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Point-of-care biochemistry for primary healthcare in low-middle income countries: a qualitative inquiry

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Abstract

Background Access to essential diagnostics is crucial for primary healthcare (PHC) in low-and-middle income countries (LMICs). Many LMICs have invested in equipping PHC with point-of-care (PoC) diagnostics for infectious diseases, however there has been no similar investment to improve PHC capacities for clinical chemistry. The biochemistry gap is among the deterrents to universal health coverage.

Methods A social sciences project was conducted with the aim to understand the key PHC stakeholders' insights on the pertinence of PoC biochemistry for PHC in LMICs. Data generation was conducted between July-November 2023 in Mongolia, Nigeria and Peru. Decision-makers in healthcare delivery, healthcare professionals, and patient and community advocates were engaged using a combination of sampling techniques. Unstructured individual and group conversations, and non-participant observation were conducted. Analysis involved an inductive line-by-line coding on printed transcripts, followed by a deductive coding and theme-by-theme analysis on digitized transcripts.

Results Fifteen, 51 and 20 informants from Mongolia, Nigeria and Peru, respectively, participated. Fifty-five of the 94 informants were female. Most informants considered that PoC biochemistry in PHC would be pertinent, from a clinical and a resources-saving perspective. Those households that currently bear the burden of referrals (i.e., the poor, the bedridden, the older adults) would benefit the most from the deployment of PoC biochemistry for essential biochemistry parameters. Improved access to PoC glycated hemoglobin (HbA1c), lipid, liver and kidney profile was perceived as helpful to inform clinicians' decision-taking. The value of PoC biochemistry for the management of noncommunicable diseases (diabetes, hypertension) and infectious conditions (dengue, malaria, tuberculosis), to improve child health outcomes (severe dehydration in children with diarrhea and/or malnutrition) and to reduce preventable causes of death (dengue-related renal failure) was highlighted.

Conclusions PoC biochemistry holds potential to revert the impact that the biochemistry gap has for patient care in some LMICs' PHC settings. PoC equipment for parameters such as HbA1c, urea, creatinine or electrolytes could

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enhance community-level management of preventable causes of mortality, improve service delivery for patients affected by locally-prevalent infectious conditions, and improve the psychosocial and economic wellbeing of patients facing the burden of referrals to remote biochemistry-equipped centers.

Trial Registration Not applicable.

Keywords Primary healthcare system, Low-middle income countries, Laboratory capacities, Primary care strengthening, Noncommunicable diseases, Clinical chemistry, Biochemistry, Qualitative research

Introduction

Achieving the United Nations' Sustainable Development Goal (SDG) 3, "Ensure healthy lives and promote well-being for all at all ages," by 2030 is contingent upon the extent of access to high-quality essential healthcare services [1]. While access to essential diagnostics was not explicitly addressed in the definition of targets or indicators related to SDG 3, its significance for primary healthcare (PHC) has been underscored by the World Health Organization Global Action Plan for the prevention and control of noncommunicable diseases (NCDs) [2] as well as in the 2018 Astana Declaration [3].

Global initiatives have notably supported the decentralization and integration of test-and-treat services for individuals with tuberculosis, malaria, and human immunodeficiency virus (HIV) in many low-middle income countries' (LMIC) PHC [4–6]. The coronavirus disease 2019 (COVID-19) pandemic has further accelerated efforts to decentralize rapid diagnostic testing in order to improve the detection of COVID-19 cases in the most hard-to-reach areas [7, 8]. However, there has been no comparable investment to scale up community-adapted capacities for clinical chemistry or biochemistry. The biochemistry gap in many LMICs' remote and rural settings, where populations heavily rely on public hospitals or central laboratories for biochemistry testing, is among the impediments to reaching universal health coverage [9].

Biochemistry tests play a critical role in life-saving emergency procedures. These include assessments of cardiac markers such as troponin and other parameters like glucose, creatinine, potassium, and other electrolytes [10]. These available parameters serve as valuable tools in managing both NCDs and infectious diseases. For instance, liver function panels are essential for assessing the hepatotoxicity of anti-tuberculosis drugs [11] and liver staging as a pre-treatment evaluation in individuals who receive a virological confirmation of hepatitis C virus infection [12], and are also recommended for the diagnosis of patients with chronic liver disease at community-level, particularly in the pre-cirrhotic stage [13].

Similar to point-of-care (PoC) tests for the detection of infectious diseases, PoC for biochemistry that meet the ASSURED criteria (i.e., affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free, deliverable to end users [14, 15]) can facilitate the decentralization of diagnosis, patient monitoring and treatment services. Despite the availability of some basic PoC biochemistry in the market (e.g., rapid glucose or bilirubin measurement testing devices), access to such PoC in LMICs remains limited. Several factors contribute to this gap, including the cost associated with biochemistry alongside insufficient funding at national-level, frequent disruption of supply chain for equipment and consumables [16], manpower shortages, power failures, the absence of policy frameworks and national essential diagnostic lists mentioning PoC biochemistry [17], or a dearth of economic evaluations of PoC biochemistry in health resource-constrained settings [18].

In an attempt to contextualize the relevance of PoC biochemistry at PHC in LMICs, an inquiry was conducted in the frame of a larger market study project on PoC biochemistry. The anticipated outcome of this inquiry is to provide information to industry on low-resourced markets' needs for PoC biochemistry as well as to enhance the quality of services provided by PHC in LMICs by offering key PHC stakeholders' insights on the most pertinent biochemistry panels and parameters to industry stakeholders, patient advocates, and policymakers.

Methods

Aims

Our project aims to understand the insights of PHC stakeholders on the pertinence of PoC biochemistry for PHC in LMICs, and to identify the most important PoC biochemistry panels or parameters that the diagnostics industry could consider in their development of PoC biochemistry to make an impact on strengthening the quality of care provided by PHC in LMICs.

The conduct of the project was led by the Obafemi Awolowo University (Nigeria) in collaboration with FIND (Switzerland). FIND is a non-governmental, non-profit organization that seeks to support the health of people in developing countries through the provision of affordable, accurate, reliable diagnostic tools for infectious diseases. FIND provides provides market landscapes, forecasting, and consumer behavior analyses to industry and policymakers to enable strategic decision-making. No funding for this study was received from the diagnostics industry.

Design, duration and settings

This is a social sciences project that consists of (i) an initial formative phase in which qualitative methodologies were used (July-November 2023) to inform (ii) a subsequent longitudinal quantitative phase utilizing the Delphi technique to solicit expert consensus (throughout 2024) [19, 20] (iii) to define recommendations to diagnostics industry and the community of diagnostics developers as a whole (throughout 2025). This article presents the methods and findings of the initial phase only. The initial phase was informed by ethnography [21] and followed recommendations for conducting qualitative research in resource-constrained settings [22].

The initial phase took place between July and November 2023, while the consensus-building phase is to commence in 2024. This initial phase encompassed non-participant observation and the gathering of insights from key informants in Mongolia (in its capital Ulaanbaatar, and in five localities across north-western Mongolia), Nigeria (in Lagos and Osun States), and Peru (in Lima, and the provinces of Tumbes and Piura). An overview of characteristics of PHC in Mongolia, Nigeria and Peru is provided in Table 1.

Participants

The initial phase targeted three PHC stakeholder groups: healthcare professionals (e.g., infectious disease specialists, hematologists, endocrinologists, laboratory scientists, clinical pathologists, and PHC medical and nursing staff), patient and community advocates (e.g., patient support groups, non-profit organizations), and decision-makers in healthcare delivery (e.g., policy-makers at the level of Peru's National Health Institute or Tumbes Regional Health Directorate, or of Nigeria's Osun State Ministry of Health or Ilesa West Local Government).

To be eligible for participation as study informants, individuals had to be over 18 years old, self-identify as a member of at least one of the three targeted PHC stakeholder groups, possess the ability to communicate in Mongolian (in Mongolia), English or Yoruba (in Nigeria), or Spanish (in Peru), and have knowledge and experience in the use of biochemistry in PHC.

As the initial phase aimed to gather information that could shape the development of a survey tool for a subsequent consensus-building phase, this study considered published evidence of past Delphi studies proposing that a minimum of ten informants per targeted study population group should be recruited to generate sufficient insights to develop survey instruments [23].

