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Point of care diagnostics; Needs of African health care workers and their role combating global antimicrobial resistance.

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Abstract

Background—Point of care technologies (POCT) offer the opportunity for increased diagnostic capacity in resource limited settings, where there is lack of electricity, technical capacity, reagents, and infrastructure. Understanding how POCT are currently used and determining what health care workers (HCW) need is key to development of appropriate tests.

Methods—In 2016 we undertook an email survey of 7,584 HCW who had received training at the Infectious Diseases Institute in a wide variety of courses. HCW were contacted upto 3 times and asked to complete the survey using Qualtrics software.

Results—Of 555 participants answering the survey (7.3% response rate), 62% completed. 91% were from Uganda and 50.3% male. Most common POCT were pregnancy test (74%), urine dipstick (71%), syphilis (66%) and Gram stain (41%). The majority (74%) practiced syndromic diagnosis for STDs/HIV. Lack of availability of POCT, increased patient wait time, and lack of training were the leading barriers POCT use.

Conclusion—Increasing POCT availability and training could improve uptake of POCT for STIs in Africa and decrease syndromic management. This could reduce overtreatment and slow the emergence of antibiotic resistance. This is first published email survey of HCW in Uganda; mechanisms to increase response rate should be evaluated.

Keywords

Point of care tests; STIs; Africa; needs for health care workers in Africa

Corresponding Author Rosalind Parkes-Ratanshi, PO Box 22418, Mulago Hospital Complex, Kampala, Uganda, rratanshi@idi.co.ug. Authors' contributions AR, RMPR, YCM, RK conceived of overall study design and developed protocol with input from CG and ENJ. RK performed on data collection and study co-ordination. YHH and AR analyzed the data with input from RMPR, ENJ, CG, and YCM. RMPR, YHH and AR developed the manuscript with input and final approval from all authors.

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Background

Globally sexually transmitted infections (STIs) affect around 500 million people a year, and *Chlamydia trachomatis* (CT), *Neisseria gonorrhoea* (NG) and *Trichomonas vaginalis* (TV) are the most common. STIs can increase the risk of HIV acquisition(1). There are around 12 million cases of syphilis per year worldwide with 4 million cases in Sub-Saharan Africa (SSA) (2). Morbidity is particularly high for infants of untreated pregnant women. 2.1% of the Ugandan population has active syphilis, with 6.0% ever infected. Most recent HIV prevalence data show that the rate stands at 6.2%(3). A review of STI studies in sub-Saharan Africa, showed rates 1.0–9%between for NG and 0.5–14% for CT across community and primary care sites (4). For other STIs, data are scarce and old; in 1998 trichomonas prevalence in women was 23.8%(5). For ulcerative conditions *Hemophilus ducreyi* prevalence was in men 9.8% and 7.3% in women; HSV-2 prevalence rates were considerably lower in males (36.0%) than in females (71.5%), $p < 0.001$ in 1999(6). This represents a significant burden of diseases that are currently being treated syndromically. If point of care tests (POCT) were available for these infections, asymptomatic patients could be diagnosed, specific treatment could be given to symptomatic patients, and many without infections would not be over treated, allowing improved antibiotic stewardship.

There is great interest in development of POCT, led by organizations such as the World Health Organization (WHO) and the National Institutes of Health (NIH)(7,8). The WHO has stated that *“From a public health perspective, rapid point-of-care diagnostics will achieve their greatest impact on disease prevalence (and, in time, incidence) if they are used in well-planned and coordinated screening programme.”*The ASSURED criteria were internationally developed as a framework for all new POCT. The criteria state that the tests should be Affordable, Sensitive, Specific, User-friendly, Rapid & Robust, Equipment-free, and Delivered to those who need them(7). The use of POCT has allowed scale-up of diagnostics in resource limited settings. For example, use of POCT for HIV and malaria has facilitated testing of millions of people for these conditions in SSA every year and allowed diagnostic certainty with targeted treatment (8, 9). With STIs, the only commonly used POCT is a lateral flow test for syphilis(10) (11); there is still no real POCT for gonorrhea and chlamydia(12)

