Update to device-related pressure ulcers: SECURE prevention. COVID-19, face masks and skin damage

Abstract: The 2019 novel coronavirus disease (COVID-19) pandemic has brought the effects of device-related pressure ulcers (DRPU) into sharp focus. With the increased use of personal protective equipment (PPE), including face masks, continuous positive airway pressure (CAPP) masks and other devices, the incidence of DRPUs among health professionals and patients alike has risen starkly. As such, the *Journal of Wound Care* (*JWC*) consensus document, *Device-related pressure ulcers: SECURE prevention*, published in February 2020, is more relevant than ever. To help support patients and frontline health professionals, *JWC* is republishing the consensus in a digital format, along with a new introductory article outlining the DRPU risks posed by PPE and other medical devices used by patients and health professionals during the pandemic, and how the skin damage can be avoided. The aim is to provide frontline staff with a clear, simple strategy on how to prevent the risk of personal skin damage and/or DRPU during the pandemic, as well as point them in the direction of more indepth guidance on long-term strategies for prevention, for both themselves and patients.

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acute respiratory distress syndrome • COVID-19 • device-related pressure ulcer • face masks • personal protective equipment • skin damage

Until now, device-related pressure ulcers (DRPUs) and measures to prevent them have been concerned with the effect of devices on patients. However, in the 2019 novel coronavirus disease (COVID-19) era, things have changed and it is now health professionals who require help in preventing skin damage and DRPUs. The COVID-19 pandemic has brought the effects of DRPUs into sharp focus. With such a considerable global rise in the numbers of patients requiring intensive care and the increased use of prone positioning to treat acute respiratory distress syndrome (ARDS), the incidence of DRPU is expected to increase. In addition, a new and common type of DRPU associated with the pandemic appeared among medical workers is that of facial injuries caused by personal protective equipment (PPE). These injuries are primarily caused by medical face masks and goggles, although reports are now emerging of PPE-induced skin damage in other areas including the armpit, groin and extremities.[1] The same study, by Jiang et al. published 27 April 2020, reported the overall prevalence of skin injuries caused by PPE in medical staff was 42.8% (95% confidence interval (CI)41.30–44.30%), with three distinct types reported: DRPU; moist-associated skin damage (MASD); and skin tears. Furthermore, logistic regression indicated that sweating (95%CI for odds ratio (OR) 87.52–163.11), daily wearing time (95% CI for OR 1.61–3.21), being male (95% CI for OR 1.11–2.13) and wearing grade 3 PPE (95% CI for OR 1.08–2.01) were associated with these skin injuries.

This PPE-related tissue damage manifests as a skin wound under the contours of the gear. This skin damage has been described as skin tears, DRPU, friction injury (lesion), irritant contact dermatitis and MASD.[1,2] Clearly, in clinical settings, these PPE-related injuries introduce the risk that bacteria, fungi and viruses, including the coronavirus (COVID-19), could penetrate through the skin and reach the bloodstream, with potentially fatal results to the affected health professionals.[3,4] As such, the recently published *Journal of Wound Care* (*JWC*) international consensus document,[5] *Device-related pressure ulcers: SECURE prevention,* is more relevant than ever. To help support patients, frontline health professionals and those who work at the more peripheral circles of the healthcare services, *JWC* is now republishing the consensus document[5] in a digital format, along with this introductory article which highlights the DRPU risks imposed by PPE. This also addresses other medical devices used to treat patients in the context of the COVID-19 pandemic. The aim of this article is to provide health professionals and non-medical workers with clear and simple guidance on how to prevent the risk of DRPU during this pandemic, as well as to direct them to further indepth information on strategies for prevention of DRPUs, as a update to the consensus document.[5]

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Global increase in patients requiring intensive care

Based on data from Italy, 12% of all COVID-19 positive cases required admission to an intensive care unit (ICU).[6] The ICU length of stay with this diagnosis is relatively long. As of 5 May 2020, there are over 3.7 million COVID-19 positive cases globally,[7] indicative of approximately 444,000 ICU patients who have added to the healthcare system worldwide in about two months (based on the Italian estimation of 12%).[6] Diagnosis and treatment of each of these new ICU patients will involve at least one (and likely several) of the medical devices and equipment identified in our consensus document,[5] strongly associated with DRPUs (Table 1).

