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ORIGINAL PAPER

"Closing the Gap": Provider Recommendations for Implementing Birth Point of Care HIV Testing

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Abstract

Delays in traditional HIV DNA PCR testing for early infant diagnosis (EID) at 6 weeks of age result in late antiretroviral treatment (ART). Birth point of care (POC) testing is an emerging strategy with the potential to streamline EID services. We elicited providers' recommendations for introducing birth POC testing to guide strategies in Kenya and similar settings. We conducted formative interviews with 26 EID providers from four Kenyan hospitals prior to POC implementation. Providers discussed the need for comprehensive training, covering both EID and POC-specific topics for all key personnel. Providers highlighted equipment considerations, such as protocols for maintenance and safe storage. Providers emphasized the need for maternal counseling to ensure patient acceptance and most agreed that specimen collection for birth POC testing should occur in the maternity department and supported a multidisciplinary approach. Though most providers supported ART initiation based on a positive birth POC result, a few expressed concerns with result validity. To maximize implementation success, provider training, equipment security, maternal counseling, and logistics of testing must be planned and communicated to providers.

Keywords HIV testing · Point of care · Early infant diagnosis · Implementation recommendations · Birth testing

Introduction

Early initiation of antiretroviral treatment (ART) for HIV-infected infants can reduce mortality by up to 75% and slow disease progression [1]. Coverage of early infant diagnosis (EID) for HIV-exposed infants at 6 weeks of age in Kenya and other low and middle-income countries (LMIC) has increased markedly over recent years [2, 3], yet most infants diagnosed HIV-positive are not initiated on ART by the critical benchmark of 12 weeks of age [4–7]. Delays with traditional HIV DNA polymerase chain reaction (PCR) infant testing (late infant presentation for care [8], long turnaround times for sample processing [9], and delayed ART initiation [10]) result in Kenyan infants not being started on ART until a median age of 17.1 to 24.5 weeks [6, 10]. To expedite infant diagnosis and ART initiation, 2016 Kenyan guidelines included birth PCR testing (< 2 weeks of age) for HIV-exposed infants [11]. Implementation of birth PCR testing in Lesotho hospitals reduced infant age at initiation of ART by more than half (14.6 weeks to 6.1 weeks of age) [12]. However, as of 2018, birth testing was still not widely implemented in Kenya, as national piloting occurred.

Point of care (POC) technology is an emerging strategy with the potential to streamline infant HIV diagnosis and minimize challenges with traditional HIV DNA PCR testing for EID. Two such POC diagnostic tests are GeneXpert HIV-1 Qual [13] and Alere q HIV-1/2 Detect [14]. Both of these systems detect viral nucleic acids and, in studies, these

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tests have shown high sensitivity (93.3-98.7%) and specificity (100%) [15–20], resulting in WHO prequalification in 2016 [15, 16]. These cartridge-based tests can be performed at the hospital by trained clinical or laboratory staff, making a result available to the patient at a median time of 1.8 to 2.8 h after sample collection [19, 21] and facilitating same-day results and the potential for same-day ART initiation for positive infants [22, 23], if test and treat guidelines are followed. In field evaluations, implementation of POC systems has been shown feasible in hospital-based settings in South Africa [17, 19, 20] and Mozambique [24] and acceptable to providers [20].

Designing implementation strategies informed by providers' preferences for implementation will be critical for successful uptake as Kenya and other countries move towards integrating birth POC testing for EID into more routine use [25, 26]. Birth POC testing housed in clinical settings represents a substantial shift from centralized laboratory-based HIV DNA PCR testing and blurs the traditional departmental roles in diagnosis, caregiver counseling, and treatment. Healthcare facilities attempting to integrate HIV services in broader patient services (e.g. PMTCT into antenatal care, EID into immunization visits) or to expand use of POC tests in existing HIV services have met challenges with supply of materials, patient flow, provider workloads, and physical spaces affecting patient confidentiality [27–30]. Facilities implementing birth POC HIV testing in Maternity or Maternal and Child Health (MCH) departments will also face operational challenges [31, 32], some which may be heightened by the time-sensitivity of EID services.

