The reusability of PPE as an alternative to stockpiling in preparation for a potential pandemic

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Preface

This paper is the result of a discussion with PPE industry experts from manufacturing, service and regulatory backgrounds. It intends to raise thought-provoking questions to further the discussion on the reusability of PPE as an alternative to stockpiling in preparation for a pandemic.

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Introduction

The WHO predicts that the next pandemic will be caused by influenza, as it did prior to the coronavirus pandemic.

Before Covid-19, the Pandemic Influenza Preparedness Programme (PIPP) stockpile consisted of 400 million items of PPE, with further supplied in the EU exit stockpile. Between March and May 2020, the Department of Health and Social Care ordered 14.6 billion items of PPE at an inflated cost and with logistical problems.

The Royal College of Nursing (RCN) states that 'access to high quality PPE, that is appropriate to the level of care and type of setting, is essential to ensuring the health and safety of health and care staff across the UK. It is critical to the stability of the psychological contract between staff working across the health and social care sector and their employers. The onset of the Covid-19 pandemic exposed global shortages in the supply of PPE.

'A lack of sufficient PPE can expose health and care staff to unnecessary risk and serious harm. In some cases, this may have led to staff members contracting Covid-19, becoming unwell and tragically losing their lives.'[1]

The UK Covid-19 Inquiry will examine the UK's response to and impact of the Covid-19 pandemic, and learn lessons for the future.[2] Whilst the UK government has set an ambitious target for developing a vaccine within 100 days of encountering a pandemic, there is an acknowledgement that this is not easy and never guaranteed. PPE will therefore be as fundamentally critical as it was during the Covid-19 pandemic.

The reuse of PPE as an alternative to stockpiling can have environmental and sustainability advantages, but in the acuteness of the moment of a sudden onset of a new biological hazard that threatens the population the issue fundamentally is focused around PPE supply and availability. The first priority is that PPE is **available** and that it has the **ability to perform**.

What can be done to help remove potential barriers, to ensure suitable PPE that performs is always available and how does reusable fit into this? Is a contingency plan for reuse of PPE a realistic option for dealing with a crisis such as a pandemic, or is a service approach, that can be scaled and escalated efficiently to meet a surge in demand, more appropriate?

Furthermore, how can an eco-system be developed, complete with testing to appropriate standards and regulations, to provide trust and assurance in reusable PPE, in times of both regular and high demand?

1 https://www.rcn.org.uk › Documents › 2020 › May

2 https://covid19.public-inquiry.uk/

The challenges of stockpiling

Stockpiling PPE in preparation for a potential pandemic raises several challenges. These include availability, supply and performance. Some PPE products have a limited shelf life and will be subject to degradation. For example, over time, filtering and barrier layers, elasticity and gluing elements that bond a particular product may degrade. The whole lifetime performance of PPE products therefore has to be proven.

It is possible, with the agreement of the manufacturer and specifying bodies to extend the life of some products during their stockpiling existence. Some products were assessed and life extended dynamically during the Covid-19 pandemic. However, there may not be sufficient awareness of the consequences of shelf life and the need to maintain a dynamic turnover.

Stockpiling is often based on a planning and preparedness strategy, influenced by previously encountered pathogens. However, should a new pathogen be encountered, with perhaps different transmissibility or physiological consequences for those affected, stockpiling preparations may be insufficient or unsuitable.

Chains of command are vulnerable in other ways too, with individual trusts having autonomy to engage in stock procurement and distribution among staff. In the case of a rapid pandemic escalation, this can lead to shortfalls in stockpile management if it is not dynamic and controlled centrally.

While there will always be times when single use PPE will be appropriate, reusable products also have their place within the healthcare sector.

Types of products suitable for reuse

While the visibility of future pathogens cannot be fully known, what is consistent across all biological hazards are the routes by which the agent can gain access into the body. This is either through the mucous membranes of the mouth, nose, eyes, ingestion, the respiratory route, or routes via the skin. Therefore, whatever future pathogens emerge, the types of protection to deal with the vulnerable sites remain the same. This can be used as a model to gauge what type of PPE would be required for future pandemics, even though the type of virus is unknown.

It is important to define the products that are termed PPE. Broadly, these cover respiratory base protection, eye protection and clothing that creates a biological or chemical barrier. All of these have reuse variants, and it is a case of choosing which are appropriate for reuse and which are more effective as single use items.

Ordinarily, personal protective equipment is designed for the protection of workers in the workplace, and is regulated accordingly. From the perspective of the healthcare worker and those responsible for protecting them, in general parlance anything worn as protection is regarded as PPE.

