



Challenges and solutions for addressing critical shortage of supply chain for personal and protective equipment (PPE) arising from Coronavirus disease (COVID19) pandemic – Case study from the Republic of Ireland



Neil J. Rowan ^{a,b,*}, John G. Laffey ^{c,d}

^a Department of Nursing and Healthcare, Athlone Institute of Technology, Ireland

^b Centre for Disinfection, Sterilization and Biosecurity, Athlone Institute of Technology, Ireland

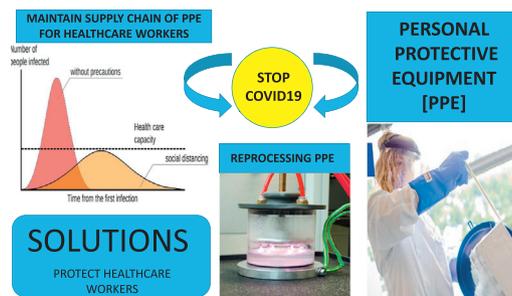
^c Lung Biology Group, Regenerative Medicine Institute at CURAM Centre for Medical Devices, National University of Ireland Galway, Galway, Ireland

^d Anaesthesia and Intensive Care Medicine, University Hospital Galway, Galway, Ireland

HIGHLIGHTS

- There is pressing need to find solutions for reprocessing of PPE for COVID19
- Reprocessing of PPE is challenging as made for one-time-use
- Most sterilization technologies are not suitable for PPE reprocessing
- Use of vaporised hydrogen peroxide and UV irradiation may prove effective for PPE

GRAPHICAL ABSTRACT



ARTICLE INFO

Article history:

Received 5 April 2020

Accepted 5 April 2020

Available online 6 April 2020

Editor: Damia Barcelo

Keywords:

COVID19

PPE

Sterilization

Healthcare workers

Resource utilization

Sustainability

ABSTRACT

Coronavirus (COVID-19) is highly infectious agent that causes fatal respiratory illnesses, which is of great global public health concern. Currently, there is no effective vaccine for tackling this COVID19 pandemic where disease countermeasures rely upon preventing or slowing person-to-person transmission. Specifically, there is increasing efforts to prevent or reduce transmission to front-line healthcare workers (HCW). However, there is growing international concern regarding the shortage in supply chain of critical one-time-use personal and protective equipment (PPE). PPE are heat sensitive and are not, by their manufacturer's design, intended for reprocessing. Most conventional sterilization technologies used in hospitals, or in terminal medical device sterilization providers, cannot effectively reprocess PPE due to the nature and severity of sterilization modalities. Contingency planning for PPE stock shortage is important. Solutions in the Republic of Ireland include use of smart communication channels to improve supply chain, bespoke production of PPE to meets gaps, along with least preferred option, use of sterilization or high-level disinfection for PPE reprocessing. Reprocessing PPE must consider material composition, functionality post treatment, along with appropriate disinfection. Following original manufacturer of PPE and regulatory guidance is important. Technologies deployed in the US, and for deployment in the Republic of Ireland, are eco-friendly, namely vaporised hydrogen peroxide (VHP), such as for filtering facepiece respirators and UV irradiation and High-level liquid disinfection (Actichlor+) is also been pursued in Ireland. Safeguarding supply chain of PPE will sustain vital healthcare provision and will help reduce mortality.

© 2020 The Authors. Published by Elsevier B.V. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

* Corresponding author at: CDSB, Athlone Institute of Technology, Ireland.
E-mail address: nrowan@ait.ie (N.J. Rowan).

1. Introduction

Coronaviruses (CoVs) (order Nidovirales, family Coronaviridae, subfamily Coronavirinae) are enveloped viruses with a positive sense, single-stranded RNA genome (Schoeman and Fielding, 2019). With genome sizes ranging from 26 to 32 kilobases (kb) in length, CoVs have the largest genomes for RNA viruses. Coronavirus is one of the major pathogens that primarily targets the human respiratory system (Rothan and Byrareddy, 2020). Previous outbreaks of coronaviruses (CoVs) include the severe acute respiratory syndrome (SARS)-CoV and the Middle East respiratory syndrome (MERS)-CoV that are a great public health threat (Carty and DiNicolantonio, 2020). A global pandemic status has been recently declared by the World Health Organization (WHO) for COVID19. The first number of cases were identified in Wuhan, a large city of 11 million people in central China in December 2019, which were linked to the Huanan (Southern China) Seafood Wholesale Market (Rothan and Byrareddy, 2020). These were identified by local hospitals using a surveillance mechanism for “pneumonia of unknown etiology”, which was established in the wake of the 2003 severe acute respiratory syndrome (SARS) outbreak with the aim of allowing timely identification of novel pathogens such as 2019-nCoV (Li et al., 2020). Globally, the number of confirmed cases as of this writing (3 April 2020) has reached 1,000,249 including 51,515 deaths (<https://www.ecdc.europa.eu/en/geographical-distribution-2019-ncov-cases>) (Fig. 1). Covid19 is now globally distributed (Fig. 2), suggesting that universal solutions are required to prevent or slowdown its rapid spread until effective control measures are developed and deployed, such as vaccine (Fig. 3). COVID19 is much more lethal than the typical flu, where former has a mortality rate of about 2.92% (Carty and DiNicolantonio, 2020). The annual flu has a mortality rate of just 0.05 to 0.1%, inferring that COVID-19 is around 30 to 60 times more lethal (Carty and DiNicolantonio, 2020). COVID19 causes an inflammatory storm in the lungs and it is this inflammatory storm that leads to acute respiratory distress, organ failure, and death.

Swaminathan et al. (2007) previously considered that while a new influenza pandemic may appear inevitable, critical parameters of transmissibility and attack rate are uncertain. These authors reported that estimates based on extrapolations from the 3 influenza pandemics of the 20th century suggest that healthcare facilities in the United States alone may be required to cope with 314,000–734,000 additional hospitalizations and 18–42 million outpatient visits (Meltzer et al., 1999). During the early containment phase of a pandemic, patients with

suspected infection are likely to be referred to hospitals for isolation, diagnosis, and treatment until the transmissibility and virulence of the pandemic strain are known. Although social distancing and school closures may reduce risk in the wider community, healthcare workers (HCWs) are likely to encounter repeated close exposures. Swaminathan et al. (2007) suggested that if hospitals are to continue to function adequately, reliable access to effective personal protective equipment (PPE; gowns, N95 masks, gloves, and eye protection) and antiviral drug therapy will be necessary for an unpredictable period. With awareness of the recent severe acute respiratory syndrome (SARS) outbreak and with growing concern about human deaths from avian influenza (H5N1), governments worldwide have begun to stockpile PPE and antiviral medication.

