SELECTING EFFECTIVE RESPIRATORY PROTECTIVE EQUIPMENT FOR SARS-COVID2

OHCOW 2020

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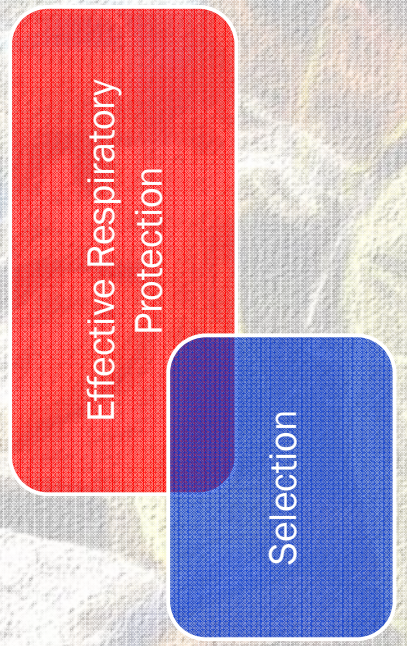
PRESENTATION PLAN

- Overview of Respiratory Protection
- Respirator Types relevant in Healthcare
- Filtration, Fit and Function
- Standards for Respiratory Protection
- Selection Guidance for Respirators
- Conclusions



Focus on protection of wearer
Not addressing public use of masks

UP-FRONT COMMENTARY ON RESPIRATORY PROTECTION

- Highly technical area
  - Advanced technologies are used in equipment
  - Extensive studies on performance, test requirements and methods
- Highly Regulated area
  - Legislation for use when workplace exposure conditions require it
  - Regulatory structure to ensure that equipment sold is capable of protecting people
  - Likewise guidance to cover selection, fitting, use and maintenance
- But conventional provisions overridden by issues of equipment shortage and nature of the Covid-2 pathogen
- Not since World War II has the general public and mass media had such strong interaction with the respirator world

Imperial War Museum, UK

D. J. Smith

EXAMPLES OF RESPIRATORY PROTECTIVE EQUIPMENT (RPE)

Respirator:
A component of Personal Protective Equipment (PPE), designed to protect the wearer's respiratory tract against inhalation of hazardous atmospheres

Selection includes balancing desired protection with other factors

Equipment	SCBA	PAPR (T)	FF-APR	PAPR (L)	HF-APR	FFP
Protection Hierarchy Level	5	4	3	2	1	1
Assigned Protection Factor	10,000	1,000	100	25/1,000	10	10

Photos: 3M Company/BBC

IMPORTANT POINTS

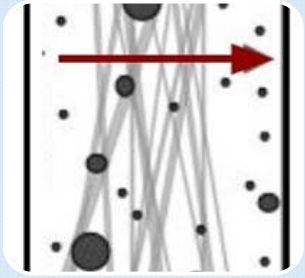
- No respirator can provide 100% protection!
  - Any claim of doing that is suspect
- They cannot “prevent” infection
- Typical understanding is:

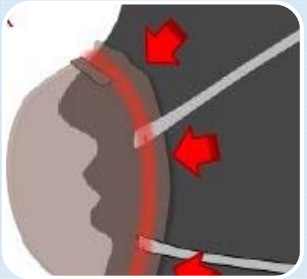
  “A properly selected, fitted and maintained approved respirator can be effective in reducing the transmission of infection to the wearer”
- Surgical masks/procedure masks do not seal to the face and are not considered respirators

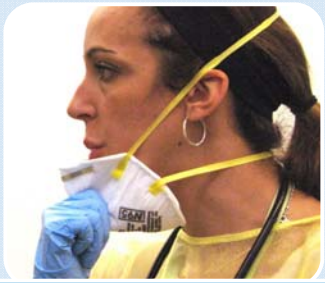
POINTS COVERED ELSEWHERE OR SEPARATE DISCUSSION

- Hierarchy of Controls
- RPE are one element of PPE which works as an ensemble and compatibility is a necessary goal
- Air Supplying respirators – air-line and self-contained
  - Used in cases of oxygen deficiency, poorly filtered gases or potential high contaminant concentrations which would overwhelm a filter
- Gas/Vapour Filters
  - For contaminants in the gaseous state
  - Remove contaminants by adsorption on a sorbent and/or chemical reaction
  - Use in healthcare facilities may be by specific personnel such as during construction, maintenance, decontamination and cleaning operations and in laboratories

KEY ASPECTS OF RESPIRATORY PROTECTION INFLUENCING EFFECTIVENESS (“3Fs”)



