barriers: “The mother refused”

Participants also pointed to patient-related factors as contributors to missed testing. These included caregiver fatigue with testing procedures, refusal due to overall lab costs or inconvenience, or assumptions about the test result based on previous experiences. *“Mothers also refuse… They say, ‘I have already tested him, I cannot test him again. Can you do something else nurse?’”* (Female, 32, Registered Nurse, Council MTPR = 1.7%). Some healthcare providers, after being informed during the interview that almost one out of 10 febrile children were not tested, reported that there could be data inconsistencies that obscured whether testing actually occurred: *“They might say they did not test them when actually they did, because when a child has a fever, you cannot leave them without testing for malaria.”* (Female, 29, Enrolled Nurse, Council MTPR = 1.4%). And: *“It could be due to either a lack of attentiveness on our part or forgetting to fill in the information.”* (Male, 31, Enrolled Nurse, Council MTPR = 1.7%). These findings reflect the interpersonal and administrative dynamics that influence whether a child ultimately receives a malaria test even when protocols are in place.

6. Provider knowledge and training gaps

A smaller, single-participant observation worth noting concerns provider understanding of when testing is clinically indicated. One provider suggested that staff covering consultations outside their primary training, such as a nurse whose professional background is not treatment-focused, may not always recognise when a given presentation warrants a specific test: *"you might find sometimes when the doctor is not available, they find a nurse whose profession is not treating… they may not think that if a patient presents with certain features, they should do a certain test."* (Male, 31, Clinical Officer, Council MTPR = 1.4%). Given this was raised by only one participant, it is presented here as a preliminary observation rather than an established pattern, and may warrant further investigation.

Taken together, contextual risk perception and systemic supply issues were the two most frequently cited reasons for not testing (8 and 7 of 15 participants respectively), followed by human resource limitations, clinical rationalisation, and social/relational barriers (5 participants each). Provider knowledge and training gaps were raised by only one participant and are noted as a preliminary observation.

DISCUSSION

This pre-specified secondary analysis of a cluster-randomized controlled trial evaluated the malaria case management cascade in febrile children. It compared clinicians providing routine care with those using the ePOCT+ digital CDSA supported by mentorship based on quality of regular audit and feedback indicators (visualized on dashboards). The use of ePOCT + was associated with a significant increase in malaria testing of febrile children (from 72% to 89%). However, no difference was observed in 1) treatment of patients with a positive malaria test, 2) treatment of patients with a negative malaria test, or 3) presumptive treatment of untested patients. The strongest effect on testing rates occurred in low malaria prevalence areas, where testing rates in control facilities were lower, and clinicians appeared more responsive to CDSA prompts. In contrast, in higher-transmission settings, testing rates were already high, leading to a ceiling effect that limited further improvements by the tool.

These findings must be understood in the context of the micro-epidemiological heterogeneity of malaria transmission, a growing challenge in Tanzania and sub-Saharan Africa [48–51]. Following substantial declines in malaria burden since the early 2000s, transmission has become more spatially heterogeneous, with areas of very low transmission coexisting alongside moderate and high-transmission settings, sometimes within the same district [50]. This creates a fundamental challenge for policy and clinical decision-making. While national guidelines in Tanzania recommend universal malaria testing of febrile children regardless of endemicity, operational guidance [52] and other studies [53] suggest that in areas with low positivity rates, real-time adaptive diagnostic algorithms, capable of adjusting to shifting case trends, seasonality, and localized outbreaks, could be considered in place of static, universal testing protocols, emphasizing the need for context-specific strategies over fixed rules. In regions experiencing resurgence over the past decade, malaria transmission may be rising again, further complicating the balance between universal testing and adaptive approaches. Frontline clinicians are thus confronted with the challenge of integrating local epidemiology into clinical decision-making, while adhering to national guidelines [5] .

