COLA's Winter Edition 2025

inSIGHTS

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LETTER FROM THE CHAIR

WINTER EDITION 2024

Adapting to the ever-changing landscape of laboratory science is vital for maintaining excellence in testing and supporting better patient outcomes. COLA's commitment over the past 35 years has been to empower laboratories with the resources and insights they need to navigate these changes successfully.

This edition of inSights focuses on several critical and timely issues impacting laboratories. We explore the emergence of new pathogens and their implications for public health, while also addressing the growing challenge of antimicrobial resistance—a pressing concern requiring innovative solutions.

Additionally, we delve into advancements in antimicrobial identification techniques, showcasing how laboratories can enhance their diagnostic capabilities to combat these challenges effectively. Lastly, we examine current trends in transfusion medicine, highlighting the transformative innovations shaping this essential field and the practical steps laboratories can take to stay ahead.

We are excited to share this wealth of information with you and hope it serves as a valuable resource. Your thoughts and feedback are always welcome as we continue supporting the laboratory community.

Keith Davis, MD, FAAFP
Chair, COLA Board of Directors

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Keeping Your Laboratory Informed in a Rapidly Changing World

By: Jennifer MacCormack, MLS (ASCP)[CM]

Jennifer MacCormack is an experienced science and medical writer with a background in clinical laboratory testing, medical & health science, and regulatory oversight. She received her Bachelor of Science in Physiology from McGill University.

Several relatively obscure infectious diseases have been in the news in the past year. Some, like dengue and oropouche, are tropical or subtropical viruses expanding into new areas as climate change leads to warmer and shorter winters. Without a deep freeze, the insect vectors that serve as a transmission route to humans remain active for longer, extending both their active months and their geographical ranges. Others, like Marburg virus and mpox, are not endemic to the United States but are viruses of significant concern that can easily cross borders with international travelers. Meanwhile, H5N1 avian influenza is spreading among cattle and poultry in many states; while human-to-human spread is not yet apparent, robust surveillance and rapid response could be key to preventing another global pandemic, should the wrong series of mutations appear.

Pathogens In the News: Raising Questions and Concerns

Medical laboratories handle pathogen-containing specimens as a matter of routine and are already equipped to maintain personnel safety with procedures, equipment and training. However, new or emerging pathogens may have different requirements than the laboratory is used to. Healthcare systems, including medical laboratories, need to be prepared for the unknown by collecting and disseminating important information to staff about pathogens they may encounter. Healthcare providers need to know what to look for: what unusual diseases are circulating locally? What symptoms or patient history are red flags suggesting something out of the ordinary?

The laboratory, meanwhile, must also have answers ready when providers call. How should specimens be collected? What tests are available and approved for use? If specimens are to be sent out, where should they go and how should they be packaged and shipped?

Staying Informed and Connected

Anyone who was working in a laboratory during the early days of SARS-CoV2 testing in the COVID-19 pandemic remembers the initial confusion around Emergency Use Authorization, test complexity, acceptable specimen types and approved transport media. While that situation is no longer rapidly shifting, laboratories cannot afford to be in the dark about new health threats. If something serious occurs, such as new

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strains of mpox spreading via travel or sustained human-to-human transmission of an avian influenza virus, how can a laboratory ensure they are getting the most up-to-date information to continue providing accurate results while keeping patients and the community safe from additional spread? When it comes to understanding the most current recommendations and regulatory requirements, it's wise to tap into federal expertise.

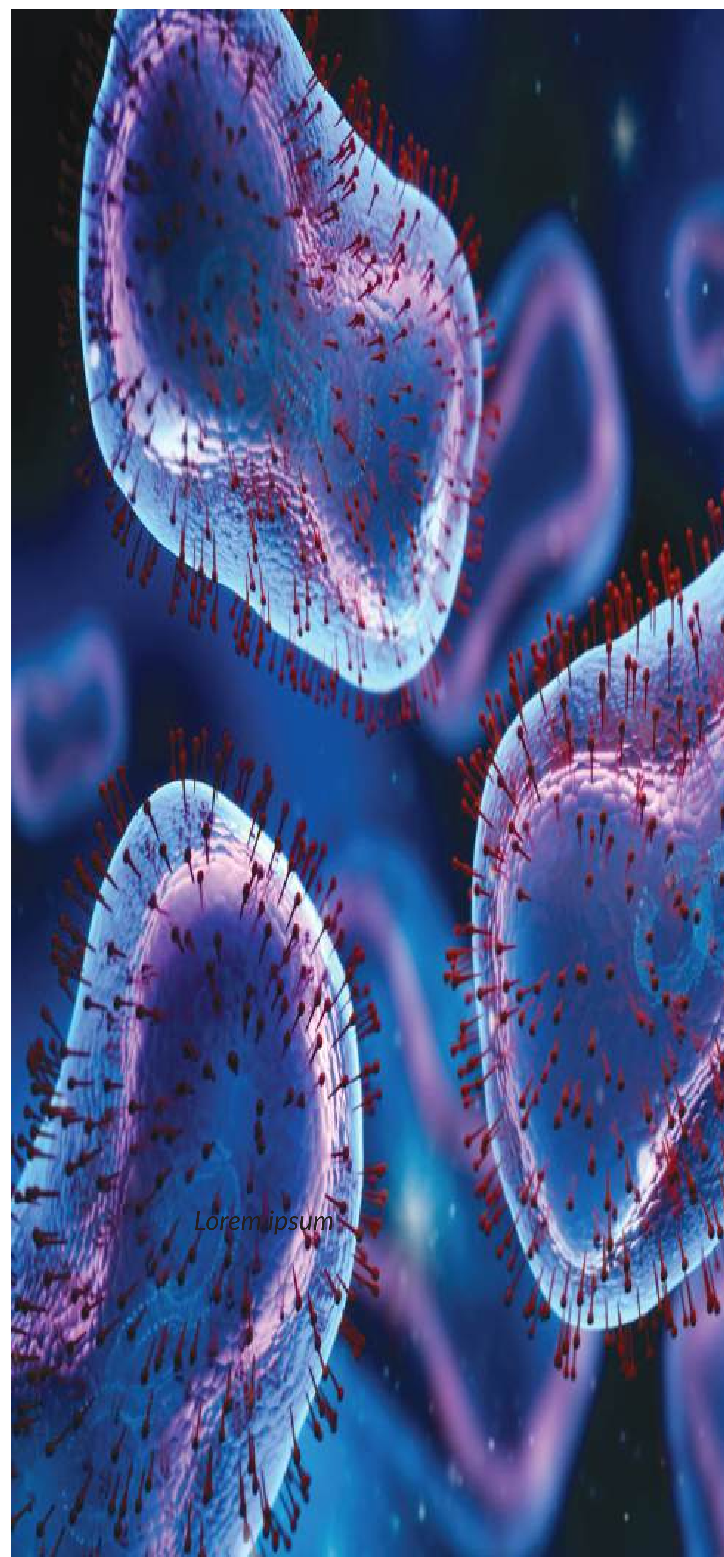
The U.S. Centers for Disease Control (CDC) regularly publishes communications for laboratory professionals and healthcare providers to provide important information about emerging pathogens, epidemics and pandemics. The Laboratory Outreach Communications System (LOCS), operating within the Division of Laboratory Systems (DLS), was developed to provide the nation's clinical laboratories with real-time information and technical guidance relating to diagnostic testing, quality and laboratory safety.