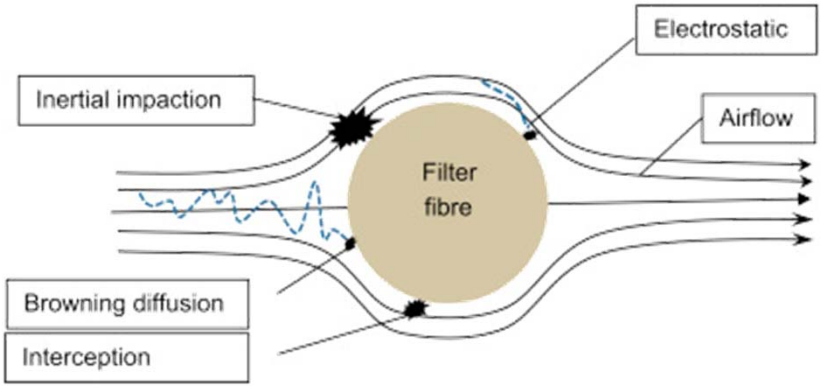


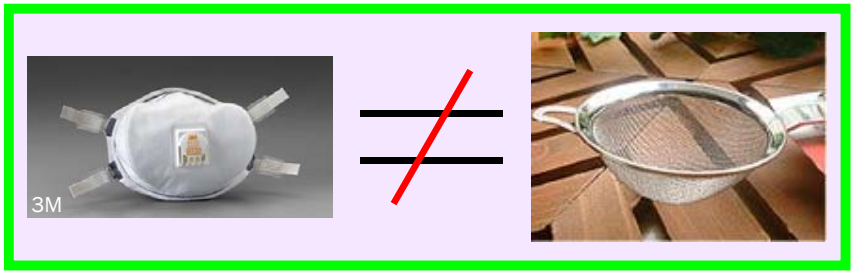


	Filtration	Fit	Function
Associated Terms	Efficiency (%) Penetration (100% - Efficiency%), Quality Factor, Degradation	Protection Factor Qualitative, Quantitative Simulated/Simulated Workplace Assigned Protection Factor	Impact on work activities, communication, physiological burden, CO_2, heat and moisture build-up
Influenced By	Particle size, Size distribution, Air flow rate, measurement method,	Measurement method, activities – movement, heat and skin moisture level	Lab exercises and on-site studies

FILTRATION OF PARTICULATE MATTER

- Effective filtering layers in a filtering facepiece (and most other particulate filter types) are a fibrous web (usually glass or polymer) and there are multiple mechanisms for removal of particles
- Some are more effective for larger particles, some more effective for smaller particles





NOT like a fishing net or tea strainer!

- Filter media are often treated to create dispersed electrostatic charges on fibres to improve removal of smaller particles allowing lower airflow resistance
- Oil can interfere with these charges by coating the fibres, so either:
  - Both inorganic salt and oil-based aerosols are also used for approvals testing (EN 149 FFP2 for example)
  - There is distinction of classes for non-oil and oil-based aerosols (NIOSH N, R & P classes)

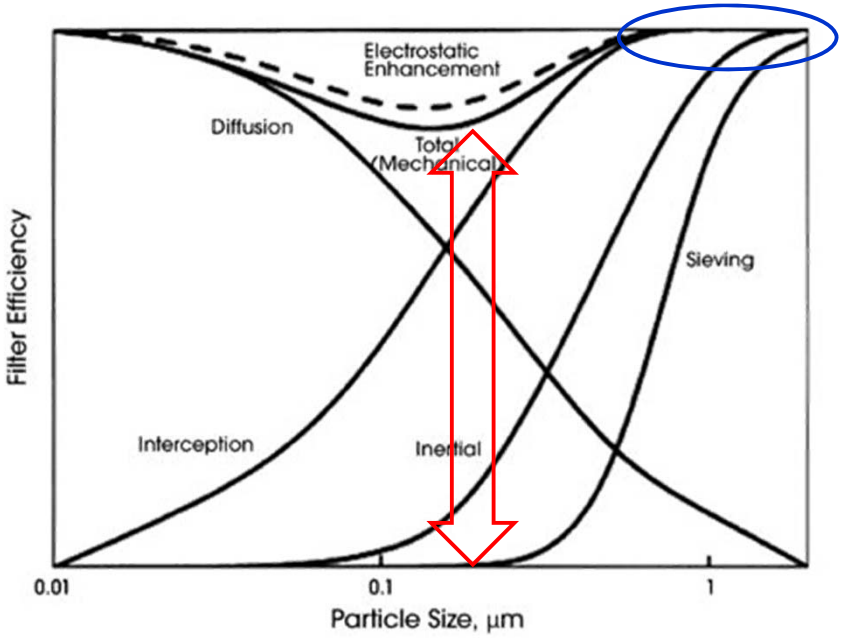
FILTRATION

- Removal mechanisms effects combine resulting in a "most penetrating particle size" at the minimum efficiency level - in the range 0.2 to 0.3 microns
- Filters are tested with particles of this size
- Salt (sodium chloride) aerosol is generally used as a representative aerosol by world-wide standards – many studies show it is a suitable surrogate
- The "95" in N95 represents 95% efficiency at this size
- Sizes of expelled respiratory fluid mean that filtration efficiency for them is close to 100% for a N95 filter
- Note that there is surgical mask "clearance" standard by the US FDA covering fluid resistance/biological filtration though filtration requirements are much lower than NIOSH. Some respirators have this in addition to NIOSH approval. NIOSH/FDA have created a combined designation (recently released) which will be "N95F".

* US National Institute for Occupational Health and Safety which approves respirators for use in North America

NIOSH* Classifications

Negative Pressure		Type		
		Non-Oil	Oil 1-shift	Oil indef.
		N	R	P
Efficiency	95	N95	R95	P95
	99	N99	R99	P99
	100	N100	R100	P100
Powered Air		100N	HE	100P



FIT: WHAT AFFECTS FIT OF A FILTERING FACEPIECE OR OTHER RESPIRATOR

- Design of mask (technology, standards and head-shape)
- Airflow resistance of filter media – higher resistance may exacerbate leakage
- Flexibility of facepiece
- Nose clip/cushioning or sealing materials
- Straps – adjustment, placement, effectiveness
- Proper donning and adjustment

Additionally – changes over time:

- Loss of flexibility/seal due to heat, humidity and secretions
- Effects of decontamination on strength and flexibility if used
- Ageing of construction materials
- Studies on stockpiles show straps fail first

