Dr. Michael Noble Presents at the Biomedical Standards Exchange 2013 (Singapore)

November 2013 was the time for the twentieth plenary meeting of the International Organization for Standardization Technical Committee 212 (ISO/TC212) on in vitro diagnostics and medical laboratory quality issues. The meeting was hosted by the Singapore Standards Council at the downtown Singapore Swissôtel.

Dr. Noble has been a member of the Canadian delegation since its inception in 1995. The technical committee has been very productive, having developed over 20 international standards, all of which have had significant impact on medical laboratory process improvement.

It has become a common tradition for host countries to take advantage of the presence of international experts and to hold side conferences for their own audience. For many countries, this is a unique time to bring their own community together with international delegates to create opportunities, to share ideas and create possible collaborations. It was in that spirit that the Singapore Standards Council held the Singapore Biomedical Standards eXchange 2013 to discuss the impacts of international standards on industries critical to Singapore, including cosmetics, pharma, and medical laboratories.

Two people invited to speak on standards and related issues on medical laboratories were Dr. Graham White from Australia who spoke on Measurement Uncertainty and Dr. Michael Noble from Canada who spoke on Risk Management as an approach to reduce error in medical laboratories. The Risk Management presentation was based on the ISO/TC 212 document, ISO/TS 22367:2008, which is in the process of revision and update.

All the presentations were well received and resulted in a productive dialogue. Dr. Noble’s presentation is available at www.POLQM.ca

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Guest Article

Pitfalls in handling positive blood cultures for rapid diagnosis
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Modern, automated, continuous-monitoring blood culture systems allow the detection of pathogens more promptly and with more efficient recovery than manual methods. Rapid detection of pathogens in positive blood cultures plays an important role in the definition of sepsis and streamlining of treatment. However, there are a few pitfalls in the rapid diagnosis of positive blood cultures.

Blood culture positive flag at night
Many blood cultures become positive at night when most of the microbiology staff are absent from the laboratory, which results in a delayed report and loss of an optimal treatment opportunity for the patient. The problem can be solved by the following strategies:

- Implementation of a 24 hour service in the microbiology laboratory, although this may not be possible for small laboratories.
- A beeper could be linked to the automated blood culture system to alert the night shift staff to process the positive blood culture in real time.

Gram stain report
Gram stain reports are the most important factors influencing the selection of an appropriate therapy. Studies have demonstrated that the first telephone call alerting a positive blood culture and Gram stain results was more influential than the release of antimicrobial susceptibility data.1

Not all microbiologists report positive blood cultures with a Gram stain report to the clinicians on the first day. Reasons for not telephoning include busyness, suspicion of contamination (gram positive cocci, probable coagulase negative staphylococci, CNS), etc. Regardless of the reasons, laboratory personnel should report Gram stain results to clinicians as quickly as possible.
Rapid identification
Rapid identification of pathogens by the use of the positive blood culture inoculum supports early targeted antimicrobial therapy, and is of value for patients with sepsis.

Direct stain
Some reports have claimed the usefulness of the Gram stain to discriminate Staphylococcus aureus from CNS directly in blood culture based on morphological differences. Similarly, clusters of pseudohyphae have also been described useful for differentiating Candida albicans from other yeasts in blood culture. According to our experience, it is very hard to discriminate Staphylococcus aureus from CNS based on the Gram stain.

Gram stain reports should be reviewed by the laboratory director, and staff should be continually educated and trained to become familiar with the morphological characteristics of different bacteria.

Direct identification by use of positive blood culture in automated microbiology system.
Many researchers have shown that using an inoculum directly from a positive blood culture bottle can reduce the turnaround time and thus, improve timely intervention in the treatment of bloodstream infection. However, misidentification and non-identification rates range from 9% to 17% and therefore, special precautions are needed for direct identification:

1) If the blood culture bottle contains charcoal, centrifugation steps should be performed to remove charcoal present in bottle.
2) Direct identification is only useful for gram-negative bacilli.
3) This protocol is for guiding empirical therapy only. The formal report is still required, using traditional identification procedures.

Rapid Antimicrobial Susceptibility Testing (AST)
Empirical broad-spectrum antibiotic therapy is used to cover potential pathogens causing bacteremia. To limit the emergence and spread of antibiotic resistance, narrower-spectrum antibiotics should be adopted based on the results of AST.