DLS hosts monthly live LOCS calls during which subject matter experts provide updates and answer questions relating to laboratory testing and public health. Initially developed as a means for laboratories to share knowledge during the COVID-19 pandemic, the calls now cover a broad range of topics including shifts in arboviral spread, updates on shortages of laboratory supplies and important information about pathogens of international concern such as mpox.

In addition to the regular public calls, LOCS hosts a mailbox where laboratory professionals can submit questions and send out periodic communications and alerts about new and ongoing areas of concern. COLA, as part of our mission to improve health and safety, shares these critical updates with our accredited laboratories and others who sign up to receive email alerts.

Weathering Change Together

Even the most independent laboratory does not operate within a vacuum. On the contrary, with so many emerging threats and changes to pathogens' endemic areas, a laboratory cannot operate within a vacuum and continue to adequately serve patients, physicians and the public. Connecting through networks such as CDC OneLAB, building connections with colleagues in nearby laboratories and getting to know the local public health entities are key to staying in the loop about what might be coming. Building resilience through connection can help laboratories better weather outbreaks and supply shortages and continue delivering accurate and timely results.



Discussion of Antimicrobial Resistance

By: Nicole Colby, MLS(ASCP)CM, SBBCM, SCCM, MBCM

After graduating from the University of Kansas, Nicole accepted a position as a lab tech at York Hospital in York, Maine. In 2017, she left the hospital laboratory for COLA, where she worked as a surveyor, improving the quality of the laboratories and the skills of those she met. Currently, she works as the Technical Training Specialist. She is responsible for educating all COLA Technical Staff, as well as assisting with creating tools to educate laboratorians.

Ever since the first antibiotic was used to treat patients in 1941, bacteria have developed new ways to resist the effects of drugs used to treat them. Antimicrobial resistance has evolved into one of the top global public health threats. According to the CDC, an estimated 2.8 million infections and 35,000 deaths occur each year from antibiotic-resistant bacteria and fungi. [12] Between 2019 and 2020, statistics demonstrate a 35% increase in infections from carbapenem-resistant *Acinetobacter*, a 60% increase in antifungal-resistant *Candida auris*, a 10% increase in extended-spectrum beta-lactamase (ESBL)-producing *Enterobacterales* and a 16% increase in vancomycin-resistant *Enterococcus*. The cost to treat antimicrobial resistance in the U.S. tops $4.6 billion each year.

Antimicrobial resistance is a normal evolutionary process that inevitably occurs over time. Our actions, however, can speed up this process through excessive or inappropriate antibiotic use. This leaves fewer options available to treat infections, and increased morbidity and mortality. The laboratory plays an important role in the response to antimicrobial resistance, and all laboratory professionals should have basic knowledge of the issue.

Basic Mechanisms of Resistance

Bacterial and fungal organisms have four basic mechanisms for resisting the action of antimicrobials: reducing effectiveness of drug entry, increasing the ability to remove the drug, changing the target of the drug or altering the drug itself. [1]

Some organisms have intrinsic (natural) resistance to the uptake of antimicrobials due to the structure and composition of the cell wall and cell membrane. For example, the cell wall of gram-negative bacteria contains lipopolysaccharides which prevent large molecules from entering the cell. Many bacteria have porin channels in their cell membranes that allow nutrients and antimicrobials to enter the cell. Various *Enterobacteriaceae* can alter the selectivity or type of porins expressed or even reduce the number of porins altogether, which enable the bacteria to resist the effects of antimicrobials including carbapenems and cephalosporins. [2]

Bacteria can adapt their methods for expelling antimicrobials from the cell. Bacterial efflux pumps transport different substances across the cell membrane. The genes of some efflux pumps that target antimicrobials are part of the bacteria's chromosome and can be expressed when needed. Others can be transferred between bacteria to gain antimicrobial resistance via mobile genetic elements. One example of this is the *tet* genes which encode for a pump that selectively expels tetracyclines in both gram-positive and gram-negative bacteria. [2]

Many antimicrobial families act by binding to a specific bacterial target site, and bacteria have adapted through genetic tweaks that change the target site and interfere with binding. This is the mechanism used by methicillin-resistant *Staphylococcus aureus* (MRSA). Methicillin acts by binding to penicillin-binding proteins (PBPs) involved in cell wall synthesis. When the *S. aureus* bacteria gain the *mecA* gene, it produces an altered protein (PBP2a) which methicillin is unable to efficiently bind to. [1] The change to the antimicrobial binding site can also be due to enzymes produced by the bacteria. *Erm* genes code for an enzyme that adds one or more methyl groups to the cell's ribosomes, making drugs in the macrolide class ineffective as they are unable to bind to the methylated ribosome. [2]

