Bacteria, viruses, fungi and other pathogenic microorganisms which cause infectious diseases know no national boundaries. They are global forces of nature that need to be guarded against in each and every country. The practice of reducing and eliminating the spread of these microorganisms, known as effective infection control, has evolved rapidly during the past few years. Because this area is constantly evolving, it is difficult to remain up-to-date and knowledgeable about how to best provide safe services. This article is designed to focus specifically on effective methods of cleaning, sterilizing, and disinfecting the instruments critical to our profession in the safest, most efficient manner as well as addressing appropriate use of personal barriers. Adherence to appropriate standards in both of these areas is critical due to the clients that we serve, regardless of the country in which we practice.

Each of our patients has unique combinations of age, socioeconomic/
nutritional status as well as current (and past) pharmacological histories, and so each brings with them the potential for unique combinations of opportunistic infections that we can easily transfer from one patient to another. In order to provide the safest possible environment for our patients, it is important that we employ the highest standard of infection control with the instruments we re-use on more than one patient. It is imperative that we use personal barriers to prevent transmission from a patient to ourselves or to another patient. Methods that we have transitionally employed such as the use of alcohol swabs and the cleaning solution in our ultrasonic cleaners, no longer meet the requirements to provide our patients with a risk-free infection controlled environment. It is critical that we implement new infection control protocols in the workplace.

Additionally, our society has become a far more international and we have seen increasing number of stories where diseases have transferred easily across international borders. MacPherson et al stated that population mobility is the main factor in globalization of public health threats and risks. Tourists, refugees, retirees, border neighbors, international business travelers, etc can return from their travels bringing with them infections that can easily be spread to other parts of the world. An increasingly large number of hearing instrument practitioners travel around the world in order to provide the gift of better hearing to nations not so fortunate. We often find ourselves in areas of the world with unique infection control issues and are exposed to a variety of organisms that we might not know or understand.

What is even more of an issue is that how we manage these organisms constantly evolves—meaning that we must stay current on our knowledge. An example of this in my life is tuberculosis. I traveled with my brother, an infection control physician, to South Africa in 1997 and at the time was concerned with the patients I saw who had tuberculosis and, in particular, drug-resistant tuberculosis. It is critical to be aware of these types of issues as we travel abroad. However, it is now true that infection control issues around the world impact our practices regardless of where we live. If we don’t go to the germs, then the germs will eventually come to us! While this article is not designed to be comprehensive in terms of world infection control practice, it will highlight a few issues of infection control in different parts of the world.

**Personal Barriers**

Personal Barriers is one of the items addressed as part of the standard precaution guidelines outlined by the Center of Disease Control and Prevention (CDC) in the United States. Standard precautions, previously known as “universal precautions,” help us understand how to prevent the transmission of pathogens from one individual to another. The CDC outlines appropriate use of hand hygiene and isolation precautions; the use of personal protective equipment, employing appropriate medical waste disposal, and proper procedures for repurposing reusable equipment. Recommendations regarding personal barriers are one of the areas that have changed rapidly in our profession during the past few years. Personal barriers, or personal protective equipment, includes gloves, face masks, gowns, protective glasses, and other equipment used to provide a barrier of safety between the healthcare professional and the patient.

Properly fitted gloves are a required component of an appropriate infection control program. Gloves must be incorporated while performing potentially infectious or “dirty” procedures. Gloves should be used:

1. When ear drainage, blood, sores or lesions (on the scalp) are evident.
2. When handling ear molds or hearing aids directly from the patient.
3. During the removal or handling of ear mold impressions.
4. When performing cerumen management.
5. When cleaning or disinfecting instruments contaminated with cerumen.
6. In environments where the need for additional precautions have been identified.
7. When handling dirty laundry or waste materials.
8. When cleaning up spills of body fluids or when disinfecting a contaminated area.
9. When dealing with immuno-compromised clients.

