Towards a Theory of Pandemic Proof PPE

March 3rd, 2023

GRYPHON SCIENTIFIC

Welcome

Rocco Casagrande, PhD

The Problem

Shortcomings related to personal protective equipment (PPE) were widely recognized to exacerbate the toll of the COVID-19 pandemic. However, because these shortcomings were varied and had logistical, engineering, biomedical and societal underpinnings, the most effective interventions to improve PPE are unclear.

Moreover, if we prepare for the previous pandemic, an emerging infectious disease with different properties could obviate our preparedness efforts. We must use scientific-based analysis to understand what the next pandemic COULD resemble to "pandemic proof" the PPE enterprise.

Global pandemics have catastrophic consequences

Exact timing and characteristics are difficult to predict

Immediate need to develop pandemic interventions

Personal protective equipment (PPE) investment is competitive with other high-impact interventions

The highest-impact PPE investments are unclear

The Effective Altruism community lacks institutional knowledge to make PPE investments towards pandemic preparedness goal

P4E: Towards a Theory of Pandemic Proof PPE

This study will inform investments in PPE to reduce the size and impact of the next pandemic

Introducing Our Team

Rocco Casagrande, PhD
Principal Investigator

Margaret Rush, PhD
Deputy PI

Bob Stephan
Senior Advisor

Tom Mullen
Senior Partner

Landy Sun
Senior Analyst

John Baggett, PhD
Senior Analyst

Daniel Greene, PhD
Senior Analyst

Mindy James, PhD
Senior Analyst

Anna Muldoon, MPH
Senior Analyst

Introducing Our Team

Greg Burel
Project Consultant

Peter Mihalopoulos
Consultant

Theresa Li
Consultant Analyst

Rob Dettmann
Analyst

Noah Gunther
Technical Specialist

Evan Turner
Research Assistant

Matthew Kegley
Research Assistant

Truman Grimm
Research Assistant

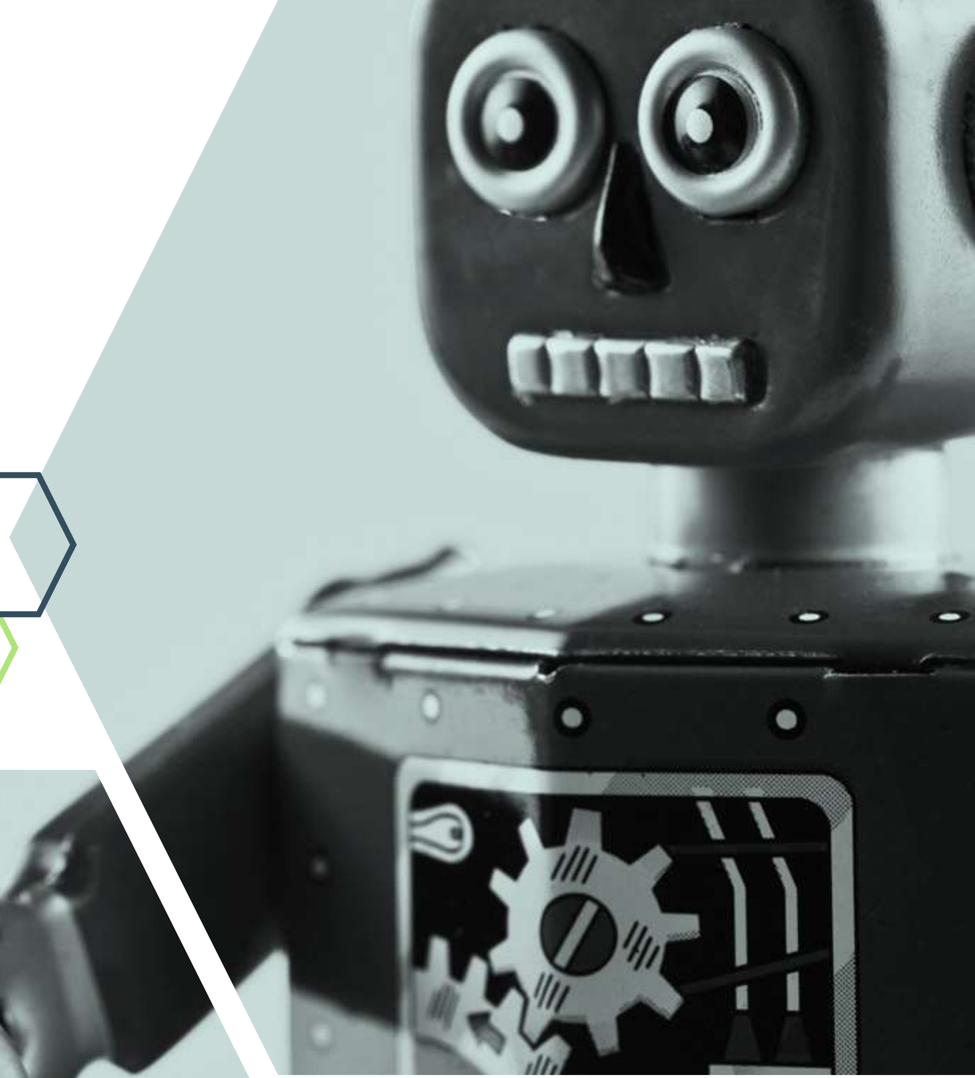
Navin De Silva
Research Assistant

Katherine Miller
Intern

Group Introductions

Name & Title/Role

Interest in PPE



This work was conducted with the generous support of

EFFECTIVE GIVING

Project Approach Overview

- This is the midpoint of a 1-year, 4-phase project

1. **Characterize PPE gaps that hampered responses to previous pandemics**
2. **Parametrically analyze PPE performance and demand against next-generation pandemic threats**
3. *Use data from Phase 1 and 2 to describe requirements for effective PPE*
4. *Identify opportunities for funding to reach PPE goals set in Phase 3*

What are the gaps? → What are the goals? → How are the goals achieved?

Meeting Overview & Expectations

- We organized the review of the state-of-the-PPE enterprise by subtopic
- On each subtopic, we describe the gaps that seem to us to be the most critical to address – we don't have time to talk about them all!
- In each section, we will have time to discuss the gaps with two main considerations:
  - Did we skip over any gaps that you think should be priorities?
  - Are the gaps we discussed truly worth focusing on to improve PPE for the next pandemic?
- Questions before we begin?

Morning Agenda

01

Welcome

9.00 am – 9.45 am

Rocco Casagrande, PhD

I: Introductions, Scope & Purpose

II: Setting the Stage: Possibilities of the Next Pandemic

02

Defining PPE

09.45 am – 10.00 am

Meg Rush, PhD

Definition & Gaps in Standardization of PPE

03

PPE Design Gaps

10.00 am – 10.45 am

Mindy James, PhD

I: Gaps in PPE Design

II: Gaps in PPE Performance

III: Gaps in PPE Use

04

Coffee Break

10.45 am – 11.00 am

Mid-Day Agenda

05

Gaps Revealed by Modeling

11.00 am – 12.30 pm

Rocco Casagrande, PhD

Rob Dettmann

Parametric Analysis of PPE Performance Requirements

06

Lunch

12.30 pm – 1.30 pm

Buffet

07

PPE Supply Chain Gaps

1.30 pm – 3.30 pm

Tom Mullen

John Baggett, PhD

I: Global Supply Chain Analysis

II: PPE Production & Distribution Gaps

08

Coffee Break

3:30 pm – 3.45 pm

Afternoon Agenda

09

Additional Gaps

3.45 pm – 4.15 pm

Anna Muldoon, MPH

10

Exercise

4.15 pm – 4.45 pm

Meg Rush, PhD

11

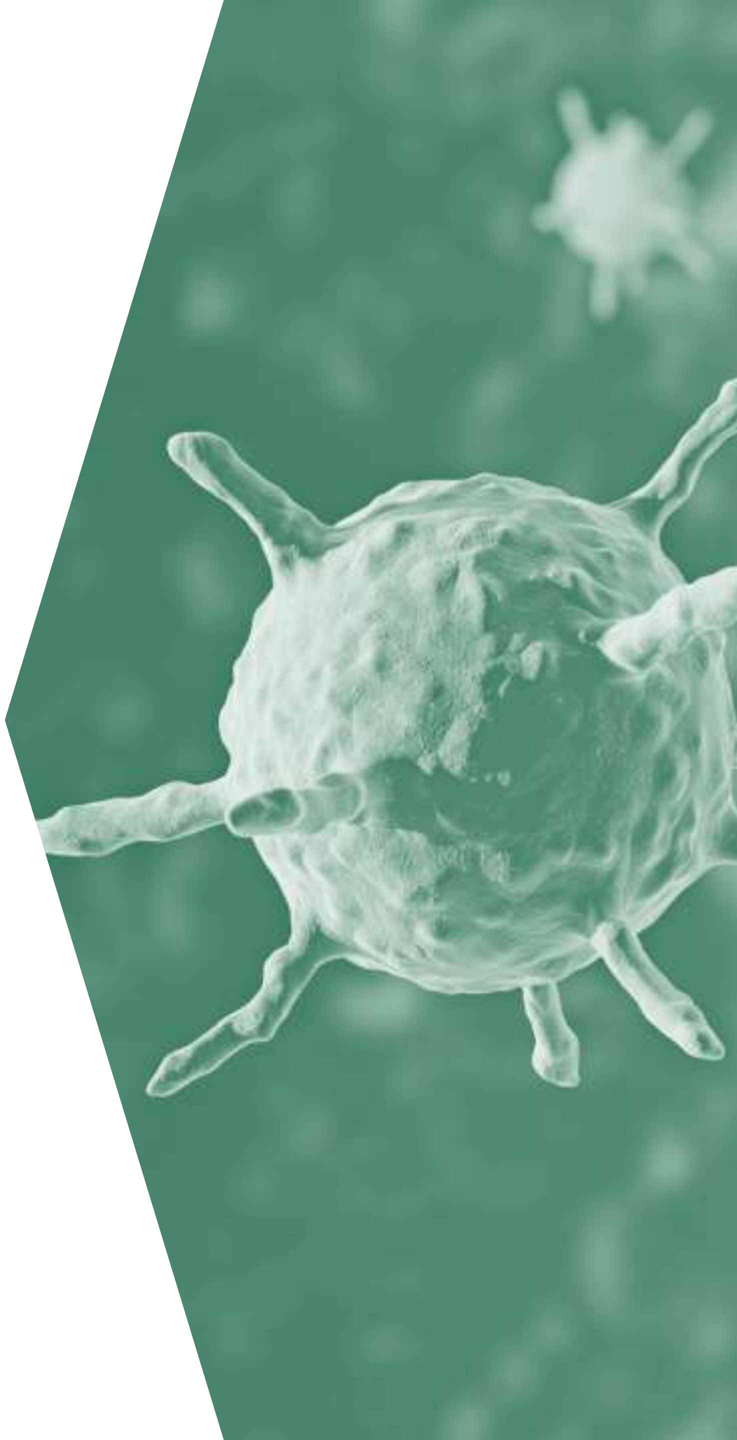
Next Steps

4.45 pm – 5.00 pm

Rocco Casagrande, PhD

Motivating Scenario

- One reason that COVID did not cause the collapse of societal structures is that mortality was low and disproportionately affected those beyond working age
- Previous pandemics have caused much higher mortality that disproportionately affected the young
  - Pandemic flu outbreaks disproportionately kill children and the 1918 pandemic killed young adults
  - Case fatality rates approaching or exceeding 10% are possible
    - Nipah virus, SARS-CoV-1, etc.
- As you'll see, SARS-CoV-2 (the virus that causes COVID) is not far away from the worst viruses regarding transmissibility or infectiousness
- As a motivating scenario to pandemic-proof our analysis against future threats, we will imagine a newly emerging virus as infectious and hardy as measles, as aggressive as SARS-CoV-2, and as pathogenic as 1918 flu



Motivating Scenario

- As you'll see, we used the capabilities of pathogens already known to science to bound our analysis
- The combination of these traits is unknown in any human pathogen
- We are positing the evolution of a Rinderpest-like virus that infects humans
  - Mortality rates approaching 100% in naïve animals
  - Transmits rapidly through an entire herd
  - In the measles virus family (paramyxovirus)
  - Spreads mostly by direct contact
    - Measles virus can spread via respiratory route