Microorganisms may create enzymes which inactivate or destroy antimicrobials. Beta-lactamases are a well-known example of bacterial enzymes which destroy beta-lactam drugs including penicillins, cephalosporins and carbapenems. Many of the beta-lactamase genes, including CTX-M, OXA and TEM, are found on plasmids which can be transferred between bacteria. Carbapenemases (e.g., KPC, IMP and NDM) are a specific type of beta-lactamase which have gained significant nationwide attention in the last few years due to the increased mortality rates from carbapenem-resistant *Enterobacteriaceae*. [1]

Detecting Antimicrobial Resistance

Detection of antimicrobial resistance in microorganisms is key to identifying appropriate treatment for an infection. There are two different types of tests that can evaluate resistance: susceptibility testing and molecular testing. Susceptibility testing determines whether bacterial growth would be inhibited by the antibiotic being tested at relevant concentrations and is currently the standard of care for determining appropriate treatment for

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patients with a bacterial infection. Depending on the test method used, minimum inhibitory concentration (MIC) values may be provided in addition to the resistant, susceptible or intermediate interpretation which can aid in selecting an appropriate antibiotic.

Susceptibility testing is performed by culturing bacteria in the presence of selected antibiotics and assessing microbial growth. The results are determined either by detecting turbidity in the culture broth (e.g., automated methods), or by measuring the zone of growth inhibition (e.g., Kirby Bauer method). Because the testing requires bacterial growth, results are usually available 2-4 days after the specimen is collected. While susceptibility testing is the standard for selecting an appropriate antibiotic(s), treatment failure may still occur due to factors such as the status of the patient's immune system and drug concentrations at the site of the infection. [3]

Molecular testing, including real-time PCR and DNA sequencing, identifies the presence of genes or mutations relating to antimicrobial resistance. [4] Molecular testing may appear superior because results can be obtained much faster than traditional susceptibility testing; however, there are a few important considerations.

Molecular Testing Considerations

Non-sequencing molecular tests look for the presence or absence of *specific* genes. If the microorganism in question has a resistance gene not targeted by the laboratory's assay, it will not be identified. In addition, while the test detects the presence of the gene, it cannot identify which organism in a mixed culture contains that gene.

The significance of an antimicrobial resistance gene being present changes depending on the virulence of the organism containing it. For example, the presence of the *mecA* gene in *Staphylococcus aureus* (MRSA) is significant when selecting an appropriate treatment. But the *mecA* gene can also be commonly found in coagulase-negative Staphylococcus (CoNS), part of normal skin flora. While CoNS have the potential to cause infection, they usually are found in cultures as a contaminant and not a pathogen. [5] The finding of the mecA gene in coagulase-negative Staphylococcus (MRCoNS) would have to be carefully evaluated to determine its significance.

Additionally, the presence or absence of a particular resistance gene may not correlate with susceptibility testing results. Bacteria may be resistant to an antibiotic via non-genetic mechanisms such as increased numbers of efflux pumps or decreased numbers of porins. Conversely, a bacteria may be susceptible to an antibiotic despite carrying an antibiotic resistance gene if the gene is not being expressed.

Correlating Molecular and Traditional Susceptibility Testing

The agreement of susceptibility and molecular results is well established with gram-positive resistance genes including mecA and vanA. As seen in Table 1, there is a high degree of correlation between the two sets of results. Additionally, gram-positive organisms have limited resistance mechanisms that lead to clinically significant resistance. [6]

Table 1: Comparison of antibiotic resistance gene detection and susceptibility results in gram-positive bacteria

	Sensitivity	Specificity	PPV	NPV
mecA gene / methicillin resistance (*Staphylococcus* sp.)	100%	89.9%	91.2%	100%
vanA/B genes / vancomycin resistance (*Enterococcus* sp.)	98.8%	98.8%	99.4%	97.5%

Sources: [7] & [8]

Gram-negative bacteria on the other hand have a wider range of resistance mechanisms, leading to higher numbers of discrepancies between the molecular and susceptibility results. Correlation of susceptibility and molecular results vary depending on specific antibiotics and bacterial species. Reviewing the aminoglycoside results in table 2, the positive predictive values (PPV) are high (84.6 – 100%) in comparison of the genes to resistance with gentamicin and tobramycin. This indicates that the detection of aminoglycoside genes using a molecular method will identify a resistant organism 84.6 – 100% of the time. The negative predictive values (NPV) are significantly lower which demonstrates that a negative result will not reliably identify susceptible organisms. If we look at the comparison of aminoglycoside genes with resistance to amikacin, different organisms demonstrate varying responses. There is a wide gap in the PPV values for this comparison in *P. aeruginosa* (83.6 – 92.3%) and other gram-negative bacteria (0.0 – 64.7%).

Table 2: Comparison of antibiotic resistance gene detection and susceptibility results in gram-negative bacteria

	Sensitivity	Specificity	PPV	NPV
Aminoglycoside genes / gentamicin & tobramycin resistance	9.5 - 92.6%	72.0 - 100%	84.6 - 100%	23.0 - 83.9%
Aminoglycoside genes / amikacin resistance (*P. aeruginosa*)	36.0 - 46.0%	83.6 - 94.5%	83.6 - 92.3%	44.8 - 46.0%
Aminoglycoside genes / amikacin resistance (other gram-negative bacteria)	0.0 - 86.7%	35.8 - 95.9%	0.0 - 64.7%	51.5 - 88.9%
Beta-lactam genes / ampicillin resistance	6.5 - 67.2%	92.9 - 100%	97.7 - 100%	3.4 - 38.2%
	32.2%	99.4%	99.3%	34.9%
Beta-lactam genes / ampicillin-sulbactam resistance	3.4 - 73.8%	63.9 - 100%	64.3 - 100%	4.8 - 67.6%
	18.0%	93.6%	58.8%	69.1%
Beta-lactam genes / piperacillin-tazobactam resistance	0.0 - 75.0%	41.1 - 100%	0.0 - 100%	21.8 - 97.1%
	32.4%	91.5%	22.0%	94.8%
Beta-lactam genes / cephalosporin resistance	0.0 - 56.5%	64.2 - 100%	0.0 - 100%	9.1 - 84.4%
	53.8 - 95.8%	85.7 - 100%	46.0 - 100%	72.2 - 99.3%
Carbapenem genes / carbapenem resistance	4.0 - 35.1%	98.7 - 100%	97.1 - 100%	24.7 - 97.4%
DFR genes / trimethoprim-sulfamethoxazole resistance	6.0 - 58.8%	95.6 - 100%	97.1 - 100%	16.9 - 47.8%
Sul genes / trimethoprim-sulfamethoxazole resistance	56.7 - 80.0%	60.0 - 90.9%	89.6 - 97.6%	27.0 - 57.4%