Key strategies to control the speed and extent of viral spread within healthcare settings have been advocated by national government guidelines and the WHO (Swaminathan et al. (2007)). These include rigorous infection control practices, prescriptive instructions for the use of PPE, and dissemination of antiviral medication. These authors reported that information regarding the required quantity and rate of use of these valuable resources in an outbreak situation is lacking, thereby limiting valid assessments of the adequacy of current stockpiles. This was corroborated by a previous simulation study conducted by Mitchell et al. (2012), where a patient with suspected avian or pandemic influenza (API) sought treatment at 9 Australian hospital emergency departments where patient–staff interactions during the first 6 h of hospitalization were observed. Based on World Health Organization definitions and guidelines, the mean number of “close contacts” of the patient was 12.3 (range 6–17; 85% HCWs); mean “exposures” were 19.3 (range 15–26). Overall, 20–25 PPE sets were required per patient, with variable HCW compliance for wearing these items (93% N95 masks, 77% gowns, 83% gloves, and 73% eye protection). These data indicate that many current national stockpiles of PPE and antiviral medication are likely inadequate for a pandemic.

At this time of writing, in the Republic of Ireland, there is a national lockdown imposed by the Irish government where citizens are requested to remain at home to prevent the spread of COVID-19 infection. Where new positive COVID19 cases arise, the role of contact tracing and data analytics are important. Social distancing and cocooning of the elderly and vulnerable groups has been adapted. Only essential services, such as agriculture and fisheries, manufacturing and healthcare, have been granted permission to travel. There is a concerted effort to slow the rate of infection so as along with capacity of healthcare to meet

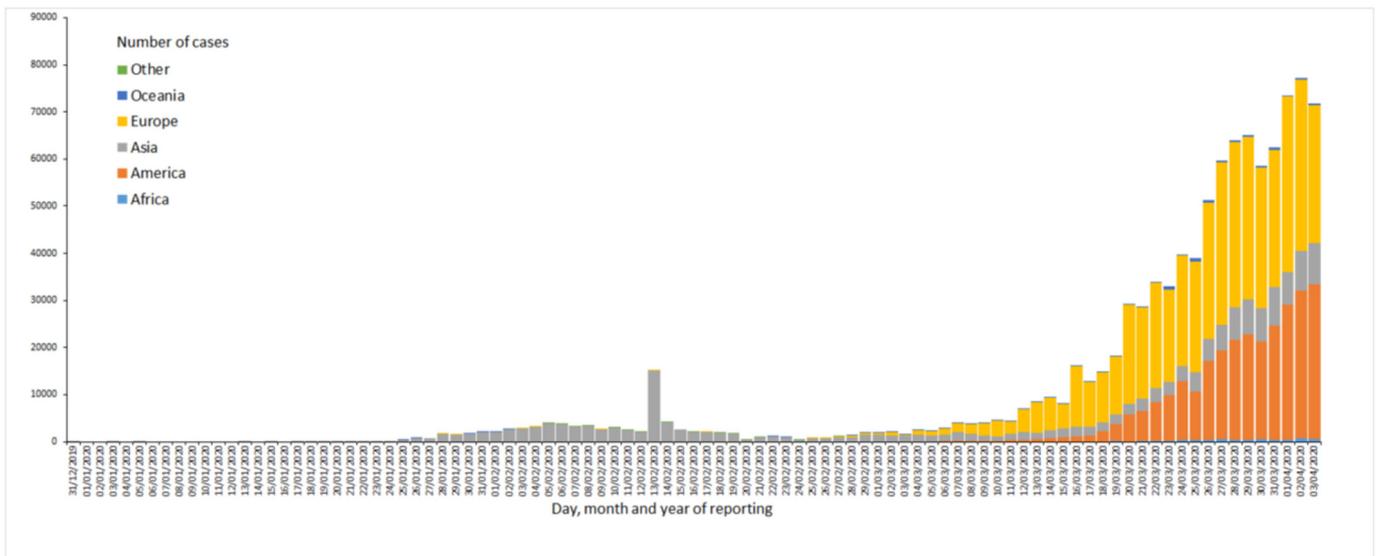


Fig. 1. Distribution of COVID19 worldwide, as of 3 April, 2020. (Source <https://www.ecdc.europa.eu/en/geographical-distribution-2019-ncov-cases>)

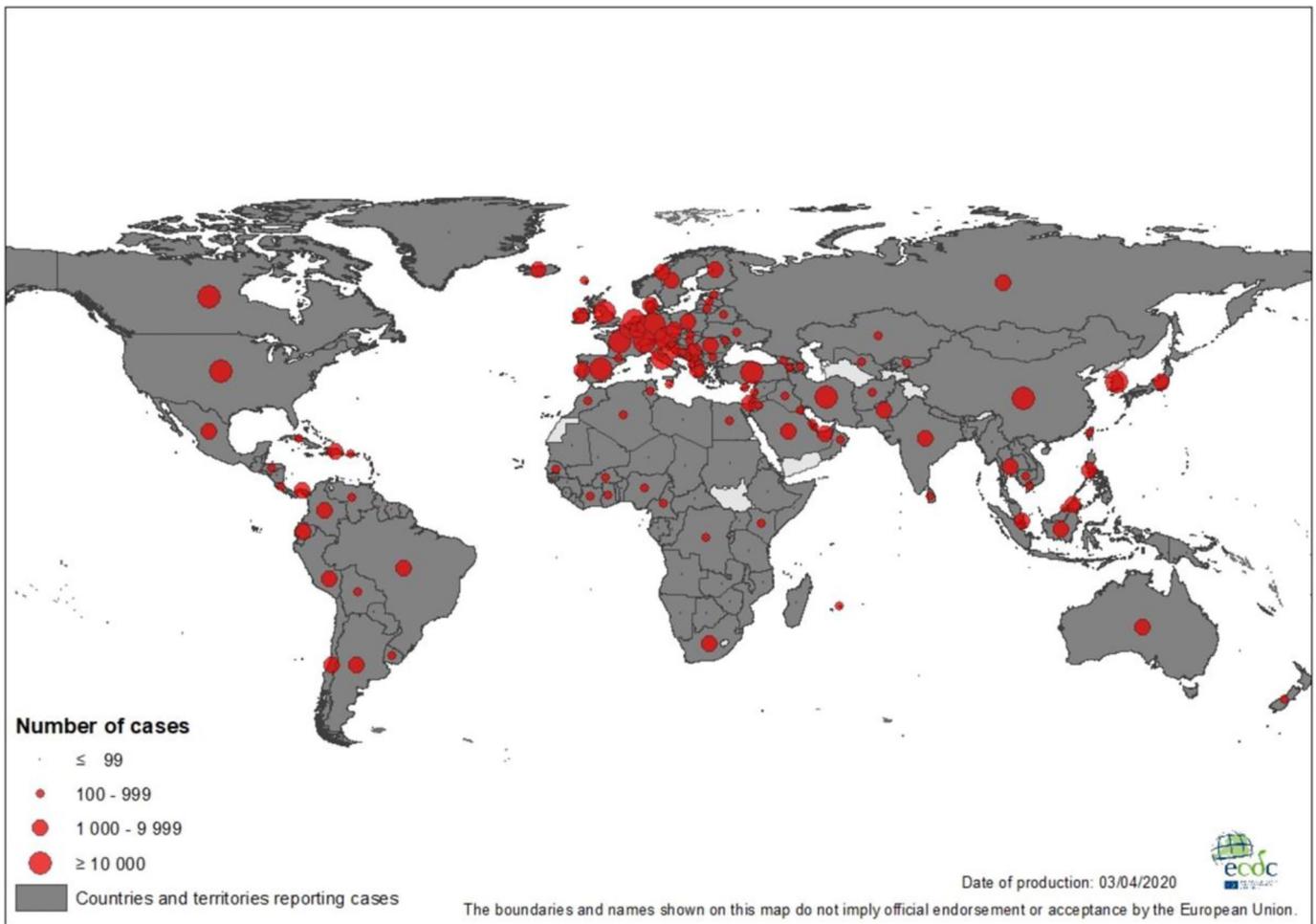


Fig. 2. Geographic distribution of COVID19 worldwide, as of 3rd April, 2020. (Source, <https://www.ecdc.europa.eu/en/geographical-distribution-2019-ncov-cases>)

number of cases, thus avoiding a mismatch in early peak in infections (Fig. 3). Given need for react quickly, solutions (where appropriate) are based upon adaptation, blending and re-purposing of existing

products, processes, technologies and infrastructures. Solutions and challenges to address shortage of PPE in a regional Irish hospital are described.

