INTERNATIONAL SOCIETY FOR INFECTIOUS DISEASES

GUIDE TO INFECTION CONTROL IN THE HEALTHCARE SETTING

Extended Use and Reuse of Personal Protective Equipment in the Health Care Setting, and in the Community

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KEY ISSUES

- Personal protective equipment (PPE) designed as single use disposables in the health care setting are commonly used for longer periods than manufacturers' recommendation or reused when supplies have been limited.
- PPE use-times are extended or reused without regard to their continued integrity.
- Wearing of face coverings (medical and cloth) in the community has been widely implemented without standards and/or self-testing reduction in overall transmission or duration of its protective effects.
- The COVID-19 pandemic has highlighted the inequities of access to PPE:
    - the lack of evidence-based recommendations for their safe use/extended use/reuse,
    - the lack of harmonized standards for PPE and,
    - the disruption of the global supply chain.
- Prolonged PPE wear poses a challenge for health workers' health.
- PPE disposal poses an environmental stress load.

KNOWN FACTS

Introduction

Many medical devices are marketed as disposable units intended to be discarded after a single use. Reusing such devices pose risks including infection, bio-incompatibility, toxicity, particulate contamination and unit integrity breakdown (Ponce, 2018; Shuman and Chenoweth, 2012). Despite the risks, these disposable devices have been reused when the supply chain and the local economy is unable to keep up with the demand. Reuse and extended use are common practices in resource limited healthcare settings and increasingly undertaken without appropriate regard to ensure safety and integrity. This decision to use

personal protective equipment (PPE) beyond its intended single use incurs uncertainty and fear and often without supportive evidence, thus affecting the safety of the health worker and putting patient care at greater harm (Mansur, 2017). In the COVID-19 pandemic, severe and prolonged global shortages led to nationally mandated-restricted distribution of PPE, particularly of N95 or Filtering Face Piece-2 (FFP2), thus encouraging hoarding and black market selling. This put health workers at the gravest risk without appropriate protection. Adherence to infection and prevention control (IPC) practices is critical to prevent infections and the authoritative IPC strategies in their current versions do not include a section on PPE extended use/reuse because this practice is highly risky with inadequate evidence based information (CDC, 2020a; ECDC, 2020, 2022; WHO, 2020a, 2020c). There is also increased concern about the harm of PPE materials (polypropylene/meltblown) to the wearer and its environmental impact upon disposal.

Interim guidance on PPE extended use and reuse (shifting standard PPE use practice to address a global problem)

Severe shortages of PPE, especially medical masks and respirators, in COVID-19 response led the World Health Organization (WHO) (WHO, 2020b), European Centre for Disease Control (ECDC, 2020), Centers for Disease Control and Prevention to issue recommendations for interim reuse or extending use (CDC, 2020a) of PPE elements (masks and respirators, eye protection, surgical gowns). These recommendations were made to mitigate against limited supplies on how to extend the use or the reuse of a PPE element and suggesting alternatives as a last resort if that PPE element is not available. Extended use included a strategy to use PPE beyond the manufacturer's-designated shelf life or expiration date for a limited time. Approved methods to decontaminate soiled/used respirators needed to be established with the use of hydrogen peroxide vapor, ethylene oxide, ultraviolet germicidal light,

moist heat, chemical disinfectants or gamma radiation (Rowan et al., 2020; WHO, 2020b; Probst et al., 2021). These methods generally require specialized equipment to reprocess PPE under carefully controlled conditions. In low resource settings these methods may either not be available or not suitable particularly where reuse of PPE is common practice due to an erratic supply of PPE and financial constraints.

