Breach in the Protective Barrier System: Glove and Gown Interface

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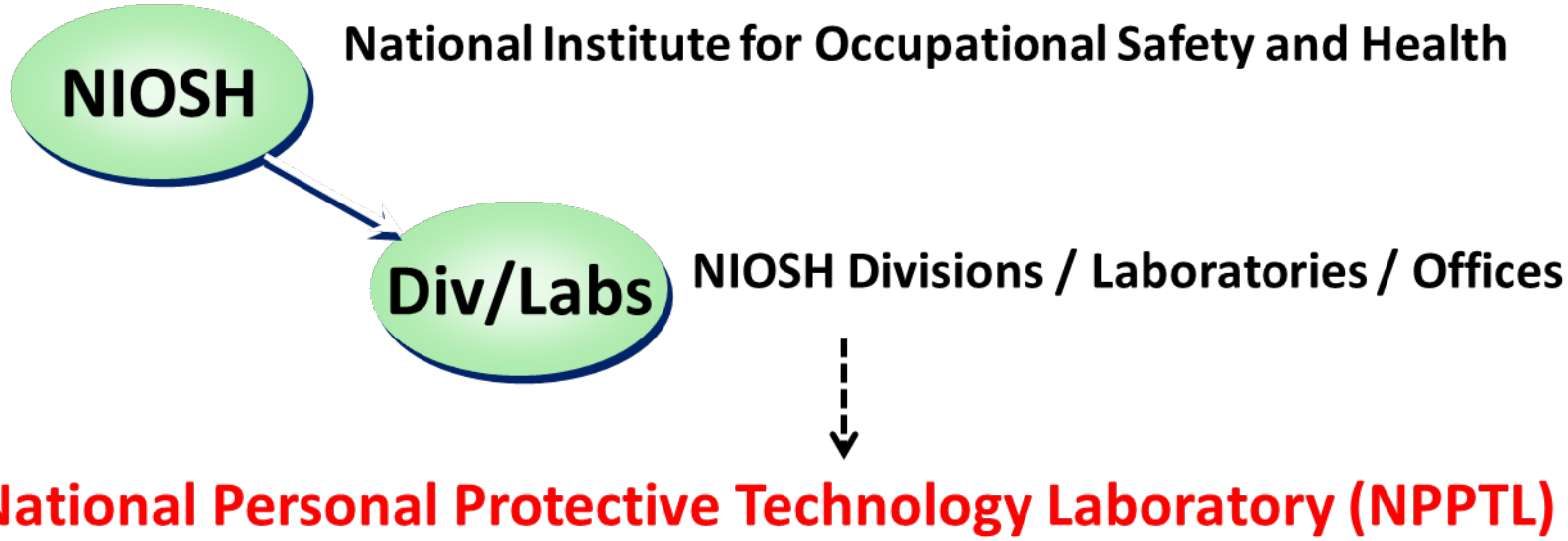
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

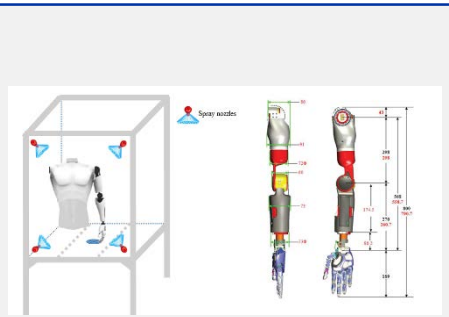
The National Personal Protective Technology Laboratory was created by NIOSH at the request of Congress in 2001 to...

Prevent work-related injury, illness, and death by advancing the state of knowledge and application of personal protective technologies.



Outline

Motivation



Objective

Design of Experimental System

Simulation of Surgical Settings

Results & Conclusion

Dissemination

Directions

Questions

Photo Credits: CBS News, NIOSH NPPTL, *Shutterstock*, Ward, W.G., Sr., et al., 2014 and Fraser, J., et al., 2015
NFPA, ASTM, ISO, ANSI, AAMI, AATCC

Motivation for the Project

2014 Ebola Epidemic

- The large number of workers affected around the world during 2014 Ebola epidemic directed particular attention toward personal protective equipment (PPE) to protect against exposure to blood and body fluids

  >28,500 cases *>11,000 deaths*
  >900 healthcare worker cases *>500 healthcare worker deaths*

- The glove-protective clothing interface was frequently reported as an area of concern during the 2014 Ebola epidemic, as blood or body fluids can flow through system worn by healthcare personnel (HCP)

- The World Health Organization (WHO) highlighted for the *need for studies on interfaces*




Photo credit: CDC PHIL 18149 , 18351, 17843, 17842

Leakage is common in healthcare

Photo Credits: NIOSH NPPTL

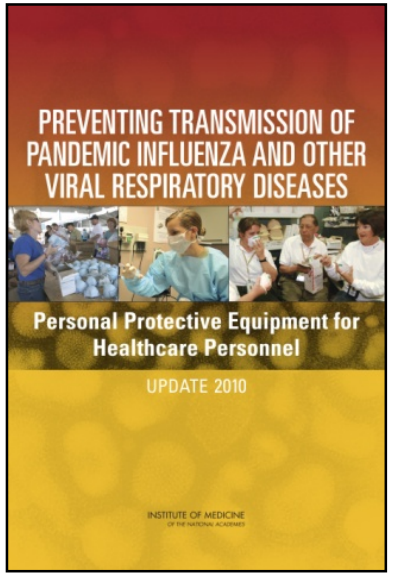
Photo Credits: CBS News/60 Minutes

'A chain is only as strong as its weakest link'

Limited Research

- The interface between the gown and the glove is considered as one of *the weakest points* of the protective apparel system(1)
- There are *limited studies* about the effectiveness of the glove and protective clothing interface(2-4)
- The Institute of Medicine (IOM) *recommended increased research on interfaces* with HCP personal protective equipment