Direct inoculation of Vitek 2 cards from positive blood culture bottles enables valuable susceptibility results to be obtained for gram-negative bacilli and Staphylococcus species. The results are acceptable, except for trimethoprim-sulfamethoxazole.

Direct disk diffusion AST has also been investigated. A high rate of disagreement with the results obtained with standard methods has been observed with oxacillin and gentamicin in gram-positive cocci, and with cefuroxime, amoxicillin/clavulanate, and piperacillin/tazobactam in gram-negative bacilli. The interpretation of results should be done with caution and the direct AST cannot be conducted routinely.

Blood culture contamination
Contamination is a troublesome issue and limits the diagnostic value of blood cultures. Prevalence of contamination varies from 0.6% to 6%. Most laboratories have protocols to rule out contaminants, some of which are more helpful than others. These include the identity of microorganism, clinical diagnosis, number of positive blood cultures per set, time to positivity, etc.

There is no gold standard to differentiate pathogens from contaminants in positive blood cultures, so emphasis should be put on adopting strict aseptic technique to decrease the number of contaminated blood cultures.

In summary, there are a few pitfalls in handling of positive blood culture for rapid diagnosis. Microbiology staff must be aware of these pitfalls and care must be taken for the processing and the interpreting of positive blood cultures.

References:
Did you know that while 85% of Canadians agree that emergency plans are important, only 40% have prepared a personal emergency response plan?²

An emergency can be described as any situation that poses risk to health, life, property or environment. Emergencies can, and often do, strike without much warning and can come in many forms, including natural disasters, workplace hazards, bomb threats, chemical releases, and pandemics.

Across the country, Canadians face a number of natural disasters specific to their region, including, but not limited to, earthquakes, flood, snow avalanches, wild fires, and severe winter or thunder storms. Correspondingly, there are many different kinds of emergency plans and procedures.

According to the Canada Occupational Health and Safety Act, all workplaces must have emergency evacuation plans and procedures in place for different kinds of emergency situations. These regulations recommend that all organizations have protocols that cover what to do and what not to do before, during and after emergencies, how to prevent injuries or fatalities by using employer provided control measures, like fire extinguishers, emergency showers, alarms, etc., and how to manage potential risks specific to working conditions.

In a study by Saint-Cyr, 72% of 146 employees that were interviewed about their workplace being prepared for emergencies had an Emergency response plan in place. Being prepared at the workplace will help reduce the impact to individuals, will help care for injuries and, if possible, remain healthy until help arrives. As part of being prepared, many organizations participate in annual or semi-annual drills. Drills allow organizations to review and update their response plans and also allow employees to be aware of what to do when an emergency situation arises.

After any major disaster, power and phone lines can be down slowing the process of getting immediate assistance for injured or trapped individuals. That is why, besides having an emergency plan, the government of Canada recommends to store an emergency kit at home, workplace, and car with enough supplies to survive for at least 72 hours.

There are many different kinds of emergency kits available commercially. Typically, the survival kit should commensurate with the size of the workplace and number of employees. As the kit can vary in size, the basic requirement is that the kit is easy to carry.

In large institutions, the survival kit can be divided into few smaller kits, which would have to be carried by more than one individual.

Planning for a natural disaster will also help prepare for other kinds of emergencies. So, be aware and be prepared!

According to Get Prepared⁴, a basic workplace emergency kit must contain the following items:

- Gloves
- Outdoor or winter clothing
- Water: one gallon of water per person per day for at least three days (for drinking and sanitation)
- Water purification tablets
- Food: three-day supply of non-perishable such as canned and dehydrated food, dried fruits and canned juices. Food, in emergency kits, cannot be expired and should be replaced periodically.
- Manual can opener for food
- Battery-powered or hand crank radio with extra batteries
- Flashlight and extra batteries
- First aid kit
- Whistle to signal for help
- Dust mask to help filter contaminated air and plastic sheeting and duct tape to shelter-in-place
- Moist towelettes, garbage bags and plastic ties for personal sanitation
- Wrench or pliers to turn off utilities
- Local maps
- Other items that can be included are:
  - Waterproof matches and candles
  - Blanket
  - Garbage bags
  - Rope, heavy tape
  - Crowbar or prybar
  - Money, including coins

Learn more about Emergency response at: www.publicsafety.gc.ca. More information is available through provincial and territorial resources.