In a systematic review of barriers to implementing rapid POC tests for HIV, the primary barrier cited at the patient and health system levels was integration into local clinical workflow and national systems [31]. These challenges can be addressed proactively with strategic planning using formative research to identify solutions acceptable to the implementing providers who are most familiar with their local context. To date, there are no recommendations for integrating POC at the hospital-level. In this paper, we aim to describe providers' recommendations for optimal implementation of birth POC testing, as pragmatic guidance for the introduction of infant POC testing in Kenya and similar settings.

Methods

This formative evaluation with key stakeholders at each of the four study hospitals was conducted to elicit feasible and effective strategies for the introduction and implementation of birth POC testing in varied Kenyan health facilities. Health facilities were randomized to implement Alere q (n = 2) or GeneXpert (n = 2) for birth POC testing; however, at the time of the interviews, POC machines had not yet been introduced to the study hospitals and no training for POC implementation or study procedures had occurred.

Study Participants and Interview Procedures

In February 2017, we conducted semi-structured interviews with health care providers from four study sites to elicit recommendations for introducing and implementing birth POC testing at their hospital. The hospitals in coastal and western Kenya represent three strata (county referral, district, and provincial referral) with annual EID volumes in 2017 ranging between 159 and 704. A total of 26 key EID providers were recruited for key informant interviews by on-site research coordinators. Participants were selected to provide perspectives from different departments (Laboratory, Maternity, MCH) and different roles (clinical officer, nurse, lab manager, lab technician, mentor mother, midwife). Hospital and provider characteristics are outlined in Table 1.

Frameworks and recommendations for implementing POC for EID at the national level recommend evaluations to determine when, where, and how POC for EID can be best implemented [32]. While not comprehensively linked to one theoretical framework, pragmatic questions to optimize implementation in each setting reflected some of the constructs in the Conceptual Framework for Implementation Research (CFIR) domains of *intervention characteristics, inner setting, and implementation process* [33]. Question topics included perceived benefits and barriers of birth POC testing, suggested logistics of birth POC testing (including who should conduct the testing, where, and when), and concerns with introduction of birth POC testing. Interviews lasted approximately 1 h and were conducted in English by trained study staff in a private setting. Written informed consent was obtained from each participant prior to the interview and a remuneration of 500 Kenyan Shillings (approximately USD $5.00) was given in appreciation of providers' time. All study protocols were approved by ethical review committees at the Kenya Medical Research Institute (KEMRI) and the University of Kansas Medical Center.

Analytic Strategy

All interviews were audio recorded and transcribed verbatim. During the first cycle of coding, transcripts were coded independently by two study team members for a priori and emergent themes. These initial thematic codes were then combined into axial codes through group consensus. We identified axial codes related to the considerations for the "preparation" (i.e., suggestions for what needed to occur prior to POC machine implementation

Table 1 Hospital and participant characteristics

Hospital code	Hospital resource level	2017 EID volume (% positive)[a]	Provider code	Provider Role
A	County referral hospital	704 (2.4%)	Participant 1	Mentor mother
			Participant 2	Nurse, MCH in-charge
			Participant 3	Lab technician
			Participant 4	Nurse-midwife, Maternity in-charge
			Participant 5	MCH nurse, midwife
			Participant 6	MCH nurse
B	District hospital	605 (4.1%)	Participant 7	Nurse, MCH in-charge
			Participant 8	Lab manager
			Participant 9	Maternity nurse
			Participant 10	MCH nurse
			Participant 11	Nurse-midwife, maternity and MCH in-charge
			Participant 12	MCH & maternity clinical officer
C	Provincial referral hospital	686 (1.3%)	Participant 13	MCH nurse
			Participant 14	Nurse in charge, unspecified department
			Participant 15	MCH nurse
			Participant 16	Midwife
			Participant 17	Mentor mother
			Participant 18	Lab technician
			Participant 19	MCH nurse
D	District hospital	159 (2.5%)	Participant 20	Lab manager
			Participant 21	Lab technician
			Participant 22	MCH nurse
			Participant 23	MCH nurse
			Participant 24	MCH nurse in-charge
			Participant 25	Maternity nurse
			Participant 26	MCH nurse

Mentor mothers are HIV-positive mothers who have had firsthand experience of EID, received training, and provide a range of services including case finding and referral, defaulter tracing, case management, support group facilitation, health education, and support for enrollment, retention, and adherence

MCH maternal and child health department; including ANC, PMTCT, and EID services

[a]EID volumes and % positive taken from National AIDS/STD Control Programme's EID Dashboard [42]

and start of testing) and "implementation" (i.e., suggestions for POC testing implementation) phases of birth POC implementation. We present our data in these two phases. Findings from this formative research directly informed the subsequent POC preparation and implementation strategies currently being piloted and evaluated at each study site.