Aminoglycoside genes (*AAC, ANT, APH*)
Beta-lactam genes (*CTX-M, OXA, SHV, TEM, VEB*)
Carbapenem genes (*IMP, KPC, NDM, VIM*)
Sources: [9] & [10]

Limitations of Molecular Tests

There are several different FDA-cleared molecular assays that identify the presence or absence of antibiotic resistance genes. Some are intended to be used to aid in the prevention and control of antibiotic-resistant infections in healthcare settings, such as those that identify MRSA (*mecA* and *SCCmec* or *MREJ*) in nasal swabs, vancomycin-resistant organisms (*vanA* or *vanA/B*) in rectal swabs or carbapenem-resistant organisms (*KPC*, *NDM*, *VIM*, *OXA-48*, *IMP*) in rectal swabs. Several assays are designed to identify bacterial organisms in positive blood cultures: gram-positive panels typically identify *mecA/C*, *vanA* and *vanB*, while gram-negative panels include *CTX-M* in addition to the carbapenem genes listed above. Panels are available that identify both bacterial organisms and associated antibiotic resistance genes in synovial fluid and lower respiratory specimens. Identifying carbapenem genes in pure culture colonies using molecular testing is also now a possibility. All these tests can play a role in identifying potentially antibiotic-resistant organisms sooner which leads to improved patient outcomes and lower healthcare costs. [6]

However, as described earlier, the results of molecular tests do not always agree with susceptibility test results. There are several limitations commonly seen in FDA-cleared molecular tests. The first is the requirement that cultures are performed in *addition* to molecular testing to obtain susceptibility results and information relevant for epidemiology. Antibiotic resistance genes are only reported for relevant bacteria. Panels that use culture colonies as samples require the identity of the bacteria in question to be known. Panels that identify both bacterial species and antibiotic resistance genes will only report the results of the resistance genes if an applicable bacterium is also detected. The syndromic panels include the limitation that the resistance gene may or may not be associated with the bacteria causing the infection, and that positive results do not rule out co-infection with other organisms.

Discrepancies are bound to occur when performing both molecular testing and cultures on specimens. CLSI's Performance Standards for Antimicrobial Susceptibility Testing (M-100) includes a section which includes reporting considerations when performing both molecular and susceptibility testing. This section provides suggestions when evaluating resistance to methicillin (*mecA*), vancomycin (*van A/B*), ESBLs (*CTX-M*, *SHV*, *TEM*) and carbapenems (*KPC*, *OXA-48*, *VIM*, *NDM*, *IMP*). This document is available free of charge through CLSI's MicroFree Portal.

The Laboratory's Role

As laboratorians, we play an integral role in controlling and preventing antimicrobial resistance. Laboratories have a responsibility to provide quality

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results to clinicians regarding organisms that may be causing an infection as well as information that can aid in selecting appropriate antimicrobial therapies. Test reports must accurately and efficiently communicate this information. Consultation should be available to clinicians who need assistance with understanding how to interpret and use the test results. Additionally, it's up to us to sound the alarm when unusual or increased numbers of antimicrobial-resistant organisms or genes are identified.

A laboratory can also undertake antibiotic stewardship activities, even if it's not part of a larger healthcare system. These may include educating clinicians about testing being performed, monitoring contamination rates to improve training for specimen collection, following best practices for performing and reporting identification and susceptibility testing and reporting results in a manner that promotes appropriate use of antibiotics. [11]

Dr. Ian Malcolm in the movie Jurassic Park said, "Life finds a way." Microorganisms are no different. When threatened, they will evolve in order to survive. Bacteria share genes and random mutations change the organism just enough so the antimicrobials have little to no effect. Bacteria evolving to resist antimicrobials is a sure thing. We, as human beings, need to make sure our decisions around antimicrobial testing and treatment aren't helping evolution along.

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The Return of Whole Blood Transfusion

By: Runyararo M. Munyikwa, MSTM, MLS^{CM} (ASCP)SBB^{CM}

Runyararo M. Munyikwa, MSTM, MLSCM (ASCP)SBBCM joined COLA in 2022 as a surveyor before taking the role of a Technical Advisor in 2023. Ru has over 20 years of clinical laboratory experience especially in the field of blood bank. Runyararo earned the Specialist in Blood Bank in 2017 and Master of Science in Transfusion Medicine in 2021 at University of Texas Medical Branch (UTMB), Galveston Texas.

Introduction

The field of transfusion medicine (TM) is not static. Recently, an explosion of clinical trials and new scientific evidence, combined with advanced technology, has TM back in the limelight again. This article will highlight some of the changes in the way we manage massive transfusion; specifically, the return of whole blood as a preferred product for trauma cases.

Whole Blood Transfusion: Full Circle

Following advancements in human blood group identification and blood typing, whole blood transfusion was popularized in World War I. At that time, blood was stored in glass bottles with citrate solution to prevent clotting. The introduction of new anticoagulants and plastic collection bags allowed for longer storage of blood, and whole blood was soon routinely separated into its components, each of which could benefit many recipients in treating different medical conditions. The use of component therapy showed less wastage, and most individual components had a longer shelf life than whole blood. With the increased use of blood components, colloids and crystalloids in heavily bleeding patients, the practice of whole blood transfusion declined. Component therapy with packed red blood cells (PRBCs), fresh frozen plasma (FFP), platelets and cryoprecipitate became the standard of practice.