In this context, future CDSAs could potentially be strengthened by incorporating adaptive logic aligned with such refined guidance. By integrating local epidemiological data, these systems may support more nuanced decision-making, for example, selectively triggering malaria testing when local prevalence exceeds predefined thresholds. Such an approach has the potential to allow more efficient use of limited resources [54]. However, this also carries risk: frequent or opaque changes to testing guidance could confuse healthcare providers and erode trust in clinical tools and recommendations more broadly [55, 56]. Evidence from clinical decision support systems more generally suggests that maintaining trust in adaptive or frequently updated tools requires transparent, well-communicated changes and consistent implementation, rather than silent or unexplained shifts in guidance [57]

The qualitative interviews helped understand these quantitative results. Healthcare providers identified two main reasons why some febrile children remained untested despite using ePOCT+: health system barriers (such as stockouts of malaria rapid diagnostic tests and staff shortages), and the perceived low probability of malaria in their area. Consistent with the low rate of presumptive antimalarial treatment among untested children in the ePOCT + arm (5.7%; Table 2), this suggests that decisions not to test were often accompanied by a judgement that treatment was also unnecessary, rather than reflecting indiscriminate non-adherence to protocol. This may help explain why the intervention increased testing, especially where routine care rates were low, but had little impact on prescribing behavior. This interpretation is consistent with studies from Tanzania [16, 58], and Kenya [9], which show that malaria testing and treatment practices are shaped by clinician judgement and contextual factors, with providers deciding not to adhere to guidelines for good (rational) or understandable (practical) reasons [16, 59–61].

Our findings on the impact of ePOCT + on the malaria case management cascade are broadly consistent with studies evaluating similar CDSAs in other settings. Quasi-experimental before-after studies in Nigeria[26] and South-Central Somalia [62]reported an increase in malaria testing rates following implementation of the ALMANACH CDSA, from 74.7% to 80.9%, and from 12.9% to 60.5%, respectively. Similarly, a non-randomized cluster trial evaluating ePOCT + in Rwanda found that malaria testing among febrile children increased significantly (aRR 1.27, 95% CI 1.08 to 1.41), while treatment adherence, already high at the baseline, did not change [63]. A cluster non-randomized trial in Nigeria observed a trend toward increased malaria testing, although this change did not reach statistical significance [25]. In contrast, cluster randomized trials evaluating adapted versions of ePOCT + in India and Tanzania [64], a before-after study in Kenya and Senegal [65], and a stepped-wedge cluster randomized trial assessing IeDA in Burkina Faso[27] found no significant impact on malaria testing.

Across these studies, CDSA interventions produced variable effects on treatment. In Nigeria [25], the proportion of cases requiring parenteral antimalarials increased from 6.9% to 12.4%, suggesting improved identification of severe malaria. In Burkina Faso [27], unnecessary antimalarial prescriptions (in children with a negative test result) decreased slightly from 3.9% to 3.0%. In Kenya and Senegal [65], the intervention significantly increased antimalarial prescribing among children with confirmed malaria and reduced empirical prescribing among untested children, while no significant change was observed among test-negative children.

Differences in baseline adherence, mentorship, real-time feedback mechanisms, and study design likely account for these contrasting effects across settings, although our study was not designed to formally test these explanations. A distinguished feature of our intervention was individualized mentoring combined with dashboards displaying quality-of-care indicators, which may have reinforced clinician engagement with the CDSA. This interpretation is consistent with the Rwanda trial, which used a similar mentorship and dashboard-based monitoring approach alongside a significant improvement in malaria testing [63]. However, our qualitative interviews did not specifically explore how mentorship feedback shaped providers' testing behavior, so this remains a plausible interpretation rather than a finding directly supported by our data. Future qualitative research explicitly examining the role of supportive supervision and feedback mechanisms would help clarify whether these components are indeed critical for improving testing in low prevalence settings.

There are a number of reasons for the absence of an ePOCT+ effect on malaria treatment. First, it is consistent with a ceiling effect, whereby high baseline adherence to malaria treatment guidelines limited the potential for further improvement. Second, differences in training and mentorship associated with the implementation of the CDSA would likely impact adherence to CDSA treatment recommendations and general uptake of the tool. The mentorship package evaluated in this study included the sharing of audit and feedback indicators, an approach that has shown promise elsewhere [66], while mentorship without such real-time indicators has shown more limited effects on testing

behavior in other [67, 68]. However, our qualitative data did not specifically explore how providers used or responded to these indicators, so this remains a plausible contributing factor rather than a confirmed mechanism. Finally, differences in study design and healthcare provider practices likely also contribute to the differences observed between studies.

