PROTOCOL NAME: Epicenters for the Prevention of Healthcare Associated Infections (HAIs) -- Volume of Contamination and Nosocomial Infection Control: Specific Aim II.1 [Use of Provodine to Protect HCW Hands (Aim II.1)]

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GENERAL INFORMATION

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Summary

This study seeks to investigate whether applying Provodine™ to hands protects against self-contamination during personal protective equipment (PPE) removal.

For centuries, HCWs have used special clothing and equipment to protect themselves when caring for patients with infectious diseases. Yet, we still lack basic information about the efficacy of most PPE items, the optimal removal (doffing) procedures, and the methods for educating staff and assessing their competence.(54) Recent outbreaks of severe acute respiratory syndrome (SARS), 2009 H1N1 influenza, and Ebola highlighted these deficiencies.(1, 12, 13, 55-60) Unfortunately, lessons learned from outbreaks of SARS and 2009 H1N1 did not lead to sustained improvements in PPE designs or practices. Thus, most US hospitals had great difficulty both developing protocols for Ebola PPE use and training their staff to correctly don and doff PPE.

Participants will serve as their own controls in this pilot study, first in a control arm then a Provodine™ arm. We, the research team, will contaminate participating healthcare workers' (HCW) PPE with either bacteriophage MS2 or *S. marcescens* ATCC 14756. Participants will then doff PPE using the Centers for Disease Control's (CDC) recommended protocol. We will sample their hands using the glove juice method.(124, 125) A research assistant will monitor participants as they wash their hands with soap and water then rinse their hands with 70% ethanol. Participants will then apply Provodine™ to their hands and put on (don) fresh PPE. We will repeat the contamination, doffing, and sampling procedure.

***Hypothesis*:** We hypothesize that Provodine™ will protect participants' hands from contamination with the test contaminants during PPE removal. Bacterial growth from the bag-broth cultures from the Provodine™ arm will have significantly less growth than from the control arm.

1 Background Information and Rationale

1.1 Background Information

Numerous studies have shown that HCWs' knowledge (19, 24, 61, 62) about proper use of PPE and their use of PPE (9, 10, 19, 62-68) are suboptimal. For example, Reid et al. found Canadian pediatric emergency department staff correctly identified the PPE needed for only 1 out of 6 scenarios (24). Casanova et al. noted that ~70% of simulation participants doffed PPE incorrectly despite having access to instructions from the Centers for Disease Control and Prevention (CDC); participants made errors when removing eye protection (33%-56%), N95 respirators (28%-50%), and gowns (17%).(67) In fact, few Canadian HCWs surveyed reported doing hand hygiene after removing various PPE items.(69) Moreover, only 15.4% of HCWs surveyed after the Toronto SARS outbreak reported using safe practices while caring for patients and 22.1% reported using risky practices.(65) Respondents reported being less likely to use appropriate precautions when these precautions were needed most: when caring for sicker patients (APACHE > 20) and when multiple room entries were required.(65) Furthermore, use of PPE varies by item; HCWs are more likely to wear masks, gowns, and gloves than eye protection.(62, 65, 66)

Multiple groups have assessed whether PPE prevents bacterial pathogens from contaminating the environment (70) and HCWs' clothes and bodies.(71-77) These groups demonstrated that HCWs' PPE items are often (9%-69.1%) contaminated with bacterial pathogens, including gram-negative rods (72-77), methicillin-resistant *Staphylococcus aureus* (MRSA) (75), enterococci (72), vancomycin-resistant enterococci (VRE) (73-75), multidrug resistant (MDR) *Pseudomonas aeruginosa* (PA) (76), or MDR *Acinetobacter baumannii* (AB) (76), after caring for patients and that their hands can be contaminated after they remove their gloves (0-12.7%). These investigators estimated that gloves were 77% to 100% effective in preventing hand contamination.(72, 74-76) However, Olsen et al. found glove leaks after 23.7% care episodes and only 21.9% of the participants knew their gloves were breeched.(72) Thus, HCWs often contaminate their gowns and gloves while caring for patients with resistant organisms. Furthermore, gloves, while protecting HCWs' hands, are not perfect barriers; results of the laboratory-based study by Doebbeling et al. suggest that even cleansing heavily contaminated gloves before doffing may not protect HCWs' hands from contamination.(71)

