Introduction

This module focuses on input area three, site enrollment, orientation, training and competency assessments, which includes three sub-inputs: (1) POC EID site enrollment; (2) orientation and training; and (3) competency assessments of POC EID instrument operators. For each sub-input, the module lists goals, activities, people or organizations involved, and resources needed to achieve World Health Organization (WHO)-recommended EID outcomes. It also summarizes lessons learned in terms of what worked well and what did not work well. Finally, the module provides recommendations and a list of guidance documents, tools, and references, which can be used to introduce or scale-up POC EID in a country.
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1. Site Enrollment for Point-of-Care Early Infant Diagnosis

1.1 Goal

What were the goals of site enrollment?
Across the project countries, the primary goals of site enrollment were to ensure a comprehensive onboarding and timely start-up of POC EID testing activities, and in particular to
- ensure that sub-national ministry of health (MOH) staff and site-level staff were aware of the requirements, timeline, and processes for introducing POC testing;
- complete site upgrades and provide necessary materials such as POC testing forms, standard operating procedures, and job aids for facility staff;
- (if a short-haul, hub-and-spoke network model will be used) review and finalize plans for sample transport and results communication between spoke sites and hub testing sites; and
- develop a schedule and materials for orientation and training of staff, instrument installation, and post-installation monitoring and supervision.

1.2 Activities and practices

What activities and practices were needed for successful site enrollment?
Site enrollment in the nine project countries included the following steps:
- Understanding the facility client workload
- Analysing current patient flow and work flows and, if needed, adapting them to accommodate POC testing
- Checking if patient and test volumes determined during site capacity assessments are still valid
- Analysing and defining the roles and responsibilities of staff in relation to POC testing and identifying at least two staff members at each testing site to take responsibility for operating the POC EID platform
- Identifying and appointing a designated POC EID focal person at each health care facility that will implement POC EID services
- Identifying which staff should undergo which types of training, including training in inventory management, blood sample collection, instrument operation, and results communication
- Planning for orientation and training sessions of clinic staff and instrument operators
- Completing site upgrades and sample transport plans, and providing materials such as testing forms, standard operating procedures, job aids, and sample collection and transport materials
- Prior to installing a POC EID platform at a testing site, completing the above-site orientation sessions with sub-national MOH staff, including sub-national lab managers
- Installing POC EID platforms at sites, completing orientation and training, and starting testing
- Planning for post-installation monitoring and follow-up

1.3 Key implementers and collaborators

Who were the key implementers and collaborators?
Discussions and decision-making for site enrollment took place with the full involvement of the key MOH departments. Sub-national health management teams (e.g. provincial, regional, district, county) and heads of health care facilities were involved in planning, awareness raising, and orientation prior to installing POC EID platforms at health care facilities. In some countries, the local representatives of POC EID manufacturers also were involved. Certified personnel, either provided or trained by the instrument manufacturers, installed POC EID platforms at health care facilities.

1.4 Resources (human, financial and material)

What resources were needed?
The main human resources required were implementing partners, such as EGPAF, and MOH staff at national, sub-national (e.g. provincial, regional, district, county) and health care facility level to complete the planning, site upgrades, orientation and training for each site. Where instruments were installed, certified personnel were also required for instrument installation.

The primary financial resources involved hiring of training venues, transport, accommodation, meals and expenses for visits to sub-national health offices and
laboratories, and health care facilities, for orientation and planning; and to develop and produce standard operating procedures, testing forms, job aids and training materials for health care facility staff.

Based on site capacity assessments (see Module 2), materials needed to complete upgrades were provided, such as cupboards for storage of equipment, chairs and work tables for POC instruments, desks or cabinets for filing paperwork, cooler boxes for transporting and storing blood samples, and locks and bars for windows and doors. In some cases, more extensive upgrades were needed, such as the installation of air conditioners and upgrading of plumbing and electricity for the spaces allocated for POC EID services.

