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Compounding diagnostic delays: a qualitative study of point-of-care testing in South Africa

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Abstract

Objectives: Successful point-of-care (POC) testing (completion of test and treat cycle in one patient encounter) has immense potential to reduce diagnostic and treatment delays, and improve patient and public health outcomes. We explored what tests are done and how in public/private, rural/urban hospitals and clinics in South Africa and whether they can ensure successful POC testing.

Methods: This qualitative research study examined POC testing across major diseases in Cape Town, Durban and Eastern Cape. We conducted 101 semi-structured interviews and 7 focus group discussions with doctors, nurses, community health workers, patients, lab technicians, policymakers, hospital managers and diagnostic manufacturers.

Results: In South Africa diagnostics are characterized by a centralized system. Most tests conducted on the spot can be made to work successfully as POC tests. The majority of public/private clinics and smaller hospitals send samples via couriers to centralized labs and retrieve results back the same way, via internet, fax, or phone. The main challenge to POC testing lies in transporting samples and results, while delays risk patient loss from diagnostic/treatment pathways. Strategies to deal with

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associated delays create new problems, such as artificially prolonged turn-around-times, strains on human resources and quality of testing, compounding additional diagnostic and treatment delays.

Conclusions: For POC testing to succeed, particular characteristics of diagnostic eco-systems and adaptations of professional practices to overcome associated challenges must be taken into account.

Keywords: point-of-care testing; South Africa; qualitative; diagnostic delay

Introduction

Global health experts agree that point-of-care (POC) tests have immense potential to reduce delays in diagnosing and initiating treatment for diseases like tuberculosis (TB) (1-3), HIV (4, 5), syphilis (6) and malaria (7). POC tests allow completion of test-and-treat cycles in one patient encounter (e.g. ensuring a POC continuum) with minimal user and maintenance requirements and improve patient and public health outcomes.

However, the mere availability of rapid or simple tests does not automatically ensure their scale-up as a successful POC test. Instead, we have argued earlier, that it matters how tests are employed in POC testing programs and that a range of barriers may prevent successful uptake (8). In South Africa, especially decentralized HIV (with rapid tests) and TB testing (with Xpert MTB/RIF) have gained immense political attention in recent years and offer important lessons for POC testing programs (9-13).

Most articles on POC testing focus on accuracy, cost-effectiveness, feasibility, and acceptability related to one specific disease in one specific setting (3, 14-20). Exceptions to the single-disease focus are studies on combined testing strategies for sexually transmitted infection (STI) syndromes, including HIV and syphilis tests (6, 21). However, testing needs to fit into a variety of daily work flow and care processes. Patients present at different levels of care (in clinics, health posts, labs or hospitals) with multiple or unspecific symptoms (e.g. acute febrile illness), and may need several diagnostic tests.

In order to successfully develop, validate, and scale-up diagnostics that work in such complex and dynamic settings, more research on diagnostic practices on the ground across different health-care settings and diseases is needed. Yet, to our knowledge, such studies are currently limited.

Qualitative and survey-based studies have examined clinicians' attitudes towards POC testing (17, 22, 23), patients' treatment seeking behavior (24-26) and how material dimensions (including the test platform, reagents and supplies), the actors involved, their relations and the socio-cultural context in which testing is happening are interlinked (7, 27-29). Calls have been made for more operational research into health system requirements and impact of technologies on diagnostic delays (30, 31).

Factors causing diagnostic delay have been researched particularly for TB and HIV and are commonly distinguished as patient and health system related. Most studies are single-disease focused and employ survey based methodologies (32-34), qualitative studies of patient pathways to diagnosis (f.i. 24, 25, 26, 35-37) or medical records, including laboratory and treatment registers (38, 39). Factors associated with patient delay are socio-economic factors (f.i. gender, education) (37) and stigma (35). Factors associated with health system delay are multiple visits to traditional/private providers, cost, logistics and travel time to health services (34, 37, 40), as well as poor (weak referral links, poor diagnostic performance) (33) or insufficiently decentralized public services (37, 38, 41).

