

'Shaping the Future of Laboratory Medicine: The Great Debate'

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This article is written in 20 numbered paragraphs – one for each of 20 Powerpoint slides in the accompanying presentation.

Introduction:

1. Laboratory medicine is evolving rapidly and is playing an ever more important role in modern healthcare. National and international structures to support the evolving laboratory medicine are not always able to accommodate this change. In May 2013 the IFCC Executive Board launched a one year consultation entitled 'Shaping the Future of Laboratory Medicine' which sought to stimulate discussion at national and international level. This article brings together the major points of discussion ahead of 'The Great Debate' at the IFCC Council meeting in Istanbul in June 2014.

Central Role of Laboratory Medicine:

2. It is generally accepted that a high percentage of all clinical decisions are influenced by laboratory medicine results at a small overall cost to the healthcare budget. This places great responsibility on laboratory medicine specialists to position themselves at the centre of the multidisciplinary team that is responsible for all aspects of healthcare from wellness screening through to monitoring the response to therapy.

Laboratory Medicine under Review:

3. Despite, or perhaps because of, its central role laboratory medicine services are currently under review in a large number of countries around the world. The exact terms of these reviews may differ but there three components to the review:
 - Improving quality across the spectrum from analytical quality, to quality assurance to quality management to laboratory accreditation. Different countries are on different rungs of the 'quality ladder' but the direction of travel is clear
 - Improving clinical effectiveness by targeting the use of laboratory medicine to improve clinical outcomes. The timely presentation of results is one component as is a clinical interpretive and advisory service. Recognising the growing importance of patient focussed medicine is another requirement
 - Improving cost effectiveness by doing more at equal or higher quality for a lower total cost. Laboratory medicine has a unique record of achievement in this area but the trend will continue. The appropriate use of the laboratory and demonstrating value for money are growing facets of cost effectiveness

Mega-Trends in Global Healthcare:

4. Laboratory medicine needs to adapt to the changing shape and delivery of healthcare. Experts in the business community have highlighted 12 mega-trends in future healthcare:
 - An aging population with increasing chronic disease
 - Technological advance supporting personalised medicine
 - Innovation and increasing demand, especially in developing countries
 - Evidence-based medicine and the adoption of clinical practice guidelines
 - Environmental challenges – e.g. air, water, food, climate, congestion

- Global pandemics – e.g. pandemic influenza
- Monitoring healthy people to prevent disease and keep them well
- Greater devolution of aspects of healthcare to trained non-medical professionals
- Philanthropy to speed up advances in healthcare in developing countries
- Intelligent and informed patients influencing decisions on their healthcare
- Medical tourism to get the best quality or value healthcare in another country
- Rising costs and inadequate health budgets

Laboratory medicine contributes to virtually all of these mega-trends by facilitating improved clinical effectiveness and/or cost effectiveness

Laboratory Medicine: Future Priorities:

5. It follows from the discussion to date that the future priorities for laboratory medicine must lie in three areas:
 - Continuous laboratory quality improvement
 - Improvement in clinical outcomes
 - Improvement in efficiency and cost effectiveness

One way of looking at this is by adding value to a high quality service. To deliver these priorities will require laboratory medicine specialists to work outside as well as inside laboratories

Drivers for Change in Laboratory Medicine:

6. There are many drivers for change in laboratory medicine. It is convenient to divide these into five major categories to aid understanding:
 - Globalisation
 - Technological advance
 - Smarter working
 - Integrated diagnostics
 - Adding value to improve outcomes

Each of these topics merits a detailed report. For the purposes of this review each will get a short paragraph.

7. Globalisation. We live in a world of instant communication. This provides an opportunity to share information on an international scale on a wide range of topics including:
 - Quality standards
 - Laboratory practice
 - Clinical applications.

Through sharing we can more rapidly meet the requirements of patients, clinicians and other healthcare interests

8. Technological Advance: We are in the middle of a technological revolution. Advances in technology enable us to achieve higher quality, more rapidly and on a smaller scale. Sometimes, but not always this is achieved at a lower cost. There are many examples of technological advance in laboratory medicine including:
 - Nanotechnology and point of care testing (POCT)
 - Automation including robotics, platforms and integrated systems
 - Mass spectrometry on the bench top across all of laboratory medicine
 - Bioinformatics to make sense of the huge volumes of data now available
 - Genomics informing greater understanding and driving personalised medicine
 - Proteomics and metabolomics facilitating new biomarkers