In addition to the use of gloves, we want to be sure that we use them properly. We should wash our hands and inspect the

continued on page 48
gloves for tears prior to putting them on. Anytime we move from a “dirty” to a “clean” activity we need to remove our gloves and wash our hands. If we move back to another “dirty” activity then we should rewash our hands and put on a new set of gloves. As an example, we find we require a different instrument after we have begun removing cerumen from an ear. We take off our gloves, wash our hands, select the appropriate instrument from our supply of clean tools, rewash our hands and put on a new pair of gloves.

Let us look at a practical example of this. Several years ago, I traveled to El Salvador as part of a Starkey Canada “mission” to fit hundreds of children with hearing aids. All of the children had been tested and had earmold impressions taken and earmolds made for them. My job was to fit the children with the appropriate amplification. Based upon their audiogram, hearing aids were selected and fit on the child. Many children had been assessed for the very first time prior to our arriving and we found that several of the audiograms over-estimated the degree of hearing loss and subsequently, the amount of amplification required. In the picture above you will see that the hearing aids are hanging off of very long tubing. This allows us to remove the hearing aids and try several sets without the hearing aids coming in contact with the patient or without us having to remove the earmolds, reducing the time that would be required to apply gloves each time we removed the earmold. Only when the final pair has been selected is the tubing trimmed to size and the earmolds removed. Another quick note on that particular mission, one of the children brought us a chicken as a thank you present. I have to admit that prior to going to El Salvador, I never considered the infection control protocols of handling a live chicken and fitting hearing aids!

Gloves should be disposed of in a waterproof garbage bag. If gloves contain significant amounts of blood, then they should be disposed of in an impermeable bag labeled with a biohazard symbol. It is critical to remember to never re-use gloves that have been worn, even on the same patient.

Additionally, masks might need to be employed if treating patients with an airborne microorganism such as tuberculosis or chickenpox which can be transmitted via the nose or mouth. Eye protection (safety eyeglasses or face shields) might need to be employed if we are treating high risk patients, if we have a risk of splash or splatter of potentially infectious material, or if the clinician or patient is at risk of airborne contamination.
Gowns might be worn if there is a danger that clothing could become contaminated.\(^5\)

So, how are we doing as a profession? It is impossible to assess for certain in our field, but if we look at a field with similar issues such as dentistry: in one study of dentist’s use of gloves varied widely by country. In China, only 15% of dentists reported using gloves, while 58% of practitioners in Pakistan, and 97% of U.S. practitioners regularly used gloves.\(^6\) These types of reports might change as infection control standards emerge in other nations. Internationally, glove manufacturers report that they are selling an increasing amount of gloves in Latin America and Asia as these nations implement stricter infection control standards. Manufacturers believe that awareness of hygiene requirements for protection of both the patient and the healthcare provider is improving in these regions. *Infection Control Today* reported that the Latin American region, followed by China and India, reflect the largest increases. The nations purchasing the largest amount of gloves include: the United States, China, Japan, Germany, Russia, France, India, Italy, the United Kingdom, and Brazil.\(^7\)

### Reprocessing of Clinical Equipment

For guidance in what practices we should embrace, we can turn to guidelines known as the “Spaulding Classification”. For 30 years, the Spaulding Classification (created by Earle H. Spaulding) has provided us with a strategy for reprocessing contaminated medical devices. The Spaulding system classifies all medical devices into critical, semi-critical, and non-critical categories; based upon client safety and the risk of contamination by that device. In addition, the Spaulding Classification system establishes three levels of reprocessing including sterilization, high-level disinfection, and low level disinfection and applies these reprocessing methods to each of the three previously mentioned classes of medical devices (critical, semi-critical, and non-critical).\(^1\) Spaulding’s system can be adapted to encompass the medical devices employed by any profession. Table 1 describes how the system can be utilized in a dispensing practice.\(^2,3\)