Photo Credit: NIOSH NPPTL



(1) *Fernandez M, Del Castillo JL, Nieto MJ. Surgical Gown's Cuff Modification to Prevent Surgical Contamination. Journal of maxillofacial and oral surgery. 2015;14(2):474-475.*
(2) *Edlich RF, Wind TC, Hill LG, Thacker JG. Creating another barrier to the transmission of bloodborne operative infections with a new glove gauntlet. Journal of long-term effects of medical implants. 2003;13(2):97-101.*
(3) *Fraser J, Young S, Valentine K, Probst N, Spangehl M. The Gown-glove Interface Is a Source of Contamination: A Comparative Study. Clin Orthop Relat Res. 2015;473(7):2291-2297.*
(4) *Meyer KK, Beck WC. Gown-glove interface: a possible solution to the danger zone. Infection Control. 1995;16(08):488-490.*

New Products to Minimize Leakage

- Some manufacturers market products with design features to eliminate the leakage at this interface
- However, there is *no known standard test method* for evaluating the extent of performance improvement with new designs while simulating healthcare settings

Reduce Glove Slip-Down
MICROCOOL® Gowns with SECURE-FIT® Technology have been shown to reduce glove slip-down when used with market-leading surgical gloves. Look for the SECURE-FIT® coating on the sleeves, keeping your gloves in place and you and your patients protected.

HALYARD® MICROCOOL® BREATHABLE HIGH PERFORMANCE SURGICAL GOWNS with SECURE-FIT® Technology to reduce glove slip-down

SECURE-FIT®

Product Code Sterile	Non-Sterile	Description	Items per case Sterile	Non-sterile
92338		Small	**30**	
92354	72456	Large	**30**	
92355	30734	X-Large, in Handi-Bin	**28**	40
92358	72448	XX-Large	**26**	384
92347		XXX-Large	**25**	32
10558		Specialty Gown, Large	**28**	
10550		Specialty Gown, X-Large	**26**	
10566		Specialty Gown, XX-Large	**26**	

All codes in **bold** type indicate a sterile product. Non-sterile product available for custom trays.

HALYARD® MICROCOOL® BREATHABLE HIGH PERFORMANCE SURGICAL GOWNS

Product Code Sterile	Non-sterile	Description	Items per case Sterile	Non-sterile

Source:https://www.nahhcustomerportal.com/documents/digitalassets/Halyard/SS/C14381%20MICROCOOL%20Breathable%20High%20Performance%20AAMI%204%20%20Brochure.pdf

Photo Credit: Medline Industries Inc.

Standard Test Methods, Guidelines, and Temporary Solutions

- Existing standards developed for other industries *may not be applicable or sufficient to provide guidance* for protection in the interface region between the gloves and the protective clothing (Liquid Integrity Test-ASTM F1359)
- Temporary solutions *pose a critical risk to HCP* since the protective clothing or gloves can tear during at the interface region during doffing, increasing risk of exposure to contaminated blood or body fluid

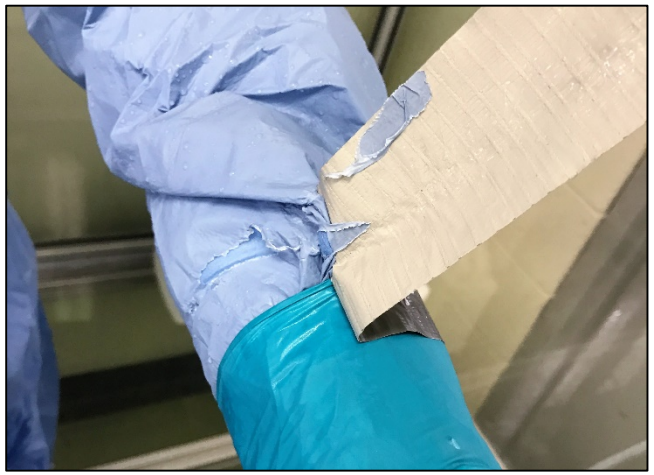


Photo Credits: NIOSH NPPTL

Objective of the Project

Development of a New Test Method

- We are developing a test method with a robotic arm to evaluate the fluid leakage at the glove-protective clothing interface
- This test method will be *shared with Standard Development Organizations to establish a new standardized test method* for assessing the fluid leakage in the glove and protective clothing interface
- The method can be added as a requirement in the current performance specifications for multiple personal protective equipment standards.
- The findings will be shared with CDC and professional organizations and other stakeholders such as AORN, APIC, AST, and Joint Commission

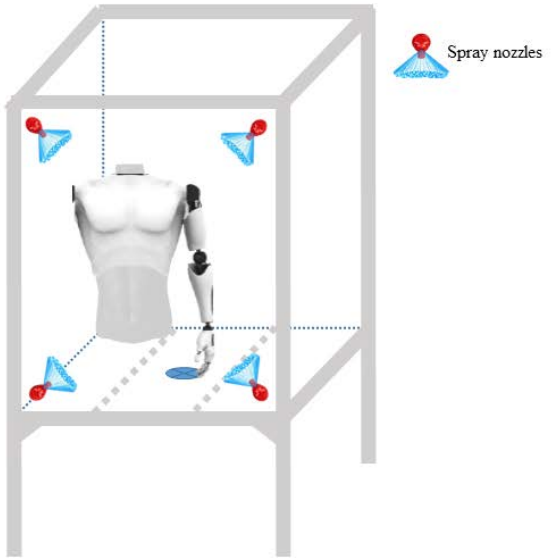


Photo Credit: NIOSH NPPTL

Experimental Chamber

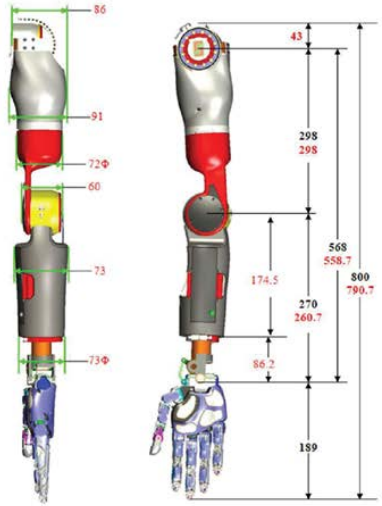


Photo Credit: Johns Hopkins University (JHU)