Several limitations should be noted. First, the data were derived from healthcare providers' own data entries in ePOCT + and the eCRF, introducing a risk of self-report bias. This risk may be asymmetric: audit and feedback dashboards showing quality-of-care targets were visible only to intervention providers, who were thus more aware of being monitored. Any resulting misreporting would likely inflate adherence to recommended practices, particularly in the intervention arm, including malaria testing, artificially exaggerating the apparent effect of the intervention. Although it was not possible to independently verify all self-reported data, observations from a sample of 225 consultations conducted across 13 health facilities in each arm indicated generally appropriate malaria treatment. All 30 malaria-positive patients in the intervention arm, and the two positive patients in the control arm, were appropriately treated with an antimalarial drug, and no negative malaria case received antimalarial treatment [69].

A further limitation arises from the fact that this study analyzed secondary outcomes not powered a priori. Notably, the ICCs for these outcomes were considerably higher than those used in the sample size calculation for the main study primary outcome, potentially leading to wider confidence intervals and reduced precision of the estimates.

In the qualitative component, findings partly relied on self-reported perceptions, which may introduce social desirability and recall bias. Nevertheless, triangulation with observed facility data strengthens confidence in the thematic interpretation. Despite these limitations, the consistency of the quantitative and qualitative findings enhances the robustness of the results and reflects the real-world complexity of implementing digital innovations in primary care.

CONCLUSIONS

By combining RCT and qualitative evidence from routine primary care in Tanzania, this study addresses a gap in prior evidence, which relied largely on short-term, controlled-setting pilots focused on under-five children. Across a broader paediatric age range in real-world East African primary care, ePOCT+ improved adherence to clinical guidelines, reflected in increased malaria testing, by nudging providers toward more systematic testing. However, this effect operates within the constraints of the underlying health system: providers described stockouts of malaria rapid diagnostic tests and staff shortages as recurring barriers, regardless of tool guidance, and algorithm design alone cannot resolve non-adherence rooted in these structural gaps. Growing micro-epidemiological variation in malaria transmission is also challenging uniform testing recommendations, prompting clinicians to informally adapt guidance to local context. Refined, adaptive digital algorithms incorporating local epidemiology, combined with mentorship and data-based feedback, could help strengthen diagnostic adherence, but only alongside a reliable diagnostic supply chain, adequate staffing, and integration within the electronic medical record system.

Abbreviations

aRR
adjusted risk ratio
CDSA
clinical decision support algorithm
CI
confidence interval

eCRF
electronic case report form
ePOCT+
electronic point-of-care test, plus
GLM
generalized linear model
GLMM
generalized linear mixed model
ICC
intracluster correlation coefficient
IMCI
Integrated Management of Childhood Illness
LMICs
low- and middle-income countries
mRDT
malaria rapid diagnostic test
MTPR
malaria test positivity rate
RR
unadjusted risk ratio

Declarations

Ethics approval and consent to participate:

This study received ethical approval from the Ifakara Health Institute ethical committee (IHI/IRB/No: 11-2020), the Mbeya Medical Research Ethics Committee (SZEC-2439/R.A/V.1/65), the National Institute for Medical Research Ethics Committee (NIMR/HQ/R.8a/Vol. IX/3486 and NIMR/ HQ/R.8a/Vol. IX/3583) in Tanzania, as well as the cantonal ethics review board of Vaud (CER-VD 2020–02800) in Switzerland. Consent was sought and documented from all caregivers of the children participating in the cluster randomized trial. A study assistant, upon identifying children who met the inclusion criteria, explained the study and permitted caregivers to ask questions for clarification. Assent was obtained from older children who visited the health facility alone but always in the presence of a witness. For the qualitative interviews with healthcare providers, information regarding the interview was provided, and they signed a consent form before the interview. Verbal consent was also obtained for audio recording. All audio files and transcripts were encrypted.

Consent for publication:

- Not applicable

Competing interests:

- The authors declare that they have no competing interests.