However, healthcare is quite unique insofar as the threat from toxic hazards is bi-directional. There is a need to protect healthcare workers from patients and to protect patients from healthcare workers. This means that not every piece of equipment can be neatly labelled personal protective equipment and regulated as such. For instance, anything that protects patients is regarded as a medical device, which falls under a different regulatory framework. Furthermore, there will be many products that fall under both regulatory frameworks for personal protective

equipment and medical devices and those that fall into neither category.

The distinction between these two regulatory frameworks can result in confusion, particularly on an international level. A possible solution to this challenge is to merge the two frameworks in the particular case of healthcare space, or to create new standards that recognise the unique requirements to protect healthcare workers from biological hazards.

During the Covid-19 pandemic, Commission recommendation 2020/403, set some stipulations aside, stating that as long as a product is safe and effective to use for essential health and safety requirements, it can be used for the unique purposes of health care protection.

Benefits of reuseable PPE

Supply and availability:

This applies in the event of a sudden onset of a not previously encountered biological hazard as a threat to the population and to the healthcare workforce. This would be partly determined by the planning and preparedness position of the healthcare trust. Without a sufficient just in case and just in time availability, stockpiles may be quickly used up, possibly without the means for restocking through production or procurement. In this scenario, the issue of reusability becomes a contingency, with the possibility of recapturing and reusing PPE when it is safe and appropriate to do so.

Sustainability:

The environmental consequence of disposal of PPE and the polymers and plastics involved.

Shelf life:

Reusing PPE could avoid the limitations of stockpiling that are due to single use items being subject to degradation over time, which can affect the integrity of the whole construct.

Identifying the barriers to reuse

The barriers to reusable PPE as an alternative to stockpiling in preparation for a potential pandemic include, but are not limited to:

Capacity:

There are reuse examples within the general framework of protected devices. However, when the dependency from single use and disposable to reuse occurs, this has to be matched with the capacity to wash, clean, disinfect, and then re-introduce the product for use, without affecting its performance. In a real-time surge demand situation, this capacity would need to continue to match demand, presenting a possible limiting factor.

Regulations:

The structured frameworks put in place during the Covid-19 pandemic to counteract the potential for opportunistic counterfeit products resulted in restrictions on otherwise plausible solutions that were available to scale.

For instance, some manufacturers who regularly supply to the NHS reported facing difficulties in offering a reuse service during the Covid-19 pandemic. An ISO accredited fabric manufacturer, supplying gowns and scrubs, with the framework already in place to level up and supply reuse was unable to agree sign off on its products by the NHS cabinet structure for procurement. The manufacturer supplied 2.5 million metres of fabric internationally, with 100,000 metres of fabric supplied to the UK over the same period.

The bureaucracy of the frameworks may need to give way to a more fluid system to get urgent products into use.

Just in time continuity:

If reusable PPE is not produced and introduce into the supply chain in a fast, quick and robust manner, depending on the incident, supply chains can be stretched. There is also a risk that large orders may lack consistency if manufacturers are entering the healthcare marketplace for the first time.

Counterfeit products:

A lack of market surveillance has the potential for counterfeit products to enter the supply chain, particularly at times when manufacturing and distribution of PPE is ramped up and manufacturers from industries who not normally supply to the healthcare sector enter the market.

Building a level of trust and assurance in the ecosystem is therefore important, with the process overseen and monitored by those in that market space. Certification and pre-approval of suppliers for reusable and sustainable PPE could help continuity and scalability and reduce the potential for counterfeit opportunities.

National commitments:

The businesses able to provide PPE at scale include multi-nationals, with various manufacturing plants outside of the UK. This puts pressure on them to serve their own domestic governments first, before scaling internationally by very nature of businesses of scale, that can participate.

Chains of command:

The NHS as a complex institution has different methods of working, using and reusing PPE across the various primary care settings. Policies on reusable PPE and stockpiling may therefore not be consistent across different regions.

The need for forward-thinking:

Much of what was upscaled during the Covid-19 pandemic was borrowed from the industry. New pieces of equipment that had long been needed were introduced to healthcare at scale for the first time. This identified the need to be forward-looking when considering the types of PPE needed. However, trust in new innovations takes time to build momentum, and this could present difficulties in getting new products into service efficiently at surge times.

Complexities around individual PPE types:

A reusable fabric gown, for example, may be less complex to reissue than respiratory protective equipment that might need to be returned to a particular worker.

Mindset:

A tendency to focus primarily on single use PPE may present a challenge. Traditionally, infection prevention and control measures are around not perpetuating lines of contamination through contaminated equipment. The starting point in infection prevention and control for serious biohazard will be to dispose of the equipment in the first instance and destroy it.