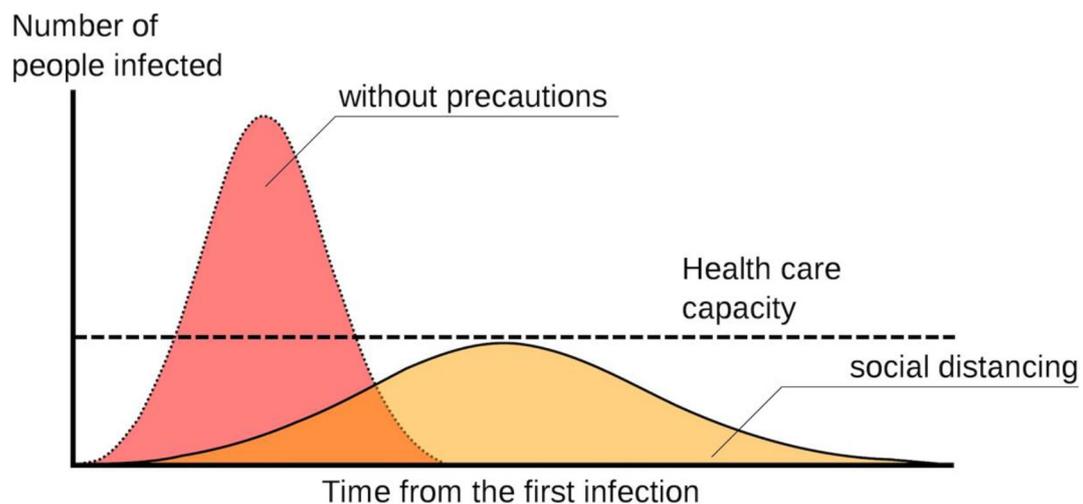


Fig. 3. A sample epidemic curve, with and without social distancing. (Image credit: Johannes Kalliauer/CC BY-SA 4.0)

Use of smart software and networking with various distribution channels to meet shortfall in PPE and infection prevention and control (IPC) methods.

A new team of experts was formed (designated REA-PPE) to deploy effective solutions in a short time frame, which included those from across academia, healthcare, Enterprise Ireland-funded technology gateways, Science-Foundation-Ireland (SFI)-funded Research Centres (CURAM for Medical Device, COMMAND for software) and industry. REA_PPE team also links with the Crisis Management Team in the regional hospital where solutions is to implemented by manager of the Hospital Sterile Services Department (HSSD). This REA_PPE team comprises experts representative of anaesthesia and intensive care, medical device technology, infection control, hospital disinfection and sterilization, minimal processing; microbiology, toxicology, virology, material science, software engineering, and social marketing Priority initially focused on delineating effective communication channels in order to inform stocks within healthcare from several routes that include use of dedicated webpage [https://covidmedsupply.org/] established by researchers from NUI Galway and University of Limerick (Ireland) that collects donations of PPE from regional industries and academic institutions. Given volatility in the global supply chain for PPE, Ireland's Health Service Executive (HSE) actively pursue PPE orders from China and other sources to meet specific requirements that are quality checked on arrival. Upon arrival, PPE are distributed to primary healthcare, step-back healthcare facilities or nursing homes. HCW are dedicated to one site to avoid risk of cross-infection. Aer Lingus (Ireland's main national airline), made no-stop flights with a team of volunteer rotating pilots to China in order to collect vital PPE stock, where this process was repeated several times in the same week. COVID19 pandemic caused uncertainty to the established norm that is addressed by teamwork, learning, adaptation and adjustment.

Stock usage will also be tracked through a new PPE mobile phone app that uses (1) backend database to save all information on PPE stock and distribution running on a cloud, such as AWS, (2) web-server as a gateway between the mobile app and the database, such as AWS, and (3) two functions for updating the database with latest PPE status along with querying the same database. Provision has been made for use of smart blockchain system to replace the database, if the system becomes too complicated for mobile phone usage, such as data immutability,

2. Bespoke manufacturing of PPE to meet identified shortage in PPE

Where possible, where there was identified shortages in PPE, bespoke production occurred to make these items using medical grade materials, such as Continuous Positive Airway Pressure (CPAP) helmets for use in intensive care. CPAP provides the maximal amount of mean airway pressure without intubation and promotes a more lung-protective ventilation pattern. Various other bespoke manufacturing initiatives have commenced in Ireland linked to international collaborators that included use of crowdfunding by group of researchers and scientists who raised €134,000 in order to develop an easy-to-build and inexpensive ventilator for Covid-19 patients with first prototype now in place (<https://www.thejournal.ie/emergency-ventilators-irish-researchers-crowdfund-5061521-Mar2020/>). Other Irish researchers in University College Dublin and IT Sligo made easy-to-assemble ventilators using 3D printers and off-the-shelf components that will be validated by Ireland's HSE (<https://www.irishtimes.com/business/health-pharma/irish-project-for-easy-to-assemble-covid-19-ventilators-bears-fruit-1.4205999>). Facial visors were also made using 3-D printers for use in regional hospitals and nursing homes. At the time of writing, it is uncertain as to what if not all bespoke manufactured PPE in Ireland that will be inspected by HSE before deployment and usage by frontline healthcare workers. The trend by many medical device manufacturers and academic institutions to redeploy expertise and resources to make PPE to address COVID19 crisis is also emerging in other international

countries (<https://www.cam.ac.uk/business-and-enterprise/help-us-tackle-covid-19>).

3. Challenges and solutions for addressing the reprocessing of single-use PPE

At this time of writing, there is a dearth in published literature on efficacy of innovations for reprocessing PPE. This is due to fact that PPE are manufactured for single use. Therefore, there is reliance on information generated by medical device manufacturers and related sterilization industries to help understand how best to address this shortage of PPE and the need for reprocessing in a pandemic. Traditionally, limited knowledge sharing occurs in the medical technology sector due to the need to protect IPR, which is understandable given nature of commerce and competitiveness. However, there is an increasing trend by leading industries to publish findings that also assists in shaping ISO standards, guidelines and regulations with a focus on future-proofing, greater resource utilization and sustainability (McEvoy and Rowan, 2019; Chen et al., 2019). Original equipment manufacturers (OEMs) of one-time-use PPE have recently provided new information on possible methods for reprocessing these items given the universal need to consider contingency plans arising from shortages during this pandemic (such as 3M Science of Life, 2020).