<table>
<thead>
<tr>
<th>Category</th>
<th>Level of Processing/Reprocessing</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Critical</strong></td>
<td>Cleaning followed by sterilization</td>
<td>Generally not applicable to hearing aid dispensing practice</td>
</tr>
<tr>
<td></td>
<td>▶ Items that enter sterile tissue, including the vascular system</td>
<td></td>
</tr>
<tr>
<td><strong>Semi-critical</strong></td>
<td>Sterilization or Disposable/Single Use is preferred. Cleaning followed by High Level Disinfection (HLD) as a minimum</td>
<td>Any item entering the ear canal: Insert earphone, impedance probe tips, curettes and other cerumen equipment, otoscope tips, and probe tubes</td>
</tr>
<tr>
<td></td>
<td>▶ Items that come in contact with non-intact skin or mucous membranes but do not penetrate them</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▶ Items that contact cerumen are considered semi-critical due to potential contamination with blood and body fluids</td>
<td></td>
</tr>
<tr>
<td><strong>Non-critical</strong></td>
<td>Cleaning followed by Low Level Disinfection (LLD)</td>
<td>Insert earphones (exclusive of foam tip), bone conduction oscillator, patient response button, and listening stethoscope</td>
</tr>
<tr>
<td></td>
<td>▶ Items that contact only intact skin or do not directly touch the client</td>
<td></td>
</tr>
</tbody>
</table>

Table 1. The Spaulding Classification

The Spaulding Classification system and subsequent reprocessing scheme can be found in a variety of nations in the world. Guidelines in the United Kingdom, Australia, New Zealand, and Canada reflect this terminology. CDC protocols in the United States also reflect this terminology but guidelines from Audiological governing bodies in the United States, such as the American Academy of Audiology, have opted to divide reusable items into either Critical or Non-Critical items (with all non-critical items requiring sterilization rather than high level disinfecting).\(^8\)

continued on page 50
Here is a brief description of each category and processing level.

1. Equipment Categories

   A. Critical Equipment
   Critical items pose a high risk for infection if they are contaminated with any microorganism. Critical items are those that either enter sterile tissue or directly enter the vascular system. Fortunately, for our practices, we do not utilize critical equipment in our practices. Examples in other fields would include surgical instruments, implants, and catheters.

   B. Semi-Critical Equipment
   Semi-critical items are those that come in contact with mucous membranes or non-intact skin. This category includes any item that enters the ear canal to include insert earphones, impedance probe tips, curettes and other cerumen equipment, otoscope tips, and probe tubes. While a disposable/single use item is preferred, semi-critical items can be reprocessed provided they are first cleaned and then processed using a high-level disinfection process. In most dispensing practices, a chemical or liquid high-level disinfection process should be implemented with these items.

   C. Non-Critical Equipment
   Non-critical items are those that come in contact with intact skin but do not come in contact with mucous membranes. It is held that intact skin forms its own effective barrier, as there has been no documented risk of transmission of infectious agents to patients through non-critical items as long as they do not contact non-intact skin and/or mucous membranes. Examples in a dispensing practice include both non-critical patient care items (such as insert earphones (exclusive of foam tip), bone conduction oscillators, patient response button, and a listening stethoscope) as well as non-critical environmental surfaces (such as a desk or display case).

2. Levels of Processing/Reprocessing

   A. Sterilization
   A properly implemented sterilization process insures the destruction of all forms of microbial life including bacteria, viruses, spores, and fungi. It is a more difficult process to achieve and most items that require sterilization are often treated with steam or hydrogen peroxide gas plasma. Liquid/chemical sterilants can be used but it is critical that the guidelines are followed regarding the proper concentration of sterilant, contact time, and temperature. Sterilization is not required of instruments used in a dispensing practice. As has already been noted, practice recommendations within the field of Audiology in the United States recommend that all instruments that enter an ear canal be either single use items or be processed via sterilization rather than receive high-level disinfecting. As chemical sterilants are most often employed in our profession, the cost of either sterilizing or using a high-level disinfectant is the same and the only variation is the amount of time the instruments remain in the solution.

   If the cost is the same, why not sterilize instruments each time? It absolutely makes sense to do so (and follows Audiological recommendations in the United States).