An important tool, referred to by all key informants, was the EGPAF Guidance for Site Enrollment. In addition, a standardized overview presentation, provided by EGPAF HQ, was adapted and used in each country. Other training materials were produced that included exercises and case studies. These were adapted to conform to national EID training materials and gave an overview of the national POC EID program.

1.5 Results

What were the results of site enrollment?
The key results of site enrollment activities were:
• Managers, laboratory and health care facility staff at sub-national (e.g. province, district) and site level were informed and prepared for POC EID testing;
• All sites, both testing and spoke sites, had the infrastructure and materials needed to support POC testing (e.g. secure working space, storage cupboards, testing forms, SOPs, job aids, sample collection and transport materials);
• Orientation and training schedules and materials were prepared; and
• Site monitoring and supervision plans were in place.

1.6 Lessons learned

What worked really well?
All countries followed a phased site enrollment approach, whereby a limited number of sites were gradually enrolled over a two-year period. The approach ensured that sufficient human resources were available to support training as well as frequent monitoring, mentoring and trouble-shooting visits during the first two to four months after a site was enrolled. With lessons learned from these early experiences, phase in times may be accelerated, depending on available human resources for site enrolment and monitoring.

In addition to engaging sub-national health management teams and health care facility managers during the orientation and planning phase, laboratory heads from within health care facilities and/or nearby laboratories, and quality assurance focal points, were also involved, when possible. In several project countries, sub-national lab managers (e.g. provincial, region district, county) participated in POC EID trainings in order to prepare them to support site level trainings and quality assurance activities. Working with local health officials and laboratory professionals in general is a good practice to ensure the sustainability of POC EID by developing broad understanding, awareness and support.

Key informants reported the importance of identifying POC focal points at sub-national level (e.g. a provincial level POC focal point) and at each POC EID site, and assigning certain tasks to sub-national MOH officers. Where it was possible to identify an MOH site supervisor, they played a key role in the site enrollment process and took responsibility for mentoring and supportive supervision at the sites, ensuring that all POC EID procedures were followed in accordance with MOH policies.

In one country, key informants reported that they started by enrolling sites that were nearby the capital city, because it was considered advantageous to be close to the MOH, airport, customs clearance offices and medical warehouses in the early implementation phase. Once procedures and processes were mastered, the program was scaled up to other areas. This geographically-phased approach was reported as a good practice.

Finally, several country representatives suggested that activity reports of site visits are key to ensuring appropriate follow up and continuous quality improvement at each site.

What did not work well?
One country reported that planning became disrupted due to the unavailability of key stakeholders—sometimes due to impromptu activities at the MOH, for example. Another country reported that plans and timelines were frequently
disrupted due to irregular attendance of TWG meetings by key TWG members, and to the delayed arrival of POC instruments in the country.

1.7 Conclusions and recommendations

What recommendations can be made for those intending to adopt the documented activities and practices for site enrollment?

Key recommendations for site enrollment, and particularly for planning and orientation prior to site level training are:

• It is vital to work closely with the MOH at national and sub-national levels and to engage with national and sub-national laboratories to ensure their buy-in and support of POC EID testing. It also is important to involve key, non-governmental partners, such as implementing partners who support laboratory, supply chain, and pediatric HIV activities in the country.

• The planning phase should take into account the actual infrastructure, workflow, and capacity of the proposed testing sites. If needed, reorganize workflows and complete site upgrades to ensure health care facilities are prepared for POC testing. This can be done by completing capacity assessments and site improvement plans during the site selection phase (see Module 2).

• The transport of blood samples from spoke to hub testing sites should build on or use existing sample transport networks, whenever possible, in order to ensure that the system can be sustained. For example, in countries where Riders for Health already provide services, it would be important to explore if POC EID sample transport could be added to their scope of work.

• It is important to have all documents printed ahead (job aids, SOP, etc.).