Manufactured PPE for the healthcare setting is not designed for reuse or for protecting the health worker

Respirators, eye protectors, hair bonnets and gowns are the items most frequently reused PPE pieces in healthcare setting with inadequate knowledge of how they may be decontaminated, cleaned and re-worn. Because they are disposable, instructions for reprocessing are not provided. Medical masks and respirators can easily become soiled, and a contaminated PPE piece can itself become a vehicle of transmission posing great risk to the user (Shuman and Chenoweth, 2012). The PPE on the current marketplace has been designed for use in high income countries (HIC) for the protection of the patient from nosocomial infections and secondarily, to protect the health worker. The health worker may be viewed as the source (to infect the patient) whereas in response to a transmissible respiratory disease, PPE protects the health worker but must be part of a bundle of interventions, such as robust yet simply laid out policies, triage of suspected or infected patients, patient isolation, and most importantly, improved ventilation. In the hierarchy of IPC interventions (WHO, 2020a) the least effective means of preventing transmission, particularly of airborne pathogens, is the use of PPE, yet these are the most discussed and promoted. Reuse of PPE, though commonly practiced in low resource settings has not been fully considered until recently when scarcity and high demand in COVID-19 patient care forced many healthcare institutions to consider extended use and/or reprocessing.

Designing, production and sale of PPE is a complex combination of source material, design, user satisfaction, regulatory standards and sales. Each individual PPE piece is manufactured to meet its own standard and tested accordingly to ensure its performance and integrity, however, when used together, each individual item of PPE may not provide the overall protection the healthcare worker requires and expects. This is evident in the WHO guidance on preferred product characteristics for PPE to protect the health worker at the frontline for Ebola and other hemorrhagic fevers (WHO, 2018). Here, there is a different level of risk when the individual item of PPE meets its own established standard but together pose an incomplete protection. The protective effect of non standardised PPE combinations for different levels of risk have to be better defined to ensure protective coverage in future studies.

Public messaging to wear cloth mask for protection

Respirators (N95/FFP2) are recommended for aerosol generating procedures during intensive care of COVID-19 patients while medical masks are recommended for wear during care of patients. Health authorities have taken different approaches in recommendations for public use of face coverings around the world (Howard, et al. 2021). Messaging how the public should use face covering at the start of COVID-19 pandemic in HICs more directed for the public not to be masked. This message was intended to retain as much of the PPE needed for health workers (Brooks et al., 2021; CDC 2021a) but it did not consider the political backlash to mask wearing. In the US, Europe, South Africa and some Asian and African countries, appeals were made to the public to use cloth masks to avoid further shortages of respirators and medical masks to health workers who needed this protection. In Asia, where face covering use is common, masks were used from the start of the pandemic. Some countries were early adopters of universal

masking (as part of a bundle of intervention) as a positive practice for the whole society (South Africa), for others strong stigma was associated with wearing a mask in public (USA, UK, Europe). Efforts since have been to improve the construction and fit of face coverings with instructions widely disseminated and integrated into the public health message. Standards for cloth masks are now available (European Committee on Standards, 2020; CDC 2021b) and these can be constructed to achieve filtration quality as medical masks and could be washed and dried at home (Clapp et al; 2020; Zhao et al.,2021)

The stakeholders who have a role to address the gaps

Ironically, most disposable PPE devices can be reused safely for a limited number of cycles without loss of performance and integrity using multiple methods (Probst et al., 2021). Medical masks and respirators have been safely cleaned, decontaminated upto five times, including 3 models of N95/FFP2 and 3 ASTM Type II medical masks, all without loss of performance integrity using methylene blue, a cheap and low technology method (Lendvay, et al., 2021). In the US, the manufacturers of these devices are examining how their product instructions can be modified to allow for reuse with regulatory authority compliance. In other sectors, PPE could be completely re-designed to become reusable units and environmentally safer to dispose. A very good reason to consider these improvements is to reduce the high burden of biomedical waste on our environment.

Concerning information has emerged on the increasing environmental burden of waste PPE polypropylene and meltblown materials that contain micro- and nanoplastics (Kutralam-Muniasamy, et al., 2021). A community-sold face mask can release more than a billion irregularly-shaped particles of < 1 µm size; particles that can be inhaled by the wearer and adsorbed onto diatom surfaces that can be ingested by marine organisms (Ma et al, 2021). The magnitude and density of PPE

pollution must be considered and balanced against single-use PPE (Torres-Agullo et al, 2021). These nano particles have been shown experimentally to be toxic to marine life (Sun, et al., 2021) and in human lung epithelial cells (Yang, et. al, 2021), suggesting that with prolonged exposure, healthworkers could be at higher risk of respiratory lung disease. So additional targeted research in the areas of environment toxicity and exacerbation of respiratory illnesses need to be investigated.