Defining PPE

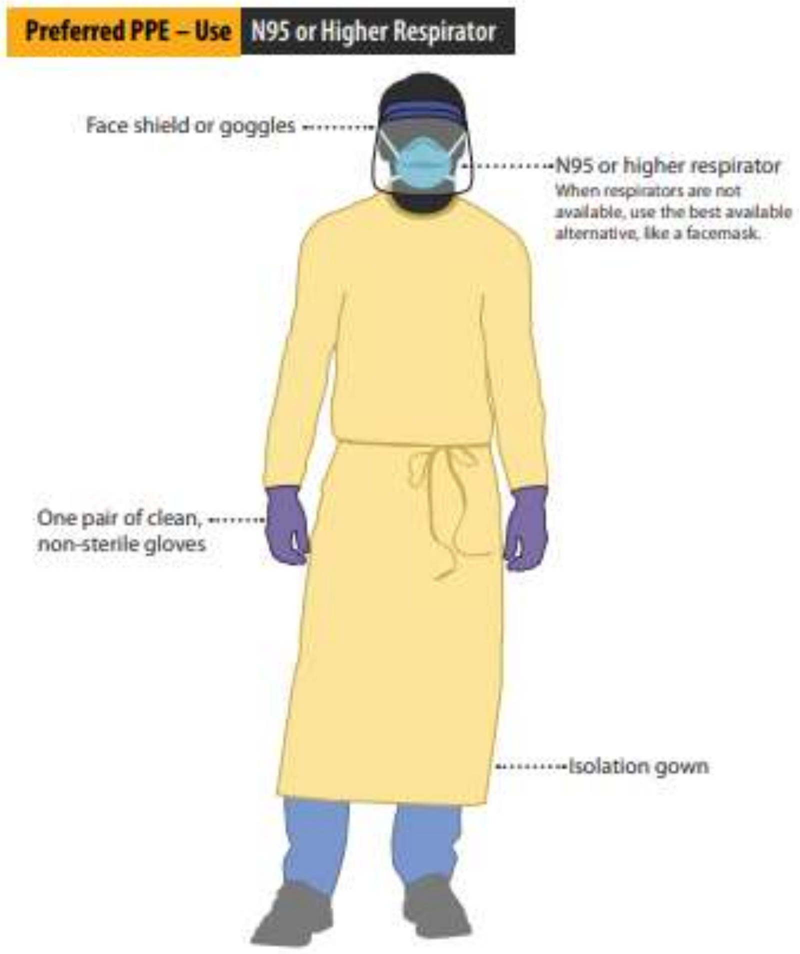
Meg Rush, PhD

Study Definition of PPE

Equipment that is **worn**/used to prevent or minimize exposure to **biological hazards**

Examples

In Scope	Out of Scope
Masks	Vaccines
Gloves	Treatments
Eye/Face Protection	Collective Protection
Body Protection	Engineering Controls
	Anti-microbial Soaps/Ointments



CDC-recommended PPE for protection of healthcare personnel from COVID-19.
Figure from CDC 2020

Gaps in Standardization of PPE

No standards for the public, including children

Not all vital workers have clear PPE standards/requirements

PPE with the same purpose have different nomenclature

Regulatory standards are different by country for the same PPE

> PPE standards currently vary across regions and create confusion, while testing capacity is often insufficient to ensure standards have been met. Going forward, standards for critical PPE should be harmonized, with a concerted effort to scale-up testing capacity in LMICs and globally.

- Transforming the Medical PPE Ecosystem, Global Fund 2021

> In 2011, the Institute of Medicine indicated that standardization of PPE terms and nomenclature would enhance government and manufacturer accountability… An international, widely used PPE inventory data standard would also support notification efforts when counterfeit or substandard equipment is identified.

- Haas et al. 2021

Gap: No PPE Standards for the Public, Including Children

In the US, the National Institute for Occupational Safety and Health (NIOSH) only develops and enforces PPE performance standards for "workers"

- There are no PPE performance or use standards for the public, including children

Some Occupations Lack Specific Infectious Disease PPE Requirements

- Unclear guidance from governments about PPE requirements for non-medical vital workers (e.g. transportation, agriculture)

- In the US, OSH Act needs revision to clarify required coverage of all workers with a Respiratory Protection Program to include pathogen exposure (NASEM 2022).

- Globally, public-facing vital workers received inadequate health & safety guidance and PPE.
  - Temporary, migrant, and informal economy workers are particularly vulnerable and common in agriculture in particular
  - Government requirements and programs do not address PPE or disease mitigation among these workers (UNPRI 2020)

Globally, PPE Occupational Standards Are Similar

- **Respirator** standards across many countries share similar requirements (more on next slide)
  - Filter efficiency; inhalation & exhalation resistance; exhalation valve leakage; flammability; fluid resistance
- **Gloves** also have similar requirements across many countries
  - Acceptance quality limit (AQL) at inspection level; tensile strength & elongation until break before and after aging
- **Eye/face protection** at this time do not appear to have widely adopted standards for biosafety by governmental agencies
  - A simple, common standard was recently released by ANSI/ISEA Z87.62

Example: Filtering Facepiece Respirator (FFR) Standards

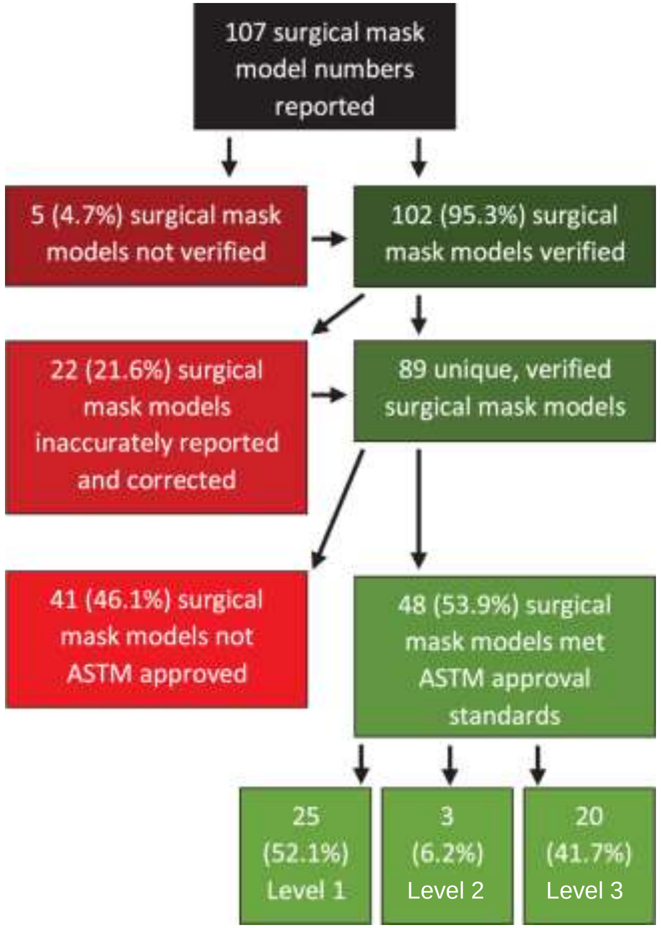
Legend:
- Green: US standard
- Orange: EU standard
- Pink: Other standards
- Gray: No standard

Applicable Regulation(s)	Product	Filter Efficiency	Inward Leakage	Inhalation Resistance	Exhalation Resistance	Exhalation Valve Leakage	Burn Time (Flammability)	Fluid Resistance
United States 42 CFR 84 21 CFR 878 ASTM F1862-17	N95	≥95%	N/A	≤343 Pa (at 85 L/min)	≤245 Pa (at 85 L/min)	≤30 mL/min	Surgical N95 only: Class 1: >3 sec Class 2: 3.5-7 sec Class 3: <3 sec	Surgical N95 only: Low: Pass at 450 cm/sec High: Pass at 635 cm/sec
Mexico NOM-116-STPS-2009	N95	≥95%	N/A	≤343 Pa (at 85 L/min)	≤245 Pa (at 85 L/min)	N/A	N/A	N/A
Europe EN149:2001+A1:2009 EN 14683:2019+AC:2019 ISO 22609	FFP2	≥94%	≤8%	≤70 Pa (at 30 L/min) ≤240 Pa (at 95 L/min)	≤100 Pa (at 30 L/min) ≤300 Pa (at 95 L/min)	N/A	≤5 sec	Operating room use only: Type IIR: Pass at 550 cm/sec
Australia/New Zealand AS/NZS 1716:2012 Australian TGA Guidance	P2	≥94%	≤8%	≤70 Pa (at 30 L/m) ≤240 Pa (at 95 L/min)	≤300 Pa (at 160 L/min)	≤30 mL/min	N/A	Demonstrate appropriate level of fluid resistance
China GB2626:2019	KN95	≥95%	≤8%	Without Exhalation Valve: ≤210 Pa (at 85 L/min) With Exhalation Valve: ≤250 Pa (at 85 nL/min)	Without Exhalation Valve: ≤210 Pa (at 85 L/min) With Exhalation Valve: ≤150 Pa (at 85 L/min)	≤30 mL/min	≤5 sec (if designed to be flame resistant)	N/A
Brazil ABNT/NBR 13698-2011	PFF2	≥94%	N/A	≤70 Pa (at 30 L/m) ≤240 Pa (at 95 L/min)	≤300 Pa (at 160 L/min)	≤30 mL/min	≤5 sec	N/A
India IS 9473-2002	FFP2	≥94%	≤8%	≤70 Pa (at 30 L/m) ≤240 Pa (at 95 L/min)	≤300 Pa (at 160 L/min)	N/A	Burning ceases after removal from flame	N/A
Japan JMHLW No. 2014, 2018	DS2	≥95%	N/A	Without Exhalation Valve: ≤50 Pa (at 40 L/min) With Exhalation Valve: ≤70 Pa (at 40 L/min)	Without Exhalation Valve: ≤50 Pa (at 40 L/min) With Exhalation Valve: ≤70 Pa (at 40 L/min)	Total depressurization ≥15 sec	N/A	N/A
South Korea MFDS-2015-69	KF94	≥94%	≤11%	≤70.6 Pa (at 30 L/min)	N/A	N/A	N/A	N/A
South Korea KMOEL-2017-64	1st Class	≥94%	≤11%	≤70 Pa (at 30 L/m) ≤240 Pa (at 95 L/min)	N/A	N/A	N/A	N/A

Case Study: Testing PPE Inventory Monitoring System for US Hospitals

- 78 hospitals of different sizes, in different regions in the US, piloted a PPE monitoring system for 15 weeks
- Daily inventory of N95 respirators, surgical masks, and face shields
- Significant challenges were found in reporting PPE, driven in large part due to the diversity of nomenclature
- PPE-naming diversity also contributed to stocking PPE that did not meet desired medical standards

Data Cleaning from PPE Inventory Test in 78 US Hospitals



Haas et al. 2021, Corrected Image

Gap: Diversity in PPE Regulatory Standards

- **To our knowledge, there is no widely-adopted, common international standard for any single PPE type**

- A common standard for each type of PPE would facilitate supply chain fluidity
  - Lower cost of entry for international markets
  - Provide more substitutes in the supply chain
  - Fewer mistakes in stocking/ordering
  - Potentially lower complexity for testing
  - Potentially less incentive for fraud

Wrap up: Gaps in PPE Standardization

Discussion

Are there any gaps we did not discuss that are important?

How should the gaps we listed here be prioritized?