During the SARS epidemic (78) and the recent West African Ebola epidemic, HCWs were at high risk of infection.(1, 55) Data from several studies indicate that surgical masks and N95 respirators significantly decreased the risk of SARS infection among HCWs caring for patients with SARS (12, 13, 56) and that inconsistent use of PPE was associated with a higher risk of infection.(16) However, some HCWs who acquired SARS wore appropriate PPE.(18, 79-81) Some of these HCWs may have contaminated themselves during unsafe doffing or during reuse of PPE.(15, 82) Similarly, PPE is an important control measure in Ebola outbreaks (55) but some HCWs who acquired Ebola in West Africa wore PPE appropriately and may have acquired the infection through self-contamination while doffing. Investigators have found similar results for influenza.(57-60, 83-85) Despite evidence supporting PPE use, Chughtai et al. found significant variations in the policies and recommendations around mask and respirator use for protection against influenza and SARS. They postulated that these "differences may reflect the scarcity of level-one evidence.(86)" In the wake of these large and deadly viral epidemics, experts have called for new, improved PPE (87, 88) and for additional robust studies to provide data to guide practice.(89, 90)

Several groups have used fluorescent markers to assess whether HCWs contaminate themselves or the environment when they use or remove PPE.(31, 34, 91-95) Rawson et al. noted that participants' hands became contaminated when they handled the "outside of a contaminated glove" and when gloves "failed.(91)" Moreover, the type of PPE affects contamination levels. Wong et al. found that self-contamination occurred more frequently with jumpsuits than with gowns (92) and Guo et al. found that self- and environmental contamination was more frequent with plastic aprons than with disposable water resistant gowns.(93) Casanova et al. found a high rate of self-contamination (70%-100%) after HCWs doffed PPE contaminated with the bacteriophage MS2, a nonenveloped, nonpathogenic RNA virus.(96) They also found that MS2 was transferred to participants' hands more frequently (78% vs. 23%) and in higher quantity with single-gloving than with double-gloving. Double-gloving did not reduce MS2 contamination

of clothes, possibly because transmission to clothes was related to inadvertant contact with contaminated hands or gowns.(96) Like Zamora et al. (34), they noted that HCWs made more errors while removing PPE when they wore more PPE (double gloves) than when they wore less (single gloves).(67)

1.2 Rationale

We did not identify any studies that assessed whether products applied to the hands could eliminate bacteria or viruses transferred to the hands from contaminated PPE either via defects in the PPE (e.g., holes in gloves) or during improper doffing. Our proposal will test Provodine™, a unique, long-acting Povidine iodine hand rub (113), to determine whether it can eliminate organisms inoculated onto hands through glove defects or by faulty PPE doffing.

Provodine™ has a patented Amidermal® delivery platform, which allows controlled delivery of povidone iodine to the epidermis. In prior laboratory and clinical studies, Provodine™, when applied to the skin, rapidly killed viral (influenza A H1N1, human coronavirus, feline calicivirus) and numerous bacterial pathogens (e.g., *S. aureus*, *Serratia marcescens*) (113) and continued to kill exogenous pathogens inoculated onto treated skin for at least 9 hours. Drs. Herwaldt and Diekema recently found that anesthesia providers who performed hand hygiene with Provodine™ before their first case of the day had significantly fewer bacterial colony forming units (CFU) and significantly fewer pathogens, particularly *S. aureus* and *Enterococcus sp*., on their hands than when they performed hand hygiene with their usual hand hygiene agent (115).

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1.3 Risks

The risks to participants are minimal. There is a risk the Provodine™ may cause very mild skin irritation. In addition, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study. Hand cultures collected from participants will be labelled with a study number.

1.4 Benefits

There are no direct benefits to participants from being in this study. However, we hope that, in the future, other people might benefit from this study because this study may help us identify ways to decrease self-contamination while removing personal protective equipment and, thereby, possibly decrease the risk of transmission of infectious diseases from patient to healthcare worker.

1.5 Risk Benefit Ratio

The potential benefits of this study outweigh the minimal risks to participants.

