Although point-of-care (POC) testing is widely considered a good idea, there is little agreement on what exactly it entails. While regulatory agencies such as the U.S. Food and Drug Administration (FDA) categorize tests based on criteria such as complexity and Clinical Laboratory Improvement Amendments (CLIA) waivers, the choice of criteria becomes vastly more complex when moving from issues concerning national to global health diagnostics.

In the global health context, the dominant viewpoint is that POC tests must meet several “ASSURED” criteria—that is, they need to be affordable, sensitive, specific, user friendly, rapid and robust, equipment-free, and deliverable. This dominant definition of POC testing thus is product-oriented, and it restricts POC testing to a particular class of products: those that are inexpensive, simple, rapid (such as widely used pregnancy tests), and which health workers can use while working in the community. From this perspective, any test that needs to be conducted in a laboratory is not a POC test—creating a dichotomy between the two.

We believe that this paradigm needs to be re-examined and, in doing so, propose an explicitly goal-oriented redefinition for POC testing, particularly applicable to resource-limited settings. On the basis that the rapid initiation of correct treatment is the most critical goal of any POC testing, we reverse engineered an alternative definition: POC testing is diagnostic testing that will result in a clear and actionable management decision such as when to start treatment or require a confirmatory test, within the same clinical encounter.

Why do we put rapid clinical decisions and beginning of treatment at the heart of our definition? Quite simply, correct and timely treatment saves lives, reduces morbidity, and reduces transmission. Thus, the impact of a POC test comes from implementing effective treatments rather than from the test itself. Thus, moving rapidly through the test-and-treat cycle in the same clinical encounter is the most important goal for any POC testing program. Needless to say, this goal is what patients want—to be rapidly diagnosed and put quickly on the right treatment. Unlike the conventional, product-oriented definition, our goal-oriented definition for POC testing is agnostic to issues such as cost, how the test or technological platform looks, size of the product, where exactly it is performed, and who performs it.

Thus, we argue that POC testing is not defined by technology but by the successful use of a technology at the point of care to make rapid decisions. The focus must be on POC testing programs or strategies rather than technologies.

**SUMMARY**

- In general, point-of-care (POC) testing refers to diagnostic products that are simple, low cost, and performed outside laboratories. This is a product-centric view of POC testing.
- We recommend redefining POC testing to make it goal-oriented, explicitly making the rapid initiation of correct treatment the most critical goal of any POC test.
- Unlike the standard definition, which creates a rigid dichotomy between POC versus laboratory tests, we suggest that POC testing should be viewed as a spectrum: of technologies (simplest to more sophisticated), users (lay persons to highly trained), and settings (homes, communities, clinics, peripheral laboratories, and hospitals).
- POC testing is not defined by technology but by the diagnostic process, making it important to think in terms of testing programs or strategies that lead to the rapid completion of the test-and-treat cycle.
- Health care systems interested in POC testing programs need to do more than purchase rapid tests; they also need to build systems for rapidly communicating test results and beginning appropriate treatments.
Tests or a Testing Program and Strategy?

A health care system can choose to implement a rapid test as a POC testing program or not. To introduce a test as part of a POC testing program, several elements need to be put in place, including systems for rapid communication of test results to patients and care providers, for rapid initiation of treatments, and to ensure appropriate follow-up of patients. The test itself is only one component of an overall POC testing program that might prove relatively costly to implement, even if some of the rapid tests within it are inexpensive.

Regardless of which technology is used, where, and by whom, the most critical elements of POC testing are rapid turnaround and communication of results to guide clinical decisions and completion of testing and follow-up action in the same clinical encounter, or at least the same day. Thus, systems for rapid reporting of test results to care providers and implementing a mechanism to link test results to appropriate counseling and treatment are as important as the technology itself. If systems for reporting the results and follow-up care, such as prescribing specific drugs to administer to a patient, are not in place, then POC testing is unlikely to have an important impact on clinical or public health outcomes.

The mere availability of rapid or simple tests does not ensure their use in POC testing programs. Various barriers prevent the successful implementation of POC testing programs, including economic, regulatory, and policy-related issues, as well as user/provider perceptions and cultural barriers. It is also important that POC testing fit within real-world workflow patterns, as well as economic and social structures. These requirements mean that POC testing programs will need viable business models to ensure that they are sustainable and will be used to make rapid treatment decisions.

Many test developers seem to consider the physical size of a technology to be a critical element of POC testing. While a small device or one that can work without a specialized instrument will certainly help, the size of the technology by itself is not a critical consideration for POC testing programs. If deployed well, even a microscope can be successfully used in POC testing programs. Although a lab-on-a-chip may be tiny, it might require a mass spectrometer to complete the analysis! Thus, it is not the size of a test that defines a technology as POC testing, but how it is implemented.

Similarly, while low cost will certainly help to increase the uptake of POC tests in resource-limited countries, cost is not an intrinsic characteristic of a POC test. Some tests such as solid cultures for *Mycobacterium tuberculosis* are inexpensive to conduct, but their low cost does not mean that they can be used in POC testing programs. On the other hand, some technologies such as handheld ultrasound devices or automated molecular tests such as the GeneXpert® technology being marketed by Cepheid Inc. of Sunnyvale, Calif., are expensive, but they can be and are being used effectively in POC testing programs. Another reason why cost should not be used to define POC testing is the fact that initiatives such as donor-led price buy down, advance market commitments, and volume-based discounts make cost an elastic concept. Willingness to pay is also elastic, and there is no easy way to separate low-cost from expensive products. While it is critical to make tests affordable, we believe cost should not be confused with the concept of POC testing.

Dichotomy or a Spectrum?