The Johns Hopkins University Center for POCT for STDs designed a survey which sought to understand the challenges and opportunities for use of POCT tests by clinicians in the USA(13). The aim of this study was to understand how POCT may have greatest impact, and how the “User-friendly” & “Delivery” sections of the assured criteria might best be achieved in different settings (14). The Infectious Diseases Institute (IDI) has been offering training programmes since 2005 and has an email database of health care worker alumni from different countries who have given permission to be contacted by IDI. A literature search of web based and email surveys of health care workers Africa found no publications using these methods for surveys in Uganda. However, a South African study using an existing registry of health care workers to evaluate TB prevalence in health care workers had an 18% uptake rates, and showed a preference for web based surveys (67% of respondents) compared to postal (33% of respondents)(15). We felt that this large alumni email database with a broad geographical coverage within Uganda and across other countries, as well as

range of health care settings provided an opportunity to gather data in a cost effective way. Therefore, we undertook a web-based survey of these training alumni to understand their use and perspectives of POCTs.

Methods

Between March and October 2016, we invited 7,584 healthcare workers (HCW) to participate in an email survey. The survey was designed using Qualtrics software. Email addresses were obtained from a database of people who attended short course trainings at the IDI over the last 6 years. Each person was emailed once and if they did not respond, and up to three email reminders were sent out until a 50% response rate was achieved. Personal level emails (rather than 'round-robins') were sent to policymakers to encourage participation from this group. The data were analyzed using SAS 9.4 (SAS Institute Inc., Cary, North Carolina). Chi-square test or Fisher's exact test were used to examine the difference between the general setting of practice/facility (urban versus rural setting).

Ethical considerations.

As per the NIH guidelines, this survey was eligible for an IRB waiver as "*research of educational tests, survey procedures, interview procedures or observation of public behavior ensuring confidentiality and that the responses of the participants do not place them at risk of civil liability or be damaging to their financial standing, employability or reputation.*" A waiver was granted from the Makerere School of Public Health Ethics committee, and the Johns Hopkins School of Medicine institutional review board (IRB). Once the HCW opened the survey they received a short-written paragraph about consent for the survey, including information that the survey was voluntary.

Results

Overall, 555 participants took the online survey (7.3% response rate). Among them, 279 (50.3%) were male and 276 (49.7%) were female. Five-hundred five (91.0%) participants reported their practice is located in Uganda, 16 (2.9%) in other Sub-Saharan countries (including Kenya, Botswana, Angola, Algeria), 9 (1.6%) in other continents (including Cambodia, Antigua) and 26 (4.7%) were without any information. 343 (62%) completed the full survey. Approximately half of participants reported that their practice/facility was in urban setting (50.8%) and another half was in rural area (48.1%). Most participants were clinicians (n=449, 80.9%) which included 336 nurses and 113 clinical/medical officers, followed by 49 (8.8%) laboratory technicians, 24 (4.3%) policy makers or managers, and 33 (6.0%) other professions. Most respondents worked in the government sector, with approximately 40% (n=217, 39.1%) of the clinicians at Level III/IV health centers; 25.4% worked at private hospitals, clinics or laboratories, and 15.0% in private not-for-profit (PNFP) institutions. The majority of patients did not pay for services (69.4%) and a minority were covered by health insurance (6.1%). Table 1 shows the cadre and type of facility by urban or rural location.

Among 449 clinician respondents, 312 (69.5%) respondents reported that they see both HIV and general patients in their practice and 309 (68.8%) stated that they diagnose at least one

patient with an STI daily. There were no differences in the frequency of STI diagnoses in rural or urban settings.

