



# Pathology and laboratory medicine in universal health coverage

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**Abstract:** Diagnostics, including both cellular pathology as well as all subspecialties of laboratory medicine, should be an integral part of national plans to implement universal health coverage (UHC). In most of the world, however, diagnostics are either lacking altogether or are of poor quality, do not produce results in a timely manner, or are unaffordable to large parts of populations creating inequitable access. More recently a number of publications have increased recognition of the essentiality of diagnostics in healthcare systems at national and international levels. These publications have described the essentiality of diagnostics in healthcare, started to analyze the barriers to increasing and improving access to diagnostics, described some of the solutions to solving those barriers, and created some proposed pathways forward. This review will summarize the most recent information on diagnostics in UHC.

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## Introduction

As part of the Sustainable Development Goals, the World Health Organization (WHO) and individual nations are working towards what is known as universal health coverage (UHC), a goal of equitable access to quality healthcare for all persons (1,2). Achieving the goal of UHC will require changes in how many nations provide healthcare to their populations, increased expenditures on healthcare services, investment in healthcare infrastructure, an increase in human capacity, developing systems of regulatory oversight to ensure both equity as well as quality, and innovative ideas on how to solve all of these issues. Over the past few years there has been increased recognition of the importance of diagnostic testing in healthcare (3-8), and especially in achieving the goal of UHC, but until recently there have been few systematic efforts designed to develop the evidence base on which policy makers can rationally increase and improve access to diagnostic testing (5). At the same time, it has only been recently that pathology and laboratory medicine (PALM) have developed the advocacy base needed to influence policy makers and funders (7). This review will

discuss the essentiality of PALM in healthcare and especially as it relates to UHC, present some of the known barriers that limit access to diagnostics in much of the world, describe some of the potential solutions to those barriers, and describe some of the ongoing efforts to further develop and implement those solutions.

## Essentially of diagnostics in healthcare

### *Diagnostics as a basic component of healthcare*

Diagnostic testing is a fundamental component of health care (9,10) and an integral component of healthcare systems (*Table 1*). Although clinical diagnosis based on clinical history, family history, review of systems, and physical examination remains the mainstay of clinical medicine, guides further evaluation including diagnostic testing, and in many situations are all that is needed to treat patients, many diseases and conditions cannot be distinguished or diagnosed based solely on clinical diagnosis (9). Moreover, treatment of many chronic diseases requires access to diagnostic testing for monitoring and adjustments in

**Table 1** Essential roles of diagnostics in healthcare systems

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Diagnostics as a basic component of healthcare
Diagnostics as part of resource stewardship
Diagnostic testing as an integral part of healthcare systems
Diagnostic testing in public health and epidemiology
Research

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therapy. Perhaps the best example is diabetes, which cannot be accurately diagnosed or treated adequately without access to simple diagnostic tests such as blood glucose levels and HbA1c measurements. For complex diseases such as cancer, effective treatment is not possible without use of diagnostic testing (11). Diagnostic testing is critical for detection of emerging infectious diseases, surveillance for diseases within populations, and for monitoring the evolution of antimicrobial resistance (12,13). As we move slowly into an era of targeted and patient-specific therapy, often referred to as precision medicine, the importance of accurate diagnostics will only increase (7).

#### *Diagnostics as part of resource stewardship*

Diagnosis and treatment in the absence of accurate diagnosis is wasteful, inefficient, and can harm patients. As an example, treatment of febrile patients in malaria endemic zones was for too long empiric and not guided by laboratory testing (14,15). Not surprisingly, many patients with fever but who did not have malaria received anti-malarial agents rather than the treatment they needed, widespread use of antimalarial drugs resulted in emergence of drug resistance, and patients with *Plasmodium vivax* or *Plasmodium ovale* infection may not have received primaquine or other drugs necessary to eradicate the infection (16). As another example, patients with bacterial or fungal infections without access to adequate microbiological testing can receive the wrong class of antimicrobial agents, antimicrobial agents to which the infecting pathogen is resistant, or the wrong drug dose, all of which lead to poorer outcomes and contribute to the development of antimicrobial resistance. Accurate and timely diagnosis is an essential part of stewardship of resources within healthcare systems.