Whole Blood Reintroduced: Low Titer Group O Whole Blood

In a typical massive transfusion protocol, where a patient is in life-threatening hemorrhagic shock, more than 10 units of red cells are transfused in a 24-hour period. In many facilities, a component ratio of 1:1:1 of plasma, platelets, and red cells is used in MTPs in an attempt to mimic the benefits of whole blood transfusion; this normally requires 6 PRBCs, 6 plasma units and 1 apheresis platelet unit to be ready at the time of need to resuscitate a trauma patient.

Recent wars in Iraq and Afghanistan have revived the interest in whole blood transfusion in treating life threatening hemorrhagic shock. In the battlefield, managing component therapy requires resources and time that are not always available. Using whole blood for severely injured soldiers simplifies the processing and storage of donor units: the blood does not need to be separated into components prior to use and there is no need for specialized equipment such as freezers, platelet rotators and plasma thawers. In addition, time is saved because the product can be administered quickly through one intravenous line, and there is no need to wait for products to thaw.

As whole blood transfusion showed promising results in war settings, many US hospitals implemented their own whole blood transfusion study protocols for severely injured or trauma patients. Current data shows that the use of whole blood transfusion in treating life threatening bleeding has better outcomes and many advantages. As a result, use of cold stored low titer group O whole blood (LTOWB) is steadily being accepted in many civilian trauma centers in U.S. The American Red Cross has seen a growing number of civilian hospitals across the country use LTOWB since 2018 when they first made this blood product available.

Cold-Stored Low Titer Group O Whole Blood

Group O whole blood can be transfused to any ABO group patient. However, group O whole blood has anti-A and anti-B antibodies present in the plasma that are incompatible with non-group O recipients. This creates a safety concern. The plasma of LTOWB donors is tested for anti-A and anti-B using antibody titration and must have levels that fall below a set threshold. There is no standard “low” titer and there is no “safe” titer that can effectively prevent a hemolytic transfusion reaction. Transfusing facilities must have policies and procedures in place to define an acceptable titer cut-off for anti-A and anti-B for their LTOWB, specific indications for use and a defined maximum number of units to be transfused to each patient.

Cold stored low titer group O whole blood (LTOWB) is FDA approved. Because group O Rh negative whole blood remains a limited

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resource, most of it comes from group O Rh positive donors preferably males to mitigate the risk of transfusion-related acute lung injury (TRALI). Hospitals should evaluate the use of Rh positive LTOWB in certain patient populations such as Rh-negative females of childbearing age and pediatric patients.

LTOWB is stored at 1 to 6 degrees Celsius for 21 days in citrate phosphate dextrose (CPD) and up to 35 days in citrate phosphate dextrose adenine-1 (CPDA-1). Most U.S hospitals or trauma centers limit use to 14-21 days, because platelet function drops after 14 days and significantly after 21 days.

Advantages Over Component Therapy

LTOWB offers practical and theoretical advantages over component therapy. The process to collect, prepare and store blood components versus LTOWB is costly. LTOWB takes less storage space and is easier to store and transport. LTOWB is one product readily available and easy to administer with speed using one intravenous line especially in pre-hospital settings and can be transported on vehicles and helicopters in coolers. Recipients of LTOWB end up with lower quantities of additive solutions and anticoagulants compared to those transfused with individual blood components. This has clinical implications, as additional fluid from additives and anticoagulants in individual components may cause dilutional coagulopathy and raise a patient's blood pressure.

One important disadvantage of LTOWB is its short shelf life. It can only be stored up to 14 days to preserve platelet function viability, which creates a waste concern. To maximize use and reduce waste, LTOWB can be separated to create a PRBC unit after a predetermined date of storage. In addition, setting appropriate thresholds for anti-A and anti-B in donor units is a fine balance: higher titer thresholds may increase the possibility of hemolytic transfusion reactions and too low titer thresholds may exclude many safe eligible donors. Published papers show a titer range of <50 to <256 is used by most civilian trauma centers.

Conclusion

The growing interest in the use of LTOWB in trauma protocols is certainly changing the use of blood in transfusion medicine and expanding blood bank inventories. While blood component therapy is useful in specific patient conditions and the products generally have a longer shelf life, LTOWB has shown that it is cost effective to prepare and store, and it is quickly becoming the product of choice in treatment of trauma and hemorrhagic shock.

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Microbial Identification: Is Culture Still King?

By: Kim Ogren, BS, MLS(ASCP)CM

Prior to joining COLA in 2015, Kim Ogren worked at M Health Fairview where she spent her time working in the Core Laboratory, Transfusion Services, and the Infectious Disease Diagnostic Laboratory (IDDL). Kim earned her Bachelor of Science degree at Minnesota State University Mankato in Microbiology and went on to receive her ASCP certification in Clinical Laboratory Science from M Heath Fairview. Kim previously held the Surveyor position for 6 years and now serves as Surveys Team Manager.

Accurate microbial identification is one of the key tasks in a clinical microbiology laboratory and is crucial for infectious disease identification and selection of appropriate treatment. Traditional culture identification has long been the gold standard for the detection of infectious pathogens. However, due to traditional culture's long turnaround times and occasional failure to identify rare or more fastidious microorganisms, diagnostic microbiology has been developing methods for more rapid and accurate identification of infectious pathogens.

Widespread adoption of molecular diagnostic technologies such as reverse transcription-polymerase chain reaction (RT-PCR) and matrix-assisted laser desorption/ionization – time of flight mass spectrometry (MALDI-TOF MS) have helped to increase efficiency in the microbiology laboratory.

