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WHITE PAPER



HEALTHCARE WORKER PROTECTION

THE KEY TO SURVIVING THE
NEXT RESPIRATORY OUTBREAK

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EVERY BREATH COUNTS

HEALTHCARE WORKER PROTECTION THE KEY TO SURVIVING THE NEXT RESPIRATORY OUTBREAK

SYNOPSIS

Serious geopolitical and social forces are converging to create the conditions, on a scale unique in history, for a major respiratory pandemic.

Few hospitals - let alone the broader responder community - are ready for the acute scale up of trained personal and equipment required to manage and contain a respiratory pandemic. In such a global crisis the initial phase will rely on the health and commitment of healthcare teams.

Prioritising protection of healthcare workers from primary to regional hospitals can ensure a resilient frontline defence. Logically when dealing with respiratory outbreaks, the focus is on the respiratory equipment. Recent experience of Severe Acute Respiratory Syndrome (SARS) in 2002 and Middle East Respiratory Syndrome (MERS) in 2015 highlighted the vulnerabilities around use and supply shortages of disposable respirators.

Commentators and industry experts are advising infection control teams to examine their PPE procedures and evaluate new re-useable respiratory protection devices in their preparations to protect staff and contain and manage an imminent public health crisis.

A GLOBAL OUTBREAK PRESCIENT

In recent years, airborne diseases like influenza, TB and measles have presented as global threats. Despite this, it is the emerging diseases (Ebola, MERS, H1N1 and SARS) with significantly higher infection rates and mortality rates that have triggered a review of the role of healthcare Personal Protective Equipment (PPE) in Pandemic Preparedness Plans.



CONTRIBUTING FACTORS

Urban populations and frequent travel promote the opportunity for rapid spread of airborne infectious diseases. More than half of the world's population lives in urban areas and the last two decades has seen the rapid growth of 'mega-cities' (greater than 10 million people).¹³ Additionally, there is unprecedented mobility with an average 8 million people flying internationally each day (equivalent to 3 billion people annually).¹⁴ This fast flow of people between heavily populated areas opens up a highly connected global network, that has made natural barriers to the spread of disease (time and distance) ineffective.

Refugee migration is also adding pressure to government and healthcare resources. This group has low rates of vaccination and a high disease burden.¹⁵ In 2014, 59.5 million people were forcibly displaced, the highest number ever recorded.¹⁶ Generally this group is housed together in close communities with reduced access to standard healthcare and presents with social and language challenges.

Aging is one of the main risk factors for acquiring respiratory disease. Approximately 8.5% of the world's population is over 65 years (617 million people).¹⁷ During an Influenza outbreak, the highest rates of infection and mortality are amongst the over 65 year olds.¹⁸ With growth of this at-risk group, there are more hospitals and aged care facilities requiring effective infection control measures.

Vaccination rates are decreasing; in recent years, the drop in vaccination rates has resulted in measles outbreaks. Diseases previously thought to be eradicated are now, thanks to genetic engineering technologies, potential threats. Pathogenic viruses, previously contained, can be readily synthesised at modest costs¹⁹ and immunity (natural or via vaccination) no longer exists in the general population.

Biosecurity agencies are discussing the heightened risk of these viruses should they be released at concentration to a naïve population where the impact would be fast and widespread.

"Any one of these external factors represents a significant challenge for effective infection control," says Prof. Raina MacIntyre, Professor of Global Biosecurity at Australia's world-renowned Kirby Institute and head of the NHMRC Centre for Research Excellence, Integrated Systems for Epidemic Response (ISER). "When we see such powerful macro-trends converging, alarm bells really start to ring.

"Systemic weaknesses on the ground – whether through inadequate personal protective equipment (PPE), low level of training or limited stockpiles - will massively compound the problem for individual hospitals when a major outbreak happens," Prof. MacIntyre warns.

