bioMérieux CONNECTION
DECEMBER 2007 • VOL 4 NO 6

IN THIS ISSUE

Message from bioMérieux

Herb Steward
Executive Vice President and General Manager, bioMérieux North America

Welcome to the December 2007 edition of the *bioMérieux Connection* newsletter. This month's newsletter focuses on the evolving role of the microbiology laboratory and the challenges facing today's microbiologist.

Shortages in skilled staff and resources make it difficult to maximize productivity and efficiency. Today's issues demand making industry professionals aware of new technologies and improvements in clinical outcomes as new products and research become available. bioMérieux realizes the need to validate the role of microbiology in the cycle of patient care in order to overcome the emerging resistance to infectious disease.

bioMérieux is dedicated to providing opportunities to share expertise, build partnerships and work together. These discussions will help shape the future of laboratories and better prepare the next generation of microbiologists.

September's Southern California Knowledge Symposium featured a range of experts who delivered presentations on the future of molecular testing, safety in the lab, antibiotic stewardship, and the importance of the rapid diagnosis of infection. The energy and commitment of the participants at the Symposium validated the work we do. We look forward to providing industry professionals with similar opportunities that we hope will stimulate thought and motivate positive change in the future of microbiology.

As the new year approaches, we thank you for your support and continued contributions to the industry and wish you a safe holiday season.

from diagnosis,
the seeds of better health

BIOMÉRIEUX

GLASS vs.

By Terry Jo Gile, MT(ASCP) MA Ed., The Safety Lady™

A colleague of mine once told me that there are three types of people who work in the laboratory – those that make things happen, those that sit back and watch things happen and those that say "what happened?!" When it comes to laboratory safety, we are often in the "what happened" category. Since November of 2001 when the Needlestick Safety and Prevention Act became final, Lab Managers have focused their attention on needlesticks and disposal of sharps. But sharps are not limited to just needles. The category includes a host of sharps that are just as dangerous including broken glass in the form of hematocrit tubes, pipettes, flasks and blood culture bottles. According to Dennis Ernst, MT(ASCP), Director, Center for Phlebotomy Education, Inc., "…broken glass exposures are among the most dangerous sharps injuries in healthcare…cleaning up the spill puts the healthcare worker at extreme risk for cuts and the implantation of bloodborne pathogens into the wound…the user is exposed to aerosols and micro droplets that can contain viruses and other pathogens if inhaled or splattered onto clothing. In addition, the healthcare worker is exposed to hundreds of shards of contaminated glass."

So what is OSHA's stance on glass vs. plastic? According to the OSHA compliance directive CPL 02-02-069 which includes specific instruction to field inspectors on proper interpretation, "If a combination of engineering and work practice controls used by the employer does not eliminate or minimize exposure, the employer shall be cited for failing to use engineering and work practice controls." Additionally, Richard Fairfax, OSHA's Director of Enforcement Programs stated in the February 2003 issue of MLO magazine, "Since plastic can be easily substituted for glass in most all cases, we expect employers to use plastic where appropriate. Since plastic tubes are readily available that do not compromise specific clinical or diagnostic tests, a facility that is not using them would have to justify why they are not being used for each specific procedure or test and document that in their exposure control plan."

Since plastic tubes are readily available that do not compromise specific clinical or diagnostic tests, a facility that is not using them would have to justify why they are not being used for each specific procedure or test.

Most laboratories have embraced the need for plastic tubes although compliance has been slow. Plastic tubes have been available for over five years. Some labs are just now using them not for the safety they bring to the laboratory but because the availability of glass tubes was waning. That is not the case for blood culture bottles. For years glass bottles have been the only alternative. Now a new safer plastic bottle for blood cultures has been developed by bioMérieux, Inc. that is revolutionizing the industry.

There are other considerations that may not be obvious in the glass vs. plastic scenario. Most laboratory

PLASTIC

managers base their decision to use one product over another on the cost to the department. But the issues that involved upstream and downstream costs need to be considered with the bigger picture in mind and the overall costs to the institution taken into account.

What about storage? Although the cases holding glass bottles (18 x 10 x 6.5) are similar in size to the cases holding plastic bottles (15 x 10 x 8), a case of 50 glass bottles weighs between 17 lbs. and 22 lbs. A case of 100 plastic bottles weighs about 16 lbs. — twice the number of bottles and less weight in the same amount of space. Why is this important? It impacts the upstream receiving and storage of the cases prior to use in terms of ergonomic complaints.