Gaps

- No standards for the public, including children
- Unclear PPE requirements for some workers
- PPE with the same purpose has different nomenclature
- Regulatory standards are different by country for the same PPE

Coffee Break

15 min

Gaps Revealed by Modeling

Rocco Casagrande, PhD
Robert Dettmann

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Two objectives of the parametric analysis

- Two key questions regarding PPE are well suited to parametric analysis:
  - How protective does PPE need to be to reduce risk of infection from the most infectious viruses?
  - Can the timing of the demand for PPE be predicted for future pandemics?
- This parametric analysis is necessary to ensure that we don't set requirements based on the last pandemic
  - Although the pandemic was devastating, nature has created pathogens with infectiousness, transmissibility and pathogenicity that outstrips that of COVID
  - A science-based assessment of needed levels of protection and predicted demand for PPE is needed to ensure that we don't fall short when the next pandemic involves a pathogen with different characteristics than SARS-CoV-2
    - And is necessary to "pandemic proof" PPE

Parametric Analysis of Protection Factors

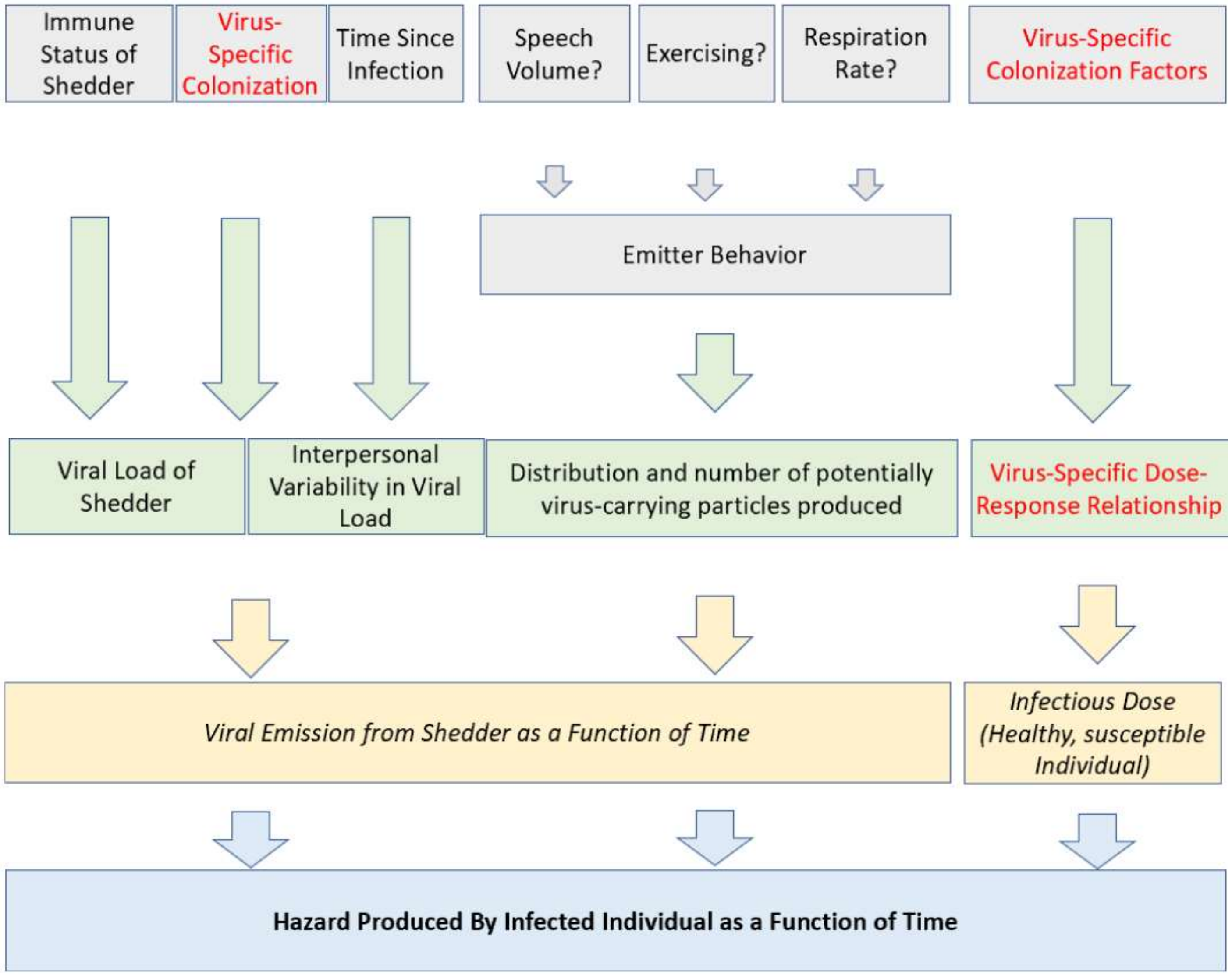
Parametric analysis of protection factors

- Purpose: the level of protection needed to defend against next-generation pandemic threats is unknown.
  - The level of protection will be dictated by the role of the individuals wearing the PPE and the hazards they face in the environment the hazards are encountered
  - This analysis should focus improvements on the proper sub-segment of the PPE enterprise
    - E.g. What is needed surgical masks vs N95s vs PAPRs vs face shields?
  - Although focused on future threats, this analysis must be based on scientific data
    - Unfortunately, respiratory viruses already exist that stress the capabilities of current protective equipment
- Overall method:
  - We modeled the time that a naïve person would accumulate enough of a dose of various respiratory viruses to become infected if they were near an infected person in various contexts
    - We then determine how this time was extended if various types of PPE was worn

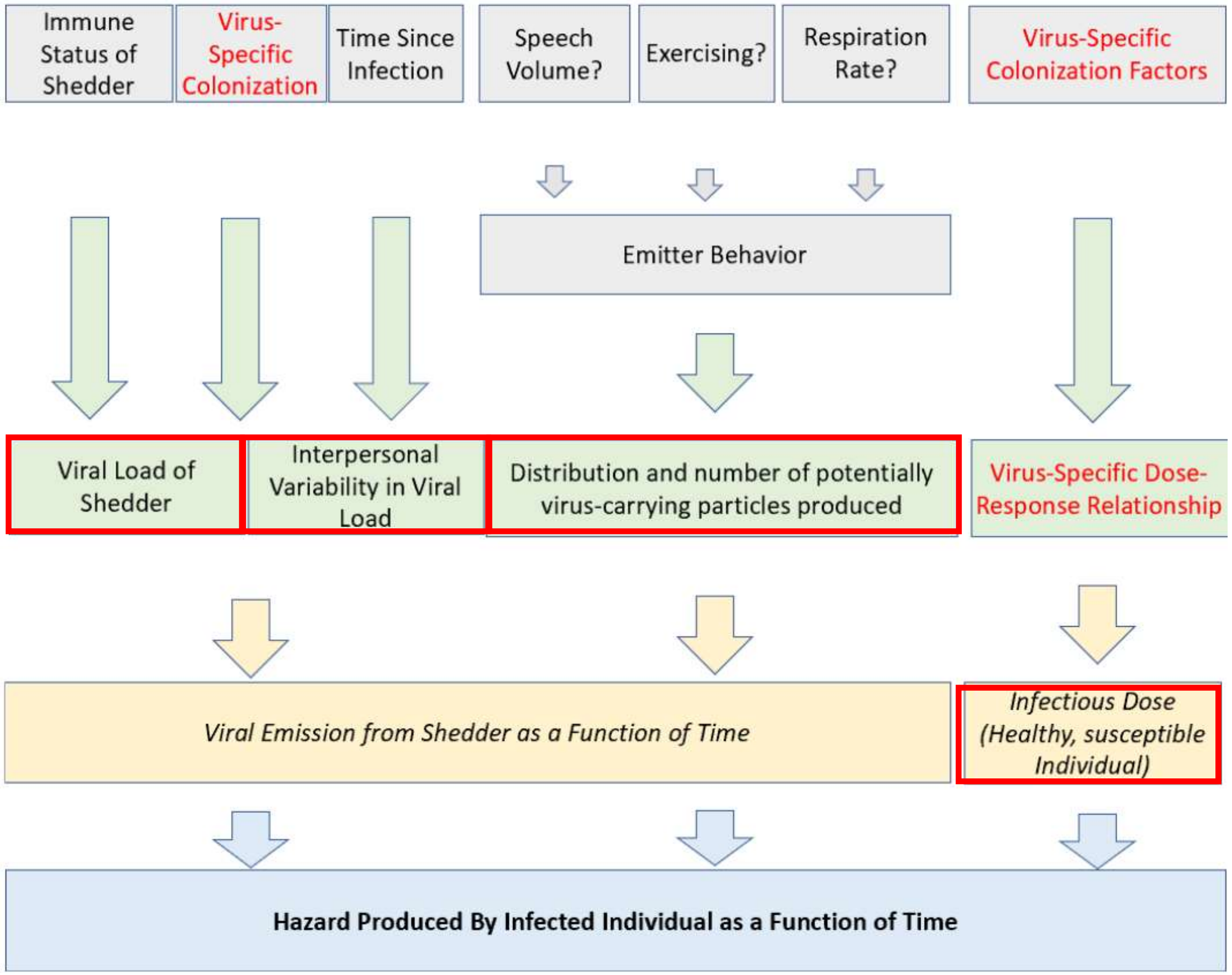
Context – Measuring the Hazard of Viruses

- There are various methods to quantify how many virus particles an infected person emits, BUT
  - These measures are not useful to determine a hazard because many of the viruses that are countable are not infectious
    - For some viruses, the vast majority of particles produced are defective or neutralized by the immune system
  - These measures are not comparable between types of viruses
- The hazard that viruses pose is typically measured by quantifying a sample's ability to infect cells in culture
  - With units such as TCID50s, PFUs, etc
  - HOWEVER, some viruses infect cells in culture much better than others—this is more of a measure of our ability to culture viruses
- Each virus exhibits a unique threshold necessary to establish infection in an intact host, typically quantified as the amount of virus required to infect 50% of hosts exposed to that dose (Infectious $Dose_{50}$ –ID50)
  - This is a direct measure of the hazard posed by a virus but an impractical measure for evaluating infectiousness of a sample
- We linked several sources of data to estimate the hazard produced by an infected person to directly compare various respiratory viruses AND understand the natural limits of infectiousness
  - Helps determine what is scientifically feasible for a next generation pandemic

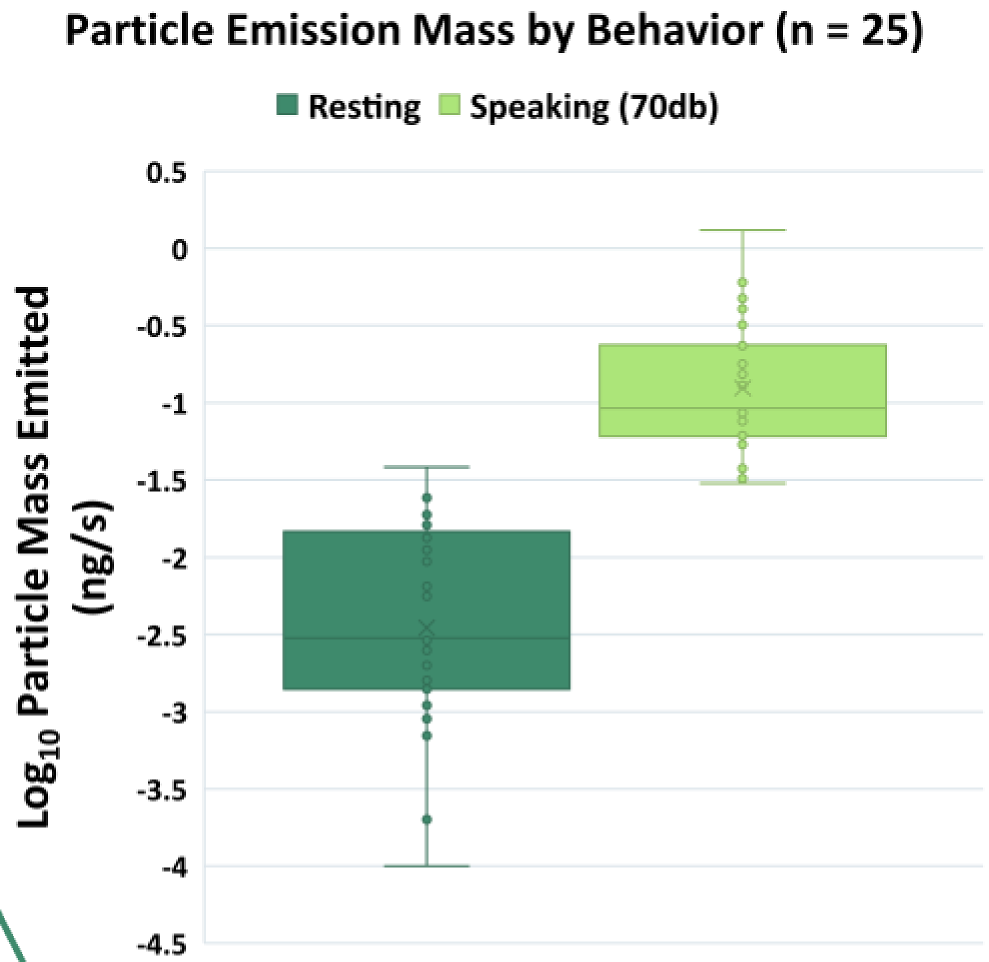
Parametrically evaluating hazard of an infected person



