In the beginning...
When we think about the pioneers in healthcare, those who were the first to establish standards or to lobby authorities in favor of a “gold standard” of patient care, one name immediately comes to mind: Florence Nightingale. When the Crimean War broke out in 1854, Nightingale led a group of nurses who served in British military hospitals. When she arrived, the mortality rate for the wounded was high, and it grew higher in subsequent months. For Nightingale, hospital management was about maintaining good housekeeping. She realized that the sanitary conditions of these hospitals were deplorable or non-existent.

In her book *Notes on Nursing*, written in 1859, she states, “The very first requirement in a hospital is that it should do the sick no harm.” The book was the first of its kind ever to be written, and it appeared at a time when the basic requirements for human health were only beginning to be discovered and discussed.

A few years later in 1874, Charles Chamberland invented the first pressurized steam autoclave, which sterilized reusable medical devices at higher temperatures in much less time than was previously possible.

One hundred years later in 1974, after scores of medical technologies and advancements improved healthcare by leaps and bounds, the Association for the Advancement of Medical Instrumentation (AAMI) Sterilization Standards Committee was established. Six years later, the first AAMI Sterilization Recommended Practice was published.

Around the same time and independently, the Association of periOperative Registered Nurses (AORN) published the first “AORN Standards of Practice” in 1978; it was 25 pages long. The first published edition of the “AORN Standards and Recommended Practices” as we know them today was published in 1982 and was approximately 80 pages. Today, the Perioperative Standards and Recommended Practices are 812 pages long.

Over the last 140 years or so, ‘best practices’ have evolved from simple housekeeping procedures to highly detailed guidance based on knowledge gained from clinical and scientific study.

The basis of best practice
Although we as healthcare professionals have access to a foundation of standards and recommended practices provided by various professional and governmental healthcare organizations, I might argue that ‘best practice’ does not begin with these standards. In most cases, the standards themselves were founded on pre-existing evidence-based processes.

In order to have evidence-based processes, someone had to be the first to develop them. Processes, in turn, require the appropriate tools and devices. In the medical device industry, rigorous studies and trials are conducted to determine or confirm a predetermined outcome or performance level for a product or device before it is made available for sale to healthcare providers. This is the science obtained and submitted as part of U.S. Food and Drug Administration 510k or Pre Market Approval (PMA) applications, highly respected and longstanding review processes by which FDA clears products to be marketed and used in the United States. Thus, evidence-based clinical practices can in some cases be traced back to the research and testing done to validate the use of a technology or device that is required for that ‘best practice.’

However, evidence-based science and practice is, by its nature, a moving target. It is directly tied to innovation, so it evolves. The discovery of new science and development of groundbreaking technologies greatly contribute to the advancement of medicine and all its supporting processes. This makes ‘best practice,’ in some cases, more like a slide rule. Over time, it must be adjusted to keep pace with the most current evidence-based validated technology.
Why is the gold standard so hard to achieve?
The terms ‘best practice,’ ‘the gold standard,’ and ‘evidence-based practice’ are almost interchangeable phrases we hear frequently in reference to optimal, standardized healthcare processes and procedures. Regardless of your favorite catchphrase, it is widely accepted that proven practices that are consistently performed lead to the best outcomes for patients. They also can result in improved workflow for staff and cost savings to a healthcare system through more efficient and effective processes.

Yet something is preventing sterile processing departments from reaching a utopian level. Why are we not seeing consistency or standardization of practice across multi-hospital health systems, or even from facility to facility within a system? What decisions and actions will help practitioners achieve their own gold standard?

Challenges undermining standardization
One of the most significant roadblocks to achieving best practices is time – the lack of it and poor management of it. Most CSSD managers find themselves caught up in the day-to-day routine. They don’t feel able to allow the time for regular research, trials, training and updating of practices that most effectively meet their customers’ current needs.

Change and innovation can also be obstacles – since surgical devices and sterile processing technologies continue to evolve, they require regular evaluation, testing and training as they are incorporated into surgical procedures and CSSD processes.

Another major impediment can be cultural – how a health system views its sterile processing professionals and the work they do, how they view themselves, and whether the CSSD has the authority (and budget) to collaborate with other critical stakeholders such as the surgical and infection control departments to develop consistent practices.

Lack of knowledge can also be a significant stumbling block to achieving the gold standard in sterile processing. CSSD managers need a good basic education in business and finance to effectively develop business plans and make a business case to justify a greater investment in their CSSD. Everyone in the CSSD also needs a good basic understanding of sterilization, decontamination, and sterility assurance principles and equipment. In addition, fully accredited sterile processing professionals have the best chance of advancing the capabilities of the department, so managers should work to achieve these levels of education for all staff members.

Although these challenges often require long-term change management efforts, there are also some tactical, more immediate actions that can be taken to eliminate some obstacles and move towards best practices (See Table).

Lack of knowledge – managers and staff
Educate beyond the department
Achieving and maintaining best practices requires a commitment to excellence and a determination to teach others the rationale for what the CSSD does, and why. Educating CSSD managers and staff about the science behind their processes and equipment is the first step. Professional development and certifications add another layer of credibility and knowledge that can be used to establish evidence-based practice. But in order to achieve a more global understanding of best practice throughout the health system, CSSD professionals must educate and continue to update hospital administration and senior management, infection control practitioners, perioperative nurses, surgical technologists, environmental services, materials management and other health professionals involved in patient safety, infection prevention and risk analysis.