Sampling and recruitment

A combination of sampling techniques was used. Initially, individuals meeting the inclusion criteria were purposively identified by the lead social scientist (first author in this publication, a male, White, Spanish social scientist) and field researchers during visits to the study sites' communities, clinics, and laboratories. Snowball sampling was utilized to complement purposive sampling wherein participating informants were encouraged to suggest other potential participants.

A total of 112 individuals were invited, either in person, via phone call, or through email, to participate in the initial phase. Of these 112, six declined due to time constraints, and 12 individuals contacted via email did not

Table 1 Overview on Study Countries' primary Healthcare systems

Mongolia	The healthcare system in Mongolia is structured into three levels (primary healthcare centers; district or provincial (*aimag*) general hospitals; central or national referral hospitals, and specialized hospitals and institutes), each providing different types of care. The healthcare system is mainly supported by women: they represent over 80% of the system's workforce. The PHC centers are typically located at the *soum* (rural district) or *bad* (urban district) level, and serve as primary healthcare providers for their respective catchment populations. These PHC centers offer general medicine, preventive care, maternal and child health services, immunizations, family planning, basic laboratory tests, and health education and promotion as well as disease surveillance within their communities [24].
Nigeria	The healthcare system in Nigeria is structured into several levels (PHC centers; secondary healthcare facilities; tertiary healthcare facilities; and specialized research institutes and national referral hospitals). Primary, secondary and tertiary levels are the responsibility of the local area government, state government and federal government, respectively. The federal government also manages the implementation of disease-specific programs at all levels (e.g., HIV, tuberculosis). The PHC centers provide basic and essential healthcare to communities, including general medicine, maternal and child health care, immunization, family planning, health education and preventive care. Due to the under-resourcing of PHC centers in Nigeria, the communities depend on access to secondary level comprehensive health centers which provide a higher level of care than PHC, including outpatient and inpatient care, emergency services, minor surgery, basic laboratory tests, radiology and pharmacy services [25].
Peru	The healthcare system in Peru is structured into several levels. Each level plays a role in providing healthcare to the population, with an emphasis on primary healthcare, disease prevention, and specialized medical care as needed. The PHC is structured in four categories: I-1, I-2, I-3 and I-4. Within these categories, the system counts on health professionals' consultations, health posts, medical cabinets, healthcare centers, medical centers, polyclinics, specialized medical centers, and medical centers with inpatient capacities. The PHC posts are smaller facilities located in rural and remote areas, serving as extensions of PHC centers, and providing basic services similar to PHC centers but focusing on preventive care and health education. The PHC centers provide basic healthcare to communities, including general medicine, preventive care, maternal and child health services, immunization, family planning, basic laboratory tests and health education and promotion. Facilities within PHC I-4 can also admit inpatients, screen for breast cancer, and conduct minor surgery, echography, radiology and hospitalization [26].

provide a response. All contacted individuals received comprehensive information about the study objectives, the responsible organizations, and the implications of participation. Oral or verbal consent was sought from those expressing interest in participating in unstructured individual or group conversations. Of the 94 who expressed interest in participation, 15 informants in Peru and two informants in Nigeria opted for videoconference rather than for in-person conversations.

Data generation

Two qualitative methods were employed: (i) non-participant observation during visits to communities, clinics, and laboratories, and (ii) unstructured individual and group conversations. In the context of this study, the group conversations were self-organized by the approached informants. Unlike in focus group discussions, group conversations involved participants deciding when to conduct data generation, in what venue within their own workplaces (e.g., hospitals, primary healthcare centers), who should be involved in the conversations (i.e., additional informants meeting the eligibility criteria that were identified by the informants that the study team approached in the first place), and who in the group would be responsible to revise the transcript of the minutes of the group conversation.

The lead social scientist led data generation in all sites. The lead researcher in Nigeria (last author in this publication, a female, Black, Nigerian academic researcher) co-conducted data generation in Nigeria, in Yoruba and English languages, during September-October 2023. A co-researcher in Peru (third author, a female, White, Peruvian health scientist) co-conducted data generation in Peru, in Spanish, during September-November 2023. Data generation in Mongolia was co-conducted by the lead social scientist and a trained local translator (a female, Mongolian, professional Mongolian-Spanish translator), in Mongolian, during the month of July 2023.

The instrument used for the unstructured individual and group conversations included a thematic guide with a list of key themes of interest to explore informants' insights on their countries' biochemistry gaps, current utilization of biochemistry for patients with NCDs and infectious conditions, the relevance of PoC biochemistry for PHC, and their recommendations for future development of PoC biochemistry based on PHC gaps and needs. Simultaneously, during the conversations, the lead social scientist maintained a memo journal to record observations gathered during non-participant observation in visits to communities, clinics, and laboratories at the study sites. Only handwritten notes were taken during the conversations.

Following requests made by some informants in the public health sectors (in all study sites) to not audio-record the conversations, a decision was taken at the outset of the study to not audio-record any encounter. To avoid the introduction of confirmation bias by the study analysts, after each encounter, conversation minutes were prepared in Microsoft Word format and shared with all informants via email, except for one informant in Nigeria who consented to participate in a conversation but declined to receive and revise the minutes. Eight and five informants in Nigeria and in Peru, respectively, requested amendments to their minutes.

Data analysis

The final versions of the conversation minutes were printed and subjected to inductive line-by-line coding. This initial analytical approach served to create a coding tree, which was then applied deductively to all minutes in their Microsoft Word format. As per this coding procedure, all minutes were read and coded twice before subjecting them to a subsequent step, in which key narratives of interest were extracted from the Microsoft Word files and organized into a single Microsoft Excel grid based on the coding tree's themes and sub-themes. This compilation informed the interpretation of the findings from this qualitative phase, and contributed to the development of a list of biochemistry panels and parameters that could potentially be considered pertinent for PHC and which were considered for the design of the survey tool for the consensus-building phase.

The analyst's memo journal and observation notes were utilized to further understand or contrast key findings from the conversation minutes. To enhance the trustworthiness of the analysis, the findings were condensed and shared with participating informants who expressed interest –during their revision of the transcripts of their conversation minutes– in contributing to the dissemination of study findings (i.e., nine co-authors of this article participated as key informants in this study).

The Consolidated Criteria for Reporting Qualitative Research checklist was consulted to guide the reporting of the study results in this article [27]. When selecting quotes to accompany the description of the core themes in the Results section of this article, priority was given to isolated or deviant cases, and careful consideration was given to ensuring the representation of all gender groups' voices. Since no informant in Mongolia provided consent for the use of quotations from their conversation minutes, only excerpts from conversations with Nigerian and Peruvian informants are included in the Results section.

Results

Ninety-four informants (55 females) took part in non-recorded, unstructured conversations. Of the 94 informants, 15 were from Mongolia, 51 from Nigeria, and 20 from Peru. The consultations involved a total of 33

individual conversations and 20 group encounters (4, 9 and 7 in Mongolia, Nigeria and Peru, respectively). The group encounters involved the participation of 61 informants. Fourteen of the 20 group encounters took place in health care establishment. Of the total data generation encounters, 13, 17, and 24 of the encounters involved informants with expertise who resided in rural, provincial/state, and capital settings, respectively.

Forty-four informants self-reported to be healthcare workers in PHC facilities. Of these 44, 14, 2 and 15 healthcare workers in Mongolia, Nigeria and Peru worked exclusively in rural PHC postings. The great majority of healthcare workers in Nigeria supported PHC from their positions at tertiary level of care or at academic health institutions.

Among the remaining 50, there was a diverse range of self-reported professional profiles ranging from medical specialists ($n=8$), to health authorities ($n=8$), laboratory personnel ($n=14$), civil society and community groups ($n=9$), and academic researchers ($n=10$, with 8 of them also being medical specialists). In Mongolia, all consulted informants were female healthcare professionals.

To safeguard informants' anonymity, no detailed sociodemographic information is provided in this section. In the following sub-sections, the acronym "o.d.n.p.o" (observed during non-participant observation) is used to indicate when informants' narratives aligned with the observations made by the social scientists during their visits to study settings' communities, clinics, and laboratories.