For all 555 participants, the most common POCT used were the malaria rapid diagnostic test (83.4%), pregnancy test (74.6%), urine dipstick (70.8%), syphilis rapid test (66.7%) and Gram's stain (41.4%)(Table 2). Urban centers were more likely to have specialist tests such as cryptococcal antigen and vaginal PH, whilst rural centers had better availability of malaria rapid tests. Table 2 shows the availability of POCT in facilities in the last 12 months. Participants working in urban settings reported using vaginal pH more frequently than did those working in rural settings (18% versus 5%, $p<0.001$). Most of participants ($n=475$, 85.6%) said that POCTs were performed by the health care worker and more than half ($n=285$, 51.4%) reported that test result was read while the patient was present. Despite this availability for POCT, the majority of clinicians ($n=332$, 73.9%) practiced syndromic diagnosis for STDs/HIV.

Most clinicians also sent blood specimens for confirmation at a laboratory (81.4% - most within the facility; 3.8% off site private or regional government laboratory). This was mainly HIV ($n=235$, 78.8%) and syphilis ($n=287$, 63.9%). Only 18.0% ($n=81$) routinely sent cultures for gonorrhea.

Most respondents (91.9%) report their results to the Ministry of Health, with 74% also reporting to their funding agency. This included 98.7% of HIV test results, but only 68.2% of gonorrhea results.

Challenges experienced by respondents with POCT include lack of availability of POCTs (42.9%), increased patient wait time (25.4%), and lack of training to perform the test (20.9%); these were the leading barriers to scale up of POCTs. Many HCW mentioned that whilst supplies of test kits should be free, they are often out of stock in government health centers. This happened more frequently for syphilis testing than for HIV and malaria.

For development of new POCT tests, cost of the test to the patient was thought to be the most important consideration (33.1% of 420 respondents), followed by benefit to the patients of a quick diagnosis (20.7 %), ease of use by HCW (16.4%) and cost to government (15.2%). Benefits to the health system, stability and shelf life of the test were less important. Over 40% ($n=223$, 40.2%) of all 555 participants chose HIV acute seroconversion (or acute HIV infection) as the biggest need for POCT development, followed by hepatitis B and/or C ($n=171$, 30.8%), syphilis ($n=138$, 24.9%), human papillomavirus ($n=113$, 20.4%), and gonorrhea ($n=87$, 15.7%). The ideal perceived cost to the patient (5329 ± 4368 Ugandan shillings, $n=289$) and government (6058 ± 4933 Ugandan shillings, $n=274$) of new POCT tests was low at less than USD\$2 (1 USD=3600UGX, January 2018) per test. Among 303 respondents, they thought that tests should ideally take approximately 20 minutes (mean: 20.1 ± 17.7 minutes).

The perceived benefits of POCT to HCW in this setting are highlighted in Table 3. Improvement in patient care rated as the highest benefit. Reduction in antibiotic use and reduced emergence of anti-microbial resistance are both important, but more so to those in the urban centers than the rural ones.

Discussion

HCW in SSA frequently use POCT for malaria, urine analysis (dipstick), and pregnancy testing. The availability of the test kits for these conditions was high, resulting in frequent use. There were some urban and rural variations; urban facilities were more likely to be regional referral hospitals or private hospital rather than smaller MOH centers; the greater availability of specialized tests such as the cryptococcal antigen test, Affirm VP II and vaginal PH may be to do with better resources at these urban facilities. The current and future value of POCT to this population was clear; 99.4% of the respondents (368 of 555) thought that increased access to POCT would be helpful for their country. It is not clear why there is less access to STI tests such as syphilis, as compared to HIV and malaria, despite sexually transmitted infections control being part of the HIV control programme. A report from the Ugandan National Medical Stores (NMS) indicates that this is likely to a combination of insufficient of government budget, combined with inconsistent requesting and reporting by health centres due to lack of training and capacity(16).