• Clearly identify all local staff and their responsibilities.
2. Orientation and Training

2.1 Goals

What were the goals of orientation and training?
Key informants reported that the primary goal of orientation and training was to ensure that all staff involved in POC EID testing have the knowledge and skills needed to perform their roles. This includes tasks such as:
- Completing testing forms and patient records
- Blood sample collection
- Sample preparation for transport (if at a spoke site)
- Sample reception from spoke sites (if at a hub site)
- Sample transport (if at a spoke site)
- Sample receipt and preparation
- Operation of POC EID instruments
- Management of internal quality control failures and instrument breakdowns
- Results communication to spoke sites (if at a hub site)
- Results communication to caregivers
- Counselling and ARV treatment initiation
- Quality assurance
- Management of POC EID commodities and waste
- General safety measures when handling blood specimens

In addition to orienting and training POC platform operators and other relevant staff at health care facilities, orientation and training aims to prepare supervisors and national POC EID trainers to provide training, supervision, mentoring, and support for the health care facilities and their staff.

2.2 Activities and practices

What activities and practices were needed for successful orientation and training?
The main activities or practices reported that aimed to develop aware and competent staff were:
- Orienting all health facility staff who are directly or indirectly involved with pediatric and/or HIV care to POC EID;
- Analysing current roles and responsibilities of staff members;
- Identifying participants, noting their job description, to decide which staff should be trained on which topic area;
- Identifying and training facilitators to carry out the training, ensuring they are competent trainers who are identified and trained by certified trainers;
- Developing a training plan consisting of:
  - A schedule with dates of trainings to be communicated with the trainees and management of facilities to ensure their presence,
  - A list of materials needed for the training such as presentations, exercises, visual supports and all necessary medical equipment,
  - The training venue, verify there is power for the machine demonstration and ensure the room has adequate capacity to accommodate all participants,
  - Theoretical training as well as a practical assessment to check correct procedure;
- Using a checklist to verify all activities have been carried out and to support the trainings themselves;
- Training of targeted health care facility staff;
- Evaluating trainings and adjusting future training plans based on evaluation results, for example, allowing additional time;
- Installing POC EID instruments; and
- Starting POC EID testing services.

The training plan consists of initial trainings, follow-up and refresher trainings. A certificate of training and competence should be issued, in collaboration with the MOH or other relevant national authority. In some countries, the equipment manufacturer issued a certificate to participants who successfully completed the instrument operator training.

2.3 Key implementers and collaborators

Who were the key implementers and collaborators?
In some countries, MOH staff led the training activities. In other countries, EGPAF, as an implementing partner, led training activities in the early implementation phase and then recruited
talented staff from well-performing sites to carry out the scale-up, reinforcing their shared experience and expertise.

Typically, certified trainers provided by the POC EID manufacturer led the initial trainings of instrument operators and the training of trainers. After local trainers were trained and certified, they took on responsibility for future trainings.

Collaborators also included the MOH, the Global Fund, regional health care providers and implementing partners, such as EGPAF.

2.4 Resources (human, financial and material)

What resources were needed?

Human resources required included certified trainers from the manufacturers, or those who completed the training of trainers’ course, as well as other MOH staff, such as staff from the national quality assurance unit. In cases where the manufacturer provided staff to carry out trainings, they did not charge for this service and paid for their flights and accommodation.

In terms of financial resources, transportation, accommodations, and meals for any staff outside their regular work station, were required.

Tools and resources used include everything on the Training Materials Checklist such as the instrument and all it accessories, testing cartridges, powderless gloves, blood collection tubes, biohazard bags, sharps containers, sanitizers, request forms, paper and pens, a computer and a projector. Training modules consisted of PowerPoint presentations, printed materials and visual aids (see, for example: http://childrenandaids.org/node/990). The instrument operator manual contains detailed information on how the platform works, how to use it and how to run the tests. In some cases, this was condensed to a one-page quick reference guide which was posted on the wall by the machine.

Finances also were budgeted for printing or photocopying of training materials, and for the practical materials used in the trainings and required by the instrument being demonstrated. Some materials, such as the operator manual, were provided by the manufacturer, and others, such as the POC EID testing algorithm and blood sample collection job aid, were provided by the MOH and implementing partners, such as EGPAF.

