Photo courtesy of Acute Care Pharmaceuticals

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Are Gloves and Gowns Safe for Handling Chemotherapy?

Pharmacists, nurses, and other health care personnel who handle antineoplastic (chemotherapy) drugs require appropriately tested gloves that protect them from dermal exposure, but there is confusion about which gloves provide adequate protection.

The American Society for Testing and Materials (ASTM) currently has two standards for testing the permeation of glove materials by chemicals: ASTM F739-99a (F739), which is the Standard Test Method for Resistance of Protective Clothing Materials to Permeation by Liquids or Gases Under Conditions of Continuous Contact,[1] and ASTM D6978-05 (D6978), which is the Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.[2] Because of the highly toxic nature of chemotherapy agents, the National Institute for Occupational Safety and Health (NIOSH),[3] the American Society of Health-System Pharmacists (ASHP),[4] the Oncology Nursing Society (ONS),[5] and the United States Pharmacopeial Convention (USP)[6] state that health care workers who handle antineoplastic and other hazardous drugs (HDs) should wear gloves that have been tested for permeation by the more robust D6978 standard rather than the standard used for other chemicals—F739.

TABLE 1
ASTM Permeation Standards

ASTM Standard	Permeation Rate	Temperature	Drugs
F739	0.1 µg/cm²/min	Room (25ºC)	None
D6978	0.01 µg/cm²/min	35± 2ºC	Seven required + two optional

TABLE 2
Required Drugs for Permeation Testing Using ASTM D6978

Drug	Concentration (mg/ml)
Carmustine	3.3
Cyclophosphamide	20
Doxorubicin HCl	2
Etoposide	20
Fluorouracil	50
Paclitaxel	6
Thiotepa	10
Two chemotherapy drugs selected by manufacturer	To be determined based on selected drugs

How the Two ASTM Standards Differ

Although the testing procedures for both standards are similar and although both require testing for up to four hours, some critical differences exist between the two (see **TABLE 1**). Glove permeation testing measures the length of time it takes selected chemicals to permeate the glove material (the breakthrough time), up to four hours. For the chemotherapy glove standard (D6978), breakthrough time is determined when the permeation rate reaches 0.01 µg/cm²/min, while for other chemicals (F739), the breakthrough time is determined when the permeation rate reaches 0.1 µg/cm²/min. Thus, F739 allows a permeation rate that is 10 times higher than D6978 does before the gloves are deemed to have failed.

In addition, testing under the D6978 standard is conducted at a temperature of 35±2°C because the temperature of gloves approaches body temperature shortly after being donned.[7] By comparison, the test temperature under standard F739 is ambient room temperature (approximately 25°C). This difference is significant because permeation increases with temperature; warmer gloves allow greater permeation of drugs.[8]

Consequences

Some glove manufacturers test the permeability of their gloves using the seven required and two optional drugs listed in ASTM D6978 (see **TABLE 2**), but then report the breakthrough times based on the higher permeation rate and the lower temperature testing parameters specified in ASTM F739. Testing gloves using the parameters of ASTM standard F739, instead of D6978, can result in a shorter breakthrough time and a substantially increased risk of exposure to chemotherapy drugs. If health care workers change their gloves every 30 to 60 minutes, as recommended in most guidelines, then using the gloves in the presence of drugs that do not permeate them within the four-hour time limit and using ASTM F739 testing parameters may not be an issue. However, for those drugs that permeate the gloves in shorter time periods, health care workers could experience substantially greater dermal exposure (see **PHOTOS 1 AND 2**).

No Equivalent for Gowns

ASTM standard D6978 is specific for testing gloves used with chemotherapeutic agents; no equivalent permeation test standard exists for protective gowns, which also are recommended by most guidelines when health care workers handle chemotherapy drugs. As a result, some gown manufacturers employ an approach similar to that used with gloves; they combine sections of standards F739 and D6978 and apply the parameters to gown permeability testing. Mixing and matching of standards and testing parameters that do not apply to gowns may lead to unnecessary exposure of health care workers to chemotherapy and other HDs that are spilled or splashed on the gowns. Because gowns have no specific standard at this time, the user and purchaser must be aware that there is a risk when mixing standards that the gown is not as protective as advertised.