Rapid technological advance has implications for knowledge and skills training

9. Smarter Working: The combination of an aging population, medical advances and rising workloads combine to put unsustainable pressure on healthcare budgets, whether they are funded by the state or the individual. The response of the laboratory medicine profession has been admirable but it will need to continue. Improved efficiency, workload management and shared resources are just some examples of smarter working but these will impact on staffing levels and the skills mix amongst staff.
10. Integrated Diagnostics: Laboratory medicine, imaging and endoscopy all contribute diagnostic patient data. Through integration and incorporation into patient pathways this data can be converted into knowledge which can be used to bring about faster and better clinical outcomes. One consequence of integrated diagnostics is an erosion of the traditional boundaries within laboratory medicine and between the diagnostic specialties, with consequences for education, training and future job roles.
11. Adding Value to quality laboratory medicine services comprises a wide range of opportunities to go beyond a simple request-result service. A simple tool to explain the complexities of adding value is the mnemonic SCIENCE, which breaks down adding value into:
 - Standardisation or harmonisation of methods and practices
 - Clinical effectiveness improvement through greater involvement with users
 - Innovation in methods, clinical settings and service delivery
 - Evidence-based medicine and clinical practice guideline implementation
 - Novel applications exemplified by the shift from reactive to 'P4' medicine
 - Cost effectiveness and value for money
 - Education of others to better understand the role of laboratory medicineThis is a professional responsibility. More detail may be found in *Clin Chem Lab Med* 2013; **51**: 221-28

'Divisions' in Laboratory Medicine:

12. We have an identity problem in laboratory medicine at national, regional and international level. We have many different names for our profession. We have different grades of staff working in the laboratory (e.g. medical doctors, scientists, technologists) not always harmoniously. We have several sub-specialties in laboratory medicine (e.g. clinical chemistry, haematology, microbiology, and genetics) with blurred boundaries and variable interpretation across the world. We deliver our services in a wide range of clinical settings (e.g. public, private, hospital, clinic, POCT) often in an unconnected way. This is not good for the patient and it is not good for the profession. Within the profession we are confused by these 'divisions' and it is hardly surprising that those outside don't really understand who we are and what we do.
13. The solution to this identity problem is to be more inclusive and to put aside professional issues in the interest of the patient, who must be the primary consideration. The laboratory medicine specialist should be a central part of the clinical team supported by an inclusive and integrated team of staff working in a co-ordinated group of laboratory sub-specialties, delivering 'joined up' laboratory medicine services. For most of us this destination is a long way off with many barriers in the way but the journey should start, driven by the quality standards and service specification needed by the patient.

'Shaping the Future of Laboratory Medicine':

14. Against this complex and dynamic background there are opportunities for laboratory medicine specialists. As part of its strategic plan the IFCC Executive Board launched a consultation document in May 2013, which challenges all involved in laboratory medicine

to consider the implications of the future for the service they deliver. The consultation would last a year and culminate in a debate ('The Great Debate') at the IFCC Council meeting in June 2014.

15. The aims of the consultation are twofold:

- To stimulate IFCC Members to discuss how best to support the changing face of laboratory medicine at local and national level
- To consider how IFCC may position itself to enhance its global leadership role

I am aware that many IFCC Members have been having local discussions and I look forward to hearing their plans for the future.

Opportunities for IFCC:

16. A more inclusive and more broadly based IFCC can be brought about through expanded membership. This will enable IFCC to develop further its global leadership through:

- Increased influence with the World Health Organisation
- More global standardisation and harmonisation initiatives
- More global practice standards and guidelines
- A more effective global voice for laboratory medicine
- Increased focus on added value and clinical outcomes
- Increased credibility with global clinical organisations
- An improved range and quality of service for IFCC Members
- Increased collaboration for Full and Corporate Members

17. There is a barrier to IFCC being more inclusive. This is IFCC Statute 4.1.1, which effectively limits IFCC Full Membership to one society per country. This Statute dates back 60 years to a very different period for laboratory medicine when IFCC was dedicated solely to the developing field of Clinical Chemistry.

18. A November 2013 survey of IFCC Full Members societies revealed that:

- 100% are active in clinical chemistry
- >70% are active in immunology and haematology
- >60% are active in microbiology, molecular pathology
- >50% are active in genetics and virology
- <50% are active in transfusion, transplantation, informatics
- Only 2 IFCC Full Members are active in anatomic pathology

From the results of this survey IFCC concludes:

- Laboratory medicine and anatomic pathology are generally organised and delivered separately and so IFCC should not include anatomic pathology
- There is considerable scope for IFCC to be more inclusive of all areas of laboratory medicine. This could be achieved through expanded membership

19. Accordingly, the IFCC Executive Board wishes to propose to the IFCC Council that it should consider:

- Amending Statute 4.1.1 that restricts IFCC Full Membership to one society per country
- Opening IFCC Membership to any properly constituted society that is active in laboratory medicine
- Facilitating Full Membership from societies active in microbiology, genetics, transplantation, bioinformatics etc
- Adopting a similar inclusive approach to Corporate Membership to expand the range of company interest in laboratory medicine

'The Great Debate':

20. The IFCC Council will debate the future of laboratory medicine from 13.45-15.45h on Sunday 22 June 2014 in the Congress Centre, Istanbul, Turkey. This is an open meeting that any interested person may attend and contribute. The key points in the debate will be:

- Drivers for change in laboratory medicine
- Divisions in laboratory medicine
- 'Shaping the future of laboratory medicine'
- Opportunities for IFCC

No formal vote will be taken by Council but the debate will inform the proposals to be put to IFCC Members for voting at a later date.