We identified no previous studies that examined how tests are used at POC across different diseases, taking into account perspectives of both patients and providers, and examining the actual testing process in terms of completing the test and treat-cycle that is so important for successful POC testing.

The overall aim of this study was to examine POC testing across major diseases in South Africa contributing to burden of disease (mainly HIV, TB, diabetes mellitus, diarrheal diseases and hypertension). We assessed what tests are done and how in public/private, rural/urban hospitals and clinics and whether they can ensure successful POC testing. The results have implications for development of new POC testing programmes.

Methodology

Study design, data collection and participants

Data were collected as part of a qualitative research project on barriers to POC testing between September 2012 and June 2013 in two South African urban settings (Durban and Cape Town) and a rural setting (Eastern Cape). The data collection included 101 semi-structured interviews with doctors, nurses, community health workers, patients, lab technicians, policymakers, hospital managers and diagnostic manufacturers. Participants were purposively sampled to represent the settings of hospi-

tals, peripheral labs, clinics, communities and homes in the public/private sector and rural/urban setting (table 1). We conducted 7 focus group discussions (FGDs) with TB patients, nurses and community health workers, all of which were selected on a convenience basis to represent different perspectives. The total number of FGD participants was 40, with a median group size of 5.7.

In this paper, we focused the analysis on testing and barriers to POC testing conducted in hospital and clinic settings. Data were collected jointly by NE and MD. The topics explored included diagnostic processes for the major diseases per setting and challenges therein, understanding of diagnosis, and visions of an ideal test. The semi-structured interviews allowed a flexible and responsive approach and specifically examined diagnostic steps for each major disease occurring in the setting in great detail; from ordering a test to acting on a result, including available material and capacities, TATs, and referral processes. The FGDs focused exclusively on challenges experienced when diagnosing. Interview and FGD guides were piloted and revised during the fieldwork to improve clarity of questions. All interviews and discussions were held in English and digitally recorded, and the note taker wrote down main points raised, non-verbal communication and setting characteristics.

Data analysis

Audio files and notes were transcribed and cross-checked. Data analysis was done using Nvivo9 (QSR International). We devised a coding scheme and coded the material, further grouping material into emerging topics in an iterative manner using thematic analysis (42-44). The analysis is based on writing thick descriptions of diagnostic practices per setting and disease and examining patterns and linkages between emerging themes and codes across settings, actors and diseases. Professional roles are used to mask study participants' identity (see table 1 for interview and FGD codes).

Ethics

The ethics review boards of the University of Cape Town, South Africa and McGill University Health Centre, Montreal, Canada approved this study. Approvals for interviews and discussions conducted at public healthcare facilities were sought from the Provincial Department of Health authorities as necessary. All participants were provided with information sheets explaining the objectives of the study and all signed informed consent forms prior to participation.

Results

POC testing in clinics and hospitals

The South African diagnostic landscape is characterized by a centralized system. This means that the majority of public and private clinics and some smaller hospitals send their sample to a centralized lab for testing via couriers and retrieve results back the same way or via internet, fax, or phone. The National Health Laboratory Services (NHLS) conducts all lab testing for the public sector, while private clinics and hospitals use one of the large private lab chains.

Centralized testing in the public sector is a political/economic choice to save costs by allocating equipment to a few central locations (45). Making changes to this centralized system is impeded by politics, human resource shortages and cost implications. According to several of our interviewees there are reasons to maintain centralization because it is cheaper than peripheral testing in terms of staffing and equipment (HD4; LT2; NGO5; NHLS1; SID1; LM1, 2). According to NHLS staff, a centralized model is preferred if the road network allows. It fits the existing organizational structure of NHLS, while public clinics are struggling with staff shortages, limited staff capacities and stock outs (LM1, 2; NHLS 1; SID1).