   It does require ensuring that there are sufficient of each item to be used during the day to allow for the instruments to be sterilized overnight. A recent example for me involved a cerumen management training I performed in Christchurch, New Zealand. I knew that we would see 4-5 patients that afternoon and I took a couple of a variety of curettes with me to be used. Upon arriving, I found that every person I saw had a very hard, dark material mixed with their cerumen. While I didn’t send the material to the lab for analysis, the practitioners I was training in New Zealand felt the material was the soil liquification from the recent earthquakes, as they had encountered a similar substance in other places. We had neither time to properly sterilize OR high-level disinfect the curettes I brought with me and were forced to use other methods than we might have wished to use in order to follow proper reprocessing guidelines.

   B. High-Level Disinfection
   The process of high-level disinfection is defined as complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. Typically, in a dispensing practice high-level disinfection is achieved by using a chemical or liquid sterilant for a shorter period of time than would be used if that same liquid sterilant was being used as part of a sterilization process. As an example, the labeled recommendation might be that a chemical sterilant but used for 8 hours to comply with sterilization guidelines but only ½ hour in order to achieve high-level disinfection. It is believed that cleaning followed by a high-level disinfection reduces the pathogen levels
sufficient to prevent transmission to another patient. Glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, and peracetic acid with hydrogen peroxide are all chemical or liquid sterilants that can be used to achieve high level disinfection and are all cleared by the Food and Drug Administration (FDA).7

When using a high-level disinfectant it is critical to keep a few points in mind:

1. The shape of the item being reprocessed must allow for effective reprocessing. For example, due to the porous nature of an insert earphone tip, it cannot be reprocessed and must be a single-use item.

2. Items must first be cleaned if visible debris is present and must be submersed completely for the time prescribed.

3. Solutions have a shelf life and the shelf life of the solution used must be followed. While this varies from solution to solution, once a bottle has been opened, it can only be used for one-four weeks. Each time the solution is used it must be clean and fresh and not reused for more than one “batch” of dirty items.

4. Following high-level disinfecting, all instruments must be rinsed with sterile saline or water to avoid introducing the chemical sterilant solution to patient ear tissue.

5. Disinfected items must be stored in a way following disinfecting that allows for the integrity to be maintained prior to use.9

In addition, it is critical that only those disinfectants approved by the FDA (for the United States) as meeting the criteria for high-level disinfecting, should be used. Items that have been classified as either intermediate or low-level (such as alcohol wipes or a cleaning solution used in an ultra-sonic cleaner) should not be used on any item where high-level disinfection is recommended. This becomes a particular issue in parts of the world that do not have a body such as the FDA which regulates the materials used. For example, in Venezuela, two companies produce and distribute BAB (quaternary ammonium compound dodecyl dimethyl benzyl ammonium bromide). The label on this product claims that it can sterilize medical and dental instruments but both BAB failed subsequent testing to support that claim and was found to be a low level disinfectant which isn’t sufficient for reusable equipment and may have contributed to surgical site infections. This particular product is distributed to Panama and other Latin American countries. In another example, an evaluation by Mexico City’s public health authorities examined three glutaraldehyde solutions (one French, one Swiss, and one made in Mexico) and all three failed to perform as expected when used as labeled.10

C. Low-Level Disinfection

A variety of low-level disinfectants are readily available for non-critical patient care items and splash surfaces. Low level disinfectants are designed to kill most vegetative bacteria and some fungi and viruses, but do not kill mycobacterium or bacterial spores. Cleaning is required prior to the use of low-level disinfection in order to be effective. Low level disinfectants include quaternary ammonium compounds, 3% hydrogen peroxide, and diluted bleach (1:1000). Often, cleaning up our splash surfaces is overlooked and yet a variety of infectious agents such as hepatitis B and MRSA (methicillin resistant staphylococcus aureus) have been known to live for extended periods outside of the body.