Harvard Medical School

Failure Mode	Problem	Impact	Tested By
Filtration efficiency	Reduced due to environmental or chemical exposure or physical damage – loss of protection	Loss of protection	Aerosol tester
Airflow resistance	Item becomes harder to breathe through because of physical change to the filtering fibrous web or accumulation of surface chemicals	Physiological burden, greater leakage	Aerosol tester
Loss of original shape or flexion	Reduced ability to fit properly to the face	Leakage	Qualitative or quantitative fit test
Nose clip	Detachment or looseness, breakage, brittleness or warping – leakage path	Leakage, discomfort	Physical inspection
Nose cushion	Loss of cushioning ability, detachment, chemical absorption	Leakage, toxic hazard	Physical inspection
Straps	Detachment at joining point to mask, snapping or weakness, loss of elasticity, damage to adjustment clips if present.	Leakage, total failure	Physical inspection
Incomplete Decon	Item remains contaminated	Infection hazard	Biological sampling
Retention of decontaminant	Surface or degassing toxic hazard to user, reduced filtration efficiency, increased airflow resistance	Toxic hazard	Chemical detector or tests as above

FIT TESTING AND FIT CHECKING (PART OF A RESPIRATORY PROTECTION PROGRAMME)

Qualitative Fit Test

3M Company

For initial selection and routine re-testing

- Subject dons respirator as normal
- Hood over head
- Bitter or sweet aerosol introduced into hood
- Taste indicates leakage

Quantitative Fit Test

TSI Incorporated

- Subject wears respirator with probe to sample interior
- Sensitive particle analyser compares ratio of airborne dust outside to inside mask
- Ratio measured during movement breathing and speech exercises

User Seal Check

Each donning

Harvard Medical School

- Subject dons mask and blocks air paths
- Sharp inhalation and exhalation, feel for air leakage around face-seal
- Attention beardies!

FUNCTION – RECENT REVIEW BY THE CENTRE FOR EVIDENCE-BASED MEDICINE "*PERFORMANCE AND IMPACT OF DISPOSABLE AND REUSABLE RESPIRATORS FOR HEALTHCARE WORKERS DURING PANDEMIC RESPIRATORY DISEASE: A RAPID EVIDENCE REVIEW*"

Submitted to:
Infection Control and Hospital Epidemiology

Review Questions

- What standards currently exist for respirators in healthcare/non-healthcare settings, how do standards compare?
- How well do respirators perform in clinical settings in terms of fit, either initially or during clinical activities?
- How do healthcare workers and organisations use and perceive different forms of respirator in practice?
- What are the impacts on clinicians and their performance of using different forms of respirators in patient care?

Research tool – "Spider"

- Sample – healthcare workers or student healthcare workers
- Phenomenon of Interest – respirators: including disposable, elastomeric and powered air-purifying types
- Design – includes cross-sectional, cohort observation, simulation and interview or focus group
- Evaluation – tests of: respirator performance; clinician performance or adherence; self-reported comfort and impact; perceptions of use
- Research types: quantitative, qualitative or mixed-method

Identified 39 eligible original publications, no relevant systematic reviews and one narrative review without a systematic search strategy.

Pre-print: https://www.medrxiv.org/content/10.1101/2020.05.21.20108233v1

CONCLUSIONS ON SUITABILITY OF RESPIRATORS IN HEALTHCARE SETTINGS

- Need for appropriate fit testing and training (10 studies, 8055 participants, cross-sectional studies)
  - At least 10% of users will need to try more than one respirator model in order to achieve fit
  - Seal check is a poor predictor of fit and is not sufficient
  - FFR fit markedly diminished in presence of facial hair.

- Reliability of fit-tested respirator in clinical activity (7 studies, 384 participants, simulation studies)
  - CPR led to failure of fit in 10-60% of FFR users (3 studies). No failure in PAPR users, no studies with elastomeric respirators
  - One study showed 0-30% fit failure with FFR during generic healthcare activities

- Adherence to standards in practice and effect of training (3 studies, 165 participants, small specific studies)
  - Problems with following guidelines for safe use is common in donning / doffing and during use
  - Repeated training appears to be necessary to ensure continuing safe respirator fit

CONCLUSIONS ON CLINICAL IMPACT OF RESPIRATOR USE

- Impact on clinical performance (4 studies, 83 participants, small simulator studies)
  - Performance of simulated procedures including endotracheal intubation minimally affected
  - Participants report some problems with vision and with hearing
- Impact on clinical communication (6 studies, 1741 participants, experiments and surveys)
  - Meaningful drop in speech quality (EFR & PAPR) and hearing (PAPR); subjective identification of difficulties in 20-40% users
  - Experimental studies indicate meaningful impact likely, surveys vary on perceived extent
- Impact on comfort (10 studies, 2604 participants, surveys)
  - Discomfort reported in 15-40% users. Higher with EFR/PAPR than FFR.
  - More than half of users unable to wear for full 8hr shift, but highly variable feedback
- Healthcare worker and organisation perceptions regarding use (3 studies, 1510 participants, qualitative studies and surveys)
  - HCW accepts a balance between discomfort and extra protection
  - HCW and organisations indicate important of practical issues (storage, access) and social context of norms and culture

PERFORMANCE STANDARDS AND CERTIFICATION

What Standards Do

- Set minimum criteria for product performance
- For respirators, cover the 3Fs (more or less)
- Provide assurance that design is capable of providing a specified level of protection
- Promote quality consistency in some cases
- Can aid minimizing trade barriers

Certification Systems

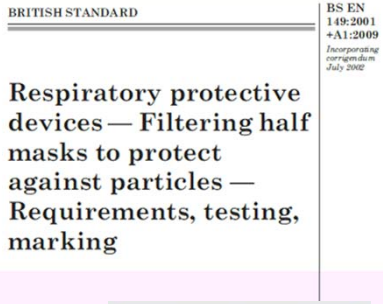
- Test and approve products to the criteria in standards
- Various mechanisms
  - May be linked to standards organisations or separate
  - Government body or independent testing
- Ensure all product sold meets standards