PPE used in healthcare includes gloves, aprons, long sleeved gowns, goggles, fluid-repellent surgical masks, eye, nose and mouth protection, face visors and respirator masks. Healthcare workers should wear protective clothing when there is a risk of contact with blood, body fluids, secretions and excretions. HCW should select the appropriate PPE based on a risk assessment of the task to be carried out (Table 1). There is particular focus airborne droplets (splatter) liberated through breathing or expelled through sneezing of infected COVID19 patients may travel several meters and remain suspended for ca 30 min and survive on surfaces for potentially several days. Surface, or contact surface, disinfection or sterilization of PPE will suffice, as coronavirus does not penetrate materials. However, greatest challenge to reprocessing on one-time-use PPE relates to ensuring material functionality post effective treatments.

If one considers medical equipment designed for pre-processing, such as endoscope, there is pre-cleaning stage to reduce bioburden in advance of sterilization processes to ensure efficacy. This is relevant as unlike therapeutics (such as vaccines and antibiotics) that rely on a specific mechanistic target for model of action, sterilization modalities are non-specific with reliance upon ensuring that processes run full cycles for achieving sterility assurance level (SAL) of products (McEvoy and Rowan, 2019). For example, the presence of organic matter may affect the oxidative nature of gaseous sterilization processes, such as ethylene oxide (EtO or vaporised hydrogen peroxide (VHP). Pre-cleaning presents an issue in hospitals as there is commensurate need to decontaminate equipment used in this process for COVID19. Consideration was given to use of Actichlor plus as a wash/disinfection phase. To prevent the spread

Table 1

WHO recommendations for HCW barrier precautions, dependent on type of exposure.^a (Adapted from Swaminathan et al., 2007)

HCW activity	Recommended PPE set
Close contact (<1 m) with potential API-infected patient within or outside of the isolation room or area	Gloves, gown, N95 mask (or equivalent particulate respirator), eye protection
Cleaning	Gloves, either gown or apron
Patient transport within healthcare facilities	Gown, gloves
Specimen transport and processing	Not defined except to use 'safe handling practices', interpreted as use of gloves (minimum) and gown if opening specimen bag

^a WHO, World Health Organization; HCW, Healthcare worker; PPE, Personal and Protective Equipment, API, Avian or Pandemic Influenza.

of health-care-associated infections, all heat-sensitive endoscopes (e.g., gastrointestinal endoscopes, bronchoscopes, nasopharyngoscopes) must be properly cleaned and, at a minimum, subjected to high-level disinfection after each use. High-level disinfection can be expected to destroy all microorganisms, although when high numbers of bacterial spores are present, a few spores might survive (CDC, 2008).

The medical device industry relies upon significant lethality of pre-determined populations of a biological indicator (BI) that is typically a recalcitrant bacterial endospore (such as *Geobacillus stearothermophilus* or *Bacillus atrophaeus*). These BIs are carefully selected for this purpose as they are more resistant to that of pathogenic microorganisms including COVID19, which are typically orders of magnitude more sensitive to same applied lethal stress (Fig. 4). These are a highly validated and controlled sterilization processes. However, SAL for these sterilization are endpoint-determination processes that rely upon 12 log reduction in BIs that is excessive duration of treatment for reprocessing single-use PPE (Fig. 5) (McEvoy and Rowan, 2019). There has been no reported cases of patient illness arising from a terminal sterilization of medical devices. Furthermore, sterilization technologies are validated for full treatment regimes. There is an absence of published knowledge as to the efficacy of operating same sterilization modalities under reduced exposure or cycle conditions, such as for the treatment of PPE. Therefore, use of penetration technologies such as gamma, electron-beam and x-ray will not be appropriate as likely to affect material and functionality of PPE post treatments. Gas-plasma generated hydrogen peroxide vapour will also be unsuitable as the plasma-process affects materials during treatment. STERIS AST have commenced studies on the combined use of real-time flow cytometry with conventional culture-based enumeration methods that will elucidate this gap, which includes frontier microbial inactivation kinetic modelling. Kinetic modelling is important for informing changes in technologies, even for potential disruption potential in emerging innovations, such as in adjacent food industry (Rowan et al., 2015). This pandemic situation will also present emerging minimal treatment opportunities for materials and treatments in medtech and sterilization industries, which will require greater flexibility in approach, such as for in situ 3D printing of medical devices in healthcare.

Future reduction in sterilization modality usage would also improve resource utilization and facilitate greater sustainability of the industries. This would also have significant knock-on influence for parametric release of treated products, with quicker turn-around supply time to clients. However, it is essential that future reductions in sterilization processes are informed by best evidence and do not compromise on product safety, which require validation and regulatory approval before usage.

It is appreciated that under pandemic situations, there is a need to do things differently, along with urgency. However, this must be measured, appropriate and best informed by critical information such as that supplied by original manufacturers of single-use devices (such as 3M Announcement, 2020), along with international standards and regulators, such as AAMI and the FDA. There is a gap in knowledge on extensive studies relating to reprocessing by this source too. 3M™ stated that “filtering facepiece respirators (FFRs), such as N95, FFP2, KN95, and similar are commonly used to help provide respiratory protection in a variety of workplaces, including healthcare settings. 3M™ reiterated that a common infection prevention practice employed by healthcare organizations is to utilize FFRs as one-time-use items when worn in the presence of infected patients. In the face of a global pandemic, associated FFR shortage, and based on currently available data, 3M™ does not recommend or support attempts to sanitize, disinfect, or sterilize 3M™ FFRs” (3M announcement, 2020). 3M™ reiterated the importance that such reprocessing methods do not compromise the respirator’s filtration performance or the ability of the respirator to seal to the wearer’s face as intended. Albeit conducting additional research, 3M did not recommend or support any specific FFR disinfection method at this time (3M Science of Life, 2020). However, 3M™ noted that the U.S. Centers for Disease Control and Prevention (CDC) has published guidance on managing respirators during pandemics including the reuse and extended use of respirators at: <https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>

What potential options are available for reprocessing of PPE to address shortage of supply chain arising from this coronavirus disease (COVID19) pandemic?

