Inside the March Issue

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INSIDE THE CURRENT ISSUE

March 2015

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Names and hospital identification will be withheld upon request.

Fecal transplanting a reality; writing on peel pouches

by Ray Taurasi

Q Our clinical resource coordinator advised me that the medical advisory council is considering the approval to begin fecal transplant procedures at our hospital. I was asked to look into how this might impact sterile processing in regards to material resources and processing. I have never heard of a fecal transplant. Is this a legitimate procedure or am I being hoodwinked?

A You are not being hoodwinked — fecal transplantation is indeed a legitimate procedure. Referred to as Fecal Microbiota Transplant (FMT), the procedure involves taking fecal matter (stool) from a donor who has been tested, mixing it with saline or other solution, straining it, and then placing it in the receiving patient via enema, colonoscopy, endoscopy or sigmoidoscopy.

According to the Fecal Transplant Foundation, the purpose of an FMT is to restore good bacteria in the digestive system, which has been suppressed or destroyed, often by the use of antibiotics. The absence of essential "good" bacteria in the digestive system results in an overpopulation of "bad" bacteria, such as *clostridium difficile,* in the colon. This can cause a serious infectious condition known as *C. diff*. colitis and debilitating diarrhea. *C. diff* is a very serious and transmittable infection and is on the rise, having affected most healthcare facilities worldwide. In the U.S. alone, the Centers for Disease Control reported that approximately 347,000 individuals were diagnosed in 2012 with at least 14,000 associated deaths. FMT is also showing some promising results for other auto-immune-digestive health conditions, such as ulcerative colitis, irritable bowel syndrome and Crohn's disease.

Despite the success rate of over 90 percent for the treatment for recurrent *C. diff.*, there are many patients and healthcare professionals that have never heard of FMT and while more physicians are beginning to perform fecal transplants, only limited numbers currently serve the large population in need.

In June 2013, the FDA reversed their earlier decision to classify fecal matter as both an Investigational New Drug (IND) and a biologic, which allowed fewer than 20 U.S. physicians with approved IND application to perform fecal

March 2015
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transplantations. Currently, FDA allows qualified physicians to perform FMT for recurrent *C. diff.* only, with signed patient consents and tested donor stool. Oral administration in a capsule form is also being developed and evaluated with good results so far.

Should your medical advisory council allow these procedures to take place at your hospital, I would suspect there would be very little impact on your sterile processing department since there is no new or expensive technology required to perform the procedures.

Q I am an OR nurse in our hospital ambulatory surgery center where we prepare and package all of our reprocessable items and send them over to the hospital's sterile processing department to be sterilized. We have always written on our peel pouches with no problem, until now. We have a new manager in our sterile processing area who has refused to sterilize any peel pouches with writing on the paper side of the package. He claims any necessary labeling should be on the plastic side only, which makes absolutely no sense to me. What difference does it make what side we write on?

A There are two primary concerns relative to writing on the paper side of peel pouches:

1. The writing tool (pen, pencil or marker) could puncture or otherwise compromise the sterile barrier or integrity of the peel pouch package.
2. The substance, ink or otherwise, could be toxic and leach through the paper during sterilization and be deposited onto the package contents, which ultimately may come in contact with the patient posing a health and safety risk.

The plastic side of a peel pouch is not permeable and the likelihood of leaching is less likely. However, writing tools with sharp or hard tips should not be used as they can puncture and penetrate even the plastic side of the peel pouch. Soft felt-tip marker pens may be used for writing on the plastic side of the peel pouch but be certain that the inks are medical grade, nontoxic, non-leaching, permanent and compatible with sterilization (see Figure 1).

Figure 1

Traditional over-the-counter magic markers and felt-tip pens should not be used unless there is documentation qualifying them as safe for labeling packages for sterilization. Most Sharpies have not been validated for industrial usage, or for use in sterilization conditions, but there are a couple of Sharpie markers that do conform to the ASTM standard D4236. This means the product has been evaluated by a toxicologist for acute and chronic toxicity and the Safety Data Sheet (SDS) identifies ingredients as presenting any chronic health hazard, along with safe use instructions. Pens that bear the AP seal with the notation "conforms to ASTM D4236" (see Figure 2) may be used for labeling your packages but it should be noted that they do not have any sterilization compatibility claims. HPN

Figure 2

Ray Taurasi is Eastern Regional Director of Clinical Sales and Services for Healthmark Industries. His healthcare career spans over three decades as an Administrator, Educator, Technologist and Consultant. He is a member of AORN, AHA, SGNA, AAMI and a past president of IAHCSMM and has served on and contributed to many national committees with a myriad of professional organizations, manufacturers, corporations and prestigious healthcare networks. Taurasi has been a faculty member of numerous colleges teaching in the divisions of business administration and health sciences. In addition to this column he has authored several articles and has been a featured speaker on the international scene.