Some Considerations about Standards

- May not be updated frequently
  - Don't keep up with user needs or technical advances
- May not match relevant user needs
  - Healthcare needs versus general industry
  - Designed to suit certain populations not others
- May drive to commonality
  - Performance hovers just above the minimum
  - May stifle innovation and competition
- May not test everything that's important
- May be overly depended on

Note: The same standards for respiratory protective equipment apply in healthcare as in general industry

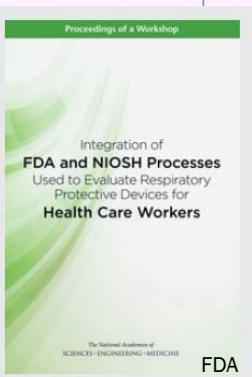
PERFORMANCE STANDARDS - EXAMPLES



- NIOSH (includes N95, P100, HE)
  - US Government set standards, performs testing and certification
  - N- types for non-oil environments, R and P types for oil-based contamination
  - Same classes for reusable filters, one class for PAPRs
- Europe (FFP2, FFP3 TH3P)
  - CEN Committee (industry and users) sets standards
  - Independent bodies and labs test and certify
  - All types tested with oil-based agents
  - P1, P2, P3 classes for reusable filters (“P” for PAPR)
- Australia (P2, P3 PAPR-P3)
  - Independent committee sets standards, gov’t certifies
  - Similar levels for FFP and reusable filters
- China (KN95 etc.)
  - Similar to NIOSH classes but lack quality assurance provisions
  - Problems with fit to Caucasian head profiles
- US Food and Drug Administration
  - Issues “clearances” for medical devices to various levels

Recent Updates

NIOSH & FDA – Combined certification process introduced in 2018, no products yet approved
https://www.cdc.gov/niosh/nioshtic-2/20049298.html



FDA

NIOSH – New Powered Air Purifying Respirator Classes:
https://www.federalregister.gov/documents/2020/04/14/2020-07804/approval-tests-and-standards-for-air-purifying-particulate-respirators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RIGHT KIND OF RESPIRATOR FOR THE JOB: SELECTION STANDARDS AND GUIDANCE

"Permanent"

- Many authorities have guidance on administering respiratory protection programmes and selecting respirators
- Canada's is very comprehensive
- Provides guidance for selection for biological aerosols
- Most others rely on "expert opinion" which is generated by authoritative bodies every time there is a new type of pathogen
- Guidance does fully support use of industrial-type respirators in industry
- https://community.csagroup.org/docs/DOC-121294

"Emergency"

- The Covid-19 pandemic has led to emergency authorizations with special allowances

https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/personal-protective-equipment/medical-masks-respirators.html

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidppe

- Use of products meeting standards not normally accepted
- Changes in the use of products – extended use and reprocessing

CURRENT ISSUES IN THE PANDEMIC

Equipment Shortage

- Use of approved respirators (e.g. industrial models) not usual in healthcare (FDA and Health Canada emergency notices)
- Inadequate alternatives
- Extended use and re-use, decontamination
  - Reliable technologies now developed
- Extension of stockpile shelf-lives
- "Foreign" respiratory protective equipment and unfamiliar standards – issues:
  - Counterfeit products
  - Certified products – but poor quality
  - Certified products, good quality but not fitting well (head shape differences)
- New manufacturer start-ups
- Beware of claims
  - Filtration only, not fit or function (selective sections of stds quoted)
  - Filtration with non-standard test method

Note: for NIOSH-approved products in North America, it is not mandatory to set a shelf-life for respirators

Alternative Measures/Alternative Facts

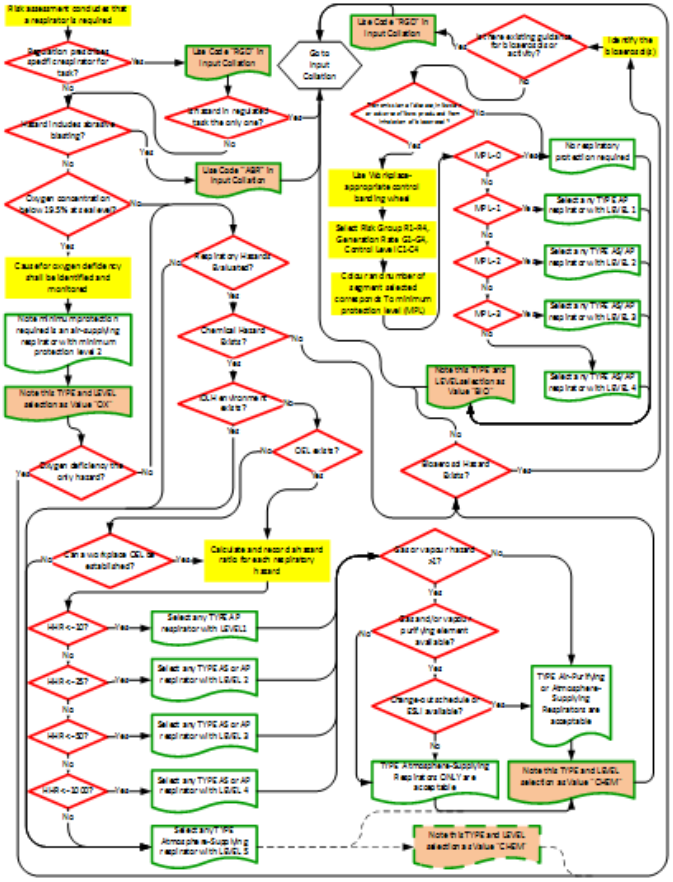
- Surgical mask standards are considered as protective as respirator standards
- Focus on filtration not fit
- Cloth masks and effective protection
  - Generally at least order of magnitude difference
  - Some studies questionable (data selection, inappropriate test methods)
  - Reasonable for removal of large exhaled particles
- Fit testing and fit-checking confused