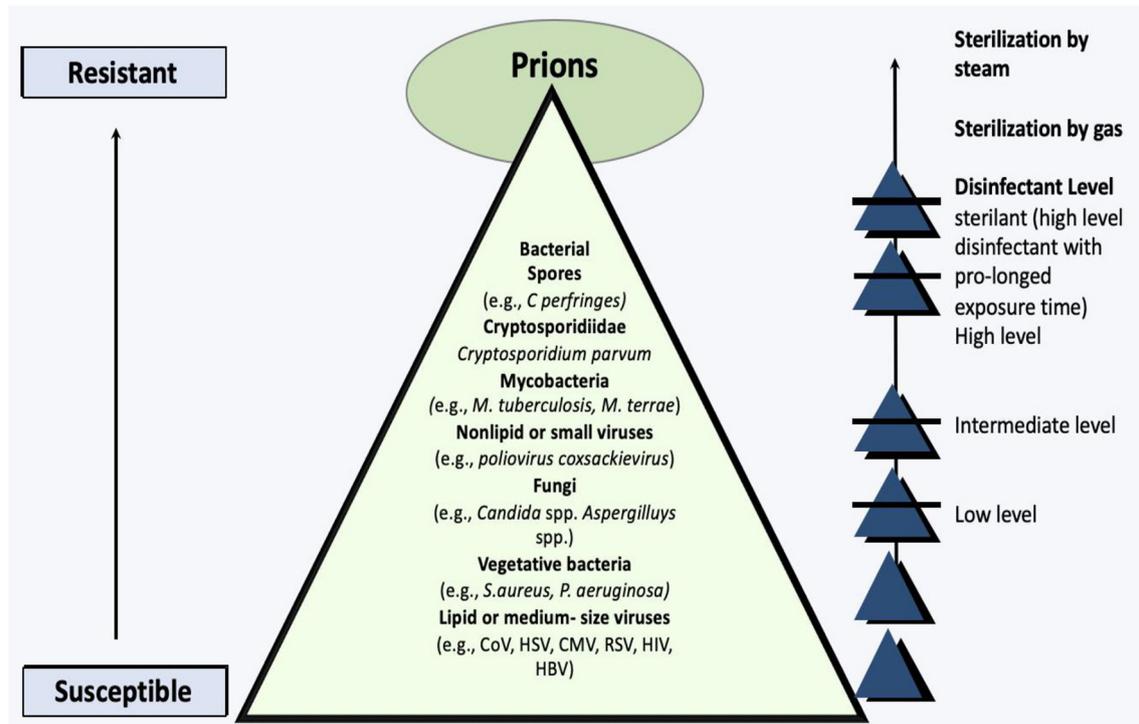


Fig. 4. Pyramid of resistance of increasing resistance to disinfection and sterilization. (Adapted from Wendt et al., 2015)

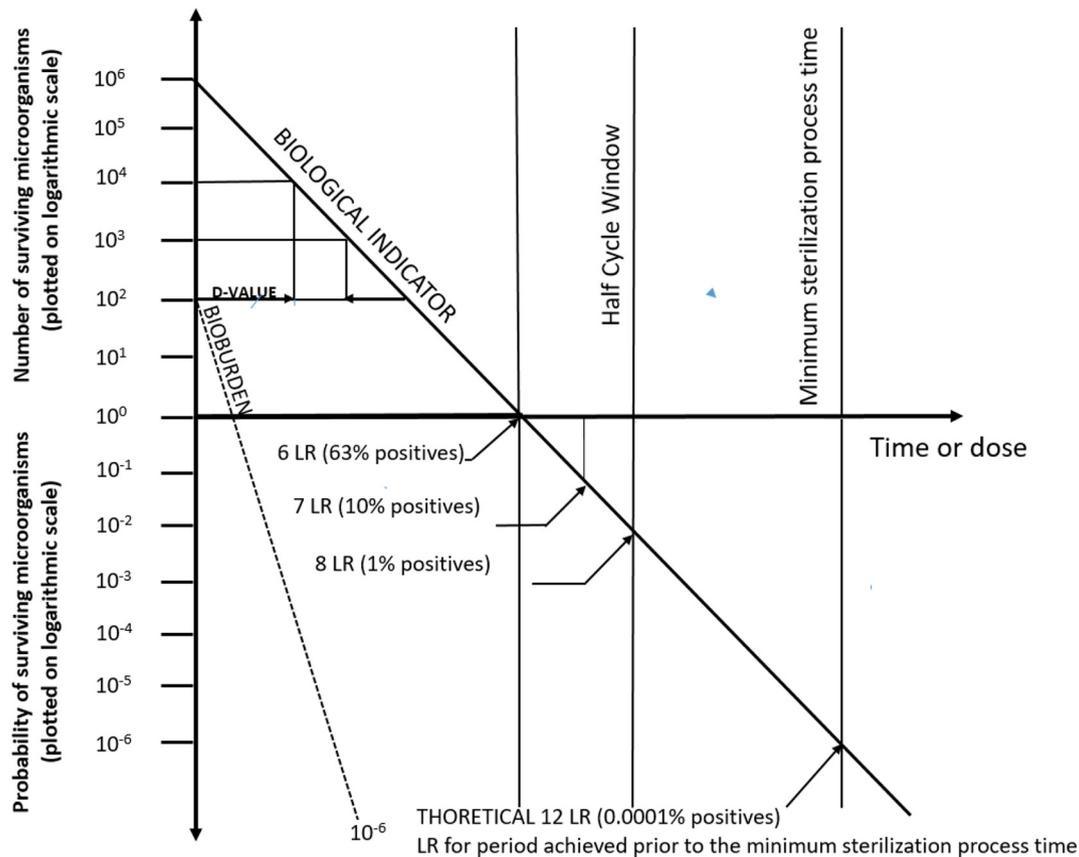


Fig. 5. Sterility assurance level and example of the relationship between biological indicator and product bioburden. For illustration purposes, this graphical representation has been obtained from AAMI TIR16:2017, which was also adapted from McEvoy and Rowan, 2019).

The contingency approach to be adapted by REA_PPE team in Ireland will make provision for the deployment of vaporised hydrogen peroxide, such as for FFRs, on site at or near the hospital. This approach is to align with Columbus-based Battelle process, where it has been reported that up to 10,000 N95 masks will be sterilized by VHP in the United States, which has been authorised by the Food and Drug Administration (FDA, 2020a; FDA, 2020b). Final report for the Bioquell hydrogen peroxide vapour decontamination for reuse of N95 respirators is available at FDA (2020a). The FDA (2020b) also released details on enforcement policy for face-masks and respirators during the coronavirus disease (COVID19) public health emergency (revised April 2020) – guidelines for industry and food and drug administration staff. These are important documents to inform reprocessing of PPE. This Battelle approach involves filling a room or enclosed environment (up to 200m³) with VHP for the treatment of PPE. VHP is an emerging technology for the medical device sterilization industry where its application, opportunities and discussed limitations by McEvoy and Rowan (2019). VHP technology is operative in Ireland now at STERIS AST. However, there is also a pressing need for rapid turn-around for reprocessed PPE on site in the hospitals, such as for critical support in ICU. VHP has potentially additional benefits over use of EtO (which currently sterilizes ca. 50% of medical devices globally) as it is safer and environmentally acceptable from a future sustainability perspective. Use of gamma irradiation and EtO constitutes ca. 95% of the terminal sterilization market (McEvoy and Rowan, 2019). VHP has great promise, but exhibits limitations such as against cellulose-based medical materials whereas EtO has broad material compatibility (McEvoy and Rowan, 2019). There is still uncertainty as to ensuring safe distribution of contaminated PPE for external contract VHP sterilization services for treatment that negates reprocessing of PPE at plant level. The RAPPE team have placed an order for BQ50 VHP system, similar to what is been deployed in the US. Strict procurement rules on purchasing of assets over €25 k were

relaxed to enable rapid uptake of technologies during this pandemic. Recent studies supports that RNA viruses, including coronavirus, are highly susceptible to hydrogen peroxide exposure where significant lethality is achieved with 0.5% hydrogen peroxide (a fraction to what is used in standard contact lens disinfection) in <1 min on glass. Studies recently reported from China have also revealed that introducing hydrogen peroxide inhalation may improve COVID19 patient outcomes (http://www.adledlight.com/news_show34.html).