Find out more about Natural Hazards of Canada at: www.publicsafety.gc.ca/cnt/mrgnc-mngmnt/ntrl-hzrds/index-eng.aspx

References:


REPORTING NOTIFIABLE DISEASES AND CONDITIONS

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MPT proficiency specimens commonly have a component for the notification (or “reporting”) of certain isolates to Public Health Authorities. The purpose is similar to the reporting of certain infectious agents to Infection Control: to evaluate an important post analytic function. There are a few differences, though, in the process. While both communications are to allow control of infectious agents, notification to Public Health authorities is a specifically defined and legally mandated duty for laboratories.

One of the functions of Public Health Services is to protect the public from communicable diseases and the laboratory plays an important role in enabling this protection.

Notification is the duty to inform Public Health Authorities of the occurrence of a disease or organism, which is of public health interest and which is included on the list of notifiable diseases and conditions. This requirement is a legal requirement for physicians, and in most places, it has become a legal requirement for laboratories as well.

This requirement was first established in Canada in 1924 and is defined in the Statistics Canada Act and the Health Canada Act, as well as in the provincial legislation.¹

The list may include clinical conditions, such as “Hantavirus Pulmonary Syndrome” or “viral encephalitis”, or organisms, such as “methicillin-resistant Staphylococcus aureus”.

Some organisms are only reportable in certain circumstances, for example, “invasive group A streptococcal disease” and sometimes the requirement may be less specific, like reporting a “respiratory outbreak in long-term care”.

Some jurisdictions may have a “catch-all” report such as the requirement to report “diseases occurring more frequently than expected or in a rare or unusual form”. This allows the laboratory to report an isolate that may not be normally included on the local list because of rarity or non-endemicity.

The list also includes many clinical infectious diseases that should be notified regardless of the type of test used for the diagnosis, for example “Legionellosis”.² Whether the infection is detected in the laboratory by a urine antigen test or by culture, the result is still notifiable to public health.

The organisms and conditions that are included on the list are developed by the public health agencies in each province and thus, the lists may vary. In addition to the provincial lists, there is a federal list of reportable diseases. This list is not mandatory, but most provinces tend to include the agents reportable federally within the provincial list. The public health authorities perform the federal notification, and laboratories are not usually involved directly. These lists are not static documents, they adjust as particular infections become more or less prominent or as circumstances change.³

In most cases, notification needs to be done as soon as possible, usually by telephone (“fastest means possible” in Alberta) for agents or conditions of particular public health concern for example, because of transmissibility or a need for rapid action to protect the public.

It can also be important for Public Health Services to be informed rapidly to maintain public confidence in their activities and their ability to respond to outbreaks and to be able to respond to media inquiries rapidly, particularly in this age of social networking and tweets.

There are a number of reasons why we notify. Locally, the identification of outbreaks and initiation of a response to them is crucial. Although some outbreaks are identified clinically, particularly if a point source is the cause, others may be first detected by changes in the frequency of positive laboratory testing. Food borne outbreaks may be diffusely distributed in the population, so that even large outbreaks spread over provinces may not be recognizable to a single practitioner or laboratory. As the outbreak progresses laboratory testing is often used to determine who can be included in an outbreak, when the outbreak has become controlled, and when it is finished.

At the provincial and national level, notification facilitates the control of diseases that are under surveillance so that incidence and trends can be identified to assist in the development of feasible objectives for the prevention and control of the disease and the evaluation of control programs.

The agents and conditions that are included in the list of notifiable diseases and conditions are selected on the basis of a number of criteria.¹ Cholera, plague, and yellow fever are reported as part of the International Health Regulations and reporting cases is an international duty to which Canada has agreed. Other considerations to include organisms or conditions are incidence and whether the pattern is changing, the severity of the illness in affected cases, and the potential for spread and ability to cause outbreaks.

