Changing needs, opportunities and constraints for the 21st century microbiology laboratory

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ABSTRACT

Clinical microbiologists and microbiology laboratories are experiencing changes due to evolving views on 'healthcare delivery' as an economic activity, due to changes in the medical environment and the demographics of the workforce, and technical evolution. Cost-effectiveness of laboratory procedures has been achieved through consolidation and integration of laboratories. Consolidation offers economy of scale and reduction in numbers of on-site staff, but also leads to separation of microbiologists from their clinical colleagues. Integration puts different laboratory disciplines under a single management, and leads to reorganisation of laboratories along common work-lines. Cost-savings combined with on-site availability of laboratories are achieved at the expense of a reduction in the influence of microbiologists in the daily running of the laboratory. Medically, there is growing emphasis on evidence-based diagnostics. Because of time-delays inherent in culturing, microbiology has a limited impact on patient outcomes. Increased clinical relevance of microbiological testing through rapid testing is mandatory. There is an increasing shortage in Europe and the USA of trained microbiology laboratory technicians and microbiologists. This reinforces the trend towards more automation and integration. Technological advances, particularly in molecular diagnostics, offer the possibility of rapid reporting and improvement of the impact of clinical microbiology on patient management. Molecular tests, however, fit perfectly the concept of an integrated laboratory and may further loosen the link between microbiologist and microbiology tests. The challenge for clinical microbiology will be to use new techniques to improve its cost-effectiveness and impact on infectious disease management. The future organisation of microbiology laboratories must support this but is itself of secondary importance. The training of future microbiologists must prepare them for this changing environment.

Keywords Laboratory consolidation, laboratory integration, microbiology laboratory, molecular diagnostics

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INTRODUCTION

Many factors will have an impact on the future development and daily practice of clinical microbiology. These factors can be roughly subdivided into four overlapping categories: the changing economic environment, changes in the demographics of the workforce, the changing medical environment, and technological advances.

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THE ECONOMIC ENVIRONMENT

There is a clear tendency to move away from the fee-for-service type of medicine to a managed-care type of medicine that tries to optimise the cost-efficient use of the available resources. This evolution will also impact on the organisation of clinical microbiology laboratories. Two kinds of response are already clearly visible. The first is the consolidation of separate laboratories into bigger entities via mergers, acquisition of smaller laboratories by large laboratories, or the formation of networks. A second possible response is to streamline different sub-specialty laboratories into unified and integrated large-scale laboratories.

In a 1998 American Society for microbiology (ASM) survey [1], 33% of 351 survey respondents acquired another institution, 26% merged with another institution, and 50% reported increased partnerships or affiliations with other laboratories. Similar changes are taking place in Europe. There are, of course, clear advantages to consolidation. There is, for example, the removal of tests to (off-site) central laboratories. Particularly expensive and rare tests that do not demand short turn-around times are relegated to such central laboratories. This will, of course, lead to an economy of scale and reduction in staff numbers, and might even improve the quality of testing. On the other hand, it will also lead to a physical separation of supervisory staff from the clinical services and clinicians with whom they are working.