Robotic Arm

Design of the Experimental System and Setting Parameters

Factors Affecting Leakage at the Interface

Clothing
- Gown
  - Isolation
  - Surgical
- Coverall

Glove
- Single
  - Standard
  - Extended
- Double
- Examination
- Surgical

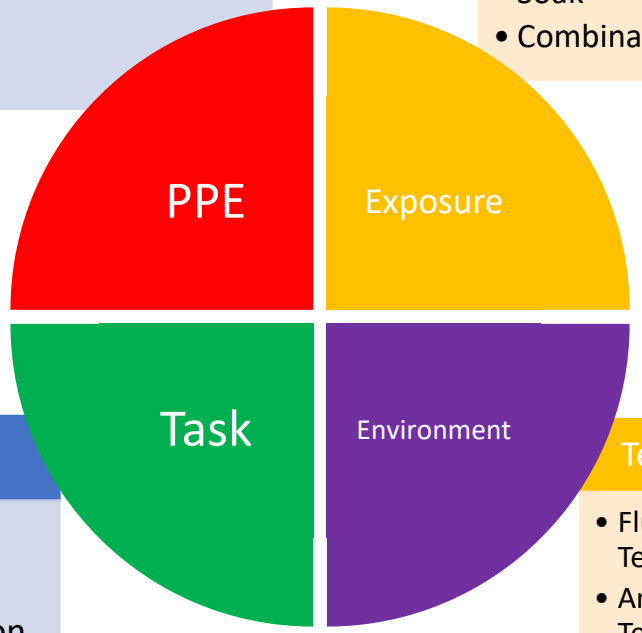
Fit
- Cuff Type
  - Knit
  - Thumb Hook
  - Elastic
- Cuff Diameter & Size
  - Clothing/Glove

Precondition
- Perspiration

Type
- Spray
  - High Pressure (arterial)
  - Lower Pressure
- Soak
- Combination