Innovations

- Certification fast-tracking by NIOSH
- New Powered Air Purifying Respirator Standards
  - PAPR-100N, PAPR-100P

RESPIRATOR SELECTION, USE AND CARE GUIDANCE IN ONTARIO AND CANADA – CANADIAN STANDARD CSA Z94.4-18

- Respirator use requires a respiratory protection programme
- Medical clearance for prospective wearers
- Hazard and risk assessment
- Selection guidance for appropriate level of protection and type
- Fit testing and training programmes
- Cleaning, inspection, maintenance and storage
- Appropriate training
- Recordkeeping



Note mandatory in Ontario but considered a “best practice”

APPROACHES FOR RPE SELECTION FOR BIOLOGICAL HAZARDS

Method	Advantages	Disadvantages
Guidelines based on Expert Opinion	Often authoritative sources Well recognised	May cover specific circumstances but also leaves gaps Sources' guidance may be inconsistent with each other Sometimes inconsistent with occupational hygiene principles May take time to develop for emerging threats
Quantitative Modelling (e.g. ANSI Z88.12)	Supports wide range of scenarios Accuracy	Needs numeric data as inputs which may be hard to obtain (e.g. pathogen concentrations in sputum, coughing rates) How acceptable is the resulting "Probability of Infection"?
Control Banding	Relatively simple Covers range of scenarios	Relies on qualitative assessment of some inputs May lead to over-simplification or wrong assumptions by users

CSA Z94.4-18 SELECTION PROCESS

FOR BIOLOGICAL AEROSOLS

Step	Action
1	Identify the bioaerosol
2	Confirm that a risk of transmission of disease, infection or adverse effects is produced from inhalation of bioaerosol and there is no applicable existing guidance
3	Select applicable control banding wheel (Healthcare or General Workplace)
4	Determine the bioaerosol risk group (R1 to R4)
5	Determine the generation rate (G1 to G4)
6	Determine the control (ventilation) level (C1 to C4)
7	Identify the protection level in the segment in the applicable wheel at the intersection R, G and C values and select respirator based on this.

Biological Hazard Risk Group

Risk Group	Health impacts (transmissibility, infectivity and adverse health effects of the biohazard)
Risk Group 1 (R1)	Agents that are not associated with disease or serious adverse health effects in healthy adult humans
Risk Group 2 (R2)	Agents that are associated with human disease or adverse health effect which is rarely serious and for which preventive or therapeutic interventions are often available
Risk Group 3 (R3)	Agents that are associated with serious or lethal human disease or adverse health effect for which preventive or therapeutic interventions may be available (high individual risk but low community risk)
Risk Group 4 (R4)	Agents that are likely to cause serious or lethal human disease or adverse health effect for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk)

Classifications correspond with the US National Institutes of Health "Guidelines for Research Involving Recombinant DNA Molecules" (March 2013)

Generation Inputs

Rank	Qualitative Example	Factor Used
Healthcare		
G1	Patient not coughing or sneezing	1
G2	Patient coughing or sneezing with mouth covered	3
G3	Patient coughing or sneezing with mouth uncovered	5
G4	Aerosol generating procedure	12
General Workplace		
G1	Low - Vacuuming with a HEPA filter	1
G2	Medium - Soaking then shovelling pigeon droppings	2
G3	High – Misting then shovelling pigeon droppings	3
G4	Very High – Dry Sweeping pigeon droppings	6

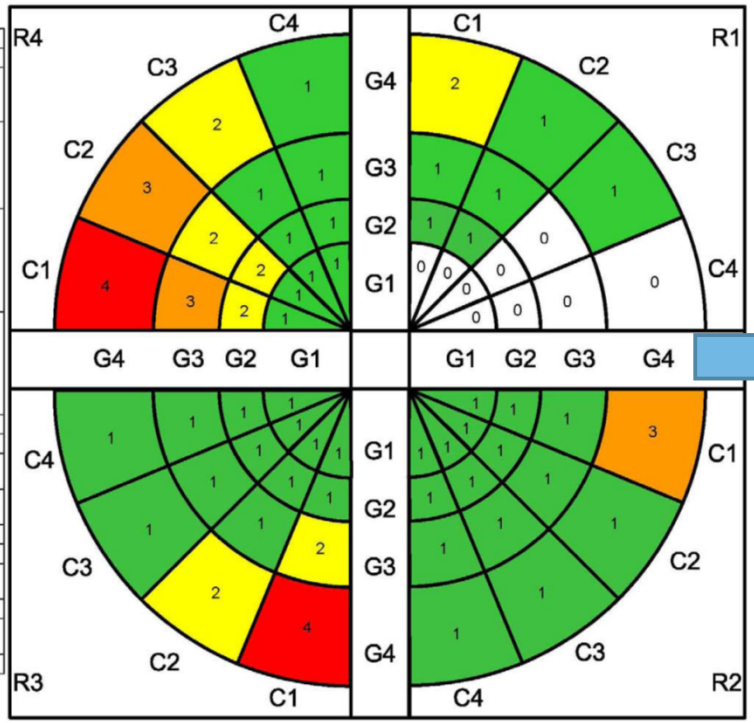
Control (Ventilation) Inputs

Level	ACH	Qualitative Example	Factor Used	Guidance
Healthcare				
C1	<3	Storage Area	3	Adapted from Canadian Standard Z317.2 (and simplified) Similar to ASHRAE
C2	3-6	Patient Room/Corridor	6	
C3	6-12	Autopsy	12	
C4	12-25	Surgery	25	
General Workplace				
C1	<1	Indoor/Poor Ventilation	1	Quebec Occupational Health and Safety Regulation 2011
C2	1-4	Indoor Natural Ventilation	2.5	
C3	4-6	Indoor Mechanical Ventilation/Outdoor low wind	4	
C4	>6	Outdoor moderate wind	6	