Integration implies a reorganisation of laboratory workflow based on common processes and technologies. Usually, there is a core laboratory that contains the large automated equipment which is surrounded by satellite laboratories specifically concentrating on, for example, immunoassays, molecular techniques, microbiological cultures, haematology, or special chemistry. The core laboratory offers the advantage of concentrating highly automated, cross-capable instrumentation with a 24-h service. Streamlining of work processes into core and satellite laboratories implies training of technicians according to common techniques as opposed to medical sub-specialties. In our own laboratories (University Hospital Leuven, Belgium), integration of many different small and large sub-specialty laboratories into a single service was accomplished several years ago. The former independent laboratories of clinical chemistry, hormonology, bacteriology, virology, immunology and haematology were re-localised in a single custom-designed laboratory space, and all activities were reorganised into so-called production teams. These production teams are organised around the use of common techniques or instruments rather than medical sub-specialties. We have a core laboratory (so-called production team 1) that is organised around the large automated equipment and production teams for semi-automated and manual immunoassays, specialised chemistry, bacterial cultures and molecular diagnostics. Financial constraints have certainly been important in this reorganisation. The advantages of the integrated laboratory have been self-evident. They are the economy of scale, shorter turn-around times for many tests, standardisation of quality, and higher throughput. The economy of scale that comes from using common platforms and technicians specifically trained for molecular diagnostics has, for example, made it possible to double the number of molecular tests without increasing the number of laboratory technicians, thus almost halving the cost per test. However, there are also disadvantages of integration. It might lead to a loss of specific (microbiological) expertise because of the increased cross-training and trans-sub-specialty use of technicians. Another potential problem is that the disappearance of medical sub-specialty laboratories induces a sense of loss of identity and purpose in many microbiologists, not least because their responsibilities in the actual running of the laboratory are reduced. Microbiology as such plays only a minor role within the totality of laboratory diagnostic services. For example, in Europe as a whole, microbiology occupies only 5% of the in-vitro diagnostics market in financial terms [2]. As a consequence, in integrated and in consolidated laboratories, the majority of microbiologists who experienced changes judged that their decision-making authority declined [1].

It is not surprising that some predict that the integration of microbiology into an integrated laboratory structure may augur the end of the traditional hospital-based microbiology laboratory as a physical entity. However, it will not eliminate the need for clinical microbiologists. In this new organisation, microbiologists must redefine their functions and tasks more at the level of the medical interface than in the day-to-day running of the laboratory [3].

THE WORKFORCE

A second factor that is often underestimated, but will also have an impact on the way in which clinical microbiology will develop in the coming years, is the availability of a trained workforce. Age distribution data available in a few European countries suggest that in many countries, a large part of the medical microbiology technician workforce will retire in the next 10–15 years. There are already shortages of technicians in many laboratories, particularly in the field of microbiology, with its need for highly trained technicians. In Belgium, the majority of microbiological medical laboratory technicians are in the

age group 45–55 years, and therefore due to retire within the next 10–15 years [4]. There are not sufficient newcomers to fill these vacancies, and there is a declining interest in the training of medical laboratory technicians. In the USA, it is predicted that in each of the next 10 years a shortfall of *c.* 4400 workers per year will occur [5]. Of 86 medical microbiology laboratories interviewed in the USA, 31% reported no vacancies; 37% of the available positions had been unfilled for more than 6 months [6]. This trend can only increase in the coming years.

It could be that the trend towards increasing automation will reduce the need for highly trained microbiological staff. Thus, technicians with less training could comprise a larger part of the medical microbiology workforce. It is a matter of debate whether this will have an impact on the quality of the service. The introduction of, for example, molecular techniques, with their potential for miniaturisation and automation, will only strengthen this trend.

Shortages are not only imminent at the level of technicians; the same shortage is also apparent at the level of microbiologists. In Belgium, more than half of the microbiologists are in the age group 45–55 years [4]. Similar data come, for example, from Sweden and The Netherlands, with documented shortages of microbiologists in the near future [7,8]. Together, these data reveal an additional factor that might impact on the development of clinical microbiology and might reinforce the trend towards more automation and integration in order to maximise the efficient use of a (reduced) available workforce. These observations strengthen the need to clearly define the function of the microbiology technician and medical microbiologists in such a way that a sufficient number of good people will continue to be attracted.

THE MEDICAL ENVIRONMENT

The change in the medical environment is particularly apparent in the increasing emphasis on evidence-based medicine and the use of guidelines. This trend is not specific to medicine but is apparent in all aspects of human activity. The emphasis on evidence-based diagnostics and the proven impact of diagnostic interventions on patient outcome will also put further pressure on clinical microbiology to prove its cost-effectiveness. The importance attributed to cost and cost-effectiveness is apparent from the number of publications dealing with this subject. A quick search of Medline shows that the number of papers that included the search term 'cost' or 'cost effectiveness' in conjunction with 'clinical microbiology' almost doubled from six per 1000 at the beginning of the 1990s to 12 per 1000 at the end of the 1990s.