Duration
- 2 seconds
- 5 seconds
- 10 seconds

Fluid Type
- Blood
- Amniotic Fluid
- Urine
- Irrigation Fluid



Wear
- 15 minutes
- 30 minutes
- 60 minutes

Physical Stress
- Pressure
- Extension

Activity
- Surgery
- Isolation
- Decontamination

Temperature
- Fluid Temperature
- Ambient Temperature

Humidity

Experimental Chamber and Modular Prosthetic Limb

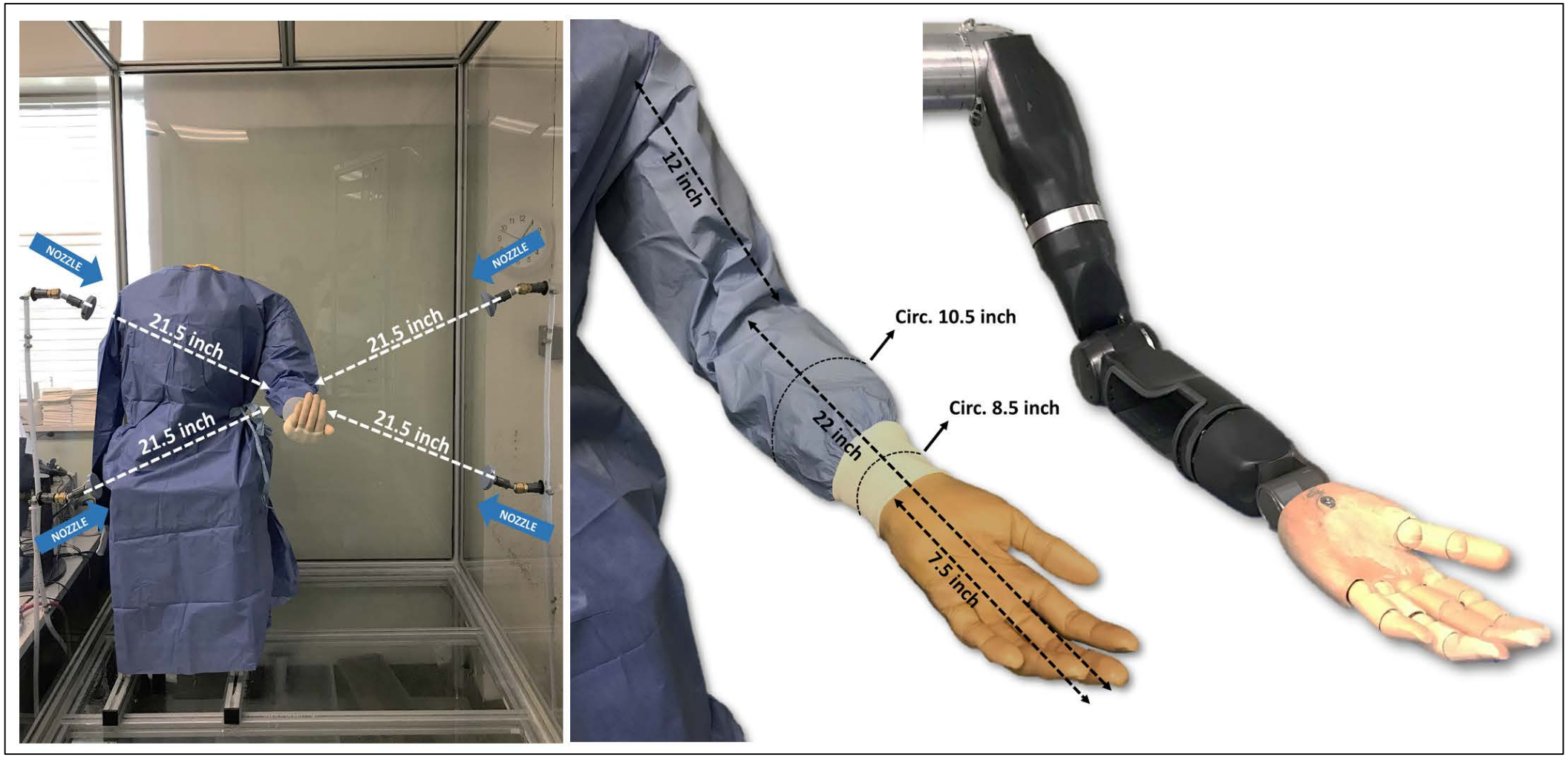


Photo Credits: NIOSH NPPTL and Johns Hopkins University

Specially printed nozzles and use of a pump allows control of the fluid flow

Photo Credit: NIOSH NPPTL

Fluid Amount:
560 ml/min/each
- 5 sec Spray ~187 ml total

Fluid Composition:
D.I. Water + Surfactant
Surface Tension: 42±2 dynes/cm
- Synthetic Blood: 42±2 dynes/cm
- Blood: 56, 58, 61 dynes/cm
- Saliva: 42, 15-26 dynes/cm
- Sweat: 38, 41, 61-75 dynes/cm
- Water: 72 dynes/cm
- Gastric Juices: 47, 35-45 dynes/cm

- It was found that a high risk factor of being exposed to possible infectious blood occurred with patient loss of more than 250 ml blood, and an operation time of >1 hour [(1)]

(1) Panlilio, A.L., et al., Blood contacts during surgical procedures. Jama, 1991. 265(12): p. 1533-1537

Modular Prosthetic Limb

- JHU Robotic Arm Video

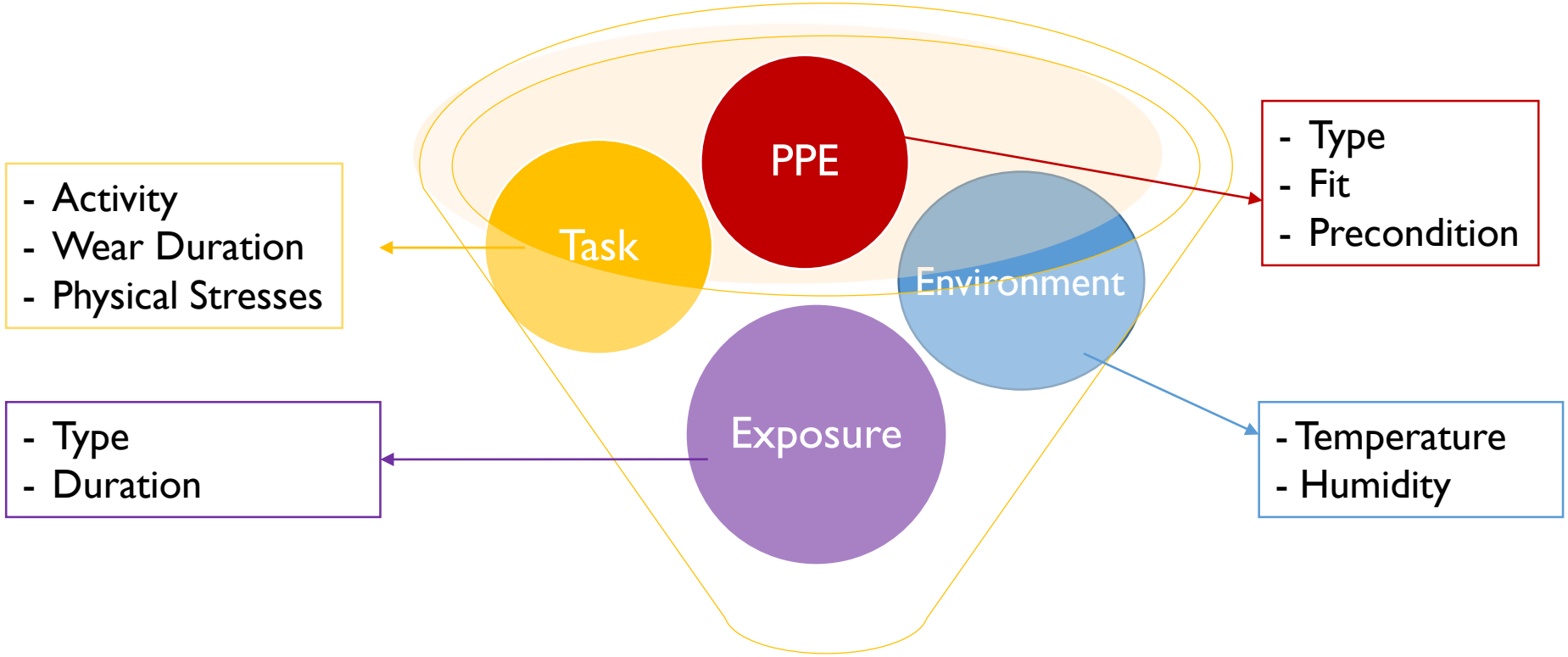
Video Credit: JHU

What have we done so far?

- Investigated the effect of:
  - Exposure type (spray, soak, combination)
  - Exposure duration (2, 5, 10 sec)
  - Degree of movement
  - Procedure (wear) duration
  - Physical stresses (pressure)
- Simulated surgical settings using:
  - 3 gown models
  - 2 glove materials (latex, synthetic)
  - 4 glove models
  - 2 double glove configurations
- Simulated isolation settings using:
  - 7 gown models (elastic, knit, thumb loops; No AAMI to Level 3)
  - 2 glove models (standard and extended)

An Example: Simulation of Surgical Settings

Factors Affecting Leakage at the Interface



Leakage

Objective

- The main objective of this study is to investigate the degree of leakage through glove-gown interface in simulated surgical settings. The study simulates surgical settings in terms of:
  - HCP activities (flexion, abduction, pronation/supination, etc.)
  - Exposure types (spray, soak)
  - Exposure durations
  - Physical stresses (pressure)

Gown Model A? Gown Model B?

Glove Model A? Glove Model B?

Latex ? Isoprene?

Single ? Double?