Biochemistry gaps

There was unanimous agreement across all countries that, despite the importance of biochemistry for patient management, there is a widespread lack of laboratory equipment for biochemistry at the PHC facilities, poor staff capabilities to use biochemistry equipment and poor-quality assurance measures instituted to ensure the proper provision of biochemistry services where these services are available (o.d.n.p.o). The absence of biochemistry equipment was described as "troubling." Many informants in Nigeria and Peru stated that in many rural clinics and health posts in Nigeria and Peru, it would be common to find a complete absence of biochemistry equipment—although urine strips and glucose meters might occasionally be available (o.d.n.p.o).

Allegedly, the PHC clinics in Mongolia, Nigeria, and Peru that are designated as "comprehensive" by the countries' respective health authorities (i.e., categories I-III and I-IV as described by the Peru Ministry of Health [28]), "comprehensive" or "flagship health care centers" by the health authorities in Lagos State [29]) should be equipped with biochemistry platforms to perform urinalysis, liver, and kidney profiles. During data generation, platforms like the Mindray BS-230, Mindray BC-800, or the ComboStik R-300 were physically on-site in some visited clinic laboratories in Mongolia and Nigeria (o.d.n.p.o). However, in some of these "comprehensive" clinics, some of these platforms might remain unused due to either a lack of laboratory staff or a shortage of supplies, especially reagents (o.d.n.p.o).

In a few Mongolian rural clinics, the lack of laboratory staff was circumvented by having nurses trained in the use of biochemistry platforms and who–at the time these clinics were visited–were playing a double nurse-laboratory technician role (o.d.n.p.o). Although this solution was described as necessary to follow-up some of the chronic patients in the clinics' catchment areas, a Mongolian nurse explained that the biochemistry platforms were "underutilized" as she had the capacity to run it just for a few of the tests that the platforms can perform. In Nigeria, the lack of biochemistry platforms and related supplies was described as *"frustrating"* since, according to some informants, current regulations specify that *"comprehensive"* PHC clinics should have biochemistry-equipped laboratories. The laboratory manager of a public PHC clinic in Lagos detailed the biochemistry gaps that the local health system administration was expected to tackle:

> *This PHC is a flagship PHC. But our lab is not equipped as it should be. We are waiting for the equipment to arrive so that we will be equipped as other comprehensive PHC in Lagos. We have a glucometer. We have Combi-10 for urinalysis. There is a need here for electrolytes, urea, creatinine. We need equipment to do lipid profile, kidney function and liver function. The equipment is not available because there is no provision from the local government.*
>
> *(Female laboratory technologist, Lagos State)*

In Nigeria and Peru, in addition to the lack of biochemistry platforms and supplies gaps, some informants highlighted the dearth of clinical capacity to interpret biochemistry tests results. In Mongolia, all visited PHC clinics were manned by generalists and medical specialists (e.g., internal medicine, pediatrician) while, on the contrary, in Nigeria and in Peru the majority of PHC were described as understaffed and, oftentimes, as non-staffed (o.d.n.p.o). As one male decision-taker in Lagos explained: *"In PHC centers you can find only community health officers or community extension workers. There may be a nurse, but not always"*.

In Peru, where some consulted informants were physicians contracted to do their post-graduation Rural and Marginal Urban Health Service (i.e., the SERUMS institution, see [30]), it was explained that some PHC clinics

might be appropriately staffed. However, a few informants in Peru suggested that some medical staff posted at PHC might need to update their biochemistry skills as they have low motivation to use biochemistry panels because, in their opinion, they need to refer most patients with chronic diseases to hospital-based specialists. This same concern was observed in Nigeria. However, in Nigeria, a few informants reflected that past successful efforts to decentralize testing for infectious diseases (i.e., in reference to malaria, HIV or COVID-19) suggest that training staff at the PHC facilities to conduct biochemistry tests is more than feasible. There would be, however, in their opinion, a need to *"synchronize"* the biochemistry test results interpretation *"with specialized services"* at the tertiary health facilities. As of mid-2023, there were initiatives in place to address this lack of interpretation capacity of biochemistry test results at the PHCs in Nigeria:

> *We need medical officers placed at PHC with the capacity to interpret biochemistry, so the need to refer patients to secondary-level facilities will decrease. Part of the Nigeria National Primary Health Care Development Agency training is to train PHC staff and assist them, in a supervisory role, on how they use some tests at the PHC centers. With training, even midwives could handle biochemistry tests.*
>
> *(Female PHC consultant and university professor, Lagos State)*

In Peru, some informants explained that, although biochemistry platforms ought to be available in *"comprehensive"* PHC clinics, the lack of reagents was a recurrent impediment to their use (o.d.n.p.o). A male informant in Peru recommended the work by scholar Viva-Mendoza, which describes how systemic corruption also implies an unnecessary over-prescription and overinflation of the cost of laboratory tests for patients [31]. Even if available and utilizable, medical specialists in tertiary care in Peru were described to commonly *"doubt of the quality of tests done at PHC and tend to repeat all tests of referred patients"*. Uncertainties around the quality of laboratory tests done at PHCs were also mentioned by a few informants in Nigeria. Consulted informants responsible for the management of a private clinic and a private laboratory offering PHC services in rural parts of Osun State stated that their laboratories are not subjected to any regular or stringent quality controls from the state's health authorities (o.d.n.p.o). No similar mentions to a gap in state-led quality control were mentioned by informants in urban Nigeria or in the other study countries.

Impact on patients

There was a perception that biochemistry is an unmet need at PHC by all stakeholder groups. There was also consensus that the community burden of NCDs (diabetes, hypercholesterolemia, hypertension and chronic kidney or liver disease were mentioned in all countries) and infectious conditions (chronic HIV and hepatitis B and C infections were mentioned in all countries) make evaluations of biochemistry parameters pertinent for PHC to improve the access of patients to prompt diagnosis and management. In Peru and Nigeria, there were also voices stating that biochemistry panels are currently needed to provide support to child health (malnutrition, diarrheas) and to community members' demand to address fertility issues.

The biochemistry tests gap was partly addressed at PHC level, in all countries, by referring patients to private clinics and public secondary and tertiary facilities (o.d.n.p.o). This approach was not perceived as a major issue by some informants in Nigeria with experience in states other than Lagos and Osun since, in their opinion, some private clinics can be more readily accessible by the patients in Lagos and Osun States in comparison with other states in the country. Hence, some patients would prefer, allegedly, to incur the cost of tests in the private sector and forgo the cost, travelling time and waiting queues associated with public laboratories (o.d.n.p.o). It was noted by most Nigerian informants that the out-of-pocket expenditure for procuring biochemistry tests where available in the public sector was exceptionally high (o.d.n.p.o). Contrary to Nigeria, referral to private clinics was described as a major issue in rural Peru and Mongolia, where, according to some informants, private laboratories were absent in many localities in the studied regions, and patients had to pay high costs and travel long distances to accessing biochemistry tests from the private sector (o.d.n.p.o).

Irrespective of whether patients are referred to private or public laboratories, the unavailability of biochemistry tests in most PHC facilities has, in the opinion of most informants, a negative impact on patients' care. The older adults, the bedridden and the poor were identified in all countries as the ones that suffer the most the gap created by the lack of biochemistry tests at the PHCs. In Peru, a few also identified the young as also adversely affected because they *"also lack financial capacity and freedom of movement to self-refer to other laboratories"* just like the older adults, the bedridden and the poor. In Mongolia, additionally, harsh weather conditions in the winter would make many patients disregard any recommendation to travel to the country's capital (Ulaanbaatar) to access a biochemistry-equipped laboratory.

Patient groups identified to bear the burden of the biochemistry tests gap were persons with diabetes who

"can't access glycated hemoglobin (HbA1c)*"*, persons living with hepatitis or tuberculosis who *"can't have a liver profile for disease monitoring"*, and persons with cardiometabolic diseases such as obesity, hypertension or hyperlipidemia and who can't access lipid profile. In Mongolia, several PHC staff expressed that aged patients with osteoarticular conditions such as *"radiculopathies*, *osteoarthrosis*, *monoarthritic disease"* are also negatively impacted by the lack of biochemistry tests in their PHC clinics. In contrast to this opinion by Mongolian PHC staff, a Nigerian endocrinologist expressed that *"many patients with radiculopathies*, *or mono- or osteoarthrosis have no or minimal biochemistry needs"*.