A conservative (midrange) estimate of the incidence of DRPUs associated with use of the above equipment in ICUs is 20% and a pessimistic estimate is 40%,[8] which implies that COVID-19 positive patients in ICU could experience between 89,000 and 178,000 hospital-acquired DRPUs in connection with the pandemic. The costs of treating these new wounds, considering again a conservative (midrange) estimate of US$5000 per DRPU case,[9] would be somewhere in the range of US$445–890 million (as of 5 May 2020), without considering indirect costs and possible litigation. In addition, prone position ventilation for sessions of approximately 9–16 hours (in between standard supine ventilation periods) has become a standard of care for COVID-19 positive patients in the ICU with ARDS, to improve their lung mechanics and gas exchange.[10] However, prone positioning applies localised elevated forces to delicate organs and tissue structures, particularly to the facial tissues and eye globes (but also to the breasts for females, the lower costal margins, the anterior iliac crests, the genitalia for males, the knees, the shins and the dorsal foot). Accordingly, COVID-19 positive patients with ARDS who are positioned prone are at a higher risk of DRPUs; the rate of DRPUs acquired in prone position in general is over three times the corresponding risk for supine postures.[11]

Use of a protective suit that includes prophylactic dressings to protect the eye globes, forehead and chin, positioners which offer good immersion and envelopment to adequately distribute the head weight, and drying sheets to wick away salivary secretion fluids for moisture management are good clinical practices aimed at reducing the risk of facial DRPUs in prone positioning.[12–15]

The steep rise in the numbers of ICU patients, with the associated increased interactions with risk-causing devices, and the growing use of prone positioning in ICUs to treat ARDS, together make the consensus document[5] pivotal in the current crisis.

Also, it appears that COVID-19 with its fundamental characteristics of a cytokine release syndrome ('cytokine storm'), endothelial dysfunction, drop in oxygen saturation, hypercoagulability leading to microthromboses and potential effects on cardiac output interacts with two of the three primary aetiological factors in DRPUs, i.e. inflammation and ischaemia (Fig 1).[16–18]

Table 1. Medical devices and equipment identified to be strongly associated with device-related pressure ulcers (DRPU)[3*]

Medical device/equipment
Continuous positive airway pressure (CPAP) masks
Endotracheal tubes and tube fixators
Nasogastric tubes
Oxygen saturation probes
Temperature probes
Electrocardiography (ECG) electrodes
Arterial lines
Other intravenous cannulas
Blood pressure cuffs
Urinary catheters
Fecal containment devices
Identity bands