Results

Preparation Phase

Providers discussed the need for comprehensive training and establishment of protocols to ensure machine security prior to implementing birth POC testing.

Training Recommendations

Providers indicated the need for both general training on EID guidelines and POC-specific training. Many providers either explicitly stated that they would benefit from additional EID training or made statements that indicated a lack of familiarity with the revised 2016 EID guidelines [11] that could hinder implementation. Additional EID training was seen as necessary to ensure all providers were familiar with the most recent recommendations, with several providers indicating that "people need to be trained because for example, there are some specific points where you are supposed to get samples, and most of our people they're not sure…" (Participant 16).

The need for birth POC-specific training was also a salient theme, with providers emphasizing that birth POC testing would require an adequate number of well-trained personnel.

Providers indicated that staff rotations, turnover, and multiple shifts with varying levels of staffing could serve as barriers to birth POC testing if adequate personnel in pertinent roles were not trained, "The most important thing is to train the health workers and train as many because this facility might get someone today and tomorrow they are not there. So if you train few people and maybe tomorrow they are not there and those who are left are not introduced or trained, the services will stop." (Participant 17). Providers emphasized the importance of training multiple people within each shift to do the same task to minimize the potential for missed opportunities if a single trained person was unavailable when needed: "We [need to] make sure anyone who is around that machine has the skill of at least drawing the sample. The NO [nursing officer] in maternity should know how to collect the blood, the CO [clinical officer] in maternity should know how to collect the blood, and the nurse in maternity should know how to collect the blood. So that at least always when we have those patients, we're sure there's someone around who can help not to miss opportunities." (Participant 24).

A few providers recommended making training materials such as standard operating procedures (SOPs) and job aids easily accessible. Others suggested providing regular continuing medical education (CME) and on-the-job training (OJT) opportunities to all implementing staff. Providers proposed that doing so would not only help standardized operations and streamline training across sites, but suggested that it could also motivate provider engagement in the initiative, saying "So we also need to be having the CMEs and OJTs, and mentorship, and supervision. That is also a kind of motivation so that we do our work the way we're supposed to do. The SOP, so I wish we could come and start the operations procedures pinned on the wall so that at a glance, when I'm doing this, I know I'm doing the right thing." (Participant 11).

Key recommendations for training
Support EID-specific training to ensure all providers know current guidelines
Ensure that birth POC-specific training includes relevant personnel on all shifts so that staff rotations and turnover do not halt implementation
Provide SOPs and job aids to standardize procedures
Provide opportunities for continued training (OJT and CME) to enhance provider motivation and skills

Equipment Considerations

Providers also expressed concerns related to the POC equipment that they felt needed to be addressed prior to implementation. Of these concerns, the most commonly cited was the need for safe equipment storage and a clear process for "handing over" the machine at the end of every shift to ensure machine security: "The storage of the machines, in our case, we need to have a cabinet that is lockable, and the key should be [with] the in-charge and the key should be handed over to the next person. And they should have a book where they record the handing over, the one who is handing over and the one who is taking over, and timing, until what time, for accountability because these are expensive machines, and we don't want them to get lost before the study and after the study" (Participant 11).

A lockable cupboard or separate room within the testing location was often cited as the best solution to ensure safe machine storage. In most instances, providers were able to identify an ideal storage location for the machine; however, in some cases these storage locations required minimal repairs or alterations to make them suitable.

Suitable storage of the GeneXpert and Alere q cartridges, which need to be kept at 2–28 degrees [15] and 4–30 degrees [16] Celsius, respectively, was also seen as a potential issue. Some providers indicated that the procurement of a refrigerator for cartridge storage would be required, "Maybe the challenge will be the storage. Like you said, it needs a fridge. Maybe if you can provide us with a fridge, that's good" (Participant 20). Most providers did not see power outages as a major concern for either processing samples or keeping refrigerators running, since generators were typically available.