As per most informants' perspectives, the lack of biochemistry tests to manage patients at the PHC level implies a *"poor"*, *"insufficient"* or *"inexistent"* patient management. In Nigeria, also, due to out-of-pocket expenditure, the lack of access to free biochemistry testing at the PHCs also contributes to the *"impoverishment"* of patients and families. According to informants from the civil society and community groups in Nigeria, this is one of the reasons why some patients would rather go to the *"oracle"* or to the *"traditional healer"* to seek a solution to their ailments (o.d.n.p.o). As one Yoruba religion parishioner expressed during a group conversation in Lagos: *"What should be wrong in my mind for me to decide to pay for a test? I would go to the oracle."* In all countries, informants stated that many referred patients become lost-to-follow-up either because they turn to traditional therapists, they continue their disease management at hospital-level and do not return to PHC, or, as it was put by an informant in Peru: *"they lose trust in PHC and abandon care"*.

The implications of the *"poor"* patient management driven by the gap in access to biochemistry tests at the PHCs are varied. In their perspectives, patients may receive incomplete, non-differential diagnoses (e.g., women with polycystic ovary syndrome), be inadequately followed-up and monitored (e.g., most patients with diabetes), receive empirical treatments (e.g., older adults and children with dehydration and/or electrolytes imbalance), not be referred promptly when needed (e.g., pregnant women with thyroid issues that do not manifest with goiter), or may not be screened for preventable diseases (e.g., men not accessing testing for prostate-specific antigen).

PoC biochemistry for infectious conditions

PoC biochemistry was considered as valuable for the management of infectious conditions at the community-level (see Table 2 for additional selected quotes). The need for a PoC liver profile for the management of viral hepatitis B and C patients was highlighted in all encounters held in Mongolia, where informants referred to a national comprehensive elimination program that was valued as *"successful"* in improving access to treatment for persons living with hepatitis C [32]. The importance of PoC liver profile for hepatitis B and C, HIV and tuberculosis patients was also highlighted in Peru and Nigeria.

PoC kidney profile was identified as necessary for the management of patients with HIV in Nigeria and Peru. In Nigeria, a PoC kidney profile would be considered useful at PHC since, according to one male decision-taker: *"renal failure is common due to poorly treated malaria"*. In Nigeria, it was pointed out that PoC kidney profile and PoC electrolytes would be needed for malaria, Lassa and viral hemorrhagic fevers:

> *For viral hemorrhagic fevers, electrolytes (sodium, potassium, chloride), urea and creatinine are essential chemistries for clients' management. At the time these patients came to us, they often had established*

Table 2 Informants' suggestions on parameters for PoC Biochemistry to Support Infectious diseases Management

Dengue	*There is a lot of dengue here. There are three circulating serotypes. For its clinical management, we need hemogram, hematocrit, and urea testing.* (Male decision-taker and obstetrician, Tumbes Province)
Dengue / Tuberculosis	*For the management at hospital and PHC-level of tuberculosis and dengue, the most important is to do transaminases testing.* (Male decision-taker and epidemiologist, Tumbes Province).
HIV / Tuberculosis	*What is required for tuberculosis patients is aspartate transaminase, alanine transaminase, bilirubin. And, urea. And, creatinine, which is needed for HIV patients.* (Male decision-taker and physician, Lagos State)
Lassa	*For Lassa fever, it would be useful to have a full renal profile.* (Male decision-taker and university professor, Lagos State)
Malaria	*If jaundice is suspected, liver function and electrolytes testing are necessary.* (Female laboratory scientist and researcher, Lagos State)
Neurocysticercosis	*We do hemogram to see if there's anemia. We do hemoglobin. Biochemistry, I don't know… not indispensable. If praziquantel is prescribed, there's no need of creatinine testing.* (Male decision-taker and obstetrician, Tumbes Province)
Viral Hemorrhagic Fever	*For viral hemorrhagic fever, it would be important to have electrolytes (to check for electrolytes imbalances), white cell blood count, creatinine.* (Male decision-taker and university professor, Lagos State)

renal function impairment. So, at least this could be prevented or managed early.

(Male consultant hematologist and university professor, Osun State)

Another isolated voice in Peru suggested that PoC kidney profile (especially creatinine) could be necessary for the management of neurocysticercosis cases that are treated with drugs other than praziquantel. More frequently, in Peru, PoC liver (especially, transaminases) and kidney (especially, urea) profiles were mentioned as necessary for dengue patients:

Patients with severe dengue can die to renal failure or liver impairment. Liver and renal profiles are not available in PHC. What happens is that severe dengue cases are often referred from PHC to hospitals that might also lack liver and renal profiles. What could be done at PHC is that dengue cases are monitored in the community. And, if there are signs of alarms, these could be referred. It would be optimal to have PoC urea, creatinine, aspartate transaminase and alkaline phosphatase. There is evidence that the risk of death for dengue patients increases if their aspartate transaminase is > 1000.

(Male consultant internist, Piura Province)

PoC biochemistry for NCDs

There was consensus across all countries that PoC biochemistry would be important for the management of patients affected by cardiometabolic diseases such as diabetes, hypercholesterolemia, or high blood pressure (see Table 3).

A few informants described how PoC kidney profile (including electrolytes) would be helpful for people with diabetes at risk of developing nephropathy. In most informants' opinion, the availability of PoC glucose profile (especially, HbA1c) would be especially meaningful for people with diabetes who are aware of their disease monitoring needs. It was commonly described how, in both rural and urban settings, people with diabetes usually have the motivation to self-refer and seek for private or public laboratories or medical consultations where glucose or HbA1c tests can be accessed (o.d.n.p.o). However, not all patients have the means to self-refer and, as described by a female informant from a diabetes patients' group in Lima: *"we know of patients who have not received neither HbA1c nor proteinuria nor microalbuminuria in the past 2 years"*.

There were voices in all countries and in all study population groups expressing that there is a need for PoC lipid (especially, total cholesterol, high-density and low-density lipoproteins (HDL/LDL), triglycerides) and kidney (especially, urea and creatinine) profiles for cardiometabolic diseases other than diabetes (i.e., hypertension and hyperlipidemias). A few informants in Nigeria expressed that, considering the need to optimize resources for

Table 3 Informants' suggestions on parameters for PoC Biochemistry to Support Management of NCDs

Congenital hypothyroidism	*It would be useful to have PoC for congenital metabolic diseases such as hypothyroidism or suprarenal hyperplasia at PHC. At national-level, we are not sure if there is triage for these conditions among newborn babies.* (Conversation with three female members of a persons with diabetes group, Lima)
Congenital hypothyroidism	*PoC thyroxine and TSH could assist in the detection of congenital hypothyroidism in newborn babies. Midwives should be able to handle this screening test as it reduces the risk of children having mental retardation because of failure to detect congenital hyperthyroidism early. TSH would be the key parameter.* (Male consultant endocrinologist and university professor, Osun State)
Malnutrition in children	*A child with kwashiorkor or marasmus is at risk of developing hypokalemia, hyponatremia and hypocalcemia. A child with electrolyte derangement due to undernutrition, especially in the setting of diarrhea, can be promptly identified and referred if a PoC test for electrolytes is available, and this will reduce the death rate.* (Male consultant hematologist and university professor, Osun State)
Menstrual disorders / polycystic ovarian syndrome	*We could have PoC FSH and LH to investigate women with menstrual disorders, irregular and painful menstruation, and polycystic ovarian syndrome. Many women suffer from these disorders, and affect their experiences at work. To anticipate other problems, such as polycystic ovarian syndrome, then we could have PoC testosterone.* (Conversation with a male physician and a female laboratory technologist in a private clinic, Osun State)
Pre-eclampsia	*Pregnant women who develop preeclampsia need liver profile mainly glutamic-oxaloacetic transaminase and glutamic pyruvic transaminase.* (Female obstetrician, rural PHC center, Tumbes Province)
Renal impairment	*Patients with renal impairment, who are generally assessed by the generalist, do need urea and creatinine tests to understand their health status.* (Female obstetrician, Tumbes Province)
Thyroid problems in pregnancy	*In the past year, we have lost 5 pregnant patients due to poor management of thyroid disorder at the PHC. They had manifestations of thyroid problems at antenatal care visits, and they should have been referred [. . .] PoC thyroid, for TSH, triiodothyronine and thyroxine, could be used for screening at antenatal care.* (Male consultant endocrinologist and university professor, Osun State)

health (for both health authorities and patients), PHC administrators should better prioritize the deployment of PoC *"for electrolyte, urea and creatinine to manage cost"* at the clinics. In Nigeria, a few decision-takers were of the opinion that single-parameters PoC biochemistry would be preferable:

> *I would prioritize PoC total cholesterol. This is separately from HDL or LDL, which can be measured at secondary level. But, total cholesterol is necessary at primary level. It is important to think in single parameters because when patients go to the clinics they have to pay for every parameter. A complete test with all lipid fractions can cost them 12,000 Naira.*
>
> *(Male decision-taker and researcher, Lagos State)*

Considering the current PHC capacities, PoC to test tumor markers, pancreatic profile or cardiac enzymes were not perceived as essential for deployment at PHC facilities. In Piura Province (Peru), however, one consultant cardiologist explained that PoC cardiac enzymes (especially, troponin I–T and creatinine kinase) *"would be interesting for PHC sites that are less than 6 hours from the hospital, to assist in the telemedicine-assisted management of infarcts until a referral be possible"*. In another PHC clinic in Mongolia, PoC pancreas function was mentioned as potentially useful since *"due to the quality of water, there are many gastritis and pancreatitis in this village"*.

Albeit testing for prostate-specific antigen involves immunoassay equipment, a Nigerian endocrinologist explained that testing for prostate-specific antigen *"in Nigeria, is done in the clinical chemistry or biochemistry lab. I believe it's an important parameter for the PoC that may be deployed at PHC"*. In alignment with this statement, several other informants in Nigeria and Peru mentioned that PoC prostate-specific antigen would be a potentially useful tool to screen men *"older than 40 years old"* at PHC in order to refer them to specialized care if at risk of prostate cancer.

Similar insights on the consideration of hormonal profiles (also requiring either immunoassay platforms or mass spectrometry, see [33]) for the development of PoC biochemistry were expressed in all countries. Overall, informants were not in favor of deploying PoC hormonal profile for fertility issues at the PHC facilities, arguing that *"hormonal test is not necessary as PoC, it is not for emergency care"* and that persons demanding fertility tests are usually willing to pay for them in the private sector (o.d.n.p.o). On the other hand, since fertility problems are perceived as a *"social issue"* involving *"stigmatization"* for women in Nigeria, some informants in this country also pondered about the added value of PoC hormonal profiles at the PHC facilities:

> *Women suffer from this issue more than men. Even if we had luteinizing hormone (LH) here, or hormonal panel, and results indicated that the woman is not fertile: that woman would be referred for counselling. These tests would be helpful to provide psychosocial support to women.*
>
> *(Conversation with two female and two male PHC staff, Osun State)*

Fertility concerns aside, there were a few informants in Peru and Nigeria who argued that PoC hormonal profile could be helpful for conditions such as polycystic ovaries (especially, PoC follicle stimulating hormone (FSH), LH, testosterone) or congenital hypothyroidism in newborn babies (especially, PoC thyroid stimulating hormone (TSH), and thyroxine). Three female members of a patient support group in Lima argued that newborn babies could benefit if PoC hormonal profile could be part of a nation-wide program to detect conditions *"such as hypothyroidism or suprarenal hyperplasia"* in newborn babies. An endocrinologist in Nigeria expressed that hormonal profile would not be necessary for PHC although a PoC, utilized by trained midwives and medical staff, could be used *"for serum TSH in all new newborns to refer congenital hypothyroidism. PoC serum TSH can also be used to screen all pregnant women with symptoms of thyroid disorders at the PHC-level before referral"*. Although there were no narratives on the importance of PoC biochemistry for women's health in Mongolia, in Nigeria, a few informants mentioned that PoC could be used for the management of women with menstrual disorders or for women accessing contraception and who, as one female laboratory scientist and researcher in Lagos State expressed: "*in general, are not referred for hormonal tests*". One male cardiologist in Osun State explained that there are very few *"women in family planning with literacy to demand self-assessment for their health"*.

Importantly, for a male consultant hematologist in Osun State, there could be a need for PoC thyroid function to prevent hypothyroidism associated with maternal deaths. He noted that *"in the past year, we have lost 5 pregnant patients due to poor management of thyroid disorders at the PHC"*. In Peru and Nigeria, some informants also identified that PoC liver profile was important to prevent maternal mortality:

> *There is a need for clinical chemistry for women. For maternal and child health services, to monitor pregnancy. Any test needed for pregnancy, to monitor eclampsia or hypertension, and delivery, will be very useful in saving women's lives. Maternal mortality is still very high in Nigeria.*
>
> *(Female decision-taker and university professor, Lagos State)*

To complement this insight, a female obstetrician working in rural Peru stated that, even though PoC liver profile could be useful to prevent maternal mortality in pregnant women who develop preeclampsia, she would still need *"to refer women to the hospital, even if I could manage them because there is no evening and night staff at the PHC. We don't have 24 h services"*.

Barriers to address

In all countries, PoC technologies were perceived as useful, affordable, and easy-to-use approaches that enable rapid turnover of results and have a positive impact on the management of patients at PHC facilities. Many informants expressed that their favorable opinion on PoC technologies, in general, was driven by their own experience using existing PoC devices to test for bilirubin, hemoglobin, glucose or cholesterol.

A few specialists in Nigeria and Peru suggested that *"there is a niche"* for PoC biochemistry not only at the PHC level but also at secondary and tertiary levels where medical specialists also experience the burden of delays and high costs at their institutions' laboratories. In Nigeria, there were informants highlighting the added value, from a cost-effectiveness perspective, of PoC biochemistry for the private laboratories that cater for the testing needs of patients referred from public PHC clinics.

As an exception, a spokesperson of a sickle cell anemia patients group in Lagos expressed that *"sometimes PoC machines are wrong. This can be related to the machine itself, to the staff that are manipulating the machine, or to the context. They are faulty because of their inaccuracy. And, they might not be affordable."* Despite this view, all other informants in this study favorably valued PoC biochemistry. However, many identified some conditions that PoC should meet for them not to be considered *"faulty"*, *"inaccurate"* or *"unaffordable"*. Most notably, long-term access to supplies, including reagents, must be guaranteed by industry and governments, and ongoing training and mentoring to PHC staff on the utilization of PoC should be provided. In Nigeria, a few informants added that PoC devices should be power- and water-independent. In Nigeria and Peru, there were informants who indicated that for PoC to be used effectively, quality assurance and enhanced communication between PHC staff and specialists must be put in place.

The informants also identified some systemic or structural barriers that would need to be tackled alongside any future deployment and scale-up of PoC biochemistry for PHC. A key systemic deterrent described by some informants is *"corruption"*, which was considered by two informants as a factor that may influence decision-making by policy-makers on what PoC equipment to procure for PHC. Several informants in Nigeria and Peru identified that corruption is a factor that may drive nurses and physicians at the PHC facilities to continue to refer patients to private laboratories to access care despite PoC biochemistry platforms being present at the public health facilities because their arrangements with the private facilities can make them earn more income.