Nonetheless, we found a few tests that are being done outside labs in clinics and hospital wards (Table 2), while the rest are done in labs. Prominent exceptions to the centralization of testing are HIV testing, conducted with rapid tests by community health workers, and TB testing with Xpert MTB/RIF, a molecular test promising results in 90min, that is being implemented in selected clinics at POC (while the majority of Xpert machines have been placed in centralized NHLS labs (41)).

In public clinics, the limited number of tests conducted on the spot can ensure a POC continuum with available results in one patient encounter, except the Xpert MTB/RIF. The results of basic screening tests (blood pressure, weight, glucose, rapid HB and urine dipstick) and the HIV rapid tests that are directly conducted in the clinic are available immediately and doctors or nurses act on the result. Despite availability of HIV rapid tests, actual treatment initiation for HIV happens only 4-7 days after initial diagnosis and 3-4 days after a low CD4 count was diagnosed, because of follow-up tests and counseling sessions (which is still faster than in hospitals, see below) (CN9).

In those few public clinics that have a Xpert MTB/RIF onsite to test TB, the TAT is usually 24-hours and not 90min as the device promises, due to the large amount of samples the clinic runs daily (LM4; SC1). A NHLS consultant highlights that not only were 2.5 additional nurses needed to conduct

the test in clinics (9), the machine also lies idle at night and the promise to have results available within one encounter does not translate to same-day decisions in clinical practice (NHLS 1).

For tests that are sent to a centralized lab, no same day results are possible in public clinics (even those clinics with access to the electronic lab system can only access results after 24 hours or more), due to reasons discussed in the next section (PCD2; PHM2).

In private clinics, the POC continuum is ensured for tests that are conducted on the spot. For those samples that are sent to labs, results are usually available the next day. If a sample is marked 'urgent', then results are available after a few hours and the doctor calls the patient with the results (PP1; 7-9).

In public hospitals, results for tests conducted in the wards or outpatient department (OPD) are usually available immediately and patients are seen by doctors or nurses the same day. However, a lack of human resources can lead to delays. For instance, the triage station of a rural hospital where several rapid tests are conducted (urine dipstick, pregnancy, blood pressure, weight, and temperature) sees approximately 80-100 patients per day and struggles with lack of equipment (PHN3). Due to the high patient load, triaging delays patients from entering the OPD and having samples taken for additional tests, resulting in an overall delay to wait for results and see a doctor (PHD1).

In cases where follow-up tests are needed, treatment initiation can be delayed depending on the TATs of these tests. For example: If a patient is tested HIV positive, the patient is referred to a CD4 count with cytometry assay from the in-house lab with a TAT of 24-48 hours (PCD2; LM4). If the CD4 count is less than 350 the patient will undergo testing for urea, electrolytes and liver function, which takes another one to two days in addition to five adherence counselling sessions. ARV treatment is initiated during the monthly or biweekly ARV days (PHD2). Thus, even though patients are diagnosed as HIV-infected within one clinical encounter, treatment initiation often only starts one month after initial diagnosis.

The POC continuum in public hospitals for tests using the hospital lab can only be ensured if samples are sent in the morning and patients can wait until the evening (PN7) or if patients can sleep over, which is common in rural hospitals (f.i. HM3; PHD1, 3; LM4; PHN2). TB tests take particularly long. In the emergency unit of an urban hospital, the Xpert MTB/RIF results take 24 hours. Unless

the doctors admit patients, he/she would refer patients for TB tests to their local clinics with a referral letter (HM1). Yet, there is no follow-up system to ensure that patients attend local clinics. In an urban hospital that has no onsite lab, TATs for sputum can take up to two weeks with major consequences for treatment initiation, loss to follow up and risk of transmission (PN5).