What about the downstream disposal costs? Waste disposal costs are rarely considered a part of the laboratory budget. Often they are part of the plant engineering operational budget even though every department in the hospital impacts their bottom line. For example, a typical hospital might perform 1,000 blood cultures a month which would equate to 24,000 bottles a year. If the cost for disposal is $0.30 per pound you can see by the table how glass being heavier would impact the hospital's bottom line.

In addition, you need to consider the issues associated with sharps contamination. According to CLSI document GP5-A2, Vol. 22, No. 3, Clinical Laboratory Waste Management; Approved Guideline — Second Edition March 2002, "…special precautions are necessary to minimize/eliminate the risks of physical injury that any sharp presents to waste handlers." If you are placing glass blood culture bottles into red bag waste, there is a high risk to the waste handler (such as housekeeping who picks up the bags) to receive a cut. This doesn't impact the laboratory's bottom line but it surely impacts the hospital's in terms of worker's compensation remuneration of an on-the-job injury. According to an MLO article in 1998 on safety costs, treating an accidental contaminated sharps injury costs the average facility $4,000. Should the employee acquire hepatitis or HIV the cost skyrockets to upwards of $500,000. And those figures were based on 1998 dollars. One can only imagine what the costs would be today.

WASTE DISPOSAL COST COMPARISON

Plastic Bottle A $\frac{2.5 \text{ oz.} \times 24{,}000 \text{ bottles}}{16 \text{ oz. per lb.}} = 3750 \text{ lbs./year} \times \$0.30 = \mathbf{\$1{,}125}$

Glass Bottle B $\frac{5.5 \text{ oz.} \times 24{,}000 \text{ bottles}}{16 \text{ oz. per lb.}} = 8{,}250 \text{ lbs./year} \times \$0.30 = \mathbf{\$2{,}275}$

Glass Bottle C $\frac{7.2 \text{ oz.} \times 24{,}000 \text{ bottles}}{16 \text{ oz. per lb.}} = 10{,}800 \text{ lbs./year} \times \$0.30 = \mathbf{\$3{,}240}$

How does this information affect the buying decision? When justifying the purchase of any blood culture system you need to include the cost of disposal, the cost of storage and the impact of any potential ergonomic and worker's compensation issues — you need to make things happen that are in the best interest of the employee as well as the institution as a whole.

Dispensing Advice with Medication

Pharmacists use patient management software to intervene for better and more responsible patient care.

By Renee Diiulio

Experts have estimated that somewhere between one-third and one-half of antimicrobial use in the United States is inappropriate[1]—a factor that has a negative impact on the cost and quality of health care. Pharmacists, physicians, and patients all share the blame, with some thinking the medication would help and others thinking that at least it wouldn't hurt. But science and antimicrobial infectious agents have indicated that widespread, unnecessary use of antibiotics could indeed complicate care.

With recognition of this situation have come efforts to correct inappropriate use. Guidelines from organizations, such as the Infectious Diseases Society of America (IDSA of Alexandria, VA) and the Society for Healthcare Epidemiology of America (SHEA of Alexandria, VA), provide recommendations that range from the simple, such as frequent hand washing, to the complex, such as localized data on microbial resistance.

Health care institutions have taken these recommendations seriously, often implementing policies or processes that address these concerns. "The appropriate use of antibiotics or anti-infectives is not just part of a policy but part of an expectation. I don't think there is a hospital in the country that doesn't have a responsibility for antibiotic stewardship," says Gregory Hamby, PharmD, RPh, Regional Director of Pharmacy at CHRISTUS Hospital Southeast Texas in Beaumont, TX.

This responsibility can be a challenge to manage, requiring the resources to collect and analyze data from multiple sources, interpret the analysis into meaningful information, and implement intelligent policies. These sources include not only patient-related data, such as laboratory results and medication allergies, but also evidence-based data, such as pharmacological profiles. Software systems that integrate this information can help users in all disciplines to more easily manage the data relevant for responsible antibiotic management and to positively impact care. At CHRISTUS Hospital Southeast Texas, this has been most evident in the pharmaceutical department where both clinical and staff pharmacists have used electronic data and decision making to improve care through increased interventions.

What to Say

"Everything manual is time-consuming," notes Hamby. Before installation of STELLARA® Clinical Intervention and Patient Monitoring software from bioMérieux, Inc. (Durham, NC) and powered by TheraDoc® Expert System Platform®, when pharmacists at CHRISTUS reviewed medication orders, they had to go through multiple records, pulling patient lab histories and results as well as medication profiles.