In Peru, there were informants who expressed being more concerned around any inter-professional conflicts between laboratory technologists and PHC paramedical staff being deterrents for the use of PoC biochemistry in decentralized settings. In Nigeria and Peru, it was also expressed that international non-governmental organizations and multilateral agencies who fund healthcare delivery have limited interest in biochemistry services, even when it is identified that these services could be of added value for the management of the patients that they support (i.e., HIV, malnutrition, tuberculosis). The lack of economic evaluations or market studies to guide decisions about the inclusion or exclusion of biochemistry tests in routine patients' care was also mentioned by a male Peruvian decision-taker and a male Nigerian decision-taker as a systemic barrier that must be tackled as budget holders *"will want to see these evidences"*:

> *The results of health economics studies must be taken into the Federal Ministry of Health's National Council of Health. If an equipment can conduct a lot of tests at a time and bring out direct results of either positive or negative: How will costs be minimized? The unit/cost per patient needs to be explained. How much will this PoC reduce the budget? The bottom-line in the discussion shall be that: "This PoC is doing good for a bigger number of people while reducing the cost per test". Also, that reducing the cost per test will increase the number of people going for clinical chemistry testing. Thus, it will help reduce death rates of some conditions.*
>
> *(Male decision taker and research, Lagos State)*

Discussion

This study explored PHC stakeholders' insights regarding the need for PoC biochemistry in LMICs' PHC settings. The findings suggest that, due to the myriad challenges associated with not having access to biochemistry-equipped PHC facilities, PoC biochemistry accessible in PHC would be pertinent –from a clinical and a resources-saving perspective– for patients care. Patients who would benefit the most are those who bear the burden of referrals to private and public centers with biochemistry capacity: the older adults, the bedridden, the poor and, more broadly, the populations incurring out-of-pocket expenditure in geographies that lack universal health coverage. Of particular concern is the substantial number of referrals from PHC that could be effectively

managed at the community-level if PoC biochemistry were available. As highlighted by our informants, the current biochemistry gap adversely affects the capacity of PHC staff to handle specific patient groups and erodes the trust that both communities and medical specialists place in PHC.

As per most informants' narratives, PoC biochemistry could be deployed in rural and urban areas, in private and public clinics, and PHC and secondary-level facilities. Irrespective of the setting, improved access to PoC HbA1c, lipid, liver and kidney profile would help clinicians make decisions on referral or disease management and, ultimately, would improve the retention of patients in PHC. Throughout the conversations held in our study, the added value of PoC biochemistry for the community-level management of NCDs (e.g., diabetes, hypertension) and infectious conditions (e.g., dengue, malaria, tuberculosis), to improve child health outcomes (e.g., severe dehydration in children with diarrhea and/or malnutrition) and to reduce preventable causes of death (e.g., dengue-related renal failure) was frequently highlighted.

The literature supports the rationale behind the biochemistry panels and parameters that our informants proposed for PHC in LMICs. Recent scoping reviews of PoC devices have highlighted the utility of PoC lipid profile, glucose, HbA1c and serum creatinine for decision-making on cardiometabolic diseases at PHC-level [34, 35]. PoC liver profile has been suggested as an approach to assess disease staging and prognosis for patients with hepatitis C virus living in resource-constrained settings [36]. PoC urea and creatinine to screen for kidney injury and to follow-up persons living with HIV at risk of renal comorbidities have also been recommended for LMICs [37]. Notwithstanding, a few knowledge gaps in the literature must also be noted. Further research efforts are needed to assess the functional aspects of existing PoC biochemistry devices for use in LMICs (i.e., under different environmental conditions or in settings with lack of refrigerators or temperature control) and on how feasible and realistic is to expect that PoC biochemistry devices for LMICs be indispensably ASSURED [38, 39].

With the current global prioritization of the implementation of rapid diagnostic testing and self-testing for infectious diseases [40], there is an absence of an equivalent momentum for rapid biochemistry testing. Many existing PoC biochemistry in use in high-income countries are not used in LMICs due to the absence of policy and funding [17, 18] and, possibly, due to the apprehension from some doctors that our informants described and which has been already suggested in past studies in Nigeria [41] and Peru [42]. The absence of a market of PoC biochemistry that considers LMICs' budgets, infrastructures and capacities limits the strengthening of PHC [38, 39]. The lack of access to onsite biochemistry testing for disease monitoring and management, as highlighted by some of our study informants, can be viewed through the lens of missed opportunities for the detection and management of NCDs and infectious diseases. Lessons derived from global initiatives aimed at increasing capacities to decentralize and task-shift the use of rapid PoC technologies to support efforts to test for conditions such as HIV and tuberculosis [43], syphilis [44, 45], hepatitis B and C [46, 47] or chikungunya [48, 49] could be leveraged to establish PoC biochemistry capabilities in PHC, ultimately enhancing patients' well-being and prognosis [16, 38].

In pursuing universal healthcare coverage, it is imperative to address the testing needs of all patients. A recent review shows how four of the conditions mentioned by our informants (diabetes, hypertension, malaria and health maintenance/prevention) are among the top five diagnoses in LMICs [50]. Accounts in the literature, where people living with both HIV and diabetes express that accessing quality HIV care is easier than accessing quality diabetes care [51, 52], underscore the neglect of monitoring needs for individuals affected by NCDs in some LMICs. In addressing all patients' needs, both programmatically and technologically, there is a need to transition from single-parameter approaches (VL, CD4, hemoglobin, glucose and others) to strategies that facilitate the deployment of multi-parameter, rapid, affordable PoC technologies that can seamlessly integrate into any PHC setting.

While understaffed PHC sites in remote, hard-to-reach, or conflict zones may face challenges in effectively utilizing PoC biochemistry, enhanced access to training, digital aid-decision tools, patient referral mechanisms and reagents supply systems could bolster the feasibility of employing PoC biochemistry for managing patients at the PHC level. The efforts by the Nigeria National Primary Health Care Development Agency [53], which were mentioned by a study informant, to enhance the capacities of PHC staff in utilizing biochemistry through a learning-by-doing and mentoring approach need to be reproduced in other LMICs to fostering person-centered care and enhancing professional-patient relationships. The viability of these approaches would also be heightened with improvements in countries' policies related to PHC organization, incorporating PoC biochemistry into health budgeting, and endorsing the advocacy role of local patient groups. Additionally, progress towards increased utilization of PoC biochemistry in PHC can be achieved if LMICs' essential diagnostics lists encompass these technologies. To our knowledge, countries such as India [54] and Nigeria [55, 56] have already taken steps to include them. To date, the pertinence of basic PoC biochemistry for PHC is recognized by these countries [54, 55].

Limitations and strengths

The generalizability of our findings is limited due to the limited stakeholder engagement in the visited countries due to budgetary and time constraints. Although the three study countries are LMICs, the profile of PHC delivery in Nigeria and Peru (affected by a high burden of neglected zoonotic diseases) differs from that of Mongolia. In addition, all informants in Mongolia were female and all were working exclusively as PHC clinicians, while most female and male informants in Nigeria and Peru had a hybrid profile and combined clinical roles with responsibilities either in the academic or in the not-for-profit developmental sector. The participation of stakeholders from the community (non-governmental organizations in the PHC sector, patient support groups, non-profit organizations and grassroots) was limited –due to the stringent inclusion criteria that informants must have knowledge and experience in biochemistry– and suggests that future qualitative inquiry might be needed to understand what community stakeholders know of biochemistry and what could be done to improve their competence in biochemistry at the level of the community-based health care interventions that they support. Further studies will also need to target all types of physicians at PHC level, irrespective of their experience with biochemistry, to further understand what would be the acceptability and usability of PoC biochemistry across different PHC settings (e.g., rural posts, PHC centers, mobile clinics…). Our study lacked diversity regarding the actual engagement with biochemistry at PHC level among the healthcare workers who accepted to participate as study informants.

The study has some strengths. It is one of the few studies with results that sheds light on the significance of PoC biochemistry from the perspectives of decision-makers and end-users in LMICs, where such services are critically needed. The study boasts insights collected from culturally-diverse populations operating in settings with diverse health system policies, structures and capacities. Furthermore, the alignment of insights between healthcare professionals in Mongolia, Nigeria, and Peru adds credibility to the study.

The use of a multimethod sampling approach contributed to the minimization of potential recruitment bias. However, our approach did not fully ensure equal representation of the voices of patient and community advocates compared to decision-takers and healthcare professionals. The combination of non-participant observation and conversation techniques that involved collaboration with study informants for data review, analysis, and dissemination was another strength to be noted. This multifaceted approach enabled the triangulation of study findings, ensuring that the insider perspectives of study informants are reflected in the interpretation of results that are described in this article.

Recognizing the study's failure to grasp the decision-making processes for the purchase of PoC biochemistry for PHC, the need for further qualitative market research in this regard must be underscored. Additionally, as the availability of PoC biochemistry at PHC could significantly impact countries' health indicators, further research on patients' and patient representatives' knowledge and attitudes towards biochemistry testing for disease management will also be necessary.