REAPPE contingency plan also includes provision for deploying UV-C at 254 nm (Nanoclave cabinet, Ireland) and broad-spectrum pulsed light (Claranor, France) technologies for high-level disinfection of PPE. UV-C technology is a very effective technology for disinfection and used extensively by adjacent food and water industries. Given that coronavirus (COV) and other respiratory viruses are significantly less resistant to that of BIs used in sterilization modalities, the use of high to moderate-level disinfection is conceivable sufficient to meet needs for reprocessing of PPE (Fig. 3). These are also turnkey commercial technologies for ease of operation and integration within hospitals that also considers usage by existing decontamination staff and by the manager of HSSD. Efficacy of UV-irradiation technology is governed by the applied UV dose or fluence (W/m²) and is affected by shading where it only inactivates what it irradiates – thus, PPE will need to be turned during treatments (Rowan, 2019). Nanoclave chamber has 32 × 30 W and 16 × 25 W Sylvania UVGI lamps that delivers a UV-C dose of 52 W/m² for 60s. Nanoclave cabinet was shown to disinfect 3-log viral unit of Adenovirus in 3 min at fixed wavelength of 254 nm that targets vital genetic material, such as RNA (Moore et al., 2012). High intensity, pulsed UV technology (PUV) uses broad spectrum pulsed light that is delivered at ca. 50,000 times the intensity of sunlight at contact surface where treatment time is exceptionally short duration, mere seconds (Farrell et al., 2011; Barrett et al., 2016). Previous researchers have demonstrated efficacy for extensive range of pathogens, but PUV also affected

by shading (Rowan et al., 2015; Rowan, 2019). PUV is currently been used for high-throughput food packaging disinfection commercially (Rowan, 2019). PUV has also been shown to be more effective and environmentally-friendly as a surface disinfection system compared with other minimal processing technologies tested, such as pulsed-plasma gas-discharge that produced short-lived oxidising biocidal water (Hayes et al., 2013; Garvey et al., 2015).

There has been limited studies on use of UV-disinfection technology for PPE treatment. 3M™ recently referred to a previously published study by Bergman et al. (2010) where these authors evaluated a multiple (3-cycle) decontamination processing for filtering facepiece respirators (FFRs) (3M Science of Life, 2020). The UV-germinal-irradiation (UVGI) method described was operated for 30 min at 254 nm (15-min per side) for 3M™ 1860 and 1870 FFRs where straps on 1870 lost elasticity with a strong burning odour, and the nosefoam compressed on 1860 FFR model. This study did not assess the efficiency of disinfection method to inactivate microorganisms where it would be relevant to report on UV dose over treatment regime. Prolonged and excessive exposure using low-pressure UV light source can produce significant thermal effects along with material damage over repeated use. Bergman et al. (2010) also reported on the use various other unknown FFR makes and models and reported no observable physical change using same (1) UVGI for 15 min at 254 nm using one side of FFR facing lamp with strap removed, (2) ethylene oxide for 1 h in 100% EtO Sterilizer, and (3) VHP treatment for 15 min dwell, 125 min total cycle at 8 g/m³ concentration. However, it is also unclear as to what specific FFR models were used and functionality post treatments. Fisher and Shaffer (2011) reported on the development of a method to assess model-specific parameters for ultraviolet-C (UV-C, 254 nm) decontamination of filtering facepiece respirators (FFRs). UV-C transmittance was quantified for the distinct composite layers of six N95 FFR models and used to calculate model-specific α -values, the percentage of the surface UV-C irradiance available for the internal filtering medium (IFM). Circular coupons, excised from the FFRs, were exposed to aerosolized particles containing MS2 coliphage and treated with IFM-specific UV-C doses ranging from 38 to 4707 J/m². Models exposed to a minimum IFM dose of 1000 J/m² demonstrated at least a 3 log reduction in viable MS2. Model-specific exposure times to achieve this IFM dose ranged from 2 to 266 min. Overall, Fisher and Shaffer (2011) found UV-C transmits into and through FFR materials. Log reduction of MS2 was a function of model-specific IFM UV-C doses. The supply of National Institute for Occupational Safety and Health (NIOSH)-certified N95 filtering facepiece respirators (FFRs) may become limited during an influenza pandemic [Institute of Medicine (U.S.) Committee on the Development of Reusable Facemasks for Use During an Influenza (cited in Fisher and Shaffer, 2011)]. Extending the lifetime of FFRs for multiple uses (e.g. multiple donnings) may help to alleviate the supply demand (Viscusi et al., 2007, 2009a, 2009b). Fisher and Shaffer (2011) also advocated that an option that may permit FFR reuse is the decontamination or removal of the infectious material from the FFR through one or more physical or chemical treatments. For this option to be practical, the decontamination treatment must maintain FFR fit and filtration performance and not leave hazardous residues. Other desired attributes for a decontamination method for FFR reuse would be low cost, high throughput and ease of use (Viscusi et al., 2009b). UVGI technology has been suggested as a viable option for FFR reprocessing application where nine FFR models were evaluated for changes in physical appearance, odour and laboratory performance (filter aerosol penetration and filter airflow resistance) following simulated decontamination using five different methods, including UVGI (Viscusi et al., 2009b). In latter study, UV-C treatment did not affect the filter aerosol penetration, filter airflow resistance or physical appearance of the FFRs. UV-C, as a decontamination method, is affected by several parameters, including the topography of the contaminated surface and the location of the microorganisms within the substrate. The use of UV-C for surfaces is mainly for hard, nonporous substrates (Fisher and Shaffer, 2011). Therefore,

at this time of writing, while UVGI and PUV methods appear promising, no validated decontamination methods for FFRs exist.

Lessons can also be gleaned from best-published information and hurdles arising from minimal processing technologies that have been exploited by the food industry for commercial applications (Deng et al., 2019). These technologies rely upon reduced severity of non-thermal treatments that equate to moderate of high-level decontamination (Franssen et al., 2019; Gerard et al., 2019). However, review of best-published approaches suggest that these technologies, in their current configurations, would not be suited for PPE reprocessing. These unsuitable technologies include high hydrostatic pressure, pulsed electric fields, pulsed-plasma gas-discharge, ultrasound and so forth (Deng et al., 2019). Also, the majority of chemical biocides deployed in the food industry as liquid decontaminants for surface-treatments would not be effective for PPE as these cannot be easily used in the hospital setting. However, Kampf et al. (2020) recently reported that coronaviruses persist on inanimate surfaces, such as glass, plastic and metal for up to 9 days, but they are efficiently inactivated on these surfaces with use of 62–72% alcohol, 0.5% hydrogen peroxide, or 0.1% sodium hypochlorite within 1 min exposure. Use of high level disinfection with Actichlor-plus served as both a detergent and biocide for reprocessing Starmed hoods used by COVID19 patients in ICU. Testing of Starmed hoods in heated washer at 90°C caused damage to the PVC component. High level disinfection was applied in advance of lead-time for VHP and UV technologies arriving to HSSD and as use of sodium hypochlorite was suggested as possible approach to cleaning and disinfecting 3M™ powered air purifying respirators following potential exposure to coronaviruses (<https://multimedia.3m.com/mws/media/17939560/cleaning-and-disinfecting-3m-paprs-following-potential-exposure-to-coronaviruses.pdf>). There is potential for use of combined HEPA filtration with UV light disinfection for air disinfection in critical areas that will reduce aerobiology or airborne bioburden. However, consideration would need to be given to efficacy of reduction of COVID19 or similar respiratory viruses.