PHOTOS

Example Glove Labels

These photos show examples of labels on boxes of gloves that are supposed to be tested for use with chemotherapy. The labeling information, however, is confusing to end-users. The information in both photos refers to both of the ASTM testing standards, when D6978 is the correct one.

PHOTO 1

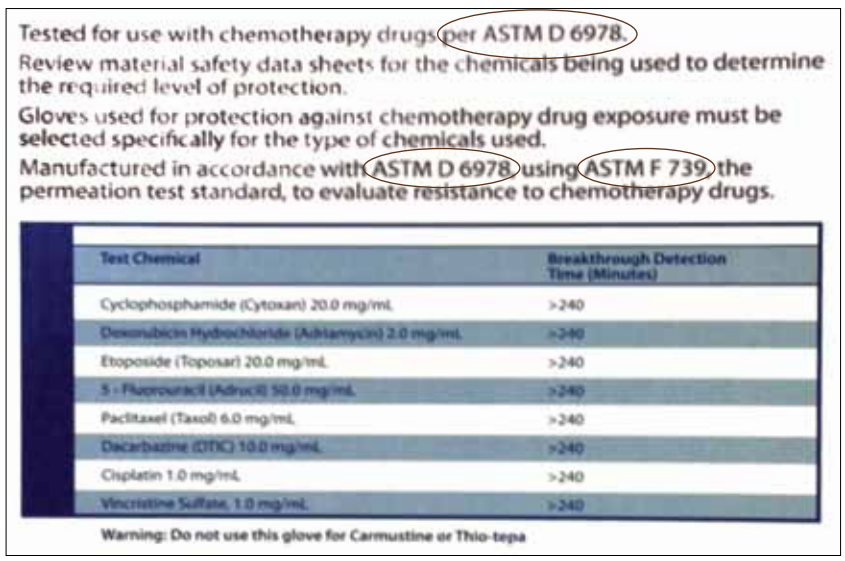
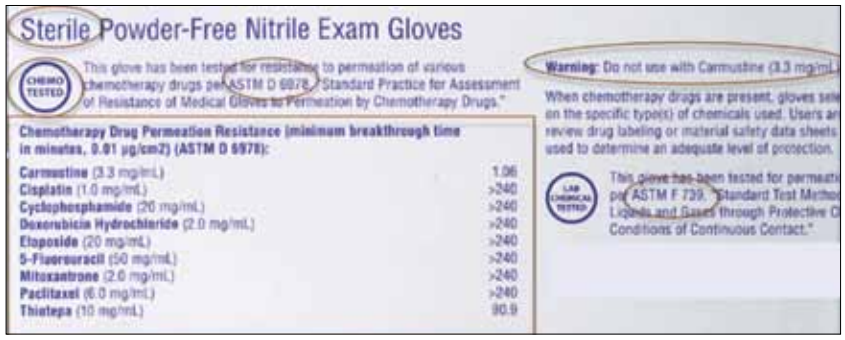


PHOTO 2



Stay Informed and Stand Firm

Because federal agencies and professional organizations, such as NIOSH, ASHP, ONS, and USP, recommend using gloves tested according to ASTM's D6978 specifications, glove manufacturers should adhere to all requirements of D6978 and provide accurate test information to health care workers who rely on the gloves for protection against exposure to chemotherapy and other HDs.

To help ensure this, health care employers and workers should be aware of the test standards and whether purchased gloves are tested to the correct standard. Purchasers should avoid procuring gloves that are not tested to ASTM's D6978 specifications; similarly, health care workers should reject using such gloves. ■

Disclaimers

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