Conclusions

Key PHC stakeholders from Mongolia, Nigeria, and Peru shared their perspectives on PoC biochemistry for PHC, and highlighted the negative impact that the poor access to biochemistry at PHC facilities has on service delivery. The introduction of PoC biochemistry in PHC facilities is perceived as holding transformative potential for patient care. PoC equipment for essential parameters such as HbA1c, urea, creatinine or electrolytes is seen as significant to enhance community-level management of preventable causes of mortality. These include conditions like diabetes, childhood diarrhea, pregnancy-related hypothyroidism or pre-eclampsia, and renal failure. The study informants recognized that the contributions that PoC biochemistry can make to improving service delivery for conditions like HIV, tuberculosis, Lassa fever or dengue will support the pertinence of deploying PoC biochemistry in high infectious disease burden contexts. This study underscores that the deployment of PoC biochemistry could benefit the patients who currently face the burden of referrals to centers with biochemistry capabilities, and improve the role of PHC providers to provide quality care for patients through the provision of prompt diagnostic and disease management services.

Abbreviations

ASSURED	Affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free, deliverable
COVID-19	Coronavirus disease 2019
FSH	Follicle stimulating hormone
HbA1c	Glycated hemoglobin
HDL/LDL	High-density and low-density lipoproteins
HIV	Human immunodeficiency virus
LH	Luteinizing hormone
LMICs	Low-middle-income countries
NCDs	Noncommunicable diseases
o.d.n.p.o	Observed during non-participant observation
PHC	Primary health care
PoC	Point-of-care
TSH	Thyroid Stimulating Hormone

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Data availability
The qualitative data generated during and/or analyzed during the current study are not available due to lack of participants' consent for sharing of their data with persons other than the responsible for this study.

Declarations

Ethics approval and consent to participate
Ethical approval was obtained from the Obafemi Awolowo University – Institute for Public Health's Health Research Ethics Committee (Ref.: HREC IPH/OAU/12/2400). As per the Mongolia's 2011 Law (Oct 6th) on Company and the Peru's 2023 Law (31675) on Strengthening Scientific Research, Technological Development and National Innovation of Medical Devices, this social sciences project was exempt from requesting ethical approval from a medical research ethics committee in Mongolia and Peru. Oral informed consent to participate was obtained from all of the study participants. This research was conducted in accordance with the Belmont Report and the Declaracion of Helsinki.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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References

1. United Nations. Goal 3. Ensure healthy lives and promote well-being for all at all ages. https://sdgs.un.org/goals/goal3. Accessed 25 Dec 2023.
2. World Health Organization. Global action plan for the prevention and control of noncommunicable diseases 2013–3030. WHO: Geneva; 2013.
3. World Health Organization, United Nations Children's Fund. Declaration of Astana. https://www.who.int/docs/default-source/primary-health/declaration/gcphc-declaration.pdf. Accessed 25 Dec 2023.
4. Hudson M, Rutherford GW, Weiser S, Fair E. Linking private, for-profit providers to public sector services for HIV and Tuberculosis co-infected patients: a systematic review. PLoS ONE. 2018;13(4):e0194960. https://doi.org/10.1371/journal.pone.0194960.
5. Newby G, Cotter C, Roh ME, Harvard K, Bennett A, Hwang J, et al. Testing and treatment for malaria elimination: a systematic review. Malar J. 2023;22(1):254. https://doi.org/10.1186/s12936-023-04670-8.
6. Pham MD, Nguyen HV, Anderson D, Crowe S, Luchters S. Viral load monitoring for people living with HIV in the era of test and treat: progress made and challenges ahead - a systematic review. BMC Public Health. 2022;22(1):1203. https://doi.org/10.1186/s12889-022-13504-2.
7. Chen CC, Lu SC, Bai CH, Wang PY, Lee KY, Wang YH. Diagnostic accuracy of SARS-CoV-2 Antigen tests for community transmission screening: a systematic review and Meta-analysis. Int J Environ Res Public Health. 2021;18(21):11451. https://doi.org/10.3390/ijerph182111451.
8. Wu Y, Zhang Q, Li M, Mao Q, Li L. Global experiences of community responses to COVID-19: a systematic literature review. Front Public Health. 2022;10:907732. https://doi.org/10.3389/fpubh.2022.907732.
9. Yadav H, Shah D, Sayed S, Horton S, Schroeder LF. Availability of essential diagnostics in ten low-income and middle-income countries: results from national health facility surveys. Lancet. 2021;9:e1553–60. 10.1016/S2214-109X(21)00442-3.
10. Roca P, Oliver J, Rodríguez AM. Bioquímica. Técnicas Y métodos. Madrid: Ed. Hélices; 2003.
11. Chang TE, Huang YS, Chang CH, Perng CL, Huang YH, Hou MC. The susceptibility of anti-tuberculosis drug-induced liver injury and chronic hepatitis C infection: a systematic review and meta-analysis. J Chin Med Assoc. 2018;81(2):111–8. https://doi.org/10.1016/j.jcma.2017.10.002.
12. Kohli A, Shaffer A, Sherman A, Kottilil S. Treatment of hepatitis C: a systematic review. JAMA. 2014;312(6):631–40. https://doi.org/10.1001/jama.2014.7085.
13. Abeysekera KWM, Macpherson I, Glyn-Owen K, McPherson S, Parker R, Harris R, Yeoman A, Rowe IA, Dillon JF. Community pathways for the early detection and risk stratification of chronic liver disease: a narrative systematic review. Lancet Gastroenterol Hepatol. 2022;7(8):770–80. https://doi.org/10.1016/S2468-1253(22)00020-6.
14. Land KJ, Boeras DI, Chen XS, Ramsay AR, Peeling R. REASSURED diagnostics to inform disease control strategies, strengthen health systems and improve patient outcomes. Nat Microbiol. 2019;4:46–54. https://doi.org/10.1038/s41564-018-0295-3.
15. Naseri M, Ziora ZM, Sion GP, Batchelor W. ASSURED-compliant point-of-care diagnostics for the detection of human viral infections. Rev Med Virol. 2002;32(2):e2263. https://doi.org/10.1002/rmv.2263.
16. Kuupiel D, Bawontuo V, Mashamba-Thompson TP. Improving the accessibility and Efficiency of Point-of-Care Diagnostics Services in low- and Middle-Income countries: lean and agile supply Chain Management. Diagnostics. 2017;7:58. https://doi.org/10.3390/diagnostics7040058.
17. Koster W, Mutegi EM, Ocen F, Odhiambo CO, Waweru MM, Ndione AG, et al. Contexts for developing of national essential diagnostics list. Lessons from a mixed-methods study of existing documents, stakeholders and decision making on tier-specific essential in-vitro diagnostics in African countries. PLOS Glob Public Health. 2023;3(5):e0001893. 10.1371/ journal.pgph.000189.
18. Lingervelder D, Koffijberg H, Kusters R, IJzerman MJ. Health Economic evidence of point-of-care testing: a systematic review. Pharmacoecon Open. 2021;5(2):157–73. https://doi.org/10.1007/s41669-020-00248-1.
19. Okoli C, Pawlowski SD. The Delphi method as a research tool: an example, design considerations and applications. Inf Manag. 2004;42(1):15–29. https://doi.org/10.1016/j.im.2003.11.002.
20. Slade SC, Dionne CE, Underwood M, Buchbinder R. Standardised method for reporting exercise programmes: protocol for a modified Delphi study. BMJ Open. 2014;4(12):e006682–e. https://doi.org/10.1136/bmjopen-2014-006682.
21. Gobo G. Doing ethnography. Los Angeles, CA: SAGE; 2008.
22. Kielmann K, Cataldo F, Seeley J. Introduction to Qualitative Research Methodology. London: DFID; 2011.
23. Harman NL, Bruce IA, Callery P, Tierney S, Sharif MO, O'Brien K, et al. MOMENT – management of Otitis Media with Effusion in Cleft Palate: protocol for a systematic review of the literature and identification of a core outcome set using a Delphi survey. Trials. 2013;14(1):70. https://doi.org/10.1186/1745-6215-14-70.
24. World Health Organization. Human resources for health country profiles: Mongolia. https://iris.who.int/bitstream/handle/10665/208137/9789290616382_eng.pdf?sequence=1 Accessed 21 July 2024.
25. World Health Organization. Nigeria. Country Cooperation Strategt at a glance. https://iris.who.int/bitstream/handle/10665/136785/ccsbrief_nga_en.pdf?sequence=1 Accessed 21 July 2024.