Perceived benefits and future directions for the control of COVID19 with a focus on addressing shortages in supply chain.

The perceived indicative benefits of deploying solutions for reprocessing PPE to address front-line shortage have listed in terms of making potentially significant qualitative and quantitative difference are listed in Table 2. The world, as we know it, will be a changed place post COVID19, where there will be greater focus on mitigation planning for managing pandemics nationally and transnationally with either increased provision and/or less reliance on one-time-use medical devices and PPE. Future provision in hospitals and healthcare will also consider duality of sterilization treatments with reduced processing capability for to deliver if required, high or moderate level of disinfection. There will be increased emphasis on convergence of technologies and knowledge from adjacent disciplines, such as the food industry, to improve our understanding of minimal processing linked to sterilization. This will be framed upon increased demand for evidence-based research and shared publications so to inform validation and new regulations using potentially new smart innovations and services or adapting existing modalities. It is envisaged that there will be a commensurate push to promote more eco-innovations, along with review of exiting sterilization processes, for sustainability of resources and to meet existing needs arising and emerging from this COVID19 pandemic. This pandemic also highlights the value of converging areas of expertise that will inform education and workforce training processes. This pandemic also highlights that despite staggering advancements in innovation, society is still very vulnerable to global treats to our health from what is a microscopic virus. Commensurately, our collective creativity and ingenuity will enables us to countermeasure these challenges.

In summary, providing solutions for the shortages in supply chain for one-time-use PPE is extremely complex. Preference would always be for usage of single-use items as described by the manufacturers as ensuring the safety of our healthcare workers is paramount. Logical

Table 2
Perceived qualitative and quantitative differences to healthcare provision by deploying reprocessing of PPE to address shortages during COVID19 pandemic.

Qualitative	Quantitative
Reduction of infection rates seen in HCW resulting in sustainability of scale and capacity to underpin national strategic plan for addressing the COVID-19 pandemic	Increased availability of PPE and other critical care equipment
Sustainable enhancement of flexible decontamination process linked to (new) education provision in order to hurdle challenges and bottle-neck presented by shortfall in single use PPE for HCW	Reduced impact on environment with less incineration using sustainable eco-sustainable treatment modalities
New transferrable knowledge for replication across healthcare/medtech sectors with global orientation	New technologies and strategies identified as countermeasures to help address and manage COVID-19 – particularly for high risk situations, such as intensive care
Confidence in maintaining health outcomes for frontline HCW and patients	Potential generation of new IP and innovations
Cross-cutting knowledge acquisition from converging areas to address this specific solutions and to inform future policies surrounding preparedness for future pandemics	Increased number of trained experts equipped with new converging knowledge nationally with global orientation
Evolving medical device industry by way of informing need for operating sterilization modalities under reduced processing conditions for this need and for future opportunities	Reduced economic burden in terms of offering alternative options to procurement where there is global pressure on supply chain
Positive disposition towards related mental health issues arising due to uncertainty of existing technologies and provision for front line healthcare staff	Increased number of new policies and guidelines to address pandemic

first step solutions would be to improve communication lines for better stock management of PPE that exploits webpage and mobile phone app development along with dual bespoke production of PPE using medical grade materials where gaps are identified, such as ventilators. However, a pandemic foists untold and unexpected demands on society that includes provision or contingency planning for reprocessing PPE. Under such situations, it is imperative to follow closely advice from original manufacturer of PPE on material composition and design features with view to making reprocessed PPE (where possible), fit for purpose. This also includes adhering to close advice provided by regulators, such as FDA. The majority of existing in house hospital, external terminal sterilization and adjacent minimal processing technologies (as used in food industry) will not be effective for reprocessing PPE. However, review of best evidence suggest that preferred candidate methods for meeting this gap appears to be use of vaporised hydrogen peroxide (VHP) and UV irradiation technologies, which are likely be deployed in the Republic of Ireland.

Funding

Science Foundation Ireland – Rapid COVID19 fund Grant with CURAM medical device Centre.

Authors' contributions

NR and JGL conceptualised the manuscript. NR drafted the manuscript. Both authors read, edited, and approved the final manuscript.

Consent for publication

Not applicable.

Declaration of competing interest

The authors declare that they have no competing or conflict of interests.

Acknowledgements

The authors would like to thank Dr. Emma Murphy for assisting with graphics editing of figures.

