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To Whom It May Concern,

Medline is the largest supplier of exam gloves in the world, distributing over 2.1 billion gloves every month. We are deeply concerned by the prospect of a serious exam glove shortage. The purpose of this communication is to help the health care community prepare. We urge you to consider developing an emergency hand hygiene protocol and guidance to reduce consumption of exam gloves.

Production capacity of exam gloves cannot significantly increase in a relevant timeframe. Unlike facemasks, where new production capacity can be built relatively quickly and inexpensively, there is almost nothing that can be done in the short term to increase the supply of exam gloves. Prices may go up, but the number of gloves available in the world will not grow very much. Demand for gloves is increasing enormously around the world, and this demand will far outpace availability in the near future. About six months are required to build a new nitrile glove production line. Each modern line produces 25-30 million gloves per month and operates 24 hours a day, 7 days a week. Since it is not possible to significantly increase the output we anticipate a severe exam glove supply shortage as early as 15 May 2020.

The most practical solution is to use fewer exam gloves. When a shortage of gloves makes it necessary, a viable, effective and inexpensive emergency protocol may be for healthcare workers to rinse their hands to remove visible soil, and then either spray, wipe, or dip their gloved hands in a receptacle containing a disinfectant solution (such as bleach), without replacing their gloves. Medline is not aware of any existing glove disinfection protocol, recommendation, or practical guide that can be easily and effectively implemented in a fast-paced healthcare setting. Therefore, Medline would like to offer our

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research, test data, and practical solutions to help development.

On 20 March 2020, the US Food and Drug Administration published a letter to healthcare providers regarding medical glove conservation strategies. The letter states that when supply is critically low and demand is high to “Extend the use of medical gloves for health care providers without changing the gloves between patients with the same infectious disease diagnosis or exposure and no other infections. Gloved hands can be cleaned between patients and at other times when hand hygiene would normally be performed during routine patient care.”¹ We have explored this consideration with the use of bleach, as it is a widely available and inexpensive chemical for effective disinfection.

Sodium Hypochlorite (i.e. household bleach) can be used as an effective disinfectant against viruses, and there is a precedence for using bleach to disinfect hands between patients with known viral infections. The footnote link below was guidance published by the CDC during the Ebola crisis on the use of bleach as both a surface and a hand disinfectant². The letter outlines considerations for the preparation of chlorine solutions to disinfect hands with bleach solutions at relatively low concentrations. Additionally, the US Environmental Protection Agency has published a list of disinfectants (and minimum contact times), including various manufacturers of sodium hypochlorite, that can be used against the SARS-CoV-2 virus that leads to COVID-19 disease³. Lastly, a recent study published by The University Medicine Greifswald, Institute for Hygiene and Environmental Medicine (Greifswald, Germany) in February 2020, evaluated the reduction of viral infectivity of coronaviruses with the use of various disinfectants. The study confirmed that a 0.1%-0.5% bleach solution produced a >3 Log₁₀ reduction of viral infectivity in one minute⁴.

The attached study, “Preventing Viral Contamination: Effects of Wipe and Spray-based Decontamination of Gloves and Gowns”, published in 2019 by Clinical Infectious Diseases: An Official Publication of Infectious Disease Society of America, demonstrated that using bleach solutions that are either wipe or spray-based for one minute are equally effective. Moreover, the study concluded that the use of the spray-based solution did not contaminate the immediate environment.⁵ Additional

1 United States Food and Drug Administration. Medical Glove Conservation Strategies: Letter to Health Care Providers. Available at: <https://www.fda.gov/medical-devices/letters-health-care-providers/medical-glove-conservation-strategies-letter-health-care-providers>.

2Centers for Disease Control and Prevention. Ebola virus disease. Available at :<https://www.cdc.gov/vhf/ebola/clinicians/non-us-healthcare-settings/chlorine-use.html>.

3 United States Environmental Protection Agency, Pesticide Registration. List N: Disinfectants for Use Against SARS CoV-2 Available at:<https://www.epa.gov/pesticideregistration/list-n-disinfectants-use-against-sars-cov-2>

4See attached study “Potential role of inanimate surfaces for the spread of coronaviruses and their inactivation with disinfectant agents”.

