Shaping the Future of Laboratory Medicine

Opportunities and Challenges for Laboratory Medicine Specialists in Modern Healthcare

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'Shaping the Future of Laboratory Medicine' is an IFCC policy, which is being implemented by the IFCC Executive Board. This article, the first of two, is an opinion paper written by two members of the IFCC Executive Board. It is based on issues identified in laboratory medicine (LM) communities around the world. This article is an overview rather than a detailed scientific treatise. Seven topic areas have been identified. Three will be covered in this article with the remaining four addressed in the subsequent article. In each case there is a broad statement from which illustrative opportunities and challenges may be identified. A general comment is included for each area.

Centrality of Laboratory Medicine to Healthcare:

Statement. LM results influence a high percentage of all clinical decisions, meaning that LM is central to modern healthcare. However, this is not always recognised and LM is undervalued.

Opportunities:

- Achieve LM input to multidisciplinary teams and clinical networks at local and national level;
- Establish interactive links with primary care centres and patient organisations;
- Provide clinical interpretation and advice on appropriate use of the laboratory to users and directly to patients.

Challenges:

- To convince users that LM is a service provider, not a numbers factory or a commodity;
- To present LM as a coherent clinical specialty and not several separate sub-specialties.

Comment. The centrality of LM in healthcare places a responsibility on laboratory specialists to understand the requirements of users and assist them to use the LM service for maximum clinical benefit. This will mean working outside as well as inside the laboratory.

New Technology and Locations for Delivery of Laboratory Medicine:

Statement. Rapid advances in technology are leading to higher quality and a wider repertoire of LM services. Technology is also enabling LM services to be provided outside traditional clinical laboratories.

Opportunities:

- Adopt new technology that facilitates the production of faster, higher quality results and positive clinical outcomes ;
- Adopt and be responsible for quality management of point of care testing (POCT) in a range of hospital and community based healthcare settings;
- Introduce informatics to facilitate new

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ways for interpreting and delivering data. For example, analysing 'big data' and reporting results via smart phone apps.

Challenges:

- To accommodate disruptive technologies that change testing strategies;
- To avoid the uncoordinated introduction of new technology outside the laboratory.

Comment. Technological advance is at the core of LM in a modern healthcare system. That technology is likely to be used more frequently outside the laboratory, closer to the patient. LM specialists and their partners in the diagnostics industry should promote the benefits of integrated diagnostics, including effective connectivity.

Managing the Costs of Laboratory Medicine:

Statement. Every country is struggling to manage the financial demands of modern healthcare. LM services are visible targets because our workload and costs can be measured.

Opportunities:

- Strengthen business and management training for LM specialists;
- Present LM as part of the cost of patient investigation rather than an isolated cost;
- Engage positively with those responsible for reimbursement schedules;
- Lead projects aimed at appropriateness of testing (also known as laboratory utilisation);
- Consider service rationalisation and smarter ways of working to improve laboratory cost effectiveness.

Challenges:

- To convince clinical users that laboratory costs are central to effective clinical care;
- To convince managers that appropriate use of LM can reduce overall healthcare costs ;
- To introduce new, improved services in an environment of financial restraint.

Comment. Demonstrating cost effectiveness is a responsibility for LM specialists. Positive engagement with users and management at local and national levels should focus on LM costs as part of the patient pathway rather than being considered in isolation.

IFCC eAcademy Aims for Online Scientific Education and Training Worldwide

by Peter Vervaart, Chair, IFCC Committee on the Internet and e-Learning;
Janet Smith, Chair, IFCC Committee on Distance Learning

In recent years distance learning has become a key initiative of the IFCC and is a strategic priority for the Executive Board. The Education and Management Division (EMD) Committee on Distance Learning (C-DL) and the Communications and Publications Division (CPD) Committee on the Internet and e-Learning (C-IeL) were established to work together on the development of the IFCC eAcademy, which aims to make high quality educational modules available to its membership and will provide a resource for individuals in their training and CPD requirements as well as for those involved in the planning and organisation of educational programmes.

The eAcademy is a Learning Management System using a curriculum based approach to catalogue and access educational material and contains linked presentations, webinars and other educational material managed through the Umbraco content management system. There are 3 phases in its development, the first was launched in Paris in 2015. The second released in Madrid in 2016 and the third phase currently under development.

Two approaches are being used to acquire novel high quality material for the eAcademy. The first is to identify interesting presentations at IFCC and National Society scientific meetings and courses for recording and inclusion in the eAcademy. Appropriate presentations are identified from the published programmes for upcoming events and we need the support and help of National Societies to work with us to arrange the recordings.

The second approach, to which we are devoting most of our effort and resources, is to commission international experts to prepare single or series of short modules on specific topics for incorporation into the eAcademy. Using the present.me software, PowerPoint slides can be coupled with author voiceover and even video to produce these modules. Each module includes keywords, searchable on the website and learning objectives. When the 3rd phase in the eAcademy, currently under development, is launched, a series of questions, designed to assess how well the learning objectives have been met, will be incorporated into each module.