*Note: this is not an exhaustive list

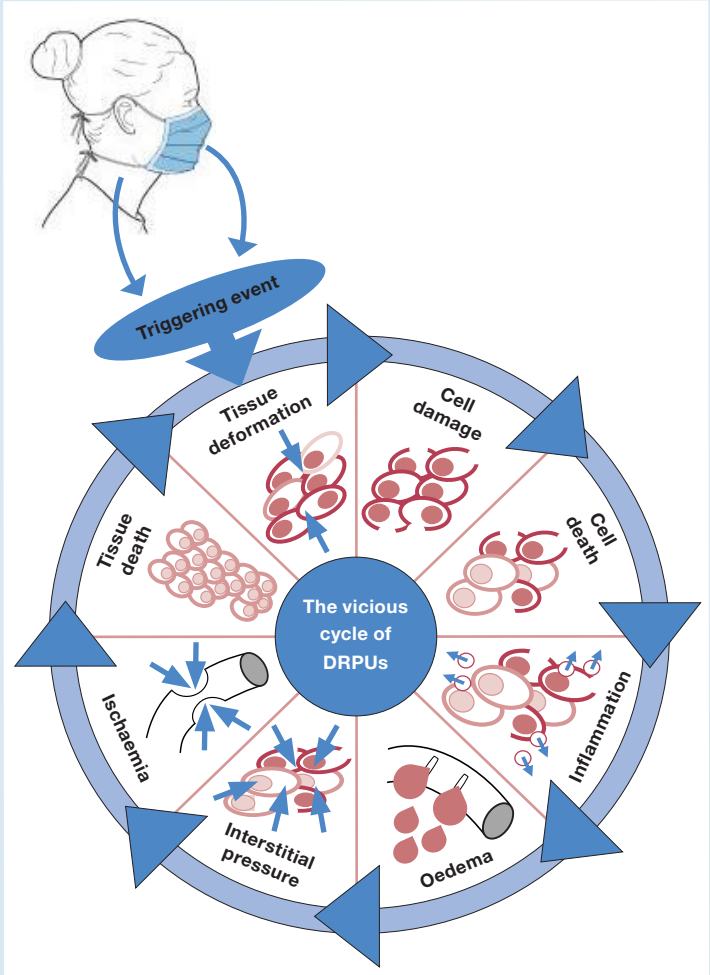
DRPU extended to protective equipment

The current pandemic requires widespread use of PPE, not only by those medical workers who are in direct contact with COVID-19 patients, but also, by hospital personnel in the more peripheral areas of care and maintenance, such as receptionists and cleaners, as well as those providing food, security, technical support and other essential services. Hence, the numbers of professionals and service providers now needing to use PPE, which is in continuous contact with skin and, specifically, medical face masks and goggles, has increased remarkably. In parallel, skin tears or friction lesions caused due to intensive use of these types of PPE have been mentioned and photographed extensively in the general media worldwide since the outbreak of the pandemic in China, and in the past several weeks this problem has also begun to be reported in the wound and dermatology literature.[3,19,20] The clinical teams engaged in all types of COVID-19 care settings are consistently reporting facial skin damage and wounds at the dorsum of the nose and sometimes on the cheeks.[3,19,20]

Skin damage caused by PPE may result in COVID-19 infection

Yan et al.[21] identified mucosal membranes as the most common entry for the coronavirus infection, with the otic canal having the lowest risk of transmission. Although early reports from Darlenski and Tsankov[19] that specific skin changes due to COVID-19 infection have not been described, iatrogenic secondary involvement of the skin could be expected. This is now supported by two case reports of cutaneous manifestation of COVID-19 on the skin.[22,23] Darlenski and Tsankov further highlight that individuals with

Fig 1. The damage spiral ('vicious cycle') of a device-related pressure ulcer (DRPU) formation. Sustained cell and tissue deformations are always the triggering event and driving cause for the primary tissue damage. Accordingly, alleviating the exposure to sustained tissue deformations (including by means of reducing the coefficient of friction at the skin-device interface using approved lubricants, or redistributing the loads applied by a device using prophylactic dressings) is effective for maintaining the integrity and health of skin



autoimmune and chronic inflammatory disorders, such as psoriasis, atopic dermatitis, lupus, scleroderma and hidradenitis suppurativa, may require immunosuppressive therapy.[19] Health professionals with one of these disorders must be acutely aware of preventing skin damage if they are wearing PPE for prolonged periods of time, and must relieve the mechanical loads applied by this equipment every two hours or less, if there is sensation of discomfort or pain. However, there needs to be a reasonable balance between the DRPU prevention measures taken to protect the skin and the (low, but present) risk of coronavirus infection involved in every change, manoeuvre or manipulation of the PPE. Accordingly, health professionals should also consider the risk of skin damage leading to a portal for infection by the coronavirus against the risk of too rapid, excessively frequent or otherwise unsafe changes of PPE that may lead to infection. This always requires use of good judgment depending on the setting but, generally, health professionals should not bring themselves to a level of pain or injury as a consequence of wearing PPE.

Wang and Parish[24] stated that health professionals wearing PPE for extended periods of time have reported skin changes, most commonly the nasal bridge, cheeks, forehead and hands, including erythema, papules and maceration, leading to burning, itching and stinging and sometimes, to skin tears.

Increased hand washing both for health professionals and the general public has also caused reports of skin irritation and dermatitis; two-thirds of healthcare workers washed their hands more than 10 times a day, but only 22% applied skin protective cream.[25]

Injuries due to PPE are DRPUs

The damage cascade occurring at the cell and tissue scales when a DPRU develops is described in detail in the consensus document,[5] for example in the context of wearing a continuous positive airway pressure (CPAP) masks which deform the facial soft tissues, indented by the mask contours and which are distorted between the skull structure, nasal cartilage and mask frame. Sustained distortion of the cells residing in these facial tissues causes direct cell-scale damage, which triggers secondary inflammatory damage and tertiary ischaemic damage.[5] This damage spiral is also illustrated in Fig 1.