Some providers also mentioned the need to have clear protocols for machine maintenance and servicing. These providers felt that hospital personnel should either know who to contact or be trained to perform the maintenance themselves, "Of course if you bring equipment and we don't know how it will be serviced…Who is going to service this equipment in the first place…we should know those things before we implement. Because we can be given equipment, once it breaks down, you don't know what to do. You don't know who to contact. So those are some of the things we need to put into place first before we start using the equipment" (Participant 3). This was seen as a crucial component to sustainability of birth POC testing.

Key recommendations for equipment
Store POC machines under lock-and-key, either in locked cupboards or in a separate locked room
Establish protocols for "handing over" the machine at the end of every shift
Establish clear SOPs for equipment servicing and maintenance
Provide small refrigerator for appropriate temperature-controlled cartridge storage at each site

Implementation Phase

Implementation phase suggestions for birth testing focused on patient management and the logistics of birth POC testing to maximize integration of the new procedure into current workflow. Implementation phase suggestions related to maternal counseling to prepare mothers to accept birth POC testing, the logistics of conducting the birth POC test, and the timeline for ART initiation based on the results of the test.

Maternal Counseling

Most providers emphasized the need for maternal counseling at every step of the PMTCT/EID cascade of care [34]. Strong maternal counseling was seen as necessary for mothers' acceptance of birth POC testing for their infant. With proper counseling, providers felt that HIV-positive mothers would be eager to accept birth POC testing for their infants and would be prepared to accept the results of this test: "You go through the whole process of testing, you prick, tell her we're doing this to the baby, and of course, if she was coming antenatally, she knows it will happen. We prepare her antenatally knowing that when she delivers, the first test will be done at birth. So by the time she's landing in maternity, she already knows. So it's just some counseling, you do the test and then you give her the results. And of course, when counseling you're telling her either: if it is negative it will be A, B, C, D; if it is positive, it will be A, B, C, D. So she already knows" (Participant 24). They further emphasized that effective counseling was not a one-time event and needed to start early during a woman's pregnancy and continue throughout EID follow up: "The first thing we should, like, prepare these mothers before they come to deliver, before even during labor, before the child comes, we should prepare this mother that once the child comes out, the sample we are collecting and this one will be the reason" (Participant 12).

Providers described how accepting the test and the results of the test may be more challenging for mothers newly diagnosed during labor who are just learning their own HIV status, "For that mother, we will maybe know the status at delivery, it will be a challenge for her to accept, or maybe to see her child being pricked, maybe she has not come out of the disbelief that she's positive. So, I think most mothers, maybe the ones from ANC and they have gone through counseling, we'll have no challenge with them. But for that mother who's coming for delivery and then she turns positive, we may get a challenge of the mother not accepting to see her child being pricked for the sample" (Participant 15). Most believed that in the case of a newly diagnosed patient, maternal acceptance of the test and the result would still be possible, though "counseling will be a bit tactful and it will take a long time. As opposed to this other person who has been getting continuous counseling about the same" (Participant 10). A few described how mentor mothers could provide critical psychosocial support to mothers and share experiences, "if the mother is newly tested, she must be taught fast by a mentor mother. You know when a mentor mother shares her personal experience, you will bring the mother closer to you and she will be willing to listen to you because you are in the same status" (Participant 17).

Key recommendation for counseling
Provide comprehensive maternal counseling, starting early during pregnancy and continuing throughout pregnancy and delivery
Anticipate providing extra support for clients who are newly diagnosed during labor

Testing Logistics

Location of Specimen Collection Most providers indicated that the maternity department was the best place for birth POC sample collection to occur. Providers preferred the test take place in maternity "because you cannot keep moving around with the mother and they have just given birth" (Participant 17). Furthermore, they felt it would make patients feel more comfortable because "She's so familiar with you, this environment of maternity, explain everything to her. Especially for the first testers, it's very important…to do everything under one roof" (Participant 10). They also felt that would reduce the potential for missed opportunities "because the mother will be within the hospital. But if you allow that mother to go home and pass through the MCH, then you might see not all of them come back" (Participant 3).

Within the maternity department, slightly more providers stated that the postnatal ward would be the best location for sample collection, compared to the labor ward. Providers' preferences between the postnatal or labor ward were significantly influenced by their perspectives regarding privacy in each ward.

