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Invited critical review

Forces driving change in medical diagnostics

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ABSTRACT

This article reviews the external forces that affect and shape the future of medical diagnostics. A PESTELI model is retrospectively used to highlight the factors that drive change at an operational and management level. The author describes the future picture of clinical laboratory diagnostics and proposes ways to overcome current and pending challenges on clinical laboratories and university curriculum. An international committee with broad expertise in clinical laboratory diagnostics is proposed to examine these changes and provide guidance.

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Medical diagnostics, also referred to as laboratory medicine or pathology, has contributed and continues to contribute to modern medicine, the diagnosis and monitoring of disease, as well as medical research. This field is now recognized as the seat of medicine in which clinicians account for what they observe in their patients [1]. Medical diagnostics has seen tremendous progress throughout the years.

From Hippocrates in 300 BC, who used the examination of urine (urinalysis) to diagnose disease [2], to R. Bacon who experimented with optics back in the 13th century AD [3], which led to the invention of the microscope; progress has been continuous. As new diseases were identified, various means to diagnose them were found. Detection methods ranged from simple wet chemistry approaches to more complicated tests performed by automated clinical laboratory analyzers.

The first clinical laboratory was established in 1896 at Johns Hopkins Hospital in Baltimore using 12 by 12 ft room at a cost of $50 [4]. The value of diagnostic testing was not appreciated until well after the causative pathogens of diseases such as cholera, tuberculosis, diphtheria and others were discovered. It was not until the development of tests to diagnose these diseases that physicians fully recognized the importance of clinical diagnostics [5].

Clinical laboratories became an established medical entity in the 20th century and every hospital would eventually have in-house service. As the field progressed, the discovery of new forms of disease led to the design of complex diagnostic tests performed by technologically advanced analyzers. In turn, these advances led to the establishment of diagnostics in various medical specialties including hematology, biochemistry, microbiology, immunology, transfusion medicine, histology, etc. Inevitably, small generic laboratories were supplanted by larger more complex robust facilities.

Increased population had a tremendous impact on health care including laboratory diagnostics. Reasonable turnaround times for diagnostic tests led to the introduction new technologies including point of care testing (POCT) [6]. POCT involves smaller less complex analyzers that perform testing near the patient, in selected wards or theaters. Thus, clinicians can make prompt diagnostic and/or therapeutic decisions and even discharge patients sooner.

To better understand this evolution and the forces that led to these changes, one needs to examine the macro-environment of health care and how it promotes and facilitates certain types of change. The best way to study that macro-environment is by Political, Economic, Social, Technological, Environmental, Legal and International (PESTELI) [7] analysis. PESTELI is a strategic management tool typically used to shape future organizational strategy. This approach can also be used retrospectively to understand the factors (political, economic, social, etc.) that led to change in a business environment.

Politics highlights the role of governments. Economics refers to external macro-economic factors, such as exchange rates, business

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cycles and differential economic growth rates globally. Social factors include changing cultures and demographics. Technologic influences refer to innovations such as the worldwide web, nanotechnology, robotics, etc. Environmental factors include the ecologic issues such as pollution, waste management and reduction. Legal factors embrace legislative constraints and changes. International factors include global trends in business and industry as well as global phenomena both political and social, such as political instability, conflicts between countries and war [8].

As with all strategy models, PESTELI has its advantages and disadvantages. Its main advantage is that it considers most factors that may influence an organizational strategy and decision making. Moreover, it helps strategists and managers better understand key drivers of change and helps them design realistic scenarios that offer plausible alternative views on how the business environment of an organization might develop in the future [8].

The main disadvantages are that managers applying the PESTELI model may get over-whelmed by the multitude of details, the analysis of which may produce long and complex lists. Moreover, scenarios based on PESTELI, cannot offer a single forecast of how the environment will change. Therefore, managers should have contingency plans and alternative strategies for each scenario, a long and complicated task [9].

Looking at the recent past and current status, a plethora of political reasons has driven clinical diagnostics in a certain direction. Governmental decisions and reforms in both health care and education have shaped today's clinical diagnostics. Cuts in public spending have affected public, i.e. National Health Services (NHS), laboratories at an operational level. Quite often, clinicians are reluctant to request expensive tests that would enable more accurate and prompt diagnosis. Expectedly, there is quality of service considerations for what is offered by NHS laboratories due to this governmental pressure. Reforms in the structure of healthcare, as they are described in Lord Carter of Coles' review of pathology services in England [10], call for restructuring of clinical laboratories with a strong local clinical leadership and a business orientated management infrastructure. This has led to business process redesign in public laboratories and managers have acquired a more “private-sector” mentality, wherein generation of additional profit is sought by looking at business development opportunities.