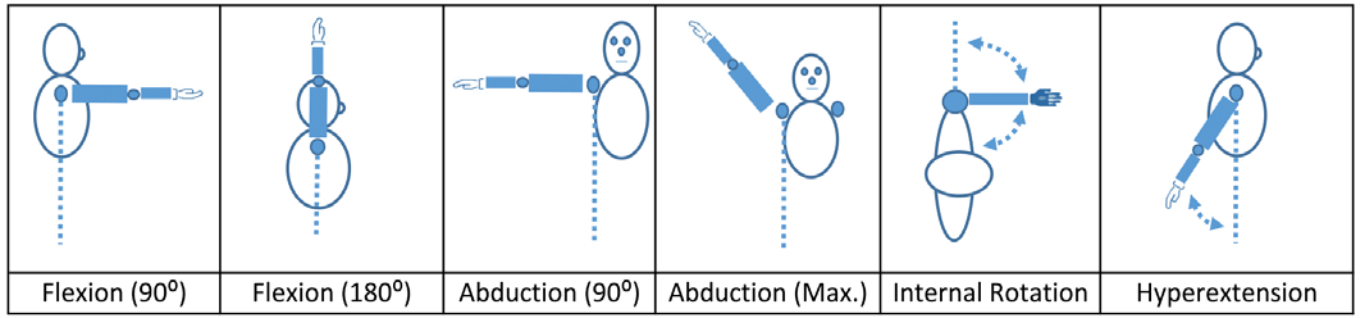
Activity Protocol

Body Part	Movement	1 Hour
Shoulder	Flexion (90°)	4
	Flexion (140°)	4
	Abduction (90°)	8
	Abduction (max)*	8
	Internal Rotation	12
	Hyperextension*	4
Elbow	Flexion (45°)	12
	Flexion (90°)	12
	Flexion (Max)*	12
Wrist	Pronation	8
	Supination	8
	Flexion	8
	Extension	8
	Ulnar deviation	8
	Radial deviation	8

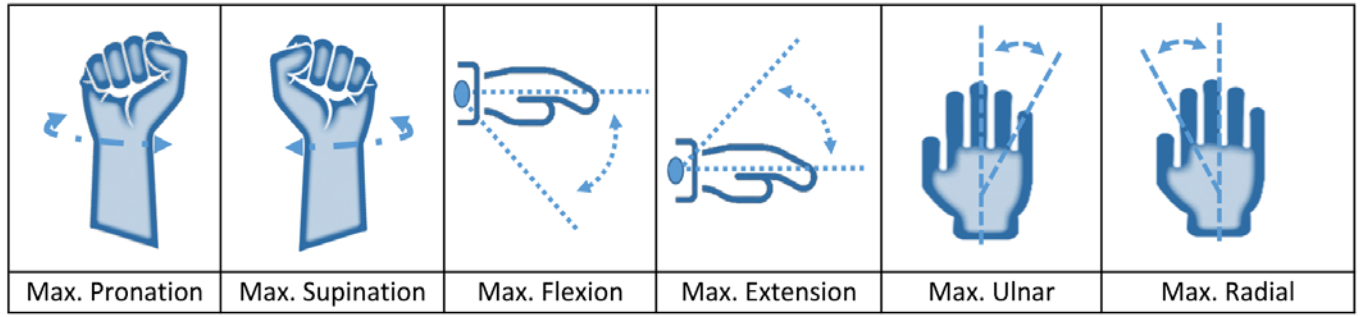
Adapted from: Nguyen, Ninh T., et al. "An ergonomic evaluation of surgeons' axial skeletal and upper extremity movements during laparoscopic and open surgery." The American journal of surgery 182.6 (2001): 720-724

(*) Added/modified for the purpose of this project

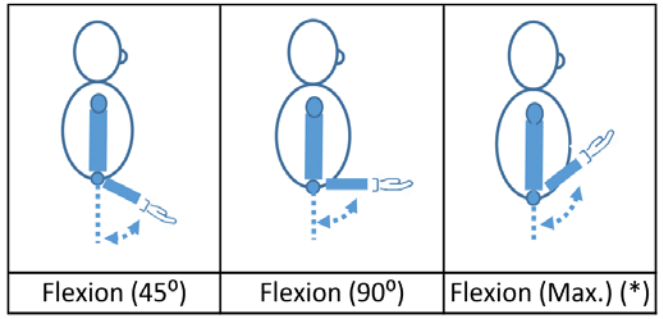
Shoulder



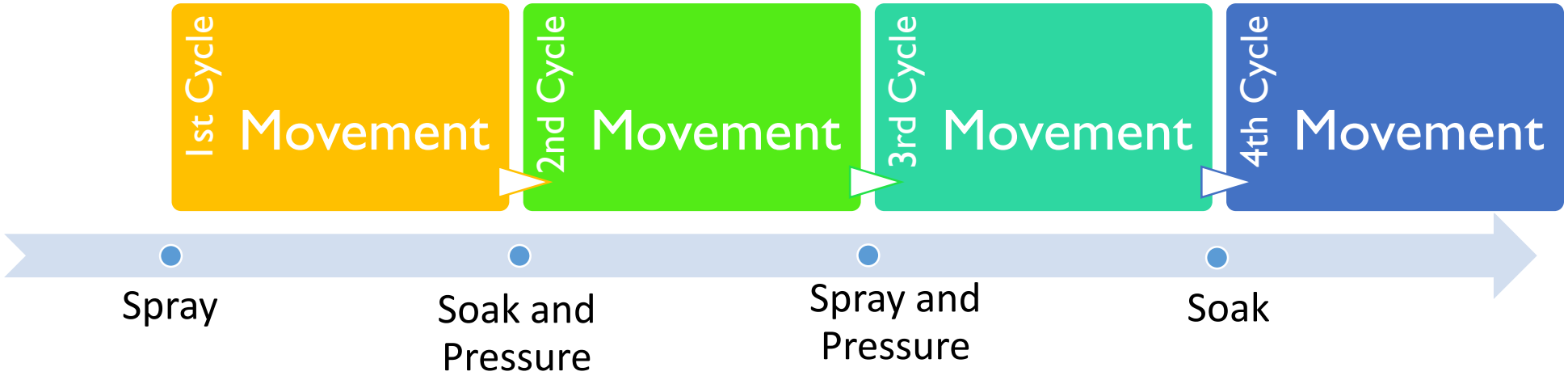
Wrist



Elbow



Test Protocol and Parameters



- **Test Duration:** 60 min
- **Cycles**: 15 min
- **Spray**: 5 sec
- **Soak**: 5 sec
- **Pressure**: 2 psi, 10 sec