Unfortunately, the real impact of clinical microbiology on the acute management of infectious diseases is a matter of dispute. Several facts illustrate this statement. Although the majority of antibiotics are prescribed in the outpatient setting, microbiological testing in the community setting is very limited. Even more worrisome, for example, are data from Belgium that show that even in the hospital setting, microbiological analyses are only performed in approximately 60% of patients who are treated with antibiotics because of an infection [9]. When a result is eventually returned from the laboratory to the clinician, several studies from 1981 onwards document with somewhat surprising unanimity that in only half of the cases are these results known or used by clinicians [10–12]. Recent publications and guidelines on the diagnosis and treatment of serious infections such as pneumonia (community-acquired and hospital-acquired) or intra-abdominal infections all indicate that the initial and adequate antibiotic treatment is the most important prognostic factor. Identifying the microbial cause of the infection may aid in clinical management, but, to date, there are few data showing that aetiological diagnostic testing can improve outcomes or reduce overall medical costs [13,14].

This controversy will continue and will put increasing pressure on clinical microbiology laboratories until rapid and accurate tests become available and have proven cost-effectiveness in the management of infectious diseases.

THE TECHNOLOGICAL CONTEXT

The specialised press, as well as financial analysts, expect molecular genetic diagnostics to be a real growth market in the coming years. The greatest threat to this growth scenario is the, so far, very limited reimbursement for these expensive tests. Nevertheless, large pharmaceutical and diagnostic firms continue to invest in molecular testing. They believe that molecular diagnostics will play an increasing role in the marketing and development of new drugs and that they will lead

to more synergy between diagnostics and therapy. Molecular diagnostics will facilitate identification of persons at risk, will allow early detection of asymptomatic disease, and will allow monitoring of treatment and thus pave the way for new drugs for early stages, for prophylactic drugs, for the more efficient use of existing drugs, and for new drugs for non-responders. Added to this are the public awareness of molecular testing and the public perception of molecular genetic tests as the most advanced and reliable kind of test. These forces will, in the coming years, drive the further development of molecular tests.

As regards clinical microbiology, we must consider the impact of these molecular tests on the evolution of the laboratory 'landscape'. Molecular diagnostics fit very nicely into the concept of consolidation, integration and automation. They fit very nicely into the evolution towards technology-based specialty laboratories and might thus contribute to the decline of the classic microbiology laboratory, which centralised all the microbiological testing, irrespective of the technology used.

But can clinical microbiology afford not to invest in molecular diagnostics?

Molecular diagnostics, with their promise of short turn-around times and their potential for more detailed genotypic analysis of the causative pathogen, have the potential to increase the impact of clinical microbiology on infectious disease management. Even though it is certainly true that there are still many problems with molecular tests in infectious disease management, such as determination of antibiotic susceptibility or even the clinical interpretation of quantitative PCR, the possibility of rapid testing offered by molecular tests is very important for the long-term cost-effectiveness of clinical microbiology.

CONCLUSION

Clinical microbiology must adapt to the new healthcare environment. In this context, it is important to monitor and evaluate the factors affecting clinical microbiology laboratories. Do we have an idea of the changing economic and workforce environment in Europe and do we know what the impact of these changes will be? We must also reflect on the changes that are already taking place in clinical microbiology laboratories. Is the consolidated/integrated laboratory a valuable model for microbiological laboratories in Europe? What is the role of the microbiologist in a consolidated/integrated laboratory and must we prepare microbiologists for this role? How can we exploit the potential of molecular genetic diagnostics to increase the impact of microbiology on infectious disease management?

There is no doubt that the primary objective of clinical microbiology is to improve infectious disease management. In order to increase the cost-effectiveness of clinical microbiology, we must invest in more rapid testing and evaluate tests in terms of patient outcome. The organisation of the microbiology laboratory must support this objective, even if this implies that microbiologists would lose part of their responsibility in the daily running of the laboratory.

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