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Author Contribution

LBL contributed to the study design, coordinated data collection for both the quantitative trial and qualitative sub-study, conducted the quantitative and qualitative data analysis, and drafted the manuscript. LFB supervised the study design and analysis, and critically revised the manuscript. PT contributed to the statistical analysis plan and supported the quantitative analysis of the cluster-randomized trial data, and critically revised the manuscript. AVK critically revised the manuscript. GAK contributed to site-level implementation and data collection in the Mbeya region. PA contributed to site-level implementation and data collection in the Mbeya region. CE contributed to data collection and critically revised the manuscript. CDM contributed to site-level supervision in the Mbeya region and critically revised the manuscript. FH contributed to transcription and translation of the interviews and critically revised the manuscript. MJ contributed to data collection. AM critically revised the manuscript. IM contributed to data management and critically revised the manuscript. GIA contributed to quantitative data collection. HM provided overall national oversight of the DYNAMIC project and critically revised the manuscript. NEN provided overall national oversight of the DYNAMIC project and critically revised the manuscript. VD conceived the DYNAMIC project and the trial design, acquired funding, and critically revised the manuscript. RT supervised the study design and analysis, and critically revised the manuscript. All authors read and approved the final manuscript.

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Data Availability

The RCT dataset supporting the conclusions of this article is available in the Zenodo repository, https://doi.org/10.5281/zenodo.18187272

