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EQALM Symposium 2017

October can be a busy month! This year, that was especially so, with the Program Office for Laboratory Quality Management hosting its October Quality Conference: "Laboratory Quality in Challenging times", and the CMPT Annual General Meeting, and also the European Organization for External Quality Assurance Providers in Laboratory Medicine (EQALM), which was held this year in Dublin, Ireland. All three events are both excellent and exciting, with the EQALM meeting perhaps more so, being bracketed with Hurricane Ophelia at the beginning and Storm Brian at the end.

EQALM is the annual conference for folks interested in proficiency testing (EQA) in all medical laboratory disciplines. This year, there were near 100 people coming from 32 countries from 5 continents. Dr. Noble was attending, not only representing CMPT, but also as the current chair of the Microbiology Working Group. In the latter capacity, he hosted two symposia.

Within the Working Group, he presented on a recent survey involving 7 EQA organizations with a capacity of some 1500 microbiology laboratories. The survey was on the performance of laboratories testing bacteria with known antibiotic resistance. For Methicillin Resistant *Staphylococcus aureus* and Vancomycin Resistant Enterococci, the Very Major Error (VME) Rate (reported as Sensitive when verified and validated as Resistant) was 2.5%. For Carbapenem Resistant Enterobacteriaceae, the VME rate was over 6 percent. Plans for two future studies were discussed.

This year, the EQALM main symposium was focused on microbiology issues, but as markers of broader EQA topics. Dr. Hilde Skar Norli of the Norwegian Veterinary Institute, spoke on Validation of Alternative Microbiological Methods for Good, Feed, and Environmental Samples.

Dr. Rosanna Peeling at EQALM Symposium 2017

Dr. Rosanna Peeling from the London School of Hygiene and Tropical Medicine (and formerly of the National Microbiology Laboratory in Winnipeg) spoke about EQA for Point of Care Testing for Chlamydia, as one example of Sexually Transmitted Infection, with particular reference to Developing Countries.

Dr. Willy Urassa, of the World Health Organization, spoke about WHO efforts to support the development of national EQA programs, again with special focus in Developing Countries. (CMPT has been an active participant with WHO for many years).

Dr. Noble presented on the development of video clips as a new modality for delivering pre-, post- and peri- examination EQA, a program the CMPT developed over the past two years. There was particular interest by several countries that see great flexibility and appeal for EQA in their own regions.

Next year the meeting will be hosted in Zagrab, Croatia. We are all looking forward to it, and hoping that we can do without the extra excitement of hurricanes and storms.

CMPT's AGM

This year, we had our Annual General Meeting at the beautiful Alumni Centre at the UBC campus.

We were glad to see many of our faithful committee members and we took the opportunity to thank them personally.

We have had a very productive year, with the certification for ISO9001:2015 and we completed our audit for compliance to the international standard ISO/IEC 17043:2010.

We have improved our *Trichomonas* program and we are now our samples can be used by laboratories that perform antigen and/ or DNA testing.

Our Molecular and Screening programs continue to grow as well as our Water microbiology programs.

We are very excited to have more international visibility and we will start providing samples to EQA programs in different countries.

Our Professional Development course was also very successful (you can read more about it in another article in this newsletter), with 5 participants from Ethiopia, and the participation of Microbiology residents.

We had the opportunity to personally thank Ms. Tara Bonham for all the years she collaborated with us as part of our Enteric Parasitology Expert Committee member. Tara has been an invaluable resource and help and she supported the program with her knowledge, support, expertise and any sample she can find for us to increase our Parasitology inventory!

We are sad to see her go, but we wish her the best on her new endeavors.

Esther Kwok, the program coordinator, updated us on CMPT's finances, new programs and partners; Caleb Lee talked about the stability and quality of CMPT samples and how he has been working to make sure CMPT offers PT samples that are reliable and homogeneous for the performing of PT challenges.

Veronica Restelli presented a summary of activities related to our newsletter Connections, the Professional Development course and a brief presentation on tools to test the extra analytical phase of the total laboratory testing process.

Dr. Noble talked about our achievements during the year and the continuing presence of CMPT in the international sphere, that continue to increase CMPT's profile as a PT provider and Quality adviser.

It has been a very productive year and 2018 looks very exciting.

We want to thank all those who continually give of their time and expertise to help CMPT to be a Quality pillar in the laboratory medicine and beyond.