Developing the knowledge to safely reuse PPE and protecting healthworkers and the environment

The paucity of evidence-based guidelines to assure the quality and the safety of this practice for PPE and other medical devices is an area that needs practical evidence-based solutions. In addition, as more PPE polypropylene/meltblown materials are disposed, evidence for safe reuse may reduce medical waste and have beneficial impact on an already stressed environment.

Controversial Issues

Reuse of PPE in low resource settings need simple and effective decontamination with strict guidance

The current methods used for PPE decontamination (Rowan et al, 2020) are resource-intensive, expensive and are applied for mass decontamination which require robust infrastructure and quality control. Some of the methods, like moist heat could be used, or the use of methylene blue and light (Lendvay et al, 2021; WHO, 2020b). Standard methods have to be developed to reprocess with appropriate training to put in the required safety and security standards for ensuring that IPC principles are followed.

Mask use in the community as part of public health strategy

The continued wearing of cloth masks during the COVID-19 pandemic has sensitized the general public to public health measures for reducing transmission. In countries where the wearing of a face cover is mandatory and universally accepted, evidence shows that there has been definite reduction in overall transmission and this reduction has been sustained over long periods of time (Brooks and Butler, 2021; Howard et al., 2021). In HIC, the universal use of masks has been controversial and manifesting in public resistance to such measures. More targeted social behavior and messaging have to be developed to promote uptake of mask use in the community.

Standards are not harmonized

While some national standards exist for the manufacture of PPE, these are not always universally applied or accepted. National standards are based on the local availability of materials, industrial development and occupational health requirements (health workers). Global standardization of all types of PPE should vastly improve the quality of currently available products.

PPE supply chain unable to keep up with demand

The COVID-19 pandemic revealed a global lack of coordination and access to PPE globally (Burki, 2020)). Asia supplies the majority of the PPE (ADB, 2020). China alone provides half the world's supply of medical masks and the only place capable of mass-producing clinical gowns. Surges in domestic demand, export restrictions and travel restrictions compounded the problem (ADB, 2020). Though, the disruptions have been alleviated as Asian producers have stabilized, the production issues are not addressed especially mechanisms for fair and equitable distribution if another shortage arises.

SUGGESTED PRACTICE

Develop a multi-faceted strategy for improving PPE reuse to ensure a safer and more practical approach including (but not exhaustive):

(1) Re-examine and re-design a PPE system that fits, protects and is comfortable. PPE could be designed with the intention for its reuse with a decontamination method(s) that is practical for all settings, LIMC and HIC. A PPE system borne of designs that is meant to contain the source and protect the contacts using materials engineering, human use design and safety and health security disposal considerations.

(2) A paradigm shift on decontamination that is simple, cheap coupled with ability to test integrity of the PPE at the local level. This has to be integrated as common practice in the system and in the community.

(3) Review the standards testing methods to include reuse methodology that is practical and usable, providing testing methods for safety, comfort and fit in certified testing laboratories but also adapt for use in community and hospital settings.

(4) Sustain IPC training and education appropriately designed for target audiences in the health setting and in the community about the appropriate use and role of PPE, infection prevention and risks posed by reuse of PPE and understand how to evaluate PPE integrity after decontamination.

(5) Ensure motivation for good practice with continuous evaluation, feedback and improve practice of PPE use in the health setting and in the community in a structured method to measure reuse and safety metrics.

(6) Assess the global supply chain to allow for local production of PPE based on the standards especially to meet surge capacity needs when called upon during high demand.

SUMMARY

COVID-19 has highlighted the underlying issues of uneven global access to medical supplies, equipment, devices and treatments. Equitable access is complex that include issues with supply chains, with PPE design, with manufacturing and with waste disposal and finally the issue of demand. With the COVID-19 experience, the severe shortage also highlighted the issue of reuse, a practice that is admittedly common in LMIC settings but also practiced during shortages in HIC. Reuse poses great risk if PPE is not properly decontaminated, or the process of decontamination leads to loss of integrity. All this requires the global medical, research, manufacturing and the regulatory communities to collaboratively take up the challenge with innovative approaches to design, materials engineering, novel decontamination and waste disposal coupled with practical standards and human use consideration to develop PPE that is suited for its intended use, allow for local solutions and reduces burden to the environment.

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