These delays in diagnosing and initiating treatment in clinics and hospitals cause disruptions to the POC continuum and risk patient loss from diagnostic/treatment pathways. Cost and distance might deter patients from coming back; they might develop advanced stages of disease which spread within communities and are much more difficult to diagnose and treat; or they might seek care in other clinics/hospitals in the hope for faster results. The latter results in higher workloads for certain clinics, unnecessary repeat testing and a high potential of loss to follow-up, as patients become non-traceable when they need to give wrong addresses in order to be eligible for clinics farther away (121003_SCNHLS1_CT)).

Responding to the challenges of centralized testing

The centralization of most testing means professionals and patients rely on samples reaching labs safely and reports being returned in a timely manner to avoid diagnostic delays. Yet, challenges with precisely this requirement were reported to us across all hospitals, labs and clinics and range from: Poor sample quality because of leaking samples, incorrect packaging or testing tubes, transport damages, insufficient sample volumes (f.i. sputum) and incomplete/incorrect request forms (LM1, 2, 5, 6; M1).

Transport challenges, such as long distances, poor road conditions, worker strikes, bad weather, or shortages of messengers between labs and hospital wards, can result in lost or delayed samples (LM1, 2, 4). In addition, in some clinics, lab results are not filed into patient folders but piled up in corners, lost due to misspelled names, or delayed due to breakdowns of computer systems to access result (HD1; HM3; SN1; LM1, 2, 4; NGO1; PHD1, 5; M1, 3; LT1).

This means that TATs for tests conducted within labs are being prolonged due to the challenges in interacting between clinics/hospital wards and labs. This delay in lab-based testing has further consequences for the diagnostic practices of professionals: In order to ensure that results are available, nurses usually tell patients to come back within a week for results that are expected to be available within two or three days (PCN4; PHM1; PCD2; CHW 2, 3).

"I came to realize (...) that we are constantly telling the patients, okay give us the specimens and come back tomorrow or come back in two days or why don't you come back next week, because for sure [sic!] that the results will be here. That's how we translate in reality."(PHM1)

"...so we try and get [HIV] patients back within a few days of doing the blood tests, (...) within 2-3 days. Simply because I can check the results on my computer or on the phone, you know, and I'll have access to it... the nurses for example if they do simple CD4's and viral loads, as a routine management, and creatinines, they only get patients back after a month or so (...) it doesn't take a month to get the result, but it takes the patient a month to know the result, because patients are brought back in a month" (PCD2)

With this strategy, the providers are preemptively taking into account prolonged TATs due to challenges in transporting samples to labs and results back timely. The implications are that actual TATs are further prolonged.

Apart from telling patients to come back later for results, professionals apply other strategies to overcome challenges in interacting with labs; those result in yet additional delays and put strain on workloads, manpower and patient interaction. Nurses or doctors call labs for patient results and disrupt (and further delay) the laboratory works (in both rural and urban setting) (HD1, 4; PHD3; LM1, 2, 4; HM3). With time, overworked lab technicians, who constantly get disrupted in their lab work by phone calls from clinics, stop answering the phone; causing great frustration to doctors (SC2; LM4).

To counteract this, private labs have established call centers for communication with their clients. Some professionals go beyond their responsibilities to avoid delays: Hospital doctors and nurses go to the lab themselves to fetch missing reports resulting in less time for patient interaction (PHD3) and leaving work in the ward (PHN4).

"It's a little bit frustrating for that doctor [at the clinic] getting the results, because the computer system doesn't always work (...) because the blood and the test is done here [hospital lab] and then he [the doctor] needs to try and access the result at the clinic, so... they do it but sometimes it doesn't work.(...) not all the clinics have good Internet or signal.

INT: And then you have to do what?

They either SMS one of us to try and go down to the lab or try phoning the lab, yeah, a little bit frustrating. Sometimes it's fine but sometimes it's very time-consuming. If you trying to see 50 or 60 patients a day, you don't have time to sit on the phone for half an hour or an hour..." (PHD1)

Some rural hospital doctors drive reports to clinics as their 4x wheel drive cars manage poor roads in bad weather conditions better than the smaller courier cars, yet put a strain on manpower availability (HM3; LM4).

