The Right Diagnosis: Pathology is Essential

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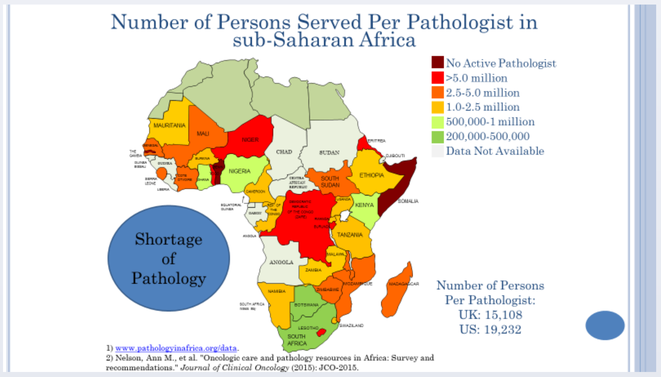
WHY PATHOLOGY (and what do Pathologists do?)

- Rapid diagnosis increases probability patients initiate CORRECT treatment, this means cost effective care with better outcomes
- Accurate diagnosis is the basis for clinical care, scientific research and health surveillance
- A study of U.S. and German cardiologists and oncologists found 66% of clinical decisions were guided by pathology tests

ISSUES AROUND PATHOLOGY

Lack of human resources



Out-of-pocket payment and presumptive diagnosis

In low income countries much of health care is paid out-of-pocket. Individuals may not appreciate the value of good diagnosis and use scarce funds for treatment. Incorrect treatment exacerbates anti-microbial resistance, worsens health and – in the extreme – leads to premature death.

Quality issues – the need for accreditation

In low and lower middle-income countries, accreditation of labs is often not required. This can lead to a proliferation of labs of variable quality, with results which are not reliable as a basis for treatment

THE TIERED LAB SYSTEM – A POSSIBLE SOLUTION?

In order to make best use of scarce resources, various groups have proposed a system of integrated tiered labs as the way for low and lower-middle income countries to build their pathology systems (Fleming et al 2016; WHO 2008).

The staffing and functions increase going from the Tier 1 lab (in a primary health care centre) to a Tier 2 lab (at a first-level hospital) to a Tier 3 lab (in a referral hospital).

The system is also supported by a reference lab or a Tier 3+ lab, which undertakes specialized tests and functions such as disease surveillance and investigation of antimicrobial resistance. The reference lab may be shared regionally for small countries.

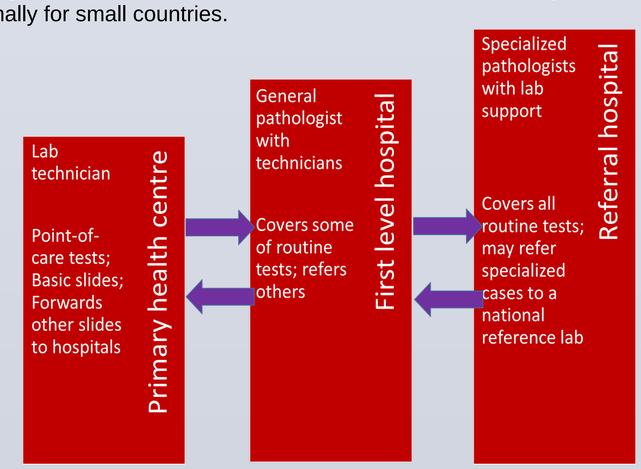


Figure 1. A schematic for a 3-tier lab system

Successful functioning of the network requires:

- Good communication between the labs
- Timely transmission of results back to the lower tier facilities and to the patient
- Good laboratory information systems
- Pathologists guide test selection, quality, and results interpretation throughout

IS POINT-OF-CARE TESTING A "LEAP FROG" SOLUTION?