#### *Diagnostic testing as an integral part of healthcare systems*

Functional healthcare systems rely upon overlapping and

intersecting networks of providers, facilities, programs, and data. Diagnostic testing is one of these networks. Accurate and timely test results enable practitioners to diagnose and treat patients more quickly and efficiently, and also enable them to move patients to the right level of care, the right facility, make referrals, and ask for more appropriate consultations. For all of these systems to work as intended there must be trust in the results/outcomes; if practitioners do not believe or trust test results (which also holds true for diagnostic radiology and other forms of diagnostic testing), patients may not receive the treatment they need, patients may not be treated at the right level of care, and referrals and consultations can be delayed or not requested (17).

#### *Diagnostic testing in public health and epidemiology*

Diagnostic testing provides much of the data used for epidemiology and disease surveillance, outbreak detection and monitoring, and diagnosis and treatment of communicable diseases of public health interest (e.g., tuberculosis). Some of this testing occurs in public health settings, but much of it is generated in the course of routine patient care. Diagnostic testing also generates much of the data used in registries, such as diabetes or cancer registries, and is essential for detection and monitoring of antimicrobial drug resistance, which is a major public health concern in much of the world (18-20).

#### *Research*

Diagnostics themselves can be studied through research, particularly for their performance characteristics and impact on patient care, but they also are integral to most types of clinical research. Diagnostics are used to evaluate the effectiveness of new drugs, to monitor safety and detect side effects, and to establish safe and effective drug levels. Diagnostics are also used to evaluate the effectiveness of new procedures.

#### **Gaps between what exists and what is needed for UHC**

Despite the essentiality of PALM services in healthcare systems, most of the world's population lacks access to these services. As described in the recent *Lancet* Series on PALM in low-income and high-income countries (HIC), there are several main gaps between what exists and what is needed for UHC (7,8). This review expands on what was described

**Table 2** Barriers to providing diagnostics for healthcare systems

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Workforce capacity
Education and training
Infrastructure
Systems to support quality
Integrated tiered diagnostic networks
System fragmentation
Overall strategic planning
Information management
Systems of finance

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in that Series, as our understanding of these gaps increases over time, and it bears emphasis that our knowledge about this issue has many gaps (*Table 2*). In conducting literature reviews and surveys about these gaps, it has become clear that we have good data for some countries that can be used to establish benchmarks, but our data for much of the world is very limited in scope and quality. For some countries there are almost no published data. Our knowledge base, then, is one of the most important gaps between what exists and what is needed to embed diagnostics in UHC.

### *Workforce capacity*

Although data are lacking for much of the world, the available data indicate that there are far too few professionals working in PALM than are needed to provide diagnostic services for most of the world's population (7,21). As one example, in sub-Saharan Africa (SSA) there are less than 10% the number of pathologists per population compared with HICs, with some countries having no pathologists at all (7,21,22). Data regarding non-physician doctoral scientists are even more sparse, but what little is known suggests that there are just as few of these professionals working in many LMICs. The available data on technical staff indicates a similar lack of workforce capacity. It is by now clear that existing education and training programs cannot build the workforce at the pace needed; there are success stories from SSA, but these are insufficient to bridge the gap across the continent and in the time frame needed. Building workforce capacity should continue, but at the same time, alternative approaches that will allow healthcare systems to leverage the available workforce need to be developed. Whether these involve

task shifting, task sharing, or technological approaches will vary by local circumstance (6).

### *Education and training*

Although this is closely related to workforce capacity, as education and training are needed to both build as well as sustain a workforce, one of the most important gaps in what is needed for PALM to support UHC is ongoing education and training, often referred to as continuing medical education (CME) or, perhaps more accurately, continuing professional development (CPD) (23,24). Diagnostics are not static: they change continually and the workforce needs to stay up to date with these changes. This will become increasingly important in the upcoming years as new technology such as image-based analysis, artificial/augmented intelligence (AI), and molecular diagnostic testing become more widely used. It is likely that the role of pathologists, laboratory scientists, radiologists, and others involved in diagnostic testing will change substantially in the immediate future. The education and training systems need to evolve in order to support these rapid changes.