THE PERSONAL IMPACT

In such a health crisis, sudden increases in patient input create enormous strains on hospital resources (people and equipment). Healthcare systems and agencies may only have weeks to scale up to cope with significant numbers in patient triage and care. The resources already in place must be managed through the initial phase. During this time, healthcare staff are working long hours with time pressures and equipment constraints.

Hospitals have the added risk of staff exposure, infection and subsequent absenteeism. There are recorded incidents of high rates of infection and mortality amongst healthcare workers during a pandemic. Even with active vaccination and hygiene programs in hospitals, at least an estimated 20 per cent of health care workers are infected with seasonal flu every year.²⁰

During SARS (2003) healthcare personnel represented a significant proportion of recorded infections; 16% (Australia), 22% (Hong Kong), 19% (China) and 43% (Canada) of workers were infected while caring for patients.²¹ Federal US health authorities use 25% infection rates in their pandemic planning projections.²²

In treating respiratory infections, certain medical procedures are associated with expulsion of aerosols from the patient, putting staff conducting procedures at elevated risk. A study of nurses in Toronto during SARS, found that assisting during intubation, suctioning before intubation and manipulating the oxygen mask were high-risk tasks for acquiring the disease.²³

“The people at greatest risk for SARS were health workers who either became infected by close face-to-face contact with patients or by procedures that brought them into contact with respiratory secretions,” according to WHO.²⁴

Overall, SARS, which eventually affected 30 countries and had a nearly 10% mortality rate, provides a stark but valuable illustration of the impacts of a recent acute respiratory crisis.²⁵ The direct costs were high: over 8,000 people were infected including 21% of healthcare workers.²⁶ Socially disruptive measures such as mass screening, contact tracing and active surveillance of contacts were an additional burden.



SARS – A FIRST-HAND STORY

Dr Cathryn Murphy knows too well how quickly acute respiratory disease can cut a swathe through orderly hospital procedures.

“When I went to the frontline of SARS, chaos reigned everywhere, from rural and regional hospitals in China to leading teaching hospitals in the heart of Singapore,” she relays.

“I wasn’t prepared for the extent of disruption and the urgency, and had great difficulty finding a spare mask even in a metro centre. In this situation, people did not use the disposables

according to guidelines. They were ‘double-masking’, wearing masks for much too long or, dangerously, cutting off the ties for added airflow and comfort,” Dr Murphy says.

“SARS highlighted for me healthcare worker inconsistency and confusion regarding selection, application, safe use and disposal of PPE. In the 15 years since then, we have learned a lot but I think there is still confusion about which equipment to use, for which diseases, and in what situations.”

Federal US health authorities use 25% infection rates in healthcare workers in their pandemic planning projections.

INFLUENZA: A CLEAR AND EVER-PRESENT DANGER.

Globally influenza contributes to estimated 3 - 5 million cases of severe illness and up to 650,000 deaths annually, despite the availability of vaccines, antibiotics and other medications to alleviate complications.¹

- **1918** 50 million deaths (Spanish Flu)³
- **1968** 1 million deaths worldwide³
- **2018** 291,000 - 646,000 deaths worldwide.⁴ In USA, 900,000 hospitalized and 80,000 died.⁵

MEASLES: AN OLD FOE RETURNS.

Measles is so contagious that 90% of the people without immunity in close contact with an infected person will contract the infection.⁶ Prior to the 1980 global vaccination program, measles caused an estimated 2.6 million deaths each year.⁷ In 2018, according to WHO, Europe reported record levels of measles – 41,000 cases and 37 deaths compared with 24,000 cases in 2017 and 5,273 in 2016.⁸

MERS: SARS’ TROUBLESOME COUSIN.

A variation of the coronavirus that causes severe acute respiratory syndrome (SARS). Due to its highly infectious nature and high fatality rates (35%), MERS is closely monitored by global agencies.⁹ MERS impacts all ages: with deaths from under 12 months to 99 years.¹⁰ In 2014, there were more than 2,200 laboratory-confirmed cases from 27 countries including two healthcare workers in the US.^{11, 12}

SYSTEM DEMAND SURGE AND SCALE

During a major outbreak, the abrupt changes on health systems are felt quickly, giving little time for hospital preparedness policies to be implemented and resources scaled up.