From an aetiological perspective, there is high similarity between the damage caused by CPAP masks and the damage caused due to prolonged use of PPE, especially medical face masks (including N-95 respirators) and protective goggles. The face mask materials, with their relatively stiff flange and straps, and the near rigid goggle frames mechanically indent and damage facial skin.[26–29]

Speaking while wearing a mask or goggles, in particular, contracts different facial skeletal muscles and dynamically changes the face topography, which may cause the straps of the PPE to tighten and the mask/goggle frames to frictionally slide upon the facial skin at the contact regions. Hence, skin tissue is exposed to continuous static (strapping) and dynamic (sliding) frictional forces, causing considerable shearing in skin and subdermal tissues. The latter effect is further escalated by profuse perspiration due to the intense mental stress and workload that individuals wearing the equipment are experiencing—the coefficient of friction (COF) between the skin and PPE, and thereby, the magnitudes of the static and dynamic frictional forces at the skin-PPE interfaces rise. Simultaneously, the accumulation of humidity at the skin-PPE interface softens the stratum corneum and dissolves the molecular collagen crosslinks in the dermis.[5] The combination of high frictional forces and weakened structure and function of the skin, result in substantial tissue deformation and cell distortion. These sustained cell and tissue deformations trigger cell death and tissue

damage mechanisms described in the consensus document[5] and depicted in Fig 1.

There is, however, a fundamental difference between the tissue damage spiral under ventilation masks of an insensate or sedated ICU patient (including patients who are unable to communicate) and the tissue damage potential with respect to PPE applied on the face of healthy medical workers. The extent of tissue damage will be smaller and nearly always reversible under PPE, since a PPE user (who is not a patient) is able to sense and respond to discomfort and pain, and thereby terminate the cycle shown in Fig 1. That said, similar to the medical devices for diagnosis or treatment reviewed in the consensus document,[5] PPE has never been optimised for tissue deformation exposures, nor was it designed for such intensive, long-duration and continuous use, and where staff are tightening them even more than necessary to seal their airways and eyes, but at a risk of compromising their skin subdermal health. It should also be noted that single-use face masks were not originally designed to be worn continuously for several hours and or designed to be used when treating different patients without first being changed, so the pattern of use of PPE that has developed due to the shortage of supplies, contributes to the facial skin damage seen among health professionals.

Clinical and biomechanical principles of skin protection applied in practice

Healthy facial skin is more resistant to the compressive and frictional forces applied during prolonged and intensive use of PPE. Loss of facial skin integrity, even on a microscopic scale, creates a portal of entry for pathogens including the coronavirus, but this also applies to other hospital-acquired bacterial, viral or fungal infections.[4] The following information is intended to support health professionals in protecting their facial skin through correct usage habits, application of skin barriers and prophylactic dressings.

Practical recommendations for medical workers

The dos and don'ts in using face masks and goggles

Each country has developed and published guidance regarding the use of masks and goggles; this guidance must be adhered to. An example of high-quality and rigorous national guidance is the informative document published by the Portuguese Wound Care Association,[2] which is freely available online in both Portuguese and English versions. The association's work,[2] led by Dr. Paulo Alves, a member of the consensus document's expert panel,[5] has been internationally reviewed by experts (author AG was a member of the international committee overseeing the development of the association's document) and provides excellent, detailed information including graphic examples with regards to specific prophylactic measures. In addition, the World Health Organization offer general advice to health professionals stating that:[30]

- A medical mask must be worn when entering a room where patients have suspected or confirmed COVID-19
- Use a particulate respirator at least as protective as a US National Institute for Occupational Safety and Health certified N95, European Union standard FFP2, or equivalent, when performing or working in settings where aerosol-generating procedures, such as tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual ventilation before intubation and bronchoscopy are performed.

WHO also provide clear advice regarding appropriate use and dispose of masks to avoid any increase in transmission (Fig 2). When putting on a mask:

- Place the mask carefully, ensuring it covers the mouth and nose, and tie it securely to minimise any gaps between the face and the mask
- Avoid touching the mask while wearing it.

To remove the mask using the appropriate technique (Fig 2):

- Do not touch the front of the mask but untie it from behind
- After removal or whenever a used mask is inadvertently touched, clean hands using an alcohol-based hand rub or soap and water if hands are visibly dirty
- Replace masks as soon as they become damp with a new clean, dry mask
- Do not reuse single-use masks
- Discard single-use masks after each use and dispose of them immediately upon removal.

NHS England and NHS Improvement[31] and Public Health England[32] recommend that before undertaking any procedure, staff should assess any likely exposure and ensure their PPE is adequate for protection against the risks associated with the specific procedure or task being undertaken. All equipment should be fitted correctly before commencement of any intervention. If possible, masks should be removed every two hours to relieve pressure and shear from the skin. In addition, if masks or any other PPE feels uncomfortable it should be removed as soon as possible in a safe area and the skin should be checked for any signs of damage. Clearly, new equipment should be properly and comfortably mounted before returning to the clinical area.