Whole life product costs:

If the [initial purchase] cost of single use products is significantly lower than for reusable products, there may be a reluctance to shift (even if whole life product cost may be lower).

Trust:

All stakeholders need assurance that reusable PPE is safe to use. Attitudes are conditional upon perceived threat, need and perceived supply, and dependent on what type of equipment is being reused. In terms of respiratory retaining equipment, for instance, there was some reluctance among healthcare workers during the Covid-19 pandemic to accept the reuse of masks initially, an attitude that changed when supplier shortages were understood.

It is necessary to socialise the concept, by sounding out not only manufacturers, or those responsible for disinfecting equipment, but also those who are going to wear it.

The current process for reuse

From a respiratory protection standpoint at least, the trend is shifting towards a combination of single and reuseable PPE.

This differs for products such as gowns, which can be subject to greater contamination. In this case single use is often considered to be more appropriate and cost effective.

Northumbria Healthcare NHS Foundation Trust is piloting the provision of a closed loop solution, including sewing and laundry facilities and the necessary framework to identify the effective reuse of PPE. Its overall production ambition is to produce as much high quality PPE locally, securing the supply chain. Its current production facility is producing isolation gowns, scrubs, theatre hoods, masks, theatre hats and pillows, witht the aim of bringing cost savings to providers which can then be re-invested directly back into healthcare services.

The Trust was also among the first wave of NHS organisations to install a special recycling machine for the reuse of masks, albeit with the aim to to reduce environmental impact.[3]

Acceptance criteria

What acceptance criteria should be in place for reusable PPE? At its most basic level, the product should perform in the way that it was intended, in adherence to relevant standards.

The sustainability of products may also be an important criteria. In the case of single use products, it should offer some sort of acceptance of its sustainability purpose. If a product is reusable, what are its abilities to prove it's safe to clean, etc? Within that there is already a space in the world for testing certification, but how can this be packaged together and what are the benefits? How can trust and assurance be proven?

As healthcare workers have become more aware of potential threats of contamination, they want to know how they can protect themselves or how they should be involved in a system that protects them. They want to know that after a product has been reprocessed it works in the way that it's designed to and that it is safe for them to use. Having approval and certification and a method of having manufacturer claims verified could be a way of improving trust.

The creation of an ecosystem, which results in trust and engagement due to provability, may allow reusable innovations in the future and lead to a greater willingness to engage within the reusable cycle.

[3] https://www.northumbria.nhs.uk/media-centre/news-and-blogs/news-stories/northumbria-healthcare-underlines-green-credentials-mask-recycling#764ddcd5

Regulatory requirements

When looking at introducing reusable PPE in a meaningful way, either in service or as part of a contingency plan, do the regulatory requirements of PPE in general need to be changed? UKCA marking gives the autonomy to do that, but is that the right thing to do in the case of reusable PPE? While regulations exist to do something positive, and give some sensible means of measuring claims, are current regulatory requirements siloed and therefore affecting some issues around reusable new products, such as availability and performance?

When considering products for life protection in abnormal circumstances how can regulations ease the ability for manufacturers to make their products available for use? Would regulatory considerations written into a specification for times of crisis, that follow a baseline defining the right product for the job help?

Responsibility and accountability

When a product is reprocessed for a biological hazard, it has to be evidenced that the hazard has been neutralised before it is reused. This is an involved process that comes at cost.

Some products, such as laundry, already have to prove their quality management systems to meet certain standards. However currently for decontamination cleaning and reusable products, users rely on manufacturer's instructions, many of which aren't designed around biological hazards, a point that needs to be revisited and recaptured.

Would a framework for an in-service approach to reusable and single use PPE help determine responsibility and accountability? This may detail a network of pre-approved suppliers from relevant industries, proven to be able to scale up to produce regulated products. The purpose of such a framework would be to create a go-to trust position where all stakeholders can gain assurance that the innovations they prepare for the future of PPE and a future pandemic situation have a productive outcome. This framework could be submitted to government for consideration after the conclusion of the Covid-19 public enquiry.

In summary

With a valid space for both reusable and single use PPE within the healthcare system, not only during a pandemic but in service, a clear definition of which products are suitable for reuse could help make them the first choice over single use whenever appropriate. Clearly defined standards could also help improve trust in reusable PPE products, with the potential to remove some of the bureaucracy around innovation and providing peace of mind for the end user.

Availability and sustainability awareness around reusable PPE are driving acceptance of this as an alternative to stockpiling. Acceptance is likely to be even higher once that trust and assurance framework is in place as an assurance of performance.

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