For STIs, use of HIV tests kits was high, but there was a perceived need for a wider range of test kits; including for hepatitis B and C. In expressing desire for a POCT for HIV acute seroconversion, the HCW indicated that they do not yet have access and were not aware of newer POCT kits that can test for early HIV infections (e.g. Alere 4th generation HIV test). However, whilst there are early antigen tests, in prevention of mother to child transmission HCW in Africa are also using dried blood spots to detect viral load in infants born to infected mothers. Therefore, a POCT viral load capability may also be able to perform this function. Those who worked in urban settings were more likely to see the potential in reducing antibiotic use, and tackling the emergence of resistance. This may be due to increased capacity for diagnostics and therefore less syndromic management as the urban centers tend to be larger with more access to tests. It may also be due to better sensitization about antimicrobial resistance (AMR) and antibiotic stewardship.

Whilst use of POCT was welcome, in addition to problems with availability of the kits, 2 major challenges were noted. Firstly undertaking diagnostic testing can lengthen appointment length. In areas with few HCWs, there may only be one person on duty at a health care center, and so they will be acting as nurse, doctor, and pharmacist already. Adding POCT tests means that they then take on the role of laboratory technician, thereby increasing their workload and patient waiting times. Despite this, 86.7% still thought that more POCT would reduce patient waiting times. Secondly, training and confidence in using the tests was the other major challenge highlighted. This training aspect is the area where potentially the largest gains could be made, and this has been seen in the scale up of HIV testing. Training a wider range of health care workers to do POCT would allow sharing of task between HCW, therefore the burden would not rest on doctors only. POCT may be available but not be used due to lack of confidence in using the test, or communicating results. This may lead to delays or omissions in requesting of tests from the National Medical Stores, leading to stock outs and reduced use. These concerns mirrored those expressed by the US-based clinicians in previous surveys taken by the team (13).

Whilst the reporting of the test results to the Ministry of Health was high overall, it was highest for HIV results, since HIV attracts much resources and attention, and lowest in gonorrhea, which is difficult to diagnose in Uganda due to limited diagnostic capacity. The widespread adherence to strong algorithms for HIV and syphilis was evidenced by the confirmation testing done for these conditions, with repeat blood samples being tested in an on-or- off site laboratory.

Of respondents, 95% thought that POCTs would reduce use of unnecessary antibiotics, and 91.5% acknowledged possible reduction in emergence of AMR. Through the World Health Organization Global Action Plan on AMR the global research community is being encouraged to “*invest in the development of low cost tools for diagnostic tools for infections and anti-microbial susceptibility testing in points of care and dispensaries*” in order to help with the AMR response(17). *Neisseria gonorrhoeae* resistance in Africa and beyond is increasing rapidly and a combination of high rates, lack of diagnosis, access to over the counter antimicrobials and limited access to optimal treatment are driving this situation (18). Increased access to point of care testing to accurately diagnose and treat STIs, as well POCT with AMR prediction are essential tools for combating this global health emergency(19, 20). This study shows that test availability alone is not enough; a corresponding increase in knowledge on the benefits of diagnostic testing above syndromic management at a patient and population level is also essential to increase uptake of POCT and in stopping spread of AMR.

This study has some limitations. The response rate was very low at 7.3%, compared to the STI survey done by the JHU team in the US which was around 35% (256/700)(13). We found only 2 African eweb-based/email surveys; one from South Africa which showed a response rate of around 18% using a database of health care workers(15), and a smaller Ghanaian study targeting members of a professional body that reached 85% response rates(21). Two other multi-site surveys of health care professionals that showed varying rates for the African sites between 1.7% (registered individual pharmacists in South Africa)(22) to 27% (hospitals in East and South Africa rather than individuals)(23). A further 2 manuscripts included only global combined rates (rates for African not reported separately) of 19.4% and 42% (24, 25). Reasons for our low response rate may include low e-literacy and access to internet at work in Uganda and sub-Saharan Africa compared to resource rich settings(26). Whilst survey fatigue is becoming an issue in resource rich settings(27), both literature and our experience in Uganda would suggest that lack of experience with web-based surveys is more likely to be a problem for our healthcare workers. Adding a postal component has worked to increased response rate elsewhere(28) and was given as an option in the South African study(15), however, practically this is not possible in Uganda as the postal system is extremely limited. Other proven uptake strategies such as monetary incentives, and follow up phone calls(29) were unfortunately financially not possible in this study, but should be considered for further web-based/ email surveys in Uganda in the future.