For a complete review of the 2016-2017 year, please read our Annual Report (http://cmpt.ca/publications-newsletter/annual-report/)

Extending the scope of EQA to the extra analytical phases

By Veronica Restelli

EQA is an essential component for assuring quality testing in a laboratory. By participating, laboratories gain confidence in the quality of their performance, can evaluate staff competency, compare their performance with other laboratories, and take advantage of educational opportunities.

In recent years, the increasing interest in quality improvement and patient safety has made laboratories increasingly aware than focusing only in the analytical phase is not enough, and that the assurance of quality has to be extended throughout the total testing process.

Unfortunately, many EQA providers do not systematically assess the pre- and post-analytical phases, focusing instead only on the analytical quality. This approach is outdated since laboratory testing is increasingly reliant on analytical instruments, thereby making EQA schemes directed to the analytical phase a measurement of equipment and manufacturer's performance rather than of laboratory performance.

Most EQA schemes do not tend to look at how laboratories handle improper containers or transport, compromised samples, mislabeled samples and neither do they address the appropriateness of the final report. Are the negative samples or contaminated reported as such? Are complex samples referred? Are the reports reaching the right patient or physician?

Evidence collected in the last few decades demonstrates that pre- and post-analytical phases of the total testing process (TTP) are more prone to error than the analytical phase. Figure 1 represents the different phases of the TTP, with 90% of the reported errors falling within the pre- and post-analytical phases, and the analytical phase accounting only for 10%.

The problem with EQA targeting the analytical phase is then evident: 90% of the errors remaining unchallenged.

Accreditation agencies are increasingly requiring laboratories to go beyond the analytical quality and take responsibility for the extra-analytical phases. The Joint Commission International defines international patient safety goals with the objective of improving patient identification, and communication among caregivers; the College of American Physicians (CAP) requires that laboratories monitor certain quality indicators (QI) that deal with extra-analytical phases.

ISO15819 "*Medical laboratories – Particular requirements for quality and competence*" states that "EQA programs should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures."

However, providing EQA programs for the extra-analytical phases has many challenges. Most EQA providers lack the tools for it as evaluating the extra-analytical phase involves targeting different locations and staff groups, many of them outside the laboratory's control.

In a fairly recent publication, Kristensen from the Norwegian EQA program (NKK) describes three different approaches that are currently used to test the extra-analytical phases.

Type I EQA schemes - Registration of procedures – they seek to challenge laboratories through questionnaires, registration of procedures, and evaluation of reports. A scenario is usually presented and laboratories are asked to report how they would handle certain situations. This type of scheme has the advantage of needing limited resources, it can address several aspects of the TTP, and as it can be available online, it can have a very broad reach. This approach requires the questionnaires to be validated by experts.

"We should be challenging laboratories in the pre- and post- examination phases… because that's where the errors are." Dr. M. Noble