Surgical Gown Models

Photo Credit: NIOSH NPPTL

Physical properties of surgical gown models

		7G	8G	9G
Dimensions of Sleeve and Sleeve Cuffs (inch)*	A	14	14.22	15
	C	11.25	11	11
	D	2.75	3.25	3
	E	4.5	5.11	4.5

**A, C, and E are the circumference measurements at marked locations. B=6 inches*

Surgical Glove Models

Photo Credit: NIOSH NPPTL

Physical properties of surgical glove models

Glove ID	Material Type	Cuff (cm)		Size	Grip
		Length	Diameter		
3GLV	Synthetic	30.7	20	7.5	1.5
4GLV	Synthetic	30.7	20	7.5	1.5
5GLV	Latex	29.7	17.2	7.5	3
6GLV	Latex	29.7	19.6	7.5	1

Experimental Design

Surgical Gowns and Surgical Gloves	Single Glove				Double Gloves	
	Synthetic		Latex		Synthetic	Latex
	3GLV	4GLV	5GLV	6GLV	3GLV over 4GLV	5GLV over 6GLV
7G	x	x	x	x	x	x
8G	x	x	x	x	x	x
9G	x	x	x	x	x	x

How is the test conducted?

Video Credit: NIOSH NPPTL

Why does the fluid leak?