2 Study Objectives, Aims, and Hypothesis

Participants will serve as their own controls in this pilot study, first in a control arm then a ProvodineTM arm.

Hypothesis: We hypothesize that Provodine™ will protect participants' hands from contamination with the test contaminants during PPE removal. Bacterial growth from the bag-broth cultures from the Provodine™ arm will have significantly less growth than from the control arm.

3 Study Design and Procedure

Study Design: We will perform a two-armed pilot test among 40 front-line healthcare workers (nurses, doctors, respiratory therapists, etc) at the University of Iowa Hospitals and Clinics. Participants will serve as their own controls. First, participants will perform hand hygiene with alcohol-based hand rub as they normally would in clinical practice then don PPE. We, the research team, will contaminate participating healthcare workers' (HCW) PPE with either bacteriophage MS2 (twenty participants) or *S. marcescens* ATCC 14756 (twenty participants). MS2 preparation and propagation and *S. marcescens* culture suspensions will each be performed as previously described.(123, 124) The MS2 bacteriophage will be suspended in 0.01 M phosphate-buffered saline and each PPE site will be contaminated with 105 plaque-forming units (PFU) of MS2 in 5 drops of 5 µL each. Aliquots of 3 mL of *S. marcescens* broth suspension (yielding bacterial titers of ~1 X 109 CFU/ml) will be applied to each PPE site. Participants will then doff PPE using the Centers for Disease Control's (CDC) recommended protocol. We will sample their hands using the bag broth method. A research assistant will monitor participants as they wash their hands with soap and water then rinse their hands with 70% ethanol. Participants will then apply Provodine™ to their hands and put on (don) fresh PPE. We will repeat the contamination, doffing, and sampling procedure. For MS2 recovery, we will assay the eluent using the most probable number (MPN) enrichment infectivity assay.(126) For *S. marcescens* recovery, we will dilute the eluent, plate it, incubate the plates, and count the colonies as described.(124, 127)

4 Selection and Withdrawal of Participants

4.1 Selection of Study Population

Email, plus referral from colleague? Nurses, doctors, others?

4.2 Inclusion Criteria

Front-line healthcare workers (how to make sure we get clinical staff who use PPE regularly?)

4.3 Exclusion Criteria

Healthcare workers with known skin allergies to povidone iodine.

4.4 Participant Withdrawal

Participants may withdraw from the study at any time. Any cultures collected from participants wishing to withdraw will be destroyed.

4.5 Participant Compensation

Upon completion of the two study arms, participants will receive a $30 gift card to thank them for their time. Gift cards will be sent from the XXXXXX to participants via University of Iowa Campus Mail.

5 Informed Consent Process

5.1 Recruitment

Email? Referral?

Then set up appointment for consent – where will we do this? Lab?

5.2 Informed Consent Process

Participant meet with RA, go through consent form, questions, proceed immediately to pilot test. Whole thing take 2 hours?

6 Statistical Plan

6.1 Power Calculations

On the basis of the literature, we assumed that 80%-90% of participants will contaminate themselves with MS2 and 60%-70% with S. marcescens. If Provodine™ is effective, 20 participants in each group would provide 80% power to detect a 60%-70% relative decrease (rate ratio = 0.3 to 0.4) in the rate of self-contamination (present or absent) and higher power to find a significant difference in the quantity of MS2 or S. marcescens recovered from participants' hands.

6.2 Analytical Plan

We will use the paired t-test or Wilcoxon signed-rank test to compare the quantity of MS2 bacteriophage or S. marcescens recovered after participants who applied Provodine™ to their hands before donning gloves with the quantity recovered from the control arm where participants who did hand hygiene with an alcohol-based product before donning gloves.

7 Data Collection, Handling, and Storage

All data collected will be stored in an electronic database on a shared drive within the University of Iowa Healthcare servers. Only members of the research team will have access to the database. No PHI will be collected. All participants will be identified in the database by a study number.

We will bank the isolates so that we can do susceptibility testing and pulsed field gel electrophoresis (PFGE) on the isolates in the future if this information is deemed important. All cultures and isolates will be labelled with study numbers and stored in XXXXXXXXX in the Diekema lab.