Discussion and Conclusions

This is the first study that maps POC testing across different diseases in clinics and hospitals in South Africa, revealing challenges for POC testing programs. Our results show that much of the testing in South Africa occurs via centralized lab services, and rapid clinical decisions are challenging in this context.

However, when tests are conducted on the spot in clinics and hospital wards (with sufficient manpower and equipment), test result-based management decisions (treatment, referral, follow-up testing) are being made in one patient encounter and POC continuums can be ensured. The exception is Xpert MTB/RIF that cannot be made to work in one encounter, because results are only available after 24 hours due to backlogs and manpower requirements, confirming previous findings (9). If samples have to be sent to a peripheral lab (clinic) or in-house lab (hospital) no results are available within one patient encounter, unless for patients in hospitals who are able to wait until the evening or sleep-over. Delays risk patient loss from diagnostic/treatment pathways. Previous studies have shown high rates of loss to follow-up during f.i. centralized TB testing in South Africa (and elsewhere) (38, 39).

These results justify the current hope in POC testing to cut (health system) delays in diagnosis (1, 4, 6). Yet, the experiences with Xpert MTB/RIF also show how essential it is that tests fit into workflows and human resource capacities at POC. If manpower is insufficient and workload too high, delays deter the POC continuum. Also, it matters how tests are embedded in follow-up testing schedules; additional testing with long TATs can again delay treatment initiation. These factors are absent in the current literature on health system delays in diagnosing TB and HIV.

The main challenge to POC testing in South Africa lies in transporting samples and results in-between clinics/hospitals and labs. Recent studies from South Africa have shown that even with the introduction of rapid molecular tests for drug resistant TB, treatment delays due to centralized lab testing continue to be lengthy (46), including inefficiencies in sample transportation, lab processing time, accessing results and recalling patients (13, 41, 47). Thus, there is a gap between the promise of rapid tests, and the real-world pathways for patients to get appropriate therapy.

We show how the strategies to circumvent these challenges and delays in lab-based testing create new problems, such as artificially prolonged turn-around-times, strains on manpower, workload and quality of testing, compounding additional diagnostic and treatment delays. These results have implications for how tests fit into workflows, interaction between professionals and their roles, and quality of testing.

These findings add to the literature on diagnostic delay which is largely single-disease focused, and often limits itself to medical records or surveys and interviews with patients, excluding diagnostic processes. With our focus on diagnostic processes across multiple diseases, healthcare providers and patients at the POC, we are able to show how patient and health system delays interact. Professionals responding to anticipated health system delay (in South Africa mainly caused by centralized testing) create further delays to avoid additional patient delays.

Another way providers may be responding to dysfunctional health systems is to provide empiric treatment, without waiting for lab results, as was found in a South African trial on Xpert MTB/RIF (11). The authors discussed how empiric treatment is often same-day and might still be predominant in high-burden settings, even after implementation of new tests.

Artificially prolonged TATs also mean that in this setting TATs are not necessarily a good indicator of whether a test is working and/or fits the POC. This finding shows the importance of conducting operational research into health system requirements and impact of technologies on diagnostic cycles and delays to evaluate new diagnostic technology (30, 31). While the situation might be different in countries with more peripheral testing, our results highlight the urgent need to pay attention to particular characteristics of diagnostic eco-systems and how professionals adapt their practices to overcome challenges associated to those conditions.

In summary, our results provide insights into challenges when developing and implementing new POC tests in the South African context and how strategies of professional's to circumvent these challenges create additional diagnostic delays, defeating the purpose of POC testing.