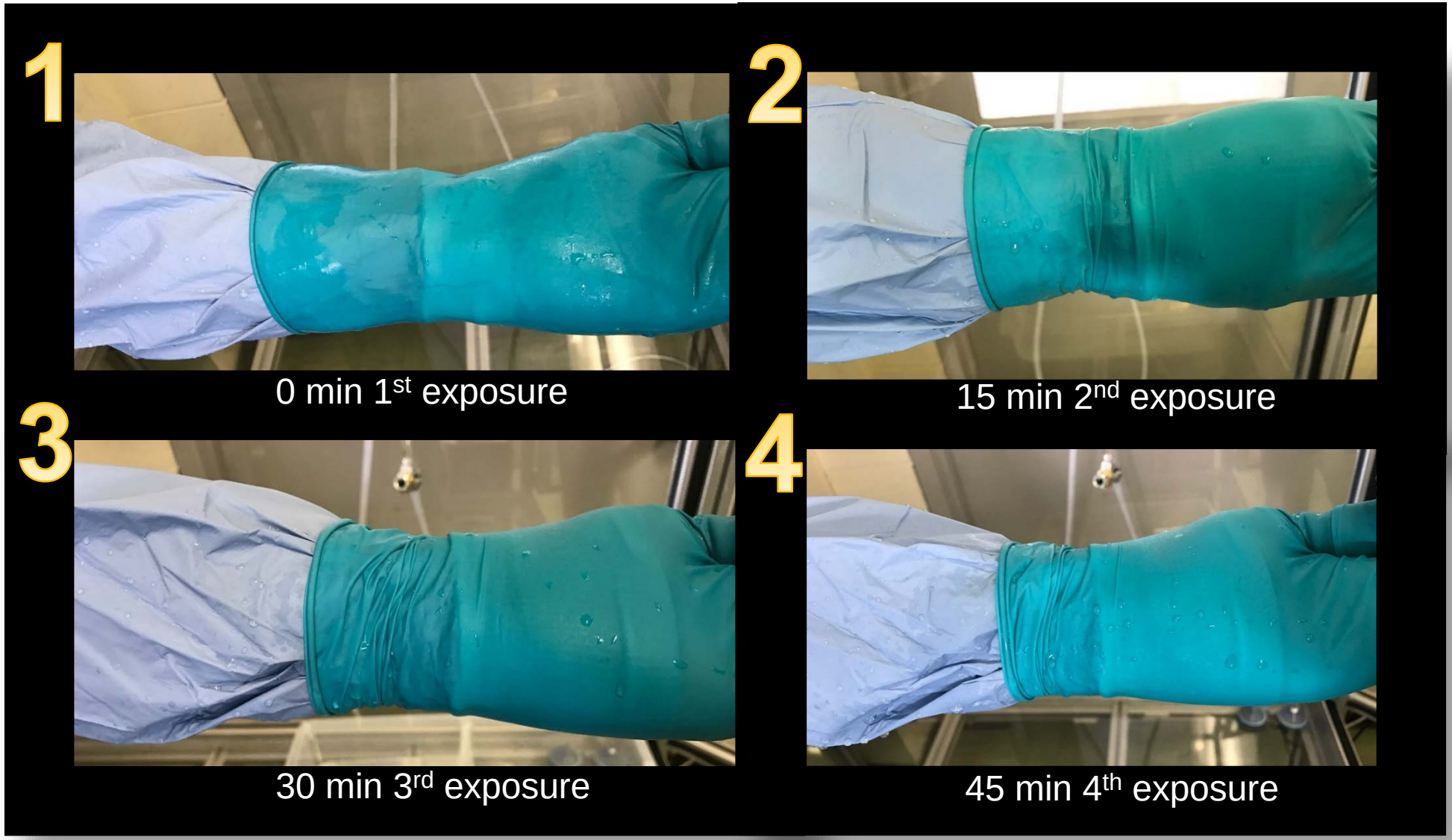


Photo Credits: NIOSH NPPTL

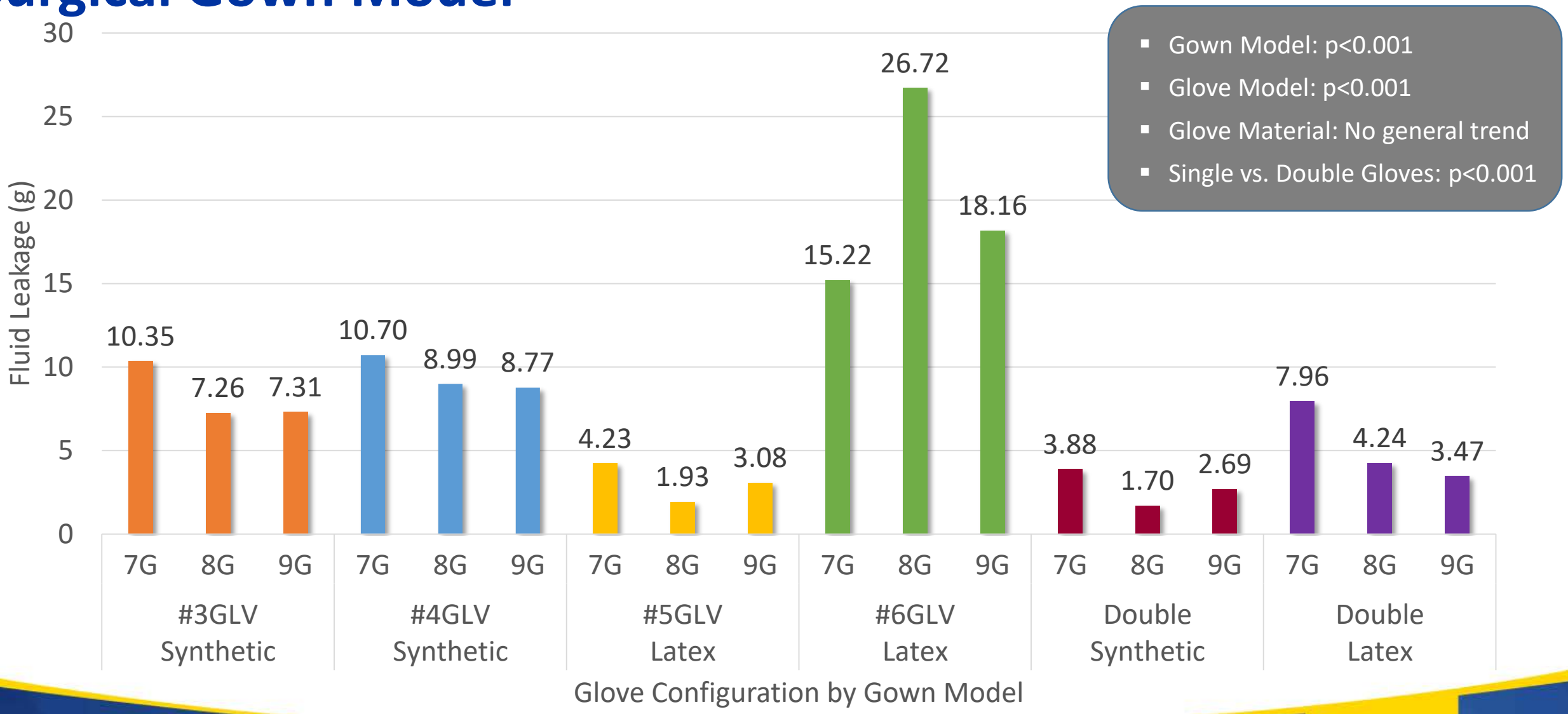
Why does the fluid leak?

- Soaking exposure

Video Credit: NIOSH NPPTL

Results and Conclusion

Mean Fluid Leakage by Surgical Glove Configuration and Surgical Gown Model



- Gown Model: p<0.001
- Glove Model: p<0.001
- Glove Material: No general trend
- Single vs. Double Gloves: p<0.001

Conclusion

- There is a significant interaction between glove and gown models
- Gown and gloves should be designed together as a system to minimize or eliminate the fluid leakage

Photo Credits: NIOSH NPPTL

Recommendations for Operating Room Personnel

While results of our studies are still preliminary and subject to change as we continue our research, based on the data collected so far we suggest :

- Avoid soaking exposures as much as you can. Soaking exposures such as procedures that involve placement of operating room personnel hands into body cavities appear to confer higher risk of fluid leakage at the glove-gown interface versus exposures involving splashes or sprays
- Avoid leaning or application of pressure. The amount of leakage seems to increase with the duration of exposure and application of pressure
- Appropriately sized gown and gloves. Appropriately fitting PPE is likely to minimize the roll up of gown sleeves that may result in less fluid leakage through the glove-gown interface, and
- Conduct proper hand hygiene immediately after removing PPE because of the risks for contamination from contaminated hands due to fluid leakage through glove-gown interface