26. Gobierno de Perú (gob.pe). Servicios y categorías del primer nivel de atención de salud. https://www.gob.pe/16728-servicios-y-categorias-del-primer-nivel-de-atencion-de-salud. Accessed. 21 July 2023.
27. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care. 2007;19(6):349–57. https://doi.org/10.1093/intqhc/mzm042.
28. Gob.Pe. Plataforma digital única del Estado Peruano. Servicios y categorías del primer nivel de atención de salud. https://www.gob.pe/16728-servicios-y-categorias-del-primer-nivel-de-atencion-de-salud. Accessed 27 December 2023.
29. Lagos State. Lagos State Primary Health Care Board. Accessed 23 February 2024.
30. Bendezu-Quispe G, Mari-Huarache LF, Taype-Rondan Á, Mejia CR, Inga-Berrospi F. Effect of Rural and Marginal Urban Health Service on the physicians' perception of primary health care in Peru. Rev Peru Med Exp Salud Publica. 2020;37(4):636–44. https://doi.org/10.17843/rpmesp.2020.374.5294. Spanish, English.
31. Vivar-Mendoza A. La Eterna tensión entre lo individual y lo colectivo: El caso de la corrupción en El Perú. Acta Méd Peru. 2020;37(2):209–14. https://doi.org/10.35663/amp.2020.372.1036.
32. Chan PL, Le LV, Ishikawa N, Easterbrook P. Regional progress towards hepatitis C elimination in the Western Pacific Region, 2015–2020. Glob Health Med. 2021;3(5):253–61. https://doi.org/10.35772/ghm.2021.01065.
33. Conklin SE, Knezevic CE. Advancements in the gold standard: measuring steroid sex hormones by mass spectrometry. Clin Biochem. 2020;82:21–32. https://doi.org/10.1016/j.clinbiochem.2020.03.008.
34. FIND. Landscape of point-of-care devices for testing of cardiometabolic diseases. Accessed 27 February 2024.
35. Tenorio-Mucha J, Busta-Flores P, Lazo-Porras M, et al. Facilitators and barriers of the implementation of point-of-care devices for cardiometabolic diseases: a scoping review. BMC Health Serv Res. 2023;23:412. https://doi.org/10.1186/s12913-023-09419-2.
36. Rong X, Ailing F, Xiaodong L, Jie H, Min L. Monitoring hepatitis B by using point-of-care testing: biomarkers, current technologies, and perspectives. Expert Rev Mol Diagn. 2021;21(2):195–211. https://doi.org/10.1080/14737159.2021.1876565.
37. Kalyesubula R, Wearne N, Semitala FC, Bowa K. HIV-associated renal and genitourinary comorbidities in Africa. J Acquir Immune Defic Syndr. 2014;67(S1):S68–78. https://doi.org/10.1097/QAI.0000000000000259.
38. Heidt B, Siqueira WF, Eersels K, Diliën H, van Grinsven B, Fujiwara RT, Cleij TJ. Point of Care Diagnostics in Resource-Limited settings: a review of the Present and Future of PoC in its most needed Environment. Biosensors. 2020;10(10):133. https://doi.org/10.3390/bios10100133.
39. Kimani FW, Mwangi SM, Kwasa B, Kusow AM, Ngugi B, Chen J, et al. Rethinking the design of low-cost point-of-care diagnostic devices. Micromachines. 2017;8:317.
40. Mfuh KO, Abanda NN, Titanji BK. Strengthening diagnostic capacity in Africa as a key pillar of public health and pandemic preparedness. PLOS Glob Public Health. 2023;3(6):e0001998. https://doi.org/10.1371/journal.pgph.0001998.
41. Onovughakpo-Sakpa EO, Osemwenkha SO, Adewolu OF, Okhimamhe AF. Point of care testing: knowledge and utilization amongst doctors in Government hospitals in Edo State, Nigeria. Niger J Clin Pract. 2015;18(6):780–5. https://doi.org/10.4103/1119-3077.163279ç.
42. Anticona Huaynate CF, Pajuelo Travezaño MJ, Correa M, Mayta Malpartida H, Oberhelman R et al. Diagnostics barriers and innovations in rural areas: insights from junior medical doctors on the frontlines of rural care in Peru. BMC Health Serv Res 20155;15:454. https://doi.org/10.1186/s12913-015-1114-7
43. Engel N, Wolffs PFG. Aligning diagnostics to the point-of-care: lessons for innovators, evaluators and decision-makers from Tuberculosis and HIV. BMJ Glob Health. 2020;5(11):e003457. https://doi.org/10.1136/bmjgh-2020-003457.
44. Brandenburger D, Ambrosino E. The impact of antenatal syphilis point of care testing on pregnancy outcomes: a systematic review. PLoS ONE. 2021;16(3):e0247649. https://doi.org/10.1371/journal.pone.0247649.
45. Garcia PJ, Carcamo CP, Chiappe M, Valderrama M, La Rosa S, Holmes KK. Rapid syphilis tests as catalysts for health systems strengthening: a case study from Peru. PLoS ONE. 2013;8:e66905. https://doi.org/10.1371/journal.pone.0066905.
46. Picchio CA, Nomah DK, Araujo SG, Rando-Segura A, Fernández E, Buti M, et al. A novel model of care for simplified testing of HBV in African communities during the COVID-19 pandemic in Spain. Sci Rep. 2021;11(1):17063. https://doi.org/10.1038/s41598-021-96350-3.
47. Zhang M, O'Keefe D, Craig J, Samley K, Bunreth V, Jolivet P, et al. Decentralised hepatitis C testing and treatment in rural Cambodia: evaluation of a simplified service model integrated in an existing public health system. Lancet Gastroenterol Hepatol. 2021;5(6):371–80. https://doi.org/10.1016/S2468-1253(21)00012-1.
48. Karlikow M, da Silva SJR, Guo Y, Cicek S, Krokovsky L, Homme P, et al. Field validation of the performance of paper-based tests for the detection of the Zika and Chikungunya viruses in serum samples. Nat Biomed Eng. 2022;6:246–56. https://doi.org/10.1038/s41551-022-00850-0.
49. Moreira J, Brasil P, Dittrich S, Siqueira AM. Mapping the global landscape of Chikungunya rapid diagnostic tests: a scoping review. PLoS Negl Trop Dis. 2022;16(7):e0010067. https://doi.org/10.1371/journal.pntd.0010067.
50. Bigio J, MacLean E, Vasquez NA, Huria L, Kohli M, Gore G, et al. Most common reasons for primary care visits in low- and middle-income countries: a systematic review. PLOS Glob Public Health. 2022;2(5):e0000196. https://doi.org/10.1371/journal.pgph.0000196.
51. Bukenya D, Van Hout M-C, Shayo EH, Kitabye I, Junior BM, Kasidi JR, et al. Integrated healthcare services for HIV, diabetes mellitus and hypertension in selected health facilities in Kampala and Wakiso districts, Uganda: a qualitative methods study. PLOS Glob Public Health. 2022;2(2):e0000084. https://doi.org/10.1371/journal.pgph.0000084.
52. Ohueri CW, García AA, Zuñiga JA. Counting, coping, and navigating the Flux: a focused Ethnographic Study of HIV and Diabetes Self-Management. Qual Health Res. 2022;32(3):399–412. https://doi.org/10.1177/10497323211064231.
53. NPHCDA, Resources. CRISP HRH Operational Guideline. https://nphcda.gov.ng/resources/ Accessed 27 February 2024.
54. Indian Council of Medical Research. National Essential Diagnostics List. https://www.icmr.nic.in/content/national-essential-diagnostics-list. Accessed 3 February 2024.
55. World Health Organization. Nigeria flags-off policy document to boost diagnostic testing 2022. https://www.afro.who.int/countries/nigeria/news/nigeria-flags-policy-document-boost-diagnostic-testing Accessed 27 February 2024.
56. Kao K, Kohli M, Gautam J, Kassa H, Acellam S, Ndungu J, Albert H. Strengthening health systems through essential diagnostic lists and diagnostic network optimization. PLOS Glob Public Health. 2023;3(3):e0001773. https://doi.org/10.1371/journal.pgph.0001773.

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