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Table 1. Participant overview per setting

Setting	Type of participant	No. of interviewed participants (interview code)				Total interviews	No. of FGDs (FGD code)
		Urban Public	Urban Private	Rural Public	Rural Private		
HOME	TB patients (TB) and diabetic patients (DP), HIV patient (HIV), general OPD patients (OPD)	DP#1, OPD#1, 2, TB#1	0	DP#2,3, HIV#1	0	7	FGD#1_TB, FGD#7_TB
COMMUNITY	Community Health Worker (CHW); NGO TB coordinator (NGO), NGO nurse (NN)	CHW#1, 2, 3, 6, 7, 8, 9, 10, 11, NGO#1, 4,5 NN#1, 2,	0	CHW#4, 5, NGO#2, 3	0	18	FGD#2_CHW, FGD#3_CHW, FGD#4_CHW, FGD#6_CHW
CLINIC	Private practitioner (PP); clinic nurse (CN), clinic doctor (CD), Public clinic manager (PCM), Faith healthers (FH)	CD#1, 2, CN#1, 2, 3, 7, 8, 9, PCM#1, 2, 3,4, 5 , FH#1	PP#1, 2, 3, 4, 7, 8, 9	CN#4, 5, 6, FH#1	PP#5, 6	27	FGD#5_nurses
PERIPHERAL LAB (stand-alone)	Lab technician (LT); Lab manager (LM); NHLS consultants (NHLS), microbiologist (M)	NHLS#1, 2, LT#1,2, LM#1,2, 9, M#3	M#2, LM#8, 10	M#1, LM#6, 7	0	14	
PERIPHERAL LAB (attached to clinic)	Lab technician (LT); Lab Manager (LM);	LM#3	0	LM#4, 5	0	3	

HOSPITAL	Specialist molecular biology (SMB), -chest (SC), - dermatologist (SD), - internal medicine (SI), - infectious diseases (SID), -nutrition, (SN), - research co-ordinator (SRC), - health economist (SHE),	SMB#1,2, SC#1,2, SRC#1, SD#1, SHE#1, SIM#1, SID#1	0	SN#1	0	10	
	Hospital Manager (HM);	HM#1, 4, 5	0	HM#2, 3	0	5	
	Professional Nurse (PN), Research nurse (RN), Hospital doctor (HD),	RN#1, 2, PN#5, 6, 7, 8, HD#4, 5	0	PN#1,2,3, 4 HD#1,2, 3	0	15	
DIAGNOSTIC COMPANY	Managers from industry (MI)	MI#1,2	0	0	0	2	
TOTAL						101	7

Table 2. Tests conducted outside of labs in clinics and hospitals

		Rural	Urban
Clinic	Public	Urine dipstick, haemoglobin, blood pressure, blood glucose (finger prick), HIV rapid, pregnancy tests, weight, pulse, rapid syphilis, temperature and mantoux, x-ray, ultrasound, rhesus test.	Urine dipstick, haemoglobin, blood pressure, blood glucose (finger prick), HIV rapid, pregnancy tests, weight, pulse, rapid syphilis, temperature, mantoux and x-ray.
	Private	Urine dipsticks, haemoglobin, blood glucose (finger-prick), HIV rapid, pregnancy and blood pressure	Urine dipsticks, haemoglobin, blood glucose (finger-prick), HIV rapid, pregnancy, blood pressure, cholesterol, ECG stress tests, lung function tests, Trigs, Troponin, X-ray and ultrasound
Hospital	District	Blood glucose (finger prick), haemoglobin, urine dipstick, pregnancy, X-ray, blood pressure, temperature, rapid syphilis, HIV rapid, and Xpert MTB RIF assay.	Blood glucose (finger prick), haemoglobin, urine dipstick, pregnancy, X-ray, blood pressure, temperature, rapid syphilis, HIV rapid, Xpert MTB RIF assay, ultrasound, weight, ESR, cardiac enzymes,
	Tertiary	Not visited	Glucogen Hypokit, haemoglobin, urine dipstick, liver function and blood gas in ICU, allergy skin test, blood pressure, blood glucose (finger prick), vitals, X-ray, lung function, ECG.