This leaves existing resources to bear the brunt of the first waves of an outbreak.

A bad flu season can put sudden and intense pressure on hospital emergency departments, general wards and intensive care units, which have little spare capacity at the best of times. The scale of the surge fluctuates year on year, so predicting demand is very difficult for policy advisors and planners.

In the latest flu season in the US, for example, which was serious but not extreme, industry sources commented that hospitals quickly ran out of emergency room space and in-patient beds.²⁷

Nationally, US federal planners expect the next pandemic to give rise to:²⁸

- 45 million people in need of outpatient care
- 1 to 10 million requiring hospitalization
- 130,000 to 1.5 million in need of intensive care
- 65,000 to 750,000 patients requiring mechanical ventilation
- Between 200,000 and 2 million deaths

"As infection control experts, our biggest concern during an epidemic is that we won't have enough skilled staff, beds, medication and equipment on hand in a crisis, and that we won't be able to provide care for everyone who needs it," says Dr Cathryn Murphy, who was a consultant to the World Health Organization (WHO) infection control team working on preventing the spread of Severe Acute Respiratory Syndrome (SARS) in the Western Pacific Region.



THE PPE IMPERATIVE – FOCUS ON FRONTLINE STAFF HEALTH

At a time when the health and commitment of healthcare teams are pivotal to management and containment strategies, PPE plays a central role. During SARS, Vietnam, which previously reported a national rate of infected healthcare workers of 58%, reported no infected workers during this period and the attributed reason was the use of personal protective equipment.²⁹

Pathogens responsible for severe respiratory infections can expose workers through direct contact as well as via aerosol, covering distances or staying suspended for several hours, increasing exposure. In the healthcare setting, the time from initial presentation to isolating the patient can involve close contact with up to 10 staff and significant travel through the common areas of the hospital.

"The biggest infection risk is in the pre-diagnosis stage. Once a medical professional has a diagnosis, protective protocols and equipment are quickly triggered. Before then, the patient has potentially infected the reception staff, triage teams, patients in crowded waiting rooms, and unprotected clinical and ancillary staff," says Prof. MacIntyre. "In crowded emergency departments you may see beds lined up in hallways waiting to go onto wards, which is an infection control risk."

Protection for healthcare workers has vastly improved in 20 years. Gloves and gowns are now part of routine patient triage and care. In the US, Occupational Safety and Health Administration (OSHA), in conjunction with Centers for Disease Control and Prevention (CDC), have actively promoted worker safety and the use and adoption of PPE in healthcare. This work is aided by the significant efforts of the infection prevention community. OSHA, CDC/NIOSH (The National Institute for Occupational Safety and Health) and WHO have all recommended guidelines for protecting healthcare workers from infectious disease. These guidelines outline the use of respiratory protection devices including N95s and powered respirators (PAPRs).

CHALLENGES WITH PPE ADOPTION AND USE

While gloves and gowns have made it into daily use in patient care, protective respirators have not. There are challenges with wearer discomfort and barriers to patient interactions. Protective respirators are reserved for when a diagnosis of infectious respiratory disease is made (in the case of TB) or in pandemics.

Regardless, the use of N95s in these situations has been widely adopted by hospitals globally due to their ease of use. Most healthcare workers would have worn or been trained on N95s. The commonly adopted N95 masks have serious weaknesses for protecting healthcare staff including poor fit, discomfort (heat, moisture and breathing resistance) and improper use. The disposable nature of these devices means sudden increases in demand for high volumes cause shortages. With N95s, managers can be faced with sending staff in to care for patients with used masks, or without protection at all, and this can result in potentially high rates of healthcare worker stress, infection rates and absenteeism.