Parametrically evaluating hazard of an infected person



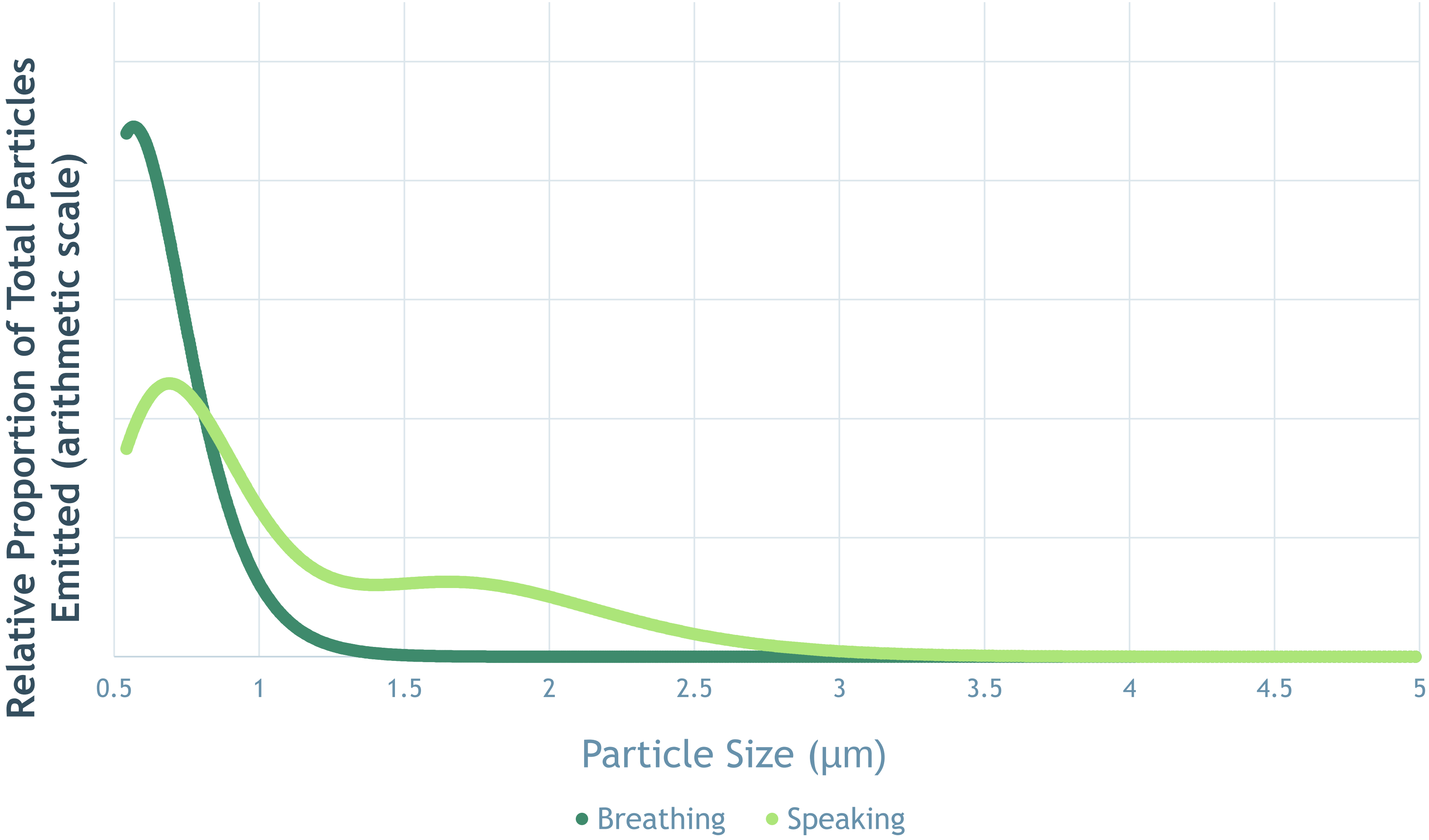
Particle Emission, Infectious Dose, and Viral Load Data



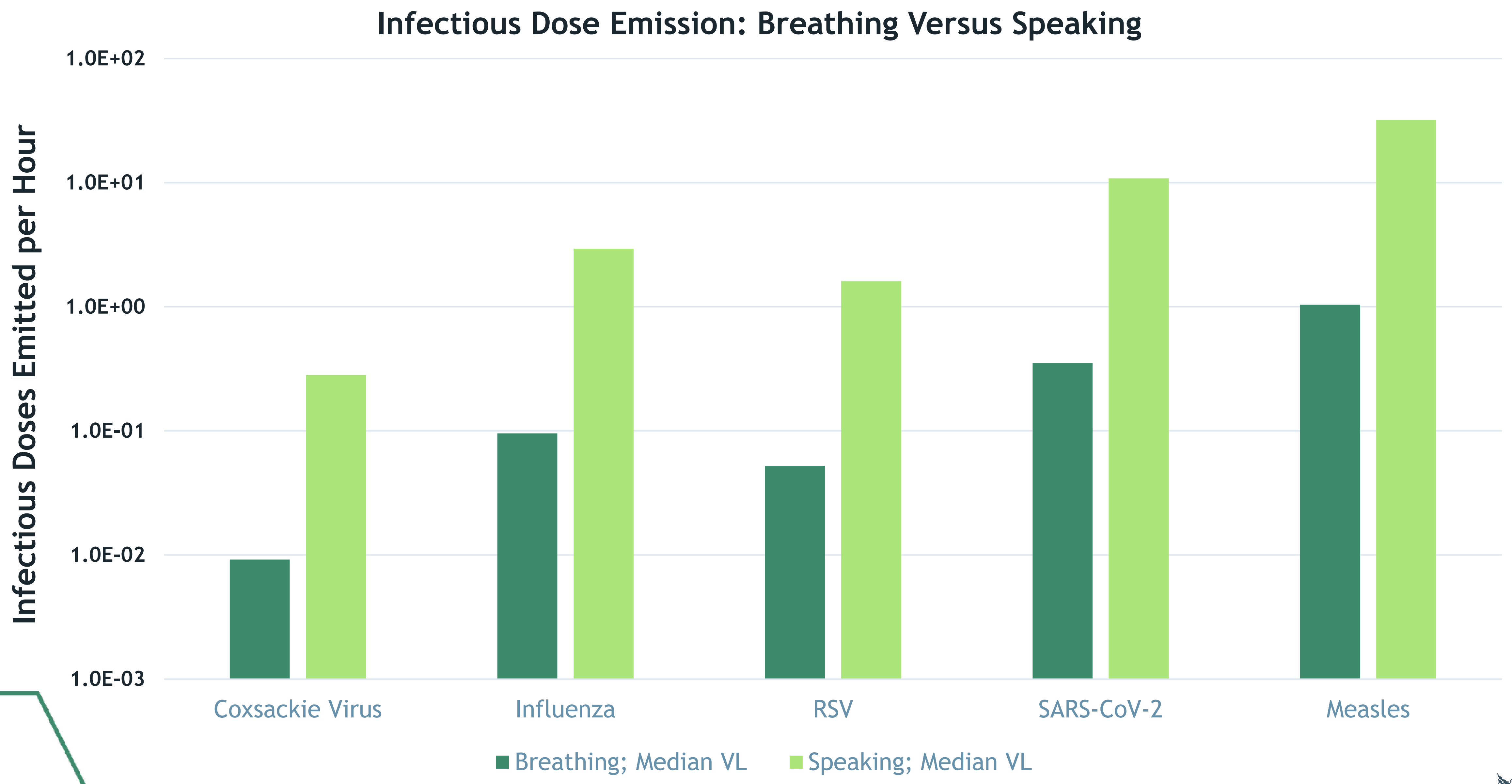
31-fold increase in particle mass emitted when speaking

Virus	ID_{50} (PFU)	Estimated VL (log_{10} genomes) by Percentile		
		Median VL	90^{th} VL	95^{th} VL
RSV - Type 39	~ 70	7.2	9.0	9.4
Coxsackie virus	~18	5.6	7.3	7.7
SARS-CoV-2	~2	6.8	8.5	8.9
Influenza Virus	~2	6.0	7.8	8.3
Measles virus	~0.2	5.6	7.4	7.8

Particle size distribution of emitted aerosols



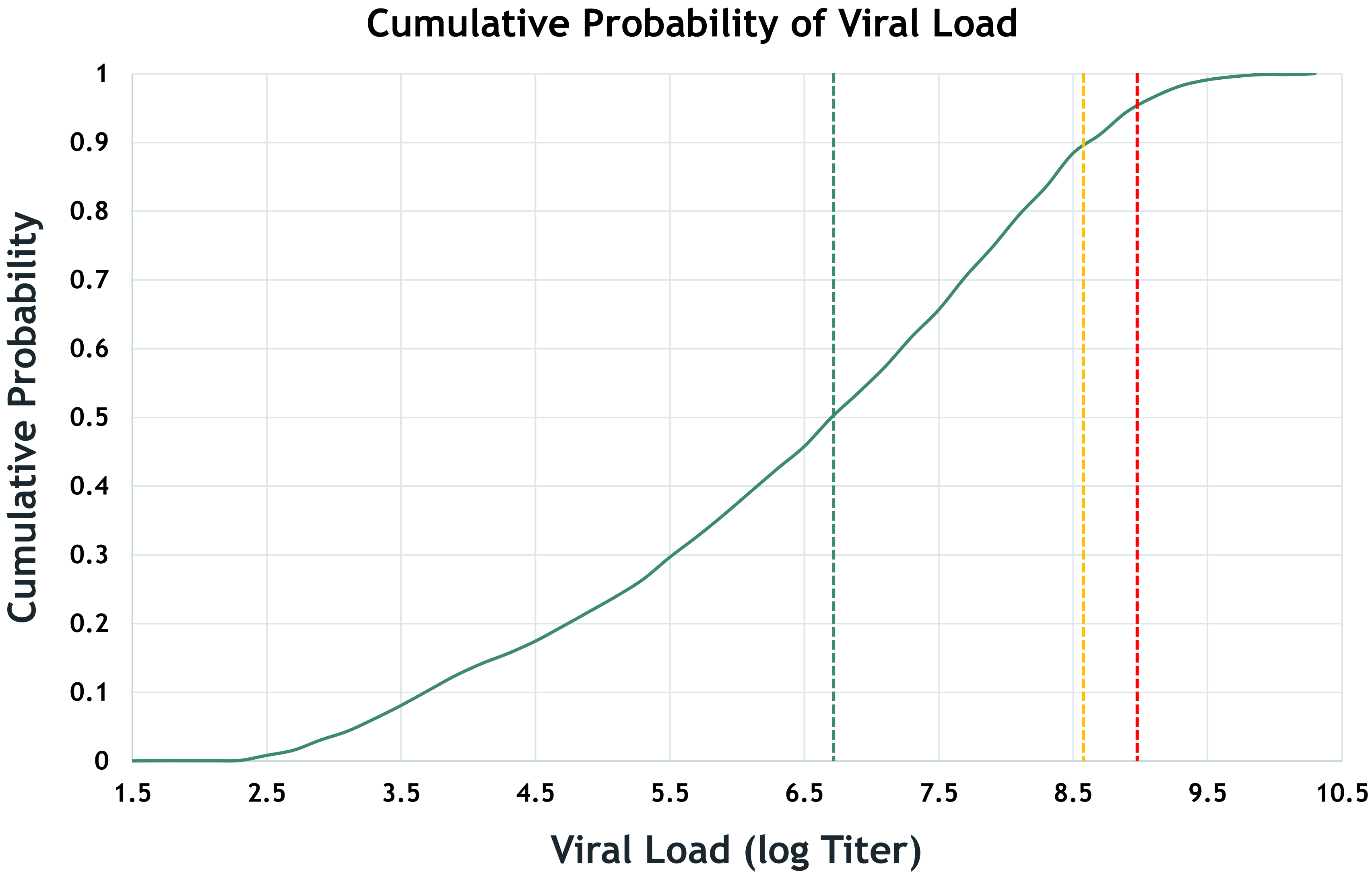
Relative Distribution of Aerosolized Particle Emitted by Size (adjusted for total particle production)