Box 1: Orientation and trainings should be tailored to specific levels and roles

- Orientation of national and sub-national health managers, heads of health care facilities, and laboratory managers through specific orientation sessions or participation in actual trainings of health care workers in order to gain a general understanding of POC EID.

- Training of Trainers (TOT) who will train or supervise health care facility staff and POC EID instrument operators.

- Training of instrument operators in POC EID technology and how to process a POC EID test.

- Training of other relevant health care facility staff in tasks such as the updated prevention of mother-to-child HIV transmission (PMTCT) guidelines, adhering to the POC EID testing algorithm, completing testing forms and patient records, collecting blood samples, transporting blood samples to hub testing sites, communicating test results to caregivers, supervising and mentoring staff, and managing POC commodities, including maintaining an inventory, ordering supplies, and managing waste.
In addition, data collection tools were used, including attendance registers and transmittal sheets, which were then entered into an electronic data base to keep a record of trainings conducted and people trained.

Wherever possible, staff were trained at their own health facility in order to practice and learn how to manage site-specific challenges (e.g. electricity cuts). This also allowed staff who may work at other healthcare entry points, such as pediatric outpatient or inpatient clinics to attend and increase the likelihood that they will utilize POC EID testing. The on-site training venue can be considered as a resource, provided by the MOH.

2.5 Results

What were the results?
The concrete result of training activities was that training was successfully completed in all sites operating POC EID machines and that those operating the machines were able to perform the test successfully. In all countries, this goal was achieved. Clinical and supporting staff at sites knew about the services provided by the testing machine and operators were competent, with accurate test results being provided in a timely manner. Uptake of POC EID was achieved both in PMTCT settings as well as in other settings, such as pediatric outpatient clinics.

2.6 Lessons learned

What worked really well?
The best results were achieved when preparations for the training took place a minimum of one month before the training, and the introduction of POC was staggered at different sites over time.

TOT courses were held at the beginning of implementation with support to end-user training as the activities progressed. In several countries, sub-national managers (e.g. provincial, district) were trained as trainers to conduct instrument operator trainings as well as provide supervision to health care facility staff and support quality assurance activities.

Whenever possible, staff were trained at their own health facility, rather than taken off-site to a group-based training, as on-site training has proven to be more effective than off-site training. Hands-on experience was a good practice, rather than having theoretical sessions in a classroom. The combination of exercises and practical use of the POC instruments were found to reinforce the theory behind the training. Trainings for a single health care facility typically lasted from three to five days.

However, it is also more difficult and time consuming to organize and conduct on-site trainings for small groups of learners. For this reason, staff from several spoke sites, which shared the same POC testing hub were trained together, either at the hub site or other venue, in order to improve training efficiency and also create linkages and facilitate contact and communication between staff based in different health care facilities. Groups of four to ten people were brought together in a shared session at the hub testing site. It was reported that group learning improved understanding of the concept of turnaround time from blood sample collection to initiation on ART for HIV-infected infants; and provided an opportunity for staff from hub and spokes to discuss and anticipate possible challenges, and to put in place mechanisms to mitigate challenges before implementation began.

Another good practice was to train at least two staff from each testing facility as instrument operators. This helped to overcome frequent staff turnover by providing overlap of staff who were already performing POC EID testing with new staff, and allowing them to participate in and support the learning process of new staff members. Refresher trainings were held as and when necessary.

Assessments of trainees and evaluations of trainings were carried out to identify additional training requirements and needs. A key informant in one country reported that they held feedback sessions from participants to see if the training met their expectations.. Sometimes people felt they needed more time, but generally, the feedback was very positive and trainees found the POC platforms quite easy to use.

In order to have maximum participation, it is better to conduct onsite training in the afternoon, because health care workers are busy in the morning.

What did not work well?
Scheduling of trainings was a challenge for most countries. One scheduling consideration was the delayed arrival of instruments or other supplies in country, which delayed training. When trainings were conducted too far in advance of machine installation,
staff forgot what they had learned during the lag time. This required the organization of retraining and refresher courses at several sites. In one country, despite trainings being organized well in advance, some trainees were not available on the day of the training either due to them leaving their post as their contract was short term or poorly remunerated, or an emergency on the day, which prevented them from attending.