> "I tend to think in a postnatal ward, because currently after delivery, maybe you are delivering five mothers in the same couch, so you'll not have an adequate space to do the testing. But when the mother is relaxed, and the baby's okay, breastfeeding, then we can do it in the postnatal ward." (Participant 16)
>
> "If you asked me, I think the moment, immediately after birth, before she leaves the labor room. Why? Because according to our postnatal ward, the beds are a bit close, so the privacy." (Participant 23)

Regardless of the preferred location of the test, clinicians emphasized the "need to have a good environment where the sample is collected without any fear of stigma and discrimination" (Participant 16).

This was seen as especially important "because not every mother in the labor ward is positive, and not all of them will understand why…a sample is being taken from this baby and not mine. So, you see, when you are answering those questions, maybe you find some of the health workers disclosing the mother's status" (Participant 15). In some cases, providers indicated that modifications would be needed to their hospital infrastructure to accommodate these requirements for confidential birth POC testing, "I would want to have an office where that specific testing and counseling is done so that it is done within a room to maintain the privacy and confidentiality of the mothers…We don't have. That is the challenge. That is why I was talking of creating a room within the space that is available" (Participant 4).

A few providers spoke of additional challenges with confidentiality if family members or partners attended the delivery, saying "Maybe the mother did not disclose to the spouse, and here we have a baby that we need to test, and maybe she does not want you to take this test when the spouse is there. So when the spouse is there, it's going to be hard, especially when the mother does not want you to reveal this thing" (Participant 9). However, in general, providers felt that this challenge could be overcome with relative ease by knowing the mother's disclosure status and allowing the mother to choose who is present during the counseling and testing.

Testing Personnel When asked who should conduct birth POC testing, respondents' answers varied by role. The majority of clinicians felt that it should be clinicians who are primarily responsible for collecting birth POC samples, "At the point of delivery, I think it is the nurse who can do it. Because this is the person who goes with the mother through labor up to delivery. You know this kid very well, the point of attention you gave this child, what you did. You went with the mother through. So I think the nurse is best placed to do this thing" (Participant 9). These clinicians felt that having clinicians conduct the test would not only make mothers feel more comfortable but would also reduce missed opportunities because "during the public holiday, you'll find in lab you have a shortage. So you'll rarely expect the person in lab…to come and collect the sample. So this nurse who is, this midwife who is delivering the mother should have some know-how on how to collect the sample. At least with that one, we'll be assured we have closed the gap of having any child going home without getting tested" (Participant 24).

In contrast, more laboratory staff felt that they should be primarily responsible for sample collection, saying "Birth testing, I strongly feel that if the lab people were to do that then it would help. Or the clinician will be taught on how to prepare those cards for PCR—it will help. They can collect once they have been certified by the lab that these people can do this. But that is the responsibility given to the lab first" (Participant 3). These technicians felt that having the lab play a key role in sample collection would improve sample quality and reduce the number of failed tests.

However, many laboratory technicians and clinicians recognized the need for a multidisciplinary approach to sample collection, where laboratory personnel and clinicians work together to ensure proper sample collection. In these cases, the laboratory was seen as playing a supportive role to sample collection by assisting during busy times when clinicians may be unable to collect a sample, providing additional training to clinicians on sample collection techniques, and by providing quality assurance assessments: "If we [nurses] are trained on how to do it, we can do it. If it is the lab guys who will do it, we work as a team. And even if we are taught and we cannot do it at that particular time because of other engagements, yeah, the lab people can come" (Participant 9).

Timing of Test Providers agreed that birth POC testing should be conducted before the mother and newborn are discharged from the hospital; however, the specific recommendations for timing of the test ranged from "Immediately after delivery, as the mother is being prepared, somebody should be running the test" (Participant 18) to "12 h post-delivery, or 24 h post-delivery, or even 72 h because we still have this mother…but immediately after birth that is not working" (Participant 9). Despite the wide range of specific timing suggested, most providers indicated that mothers should be given the opportunity to rest and agreed that "the best time will be… after the mother has completed everything, they're settled, the baby is settled, the baby has been breastfed, the mother is psychologically prepared for it" (Participant 13).

