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Selecting Protective Apparel for the Degree of Exposure Anticipated

To the Editor:

The Occupational Safety and Health Administration's Standard on Occupational Exposure to Bloodborne Pathogens mandates that the employer provide the healthcare worker with protective apparel that is commensurate with the "task and degree of exposure anticipated."¹ In effect, and as supported by the literature, this makes the selection process procedure-oriented.² The question that logically arises is how the infection control professional can determine a garment's protective capability.

At the moment, there are two tests that are being used to demonstrate a barrier material's effectiveness. The methodologies were developed by the American Society for Testing and Materials (ASTM) and adopted as standards by that organization in 1995. Both tests use the same mechanical device. One of the tests assesses a material's level of resistance to liquid penetration and the other to viral penetration.^{3,4} The results are expressed on a pass/fail basis, with a passing mark awarded to a material that is able to resist penetration when challenged at a level of pressure of 2 psi.

Unfortunately, expressing the test results on a pass/fail basis prevents the infection control professional from determining the performance capability of a product that could render it suitable for the "degree of exposure anticipated." By the same token, it prohibits the manufacturer from identifying material that is able to resist penetration at (for example) 3 psi.

Gowns are classified as Class II Medical Devices, and the Food and Drug Administration has included the ASTM's tests as a point of reference to be used by the manufacturer when submitting a 510(k) application for marketing approval. In addition, the agency is permitting the manufacturers of those materials that pass the

tests to promote their product(s) as being "liquid-proof" or "impervious."⁵ However, characterizing the performance of those materials in that manner is contrary to what has been reported in the clinical literature.

For example, one *in vivo* study found the level of pressures in the abdominal area of a surgical gown to be as high as 2.9 psi during surgery.⁶ This may well have accounted for the earlier report of liquids having penetrated gowns made of materials that had passed the ASTM tests.⁷

Not to be overlooked as well is that, whatever the material's liquid-resistant capability, the construction of a garment, particularly in critical locations such as the glove-gown interface, can render it ineffective. A study examining that area found that some 70% to 80% of the gowns tested leaked.⁸ It should be noted that the researchers proposed a solution to this problem that has yet to be pursued commercially.

More than a decade has passed since the beginning of the era of the awareness of the hazards associated with the transmission of bloodborne pathogens. What is incredible is that there is no evidence available at this time that indicates that anyone has ever acquired human immunodeficiency virus as a result of blood having penetrated a protective-type garment. Even more impressive is the fact that it is likely that an overwhelming percentage of the gowns used during this period would have failed the ASTM's tests. Nevertheless, considering the pressure to reduce costs, it would not be fiscally prudent to indiscriminately provide every employee with what the ASTM has established as being the maximum level of protection required.

Under no circumstance should this be interpreted to imply that there is no need for garments that afford both the level and extent of protection that the users deem necessary. What it does mean is that there is still a need for a test method that reports a material's resistance to liquid penetration on a graduated scale. Then and only then will the infection control community be able to intelligently assess a product's protective capability and be reasonably assured that the garment they select is suitable for the "degree of exposure anticipated."

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Using Electronic Media to Conduct an Emergency Infection Control Committee Vote

To the Editor:

Infection control committees (ICCs) have broad mandates to oversee infection control activities at hospitals. In practice, the hospital epidemiologist or medical director will direct most day-to-day activities. Occasionally, however, the ICC will need to decide an urgent matter that cannot wait until the next scheduled meeting.

On January 7, 2000, author MJW informed DS and ABK of a percutaneous blood exposure. The patient strongly refused a human immunodeficiency virus (HIV) test. The employee took HIV postexposure prophylaxis (PEP), which made her ill. The employee demanded that the patient be HIV tested so that she could stop HIV PEP if he did not have HIV.

Ohio law permits an ICC to authorize HIV testing over a patient's refusal when the ICC determines that a healthcare provider, emergency medical services worker, or peace