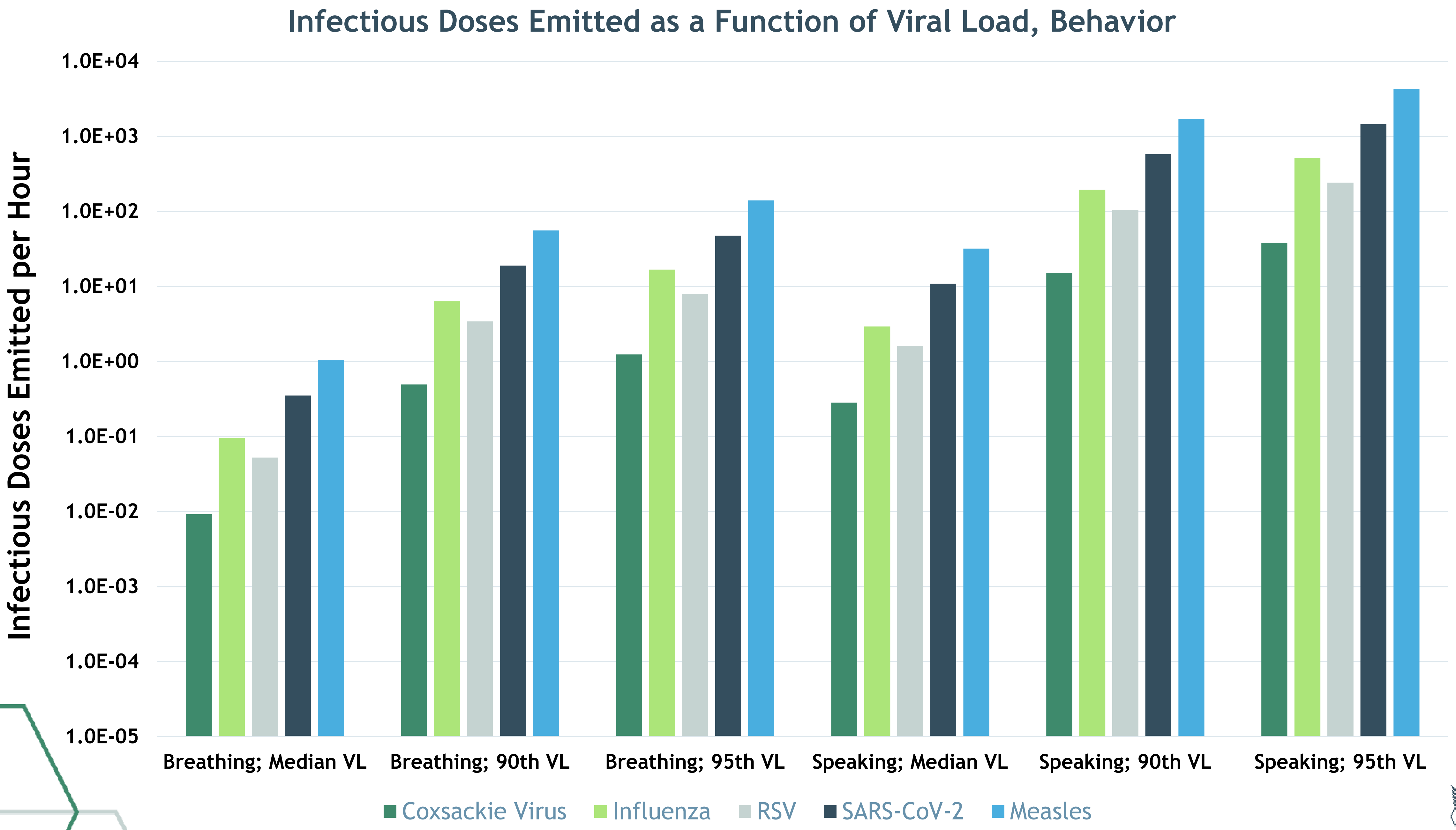

Infectious Dose Emission: Breathing Versus Speaking
Infectious Doses Emitted per Hour
1.0E+02
1.0E+01
1.0E+00
1.0E-01
1.0E-02
1.0E-03
Coxsackie Virus
Influenza
RSV
SARS-CoV-2
Measles
Breathing; Median VL
Speaking; Median VL

Interpersonal Variability of Hazard
Is the "average" infected person the right one to examine?

- Significant heterogeneity exists in interpersonal transmission potential
- Assuming a linear relationship between viral load and emission, individuals exhibiting viral loads in the 95th percentile emit more than 100x the virus emitted by individuals exhibiting median viral loads
  - This is consistent with literature suggesting that transmission is increased with viral load, and that individuals capable of infecting others generally exhibit higher viral load
- Supports hypothesis that majority of transmission stems from a smaller proportion of individuals (COVID-19) – Pareto Principle:
  - *Illingworth et al (2021):* **21%** of cases cause 80% of transmission events (Hospital)[1]
  - *Adams et al (2020):* **19%** (15-24%) of cases cause 80% of transmission events [2] (Hong King)
  - *Abbott et al (2020):* **~10%** of cases cause 80% of transmission events[3] (Shenzhen, China)
  - Bi et al (2020): **~9%** of cases cause 80% of transmission events[4] (Shenzhen, China)
  - Lau et al. (2020) **2%** of cases cause **20%** of transmission events[5] (Georgia, USA)
- Future mitigation measures should be designed to target interrupting transmission stemming from not only "normal" emitters, but rather, from these high-risk individuals (i.e., those exhibiting high or 'extreme' transmission potential).

SARS-CoV-2 Viral Load Distribution





Infectious Doses Emitted as a Function of Viral Load, Behavior
Infectious Doses Emitted per Hour
1.0E+04
1.0E+03
1.0E+02
1.0E+01
1.0E+00
1.0E-01
1.0E-02
1.0E-03
1.0E-04
1.0E-05
Breathing; Median VL
Breathing; 90th VL
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Speaking; Median VL
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Coxsackie Virus
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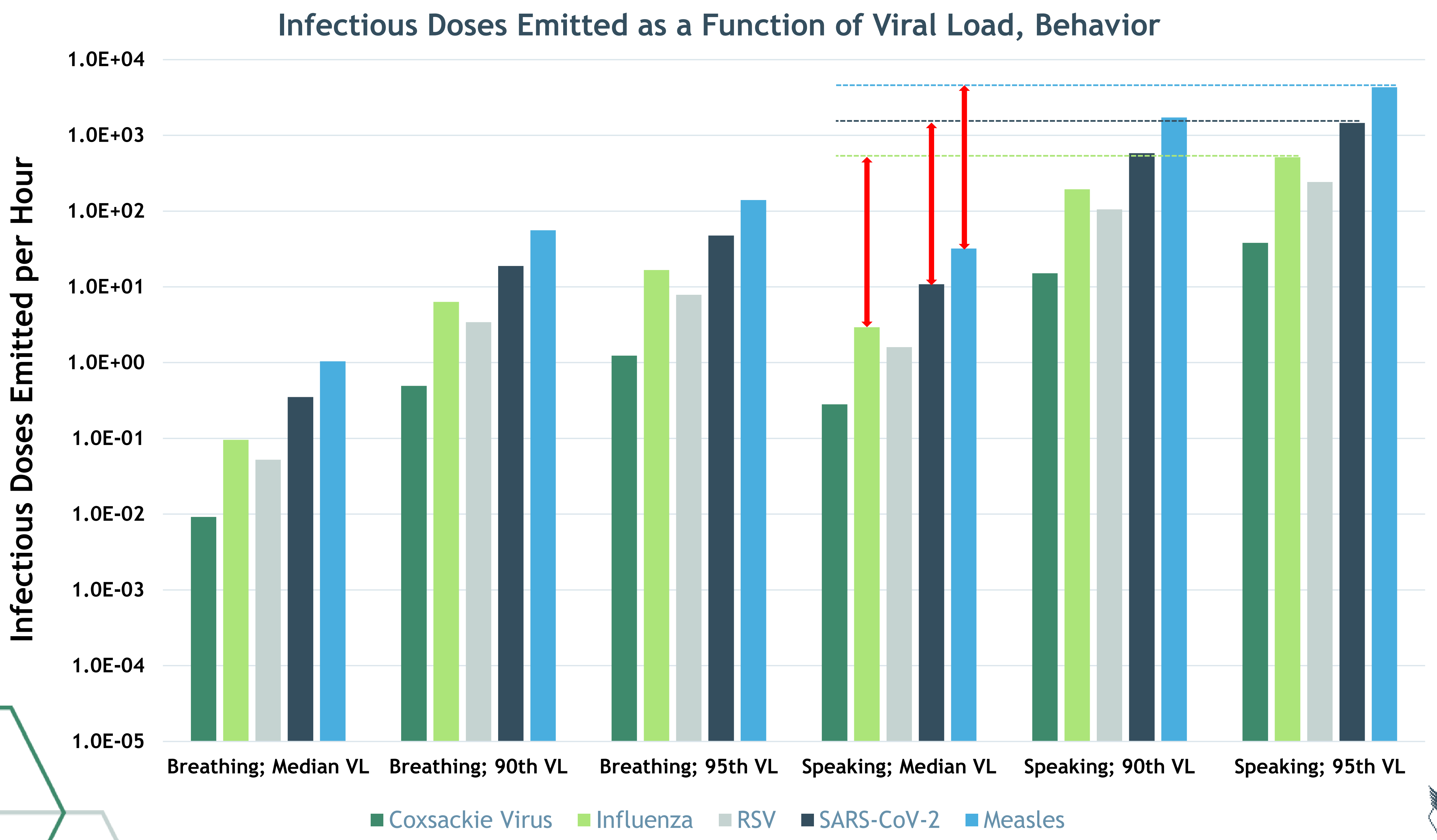
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Coxsackie Virus
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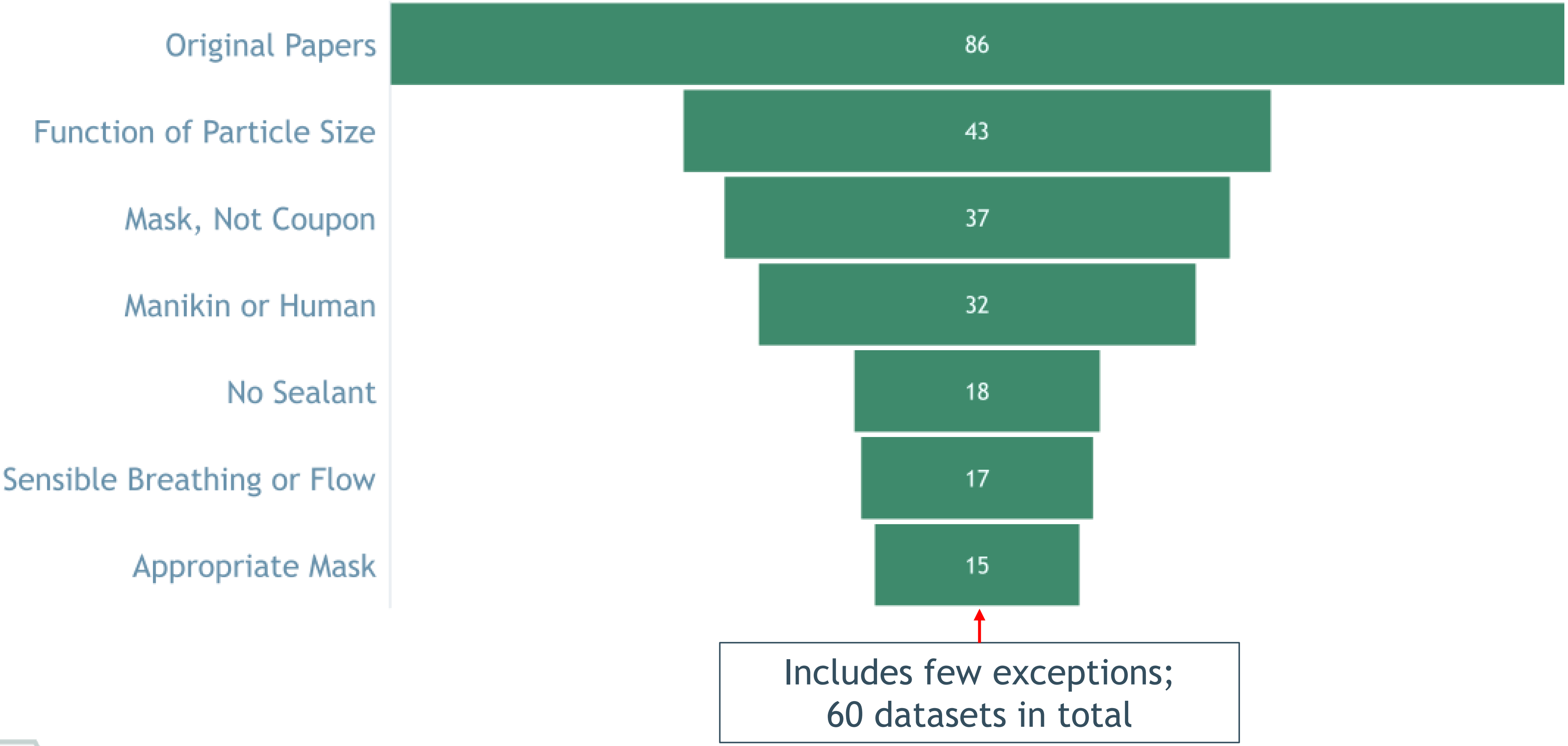
Measles