D. Cleaning

Cleaning is the actual removal of foreign material such as blood, cerumen or other body excretions from the instrument in question. It involves removing rather than killing the microorganisms. It is accomplished with water, detergents, and elbow grease. Cleaning is required if visible debris is present prior initiating any disinfecting or sterilization method.

Purdy examines a child in Jamaica.

continued on page 52
Summary

So, does it matter? Once again, I found myself on a Starkey Mission, this time as part of the pre-mission team whose job it was to provide cerumen management, hearing assessment, and earmold impression taking in Jamaica on more than 700 children. In Jamaica, the vast majority of hearing impaired children who are schooled reside in residential schools. As part of the pre-mission, we traveled from one community to another and one of the largest lessons I learned on that mission was how important it was that we ensure we did not transfer organisms from one child to another. If we went to one residential school and encountered fungus in a child’s ear canal, we could predict that most of their classmates would also have fungus. If we assessed children at another residential school where fungus wasn’t encountered, it wouldn’t be encountered for the entire school. Schools would have children with similar ages, socioeconomic status, diet, and environment. What was painfully obvious is that the fungus that entered a school via one child would spread to their classmates. We needed to ensure that the instruments we placed in one child and then used on another were not agents in facilitating this transfer.

In summary, it is imperative that we practice proper infection control in our offices and that we remain up-to-date as new recommendations emerge. It is only via these practices that we can insure that we are protecting both ourselves and our patients from a potentially deadly infection!

References

IHS Continuing Education Test

1. The practice of infection control
   a. guards against the spread of microorganisms
   b. has not changed much in the last 10 years
   c. is easy for professionals to keep up with standards
   d. all of the above

2. Alcohol swabs and the cleaning solution in our ultrasonic cleaners are effective in eliminating the spread of most pathogenic microorganisms.
   a. true
   b. false

3. Infectious diseases are caused by
   a. fungi
   b. viruses
   c. bacteria
   d. all of the above

4. Diseases transfer easily across international borders because
   a. our society has become far more international
   b. tourists and refugees spread infections from other parts of the world
   c. international business travelers spread infections from other parts of the world
   d. all of the above

5. Personal protective equipment
   a. does not include gloves, face masks, gowns, and protective glasses
   b. is used to provide a barrier of safety between the healthcare professional and the patient
   c. CDC recommendations have remained the same over the past few years
   d. all of the above

6. Gloves are not necessary when handling hearing aids directly from the patient
   a. true
   b. false

7. Gloves
   a. do not need to be properly fitted
   b. should be inspected for tears before putting them on
   c. are not really necessary for handling dirty laundry or waste materials
   d. eliminate the need to constantly wash our hands

8. It is safe to re-use gloves that have been worn, only if you are still treating the same patient.
   a. true
   b. false

9. The Spaulding Classification system
   a. classifies all medical devices into critical, semi-critical and non-critical categories
   b. is based upon manufacturer’s sterilization recommendations
   c. provides a strategy for sterilizing all contaminated medical devices
   d. all of the above

10. High level disinfectants, as approved by the FDA,
    a. include glutaraldehyde, hydrogen peroxide, and alcohol swabs
    b. can be used for six weeks, once a solution bottle has been opened
    c. should prevent the transmission of pathogens to another patient
    d. all of the above

For continuing education credit, complete this test and send the answer section at the bottom of the page to:
International Hearing Society • 16880 Middlebelt Rd., Ste. 4 • Livonia, MI 48154
• After your test has been graded, you will receive a certificate of completion.
• All questions regarding the examination must be in writing and directed to IHS.
• Credit: IHS designates this professional development activity for one (1) continuing education credit.
• Fees: $29.00 IHS member, $59.00 non-member. (Payment in U.S. funds only.)

Answer Section
(Circle the correct response from the test questions above.)

1. a b c d
2. a b
3. a b c d
4. a b c d
5. a b c d
6. a b
7. a b c d
8. a b
9. a b c d
10. a b c d

(PHOTOCOPY THIS FORM AS NEEDED.)