CSA Z94.4-18 SELECTION PROCESS (CONTINUED)

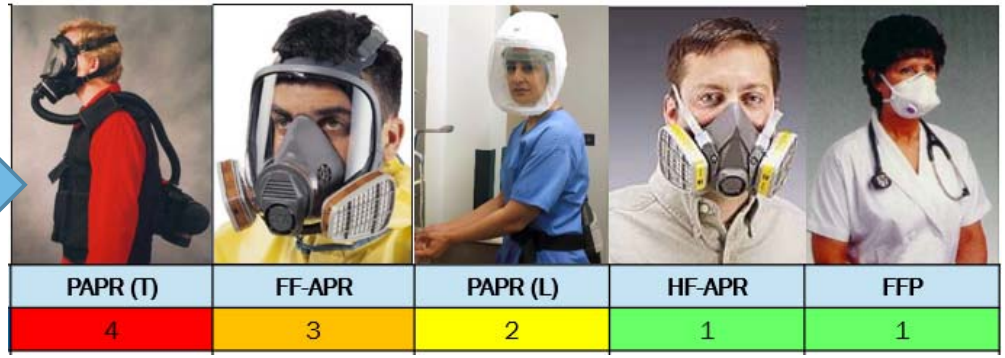
Selection guidance based on the "COSHH Wheel"

Health Care Facilities	
Risk Group	
Agents that are not associated with disease or serious adverse health effects in healthy adult humans	R1
Agents that are associated with human disease or adverse health effect which is rarely serious and for which preventive or therapeutic interventions are often available	R2
Agents that are associated with serious or lethal human disease or adverse health effect for which preventive or therapeutic interventions may be available (high individual risk but low community risk)	R3
Agents that are likely to cause serious or lethal human disease or adverse health effect for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk)	R4
Generation Rate	
Patient not coughing or sneezing	G1
Patient coughing or sneezing with mouth covered	G2
Patient coughing or sneezing with mouth uncovered	G3
Aerosol generating procedures	G4
Control Level	
Poorly Ventilated <3 air changes per hour (ACH)	C1
Corridor or patient room, 3-6 ACH	C2
Negative Pressure, Laboratory, Autopsy, 6-12 ACH	C3
Surgery >12 ACH	C4



0 = No respirator required

- Combination of workplace and pathogen type, generation and control levels provides an advised protection level allowing selection of respirator type
- Protocol was built from collation of historical expert opinion with literature study
- It usually provides comparable proposals for similar exposures but fills gaps



One important feature is that the same exposure event may lead to indication of different protection levels depending on the ambient ventilation rate

Example for Covid-2: Aerosol Generating Procedure under high ventilation indicates Level 1 (FFP/Half-facemask), but poorer ventilation indicates Level 2 or 4 PAPR usage

CONCLUSIONS FOR RESPIRATOR TYPES TYPICAL IN HEALTHCARE IN PANDEMIC CIRCUMSTANCES

Filtering Facepiece

- Familiar to user community
- Basic-level of protection
- Industrial variants accepted (e.g. P100 types)
- Intended to be disposable, but re-use now in effect

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Elastomeric Facepiece

- Half-mask (nose & mouth)
- Full-face with eye-protection
- Reusable mask after cleaning
- Longer duration filters
- Use with replaceable N95 or P100 filters

Dräger

3M

Powered Air Purifying Respirator

- Blower feeds air facepiece or head-top
- Exiting airflow provides effective protection
- Reusable after cleaning
- Requires battery charging and maintenance programme
- New NIOSH standards will lead to smaller, lighter and cheaper products than current offerings
- Belt, neck or head-mounted variants

3M

Clean Space

Maxair

SUMMARY

- Respiratory Protection is a very regulated field and if appropriate selection, use and care protocol are followed using equipment complying to standards, a satisfactory level of respiratory protection can be achieved
- Guidance on selection and use is long-established, but has been overruled by issues of equipment supply meaning new guidelines have rapidly been developed
- Generally, evidence is supporting the fact that “industrial” respirators are fully capable for use in healthcare facilities, and some even show authoritative guidance may need to be augmented
- Comprehensive selection guidance for biological aerosols is available