See SELF-STUDY on page 38

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<th>Roadblock</th>
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| Lack of time | • Establish project timelines with date specific goals and achievements.  
• Prevent procrastination and stagnation with a realistic time schedule for various goals to be achieved. |
| Lack of staffing resources to help develop policies – no policy and procedure committee | • Collaborate and invite the right people from other departments to the table as needed. Be sure that their hospital role is tied in some way to the best practice goals.
• Break the work into doable sections. Assign portions of policy to be researched and written.
• Collaborate with your OR educator or infection preventionist. |
| Constant change and innovation | • Develop a training plan for any uncertified staff members. Prepare a business case for sufficient budget to help them achieve certification.
• Look for vendor partners to assist with low or no-cost device and equipment training. |
| Lack of a departmental strategic plan to deal with change and innovation | • Define your department’s current status. Identify the best practices you wish to accomplish. Document the steps it will take to achieve them. |
| Cultural issues within one hospital | • Find a mentor in senior management to support your efforts.  
• Meet with infection preventionists and surgical department to establish a spirit of collaboration.  
• Collaborate from the start. Showing your department’s vision of achieving best practice will help to bridge the gaps. |
| Conflicting cultures at multi-hospital health systems and newly acquired hospitals | • Make sure that AAMI and AORN Standards and Recommended Practices are on site. Obtain funds to secure a departmental copy or share a copy among the CSSD, surgical and infection control departments.  
• Develop a training plan for any uncertified staff members. Prepare a business case for sufficient budget to help them achieve certification.  
• Collaborate with your OR educator or infection preventionist. |
| Lack of knowledge – managers and staff | • Contact your Finance or HR department for classes and professional development opportunities.  
• Look for a mentor to help you develop the plan.  
• Identify the costs associated with achieving the identified best practice(s). Based on difficulty or financial limitations, identify the low, intermediate and high priority items. |

www.hponline.com • HEALTHCARE PURCHASING NEWS • May 2010 37
Best practice is not an individual quest or one department’s goal. It is collaboration among patient-safety minded healthcare providers with a similar foundation of understanding and knowledge who want to achieve the best possible outcomes for the human beings walking through their doors for treatment. What Florence Nightingale wrote is still valid today: “The very first requirement in a hospital is that it should do the sick no harm.” Has your department achieved today’s gold standard on the slide rule of best practice? If not, what is preventing your team from doing so?

References

Circulate the one correct answer:

1. What compelling statement is made in Florence Nightingale’s book Notes on Nursing?
   A. “We have not begun to fight the war on infection.”
   B. “Sterilization begins with proper cleaning.”
   C. “The solution to pollution is dilution.”
   D. “The very first requirement in a hospital is that it should do the sick no harm.”

2. Which scientist working on a scientific project invented the autoclave?
   A. John J. Perkins
   B. Richard Chamberlain
   C. Charles Chamberland
   D. Louis Pasteur

3. In what year was the first AAMI sterilization recommended practice published?
   A. 1980
   B. 1974
   C. 1978
   D. 1982

4. What are the components of ‘best practice’?
   A. Evidence-based science
   B. Evidence-based practice
   C. Consistent processes and procedures
   D. Documented policies and procedures
   E. All of the above

5. Medical device manufacturers submit studies and trial results documenting the predetermined outcome or performance level of a device as part of what submission(s) to the FDA?
   A. CFR 21
   B. 510k
   C. PMA
   D. DD 214
   E. B and C

6. Which statement is correct regarding the U.S. Food and Drug Administration?
   A. The FDA approves devices for market in the United States.
   B. The FDA clears devices for market in the United States.
   C. The FDA approves devices for market in North America.
   D. The FDA clears devices for market in North America.

7. Which can help you achieve best practices?
   A. Lack of time, lack of staffing resources, constant change and innovation.
   B. Lack of a strategic plan, cultural issues within a hospital, conflicting cultures at a multi-hospital system.
   C. Having a mentor in senior management, having a training plan, collaboration with key stakeholders and customers such as the OR, Infection Control, and Human Resources.
   D. Lack of knowledge, lack of financial understanding or budget practice, lack of 1-3 year business plan.

8. Which action or actions help to overcome the lack of knowledge that prevents you from achieving best practice in the sterile processing department?
   A. Obtaining a copy of the AAMI and AORN Standards and Recommended Practices.
   B. Developing a certification training plan for new and seasoned CSSD staff.
   C. Working with the OR educator and infection preventionist.
   D. A and C
   E. All of the above.

9. What must CSSD professionals do to achieve a more global understanding of best practice throughout the healthcare system?
   A. Educate and continue to update hospital administration and senior management.
   B. Educate and continue to update the patient.
   C. Educate and continue to update infection control preventionists, OR nurses, surgical techs, environmental services, materials management and other health professionals.
   D. Both A and C
   E. None of the above.

10. How are best practice(s) achieved?
    A. With a commitment to excellence.
    B. Through department collaboration with key stakeholders.
    C. Doing the same thing you have done for 20 years.
    D. Both A and B.
    E. None of the above.

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2. “Forty Years of People, Progress, and Patient Safety,” a commemorative, pictorial publication. AAMI Publications: PD Box 0211, Annapolis Junction, MD 20701-0211.

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