Data Collection Process for Respirator Penetration

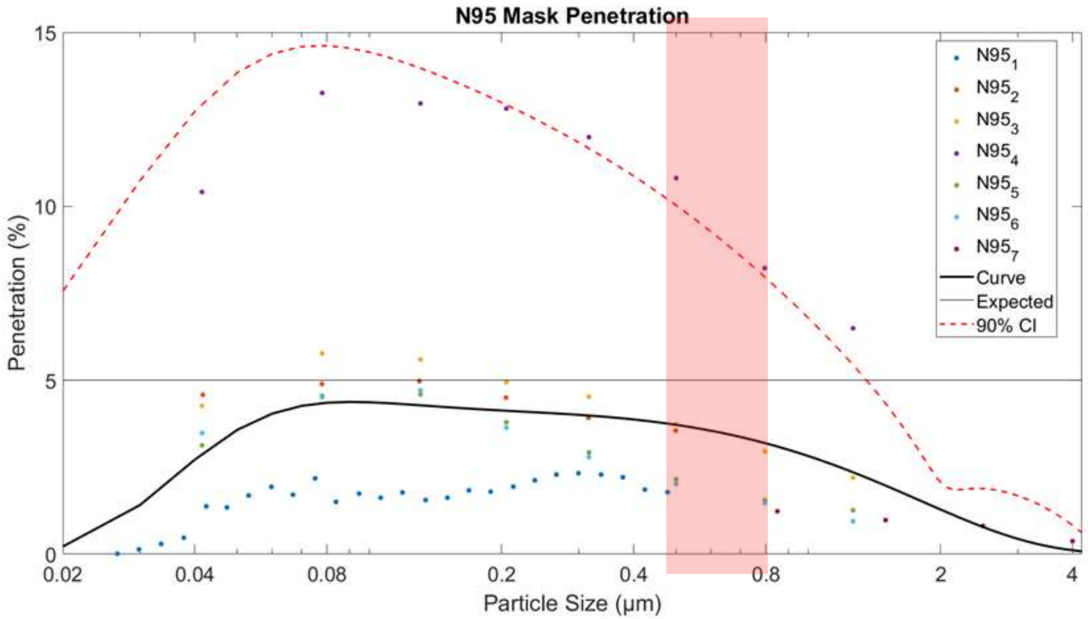


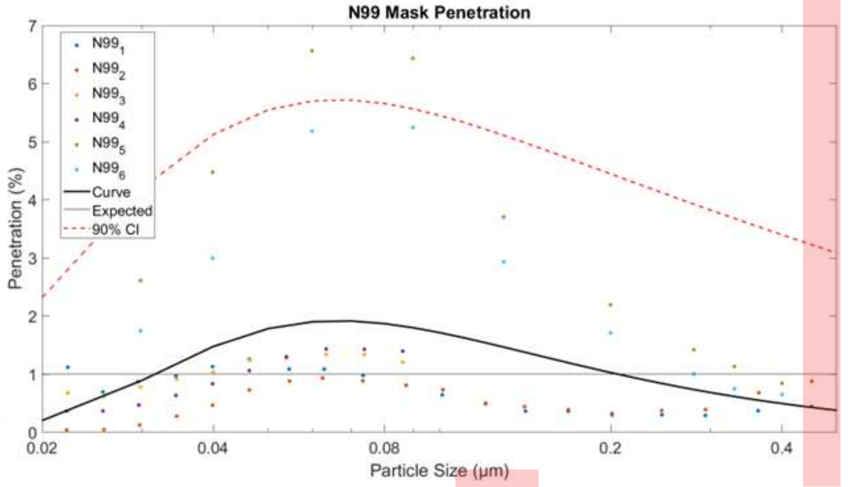
Mask Penetration Data - Infiltration

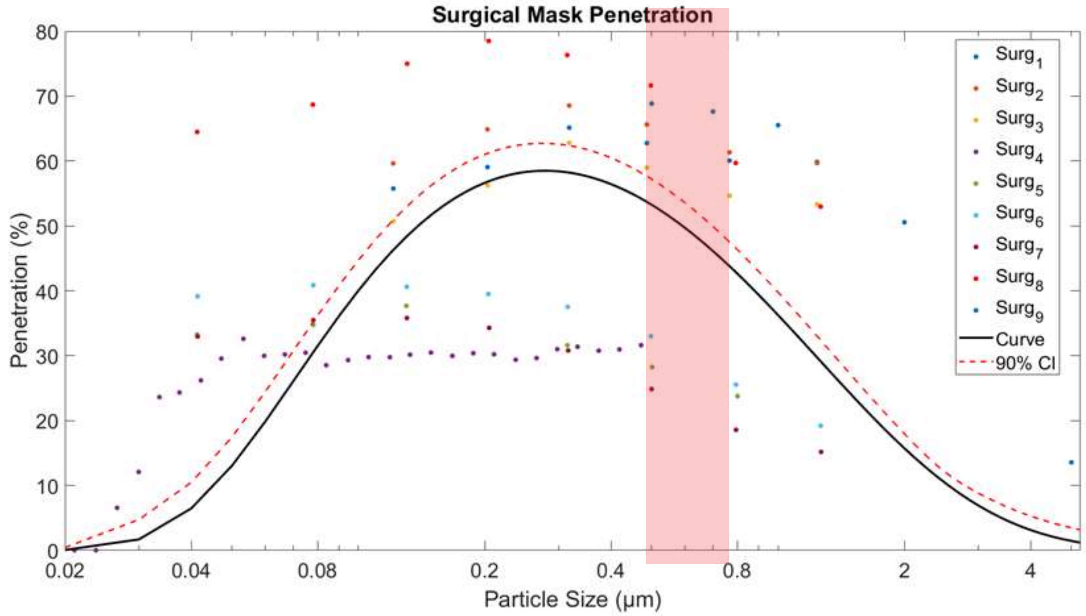
To perform the meta-analysis we used a non-linear regression model

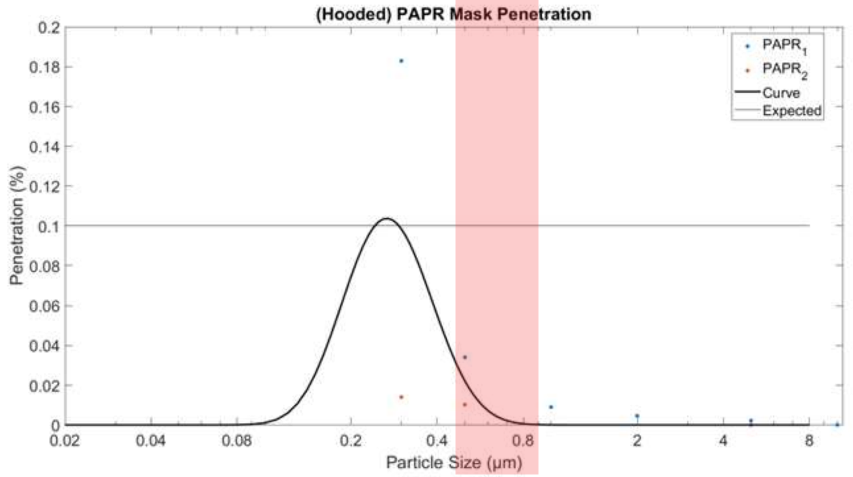
- Develop exact penetration theory for numeric data, and simplified theory for statistical plots
- Modeled the median fit and the 90% CI

Recall that the majority of the particles exhaled fall between 0.5 and 1 micron, which is not at the minimum filtration value of masks





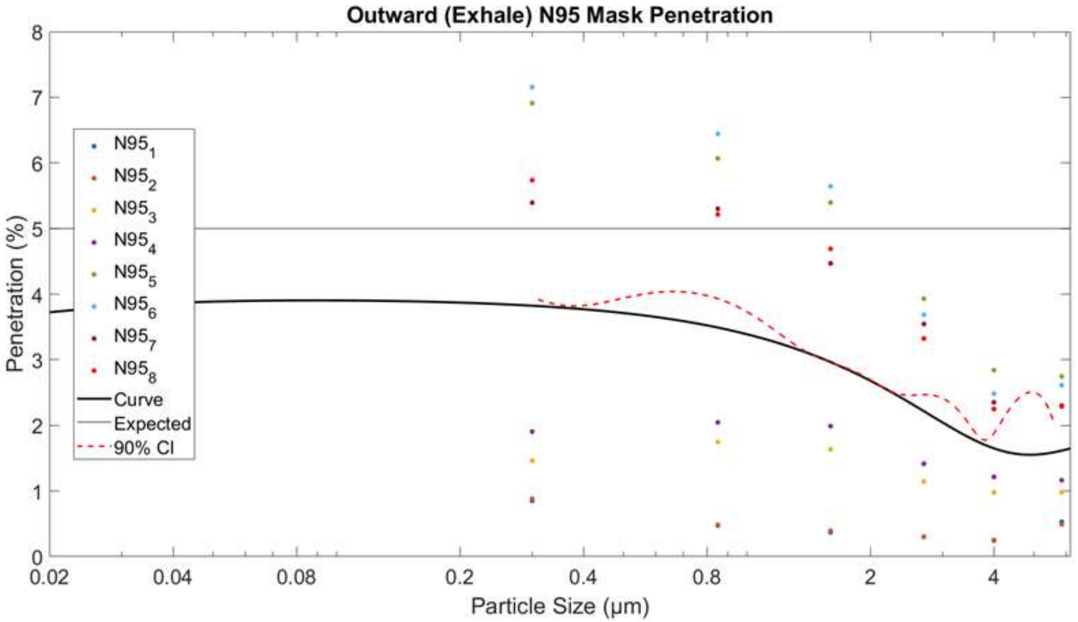


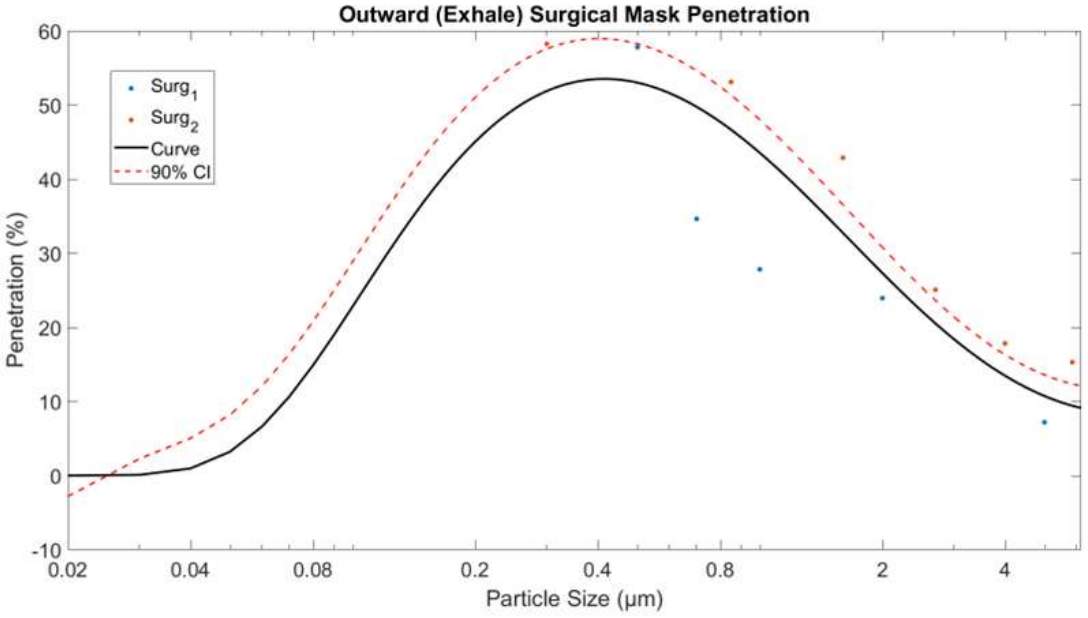


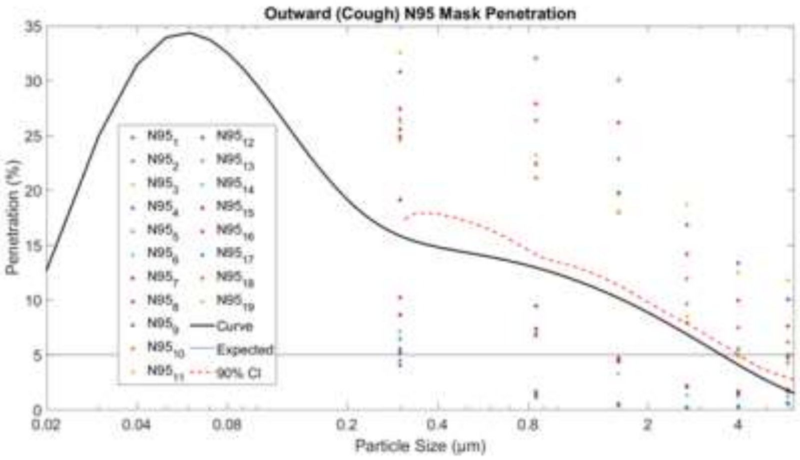
Mask Penetration Data - Exfiltration

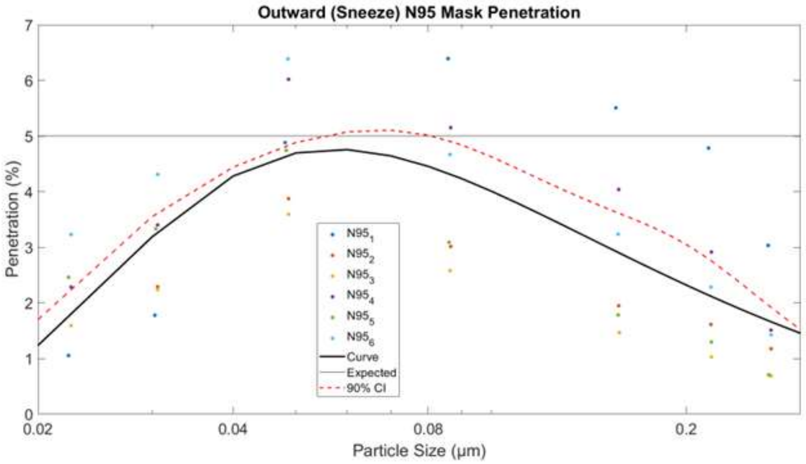
Data on exhalation was roughly similar to inhalation for all respirator/mask types (no data for PAPRS)