### *Infrastructure*

Many hospitals and clinics around the world lack the basic physical infrastructure needed to support diagnostic testing (5). Adequate space, clean water (which is particularly important for larger automated analyzers), a stable and 'clean' electrical supply with good surge protection, adequate heating/ventilation/air conditioning, sufficient storage space, and lighting all are needed for contemporary laboratory testing. In many countries, lack of equipment maintenance results in the inability to use instruments after an initial malfunction, often precluding further use of the instrument (25). Increasingly important is access to a robust information technology (IT) network to support both ordering and reporting of test results, on line ordering and tracking of supplies, and remote troubleshooting of instruments by vendors. A functional and stable supply chain also is a critical feature of adequate infrastructures and also heavily depends on access to adequate IT.

### *Systems to support quality*

Much of the healthcare around the world is of low quality (26).

This holds true for PALM, for which poor quality testing, unacceptably slow test turnaround time, and inequitable access all are the norm in most countries and regions (5). Even within HIC there are significant gaps in access and low-quality diagnostic systems are not uncommon. To achieve UHC, countries will need to develop and invest in the policy, accreditation, and regulatory systems needed to ensure quality (6). Healthcare systems will need to implement and follow quality standards. There is little point in expanding access to low-quality diagnostics because doing so will only help perpetuate low quality healthcare, waste resources, and harm patients. No one proposes that we simply export the regulatory systems in use in HIC, because these were developed and changed over time to reflect the circumstances unique to those countries. Moreover, these are complex systems that are expensive to implement and maintain; trying to duplicate these around the world would in and of itself create a barrier to building capacity.

### *Integrated tiered diagnostic networks (ITDN)*

To maximize efficiency, provide stewardship of resources, decrease costs, and maximize clinical impact diagnostic testing needs to be available at the right place in healthcare systems, and at the right time. In order to do so, healthcare systems need to develop and use ITDN where basic testing is provided at or near the bedside, with more complex testing (and testing for which immediate results are not needed) provided at ever-higher tiers within networks (8,27). Some tests, for example, kidney biopsies, are not all that common even in HIC, so it makes more sense to offer such tests in a centralized facility that can support many sites within healthcare systems. In contrast, tests such as blood glucose levels or HbA1c levels should be available at the point of care in order to provide immediate information to physicians and nurses caring for patients. Many tests fall between these two extremes and can be provided by hospital or reference laboratories. Some tests are needed only in the hospital setting (e.g., tests to support surgery) and should be provided there. Developing such ITDN should be a priority for healthcare systems that are implementing UHC.

### *System fragmentation*

With the exception of national health systems in HIC, healthcare around the world is fragmented between governmental programs, private sector for-profit programs, private sector non-profit (e.g., faith-based) programs,

and vertical (e.g., disease-specific) programs. As a result, healthcare is not coordinated, access is inequitable, resources are wasted due to duplicative initiatives (often in the same area), and unhealthy competition develops between programs. As an example, many pathologists in LMIC work partly in the public sector and partly in the private sector, but because they derive most of their income from the private sector they not surprisingly divert testing from the public sector to where they work in the private sector (which typically has better resources and infrastructure that enables the necessary testing to be done). The outcome is obvious: care becomes fragmented between sectors and test results often do not get back to where the patient is receiving care. Another outcome is that low volumes in the public sector result in low quality as well as the resulting impression that investment is not needed because of low test volumes. It becomes a pernicious cycle that is difficult to break.

Professional fragmentation also is common in many countries with different professions playing different roles and having different responsibilities for diagnostics. In part, this is due to different models of education and training, such as the United States where most pathologists receive training in both anatomic/cellular pathology as well as laboratory medicine, which is in contrast to most countries where each sub-specialty of PALM is its own discipline (e.g., clinical biochemistry or medical microbiology, where trainees learn that discipline only). In part, this is also caused by workforce shortages, where professionals in some disciplines are not available and so others help fill those gaps. Whatever the cause, the result is the same: fragmentation wastes resources, creates inefficiencies, and can adversely affect patient safety and quality. No single model of oversight is best, and any model needs to be tailored to local needs, but all healthcare systems should develop policies and processes to minimize system fragmentation.