5 Robinson, G.L., Hitchcock, S., Kpadeh-Rogers, Z., Karikari, N., Johnson, K.J., Blanco, N., Morgan, D.J., Harris, A.D., Leekha, S., 2019, Preventing Viral Contamination: Effects of Wipe and Spray-based Decontamination of Gloves and Gowns, Clinical Infectious Diseases: An Official Publication of the Infectious Disease Society of America, published online 2019 Sep 13.



disinfection studies that may be helpful are attached to this letter. Please see the footnote below⁶.

We recognize that a primary concern regarding the disinfection and reuse of exam gloves is both durability and material integrity after repeated exposure to disinfection chemicals. Therefore, using both European and US test standards (EN 374-3 and ASTM F 739-12), Medline conducted studies on both vinyl and nitrile gloves to demonstrate that they can withstand a wide range of chemicals, including 10-13% sodium hypochlorite, for greater than 480 minutes (8 hours) without chemical permeation.⁷

Additionally, Medline tested the performance of nitrile exam gloves after exposure to 0.5% bleach solution. The study concluded that after 30 minutes, 2 hours (120 minutes), and 8 hours (480 minutes) of exposure to a 0.5% solution, the nitrile exam gloves still meet Tensile Strength standards per ASTM D412-16. After 30 minutes of contact with 0.5% solution nitrile gloves still meet Force at Break standards per EN 455-2.⁸

When disinfecting a glove by submersion, spray, or wiping the glove surface, it may be difficult to safely disinfect the cuff. A possible solution may be to don two pairs of gloves at the beginning of a shift. Roll down the cuff of the outer glove to disinfect and then roll it back. If the outer glove has visible holes or damage, it can be replaced. The under glove can normally remain in place throughout the duration of the shift. The use of two gloves per healthcare worker as suggested here will still cause a significant reduction in the overall consumption of exam gloves.

Medline would like to offer an example of a potential guide for healthcare workers to prepare disinfecting solutions, and to disinfect gloved hands by submersion. Please see below:

1. Create disinfection solution of 0.5% bleach:
 - a) Do not use expired disinfection chemicals.
 - b) Change the disinfectant solution when visibly soiled or cloudy, and at least every 8 hours.
 - c) Follow the manufacturer's dilution and contact instructions to determine the

⁶ See attached studies titled "Journal of Hospital Infection 94_2016 - Glove Disinfection", "Effect of multiple alcohol based hand rub applications on the tensile properties of thirteen brands of medical exam nitrile and latex gloves", and "Antiviral Effect of Chlorine Dioxide against Influenza Virus and Its Application for Infection Control".

⁷ Attached to this letter are four chemical permeation study reports: 1) "3G VINYL, PN 103063H", 2) "MDS192075, PN 130081B - Chemical", 3) "PINK6075, PN 130081C - Chemical", and 4) "Silk, PN 120111".

⁸ See attached Medline study, "L20-089 Final Report REV 01 (Complete)"



correct dilution ratio, however, for common household bleach which is approximately 5.25% sodium hypochlorite, a dilution ratio of 1 part bleach to 9 parts water (1:10) will equate to a 0.5% solution.

- d) A contact time of 1 minute is sufficient for disinfection in a 0.5% solution⁹.
- e) Prepare a clock or timer to assure that the minimum contact time is achieved during disinfection.

2. Disinfect, rinse and dry gloved hands:

- a) Without removing gloves from hands, rinse all visible organic soil under running water. If soil cannot be removed with water alone, replace the glove.
- b) Examine gloves for holes or tears. If holes or tears are detected or suspected, replace the glove.
- c) Dip gloved hands in prepared disinfection solution for a minimum of 1 minute. Assure that all glove surfaces, including cuffs, contact the solution for the appropriate amount of time.
- d) Rinse gloved hands with running water post disinfection.
- e) Dry hands with a paper towel.
- f) Re-examine gloves for holes or tears. If holes or tears are detected or suspected, replace the glove.

In summary, there is high likelihood that the world will experience an exam glove shortage in the very near future. Production of gloves cannot be increased in time to support the demand. Therefore, we encourage you to share this information with your team of regulatory and infection control professionals so they can begin planning an emergency protocol. Medline's quality and regulatory leaders in Europe are available to support your team.

We will share with you relevant new information as it becomes available, whether from regulatory agencies or the infection control professionals among our customers.

⁹ See attached study "Potential role of inanimate surfaces for the spread of coronaviruses and their inactivation with disinfectant agents".



To access the reference studies, please [click here](#).

Sincerely,

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