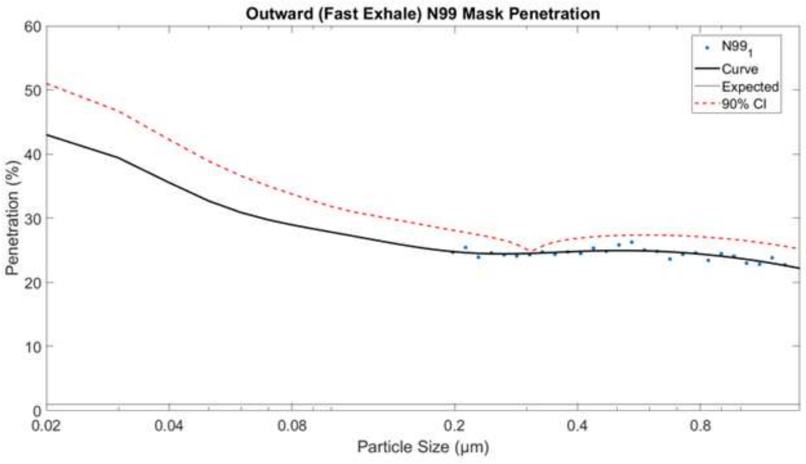
- Except for violent (coughing) exhalation











Fit Testing and Protection Capability

- As was mentioned, FFRs lose their fit over time, workers fiddle with them and a poor fit isn't immediately apparent
- Data suggests that N95s that aren't tested for proper fit show poor protection—suggesting that N95s offer the modeled protection only if fit can be ensured and maintained
- Also strong correlation with measured fit and filtration capacity

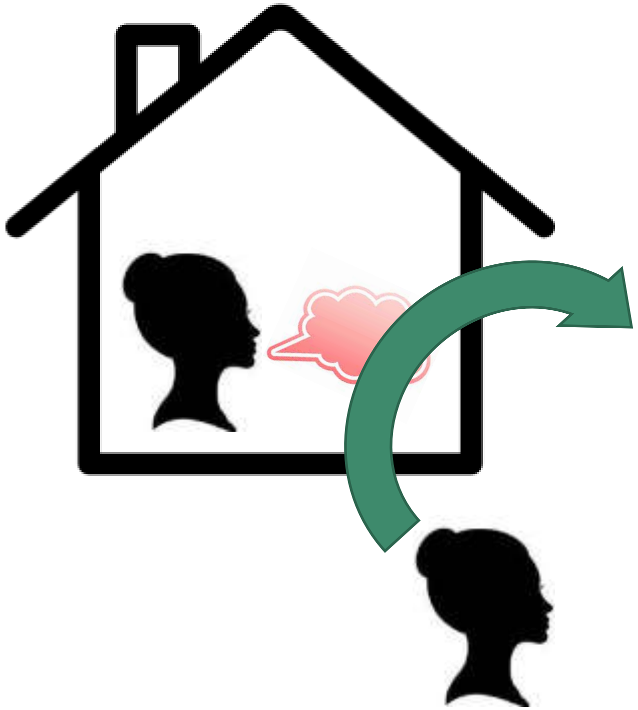
	Geometric Mean	
Test / Condition	Fit Factor	Penetration %
No fit test	5.7	**17**
Passed Bitrex test	12.0	**8.3**
Passed saccharin test	15.9	**6.3**
Passed N95 Companion	27.0	**3.7**

Four Scenarios in Parametric Analysis

1. A naïve person dwells in the same room with an infected person but both face away from each other (well-mixed room)

A naïve person faces an infected person and

2. Inhales the concentrated cloud emitted from their face
3. Small droplets from the mouth of the infected person land on their face and hands



4. A naïve person temporarily visits a room in which an infected person dwelled

Scenario 1. Well-Mixed Room

Infectious doses per hour emitted

Size of room

Air changes per hour (ACH)

Particle distribution in exhalation

↓

Amount of virus in room over time as a function of particle size

↓

Mask filtration efficiency as a function of particle size

↓

Dose per minute (at 8L inhalation)

↓

Time to 1 ID50

Ability of PPE to prevent infection
Well-Mixed Room, median infected person

Disease	Percentile	State	No Mask	High Pen Surgical	Median Surgical	Low Pen Surgical	High Pen N95	Average N95	Low Pen N95	N99	PAPR
Coxsackie	Median	Resting	NA	NA	NA	NA	NA	NA	NA	NA	NA
Influenza	Median	Resting	NA	NA	NA	NA	NA	NA	NA	NA	NA
RSV	Median	Resting	NA	NA	NA	NA	NA	NA	NA	NA	NA
SARS-CoV-2	Median	Resting	NA	NA	NA	NA	NA	NA	NA	NA	NA
Measles	Median	Resting	NA	NA	NA	NA	NA	NA	NA	NA	NA
Coxsackie	Median	Speaking	NA	NA	NA	NA	NA	NA	NA	NA	NA
Influenza	Median	Speaking	NA	NA	NA	NA	NA	NA	NA	NA	NA
RSV	Median	Speaking	NA	NA	NA	NA	NA	NA	NA	NA	NA
SARS-CoV-2	Median	Speaking	955	NA	NA	NA	NA	NA	NA	NA	NA
Measles	Median	Speaking	337	550	750	1218	NA	NA	NA	NA	NA

< 1 hour
1-4 hours
4-8 hours
8-24 hours
>24 hours

Ability of PPE to prevent infection

Well-Mixed Room, high-risk infected people

Disease	Percentile	State	No Mask	High Pen Surgical	Median Surgical	Low Pen Surgical	High Pen N95	Average N95	Low Pen N95	N99	PAPR
SARS-CoV-2	Median	Speaking	955	NA	NA	NA	NA	NA	NA	NA	NA
SARS-CoV-2	90th	Speaking	34	48	60	86	238	629	972	NA	NA
SARS-CoV-2	95th	Speaking	20	27	33	45	107	263	399	NA	NA
Measles	Median	Speaking	337	550	750	1218	NA	NA	NA	NA	NA
Measles	90th	Speaking	18	25	30	40	94	227	343	NA	NA
Measles	95th	Speaking	11	15	18	23	48	102	149	NA	NA

< 1 hour
1-4 hours
4-8 hours
8-24 hours
>24 hours

Protection greater than N95s needed to protect indoor workers for a full shift

Scenario 3. Inhalation downwind

Infectious Doses Per Hour Emitted | Size of cloud | Duration of cloud | Particle Distribution in Exhalation

↓

Amount of virus in cloud as a function of particle size

↓

Mask filtration efficiency as a function of particle size

↓

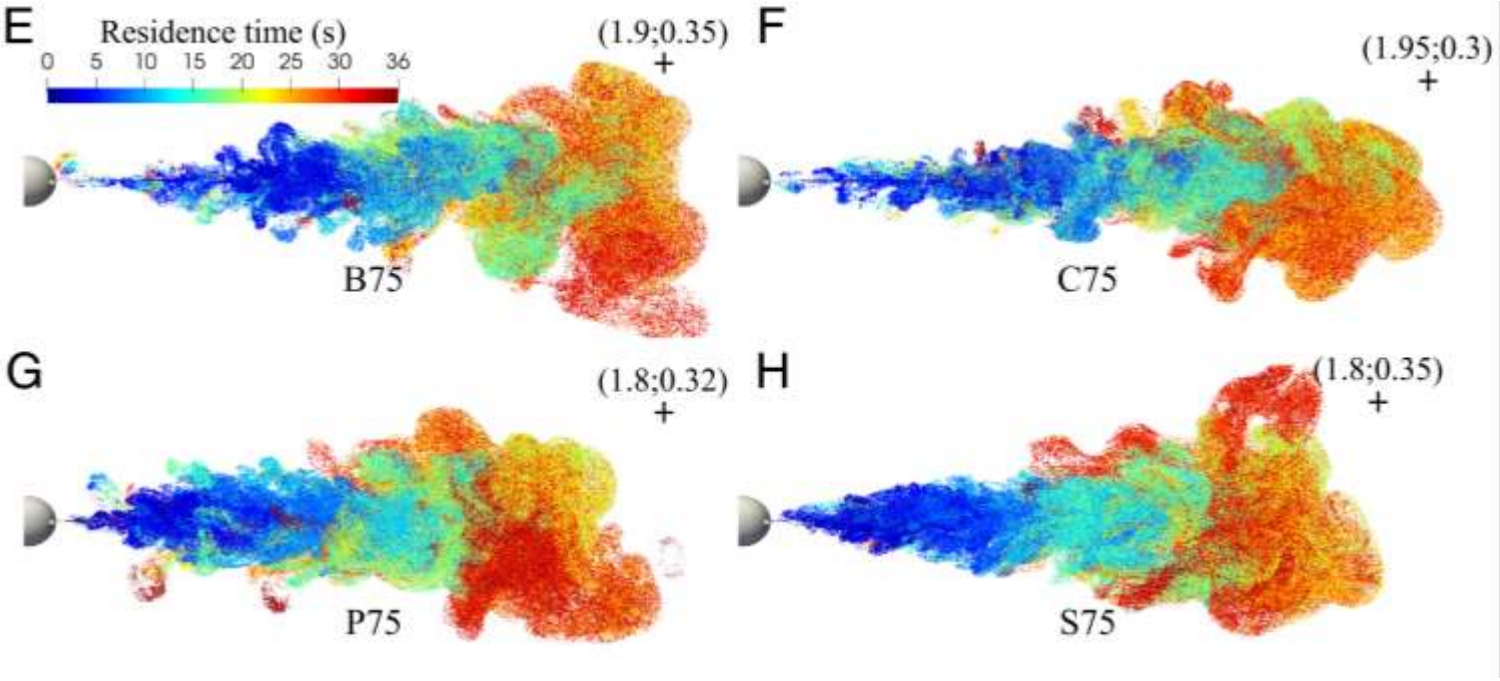
Dose per minute (at 8L inhalation)

↓

Time to 1 ID50

Calculating the size of the exhaled cloud

- Exhaled cloud of particles when speaking reaches up to 2m distance
- Cloud lasts 30-36 seconds, dependent on what phrase is spoken
- Aerosol cloud forms a 40-50º half-angle cone when speaking



Ability of PPE to prevent infection
Inhalation downwind, high-risk infected people

Disease	Percentile	State	No Mask	High Pen Surgical	Median Surgical	Low Pen Surgical	High Pen N95	Average N95	Low Pen N95	N99	PAPR
SARS-CoV-2	Median	Speaking	NA	NA	NA	NA	NA	NA	NA	NA	NA
SARS-CoV-2	90th	Speaking	93	154	211	346	1140	NA	NA	NA	NA
SARS-CoV-2	95th	Speaking	38	62	85	139	455	1269	NA	NA	NA
Measles	Median	Speaking	NA	NA	NA	NA	NA	NA	NA	NA	NA
Measles	90th	Speaking	32	53	73	118	387	1080	NA	NA	NA
Measles	95th	Speaking	14	22	30	48	155	431	673	NA	NA

- < 1 hour
- 1-4 hours
- 4-8 hours
- 8-24 hours
- >24 hours

From Scen 1

Disease	Percentile	State	High Pen N95	Average N95	Low Pen N95
SARS-CoV-2	Median	Speaking	NA	NA	NA
SARS-CoV-2	90th	Speaking	238	629	972
SARS-CoV-2	95th	Speaking	107	263	399
Measles	Median	Speaking	NA	NA	NA
Measles	90th	Speaking	94	227	343
Measles	95th	Speaking	48	102	149

Scenario 3. Droplets on Face

Infectious doses per hour emitted

Size of spray

Particles emitted per hour**

Area of eyes, nose, mouth, fingertips

↓

Dose accumulated in eyes, nose, mouth, fingertips per minute

↓

Presume barrier protection is 100%

↓

Reduction in effective dose due to altenate route of exposure

↓

Time to 1 ID50 equivalent

Route	Doses equiv. to 1 inhaled ID50
Nose	1
Eye	1,000
Mouth	Infinite**
Fingertips	100 (assumed)