### *Overall strategic planning*

To develop, implement, and coordinate the activities needed to fill these gaps, and to provide sufficient and sustainable funding, countries should develop strategic plans for diagnostics within their healthcare systems (6,26). It is increasingly recognized that PALM and radiology must be considered parts of the same diagnostic spectrum, because each provides unique but overlapping and related information used to guide diagnosis and treatment (8). Cancer care, for example, is not possible without access to

both PALM and radiology. Moreover, solving some of the gaps for one can be leveraged to solve gaps for the other; providing adequate physical infrastructures such as a good electrical supply and HVAC system supports all types of diagnostics. Despite the apparent need and high priority for strategic planning, few countries have done this for either PALM or for radiology. Such planning needs to be an integral part of planning for UHC.

### *Information management*

In SSA, countries decided to increase access to communications by going directly to mobile phone technology rather than attempt to build a traditional landline system across the continent. There is a similar undertaking in progress in some countries where use of mobile health (m-health) systems is bypassing the need for traditional ways to move health information. Unlike mobile phone systems, however, to date the use of m-health systems is not coordinated, uses a number of platforms, supports specific parts of healthcare systems (e.g., ordering tests), and is not integrated with wider networks. More importantly, current m-health systems cannot be used to move patient records of any size, do not have sufficient storage and retrieval capabilities, and lack security systems necessary to maintain confidentiality. There are efforts underway to solve all these issues, and if successful healthcare systems in much of the world could bypass the need for paper-based health records and improve communication between patients, their providers, and healthcare systems.

In much the same way, many laboratories and radiology departments around the world lack access to good information systems. Because many commercial systems are unaffordable in LMIC, the use of 'open source' systems has gained attention in the past few years. As with m-health systems, there are still hurdles to be overcome such as the ability to write interfaces with instruments, communication with other IT systems, and technical support.

### *Systems of finance*

In most of the world, diagnostic testing is paid out of pocket by patients and their families. National health plans cover diagnostic testing in many HIC, as do private insurance or managed care plans, but such coverage is lacking in most LMIC (and even for many patients in HIC). This is a complex issue to resolve. First, it is challenging to determine the actual costs of tests because of the need to account

not only for consumables and labor but also to amortize the costs of instruments, maintenance, infrastructure, quality programs, IT support, and professional oversight. In addition, for private organizations, some profit must be included so that future investment is possible, which adds to cost. For charitable organizations that provide testing free of charge or at greatly reduced prices, methods of financing other than out of pocket payment are needed which again can add to cost. For governments, financing needs to account for issues of equitable access, research and development, regulatory oversight, and support of education and training systems, all of which have costs. For all types of organizations, financing systems need to be sustainable and sufficiently flexible to adapt to changes in disease prevalence, disease outbreaks, emerging diagnostic technologies, and new forms of treatment; these require further investment and, as a result, have costs associated with them. Second, defining the economic value of diagnostics can be challenging (28), as can determining the right amount of future investment even when there are calls for such investment (29).

## **Solutions**

### *Essential diagnostics list (EDL) and disease burden as a framework*

Building diagnostic systems, much like building healthcare systems, is a daunting task for much of the world. In order for countries to design such systems there needs to be a framework to guide strategic planning (30). Until recently there has not been such a framework for diagnostics, nor has using existing systems in HIC as models been practicable or effective. In 2018 the WHO released the first edition of an EDL, with a second edition following in 2019 (31,32). The EDL is at this time includes only PALM tests, and even that is limited, but future editions hopefully will include radiology tests. The tests included in the first and second editions parallel those recently described as the most common tests used in hospitals in different regions of the world (33). The EDL is similar in many ways to the essential medicines list (EML) that was developed many years ago, and like the EML the EDL should be considered not as a static but rather evolving list that will change over time. More importantly, it can be modified and adapted to the circumstances unique to each country, which can also add to it as necessary. India, for example, already has developed its own EDL (34) and other countries

are in the process. By developing an EDL, countries can begin to prioritize testing and develop the sequence of implementation according to those priorities.