References

- 3M Science of Life, 2020. Disinfection of Filtering Facepiece Respirators, Announcement. <https://multimedia.3m.com/mws/media/18165760/disinfection-of-disposable-respirators-technical-bulletin.pdf>, Accessed date: 4 April 2020.
- Barrett, M., Fitzhenry, K., O'Flaherty, V., Dore, W., Keaverey, S., Cormican, M., Rowan, N., Clifford, E., 2016. Detection, fate and inactivation of pathogenic norovirus employing settlement and UV treatment in wastewater treatment facilities. *Sci. Total Environ.* 568, 1026–1036.
- Bergman, M.S., Viscusi, D.J., Heimbuch, B.K., Wander, J.D., Sambol, A.R.I., Shaffer, R.E., 2010. Evaluation of multiple (3-cycle) decontamination processing for filtering facepiece respirators. *J. Engineered Fibers Fabrics* 5, 33–41.
- Carty, M.F., DiNicolantonio, J.J., 2020. Nutraceuticals have potential for boosting the type 1 interferon response to RNA viruses including influenza and coronavirus. *Prog. Cardiovasc. Dis.* <https://doi.org/10.1016/j.pcad.2020.02.007> available online.
- Chen, Y., Neff, M., McEvoy, B., Cao, Z., Pezzoli, R., Murphy, A., Gately, N., Hopkins, M., Rowan, N.J., Devine, D.M., 2019. 3D printed polymers are less stable than injected moulded counterparts when exposed to terminal sterilization processing using novel vaporized hydrogen peroxide and electron beam processes. *Polymer* 183. <https://doi.org/10.1016/j.polymer.2019.121870>.
- Deng, L.-Z., Mujumdar, A.S., Pan, Z., Vidyarthi, S.K., Xu, J., Zielinsek, M., Xiao, H.W., 2019. Emerging chemical and physical disinfection technologies of fruits and vegetables: a comprehensive review. *Crit. Rev. Food Sci. Nutr.* <https://doi.org/10.1080/10408398.2019.1649633>.
- Farrell, H., Hayes, J., Laffey, J., Rowan, N., 2011. Studies on the relationship between pulsed UV light irradiation and the simultaneous occurrence of molecular and cellular damage in clinically-relevant *Candida albicans*. *J. Microbiol. Methods* 84 (2), 317–326.
- FDA, 2020a. Final report for the bioquell hydrogen peroxide vapor (HPV) decontamination for reuse of N95 respirators. <https://www.fda.gov/media/136386/download>, Accessed date: 4 April 2020.
- FDA, 2020b. Enforcement Policy for Face Masks and Respirators during the Coronavirus Disease (COVID19) Public Health Emergency (Revised), April, 2020. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health>, Accessed date: 4 April 2020.
- Fisher, E.M., Shaffer, R.E., 2011. A method to determine the available UV-C dose for the decontamination of filtering facepiece respirators. *J. Appl. Microbiol.* 110 (910), 287–295.
- Franssen, F., Gerard, C., Cozma-Petru, A., Viera-Pinto, M., Jambak, A.R., Rowan, N.J., Paulsen, P., Rozycki, M., Tsynes, K., Rodriguez-Lazaro, D., Robertson, L., 2019. Inactivation of parasite transmission stages – efficacy of treatments on food of animal origin. *Trends Food Sci. Technol.* 83, 114–128.
- Garvey, M., Hayes, J., Clifford, E., Rowan, N., 2015. Ecotoxicological assessment of pulsed ultraviolet light-treated water containing microbial species and *Cryptosporidium parvum* using a microbiotest battery. *Water Environment Journal* 29 (1), 27–35.
- Gerard, C., Franssen, F., La Carbona, S., Menterio, S., Cozma-Petru, A., Utaaker, K.S., Jambak, A.R., Rowan, N.J., Rodriguez-Lazaro, D., Nasser, A., Tsynes, K., Robertson, L.J., 2019. Inactivation of parasite transmission stages – efficacy of treatments on foods of non-animal origin. *Trends Food Sci. Technol.* 91, 12–23.
- Hayes, J., Kirf, D., Garvey, M., Rowan, N., 2013. Disinfection and toxicological assessment of pulsed UV and pulsed-plasma gas-discharge treated water containing the water-borne protozoan enteroparasite *Cryptosporidium parvum*. *J. Microbiol. Methods* 94 (3), 325–337.
- Kampf, G., Todt, D., Pfaender, S., Steinmann, E., 2020. Persistence of coronavirus on inanimate surfaces and their inactivation with biocidal agents. *J. Hosp. Infect.* 104 (3), 246–257.
- Li, Q., Guan, X., Wu, P., Wang, X., Zhou, L., Tong, Y., Ren, R., Leung, K.S.M., Lau, E.H.Y., Wong, J.Y., Xing, X., Xiang, N., Wu, Y., Li, C., Chen, Q., Li, D., Liu, T., Zhao, J., Liu, M., Tu, W., Chen, C., Jin, L., Yang, R., Wang, Q., Zhou, S., Wang, R., Liu, H., Luo, Y., Liu, Y., Shao, G., Li, H., Tao, Z., Yang, Y., Deng, Z., Liu, B., Wu, J.T., Gao, G.F., Cowling, B.J., Yang, B., Leung, G.M., Feng, M., 2020. Early transmission dynamics in Wuhan, China, of novel coronavirus-infected pneumonia. *N. Engl. J. Med.* 382, 1199–1207. <https://doi.org/10.1056/NEJMoa2001316>.
- McEvoy, B., Rowan, N.J., 2019. Terminal sterilization of medical devices using vaporized hydrogen peroxide: a review of current methods and emerging opportunities. *J. Appl. Microbiol.* 127 (5), 1403–1420.
- Meltzer, M.I., Cox, N.J., Fukuda, K., 1999. The economic impact of pandemic influenza in the United States: priorities for intervention. *Emerg. Infect. Dis.* 5, 659–671. <https://doi.org/10.3201/eid0505.990507>.
- Mitchell, R., Ogunreai, T., Astratianakis, S., Bryce, E., Gervais, R., Gravel, D., Johnson, L., Leduc, S., Roth, V., Taylor, G., Vearcombe, M., Weir, C., 2012. Impact of the 2009 influenza A (H1N1) pandemic on Canadian health care workers: a survey on vaccination, illness, absenteeism, and personal protective equipment. *Am. J. Infect. Control* 40 (7), 611–616.

- Moore, G., Ali, S., Cloutman-Green, E.A., Bradley, C.R., Wilkson, M.A., Hatley, J.C., Fraise, A.P., Wilson, A.P., 2012. Use of UVC radiation for disinfecting non-critical patient care items – a laboratory assessment of the Nanoclave Cabinet. *BMC Infect. Dis.* 3, 12–14.
- Rothan, H.A., Byrareddy, S.N., 2020. The epidemiology and pathogenesis of coronavirus disease (COVID-19) outbreak. *J. Autoimmun.* <https://doi.org/10.1016/j.jaut.2020.102433> In press.
- Rowan, N.J., 2019. Pulsed light as an emerging technology to cause disruption for food and adjacent industries – quo Vadis? *Trends Food Sci. Technol.* 88, 316–332.
- Rowan, N.J., Valdramidis, V.P., Gomez-Lopez, V.M., 2015. A review of quantitative methods to describe efficacy of pulsed light generated inactivation data that embraces the occurrence of viable but non culturable state microorganisms. *Trends Food Sci. Technol.* 44 (1), 79–92.
- Schoeman, D., Fielding, B.C., 2019. Coronavirus envelope protein – current knowledge. *Virology*. <https://doi.org/10.1186/s12985-019-1182-0>.
- Swaminathan, A., Martin, R., Gamon, S., Aboltins, C., Althan, E., Braitberg, G., Catton, M.G., Cooley, L., Dwyer, D.E., Edmonds, D., Eisin, D.P., Hosking, K., Hughes, A.J., Johnson, P.D., Maclean, A.V., O'Reilly, M., Peter, S.E., Stuart, R.L., Moran, R., Lindsay-Grayson, M., 2007. Personal and protective equipment and antiviral drug use during hospitalization for suspected Avian or Pandemic Influenza. *Emerg. Infect. Dis.* 13 (10), 1511–1547.
- U.S. Centers for Disease Control and Prevention (CDC), 2008. Disinfection of Healthcare Equipment –Guideline for Disinfection and Sterilization in Healthcare Facilities. 2008. <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/healthcare-equipment.html>, Accessed date: 4 April 2020.
- Viscusi, D.J., King, W.P., Shaffer, R.E., 2007. Effect of decontamination on the filtration efficiency of two filtering facepiece respirator models. *J Int Soc Respir Prot* 24, 93–107.
- Viscusi, D.J., Bergman, M.S., Sinkule, E., Shaffer, R.E., 2009a. Evaluation of the filtration performance of 21 N95 filtering face piece respirators after prolonged storage. *Am. J. Infect. Control* 37, 381–386.
- Viscusi, D.J., Bergman, M.S., Eimer, B.C., Shaffer, R.E., 2009b. Evaluation of five decontamination methods for filtering facepiece respirators. *Ann. Occup. Hyg.* 53, 815–827.
- Wendt, C., Frei, R., Widmer, A., 2015. Decontamination, disinfection, and sterilisation. In: Jorgensen, J., Pfaller, M., Carroll, K., Funke, G., Landry, M., Richter, S., Warnock, D. (Eds.), *Manual of Clinical Microbiology*, Eleventh edition ASM Press, Washington, DC, pp. 183–216. <https://doi.org/10.1128/9781555817381.ch13>.