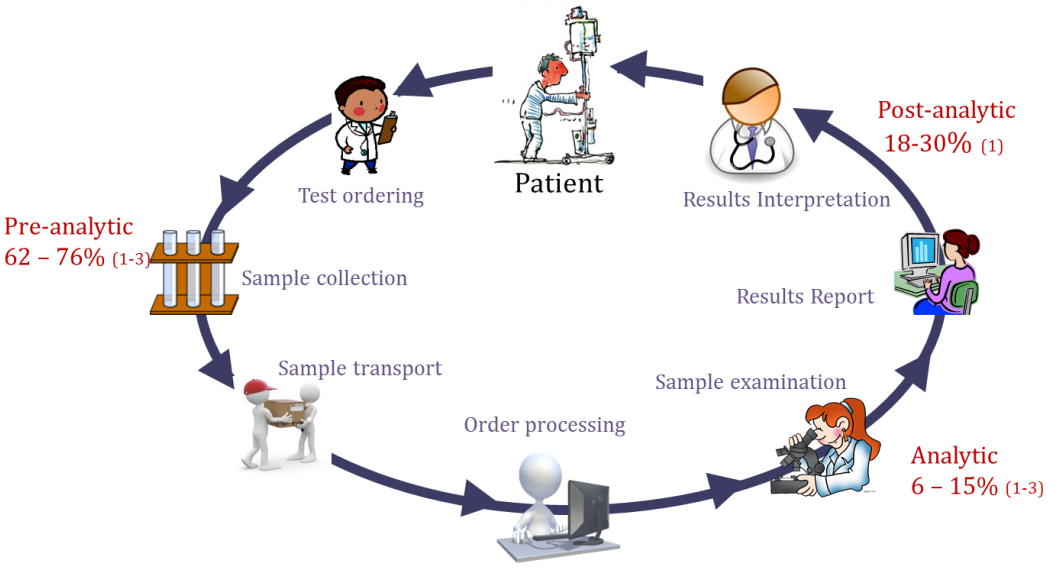

Figure 1. Total Laboratory Testing Process. In red: percentage of errors reported in that phase according to: (1) Restelli V., Taylor A., Cochrane D., Noble M. (2017) Medical laboratory associated errors: the 33-month experience of an on-line volunteer Canadian province wide error reporting system. Diagnosis (aop); (2) Carraro, P. (2007) Errors in a Stat Laboratory: Types and Frequencies 10 Years Later. Clin. Chem. 53(7) (3) Plebani, M. (2006) Errors in clinical laboratories or errors in laboratory medicine? Clin. Chem. Lab. Med. 44 (6)750-759

Type II EQA schemes – Circulation of samples with errors – similarly to regular proficiency testing schemes samples are produced and circulated with specific errors (labeling, interfering substances, etc.) and the laboratories are evaluated on the way they handle these samples. This approach requires expertise in preparing the samples, and can introduce bias, if the laboratory is expecting to receive samples with some kind of issue.

Type III EQA schemes – Registration of errors/adverse events – they use the laboratory's error reporting system to register errors/events for a particular QI over a period of time. At the end of that period, the laboratories receive feedback and comparison with all participants. This type of scheme requires harmonized QI to be able to compare among different laboratories.

Table 1 shows examples of EQA programs using these different types of EQA schemes.

Scheme	Examples
Type I	ECAT (Netherlands) NKK (Norway) LabQuality (Finland) CSCQ (Switzerland) WEQAS (UK) CMPT (Canada)
Type II	WEQAS (UK) CMPT (Canada)
Type III	CAP (US) SEQC (Spain) KIMMS QA (Australasia) CMPT (Canada)

Type IV (CMPT): Reverse PT: where the PT provider asks for samples "produced" by the participant laboratory (e.g. CMPT has asked for an isolated to be sent back to evaluate the packaging practices)

CMPT has been examining the extra analytical phases for a long time. In 1997, CMPT took a major departure from the traditional PT testing by making clinical relevancy of reports its primary target, focusing on the interpretation, clarity, and appropriateness of laboratories' reports.

Samples and challenges are designed to ensure laboratories report normal flora or contamination as such, and that the final report is clinically relevant.

Challenges can also be designed to check laboratories' adherence to current guidelines or appropriateness of susceptibility results reporting.

Challenge M091-5 consisted of gram negative bacillus in a CSF. Although laboratories reported the right susceptibility result interpretations, 31% of the laboratories reported antimicrobial agents that are specifically not recommended for treatment of CSF infections. This was addressed in the evaluation of results and in the educational critique.

Challenge **M114-3** (2012) was a simulated vaginal screen sample with group B *Streptococcus*. The purpose of the challenge was to evaluate the adherence to the 2010 CDC guidelines on prevention of group B streptococcal disease in neonates which recommended against reporting erythromycin results. Sixty per cent of laboratories reported erythromycin results, making it a good educational opportunity for the participant laboratories.

In 1998-1999, CMPT introduced the Paper Challenge (PC) as a PT tool to further evaluate the extra-analytical phase. These challenges are created through a process that involves the selection of a topic, the description of a scenario, the design of possible answers, and the selection of the best response and unacceptable ones. Group analytics is applied and an informative critique with results and inter-laboratory comparison is written. The whole process is carried out by the CMPT's Advisory Committee.

This year, CMPT introduced a new tool, the Video Challenge (VC) which uses a ~1.5 min video clip to present a scenario. The VC has the advantage of being able to present more complex scenarios and that the error is not so obviously stated as in the PC.

Since the beginning of the PC/VC program, CMPT sent 39 challenges, 69% targeting the pre-analytical phase, 10% targeting the analytical phase, 18% targeting the post-analytical phase, and 1 challenge related to safety issues. This distribution matches the error distribution observed in the literature (Figure 2).

In summary, it is important to extend the EQA to cover areas rarely challenged by PT schemes and where most of the errors tend to occur. The approaches may be "less technical," but there is room for developing creative ways to address those areas.