The training of trainers from supporting laboratories could also be more intensive. In fact, in one country, it is now mandatory for one to attend three trainings and supervision before that person can be considered a trainer.

Another issue identified was the absence of a continuing education program in case a staff member leaves and the successor needs to be trained. In some cases, the training of a new staff member was done by someone not qualified to do the training. Frequent staff turnover required the need for more than one instrument operator trained at each site, and for retraining, mentoring and refresher training.

2.7 Conclusions and recommendations

What recommendations can be made for those intending to adopt the documented activities and practices for orientation and training?

Those who complete the training of trainers’ course should be competent and must feel comfortable to lead future trainings.

In terms of planning and scheduling trainings, it is important to ensure that the machines are in-country before carrying out the training and to have on-site training whenever possible. At the beginning of the implementation, problems getting materials in-country can be challenging. By the time the platforms arrived in some countries, trainings were planned to happen the next week. Therefore, it is important to plan the training in anticipation of the materials being available.

For the training content, it is recommended to avoid being too theoretical and to include exercises and practical experience in a clinical setting, especially to ensure that new learners master key skills such as pipetting. It also is recommended to take the opportunity of the training to provide an update on PMTCT guidelines and the EID testing algorithm.

In addition, to allow time for people to share their experiences of the training and the new knowledge they have acquired. It is also recommended to have training materials in one of the national languages; for example, a Portuguese-language training kit was developed in Mozambique. In French-speaking countries, trainings were carried out in French, but some of the materials were in English.

Key recommendations are to train more than one staff to operate the instrument whenever possible and to follow-up on training immediately, possibly with a re-certification process. Field support should be made available for site visits and verification. In some cases this is possible through the machine manufacturer. One country advised that in order to assure the quality of testing, a pool of certified trainers should be developed to conduct ongoing trainings of instrument operators, including refresher trainings and training of new staff due to staff turnover. One country has already done this at the provincial level while another country is planning to train competent trainers at the closest laboratory to the POC EID facility. This is to ensure that if a staff member leaves, a local overseer of POC testing can immediately train new staff.
3. Competency Assessments of Instrument Operators

3.1 Goal

What were the goals of competency assessments?

Key informants reported that the goal of competency assessments was to systematically check the performance of POC EID instrument operators against a standardized checklist and provide feedback to instrument operators in order to ensure that patients and caregivers consistently receive accurate and timely test results. Competency assessments can be used by the MOH and partners as a valid approach to quality assurance within the national laboratory quality assurance strategy and plan. They are also an opportunity to create a register of all ‘certified’ instrument operators in the country.

3.2 Activities and practices

What activities and practices were needed for successful competency assessments?

Seven of the nine project countries conducted competency assessments of platform operators. After trainings or during site supervision visits, trained assessors observed instrument operators as they performed POC EID testing and noted their performance on a standardized checklist in order to ensure that all critical steps of the testing procedure were accurately performed. Additional notes were added to the checklist so that all observations on performance were captured. Before ending the assessment, evaluators provided feedback and mentoring to the instrument operator to support performance improvement. In some cases, evaluators may suggest additional training or a refresher training. The completed and signed checklist allows for documentation and archiving of the assessment.

The main practices observed during the competency assessment are:

1. Drawing blood
2. Receiving and checking the blood specimen (the specimen should be rejected if the blood is clotted or the transfer tube or testing cartridge is not properly labelled)
3. Cartridge preparation, including loading the blood sample into the cartridge with the correct volume
4. Starting and running the test, including start-up of the testing instrument and observation of:
   a. inserting the cartridge correctly,
   b. handling of the cartridge,
   c. closing the door, and
   d. removing the cartridge after the test
5. Interpreting and reporting results, including accurately completing the appropriate forms and registers
6. Instrument maintenance and power off
7. Stock management of reagents and consumables

3.3 Key implementers and collaborators

Who were the key implementers and collaborators?

