Glove Performance Dermal Absorption of Fentanyl

Introductory Information

With the increase in opioid sales on the illicit drug market and overdoses, opioid incidents and exposure risk are concerns for first responders, including law enforcement officers. To prevent dermal, mucosal, or inhalation exposure to opioids and other hazardous drugs, first responders rely on personal protective equipment (PPE) – including respirators and gloves – as their last line of defense within the hierarchy of controls. NIOSH, in response to requests from first responders concerning appropriate glove selection (e.g., glove material, thickness), recommended for minimal and moderate anticipated opioid exposures powder-free nitrile gloves with a minimum thickness of 5 ± 2 mil (i.e., 0.13 ± 0.05 millimeters [mm]). Some glove manufacturers have recently marketed their gloves claiming fentanyl protection. There is limited empirical PPE performance data for opioids, and no industry standard or test method currently exists for evaluating PPE performance against opioids. The purpose of this study was to provide this empirical data under conditions representative of those encountered in the field to support (1) NIOSH's current opioid PPE recommendations and (2) industry standards and test methods.

Methods Collection

Test Matrix and Test Parameters

Adapted from ASTM D6978-05, "Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs"

Test Parameters

- Fentanyl and Carfentanil Permeation Testing
  - Fentanyl Challenge Solution Concentration = 1 mg/mL
  - Carfentanil Challenge Solution Concentration = 1 mg/mL
  - Temperature (T) = 35°C ± 2°C
  - Test Duration (t) = 4 hours
  - Preconditioning Environmental Conditions
    - T = 23°C ± 3°C
    - Relative Humidity = 50% ± 5%
    - t > 24 hours
  - Test Specimen Source Location = Palm
- Fentanyl Permeation Testing of Gloves Stored in Controlled Environments
  - Fentanyl Challenge Solution Concentration = 1 mg/mL
  - Temperature (T) = 35°C ± 2°C
  - Test Duration (t) = 4 hours
  - Preconditioning Environmental Conditions
    - T = 23°C ± 3°C
    - Relative Humidity = 50% ± 5%
    - t > 24 hours
  - Test Specimen Source Location = Palm
  - Environmental Storage Conditions
    - Ambient: 22°C ± 3°C and 50% ± 10% RH
    - Cold: -18°C; RH monitored but not controlled
    - Hot: 48°C ± 3°C and 50% ± 10% RH
  - Storage durations
    - One week
    - Four weeks

- Eight weeks

- Fentanyl Permeation Testing of Stretched Gloves
  - Fentanyl Challenge Solution Concentration = 1 mg/mL
  - Temperature (T) = 35°C ± 2°C
  - Test Duration (t) = 4 hours
  - Preconditioning Environmental Conditions
    - T = 23°C ± 3°C
    - Relative Humidity = 50% ± 5%
    - t > 24 hours
  - Test Specimen Source Location = Palm

Gloves

Fentanyl and Carfentanil Permeation Testing

- 12 models differing in
  - Material
    - Nitrile – nine models
    - Latex – two models
    - Vinyl – one model
  - Thickness
  - Fentanyl manufacturer protection claims – five models
  - Claimed accordance to standards (e.g., chemotherapy-rated) – five models
- All 12 models tested against fentanyl
- Six model subset of 12 models tested against fentanyl selected for carfentanil permeation testing
  - Nitrile – four models
  - Latex – one model
  - Vinyl – one model
- One lot of each model
- Three replicates of each glove model and tested for fentanyl and carfentanil solution permeation
- Tested in a relaxed or neutral state (i.e., they were not stretched)

Fentanyl Permeation Testing of Relaxed Gloves Post-Storage in Controlled Environments

- Four model subset (G3, G4, G6, G12 – all nitrile) of 12 models tested for this phase
- One lot of each model
- Three replicates of each glove model from same box
- Tested in a relaxed or neutral state (i.e., they were not stretched)

Fentanyl Permeation Testing of Stretched Gloves

- Ten model subset (all except G1 and G11) of 12 models tested for this phase
- One lot of each model randomly selected
- Three replicates of each glove model from same box
- One lot per model
- One stretched state – 25% elongation
- G3 also tested in a relaxed or neutral state (i.e., they were not stretched) as a control

Test Specimen Physical Properties Measurements

Thickness

- Measured per ASTM 739-99a

- Measured to at least the nearest ±20 µm (per ASTM 6978-05, Section 7.1.3) using an Ames Comparator Model BG2600-1-04
- Hardness measured and exceeded 35 International Rubber Hardness Degrees (IRHD)
- Pressure of 22 ± 5 kPa (3.2 ± 0.7 psi) was applied for the thickness measurements by applying a 70-g weight to the ~5-mm-diameter foot
- Specimens maintained at 23°C ± 5°C for at least 24 hours before measuring
- Triplicate measurements made on each test specimen
    - Three locations measured once within the center of the 2.5-cm diameter of the swatch

Dimension and weight

- Test specimen diameter = 5.1 cm
- Test specimen area = 20.4 cm^2
- Specimens weighed to the nearest ±0.5 mg (using a Mettler Toledo Model AE240 electronic balance)
- Specimens maintained at 23°C ± 5°C for at least 24 hours before measuring

Permeation Test

Permeation Cell

- 1-in-diameter (~2.54-cm-diameter) glass, submersible-type permeation test cells cited in ASTM F739-99a (Part # PTC 600; Pesce Lab Sales, Inc; Kennett Square, PA)
- Operated as a closed cell (neither the donor nor the collection solutions were circulated)
- Solutions continuously agitated during the test duration by placing them on a shaker table
- Both the donor (i.e., challenge solution reservoir) and collection solution volumes were ~18 mL
- Exposed specimen area = 5.1 cm^2.

Battelle-synthesized fentanyl HCl (94% pure) and carfentanil HCl (98% pure as determined by nuclear magnetic resonance analysis)

Milli-Q water (Millipore Sigma, Burlington, MA) was used as the solvent to make the fentanyl solution

Specimens loaded into the permeation cell with no preconditioning (except for allowing them to equilibrate to test temperature)

Assembled test cells (with specimen) leak tested with ~18 mL of purified, deionized water

After removal of water, ~18 mL of challenge fentanyl solution was added to the challenge (donor) side of the permeation cell

Sample of the collection water taken to serve, in part, as a control to ensure the permeation cell was clean, or if not, quantify the carryover to appropriately interpret results

Eight samples collected from test cell during the maximum 4-hr duration (nominally one every 30 minutes)

Permeation cells cleaned and re-used

Fentanyl concentrations quantified using a Battelle-developed liquid chromatograph mass spectrometer-mass spectrometer (LC/MS/MS) method

- Waters Acquity Ultra Performance Liquid Chromatograph with a Waters Xevo TQ-XS mass spectrometer and Phenomenex Prodigy ODS-3, 3-µm, 100A, 100 x 2-mm column operating at 40°C
- Calibration curve covering a concentration range of three orders of magnitude, nominally 1 to 1,000 ng/mL, was established

- Approximately every tenth sample was a calibration standard (either 10 or 100 ng/mL) and/or water blank throughout the analysis

Citation – Publication based on the data set:

Greenawald, L. A., Hofacre, K. C., & Fisher, E. M. (2020). Fentanyl and carfentanil permeation through commercial disposable gloves. Journal of Occupational and Environmental Hygiene, 17(9), 398-407.

Acknowledgements

Project support

This work was supported by the Centers for Disease Control and Prevention's (CDC) Center for Preparedness and Response.

Disclaimer

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