"Globally, personal protective equipment that many hospitals hold may be outdated, inconsistently adopted and in short supply. This is a lethal combination to rely on in an acute, high-pressure, infectious situation," cautions Prof. MacIntyre.

There are 18 million healthcare workers across 5,500 hospitals in the US.^{30, 31} It has been calculated that 7.3 billion N95 masks would be needed to protect workers during a pandemic.³² Currently 60 million masks are stockpiled³² and there are no national guidelines (e.g. temperature, humidity, UV exposure) for maintaining PPE stockpiles, leaving it up to regional and state hospitals to fund and manage their stock.

In some cases, where a healthcare worker cannot be fitted with an N95 or where hospitals have adopted higher protection protocols, powered systems (PAPRs) are used, but despite offering advantages over the disposable mask (i.e. higher protection, re-usability and good user comfort), PAPRs are only minimally used.

The barriers for wide adoption of PAPRs are the bulkiness, heavy weight and high complexity preventing a quick don, doff, clean and re-process. When faced with an on-the-spot choice between an N95 and taking five minutes to don a PAPR, users with time pressures will choose the fast and simple option, even when this compromises their own protection.

During the Ebola epidemic, up to 800 healthcare workers, including nurses from UK and US, contracted the disease.³ Equipment related complaints around discomfort, heat and time to don highlighted the inadequacy of traditional PPE for healthcare. In response, WHO and CDC raised the call for improved respiratory protective equipment specifically designed for healthcare workers and removing the challenges to adoption and compliance (The Grand Challenge, 2015).³⁴

PROS AND CONS OF TRADITIONAL RESPIRATORY PROTECTION

DISPOSABLE APR MASKS (N95)	TRADITIONAL PAPRS (BELT OR HEAD MOUNTED)
<ul style="list-style-type: none"> ■ Simple and easy to use ■ Routine use means staff are familiar with the mask ■ Available close to patient care and ready to go ■ Compatible with other PPE – hoods, visors, gowns 	<ul style="list-style-type: none"> ■ High protection (APF 25) ■ Comfortable powered airflow to the wearer – cool fresh air ■ Flushes exhaled air - no breathing resistance ■ No fogging ■ Visor enables good view of the wearers face and promotes patient interactions ■ Reusability reduces pressure on stockpiling
<ul style="list-style-type: none"> ■ Low and unreliable protection (APF 10). Ineffective face seal may frequently compromise protection especially with presence of facial hair ■ Difficult to fit and requires multiple sizes and models to be available for all staff ■ Poor compliance - uncomfortable (hot, moist, stale air) and fogging ■ Exacerbates heat stress resulting in risk of staff health or patient care as workers are forced to leave the contaminated area early to doff ■ Dizziness (Rebreathed air) and breathing resistance result in fatigue ■ Difficulty communicating ■ Disposable generate high inventory, stockpiling and supply chain shortages during high use 	<ul style="list-style-type: none"> ■ Heavy, bulky and hard to wear for long periods or when highly mobile ■ Not compatible with other PPE - hoods, visors ■ Complex – extended donning, doffing and reprocessing times ■ Staff require significant training and retraining particularly to prevent contamination when doffing ■ Battery packs with cables; can get caught on equipment ■ Noisy and difficult to hear when using a stethoscope ■ Complex and multiple parts mean system is not available and ready to go when needed ■ High upfront costs ■ Storage constraints due to high parts inventory



A NEW ERA IN RESPIRATORY PROTECTION

There is a clear mandate for hospitals around the world to prioritise the improvement of policies, procedures and equipment for PPE. Logically when dealing with respiratory outbreaks, the focus is on the respiratory equipment. In the current environment, where the scale and magnitude of an outbreak is forecast to be significant, there is now an urgent appeal for better respirators suited to healthcare workers.

Prof. MacIntyre, who has led the largest body of international research on the use of respiratory protection by health care workers, has generated a body of important evidence that has been influential in informing guidelines on the use of PPE. She agrees that stepping up preparation is urgent.