An alternative approach to using a web-based survey would be to collect data on POCT usage by visiting health centres, however the cost of visiting a wide range of health centres in both rural and urban settings in Uganda and beyond was outside of our resource envelope.

Despite the limitations this survey has collected a range of data from different sites and health care workers. There is a large bias to Ugandan data with over 90% of respondents from Uganda thus limiting the generalizability of the survey. Additionally not all respondents replied to all questions; for example the last questions in the survey which are shown in table 3 had lowest responses with only 342/555 answering. However, the completion rate was fair (62%) compared to similar studies targeting individuals between 59%(24) – 85%(13). Whilst the study had low response rates, this is the first published study using email/web-based surveys in health care workers in Uganda. This method may may elicit more open responses than face-to-face or phone surveys, as well as being cheaper than traditional face to face surveys and interviews. Mechanisms to increase response rate should be evaluated.

Conclusion

In low and middle-income settings primarily in SSA, 98.5% of HCW believe that access to a wider range of POCTs would improve patient care. This study highlights that where strong systems support and funding for POCT tests was in place, such as for HIV, malaria and to a lesser extent syphilis, HCW found the tests valuable. When available, POCT testing was at a high level, confirmatory tests were undertaken and reporting was good. Despite this, out-of-stock of test kits still limited their use. However, for conditions such as gonorrhea and chlamydia, where there are no POCT tests readily available, the diagnostic coverage is sketchy, leading to syndromic management of these conditions. Good access to easy to use POCT diagnostic tests could reduce the risk of inappropriate antibiotic prescribing for uninfected patients, and in this era of increased anti-microbial resistance, this is particularly important. Development of new POCTs for SSA could facilitate increased attention to diagnosis and reporting of sentinel bacterial infections such as gonorrhea, a WHO priority disease which is becoming increasingly resistant to antibiotics, but will require accompanying training to be fully useful.

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Table 1 –

Survey responses by urban and rural locations

	Urban (n=287)	Rural (n=268)
Clinical/Medical officer	50 (17.4%)	61 (22.8%)
Dermatologist	0 (0.0%)	0 (0.0%)
Infectious Diseases Specialist	9 (3.1%)	4 (1.5%)
Obstetrician/Gynecologist	9 (3.1%)	4 (1.5%)
Nurse	182 (63.4%)	150 (56.0%)
Laboratory Technician	22 (7.7%)	30 (11.2%)
Policy Maker/Senior MoH official	0 (0.0%)	1 (0.4%)
Manager NGO/PNFP	24 (8.4%)	24 (9.0%)
Manager (MoH)	2 (0.7%)	2 (0.8%)
Other	39 (13.6%)	36 (13.4%)
Regional referral or national hospital	77 (26.8%)	13 (4.9%)
District hospital	26 (9.1%)	49 (18.3%)
Private clinic	49 (17.1%)	34 (12.7%)
Private hospital	44 (15.3%)	12 (4.5%)
Private laboratory	0 (0.0%)	2 (0.8%)
Health Center III or IV*	54 (18.8%)	163 (60.8%)
Health Center I or II	4 (1.4%)	24 (9.0%)
PNFP Clinic (e.g. missionary hospital/clinic)	45 (15.7%)	38 (14.2%)
HIV patients only	41 (14.3%)	16 (6.0%)
HIV and general patients	167 (58.2%)	199 (74.3%)
General patients	74 (25.8%)	65 (24.3%)
Specialist patients (e.g. Obstetrics/surgical)	51 (17.8%)	14 (5.2%)
I don't see patients	21 (7.3%)	22 (8.2%)
None	179 (62.4%)	206 (76.9%)
Cash at delivery of service	72 (25.1%)	54 (20.1%)
Insurance	30 (10.5%)	4 (1.5%)
No response	6 (2.1%)	4 (1.5%)
Every day	201 (70.0%)	197 (73.5%)
Once or twice weekly	45 (15.7%)	53 (19.8%)
Once or twice monthly	24 (8.4%)	8 (3.0%)
Once or twice yearly	0 (0.0%)	1 (0.4%)
Don't see STIs	10 (3.5%)	5 (1.9%)
No response	7 (2.4%)	4 (1.5%)