The time-consuming process could mean untimely delivery of the appropriate therapies. But interventions

can be more immediately necessary as changes in the patient's condition, prescriptions, and lab results occur. Drug-drug interactions may arise, adverse events can occur, or the drug assigned may not completely match the patient's infections. STELLARA alerts users to these conditions, using decision-recommendation technology powered by TheraDoc Expert System Platform. The integration of online evidence-based literature references allows clinicians to incorporate the strongest evidence into their daily practices.

set parameters for workflow management, intervention opportunities, and priorities. CHRISTUS pharmacists have flags to indicate possible interventions, including changes in therapy, agent, or dose. "STELLARA identifies when we need to use the big guns," says Hamby. It also identifies when the 'big guns' need to be holstered.

How to Say It

Prior to the system's installation, CHRISTUS pharmacists would write their own professional reports to personally deliver to clinicians. "There

process, which a computerized program would allow. "If a system can pull the information from a number of different sources into one place, it can save time. And many products feature standardization down to the wording of the verification," observes Hamby.

STELLARA was implemented in a staged rollout, first with clinical pharmacists, who handled departmental responsibilities, and then to staff pharmacists, who work with individualized patient reports. These reports, delivered daily, include recommendations regarding changes in response to new patient medications and/or physiology as well as antibiotic susceptibility reporting.

"Each staff pharmacist is responsible for a given patient population who they address throughout the day. We no longer have clinical pharmacists traveling through the hospital all day," says Hamby.

Armed with the clinically relevant data and discussion tips, the pharmacists' confidence and abilities have increased. "We thought that if we could get the pharmacists to a level where they were comfortable with these interactions, they would have better success rates in their interventions," says Hamby. And the process has worked. [+]

(continued on page 6)

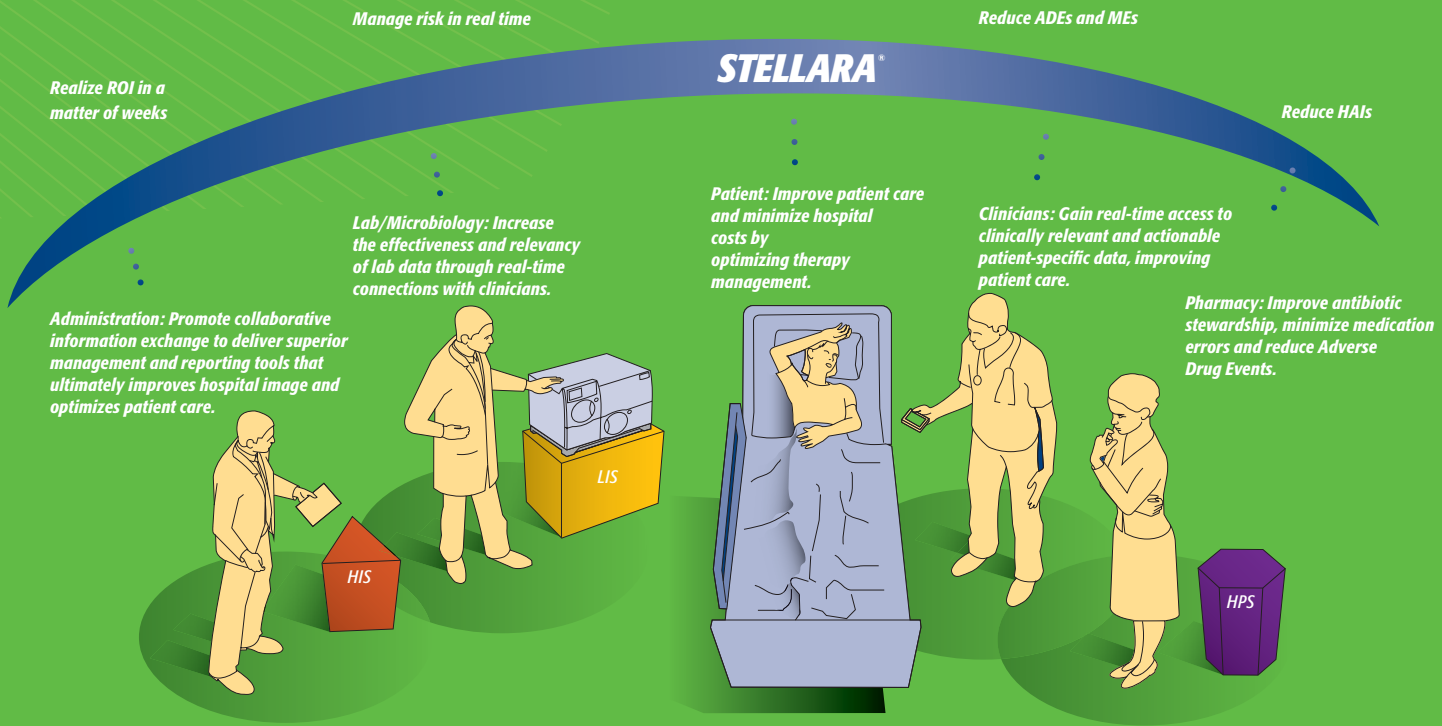
The software tool offers flexibility in reporting, allowing users to customize reports and set parameters for workflow management, intervention opportunities, and