"Most clinical staff are trained in the use of PPE but this needs to be refreshed regularly. Hospitals and agencies need to review PPE accessibility and scale up; they must evaluate new equipment

that increases comfort, protection and reusability," she says. Using PPE, on a day-to-day basis helps staff become familiar with the PPE to improve adoption, correct use and compliance when the pressure is on.

"Planners need to be mindful that tasks and responsibilities can quickly shift in a pressure situation and other clinical staff may take on an inherently riskier procedure than they're use to, in place of a busy or absent colleague. So all staff need to be trained and ready to don and doff PPE safely," advises Prof. MacIntyre.

Reports from healthcare providers and regulators at the 2018 International Respiratory Protection Conference outlined their specific requirements for respirators used in healthcare:

- **Improve fit reliability**
- **Compatible with whole PPE ensemble**
- **Easily reprocessed**
- **Used for emergent and non-emergency situations**
- **Minimise negative PAPR aspects – less noise, light weight, no belt**

At the same conference, the head of NIOSH declared that respiratory device innovation was imperative to improve user protection, compliance and adoption in healthcare settings.



TOP TIPS FOR PPE AS PART OF YOUR PANDEMIC PREPARATIONS:

- Organizations should regularly review their preparedness plans with a focus on worker protection.
- Respect the microbial world. Serious respiratory diseases can travel quickly and do not discriminate.
- Review new PPE and look at the cost effectiveness and advantages of reusable respirators.
- Invest in approved PPE with high protection and ease of use.
- Implement routine use and training to practise use, donning and doffing, correct disposal, cleaning and disinfection. Ensure staff are confident with their equipment when under pressure.
- Ensure respiratory equipment is kept close to patient care, is easily available and ready to go.
- Review protocols and planning for reusable equipment to incorporate savings in space, inventory, reduced waste and disposal, shortages and assured fit testing.
- Follow international and local guidelines to ensure use of respirators during procedures with a high risk of aerosols e.g. intubation.
- The use of tight fitting respirators, including N95s, require annual fit testing. Staff who gain or lose weight, grow or remove facial hair during this period require re-testing to check the face seal.

Assoc. Prof. Cathryn Murphy

MEETING THE DEMAND FOR BETTER RESPIRATORY PROTECTION

Over the last two decades, there has been little innovation in respirator development and few respirators have been specifically designed for the healthcare setting, with many transferred directly from industrial applications.

A next generation of respirators is now incorporating healthcare specific needs and addressing limitations of traditional N95s and PAPRs. These are not iterative changes but offer a paradigm shift in respiratory protection. Advanced technologies can now deliver significant increases in performance with user comfort, ease of use and operating efficiencies to protect healthcare workers.

Prof. MacIntyre's research found healthcare workers are more comfortable in PAPRs than other passive respirators when worn for a long period.³⁵ She notes that, the fewer parts PAPRs have, and the greater the simplicity of donning and doffing, leads to better adoption and minimises self-contamination. She feels PAPRs with a battery belt or hose may increase the risk of self-contamination with doffing, and calls for more research in this

area. In addition to reducing self-contamination risk, the fewer parts and smaller a device is, the less time it requires for disinfection and the quicker it can be put back into active service.

One innovative device has eliminated the major disadvantages of N95s and traditional PAPRs. CleanSpace respirators are ultra-light (<400g/0.9lb), simple (no hoses/belts), and small with powered airflow making them comfortable to wear: in short, offering the high protection levels of a powered respirator with the ease of use of an N95. CleanSpace has an APF 50 (half mask) or 1000 (full face mask). The patented AirSensit™ technology was developed by biomedical engineers involved in the development of CPAP devices (used to treat sleep apnea) at global medical device manufacturer ResMed. The equipment is reusable, compact and modular, providing operational flexibility and ease of storage.

With healthcare consultation, the engineering design has reduced the time for training,

reprocessing and decreases the potential for contamination at high-risk points of donning and doffing.