Dissemination

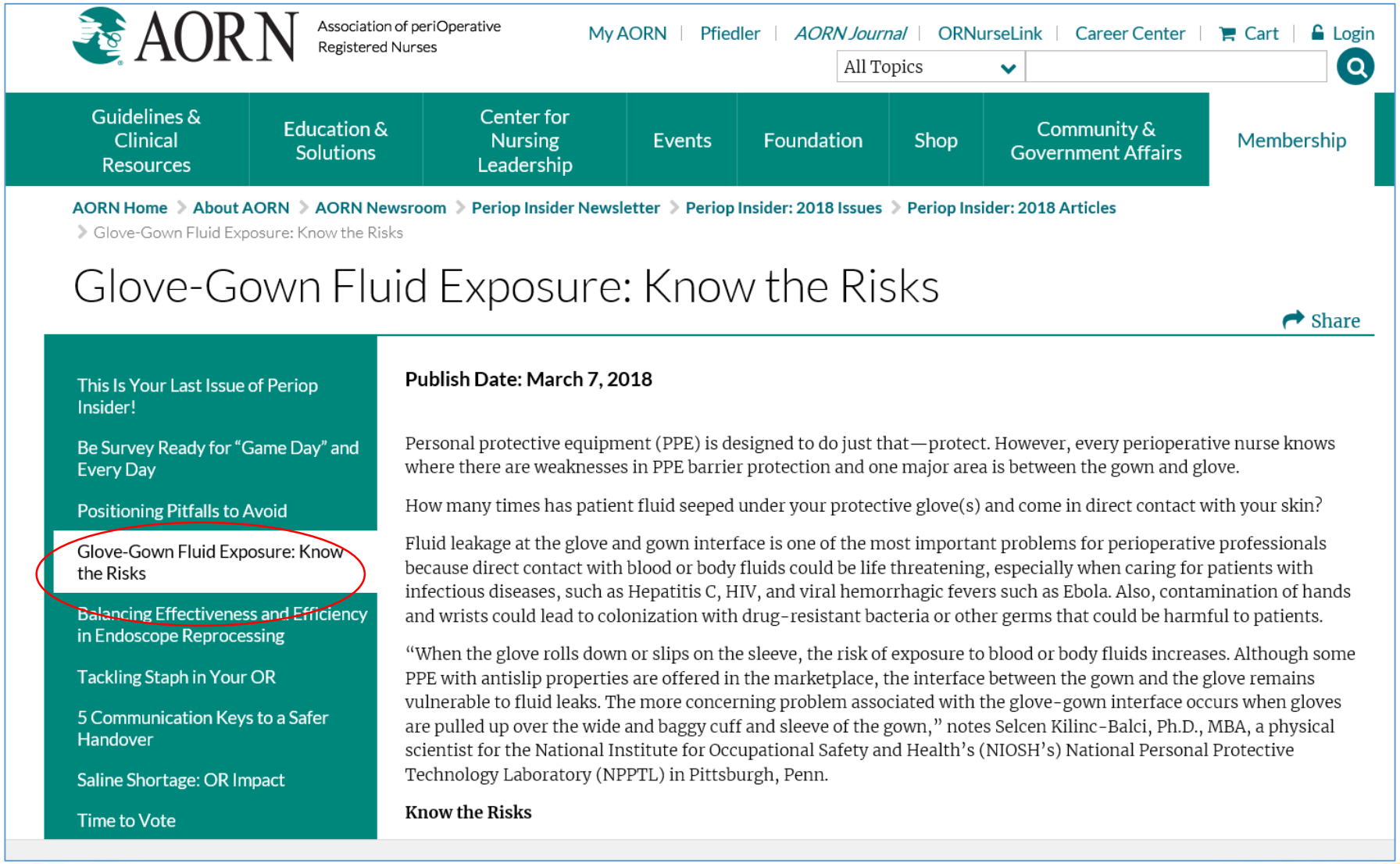
Presentations

- IOM COPPE Meeting, May 2015
- ISO TC 94 / SC 13 / WG 6 Meeting, June 2016
- WHO “Evidence for Developing Innovative Personal Protective Equipment for the Management of Patients Infected with High-Threat Pathogens”, October 3 – 4, 2016
- IOM COPPE Meeting, March, 2017
- AAMI Spring Sterilization Standards Week, March 22, 2017
- Association of Occupational Healthcare Professionals National Conference, September 5, 2017
- Third WHO Global Forum on Medical Devices, May 11, 2017
- ISEA Annual Meeting, November 30, 2017
- AORN Conference and Expo, March 24, 2018
- CDC Lab Science Symposium, March 26, 2018
- European Conference on Protective Clothing, May 7-9, 2018

Publications

- Kilinc-Balci S., Kahveci Z., Yorio P. “A Novel Test Method for the Evaluation of Fluid Leakage at the Glove-Gown Interface and Investigation of Test Parameters”, submitted
- Kahveci Z., Kilinc-Balci S., Yorio P. “A Critical Investigation of Glove-Gown Interface Barrier Performance in Simulated Surgical Settings”, ready for submission
- “The Impact of Surface Tension on the Barrier Performance of Gowns and Coveralls” – working on draft paper

The project was highlighted in AORN Newsletter



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Glove-Gown Fluid Exposure: Know the Risks

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Publish Date: March 7, 2018

Personal protective equipment (PPE) is designed to do just that—protect. However, every perioperative nurse knows where there are weaknesses in PPE barrier protection and one major area is between the gown and glove.

How many times has patient fluid seeped under your protective glove(s) and come in direct contact with your skin?

Fluid leakage at the glove and gown interface is one of the most important problems for perioperative professionals because direct contact with blood or body fluids could be life threatening, especially when caring for patients with infectious diseases, such as Hepatitis C, HIV, and viral hemorrhagic fevers such as Ebola. Also, contamination of hands and wrists could lead to colonization with drug-resistant bacteria or other germs that could be harmful to patients.

"When the glove rolls down or slips on the sleeve, the risk of exposure to blood or body fluids increases. Although some PPE with antislip properties are offered in the marketplace, the interface between the gown and the glove remains vulnerable to fluid leaks. The more concerning problem associated with the glove-gown interface occurs when gloves are pulled up over the wide and baggy cuff and sleeve of the gown," notes Selcen Kilinc-Balci, Ph.D., MBA, a physical scientist for the National Institute for Occupational Safety and Health's (NIOSH's) National Personal Protective Technology Laboratory (NPPTL) in Pittsburgh, Penn.

Know the Risks

Next Steps

- Analyze *gown and glove surface characteristics* to understand the effect of those on the fluid flow and leakage
- Determine *the effect of surface tension* of the challenge fluid on the fluid flow and leakage
- Simulate *decontamination settings* and determine the fluid leakage with common gowns and gloves
- Compare variety of protective clothing for fluid leakage *(gowns vs. coveralls, isolation vs. surgical)*
- Investigate the use of *tapes* on the fluid leakages

Photo Credit: Shutterstock

Directions

- Human subject testing in clinical simulated settings
- Design and development of novel protective clothing that minimizes leakages
- Assessing fluid leakage in real-world settings, focusing on procedures most likely to occur

Photo Credit: Shutterstock

Questions for NIOSH BSC

- Suggestions on key partnerships to pursue?
- Thoughts on the design of human subject testing protocol?
- Thoughts on other research gaps in this area?
- Suggestions for raising awareness/engaging the occupational safety and health community?
- How might NIOSH drive the need for change in PPE design and use?

Photo credit: Shutterstock

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