Conventional Microbiology Methods

Culture-based methods for the identification of bacteria include gram stain preparation, growth of bacterial cultures on appropriate nutrient rich media and identification of bacteria based on individual biochemical characteristics and/or physical traits for each species. The main advantages of traditional culturing are the ability to grow and identify a wider variety of potential pathogens that may not be on a standard molecular panel and the ability to quantitate and identify viable organisms. It is also relatively cost-effective in comparison to most molecular methods. Moreover, a culture of bacteria allows for drug susceptibility testing and molecular subtyping. This can be important in selecting appropriate treatment for patients with allergies to classes of antimicrobial drugs, as well as in tracking outbreaks and monitoring disease trends.
Despite the advantages of traditional culture methods, there are clear limitations, such as relatively low sensitivity and specificity to fastidious bacteria or bacteria whose biochemical activity is limited. Significant training and expertise are required to perform microbiology cultures, determine which colonies may be clinically significant and interpret biochemical testing performed on the bench. In addition, the overall turnaround time for these tests averages approximately 48 – 72 hours and could extend to weeks when trying to detect slow-growing organisms. Such a delay could affect the treatment of serious infections.

Microbiology Molecular Diagnostics Methods

Limitations inherent to traditional culture methods have impelled clinicians and laboratorians to explore new diagnostic approaches using molecular methods; most notably, RT-PCR and MALDI-TOF MS. Some common pathogens now more commonly identified by molecular testing instead of culture include *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Streptococcus pyogenes* (group A Strep), *Streptococcus agalactiae* (group B Strep) and gastrointestinal pathogen panels. Many viral cultures have also been replaced by molecular methods including influenza, respiratory syncytial virus (RSV), herpes simplex virus (HSV) 1 and 2 and varicella zoster virus (VZV). Furthermore, a variety of parasites formerly mainly detected by microscopy, such as *Trichomonas vaginalis* and malaria, are now more commonly detected using molecular methods.

Nucleic Acid Amplification

The introduction of RT-PCR was a technological milestone which gave rise to the modern era of molecular diagnostics testing. With high sensitivity and specificity, faster turnaround times and the ability to detect organisms that are difficult to culture, PCR-based diagnostics are a clear front-runner for the detection of infectious pathogens.

Multiplex PCR assays have been widely applied, particularly in respiratory and genitourinary infections where it is useful to screen for

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many pathogens at once. The ability to amplify several different DNA sequences in parallel significantly speeds up testing and makes multiplex systems useful in diagnosis, especially in life-threatening conditions such as sepsis. It's important to note, however, that the nature of RT-PCR restricts identification to the specific targets on a panel. Not only can the test not distinguish between viable and non-viable organisms, it may also detect the presence of organisms that are incidental to the infection and not clinically relevant. As a result, especially with large panels, there is a risk of false positive results.

The efficiency of RT-PCR relies heavily on the quality of the specimen and amount of microbial DNA collected. It is also expensive due to the need for specialized equipment and reagents, and it offers limited actionable information on antimicrobial susceptibility, as resistance genes may not correlate with the organism's true antimicrobial resistance profile.

MALDI-TOF Mass Spectrometry

The introduction of mass spectrometry technology for routine microbial workups has been revolutionary. Over the last decade, MALDI-TOF MS systems have become a powerful and effective tool for rapid bacterial identification and are progressively replacing conventional biochemical bacterial identification on the microbiology bench. With this method, identification of bacteria is based on the analysis of species-specific protein profiles using either intact cells or cell extracts. This unique protein profile is based on a comparison of detected mass peaks to a database of patterns known to be specific to different species.

Specimens still need to be cultured before they can be run on a MALDI-TOF MS system; unlike the RT-PCR systems, they cannot work directly from a swab or other specimen. That said, MALDI-TOF MS is a relatively quick method: unlike traditional biochemical identification systems that often require colonies that are 48 hours old, MALDI-TOF can use much younger cultures, cutting incubation time down to as little as 16 hours. The lower cost of operation also makes it an attractive option when compared to RT-PCR, even though there is more technical expertise required to run it well.

The biggest limitation of MALDI-TOF MS is that the accuracy of identification depends on the quality of the reference database used. Newly discovered organisms, or ones that are not well-characterized in the reference database, might be misidentified. Up until a few years ago, for example, yeast species and anaerobes were generally more difficult to identify because they were not yet well represented in the reference databases. A similar problem arises when differentiating between closely related species, whose protein patterns may be very similar.

In addition, MALDI-TOF MS cannot provide information about a detected organism's drug susceptibility profile. Despite the shortcomings, the MALDI-TOF MS is still the preferred method in many microbiology laboratories for rapid bacterial identification.

Conclusion

Diagnostic microbiology is a crucial part of a patient's targeted therapy. The methods used in a clinical microbiology laboratory depend primarily on the available equipment and expertise, and the cost, sensitivity and specificity of a method. More advanced methods such as MALDI-TOF MS and RT-PCR have proven their value in diagnostic microbiology and are certainly here to stay.

Traditional culture methods, though, will not be obsolete anytime soon. Those skills are valuable and can help to solve clinical mysteries that newer methods cannot. Molecular methods also still require extensive manual validation to ensure that results are meaningful and actionable. Our most likely future is one where microbiology laboratories will employ a blend of traditional culture methods, MALDI-TOF and PCR depending on the balance of many factors: specimen type, suspected organisms, required turnaround time, laboratory budget and expertise.