Several of these modules have already been published in the eAcademy, including a presentation on laboratory accreditation, prepared by IFCC Past President Dr Graham Beastall on behalf of IFCC and ILAC and two modules which will form a series on aspects of the laboratory assessment of thyroid function, authored and presented by Dr Carol Spencer. Others currently being prepared include a series of presentations on evidence-based laboratory medicine and one on immunoassay as well as more on a range of single analytes. In selecting topics for inclusion in the eAcademy we have taken note of those highlighted by National Societies as being priorities for distance learning requirements, as well as the need for material on basic clinical laboratory and management practice for those in training.

Much high quality distance learning material is produced by other professional bodies and we are providing links to these from the eAcademy. We are particularly grateful to EFLM and the AACB for allowing us access to material on their websites. All material published on the eAcademy or recommended by our committees is reviewed beforehand by members of the C-DL. It is through the generous financial support of Siemens that we are able to finance this approach.

We have also just begun a project, under the direction of C-IeL member Eduardo Freggiaro, to translate much of the eAcademy material into Spanish utilising a subtitling online collaborative platform called Amara. Using Amara means that a large number of people work simultaneously in the translation of videos from English to Spanish. Each of those people are called collaborators. So, a small contribution in translating the video coupled with the contributions of other partners can achieve the enormous task of translating all the educational content. As such the IFCC is currently seeking volunteer translators to take part in the project and thus convert the educational material within the e Academy from English to Spanish (and potentially other languages in the future).

We invite you to visit the IFCC website and access the eAcademy from there. Comments on ease of use and suggestions for future presentations are most welcome. Also, if you would be willing to prepare educational modules for inclusion in the eAcademy, or to help with the translation project, your contribution would be much appreciated. Contact should be made through Silva Colli-Lanzi in the IFCC Office (colli-lanzi@ifcc.org)

New IFCC App is Now Available for Download!

The IFCC Communications and Publications Division (CPD) is pleased to announce the release of the IFCC app on both iOS and Android platforms. The app is free to download from iTunes or Google Play and is the latest communication tool for use by all IFCC officers, member society members, and other lab medicine professionals.

The app is available for both Apple and android phones or tablets and provides:

- Direct access to the IFCC website
- The latest news from IFCC
- IFCC calendar of upcoming conferences and other events
- Access to the eAcademy eLearning modules
- Ability to browse the latest issues of the eNewsletter and eJournal, even when you are offline.

Everything in one place, accessible with a single click. Search for the app in the Apple AppStore or Google Play using "ifcc" today! Apple Store (iOS), and Google Play (Android).

by Khosrow Adeli, Chair, Communications and Publications Division (CPD)

Achieving Compliance with QMS- and QC-Requirements in the Clinical Laboratory: What is the Best Strategy?

by Egon Amann, Chair IFCC Committee on Analytical Quality (C-AQ);
Sedef Yenice, Chair IFCC Committee on Clinical Laboratory Management (C-CLM)

Egon Amann

Sedef Yenice

This was the title of an interactive workshop which took place at the IFCC General Conference held in Madrid on Sunday, March 20, 1216. The workshop was jointly conducted by Egon Amann, Chair of C-AQ and Sedef Yenice, Chair of C-CLM (the "moderators").

The goal of this interactive workshop (IW) was to enhance the participants' understanding of strategies for dealing with important aspects of QC (Quality Control) before running patient tests and of key steps in establishing an effective QMS (Quality Management System). As an envisioned outcome, participants should be enabled to more effectively address the problems in the processes of implementing continuous quality improvement efforts in the clinical laboratory.

The Workshop

The IW employed a "bottom-up" approach such that actual and "real" laboratory issues concerning QM, IQC, and EQA questions including aspects of regulatory requirements could be addressed by the participants.

The IW was conducted three times in a row. Each workshop lasted for 45 minutes. After a short impulse lecture was given by the moderators, spontaneous groups formed. A questionnaire was handed out to the groups to structure their debate and to collect, in a standardized fashion, their experiences with QMS- and QC-requirements in their countries' clinical laboratories. After the groups' discussions, each group leader presented their outcomes shortly to all workshop participants.

The "most burning" top three issues were listed on flip charts by the group leaders and was subsequently collated by the moderators. In combination with the filled-in questionnaires, a comprehensive analysis (the "Post Implementation Review") was compiled after the workshop by the moderators.

At the end of the workshop, moderators asked the participants for comments on what aspects of the workshop were most useful and how future workshops might be improved. These were captured as well and are part of the Post Implementation Review document.

Workshop Statistics

A total of 14 respondents out of total 23 IW participants submitted data for the questionnaire (response rate was 60.9 percent).

Workshop participants who responded to the questionnaire attended from: Argentina, Belgium, Germany, Guatemala, India, Indonesia, Iran, Malaysia, Nigeria, Russia, South Africa, United Kingdom, USA, and Uruguay.

The top three respondent work areas were in Biochemistry/Clinical Chemistry (45 percent), General Laboratory (27 percent), and Immunology or Pathology or Quality Management (9 percent).