Unlike the standard definition which creates a false dichotomy between POC versus laboratory tests, we argue that POC testing should be viewed as involving several components, including technologies that range from simplest to more sophisticated, users including lay persons to highly trained workers, and settings including homes, communities, clinics, peripheral laboratories, and hospitals (Fig. 1). As illustrated, POC testing is happening in diverse settings, ranging from homes to hospitals.

In this broad framework, the use of rapid tests in the community by front-line health workers is only one of several types of POC testing. A good example of this is the use of malaria rapid diagnostic tests by community health workers in Africa. Other examples are in-home pregnancy tests and oral fluid HIV self-tests. Here, the goal is self-assessment and linkages to care. Such tests, whether done at home or in the community, need to be very simple, preferably instrument-free (although small devices such as glucometers show that even this restriction may not be necessary), and should involve very few steps.
interpretation should be very simple and straightforward, and the requirement for training should be minimal.

At the other end of the spectrum, POC testing programs are being implemented within hospitals. For example, labor ward nurses in hospitals are using rapid, oral-fluid HIV tests to determine when to provide antiretroviral therapy to reduce the risk of mother-to-child transmission of this virus. Emergency room doctors are rapidly diagnosing and treating ectopic pregnancy and abdominal trauma using handheld ultrasound devices. Rapid tests are also being used in intensive care units to make timely decisions on patient treatments. At this level of the health care delivery system, tests do not need to be instrument-free or inexpensive, and users are often well trained. Fairly sophisticated technologies can be and are being used to achieve rapid results that can inform clinical decisions.

While the traditional definition of POC testing does not include laboratories, our framework acknowledges the important role that peripheral laboratories have in POC testing programs. In most developing countries, there are large numbers of primary health centers with small, attached microscopy laboratories that typically are run by laboratory technicians with minimal training. These peripheral laboratories have limited resources, but can perform simple microscopy tests such as malaria and sputum smears, lateral flow assays, and basic tests such as hemoglobin, urine sugar, albumin, and Gram stains (Fig. 2). Patients who visit these primary health centers typically are asked to wait for a few hours before being sent home on the correct treatment. As long as the test-and-treat cycle is completed in the same visit, we consider these to be excellent examples of POC testing.

**Diversity of Target Product Profiles**

The diversity of settings, users, and technologies suggests that restricting product characteristics makes a lot of sense once a decision is made to limit a test to a particular setting or context. In other words, every POC test does not need to meet the same target product profile (TPP) such as:

- **Simplicity**
  - User: Lay person
  - Device: RDT (pregnancy-type) or dipstick
  - Purpose: Self assessment and referral
  - Examples: HIV self-testing

- **Basic**
  - User: Minimally trained health worker
  - Device: RDT, dipsticks, mobile phone-based
  - Purpose: Triage and referral
  - Examples: Malaria, HIV, dengue

- **Intermediate**
  - User: Clinical staff
  - Device: RDT, handheld instruments
  - Purpose: Diagnosis and treatment
  - Examples: HIV, malaria, syphilis, dengue, Strep A

- **Sophisticated**
  - User: Lab tech
  - Device: RDT, microscopy, handheld devices, etc.
  - Purpose: Diagnosis treatment monitoring
  - Examples: Sputum microscopy, malaria smears and RDTs, POC CD4 counts, etc.

- **In-patients**
  - User: Hospital staff
  - Device: RDT, molecular, smears, etc.
  - Purpose: Diagnosis treatment monitoring
  - Examples: TB, HIV, malaria, HCV, flu, CD4, Strep A, viral load, etc.

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**FIGURE 1**

The spectrum of point-of-care testing. (Adapted from N. P. Pai et al., PLoS Med. 9(9)e1001306, 2012; copyright held by the authors under Creative Commons license.)
as the ASSURED criteria, for example. While a technology designed for laboratories and hospitals (right side of the spectrum, Fig. 1) is unlikely to work in community or home-based settings, the reverse is quite possible. For example, the OraQuick In-Home, which is marketed by OraSure Technologies Inc. of Bethlehem, Pa., rapid test for HIV is being used in the full range of settings from home to hospital.

All TPPs, ideally, should include sufficient information on the intended purpose of the test, the setting, and likely users. TPPs could also provide guidance to product developers on the desired cost, based on public health needs in resource-limited settings. Indeed, such TPPs have been developed for HIV and TB diagnostics.

Conclusion

By framing POC testing as a goal-oriented spectrum of activities while de-emphasizing the restrictive, product-centric view, we believe our approach is more inclusive, more reflective of reality, and will allow more industries and test developers to develop a range of products that may be amenable for use in POC testing programs.

For example, several companies are developing robust, automated, molecular assays for tuberculosis that are potentially deployable in microscopy centers. Such devices are already being used for POC CD4 testing of individuals with HIV infections, and will also be available for viral load testing. These simple, battery-operated devices do not require sophisticated, centralized laboratories, and can help doctors make rapid decisions in community care settings. A traditional definition of POC testing would exclude these examples as they are neither inexpensive nor instrument-free, whereas a goal-oriented definition would include these devices based on how well they fit within the diagnostic process.

Lastly, we believe that an approach that focuses on rapid treatment decisions as the goal is closer to what all patients want from their care providers, and might inspire health care systems and donors to think beyond just procuring rapid tests and ensure that these testing technologies...
are implemented as POC testing programs. Only then will we see the true impact of POC testing.

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Suggested Reading


Pai, M. 2013. Point of care (POC) testing for infectious diseases: diversity, complexity, and barriers in developing countries. Invited lecture at 2013 CEND Symposium at the University of California, Berkeley. Video available at http://www.youtube.com/watch?v=SqASU6uChOo


