Review Article

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.

Keywords: Laboratory medicine; pathology; diagnostics; global health; universal health coverage (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

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

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 studies 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

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

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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