THANK YOU

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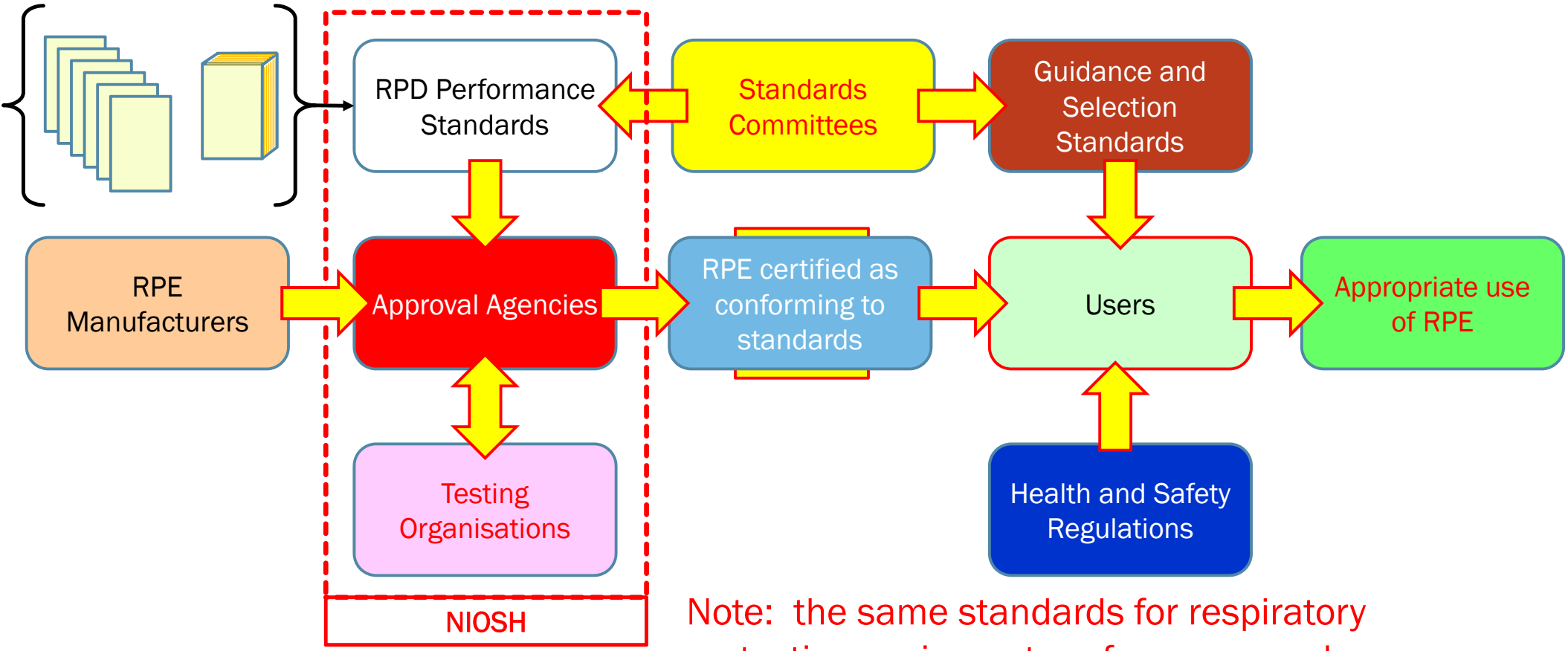
Any unattributed photographs were provided by the author.

EXHALATION VALVES AND THE SURGICAL FIELD

- All RPE designs except the simplest filtering facepieces incorporate exhalation valves which allow air from the wearer to exit without filtration
- Some FFPs have exhalation valves to improve wearer comfort
- Do such values change contamination in a sterile field?

- Even FFPs without valves seal better on inhalation than exhalation so some exhaled air by-passes them
- The exit path through an exhalation valve is generally so convoluted that large particles will not escape
- Surgical masks fit so poorly that only large exhaled particles are retained
- So possible contamination from exhalation by medical staff into the surgical field has always been a reality
- There were once (and may be in the future) specialized PAPRs which incorporate exhalation filtration, but otherwise it is difficult to manage

STANDARDS, GUIDANCE AND APPROVALS



Note: the same standards for respiratory protective equipment performance and use apply in healthcare as in general industry

COMPARISON OF STANDARDS FOR FILTERING FACEPIECES USED IN HEALTHCARE AND INDUSTRY

(BASED ON PERFORMANCE REQUIRED IN THE RESPECTIVE STANDARDS)

One document for all RPE types

Separate document for each RPE type

Country/Domain (with standards setting agency)	Applicable Standard (Year)	Filtering Facepiece Classification Examples		
		Classes Usual for Healthcare (HC) Use	Classes not usual in HC but Acceptable for HC use (Equivalent to/Greater than N95 Capability)	Classes not usual in HC and Not Recommended for HC use (Lower than N95-equivalent Capability)
Australia/New Zealand (Standards Australia/Standards New Zealand)	AS/NZS 1716 (2012)	P2, P3		P1
Brazil (Associação Brasileira de Normas Técnicas)	ABNT NBR 13698 (2011)	PFF2 S, PFF3 S	PFF2 SL, PFF3 SL	PFF1 S, PFF1 SL
China (Standards Administration of China)	GB2626 (2019)	KN95	KN99, KN100, KR95, KR99, KR100, KP95, KP99, KP100	
Europe (European Committee for Standardization)	EN 149 (2001, updated 2009)	FFP2, FFP3		FFP1
Japan (Ministry of Health, Labour and Welfare)	JMHLW Notification 214 (2018)	DS2, DS3	DL2, DL3	DS1, DL1
Korea (Ministry of Employment and Labour)	KMOEL - 2017-64 (2017)	KF94 (1st Class)	Special	KF80 (2nd Class)
Mexico (Comisión Nacional de Normalización)	NOM-116-STPS-2009	N95	N100, R95, R100, P95, P100	N90, R90, P90
United States (National Institute for Occupational Safety and Health)	42 CFR 84 (1995)	N95	N99, N100, R95, R99, R100, P95, P99, P100	