Socioeconomic burden, for example, cost of immunization, food inspection, non-hospital health care and long term disability, preventability, whether by public education, contact tracing to allow treatment of affected individuals or immunization, and public perception and risk perception are all important elements that help to draw up public policy.¹

The role of laboratories in notification is often to report organisms that have been isolated. One of the questions that may arise is when to inform Public Health Services of an organism, that is, when its identity is suspected or after it has been definitively identified. This question is particularly relevant for medium sized laboratories that lack the resources to identify some isolates that may be of public health interest. These isolates may be referred to a provincial laboratory and the results of

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further testing may take several days to become available. The urgency of the notification may depend on the type of organism and the circumstances. When active intervention to prevent further infection is possible, Public Health Services may prefer to be informed as soon as the isolate is suspected and this need may be indicated on the list of notifiable diseases and conditions (e.g. "Report as soon as suspected by telephone"). When in doubt, it is useful to check with Public Health Services. Often they would prefer to know about the possibility even if they hear it twice than not to know until later.

One of the reasons that laboratory notification is so important is that physicians are not as good at notifying public health as they should be. For a variety of reasons that have included lack of knowledge of the requirement or the components of notification, how to notify or to whom, assumptions that someone else will report, concerns regarding the effort, insufficient compensation, and a feeling of futility in reporting, notification rates have been poor.

Rates of notification have been documented to be 6-90% by the Public Health Agency of Canada. One study in the UK found that public health authorities were notified in only 73% of tuberculosis cases and 65% cases of meningococcal disease, both of which are of significant public health importance. One survey of emergency room physicians in Canada found that approximately 2/3 of the participating physicians relied on the laboratory to notify positive results to Public Health. Lack of notification is a problem in many countries.

Fortunately, laboratories are able in many cases to fill this need and improvement in the rates of notification has been seen when laboratories are also responsible for it. Electronic reporting systems can further improve the sensitivity and timeliness of notification.

Disease prevention is one of the main objectives of public health departments, but it can be hard to achieve and not obvious when it is successful. The laboratory is at the forefront of disease detection therefore its role in notification is vital.

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Dr. David Haldane is the Chair of CMPT’s Clinical Bacteriology Advisory Committee.

References

Comments:
http://www.cmaj.ca/content/184/10/E513.full

Comments by Dr. Michael Noble

In microbiology, there are some test results that are not only of importance to the patients and their physicians, but also to the institution or to the community. In those situations, it is appropriate to notify either public health or the institutional infection control team of those results. At CMPT, we support that practice.

That being said, CMPT does not expect laboratories to actually refer proficiency testing (PT) samples or to actually make such notifications. Indeed, in all jurisdictions, it is either illegal or inappropriate to refer PT samples to other laboratories for additional testing or to submit notifications of PT testing results to public health authorities.

On the other hand, it is important for laboratories to demonstrate that a referral or report would have occurred with a true clinical sample. With CMPT samples we can meet both these needs through the use of the Notification Check Box.

CMPT considers the use of the checkbox as sufficient evidence of intent. Please check this box if you consider the isolate / results should be communicated to Infection Control or/and Public Health authorities.

Absence of a check will be interpreted as active evidence of a decision to NOT refer or report your findings onto Infection Control or Public Health authorities and in situations when notification is expected, this report will be considered unacceptable.
ABOUT CONNECTIONS

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USEFUL RESOURCES

ASMMicrobeLibrary

A peer-reviewed, digital media center for microbiology sponsored by the American Society for Microbiology.
The library offers a collection of images, videos, and comments on different topics in microbiology.
The content is free to access and use for educational purposes.
Website: http://www.microbelibrary.org/home

Upcoming Events

APRIL 2014
16th International Congress on Infectious Diseases
   April 2-5, 2014 Cape Town, South Africa
   More info: http://www.isid.org/icid/

CACMID – AMMI Canada 2014 Annual Conference
   April 2-5, 2014 Victoria, BC

MAY 2014
24th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID)
   May 10-13, 2014 Barcelona, Spain
   More info: http://www.eccmid.org/

2014 Water Microbiology Conference: Microbial contaminants from watersheds to human exposure
   May 5-9, 2014 in Chapel Hill, NC
   More info: http://watermicroconference.web.unc.edu/

JULY 2014
89th Annual Meeting of the American Society of Parasitologists
   July 24-27, 2014 New Orleans, Louisiana
   More info: http://amsocparasit.org/node/79

IUMS—International Union of Microbiological Societies Congresses
   July 27 – August 1, 2014   Montreal, Canada
   XIVth International Congress of Bacteriology and Applied Microbiology XIVth
   International Congress of Mycology
   XVIth International Congress of Virology

AUGUST 2014
Thirteenth International Congress of Parasitologists
   August 10 - 15, 2014 Hotel Camino Real- Mexico City