Many of the tests on the WHO EDL are relevant to any healthcare setting, whereas some align with specialized patient populations (e.g., malaria testing). As a second part of this framework, countries should use the data available on the burden of disease for their country and region (35-37). In addition to tropical and geographic communicable diseases, which only occur in certain parts of the world, there are significant variations in other communicable and non-communicable disease burden between populations. For example, prevalence of specific cancers varies substantially between populations in different countries and regions. As another example, smoking rates vary widely between populations, so the resultant disease burden associated with smoking also varies between those populations. Developing a country-specific or population-specific EDL that is aligned with the corresponding disease burden, and then using that framework to build diagnostic capacity, will help countries to address all of the gaps described above in a rational and equitable manner.

### *Partnerships*

Few organizations or even governments have the knowledge, experience, or resources to build diagnostic systems that are sufficiently robust to meet the needs of large populations. This is especially true for complex medical care such as that needed to support intensive care units, trauma, transplantation, or cancer care. Yet this knowledge and experience does exist in many places and therefore it would be far easier, less expensive, and more efficient to make use of that expertise than it would be for nations to start *de novo*. Many professional societies offer technical expertise, some funding organizations have access to technical experts, WHO is a rich resource for technical information and guidance regarding capacity building (38), and some governmental organizations such as the US Centers for Disease Control and Prevention have both technical expertise as well as programs to help disseminate that expertise. In addition, there are organizations such as CLSI, the European Society for Clinical Microbiology and Infectious Diseases (ESCMID), Royal College of Pathologists, the International Standards Organization, and some national programs that provide guidance on complex diagnostic processes as well as standards for testing (39-45). There are many other examples, but the message should

be that rich resources already exist to help build diagnostic capacity. The challenge, as with all partnerships, is to identify suitable partners, align interests, and find a path forward that is acceptable to all parties.

Finding partnerships for funding is a greater challenge because of the need for sustainable, long-term financing that is needed to provide sufficient time to design, build, implement, and monitor diagnostic systems. Funding in global health is often vertical (developed to support one or two diseases only), varies over time, and is susceptible to political pressures/priorities. Funding also is too often project-based, with funding ending at the end of projects with no ability to continue after that. Better mechanisms of financing are needed in order for UHC to succeed. There is, however, guidance on cost-effective capacity building such as the recent series of books *Disease Control Priorities*, 3rd edition. (46,47), and as more countries move towards UHC there will be much more information available as to best approaches.

### *Improved technology and innovation*

Although we have perfectly suitable technology to diagnosis and monitor common diseases and conditions, widespread use of this technology is hampered by several factors. First of these is insufficient and inadequate supply chains. Not only are cold supply chains impractical for much of the world, developing and using multiple supply chains to support multiple test platforms is impractical and costly. Second is technical support: much of the world lacks access to adequate biomedical engineering services, which again is made more complicated by use of multiple test platforms. Third is the issue of regional and national variability: differing power requirements, instructions written in non-native languages, inability to interface with different IT systems, and inadequate technical staff to operate equipment. Although it is naïve to believe that improved technology will solve all of these problems, development of platforms using common electrical and mechanical systems, common disposable items such as cuvettes, and standardized computer interfaces all would simplify maintenance, technical support, supply chains, and training. It will also substantially reduce costs.

Increased use of 'tele-diagnostics' is another potential technological solution. Telemedicine already is in widespread use in many HIC, telepathology and teleradiology are slowly gaining traction in both HIC and some LMIC, and use of image-based analysis has the

potential to allow for improved diagnostic capability in many areas. There are, however, barriers to this solution including cost, need for technical support of systems, and access to fast Internet connections that currently are lacking in many areas. Nonetheless, use of tele-diagnostics has the potential to increase access to diagnostic testing in areas currently lacking such access, particularly until local diagnostic capacity can be built.