Some providers discussed how the timing of delivery may impact when the test can be conducted, citing particular concerns regarding how reduced staff at night may necessitate delaying birth POC testing until morning, "The only gap we have is at night. Yes. And since the mother is not discharged at night, they are told to wait in the morning. And when the counselor comes in the morning, those who delivered at night are given priority to be seen first because they will be going home in the next four to five hours" (Participant 17). Weekends were seen as less of a challenge "because we have these people every day of the week" (Participant 14); however, providers did re-emphasize the need to ensure that weekend staff are also trained on birth POC testing procedures.

Key recommendations for birth POC testing logistics
While the maternity department was widely seen as the best location for birth POC testing, the location within the maternity may be facility-specific. Ideal testing locations should:
minimize patient movement around the hospital
ensure patient privacy and confidentiality
A multidisciplinary approach where clinical and laboratory staff work together to collect samples may reduce missed opportunities for testing and ensure high quality samples
Birth POC testing should occur before a mother is discharged from maternity, but after the mother and baby have had adequate time to recover from the birthing process
Protocols should be established in advance to determine logistics of testing for infants born during times of reduced staffing or hospital operations (nights and weekends)

Key recommendations for ART initiation
ART initiation should occur based on a positive POC result
A confirmatory PCR should be requested to confirm the positivity
Additional training may be needed to ensure this confirmatory process does not delay ART initiation

ART Initiation

The majority of respondents stated that providers would be comfortable initiating infants on ART based on a positive birth POC result, and thus recommended that ART initiation happen the same day as a positive POC results, saying "I think the initiation should happen the same day. And it can be possible because what has been keeping us, it is the results. And now since we have that when we are able to get the results at the same day, I don't think there is any other issue that can hinder the initiation of the ART in the same day" (Participant 17). Many of the providers emphasized that the Kenyan national guidelines supported immediate ART initiation and, thus, they needed to follow those guidelines when it came to POC testing: "One has to go through NASCOP guidelines. Because we have guidelines. If they say it is immediate, it is immediate. So long as you persuade the clients now to agree, early intervention is better than late intervention" (Participant 3). A few providers who supported same-day ART initiation also discussed how a PCR should be used to confirm the results, but should not delay ART initiation, saying "Follow-up [PCR], I think we should do it. Despite starting the care, we should still do the follow-up [PCR]" (Participant 24).

However, a few providers preferred that "point of care results should be subject to confirmation by the PCR; it should not be strictly used as a specific test, but it should be confirmed with a PCR" (Participant 4) before ART could be initiated. These providers preferred waiting for a confirmatory PCR test because they were unsure of validity of a POC result, with a few citing concerns that the "child may be having mother's antibodies and the machines can detect those antibodies. Now, instead of giving this baby ART when the baby is negative, then it's good to wait for the PCR results to confirm the results" (Participant 1).

Discussion

These formative findings from providers identified areas of consensus, divergence, or facility-specific variables on core aspects of implementing birth POC testing in low resource settings to inform a pragmatic roadmap to guide context-sensitive adoption of birth POC strategies at other facilities. Consistent with established best practices for implementation, stakeholder engagement, thorough training, and establishment of clear procedural protocols will improve implementation [35–37]. Recommendations unique to the addition of HIV testing at birth highlight the importance of thorough antenatal counseling with mothers so they are prepared to accept birth testing, special consideration of maternal disclosure status to protect confidentiality during maternity-based testing given the frequent presence of family members, and needed collaboration between maternity nurses and laboratory technicians to manage the logistics and demand for prompt testing at delivery. Recommendations specific to new POC testing technology emphasized the importance of frequent retraining on use of the devices and clear protocols to ensure security, proper utilization and maintenance of the expensive machines and cartridges. In regard to provider training on the addition of new birth testing guidelines and POC technology, formative findings revealed inconsistent knowledge on testing and clinical management for EID per the established EID guidelines, noting baseline knowledge should be assessed and not presumed. Similarly, uncertainty regarding the appropriate management of a positive POC result should be expected given the novelty of this strategy among infants and procedures clearly outlined. The importance of immediate ART initiation for HIV-positive infants cannot be overemphasized given some hesitancy to initiate ART based on results of the new technology. Filling a gap in the published literature, these findings highlight important factors that should be considered prior to the implementation of birth POC HIV testing interventions to encourage sustainability.