Laboratory professionals, EQA providers, and accreditation bodies must increase their efforts to ensure quality is extended throughout the total laboratory testing process.

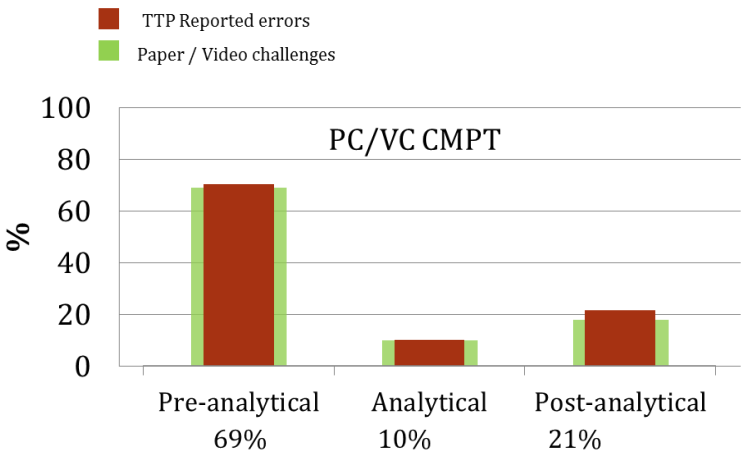

Figure 2. Distribution of PC/VC sent and reported errors.

Suggested readings

Kristensen et al. How to conduct External Quality Assessment Schemes for the pre-analytical phase? Biochemia Medica 2014;24(1):114-22

Plebani M. Performance specifications for the extra-analytical phases of laboratory testing: Why and how. Clin. Biochem. 2017

Hawkins R. Managing the Pre– and Post-analytical Phases of the Total Testing Process. Ann. Lab. Med 2012. 32:5-16

POLQM Quality Conference

The Department of Pathology and Laboratory Medicine's Program Office for Laboratory Quality Management hosted its 6th October Quality Conference at the Paetzold Education Centre at the Vancouver General Hospital from October 1-3, 2017.

The conference was attended by around 80 participants including students from the university and provincial institute of technology. While most attendees were from British Columbia, there were also laboratorians from across Canada and from the United States.

The theme of Laboratory Quality in Challenging Times seemed to be appropriate. While the reality of medical laboratories for the past twenty-five plus years, seems that it is always challenging, we seem to be reaching a capstone point with shrinking resources, fewer (and aging) staff, increasing customer expectations and demands, new sources of competition, and disruptor technologies.

Most presentations can be accessed at the POLQM website: www.polqm.ca (click on Quality Conferences)

The 2017 Quality Conference was kindly sponsored by

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Professional Development Course Report

In 2014, CMPT proposed a program where laboratorians could receive continuing education credits for reading the critiques in our Clinical Bacteriology, Mycology, and Enteric Parasitology programs and answering an on-line quiz. The program was trialed during 2015 with about 50 people participating. A post program survey indicated a very positive response rating the program as Excellent or Very Good and both Educational and Informative.

Following the survey a decision was made to open the Professional Development Course in 2016. During the first year, the course had 156 registered participants. 98/156 completed at least one quiz. 52 participants completed at least one category (Clinical Bacteriology, Mycology, or Enteric Parasitology) obtaining a certificate for it.

In 2017, CMPT decided to open the registration to Microbiology residents and other individuals that might be interested which included 5 Microbiology residents, and 1 participant from Belgium. In addition, we were reached by Dr. Makeda Semret from McGill University in Montreal, QC. Dr. Semret was involved in a capacity building project in Ethiopia and saw our course as a potential benefit for continuing education for laboratory technologists. The course was slightly modified to fit the needs of these participants: every week, a new small quiz would be released followed by a general quiz at the end of each module. 5 participants from Ethiopia took advantage of this opportunity with 4 of them obtaining certificates of completion.

This year we have 161 registered participants. 71 completed at least one category obtaining a certificate for it.

We considered the CMPT Professional Development Course an early success.

"The course was excellent and I have encouraged my co-workers to enroll in the next session. Thank you." G

Upcoming Events

APRIL 2018

28th European Congress of Clinical Microbiology and Infectious Diseases
April 21 - 24, 2018 Madrid, Spain
More info: http://www.eccmid.org/

MAY 2018

AMMI Canada—CACMID Annual Conference
May 2-5, 2018, Vancouver , BC
More info: https://www.ammi.ca/annual-conference/

ABOUT CONNECTIONS

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