NHS England[31] further recommend keeping the skin clean and well hydrated, and using a barrier skin wipe/skin protectant if equipment is to be worn for a prolonged period of time to protect against excess moisture. If a moisturising cream is being used, this should be applied at least 30 minutes before applying the PPE. Goggles and face protection (Fig 3) should be worn if blood and/or body fluid contamination to the eyes/face is anticipated or likely—for example, by members of a surgical team. Additionally, goggles and face protection should always be used during aerosol generating procedures. It should be emphasised in this context that regular corrective spectacles are not considered eye protection. Any face protection must not be impeded by facial hair or beards, and accessories such as piercings or false eyelashes.

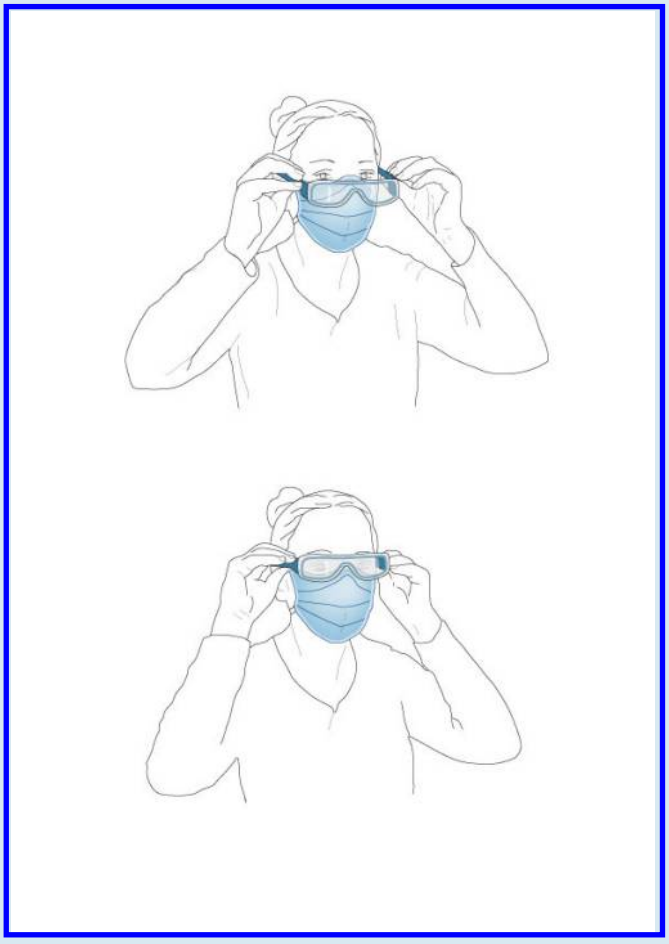
Fig 2. Correct application and removal of face masks

Use of friction-reducing skin protectants

Approved and over-the-counter skin protectants that decrease the COF through lubrication should be an effective, widely available and inexpensive means of reducing the frictional forces applied by PPE on facial skin. Reduction of the COF through lubrication is a simple and straightforward action for lowering the static and dynamic frictional forces delivered by PPE onto skin, as explained above. Clearly, the reduction in the COF should not be too excessive, to avoid the sliding of PPE over the skin. Lowering the COF and the associated frictional forces on the skin will result in less shearing on and within skin tissues and therefore, a lower risk of loss of skin integrity. Biotribology work has confirmed that petroleum jelly (PJ), an approved and affordable skin protectant, decreases the COF of skin by approximately 25% immediately post-application, though the COF value climbs back thereafter, reaching baseline again after about an hour.[33]

Other than being a lubricant, during the one-hour timeframe, the applied PJ film appears to be able to hold the perspiration moisture from reaching the skin

Fig 3. Correct application and removal of goggles



surface, which further contributes to the reduction in the COF of skin. However, without reapplication, the COF of skin will continue to rise above the basal level, after about an hour from the time of application, likely due to an overshoot effect of perspiration, leading to adhesive friction as the occlusive feature of the PJ film diminishes. Reapplication of the PJ once an hour is critically important, otherwise the aforementioned overshoot effect will elevate the COF of skin substantially above baseline[33] and, therefore, may do more harm than good. Since PJ is solid at room temperature it is easy to apply (and reapply frequently). Fluid lubricants appear to be less optimal for reducing the COF of skin; these include heavy mineral oil (paraffin) which decreases the COF of skin by approximately 18%[33] and fatty acids, such as vegetable oils (including olive oil which is commonly used in cosmetics). The latter may be used as a substitute for PJ for health professionals who are allergic to petroleum-derived products. It is noteworthy that application of PJ or the other aforementioned fluid lubricants would decrease the COF moderately (i.e., at a maximum of approximately 25%) so in practice, the PPE will not tend to slip freely over the face.