The top three respondent staff positions were: Department Head (30 percent), Pathologist or Non-Physician Lab Director (20 percent), and Physician Lab Director or Professor/Instructor or Lab Technician (10 percent).

Workshop Results

Identified Areas of Strength. The five areas of strength with the highest average percentage of positive responses were:

Areas of Strength for Respondents:

- Accreditation achieved (mostly according to ISO 15189) – 93%
- Overall grade on QMS is very good (Figure 1) – 43%
- The stage of implementations related to QMS is Phase 4 – 55%
- The top strategic objective for the laboratory in quality management- to improve patient safety is extremely important – 69%
- Overall grade on QC is excellent (Figure 2) – 42%

Identified Areas for Improvement. The areas that showed potential for improvement with the highest average percent positive responses were:

Areas with Potential for Improvement for Respondents:

- Accreditation not achieved – 7%

Top challenges in achieving the strategic objective for QM:

- the lack of training support and guidance (strongly agree) – 25%
- the lack of executive support and commitment (agree) – 42%

The main challenges in implementing QC:

- The lack of training support and guidance for IQC and the lack of budget to finance EQC materials (strongly agree) – 10%
- The lack of training support and guidance for EQC (agree) – 30%

To illustrate identified areas for improvement, the following table shows answers (grouped according to QMS elements) provided to the question: "What aspects of your laboratory's work (if any) should be improved as a result of effective QMS and QC?" in the questionnaire that are grouped in line with the quality system elements are as follows:

Facilities and Safety: Inadequate space.

Organization: Lack of leadership, lack of time.

Personnel: Short of staff, staff limitation to adequately document details of lab operation, eg.reagent lots. etc., commitment of staff, lack of qualified personnel, education and training/competency assessment, lack of motivation, Quality Culture: not involved in QM processes.

Equipment: Inadequate resources .

Purchasing and Inventory: High costs, lack of financial support for EQA, IQC.

Process Management: Pre-analytical errors, making errors on handling specimens, training to prevent failure to follow SOP, analytical – verification of methods, verification of reference materials, operational procedures, establishment of processes in pre-analytical, analytical and post-analytical phases.

Information Management: Inefficient LIS.

Assessment: Regulatory problems, inconsistency in performing the QMS, lack of communication, data presentation of QC performance with alerts or warnings showing failed and not performed, ISO 15189 too much focusing on technical details and very little on medical part, no QC run in histo- and cytopathology.

Workshop summary

Most participants evaluated the IW as useful. Participants praised the fact that they had the chance to discuss laboratory-related quality topics and issues in a "round table discussion format". Also, suggestions for future improvements for this kind of IW were obtained and put into the post-implementation report.

Although the IW was low in total participant numbers, significant learnings of laboratory's need in the participating countries revealed quite different aspects and suggestions.

These learnings were compiled in the 16-page document: Post Implementation Review on the Interactive Workshop: What is the best strategy to achieve compliance with QMS- and QC-requirements in the clinical laboratory?

The report is available upon request from the authors: Prof. Sedef Yenice Email: sedefyenice@gmail.com, Prof. Egon AMANN e-mail: egon.amann@hshl.de

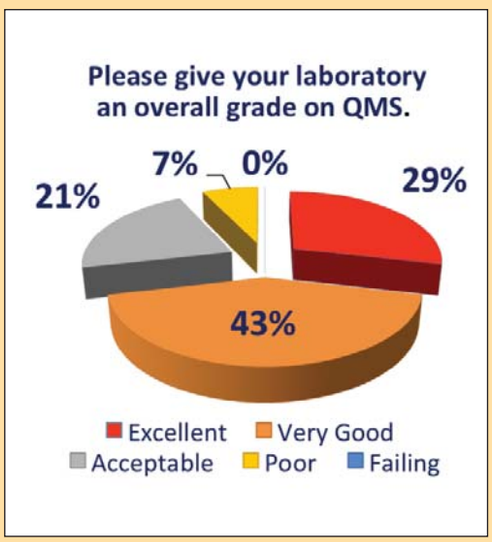

Figure 1. Percentages of responses to overall grade on QMS

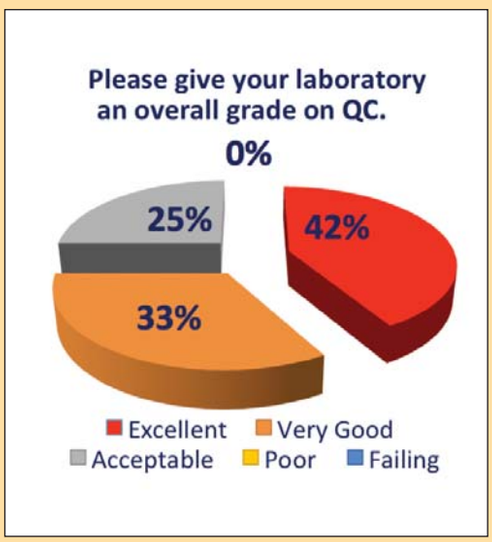

Figure 2. Percentages of responses to overall grade on QC