Summary of Major World-Wide Filtering Respirator Standards and Guidance

Organisation	Recognised in	Respirator performance standards (includes requirements, testing & marking) Latest revision year indicated		Selection, use and care standards (or nearest equivalent) (includes user testing and appropriate use)	
		Standard	Description	Standard	Description
Australia/New Zealand Standards (AS/NZS)	Australia & New Zealand	AS/NZS 1716 (2012)	Respiratory Protective Devices	AS/NZS 1715 (2012)	Selection, use and maintenance of respiratory protective equipment
Brazil Associação Brasileira de Normas Técnicas (ABNT)	Brazil	ABNT NBR 13698 (2011)	Respiratory protective devices - Filtering half mask to protect against particles	ABNT NBR 12543 (2017)	Respiratory protective devices - Terminology
Canadian Standards Association (CSA)	Canada			CSA Z94.4 (2018)	Selection, use and care of respirators
Standardization Administration of China	China	GB 2626 (2019)	Non-powered air-purifying particle respirators	GB/T 18664 (2002)	Selection, use and maintenance of Respiratory protective equipment
		GB 30864 (2014)	Powered air-purifying respirators		
European Committee for Standardization (CEN)	UK, European Union, European Free-Trade Association, Russia. South Africa	EN 149 (2009)	Filtering facepiece	EN 132 (1999)	Definitions of terms & pictograms
		EN 136 & EN 140 (1998)	Elastomeric facepiece	EN 529 (2005)	Recommendations for selection, use, care and maintenance
		EN 12941 (2008)	Loose fitting PAPR		
		EN 12942 (2008)	Tight-fitting PAPR		
		EN 143 (2000)	Filters for respirators		
Japanese Industrial Standards Committees (JIS)[1]	Japan	JIS T 8151 (2018)	Particulate respirators	JIS T 8150 (2006)	Guidance for selection, use and maintenance of respiratory protective devices
		JIS T 8157 (2018)	Powered air purifying respirator for particulate matter		
Japan Ministry of Health, Labour and Welfare (JMHLW)		Notification 214-2018	Standard for Dust Mask		
Korean Agency for Technology and Standards (KATS)[2]	Korea	KS M 6673 (2008)	Dust respirators	KS P 1101 (2010)	Guidance for selection, use and maintenance of respiratory protective devices
		KS M 6764 (2009)	Filter for dust respirators		
		KS P 8416 (2008)	Dust respirators for fine particles		
		KS P 8417 (2008)	Powered air purifying respirators		
Korean Ministry of Employment and Labour (KMOEL)		KMOEL Notification 2017-64 (2017)	Dust respirators		
Mexican Norma Oficial Mexicana (NOM)	Mexico	NOM-116-STPS-2009	Particulate FFP and replaceable filters	Annex to NOM-116-STPS-2009	Guide for selection of air purifying respirators for hazardous dusts
U.S. National Institute for Occupational Safety & Health (NIOSH)	USA, Canada[3]	42 CFR 84 (1995)	All types of respiratory protective device	29 CFR 1910.134 (1998) (USA only)	Respiratory Protection

[1] In Japan, JIS standards are not mandatory, while JMHLW notifications are mandatory
[2] In Korea, KATS standards are not mandatory, while KMOEL notifications are mandatory
[3] In Canada, there are multiple jurisdictions: NIOSH approvals are generally accepted but those of other agencies may also be applicable in some jurisdictions

Comparison of US Respirator (N95) and Surgical Mask Filtration Requirements

Copied from: "A comparison of facemask and respirator filtration test methods", Samy Rengasamy, Ronald Shaffer, Brandon Williams, Sarah Smit, Journal of Occupational and Environmental Hygiene, 14(2) p.92-103 (2019).

Test Method	Source Documents	Aerosol Type	Particle Size	Particle Charge	Particle Concentration	Aerosol Detector	Flow Rate (Face Velocity)	Test Time	Max Efficiency	Sample Type (Size)
NIOSH NaCl	42 CFR part 84	NaCl	0.075 um CMD (GSD <1.86)	Neutralized	<200 mg/m^3	Light Scattering photometer	85 L/min (Face Velocity varies between respirators	Maximum penetration	99.999%	Respirator (Entire mask)
FDA-PFE	1) FDA Guidance Document (SM 501(k)) 2) ASTM F 1215-89 (withdrawn) 3) ASTM F2100 4) ASTM F2299	Polystyrene latex spheres (FDA Guidance Document)	0.1 um (FDA Guidance Document)	Un-neutralized (FDA Guidance Document)	Generate 10^7 - 10^8 particles/m^3 and dilute as needed (ASTM F2299)	Optical particle counter (ASTM F2299	0.5-25 cm/sec (ASTM F2299	1-5 min Initial efficiency (ASTM F2299)	99.9% Increase aerosol concentration to achieve greater efficiencies (ASTM F2299)	Surgical mask (Entire mask) (FDA Guidance Document)
ASTM-PFE	ASTM F2299	Latex spheres	0.1 to 5.0 um (Mono-disperse aerosol; MPS)	Neutralized	Generate 10^7 - 10^8 particles/m^3 and dilute as needed	Optical particle counter	0.5-25 cm/sec	1-5 min Initial efficiency	99.9% Increase aerosol concentration to achieve greater efficiencies	Surgical mask (50-150 mm diameter circle)
FDA-BFE	1) FDA Guidance Document (SM 501(k) 2) ASTM F2100 3) ASTM F2101	Staphylo-coccus aureus (ASTM F2101	3.0±0.3 um (MPS) (ASTM F2101	Undefined (ASTM F2101	2200 ± 500 viable particles per test (ASTM F2101)	Six-Stage Viable Particle Cascade Impactor (ASTM F2101)	28.3 L/min (Face velocity not defined) (ASTM F2101	2 min aerosol exposure per test (ASTM F2101)	99.9% (ASTM F2101)	Surgical mask (Entire mask) (FDA Guidance Document)
ASTM-BFE	ASTM F2101	Staphylo-coccus aureus	3.0±0.3 um (MPS)	Undefined	2200 ± 500 viable particles per test	Six-Stage Viable Particle Cascade Impactor	28.3 L/min (Face velocity not defined)	2 min aerosol exposure per test	99.9%	Surgical mask (Mask material) (Test material area not defined; but should be reported)
VFE	VFE Not a Standard test method	PhiX174 virus	33.0±0.3 um MPS (adapted from ASTM F2101)	Undefined	1700 – 2000 plaque forming units per test (adapted from ASTM F2101)	Six-Stage Viable Particle Cascade Impactor (adapted from ASTM F2101)	28.3 L/min (Face velocity < 4.7 cm/sec) (per Nelson Labs)	Not Defined	99.9% (adapted from ASTM F2101)	Entire mask or 10 × 10 cm mask material (per Nelson Labs)