In countries where competency assessments were conducted, the MOH, and in particular the quality assurance unit, took responsibility for conducting the assessments. Staff at the health care facilities and the machine manufacturers also collaborated in the activity.

3.4 Resources (human, financial and material)

What resources were needed?

Human resources for competency assessment visits include:

• Quality and Assurance Advisor from the MOH or other relevant national authority
• POC testing officer from MOH (in some countries two people were required)
• National pool of supervisors
• Implementing partners, such as EGPAF, to provide oversight and support

In addition to trained evaluators, competency assessment visits required funding for travel, accommodation, meals, and materials, including the competency assessment form (which is specific to each type of testing machine) and other tools and guidance documents.

In some countries, the results of competency assessments were entered into a digital document register, with a document number, and shared with other trainers and lab managers. In other countries, a pen and paper system was used, which could be transferred to an electronic system.
3.5 Results

What were the results of competency assessments?
Overall, results show that competency is good and the fail rate of platform operators is low. In cases where the instrument operator was graded as unsatisfactory, a supervised practical session was completed and a second assessment was scheduled. The additional training was intended to make the machine operator as comfortable and competent as possible. Reassessments carried out six-months after training demonstrated increased proficiency, including the pipetting procedure which requires hands-on practice. In most cases, zero IQC failures were reported after the reassessments, following which annual reassessments were put in place.

3.6 Lessons learned

What worked really well?
The competency assessment form was reported to work well. It is simple to use and comprehensive. It allows weaknesses in performance to be identified, to see patterns of behavior behind poor performance and to address problems pro-actively. Planning and collaboration between MOH and implementing partners, such as EGPAF, for competency assessments was reported to work well.

Documentation of competency assessments was remarked on as a key ingredient to success. A personnel file may be opened, where copies of competency assessments can be kept on record. Key activities or practices for others to adopt include documentation of training per tester.

What did not work well?
A major issue of competency assessment is the mobile workforce, a person may be trained and assessed, but if they are not present for the competency assessment it is necessary to start again. The sheer logistics of performing competency assessments while rolling out a program can be daunting.

One other thing to avoid is an insufficient number of capable assessors and an inadequate competency assessment database. It is not good enough to rely on a piece of paper. Rather it is recommended to keep a digital copy so the database is a live document that gives an accurate overview in real time.

3.7 Conclusions and recommendations

What recommendations can be made for those intending to adopt the documented activities and practices for competency assessments?
The goal of competency assessments is to ensure that each POC testing site has at least two competent instrument operators. POC testing should be consistent with laboratory standards, even though the instruments are frequently located outside of the lab. For this reason, the MOH and, in particular, laboratory quality insurance units, should be involved in competency assessments, which should contribute to a country’s overarching quality assurance approach for laboratory diagnostics.

Concerning the parameters of competency assessments, the checklists should be as simple to use as possible, but also comprehensive in order to cover all aspects of testing, including pre- and post-analytical procedures. The assessment also must be adapted and designed to be relevant to the type of test and testing platform. For example, GeneExpert TB tests require sputum samples and HIV tests require blood samples. Therefore, it is important to ensure the competency assessment checklist is appropriate to the task.

Finally, competency assessments can be used as an approach to ‘certify’ instrument operators, which can include a reassessment and recertification of each instrument operator on a regular basis, such as annually. Reassessments could be scheduled to coincide with the nearest routine site visit in order to limit costs to travel.
4. Guidance, Tools and References

Several of the following guidance, tools and references are available through the CHAI/ASLM/EGPAF/CDC/WHO/Unitaid, HIV Point-of-Care Diagnostics Toolkit, available at: http://www.childrenandaids.org/poc-toolkit-page

4.1 Guidance


4.2 Tools


9. POC EID Manufacturers. Training materials, instrument trouble shooting and maintenance, instrument operator manuals, and job aids. These materials should be requested directly from the manufacturer (e.g. Abbot, Cepheid, etc).


4.3 References

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