In response, pathology manager education and training have evolved to include formal academic qualifications in management and/or business administration. Historically, in the public sector, managers were individuals who had been in the profession for a significant number of years and naturally progressed into management positions. This trend impacts educational institutions as more universities now include management modules in their biomedical sciences curricula [11].

Proposed reforms have also led some hospital laboratories to consider total pathology managed services (TPMS). Under this system, pathology services in an NHS laboratory are offered by private companies for an annual service fee [12]. This approach eliminates the financial need for pathology departments to “balance the books” or monitor budgets since cost for provision of diagnostic services is standardized. However, there are challenges with this service. Companies offering TPMS tend to put their personnel in key positions, thereby limiting potential career progression for NHS staff. Also, clinicians sometimes struggle to obtain approval for specialized high-cost testing.

Looking at the economic factors driving change, one cannot ignore the current financial climate and the crisis which has taken global dimensions. Cuts in public spending put extra pressure on hospital laboratories and managers have to make difficult decisions to balance savings while maintaining quality [13].

This evolution has forced most hospital laboratories to move from the on-call to the shift system. In the shift system, laboratory staff works three varying shifts on a rotational basis. This is contrasted with traditional on-call in which personnel would work one night and have the preceding or day after off. Financially, the shift approach is less costly to the practice. As such, savings are created. Unfortunately, the shift system also has a negative impact on employee performance and quite often morale [14].

The same economic factors have forced certain laboratories to restructure. Quite often, downsizing or extending tasks and responsibilities impacts personnel in performance and morale. Increased error rate is not unexpected.

Expensive and highly complicated diagnostic tests are usually referred to external laboratories. Although crucial for diagnosis and monitoring of disease, the clinician may be delayed or prevented from ordering these costly tests. This scenario is not the case in private, independent or private hospital laboratories, as funds tend to be more readily available.

With respect to social factors driving change in clinical diagnostics and health care as a whole, one cannot ignore the global phenomenon of our aging population. Chronic diseases, impaired vision, cognition and hearing and frailty have significant implications for health programs and expenditure [15]. A direct impact on clinical laboratories in the NHS is the increased number of tests requested by clinicians which adds financial burden on pathology departments. Another, closely related factor is the ethnically diverse population in the United Kingdom (UK).

Certain ethnic groups have a high genetic predisposition to certain diseases such as hemoglobinopathies. The Department of Health and the National Screening Committee in the UK have developed antenatal and neonatal screening programs for sickle cell disease and beta thalassemia [16]. Hemoglobinopathies are typically identified using high pressure liquid chromatography (HPLC). Abnormal results are subsequently confirmed by electrophoresis which adds to the overall cost of the test. Moreover, if a pregnant woman is a carrier for an abnormal type of hemoglobin, her husband will also be screened, thereby adding cost to this program [17].

Another social phenomenon with tremendous impact on health care is sexually transmitted infection (STI) in the young [18]. Increased infection with chlamydia and gonorrhea among UK teenagers has imposed a great burden on serology and microbiology laboratories in the NHS due to the high cost of testing. This problem has led to significantly increased workload on clinical laboratory personnel. Fortunately, public and sexual health education programs appear to have positive results in the reduction of STI especially when adults and sexually immature persons are targeted [19].

Antisocial behavior and violent crime also affect the health system and lead to increased persons seeking/requiring care. For example, there were 1,211,000 incidents of violence with injury in England and Wales in 2010–2011, which accounted for 55% of all violent incidents [20].

Undoubtedly, one of the most powerful forces of change in clinical diagnostics has come from the technological sector. Recent advances in medical technology are shaping the structure of clinical laboratories with significant impact on operations. A discipline-specific (hematology, microbiology, biochemistry, etc.) workforce has shifted to a multidisciplinary generalist model. This shift has been described in a consultative paper entitled “Modernizing Scientific Careers” in which a three year rotational training program with a broader clinical-scientific background will be required for health care scientists [21].

This change is in line with the production of test devices that cover a much broader range of analytes, i.e., biochemical, immunologic and serologic. These sophisticated instruments may now be overseen by a single individual rather than multiple discipline-specific individuals. As such, fewer health care scientists are needed.

Technologic and scientific advances in biomolecular sciences, i.e., genomics and proteomics, are also driving change. Traditional diagnostic tests are gradually being replaced with more accurate and clinically valuable molecular tests. The intense need to discover new biomarkers is pushing clinical diagnostics towards the design and manufacturing of investigative/analytical instruments for a wide range of biomarkers [22].