"All the evidence points to the status quo being a dangerous set of circumstances. We aren't adopting new equipment quickly enough; vastly improved technology is there, it should be evaluated and put into place as quickly as possible, to meet the threat head on," Dr Cathryn Murphy says.

"Safeguarding frontline staff in any serious outbreak depends on improving their familiarity with, and access to, the safest level of respiratory protection available, in a size and fit that is comfortable and light enough to wear over consecutive hours."

CleanSpace respirators have an operating time of up to eight hours, and fast recharge and top-up options. With this new generation of respirator, healthcare workers can have high protection and comfort readily available with a quick 'two click' process to don.



Complex factors are converging to increase the risk of a global respiratory disease outbreak. Both major and local hospitals, along with first responders, are a central component of government preparedness plans. During a global outbreak, in responding, these organizations and their staff will be under extreme pressure. There are deep concerns from hospitals and specialists in the field of infection control that few hospitals are ready.

Successful outcomes depend on healthcare workers being protected using appropriate PPE they are familiar with and trained on. Due to issues with traditional respiratory protection there is a strong case for reviewing new protective respiratory technology. Adopting reusable systems for both daily use and in a health crisis, that meet the best-practice requirements identified by leading international infection control agencies, will significantly increase the safety margin for healthcare staff. Such a focus would dramatically improve protection for healthcare workers to ensure they are able to work effectively and return home safe and well to their families.

A MAJOR INNOVATION IN PERSONAL RESPIRATORY PROTECTION FOR HEALTHCARE

CleanSpace HALO delivers higher protection than disposable masks, and is more comfortable and economic than any other respirator.

POWER UNIT:

- Patented AirSensit™ technology delivers cool, filtered air on demand for a high level of protection.
- Delivers up to 230 L/min airflow for up to 9 hours operating time.
- When using a stethoscope, the wearer can quiet the motor using a breath controlled technique.

MASK:

- Transparent mask with clear voice transmission allows for easy communication.
- Soft medical grade silicone mask is latex-free, providing a comfortable moulded seal. Fresh air into the mask keeps staff cool, removes moisture, stale air and prevents fogging.
- Half and full face mask options.

DESIGN:

- Lightweight device (<400g/0.9lb) with no cables, hoses or belt mounted battery packs.
- Few parts and small surface area make the device fast to clean/disinfect and put back into use.
- Customizable colored panels to denote personally issued devices or specific zones.



FILTER:

- HEPA/P3 protection 99.97% filtration efficiency for 0.3 micron and above.

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**MANY THANKS TO THE FOLLOWING EXPERT CONTRIBUTORS
FOR THEIR ASSISTANCE:**

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Professor MacIntyre is NHMRC Principal Research Fellow and Professor of Global Biosecurity. She heads the Biosecurity Program at the Kirby Institute at the University of New South Wales, which conducts research in epidemiology, vaccinology, PPE, bioterrorism prevention, mathematical modelling, genetic epidemiology, public health and clinical trials in infectious diseases. Prof MacIntyre's research work covers into four areas: personal protective equipment, vaccinology, epidemic response and emerging infectious diseases and biosecurity.



HONORARY ADJUNCT ASSOCIATE PROFESSOR CATHRYN MURPHY

Dr Murphy is a Managing Director of Infection Control Plus, an independent, international infection control consulting company. She has 30 years of experience in the global infection prevention and control community. Assoc. Prof. Murphy's career highlights include working as a guest researcher in the Division of Healthcare Quality and Infection Prevention at the CDC, Georgia in 2000 and completing a short-term mission throughout Southeast Asia with the World Health Organization during the height of the 2003 SARS Outbreak. She managed the New South Wales State Government Infection Control Program from 1997 until December 2004 with programmatic responsibility for more than 200 hospitals. Conflict of Interest. Associate Professor Cathryn Murphy is a consultant to medical industry and device manufacturers including CleanSpace Technology Pty Ltd.



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