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Figures

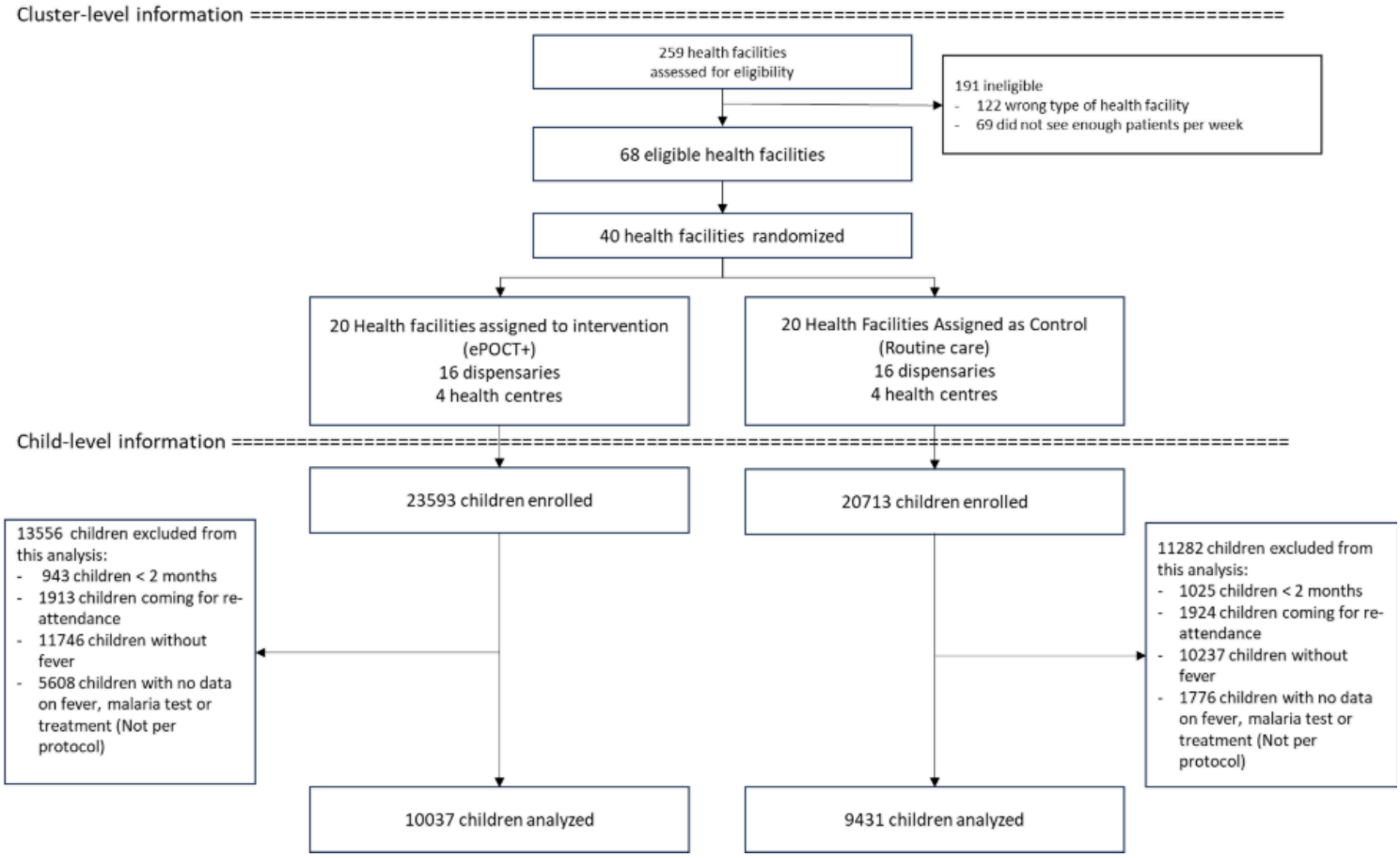


Figure 1

Participant flow chart

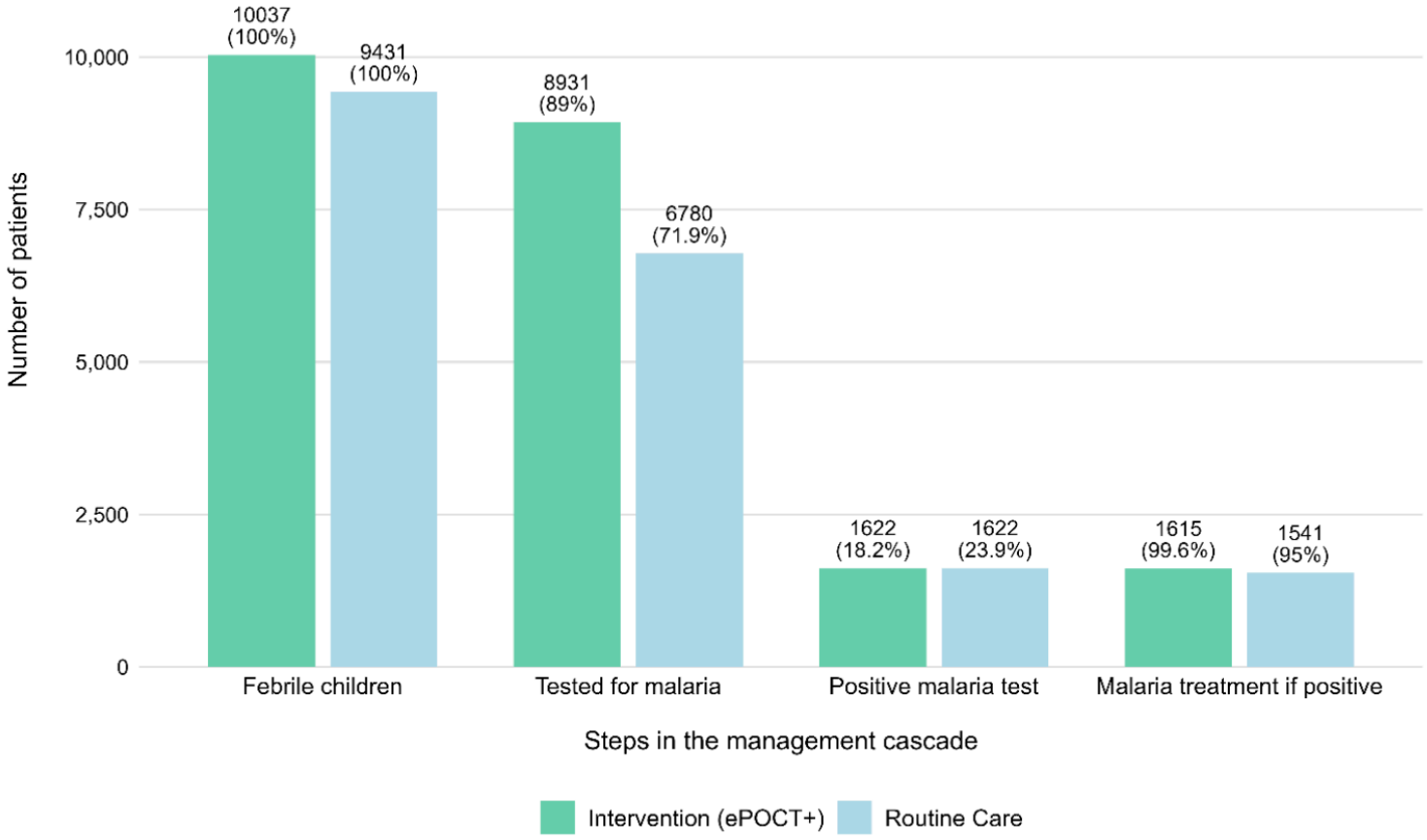


Figure 2

Malaria case management cascade among patients consulted using ePOCT+ vs routine care.