Table 2:

Available Point of Care Tests at Participant's Facility in the Past 12 Months by the General Setting of Practice/Facility

Point of Care Tests	Number (%)			
	No. (%)	Urban	Rural	p-value
Malaria RDT	462 (83.2)	229 (79.8)	233 (86.9)	0.024
Pregnancy Test	413 (74.4)	216 (75.3)	197 (73.5)	0.636
Urine Dipstick	393 (70.8)	203 (70.7)	190 (70.9)	0.966
Rapid Test for Syphilis	369 (66.5)	185 (64.5)	184 (68.7)	0.295
Gram Stain	230 (41.4)	128 (44.6)	102 (38.1)	0.118
Cryptococcal Antigen Screening	120 (21.6)	89 (31.0)	31 (11.6)	<0.001
Wet Mount Test	70 (12.6)	42 (14.6)	28 (10.5)	0.138
Vaginal pH	64 (11.5)	51 (17.8)	13 (4.9)	<0.001
Affirm VP III	9 (1.6)	9 (3.1)	0 (0.0)	0.004
None	10 (1.8)	5 (1.7)	5 (1.9)	1.000

Table 3:

Perceived Benefits of Point of Care Tests by the General Setting of Practice/Facility

Perceived Benefits	Category	No. (%)	Number (%)		p-value
			Urban	Rural	
Improve Patient Care	Yes	314 (56.6)	151 (52.6)	163 (60.8)	0.143
	No	5 (0.9)	3 (1.1)	2 (0.8)	
	Missing	236 (42.5)	133 (46.3)	103 (38.4)	
Reduce Unnecessary Use of Antibiotics	Yes	305 (55.0)	144 (50.2)	161 (60.1)	0.043
	No	13 (2.3)	9 (3.1)	4 (1.5)	
	Missing	237 (42.7)	134 (46.7)	103 (38.4)	
Provide More Epidemiological Information	Yes	296 (53.3)	140 (48.8)	156 (58.2)	0.071
	No	14 (2.5)	9 (3.1)	5 (1.9)	
	Missing	245 (44.1)	138 (48.1)	107 (39.9)	
Reduce Emergence of Antibiotic Resistance	Yes	284 (51.2)	133 (46.3)	151 (56.3)	0.041
	No	26 (4.7)	17 (5.9)	9 (3.4)	
	Missing	245 (44.1)	137 (47.7)	108 (40.3)	
Save Money for the Health System	Yes	274 (49.4)	133 (46.3)	141 (52.6)	0.336
	No	31 (5.6)	17 (5.9)	14 (5.2)	
	Missing	250 (45.1)	137 (47.7)	113 (42.2)	
Help Reduce Time Taken for Patient Visits	Yes	271 (48.8)	127 (44.3)	144 (53.7)	0.079
	No	41 (7.4)	24 (8.4)	17 (6.3)	
	Missing	243 (43.8)	136 (47.4)	107 (39.9)	
Increase Task Shifting of Health Care Workers	Yes	203 (36.6)	101 (35.2)	102 (38.1)	0.421
	No	90 (16.2)	43 (15.0)	47 (17.5)	
	Missing	262 (47.2)	143 (49.8)	119 (44.4)	