Advantages of point-of-care (PoC) tests	Disadvantages of point-of-care (PoC) tests

• **Speed**
  • PoC test results are quicker
  • Important in emergency (cardiac, sepsis), or if loss-to-follow-up is important (HIV)
	• **Resource Allocation**
	  • PoC tests can waste resources if results not used in prescribing or patients don't change behavior when self-monitoring (INR, blood glucose)

• **Some More Accurate**
  • DNA test for cervical cancer, compared to cytology
	• **Some Less Accurate**
	  • Some PoC tests are less accurate (glucometers at ends of the ranges)

• **Some Lower Cost**
  • Some PoC tests cost the same or less than conventional lab tests (Hepatitis C, NAAT test for syphilis)
  • Can be more cost effective than lab tests when ordered in low volumes
	• **Some Higher Cost**
	  • Some PoC tests are more costly than lab tests (RDTs for malaria, CD4 tests for HIV, MDR-TB, INR test for blood clotting time, blood glucose test)
	  • Single use kits are more expensive than batch reagents

Point-of-care tests do not eliminate the need for trained pathologists – trained professionals are essential to deciding which of competing tests to use, to ensure that hand-held devices such as glucometers are properly calibrated, and to ensure that tests are used in the appropriate circumstances.

DEVELOPING A PATHOLOGY SYSTEM: THE EXAMPLE OF MALAYSIA

Year	Progress
1957	Upon independence, Malaysia lost 75% of the staff of the Institute for Medical Research, when expatriates left
1973	Set up first training program in the country: previously all training was in the UK – costly, and not all trainees returned. Only 30 pathologists in country.
1987	Upgraded the Master's of Pathology from a 2-year to a 4-year program to meet growing scientific needs
1994	Although number of pathologists had risen to 120, still did not meet needs. Universities and Ministry of Health joined forces to train more pathologists
2017	Over 500 pathologists, and Malaysia trains pathologists for at least five other countries

Accreditation

Instead of using costly foreign accreditation agencies, Malaysia developed an accreditation system by agreement between the Department of Standards Malaysia, and the College of Pathologists Malaysia, using ISO 15189 (Medical Laboratories). Malaysia invested in training lead and technical assessors using an international Accreditation agency. With public support, the 2007 Pathology Lab Act was passed.

Payment for Diagnostic Tests

Malaysia has a mixed public and private health insurance system. The government allocates 4.75% of GDP for health, out-of-pocket spending for health has reduced to 30.7%, there are safety nets for vulnerable population, and a tax-based system which pools risk. This falls within the WHO Health Financing strategy framework for the Asia Pacific Region 2000-2015 (Chua and Cheah, 2012). **Diagnostic tests are included.**

SKILL/TASK SHIFTING

Training more pathologists to reproduce the model seen in high income countries like the US/UK is unrealistic

- Individuals can be trained to do one or a small number of specific tasks which normally would be done by a pathologist. Such individuals can have more modest prior qualifications and can be trained much more quickly.
- Programmes aimed at breaking down the pathologist's roles into specific tasks, and the development of courses to train staff in these tasks, should be a priority.
- The rapid availability of large numbers of such staff will help provide greater access to good quality pathology.
- Pathologists are experts in test selection, quality assurance and test interpretation, all crucial for accurate guidance

NEXT STEPS

Goals:

- ➢ Educate patients, global health practitioners and funders on the importance of accurate diagnosis and quality pathology
- ➢ Define pathology systems and position them in health care, scientific research and health surveillance systems
- ➢ Develop standards for governance, finance, accreditation and training
- ➢ Agree on standards for information systems
- ➢ Set standards for robust, efficient equipment
- ➢ Increase use of pathology tests to decrease unit cost, making an accurate diagnosis more affordable

Is it time for a global diagnostic alliance?

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ACKNOWLEDGEMENTS

This project has been funded with Federal funds from the National Cancer Institute, National Institutes of Health, under Contract No. HHSN261200800001E. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.

Facilities for meetings were provided by Green Templeton College, Oxford University

The summary presented here draws on material to be used in a series of three papers in preparation for submission as a *Lancet* Series on Pathology in Low and Middle Income Countries, expected publication in 2018. Series editors are Kenneth Fleming and John Flanigan. Paper lead authors are Michael Wilson; Shahin Sayed; and Susan Horton and Richard Sullivan