Any of these suggested lubricants require frequent reapplication to avoid the 'overshoot effect'. Interestingly, in this regard, a strong correlation was reported between the subjective perception of greasiness and the actual measured reduction in the COF value,[33] indicating that a health professional can judge whether the self-application of a lubricant effectively reduced their facial skin COF. Considering the above information as a whole, applying a thick layer of PJ once every 30 minutes to dry facial skin under the PPE, after a very thorough wash and disinfection of the hands with a hospital-quality sanitary gel product (obviously following removal of used gloves) and using a new mask each time, should be effective in lowering the COF of skin through lubrication and therefore, in decreasing the risk for facial (friction wound) injuries.

In addition, it is important and relevant to note that while it is a common belief that PJ is flammable (because petroleum can be flammable), the PJ that is commercially used as a skin protectant is not flammable. Only when heated to extremely high temperatures of >400° Fahrenheit or ~200° Celsius, PJ may release flammable vapours. These temperatures clearly do not occur near the face of healthcare workers in clinical settings. The liquid substitute lubricant, heavy mineral oil, is flammable. Olive oil is relatively involatile and must be heated to its flashpoint temperature (i.e., above 300° Fahrenheit or 150° Celsius) or sprayed in a fine mist to be ignited by an open flame. Accordingly, with respect to the flammability aspect, PJ again emerges as the best option for reducing the COF among these different potential lubricants.

Application of PJ, as noted above, would be most effective under fresh PPE; however, if staff are having to reuse face masks, which is commonly seen in the current crisis, PJ can also be reapplied under a reused mask.

Appropriate use of prophylactic dressings

In the context of patient care, our consensus document[3] recommended considering the application of prophylactic dressings under stiff devices to reduce the risk of DRPUs. Such prophylactic dressings have been shown to alleviate the sustained deformations that devices in prolonged contact with skin apply to tissues.[5] We specifically measured forces applied by a CPAP mask onto the skin, following which we used an anatomically-realistic computer model that reconstructs the detailed anatomy of the head and face to determine the resulting skin and deeper tissue loads.[34] We found that facial tissue loads at vulnerable sites were substantially alleviated by prophylactic dressings that were cut to shape to provide localised cushioning. The latter work indicates that similar biomechanical trends of effects would apply with regards to the use of prophylactic dressings for facial tissue protection from PPE, particularly since such dressings will decrease the direct indentation of the stiff PPE elements into facial skin and subdermally.

It is important to note that, at this time, there is no skin protection product in the wound care industry,[35]

including prophylactic dressings, that has been specifically and rigorously tested for permeability to the coronavirus. This is a source of debate among health professionals, as to whether applying prophylactic dressings onto sensitive facial sites may compromise the seal of a medical face mask. From a bioengineering perspective, reasonable and sensible use of dressings to protect vulnerable facial areas and the bridge of the nose in particular, is unlikely to compromise the seal, and the example of gaskets from the field of mechanical engineering may be the best to illustrate the reasoning for this. In mechanical engineering, gaskets are always made of flexible and deformable materials, which allow for 'less-than-perfect' shape-mating of touching surfaces (including those with surface irregularities), to eventually form a tight seal. The vast majority of standard face masks (excluding 3D-printed masks that are custom-made for individuals, based on a scan of their face) are produced in standard sizes. Accordingly, standard face masks do not and cannot precisely conform to the anatomical facial contours of each individual, particularly to the curved surfaces of the bridge of the nose. Therefore, by definition, there would always be gaps, however small, between the face and the mask, necessitating very tight strapping, and causing skin indentation, to overcompensate for this. In fact, there is large variability across the global markets with respect to the types and qualities of mask and respirator products. The equipment regarded and regulated as the respiratory protective device with proven air filtration effectiveness (as currently regulated according to EU, US and Chinese standards) classifies a certain minimum percentage (for example, 95%) filtration of airborne particles per class of equipment. The respective testing guidelines always include a respirator fit test which examines whether a respirator properly fits the face of the user, which is achieved by high pressure to the face and the selection of the right respirator size. The following classes of masks/respirators are common:

- FFP2 and P2: at least 94% of the airborne particulates are filtered
- N95: at least 95% of the airborne particulates are filtered
- N99 and FFP3: at least 99% of the airborne particulates are filtered
- P3: at least 99.95% of the airborne particulates are filtered.