"There is pressure to use newer, more expensive antibiotics because they are perceived as better, but if you examine the susceptibility, there are opportunities to use older agents that, in many circumstances, are just as effective," says Hamby.

The software tool offers flexibility in reporting, allowing users to customize reports and

was a reluctance on the part of pharmacists to have this interaction. But I really feel that the future of pharmacy, especially in institutions, is this information interaction exchange activity," says Hamby.

To bring his pharmacists to a level where they would be comfortable intervening regularly, Hamby wanted to standardize and automate the



(continued from page 5)

[-] "The pharmacists are still warming up to it, but we've gone from no interventions a month to 40 to 60 a month for our staff pharmacists," says Hamby. In fact, interventions have become so prevalent that Hamby intends to rewrite job descriptions to include intervention activity. "The role of a pharmacist is changing from a technical function—although those skills are still required—to expertise in information management and the interface with other disciplines," says Hamby.

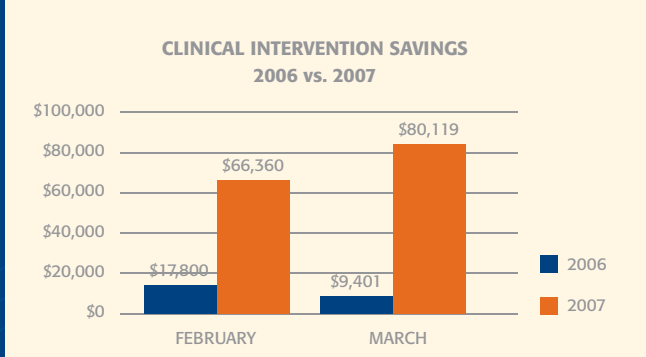
The hospital pharmacists were wary of the new system at first, suspecting it would involve more work. The hospital did want more documentation, but developed innovative ways to create it. "Previously, we had zero documentations from staff pharmacists, so we've used the new system to come up with a number of ways to document interventions," says Hamby. Pharmacists can perform these simple tasks themselves or send orders to the clinical pharmacy department for assistants to log.

"The role of a pharmacist is changing from a technical function—although those skills are still required—to expertise in information management and the interface with other disciplines."

Why Say It

Prior to the system installation, Hamby reports there were challenges with not only creating documentation but also with associating value to pharmacist interventions. Another goal in purchasing the system was to reduce antibiotic cost to appropriate levels. "STELLARA® has given us an avenue where we can take a myriad of interventions and associate a dollar value to them," says Hamby. One of the easiest, he suggests, is dollars per adjusted patient day.

Two years ago, the department used reports to the pharmacy and therapeutics committee to determine that the total value of interventions performed on a monthly basis had a modest value of about $20,000. "In the last couple of months, we've seen that rise to $80,000 a month," says Hamby.



This chart illustrates the increase in total intervention value after the implementation of clinical intervention and patient monitoring software for the months of February (273%) and March (752%) of 2006 and 2007.

He illustrates the savings further using direct comparison data from February and March of 2006 and 2007: total intervention value in February and March of 2006 was $17,800 and $9,401 respectively; in 2007, those figures rose to $66,360 and $80,119 respectively.

Hamby notes the department has also greatly decreased its expenditures, which is consistent with average reports of similar installations. "Comprehensive programs have consistently demonstrated a decrease in antimicrobial use, by 22 percent to 36 percent, with annual savings of $200,000 to $900,000 in both larger academic hospitals and smaller community hospitals."[1]

Of course, Hamby believes additional savings can be found. "We still have lots of opportunity left, but now we can see these areas more easily," says Hamby. One such area is that of discharge. Hamby would like to run numbers on return and rehospitalization rates for patients in terms of discharge. "A colleague is finding that patients who are discharged by pharmacists return less frequently than those discharged by nurses," says Hamby.