Improved technology has great potential to increase access to diagnostic testing, but as with any technological solution we need to be wary of techno-optimism (47,48). Over reliance on purely technological solutions often results in delays in fixing other problems, many new technologies do not work as intended, new technologies tend to be expensive, and there are no simple solutions to many of these barriers described above (49). Nonetheless, there is ample room for technological improvements in diagnostics, especially as it relates to use of AI and tele-diagnostics.

## Conclusions

As the world moves towards the goal of UHC, populations begin to demand better access to better healthcare, and other medical and surgical (50) disciplines increase their participation in providing UHC, diagnostics increasingly will play an important role. Not only is diagnostic testing necessary for good routine healthcare and to support public health programs, without the healthcare systems are less efficient, waste resources, and problems such as antimicrobial drug resistance become worse. Despite the barriers to providing quality diagnostic testing in much of the world, there is growing recognition of its importance and the need for countries to develop strategic diagnostic plans, create policies including regulatory and quality systems to support those plans, create sustainable systems of finance, develop the necessary infrastructure, and educate and train the required workforce. These are challenging goals, but there are examples of how this can be done successfully and relatively quickly. Professionals, and professional societies, can help drive all of this to success using the available knowledge on capacity through the EDL and GBD framework.

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## Footnote

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## References

1. United Nations. Transforming our world: The 2030 agenda for sustainable development. New York: United Nations, 2015.
2. Kieny MP, Bekedam H, Dovlo D, et al. Strengthening health systems for universal health coverage and sustainable development. *Bull World Health Org* 2017;95:537-9.
3. Carter JY, Lema OE, Wangai MW, et al. Laboratory testing improves diagnosis and treatment outcomes in primary health care facilities. *Afr J Lab Med* 2012;1:8.
4. Petti CA, Polage CR, Quinn TC, et al. Laboratory medicine in Africa: a barrier to effective health care. *Clin Infect Dis* 2006;42:377-82.
5. Wilson ML, Fleming KA, Kuti M, et al. Access to pathology and laboratory medicine services: a crucial gap. *Lancet* 2018;391:1927-38.
6. Sayed S, Cherniak W, Tan SY, et al. Improving pathology and laboratory medicine in low-income and middle-income countries: roadmap to solutions. *Lancet* 2018;391:1939-52.
7. Horton S, Sullivan R, Flanigan J, et al. Delivering modern, high-quality, affordable pathology and laboratory medicine to low-income and middle-income countries: a call to action. *Lancet* 2018;391:1953-64.
8. Wilson ML, Atun R, DeStigter K, et al. The Lancet Commission on Diagnostics: advancing equitable access to diagnostics. *Lancet* 2019;393:2018-20.
9. The National Academies of Sciences. Engineering. Medicine. Improving Diagnosis in Health Care. Quality Chasm Series. Report in Brief, September 2015. Accessed August 30, 2019. Available online: [http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2015/Improving-Diagnosis/DiagnosticError\\_ReportBrief.pdf](http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2015/Improving-Diagnosis/DiagnosticError_ReportBrief.pdf)