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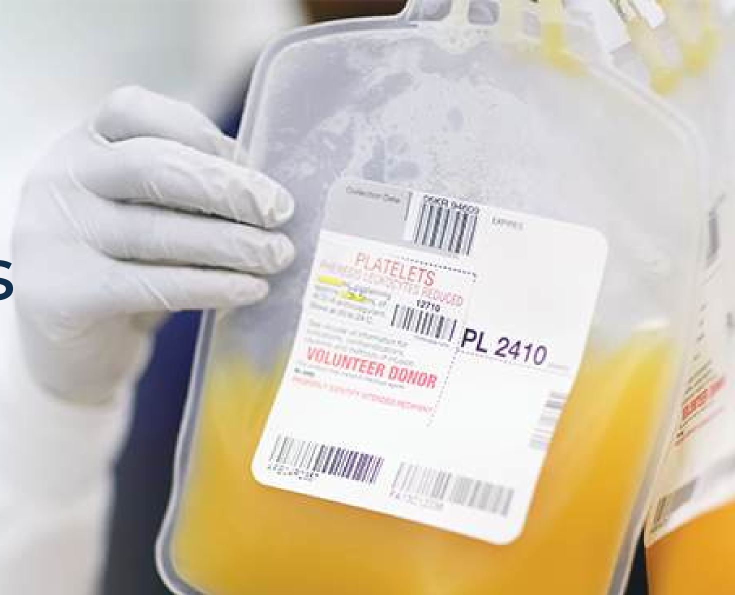

Cold Stored Platelets

By: Runyararo M. Munyikwa, MSTM, MLS^{CM} (ASCP)SBB^{CM}

Runyararo M. Munyikwa, MSTM, MLSCM (ASCP)SBBCM joined COLA in 2022 as a surveyor before taking the role of a Technical Advisor in 2023. Ru has over 20 years of clinical laboratory experience especially in the field of blood bank. Runyararo earned the Specialist in Blood Bank in 2017 and Master of Science in Transfusion Medicine in 2021 at University of Texas Medical Branch (UTMB), Galveston Texas.

Transfusion of platelets is indicated in patients with thrombocytopenia, dysfunctional platelet disorders, or active platelet-related bleeding and patients at serious risk of bleeding. Most platelets are collected by apheresis, a widely used automated procedure which collects a therapeutic adult dose of platelets from a single donor. Platelets can also be made from whole blood: 4 to 6 donors are pooled for an equivalent adult apheresis dose.

Platelets are stored at room temperature between 20 to 24 degrees Celsius with gentle agitation. They have a short 5-day shelf life because changes to their structure and function after this period render them less effective for hemostasis. In addition, storage at room temperature can encourage bacterial growth and create a risk of platelet transfusion-associated bacteremia or sepsis.

Cold-Stored Platelets

Cold-stored platelets (CSP) are not a new product. In 1975, FDA regulatory standards were established for CSP with a storage shelf life of 72 hours at 1 to 6 degrees Celsius. However, in the next several years, research showed that room temperature platelets (RTP) stored at 20 to 24 degrees Celsius had a higher post-transfusion platelet recovery and longer survival. The use of CSP stopped and RTP became the standard practice.

Clinical research on CSP continued even after they were abandoned in the late 1970s and today clinical trials of CSP are providing new data showing that they are more effective hemostatically than RTP in stopping serious bleeding and are effective over a longer period, giving them a longer shelf life. In addition, data shows that cold storage significantly decreases bacterial growth. Agitation is optional for CSP, which simplifies their storage.

Today, the need for transfusion of platelets has increased for actively bleeding patients such as those receiving cardiac surgery. The effects of blood shortage during the recent COVID-19 pandemic have pushed the much-needed regulatory approval from the FDA for clinics and blood establishments to implement the manufacture of CSP.

On June 23, 2023, FDA issued a final guidance, "Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical." This document was issued in response to a public health need and addresses the immediate need for platelets for the treatment of active bleeding when conventional platelets are not available or their use is not practical. The guidance allows blood establishments to manufacture CSP without submitting a variance request to FDA under 21 CFR 640.120. In this guidance, the FDA outlines comprehensive recommendations to be followed when implementing this alternative method to manufacture and use CSP.

FDA Guidance Recommendations

The FDA defines conventional platelets to include all platelets (as defined in 21 CFR 640.20) intended for transfusion and stored at 20 to 24 degrees Celsius. Cold-stored platelets are defined as those stored continuously at 1 to 6 degrees Celsius within a specified time after collection.

The FDA offers recommendations for blood establishments for the manufacture of CSP to perform process validations, quality control testing (21 CFR 640.25

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(b)(2), 21 CFR 211.160(b), and 21 CFR (211.165(c), and container labeling of CSP according to 21 CFR 606.121. The guidance specifies the following to be added in the Circular of information (21 CFR 606.21) to provide adequate directions for the use of CSP:

- CSP are intended for the treatment of active bleeding when conventional platelets are not available, or their use is not practical.
- CSP must be stored continuously at 1-6°C to control the risk of bacterial contamination for up to 14 days.
- Transfusion services should establish procedures for examining CSP for visible aggregates before transfusion.

The guidance states that the cold storage of platelets is an adequate method to assure the risk of bacteria is adequately controlled, but establishments may implement additional measures for bacterial control. The guidance discusses the need for additional data on efficacy of CSP to address whether their use is supported when conventional platelets are not available and not practical. For further information please refer to the final guidance on the FDA website.