Diagnostic testing is traditionally considered a role of laboratory personnel [38], but providers felt that with adequate training, nurses and other clinicians could effectively conduct birth POC testing; many supported a multidisciplinary

approach where the laboratory personnel support clinicians in conducting the test. They recommended that training prepare multiple people per shift for overlapping responsibilities to ensure continuous availability of POC testing services. Ongoing OJT and CMEs were recommended during the implementation phase to sustain motivation. It was widely felt that these activities depend on close, ongoing collaboration between clinical providers and laboratory staff. This is in line with national frameworks that indicate task sharing can reduce the additional work of birth POC testing but requires training multiple cadres of health workers and encouraging collaboration across cadres [32].

Providers also discussed the importance of careful management and attention to physical resources, starting early in the preparation phase. Mirroring key stakeholder inputs from other HIV service contexts [27, 39], most providers emphasized that facility spaces for patient engagement (i.e. counseling, sample collection) will affect confidentiality in infant testing. Also, while the preferred location for POC machines in labor or postnatal wards varied by site and provider, physical location was perceived as important in creating a private and comfortable environment for patients. Thus, prior to birth POC introduction, site-specific evaluations of facility infrastructure are recommended. At the same time, implementers should evaluate the hospital's capacity to safely store the equipment (POC machine, refrigerator for cartridge storage) and plan for any physical modification necessary to enable locked storage. Based on feedback regarding personnel and physical resources, Fig. 1 outlines a suggested sequence of steps during the preparation phase to maximize site readiness to implement birth POC testing. Each step should be a collaborative effort between the implementer and key personnel at the hospital level.

Nearly all providers discussed the need for maternal counseling, emphasizing that it should occur continuously from ANC through delivery and testing. Most providers agreed that testing should occur after the mother has rested and had a chance to breastfeed her baby, but before her discharge from the hospital. Recognizing that providers have competing responsibilities, an ideal time window (i.e. within 72 h of birth) for POC testing, rather than a specific time (i.e. 2 h after birth) is most feasible and would reduce the potential for missed opportunities. Furthermore, while nearly all providers preferred birth POC testing to occur in the maternity department to minimize patient movement, there was some disagreement as to whether the labor ward or the postnatal ward would be preferable. Patient comfort and privacy need to be considered on a hospital by hospital basis to inform this decision. Figure 2 summarizes provider-driven guidance for implementation phase activities to enhance the patient experience with birth POC HIV testing.

Current WHO guidelines recommend initiating an infant with a positive virologic test on ART without delay and then confirming positivity [40]. A few providers discussed concerns regarding POC test validity, some sharing their perception that maternal HIV-specific antibodies might be detected in the infant's blood, apparently confusing the analytic mechanism with HIV rapid antibody tests. Providers with these concerns stated that they would not be comfortable initiating ART based on a POC test. In provider training it therefore will be important to include information on POC test validity and analytic mechanism (detection of HIV RNA or DNA, rather than antibodies) [15, 16]. Many providers emphasized the need to follow guidelines, demonstrating a high level of respect for and trust in established guidelines. Thus, as birth POC testing becomes more accessible in Kenya, new national guidelines for birth POC-driven EID would help alleviate provider concerns about ART initiation and confirmatory testing in response to a positive POC test result. Since birth testing only captures intrauterine transmission, guideline-adherent POC or PCR testing at 6-weeks will remain an essential follow up service to identify infants infected intrapartum or in early breastfeeding.

To our knowledge, this study is the first to report providers' perceptions of the barriers and facilitators to birth POC HIV testing implementation in LMICs. However, there are several limitations which should be noted. First, it represents providers from only four hospitals in Kenya. While we tried to select government hospitals with a range of resource levels, patient volumes, and geographic regions, these data may not be representative of all hospitals in Kenya. Consistent with our findings, variations in hospital configuration, staffing structure, workflow, and resource level may influence optimal implementation and need to be assessed prior to implementation of birth POC testing. Second, these data were collected prior to implementation to inform intervention development and may best reflect provider concerns at intervention start-up,