As an example, filtering facepiece (FFP) protective masks are certified by the EU and serve to protect against particulates, such as dust particles and various airborne viruses.

The fit test performed to assess efficacy is typically subjective and aimed at detecting the ability of the mask/respirator to block particles that have a characteristic smell or taste, for example spraying aqueous solution of saccharin into the air and then asking the subject to indicate whether they are able to taste the sweet aerosol while wearing the mask. This common type of fit test is clearly qualitative and depends on the subjective sensing of the challenge agent. Importantly, the presence of microgaps between the mask/respirator and face which compromise the seal cannot be eliminated based on such qualitative and subjective testing.

It is our opinion that prophylactic dressings with elastic properties which facilitate flexibility and conformation of the dressing structure between the mask and facial contours will alleviate deformations and mechanical stresses in facial tissues[34] and, like gaskets, such dressings may actually improve the seal, rather than compromise it. Dressing materials should also be able to remove trapped heat away from the skin surface to reduce perspiration and the associated risk of skin irritation and maceration.[36,37] Confirmation of this, specifically for PPE, through a regular scientific process would require experimental laboratory research and testing, however, university closures including the drawing down of research activities overall in response to the COVID-19 pandemic is slowing down the 'normal' research course.

The present circumstances are highly unusual and health professionals require guidance here and now. The engineering theory described above is a good and solid foundation justifying the use of dressings prophylactically with PPE, so that they act as tight-seal gaskets between the face and PPE, as long as published, peer-reviewed evidence demonstrating their biomechanical efficacy exists. The above also indicates that dressings that appear to be either too thick or too stiff so that they cannot conform to the contours of the face under the mask, may compromise the seal. Clearly, excessively thick or stiff dressings will also be less effective in protecting the integrity of facial skin, as they cannot dissipate the loading applied by the PPE through self-deformation which relieves the loads in the facial tissues.

Finally, the effects of prophylactic dressings applied as skin protectants under PPE may be very different with the various available types of masks/respirators reviewed above. Characterising the biomechanical efficacy, including the 'gasket function' of dressings under different PPE types, will require additional research.

Practical recommendations for non-medical workers

The general public may wish to wear masks outside the home, as these will generally not be worn for prolonged periods of time or overtightened in response to an immediate threat of infection—as occurs with health professionals. Hence, there is minimum risk of skin damage caused by moisture, shear and friction to the general public. Masks used by the general public will also not necessarily be the same as those being worn by health professionals in medical facilities. Of note is that there is continued debate regarding the effectiveness of wearing these masks by the general public, and many countries have produced advice, including the WHO, which has stated that the wide use of masks by healthy

people in community settings is not supported by current evidence, and carries uncertainties and critical risks.[30] However, the use of masks does suggest potential advantages, including a reduction in potential exposure in healthy people in the community setting, including reducing potential exposure risk from an infected person during the 'pre-symptomatic' period. Additionally, the CDC have recommended wearing cloth face coverings in public settings, particularly where there are reports of significant community-based transmission and where other social distancing measures may be difficult to maintain, such as grocery stores and pharmacies.[38] At present, a few countries, for example, Singapore, Austria and Israel instructed mandatory use of masks in public spaces; however other countries such as Australia and New Zealand, have instructed against the use of face masks in public by the general public. Evidence for the use of face masks by the public is lacking, although some would argue that the precautionary principle should be used and the use of face masks advised.[39]

WHO currently only recommends face masks for people who are coughing or sneezing, or for those who are caring for suspected or confirmed COVID-19 patients. The CDC recommends cloth masks fit snugly but comfortably against the side of the face, should be secured with ties or ear loops, include multiple layers of fabric, allow for breathing without restriction, and be able to be laundered and machine dried without damage or change to shape.[38] Masks should be laundered daily in a washing machine.[38] When wearing a mask, it is essential that people do not inadvertently self-contaminate by touching and reusing contaminated masks, and that hands are washed immediately after removing the mask.[38]

Guidance for industry and other stakeholders

Industry and regulatory bodies should already have substantial real-world information to analyse and use in developing better technologies, products and testing standards that will expand the scope of requirements from PPE, to not only provide filtering of air and a good seal but also minimise the risk of skin damage. There are short-term steps and long-term solutions that will be required, as healthcare systems prepare for the next waves of COVID-19 and potentially, future pandemics. Specifically, in the short-term, manufacturers should publish instructions for use (IFU) that consider skin damage due to prolonged and intensive application of PPE products. Ideally, such IFU would guide users not only in the mounting and removal of the equipment, but also with regards to skin care.