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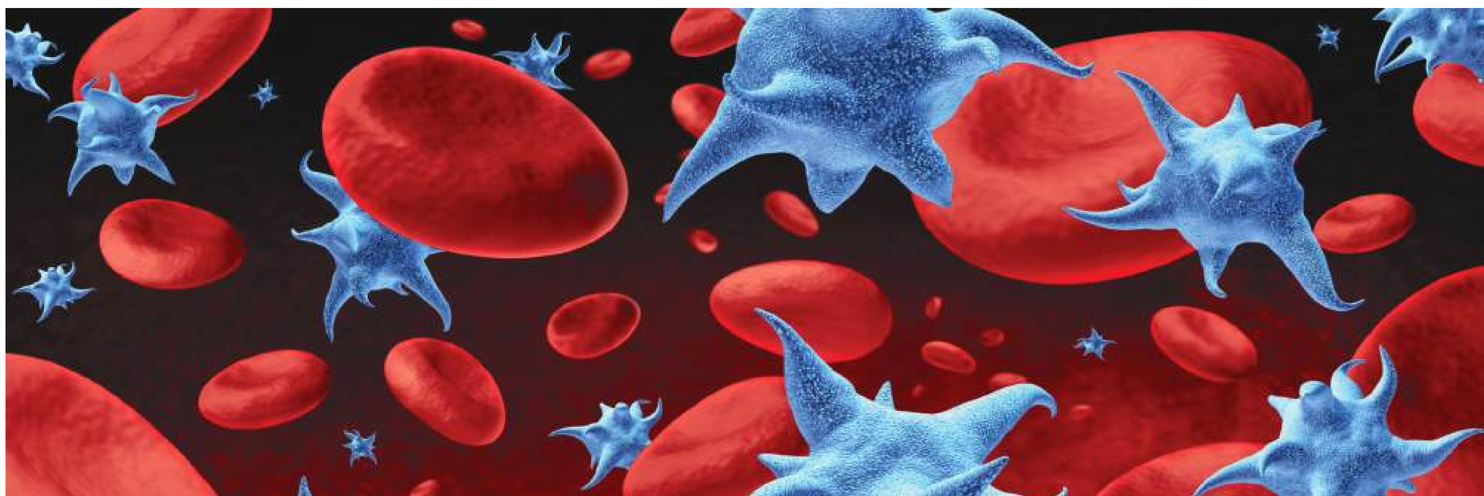

COLA Workforce Action Alliance

Moving forward to meet the needs of tomorrow's laboratories

Updates on the Workforce Action Alliance

By: Kathy Nucifora, MPH, MT(ASCP)

Kathy Nucifora joined COLA as the Accreditation Division Manager in November 2009 and in 2019 became COLA's Chief Operating Officer. Kathy was recruited from a COLA accredited lab, Hutchinson Clinic, to join Maryland General where she was responsible for creating and implementing new quality processes and procedures. In addition to managing the day to day operations of the lab, she developed and led a multidisciplinary task force to implement molecular testing for MRSA; she proposed and implemented a positive patient identification system via handheld computers; and helped lead the Laboratory and Nursing Process Improvement Committee. Kathy has also served as adjunct faculty at the Community College of Baltimore County for their Medical Laboratory Technician program.

By: Jennifer MacCormack, MLS (ASCP)[CM]

Jennifer MacCormack is an experienced science and medical writer with a background in clinical laboratory testing, medical & health science, and regulatory oversight. She received her Bachelor of Science in Physiology from McGill University.

The Workforce Action Alliance (WAA) was created to address the increasingly urgent concern of the laboratory workforce shortage. The gap between the number of vacant laboratory positions and new skilled professionals to fill them is causing considerable strain on the existing workforce – and that gap is growing. The WAA consists of executives from various organizations representing employers, public health laboratories, laboratories that serve the military and our veterans, educators, regulators, high school counselors and specialists in recruitment and retention, each with unique insight into the field of laboratory science.

During the initial WAA meeting in 2023, participants agreed on a short list of important action items on which workgroups could focus their resources and energy. In this and future editions of inSights, we will explore the progress made by these workgroups and discuss where their research and advocacy is headed next.

Standardizing Professional Titles

One of the first major priorities identified during the WAA discussions was the need to present a united front by standardizing the titles used by laboratory professionals and adopting a term to express our professional identity. The Standardizing Professional Titles workgroup was established to explore how standard and consistent language about laboratory science professionals could be used to:

1. Strengthen the profession's standing to recruit more people to the field

2. Adopt a broad designation for our professional identity that includes all the diverse academic, certification and career pathways, similar to "Nursing"

3. Elevate public awareness of our profession through consistent use to become more recognizable

Clinical Laboratory Scientist, Medical Technologist and Medical Laboratory Scientist are often used interchangeably, depending on when and from which type of program a person earned their degree. This is in stark contrast to the field of nursing, where graduates of nursing programs are all collectively known as "nurses," no matter the specifics of their program. In addition, many laboratory professionals casually describe themselves as "med techs," "lab techs" or simply "techs." These terms misrepresent the high level of

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education, skill and real-world experience that laboratory professionals contribute to the healthcare team.

Discussion and Different Viewpoints

Settling on a consensus was not a simple task and the members of the workgroup brought many different points of view to the discussions. For example, some were concerned that the use of “Medical” or “Clinical” would exclude professionals who work in public health laboratories and whose work deals with community health and epidemiology. In addition, some states have already established professional titles in state regulations; California law, for example, defines requirements for “Clinical Laboratory Scientists.” Meanwhile, different professional certifications already exist, such as the ASCP “Medical Laboratory Scientist” designation.

Because of these complicating factors, the group determined that establishing an “umbrella” term to cover the profession as a whole would be the most effective way to meet the goals of improving recognition of our profession and recruiting new talent to the field. Having a simple and consistent way to refer to the entire laboratory workforce would eliminate some of the confusion around all the different professional titles – perhaps we could begin using an equivalent to “nursing,” while still retaining whichever specific titles fit any given laboratory professional best.

After considering many options, the term that received the most support and was ultimately selected as the most appropriate name for the field was “Laboratory Science.” While this was not the first choice of all members of the workgroup, the majority were satisfied with Laboratory Science being used to refer to our collective profession going forward.

Laboratory Science: Next Steps

The WAA workgroup is encouraging the laboratory community to promote the use of “Laboratory Science” in publications and journals, communicating the change to educational and professional organizations and developing talking points for use in media communications.

It will take time to build a strong professional identity centered around Laboratory Science. It is the hope of the WAA that training programs, professional organizations and laboratory professionals ourselves can begin to make that shift as we discuss the profession with others, especially when speaking with younger people about their career options. With coordinated effort from the organizations involved in the Workforce Action Alliance, we may soon hear high school seniors telling friends “I’m going into Laboratory Science” when asked about their plans after graduation. And Laboratory Science will welcome them, whichever professional path they choose walk after they join us.

The WAA Planning Committee would like to thank the American Association of Bioanalysts Board of Registry (ABOR), the National Independent Laboratory Association (NILA) and COLA for their charitable financial contributions to help make the Summit possible.

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