10. World Health Organization. In vitro diagnostics and laboratory technology. Contributions to Millennium Development Goals. Accessed May 5, 2017. Available online: [http://www.who.int/diagnostics\\_laboratory/3by5/en/](http://www.who.int/diagnostics_laboratory/3by5/en/)
11. World Health Organization. WHO list of priority medical devices for cancer management. WHO Medical device technical series. Accessed April 21 2019. Available online: [https://www.who.int/medical\\_devices/publications/priority\\_med\\_dev\\_cancer\\_management/en/](https://www.who.int/medical_devices/publications/priority_med_dev_cancer_management/en/)
12. World Health Organization. Antimicrobial resistance. Global report on surveillance. 2014.
13. World Health Organization. Worldwide country situation analysis: response to antimicrobial resistance. 2015.
14. Reyburn H, Mbatia R, Drakeley C, et al. Over diagnosis of malaria in patients with severe febrile illness in Tanzania: a prospective study. *BMJ* 2004;329:1212.
15. D'Acremont V, Kilowoko M, Kyungu E, et al. Beyond malaria--causes of fever in outpatient Tanzanian children. *N Engl J Med* 2014;370:809-17.
16. Wilson ML. Improving malaria treatment by increasing access to accurate diagnostic tests: test results must guide treatment. *Evid Based Med* 2014;19:233.
17. Polage CR, Bedu-Addo G, Owusu-Ofori A, et al. Laboratory use in Ghana: physician perception and practice. *Am J Trop Med Hyg* 2006;75:526-31.
18. The Diabetes Collaborative Registry. Transforming the future of diabetes care. 2017. Accessed August 30, 2019. Available online: <https://www.ncdr.com/WebNCDR/Diabetes/publicpage>
19. The Diabetes Collaborative Registry. Diabetes Collaborative Registry v1.3 Data Collection Form. Accessed August 30, 2019. Available online: <https://www.ncdr.com/WebNCDR/docs/default-source/Diabetes-Public-Documents/diabetesdatacollectionform.pdf?sfvrsn=12>
20. National Institutes of Health. NIH Clinical Research Trials and You. List of registries. 2016. Accessed August 30, 2019. Available online: <https://www.nih.gov/health-information/nih-clinical-research-trials-you/list-registries>
21. Nelson AM, Milner DA, Rebbeck TR, et al. Oncologic care and pathology resources in Africa: survey and recommendations. *J Clin Oncol* 2016;34:20-6.
22. African Strategies for Advancing Pathology Group Members. Quality pathology and laboratory diagnostic services are key to improving global health outcomes: improving global health outcomes is not possible without accurate disease diagnosis. *Am J Clin Pathol* 2015;143:325-8.
23. Kasvosve I, Ledikwe JH, Phumaphi O, et al. Continuing professional development training needs of medical laboratory personnel in Botswana. *Hum Resour Health* 2014;12:46.
24. Mwaikambo L, Ohkubo S, Cassaniti J. Collaborative learning and stakeholder engagement: lessons and implications of the revitalization of the Continuing Professional Development policy for health workers in Nigeria. *Knowledge Management Develop J* 2013;9:63-78.
25. Fonjungo PN, Kebede Y, Messele T, et al. Laboratory equipment maintenance: a critical bottleneck for strengthening health systems in sub-Saharan Africa? *J Public Health Policy* 2012;33:34-45.
26. Kruk ME, Gage AD, Arsenaault C, et al. High-quality health systems in the Sustainable Development Goals era: time for a revolution. *Lancet Glob Health* 2018;6:e1196-252.
27. Fleming KA, Naidoo M, Wilson M, et al. An essential pathology package for low- and middle-income countries. *Am J Clin Pathol* 2017;147:15-32.
28. Centre for International Economics. The economic value of pathology: achieving better health, and a better use of health resources. 2016. Accessed May 12, 2016. Available online: [http://www.thecie.com.au/wp-content/uploads/2016/04/Economic-value-of-pathology\\_-Final-Report-April-2016.pdf](http://www.thecie.com.au/wp-content/uploads/2016/04/Economic-value-of-pathology_-Final-Report-April-2016.pdf)
29. Dzau V, Fuster V, Frazer J, et al. Investing in Global Health for Our Future. *N Engl J Med* 2017;377:1292-6.
30. Villalobos Dintrans P, Bossert TJ, Sherry J, et al. A synthesis of implementation science frameworks and application to global health gaps. *Glob Health Res Policy* 2019;4:25.
31. World Health Organization. World Health Organization Model List of Essential In Vitro Diagnostics, First edition (2018). Accessed April 19, 2019. Available online: [https://www.who.int/medical\\_devices/diagnostics/WHO\\_EDL\\_2018.pdf?ua=1](https://www.who.int/medical_devices/diagnostics/WHO_EDL_2018.pdf?ua=1)
32. World Health Organization. Second WHO Model List of Essential In Vitro Diagnostics. 2019. Accessed September 1, 2019. Available online: [https://www.who.int/medical\\_devices/publications/Standalone\\_document\\_v8.pdf?ua=1](https://www.who.int/medical_devices/publications/Standalone_document_v8.pdf?ua=1)
33. Horton S, Fleming KA, Kuti M, et al. The top 25 laboratory tests by volume and revenue: results from five different countries. *Am J Clin Pathol* 2019;151:446-51.
34. Indian Council of Medical Research. National Essential Diagnostics List. New Delhi: Council of Medical Research, 2018.