In the longer-term, quality indicators need to be developed by bioengineers to evaluate the level of conformation of PPE on facial contours so that, even for products made in standard sizes, it would be possible to assess the extent of adjustability of the product to the individual. Likewise, kits of personalised fit equipment, such as skin barriers and prophylactic dressings, can be developed for the specific purposes of delivering skin protection without compromising the seal. Such new products can be tested in bioengineering laboratory work using head phantoms designed to evaluate the PPE and the corresponding IFU. The phantom systems will simultaneously test the quality of the seal, the level of air filtration, the mechanical forces applied by the equipment on (simulated) facial skin and subdermal tissues, and the heating caused by the equipment, thereby facilitating relative assessments across existing, improved or future PPE products. Computer modelling can be added to that and, using such an integrative, experimental-computational approach, provide additional important information in a safe, cost-effective and reproducible manner; for example, predicting the expected viral load in cases of equipment failure, malfunction or inadequate use. This bioengineering approach is currently completely absent with respect to PPE, which is typically being evaluated using subjective measures such as fit testing that assesses the ability to smell or taste an aerosol while using the equipment. As an analogue to the case of DRPUs in patient care, there is lack of objective, quantitative and standardised measures regarding how safe specific types of PPE are, from a skin and tissue health perspective. While work concerning the safety of device designs has already started to appear in the literature and is reviewed in the consensus document,[5] there is no equivalent published bioengineering information related to PPE. Academicians, clinicians, industrialists and regulatory professionals need to work closely together to bridge this gap effectively and promptly.

Summary: the consensus document is more relevant now than ever

While in the context of patient care, the concept of DRPUs is clear and drives a constant need (though often unmet) for clinical and biomechanical information regarding prophylaxisprevention, the projected consequences of the COVID-19 pandemic makes the consensus document[3] more relevant than ever, for a number of reasons. First, there is a steep rise in the numbers of ICU patients and an associated increase in interactions of these patients with risk-causing devices, together with growing use of prone positioning in ICUs. This will lead to a proportional escalation in the absolute numbers of DRPUs among these patients. In addition, it appears that COVID-19, with its fundamental characteristics of a cytokine storm—endothelial dysfunction, drop in oxygen saturation, hypercoagulability leading to microthromboses and potential effects on cardiac output—interacts with two of the three primary aetiological factors in DRPUs, inflammation and ischemia (Fig 1).[16–18] This introduces an inherently increased fragility of soft tissues among COVID-19 positive patients, resulting from the above-listed pathophysiological components of the disease that together contribute to amplifying the DRPU tissue damage spiral (Fig 1). Considering their greater tissue

fragility, the segment of COVID-19 positive patients who will eventually suffer ICU-acquired DRPUs is expected to exceed the DRPU rates observed in the same ICUs before the pandemic. Second, and added to the above, we are seeing a new type of DRPU that has the same known underlying pathophysiology (Fig 1) but which affects a different population—health workers (as well as others who use PPE intensively). This population was not previously considered to be at a risk for DRPUs.

Photographs showing the routine of life during the Spanish Influenza pandemic of 1918 prove how little has changed in the design of the most basic form of PPE, the medical face mask. In our consensus document,[3] we discuss in detail the consequences of the newly developed understanding of the aetiology of PUs, and DRPUs in particular, identifying sustained cell and tissue deformation as the triggering event and driving factor in the injury cascade (Fig 1). Similar to the bioengineering design of numerous types of medical devices, the designs of PPE, and especially of respirators and goggles, will need to be revisited thoroughly when the first wave of the pandemic ends, to incorporate improvements related to the PPE-skin interactions. As discussed in the consensus document,[5] these improvements in PPE should include use of stiffness-matched materials that do not aggressively indent the skin, low COF at skin-PPE interfaces and effective release of trapped heat and moisture from these interfaces. **JWC**

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