

# Road to denial: patient safety and quality healthcare

The Deficit Reduction Act of 2005 reduced Medicare overpayments due to medical errors. In October 2008, the Centers for Medicare and Medicaid Services (CMS) began denying or reducing payment for specific healthcare-associated infections (HAIs): catheter-associated urinary-tract infections, mediastinitis following coronary-artery bypass grafting, and vascular catheter-associated bloodstream infections. CMS currently looks to expand the list of denied HAIs to include ventilator-associated pneumonia, *Clostridium difficile*, and methicillin-resistant *Staphylococcus aureus* (MRSA) bloodstream infections — the latter affects as many as 350,000 patients yearly in the United States.<sup>1</sup>

In 1993, there were fewer than 2,000 MRSA infections recorded in U.S. hospitals.<sup>2</sup> MRSA caused 368,600 infections in U.S. hospitals in 2005. On average, hospital stays related to MRSA infections are twice as expensive as all other hospital stays (\$14,000 vs. \$7,600, respectively)<sup>2</sup>; more than twice as long as all other stays (10 days vs. 4.6 days, respectively)<sup>2</sup>; and more than double the risk of hospital deaths (4.7% vs. 2.1%, respectively).<sup>2</sup>

The goal is not only to reduce or eliminate these infections, but also to quickly determine the infection's source in order to guide empiric therapy, leading to rapid recovery and lowered costs. Unreimbursed expenses could financially ruin some U.S. hospitals. Consider that HAIs account for up to 2 million infections, 90,000 deaths, and billions of dollars in healthcare costs.

A bundle of techniques and lab tests exist to both prevent false-positive blood cultures and rapidly identify pathogens from positive blood cultures. The bundle includes a blood-culture collection and products, coupled with a molecular test that uses a fluorescent-labeled probe. Results from this combination are available in 2.5 hours, a contrast to typical lab cultures that identify the causative organism in positive samples in 48 to 72 hours. This delay often means patients are treated with broad-spectrum antimicrobial — in some cases, with the wrong antimicrobial — which can cause adverse patient events. This new solution removes guesswork from infection determination and treatment, while averting denied reimbursements and the cost of improper antimicrobial-drug treatment.

Improperly collected blood cultures

may yield positive results from blood-culture tests via the introduction of a skin contaminant at the venipuncture site, while the patient, in fact, does not have a systemic infection. If the culture becomes positive, a Gram stain is performed to determine the colony morphology of the bacteria. The report is called to the physician who will prescribe empiric therapy if clinical signs and symptoms are consistent with a potential septic event.

Rigid infection-prevention protocols, with the help of new technology, are proving effective in guaranteeing hospitals receive full reimbursement when infections are not spread in the healthcare setting. Thus, finding the right culture-collection kit is critical. Ideal kit systems should be capable of processing blood, body fluids, and mycobacteria specimens all in the same instrument and have a well-established reputation for ease of use, high-performance detection of positive results, and a low false-positive rate. For speed and accuracy, ideal systems remove all subjectivity by providing colorimetric-sensor technology. In such a system, each culture bottle is continuously monitored for microorganism growth by a highly sensitive reflectometer. Any recognized changes are quickly reported.

The molecular-testing system relies on peptide nucleic-acid (PNA) molecules — DNA “mimics” in which the negatively charged sugar-phosphate backbone of DNA is replaced with a non-charged polyamide or “peptide” backbone. The synthetic backbone provides PNA probes with unique hybridization. Because of the non-charged backbone, PNA probes — unlike DNA probes — do not encounter electrostatic repulsion, allowing them to hybridize rapidly and tightly to nucleic-acid targets.

Growing bacteria and yeast cells produce an abundance of ribosomal RNAs (rRNA) that contain regions of highly conserved, species-specific sequences and are, therefore, ideal targets for identification assays such as fluorescence *in situ* hybridization (FISH). The target sequences, however, are frequently located in highly structured regions of the rRNA, which are virtually inaccessible to DNA probes. The unique properties of PNA probes allow access to these regions under conditions optimal for FISH, resulting in a simple yet highly sensitive and specific hybridization assay,

or PNA FISH, suited for rapid and accurate identification of bacteria and yeast.

Molecular systems that provide rapid identification of positive cultures can reduce:

- mortality and costs associated with *S aureus* bacteremia<sup>3</sup>;
- length of stay and unnecessary vancomycin use due to coagulase-negative *Staphylococcus*-contaminated blood cultures<sup>4</sup>;
- time to correct therapy and mortality for *Enterococcus faecium* bacteremia<sup>5</sup>; and
- antifungal-drug costs associated with *Candida albicans* fungemia.<sup>6</sup>

Together, the bundling of a blood-culture collection system with a rapid molecular-identification system can help hospitals and labs avoid the road to reimbursement denial. The key is to find complementary systems that meet specific needs and are fast, reliable, and accurate. □

## References

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