Footnote: Febrile children: *Number/proportion of children with fever in intervention and control arm.* Tested for malaria*: Number/proportion of febrile children tested for malaria using mRDT or blood slide (BS).* Positive malaria test:*Number/proportion of febrile children found to be malaria positive with mRDT and/or blood slide (BS).* Malaria treatment if positive:*Number/proportion of febrile children found to be malaria positive and have received antimalarials.*

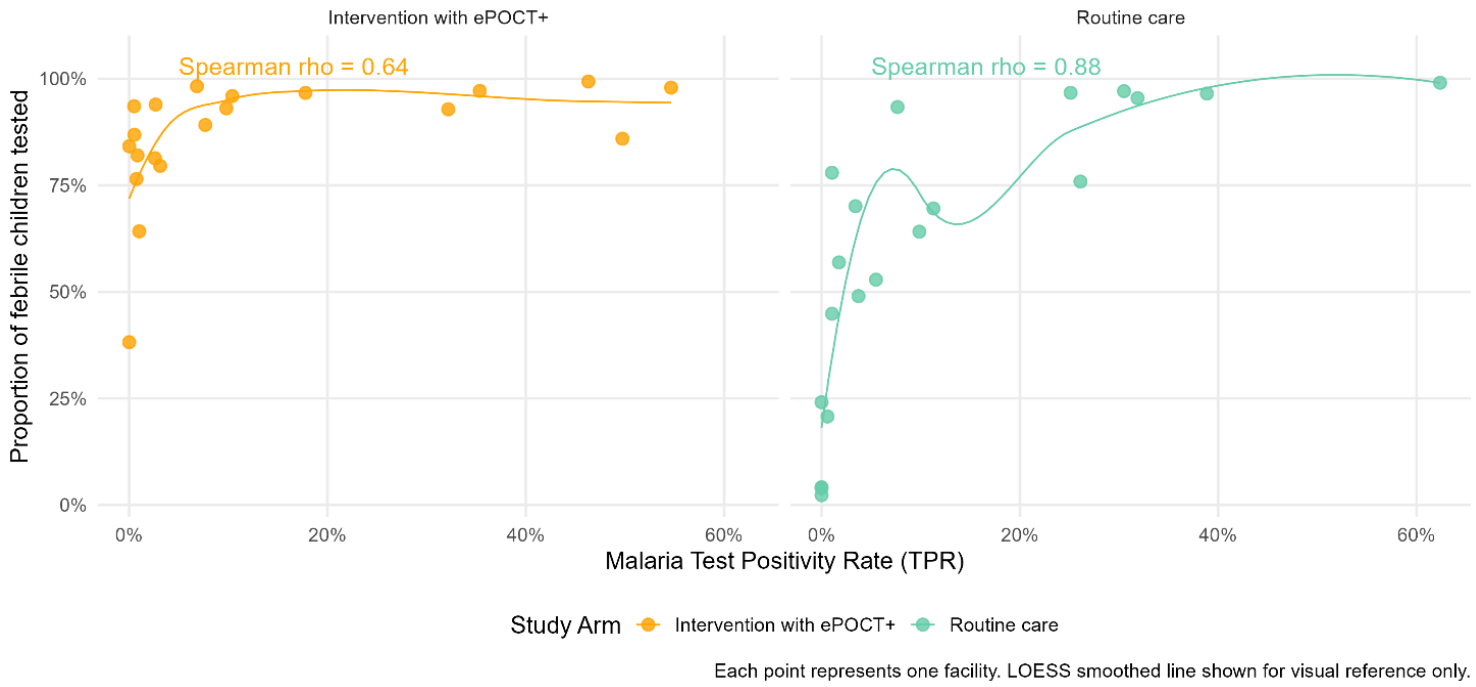


Figure 3

Relationship between malaria test positivity rate and testing rate across health facilities

Supplementary Files

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- Supplementaryfiguresandtables.docx