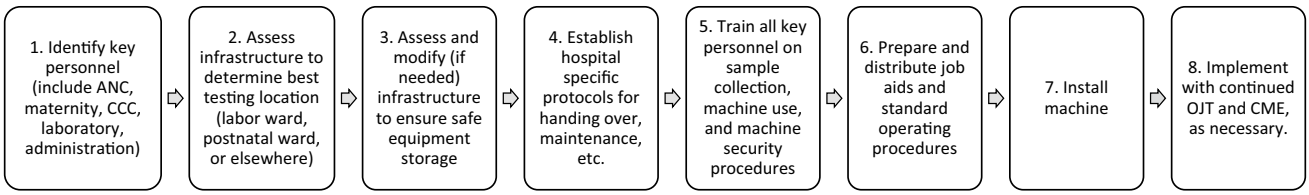

Fig. 1 Preparation phase: suggested sequence for birth POC preparation

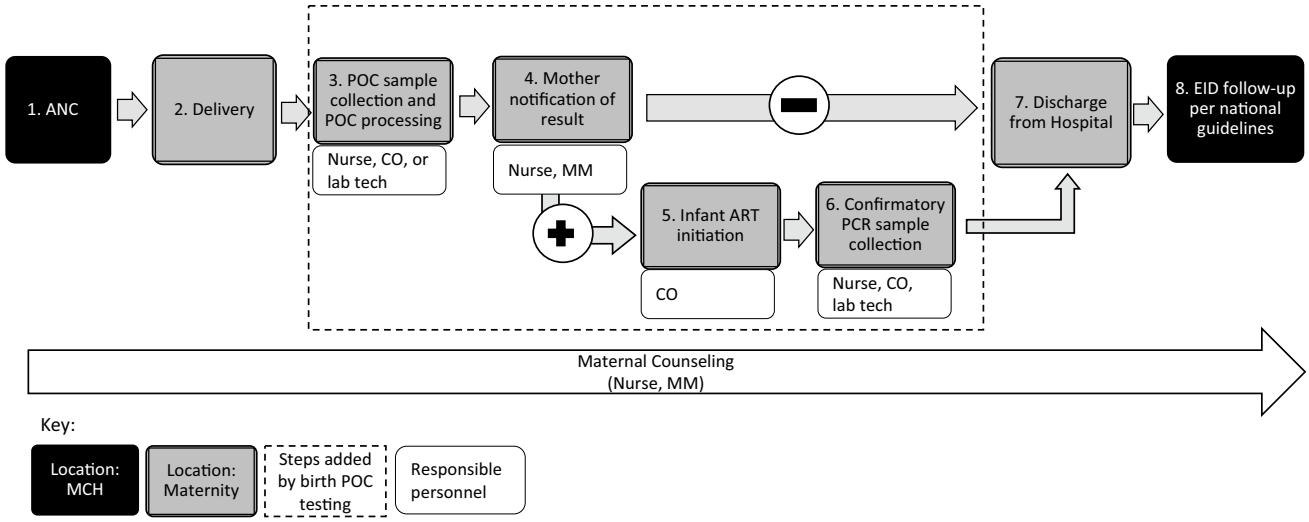

Fig. 2 Implementation phase: suggested steps for birth POC implementation

rather than considerations arising later in the implementation process. We are currently piloting GeneXpert HIV-1 Qual and Alere q HIV-1/2 Detect at study hospitals, and as part of the implementation are collecting qualitative data during routine provider meetings. These qualitative data will be used to sharpen and, perhaps, modify recommendations based on provider experiences throughout the intervention. Third, much of these data assume a hospital delivery. However, approximately 25% of HIV-positive women in Kenya do not deliver in a hospital setting [41]. Kenya defines birth testing as anytime within the first 2 weeks [11, 41]. As such, specific testing logistics recommendations are needed for women who present infants for birth POC testing within 2 weeks of delivery, outside of the maternity department, and also for infants engaging EID services upon admission to the hospital for illness. Furthermore, as 6-week virologic testing will still be required, data are needed on how to best incorporate POC testing into later testing time points. Data from pilot implementation will help inform such recommendations.

Conclusion

This study provides the most comprehensive analysis, to date, of provider recommendations for implementing birth POC testing. Providers' responses can provide a roadmap for key factors to consider when implementing birth POC testing in similar settings. With adequate planning, context-specific preparation, and inter-department coordination birth POC testing can be integrated into existing workflows and implementation decision-making.

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Compliance with Ethical Standards

Conflict of interest All authors declare that they have no conflicts of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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