These types of data lead to better patient care and reduced health care cost but also increase the value of the pharmacist. "By annualizing numbers, the value of a staff pharmacist can be well documented," says Hamby. Empowered pharmacists will have an even easier time performing interventions, allowing the antimicrobial stewardship program to improve patient care and be financially self-supporting. The advice pharmacists dispense then becomes as valuable as the medication. ▮

Reference: [1]Dellit TH, Owens RC, McGowan, Jr. JE, et al. Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship Clinical Infectious Diseases. *Clinical Infectious Diseases 2007;44:159-177. Available at www.shea-online.org/publications/shea_position_papers.cfm. Accessed on April 25, 2007.*

Source: Gregory Hamby, PharmD, RPh, regional director of pharmacy, CHRISTUS Hospital Southeast Texas, Beaumont, TX, 409.899.7042, Pager: 409.841.0764, gregory.hamby@christushealth.org

[↖] Go to www.biomerieux-usa.com/connection to read additional information and guidelines from IDSA and SHEA on enhancing antimicrobial stewardship in your institution.

In today's clinical laboratory environment, demand for automation, rapid results, and efficient technologies are not limited to only the largest institutions. Improved proficiency, better time management, and expertise in dealing with resistant microorganism are needed no matter the size of the lab. With that in mind, bioMérieux is pleased to introduced two new instruments: the VITEK® Compact 15 for ID/AST testing and the BacT/ALERT® 3D 60 for blood culture monitoring. These instruments enable small labs to provide the same quality results as quickly and confidently as their bigger counterparts.

Introducing New Additions to Two Familiar Families

VITEK 2™ —compact 15

With a 15 card capacity, the VITEK 2 Compact 15 offers the same semi-automated design as the VITEK® 2 Compact 30 and the VITEK® 2 Compact 60 at a more economical price.

Each of the VITEK 2 family of instruments is based on the same innovative VITEK 2 technology that includes:

- **Expanded identification database** using colorimetric, dual wavelength readings of biochemical reactions.
- **Most automated** platform available.
- **Rapid results** with an average 'Time to call' of 8.5 hours for both identifications and susceptibilities.
- **Improved confidence** through AES, the only "second generation" expert system.
- **Limited training time** with windows-based, icon driven, intuitive software.

BacT/ALERT 3D™ 60

Building on the same BacT/ALERT® 3D platform as the larger and more modular BacT/ALERT; the 3D 60's construction utilizes a smaller footprint and provides the same "ease of use."

The BacT/ALERT 3D 60:

- Holds 60 of bioMérieux's unique plastic blood collection bottles.
- Features keyboard directed standard 3D software.
- Offers Choice of Select or SelectLink data management options.
- Provides simultaneous testing for blood, sterile body fluids and mycobacteria.

WORKSAFE™

- Is accompanied by the WorkSafe Training Tools for reduced blood culture contamination rates.

VIDAS® B·R·A·H·M·S PCT®

As an industry leader dedicated to improving patient safety and infection control practices, bioMérieux has become the first company in the United States to launch an automated test measuring procalcitonin (PCT), a biological marker for bacterial infections.

Severe sepsis, a serious bacterial infection found in Intensive Care Units (ICU), strikes more than 750,000 people in the U.S. each year. The VIDAS B·R·A·H·M·S PCT test runs on bioMérieux's automated VIDAS® system and serves as an aid in risk assessment of severe sepsis or septic shock in critically ill patients on their first day of admission to the ICU. Test results are ready in just 20 minutes, enabling hospital workers to maximize the chance of a positive outcome. Early recognition of sepsis and timely initiation of appropriate therapy is vital for survival.

The VIDAS B·R·A·H·M·S PCT test completes bioMérieux's VIDAS Emergency Panel available in the U.S., which includes markers of cardiac necrosis (VIDAS Troponin I, CK-MB) and venous thromboembolism (VIDAS® D-Dimer Exclusion™).

EARLY 2008

SHOWS AND CONFERENCES

Society of Armed Force
Military Lab Scientists (SAFMLS)
New Orleans
February 10-14

Society of Critical Care Medicine
Hawaii
February 2-8

bioMérieux CONNECTION

bioMérieux Connection is published by bioMérieux, Inc., 100 Rodolphe Street, Durham, NC 27712. Please send address corrections and mailing list additions to biomerieux.connection@na.biomerieux.com. For customer service, call toll free 800-682-2666. Please visit our web site at www.biomerieux-usa.com.
Please share your comments and suggestions with us through your local account manager or by emailing us at the address above.
As always, we thank you for being a bioMérieux customer.