35. GBD 2015 Mortality and Causes of Death Collaborators. Global, regional, and national life expectancy, all-cause mortality, and cause-specific mortality for 249 causes of death, 1980-2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet* 2016;388:1459-544.
36. World Health Organization. Global Health Estimates 2015: Deaths by Cause, Age, Sex, by Country and by Region, 2000-2015. 2016.
37. World Health Organization. Global status report on noncommunicable diseases. 2010. Accessed October 5, 2017. Available online: [http://www.who.int/nmh/publications/ncd\\_report\\_full\\_en.pdf](http://www.who.int/nmh/publications/ncd_report_full_en.pdf)
38. World Health Organization. Regional forum on strengthening health systems for the SDGs and UHC. Access to laboratory services in the WHO African region. 2016. Geneva: World Health Organization, 2016. Accessed June 17, 2017. Available online: [www.afro.who.int/index.php?option=com\\_docman&task=doc\\_downloads/thematic-paper-access-to-laboratory-services-in-the-who-african-region\\_1511.pdf](http://www.afro.who.int/index.php?option=com_docman&task=doc_downloads/thematic-paper-access-to-laboratory-services-in-the-who-african-region_1511.pdf)
39. Royal College of Pathologists. The regulatory landscape for pathology services. 2017. Accessed June 17, 2017. Available online: <https://www.rcpath.org/resourceLibrary/the-regulatory-landscape-for-pathology-services.html>
40. Wattanasri N, Manoroma W, Viriyayudhagorn S. Laboratory accreditation in Thailand: a systemic approach. *Am J Clin Pathol* 2010;134:534-40.
41. Looi LM. The Pathology Laboratory Act 2007 explained. *Malays J Pathol* 2008;30:1-10.
42. Kenya Accreditation Service. Medical Laboratories. 2017. Accessed June 17, 2017. Available online: <http://kenas.go.ke/our-services/medical-laboratories/>
43. International Standards Organization (ISO). ISO 15189:2012. Medical Laboratories: Requirements for Quality and Competence. 2014. Accessed July 29, 2017. Available online: <https://www.iso.org/standard/56115.html>
44. Ndiokubwayo JB, Maruta T, Ndlovu N, et al. Implementation of the World Health Organization Regional Office for Africa Stepwise Laboratory Quality Improvement Process Towards Accreditation. *Afr J Lab Med* 2016;5:280.
45. Gershby-Damet GM, Rotz P, Cross D, et al. The World Health Organization African Region Laboratory Accreditation Process: improving the quality of laboratory systems in the African Region. *Am J Clin Pathol* 2010;134:393-400.
46. Jamison DT, Breman JG, Measham AR, et al. editors. Cost-effective strategies for the excess burden of disease in developing countries. In: *Priorities in health*. Washington: The International Bank for Reconstruction and Development/The World Bank, 2006.
47. Horton R. Offline: In defence of precision public health. *Lancet* 2018;392:1504.
48. Berkeley Political Review. The dangers of techno-optimism. Accessed August 30, 2019. Available online: <https://bpr.berkeley.edu/2017/11/16/the-dangers-of-techno-optimism/>
49. Wilson ML, Sayed S, Horton S, et al. Artificial intelligence can augment global pathology initiatives - Authors' reply. *Lancet* 2018;392:2352.
50. Reddy CI, Makasa EM, Biccard B, et al. Surgery as a component of universal healthcare: Where is South Africa? *S Afr Med J* 2019;109:624-5.

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