Ability of PPE to prevent infection
Droplets on Face, high-risk infected people

			1 meter distance					1.8 meter distance				
Disease	**Percentile**	**State**	**Eyes/Nose/Mouth**	**Eyes**	**Hands**	**Mouth**	**Nose**	**Eyes/Nose/Mouth**	**Eyes**	**Hands**	**Mouth**	**Nose**
Coxsackie	Median	Speaking	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Coxsackie	90th	Speaking	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Coxsackie	95th	Speaking	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Influenza	Median	Speaking	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Influenza	90th	Speaking	606	NA	NA	NA	607	NA	NA	NA	NA	NA
Influenza	95th	Speaking	230	NA	552	NA	230	743	NA	NA	NA	745
RSV	Median	Speaking	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RSV	90th	Speaking	398	NA	956	NA	399	1288	NA	NA	NA	1291
RSV	95th	Speaking	173	NA	416	NA	174	561	NA	1348	NA	562
SARS-CoV-2	Median	Speaking	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SARS-CoV-2	90th	Speaking	203	NA	487	NA	203	657	NA	NA	NA	658
SARS-CoV-2	95th	Speaking	81	NA	194	NA	81	262	NA	629	NA	262
Measles	Median	Speaking	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Measles	90th	Speaking	69	NA	165	NA	69	223	NA	535	NA	223
Measles	95th	Speaking	28	NA	66	NA	28	89	NA	213	NA	89

Data on large particles produced is insufficient to appropriately model hazard posed by droplets and the benefit of barrier PPE

- < 1 hour
- 1-4 hours
- 4-8 hours
- 8-24 hours
- >24 hours

Even so, barrier protection of hands is clearly important to prevent self infection from touching face

Scenario 4. Visiting a Room

Infectious doses per hour emitted | Size of room | Air changes per hour (ACH) | Particle distribution in exhalation

↓

Amount of virus in room over time as a function of particle size

↓

Person enters room after concentration equilibrates

↓

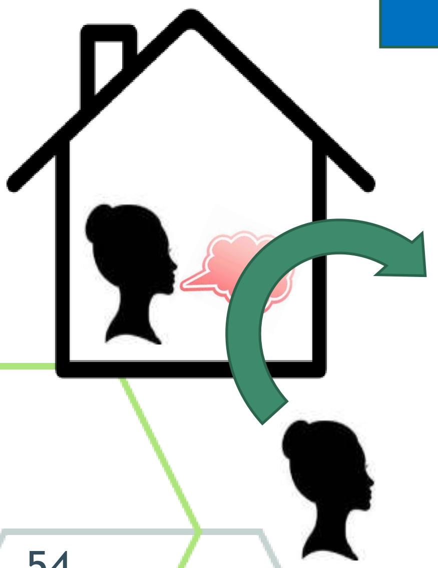
Mask filtration efficiency as a function of particle size

↓

Dose per minute (at 8L inhalation)

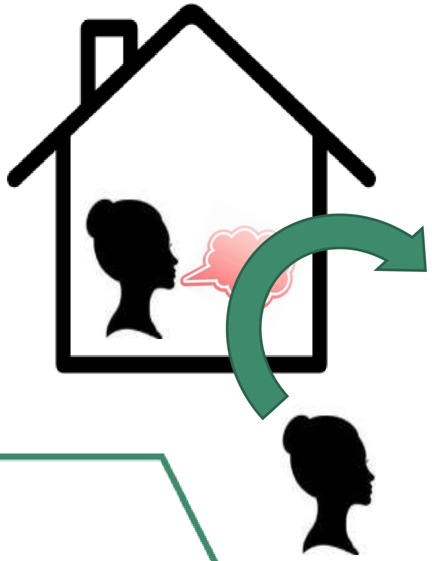
↓

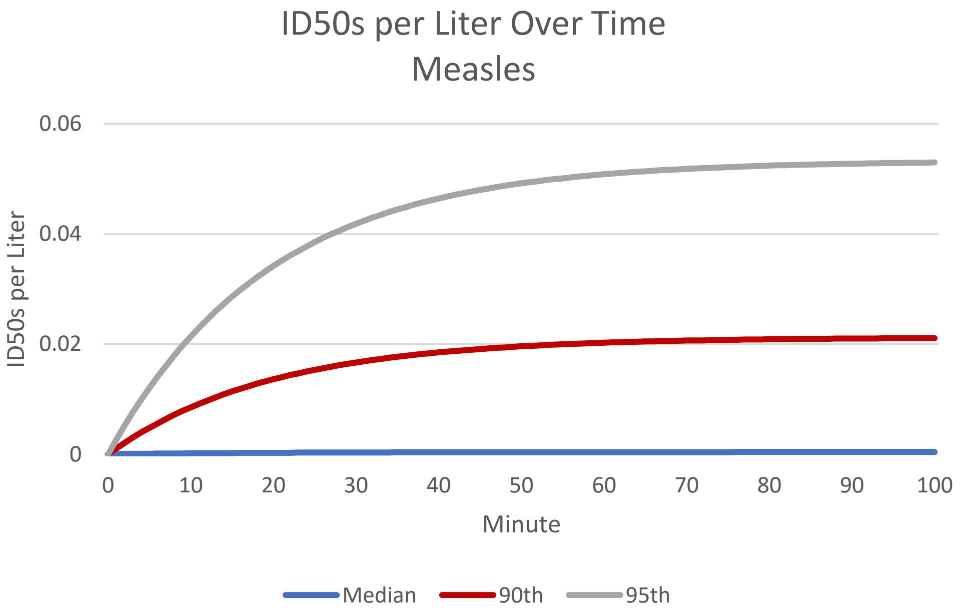
Time to 1 ID50

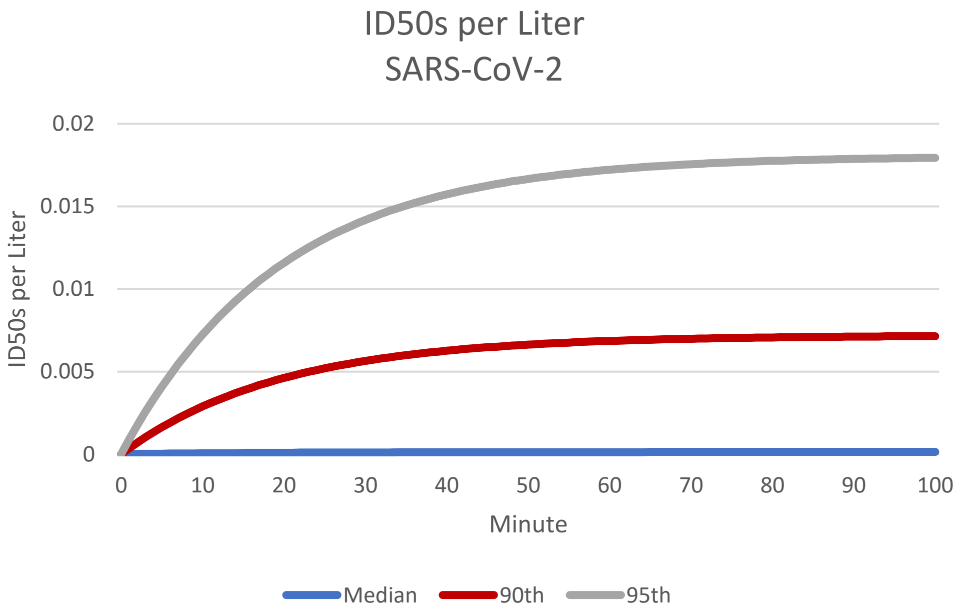


Virus Concentration per Liter - ACH 3

- Concentration of a hardy virus in a closed room stabilizes over time if infected person continues to remain and HVAC remains on

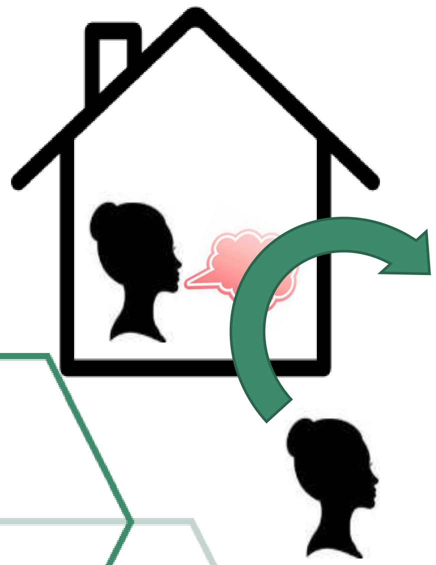






Ability of PPE to prevent infection
Visiting a room, high-risk infected people

Disease	Percentile	State	No Mask	High Pen Surgical	Median Surgical	Low Pen Surgical	High Pen N95	Average N95	Low Pen N95	N99	PAPR
SARS-CoV-2	Median	Speaking	NA	NA	NA	NA	NA	NA	NA	NA	NA
SARS-CoV-2	90th	Speaking	18	30	41	NA	NA	NA	NA	NA	NA
SARS-CoV-2	95th	Speaking	7	12	16	27	NA	NA	NA	NA	NA
Measles	Median	Speaking	NA	NA	NA	NA	NA	NA	NA	NA	NA
Measles	90th	Speaking	6	10	14	23	NA	NA	NA	NA	NA
Measles	95th	Speaking	3	4	6	9	30	NA	NA	NA	NA



N95s may be needed even for relatively short visits to buildings that may have infected individuals

Conclusions

- When focused on the most infectious, hardiest respiratory viruses that exist today, the following conclusions become clear:
  - For vital workers that may work a full shift in a room with an infected person, the protection afforded by an N95-like respirators is insufficient unless engineering controls can compensate
    - Assumes good fit the entire time
  - For anyone that may visit a room where an infected person was dwelling, surgical masks are inadequate—N95-like masks offer good protection (if they fit)
  - N95-like masks plus face protection and gloves are useful for brief encounters face-to-face with infected individuals
    - Data on large particles produced by infected people is inadequate to model barrier protection properly
  - Vital workers outside (agricultural) may require N95-like protection if they will be in close proximity with infected people for more than an hour or must visit indoor spaces

Parametric Analysis of Demand of PPE

Calculating demand

- Although significant shortages of PPE were experienced during COVID-19, the next pandemic could be worse
  - Coronaviruses have a relatively long time between infection and transmissibility
    - Two generations of flu infections can occur in one generation of COVID
  - The original strain of COVID was not as transmissible as the current variants
- We examined data on global spread of infectious disease to examine:
  - How quickly do various countries suffer community spread?
  - How many “vital” workers are in these countries?
  - To protect their populations and workforce, PPE is required at the time that initial infections occur
- If effective PPE can be provided, the spread of the pathogen in the country will be slowed and workers will have confidence to report to work
- If PPE is unavailable, the pathogen will spread unabated and workers will not be protected

Predicting Demand

- Methods
  - We examined how waves of COVID spread across the globe using historical epidemiological data
    - Gathered date of first identification from WHO reports and news sources for Original, Delta, and Omicron strains
    - Used GISAID variant proportions combined with WHO case data to create approximate case data for Delta and Omicron variants
  - We presumed that workers in countries with known cases will demand protection
    - Used existing data on the amount of PPE used per worker per day (IFC)
  - Calculated "vital" workers for each country to sum demand over time

	Respirator	Gown	Gloves	Face Shield
Non-Agriculture	1	1	2	1
Agriculture	1			
Medical	1	1	25	1

Vital worker calculation

- Sources used for determining who is included in the vital workforce
  - *CISA's Guidance on Essential Critical Infrastructure Workforce 4.0* was used as starting point
  - CDC mapping of NIACS codes to CISA's guidance was filtered by which occupations are **vital** to the survival of society in times of extreme crisis
    - US labor force by NIACS code from CDC's *Interim List of Categories of Essential Workers Mapped to Standardized Industry Codes and Titles*
    - The identified vital NIACS Codes were used for calculation of global vital workforce
- Data used to calculate the vital workforce
  - Estimated number of workers by NIACS code from CDC's *Identifying Essential Critical Infrastructure Workers to Support Public Health Interventions* for US workforce and mapped to sectors

$$ratio\ of\ vital\ workforce\ in\ sector\ (R_s) = \frac{US\ vital\ workforce\ in\ sector}{US\ total\ workforce\ in\ sector}$$

  - World bank labor force (LF) per country
  - World factbook percentage of Agriculture, Industry, and Services sector (S_p) per country

Vital Workforce in Most Populous Countries (millions)

Country	Agriculture Vital Worker Population	Industry Vital Worker Population	Services Vital Worker Population	Total Vital Worker Population
China	219	86	134	439
India	222	39	57	317
European Union	11	18	62	90
United States	1	13	51	64
Indonesia	45	11	25	81
World Total	967	309	646	1,922

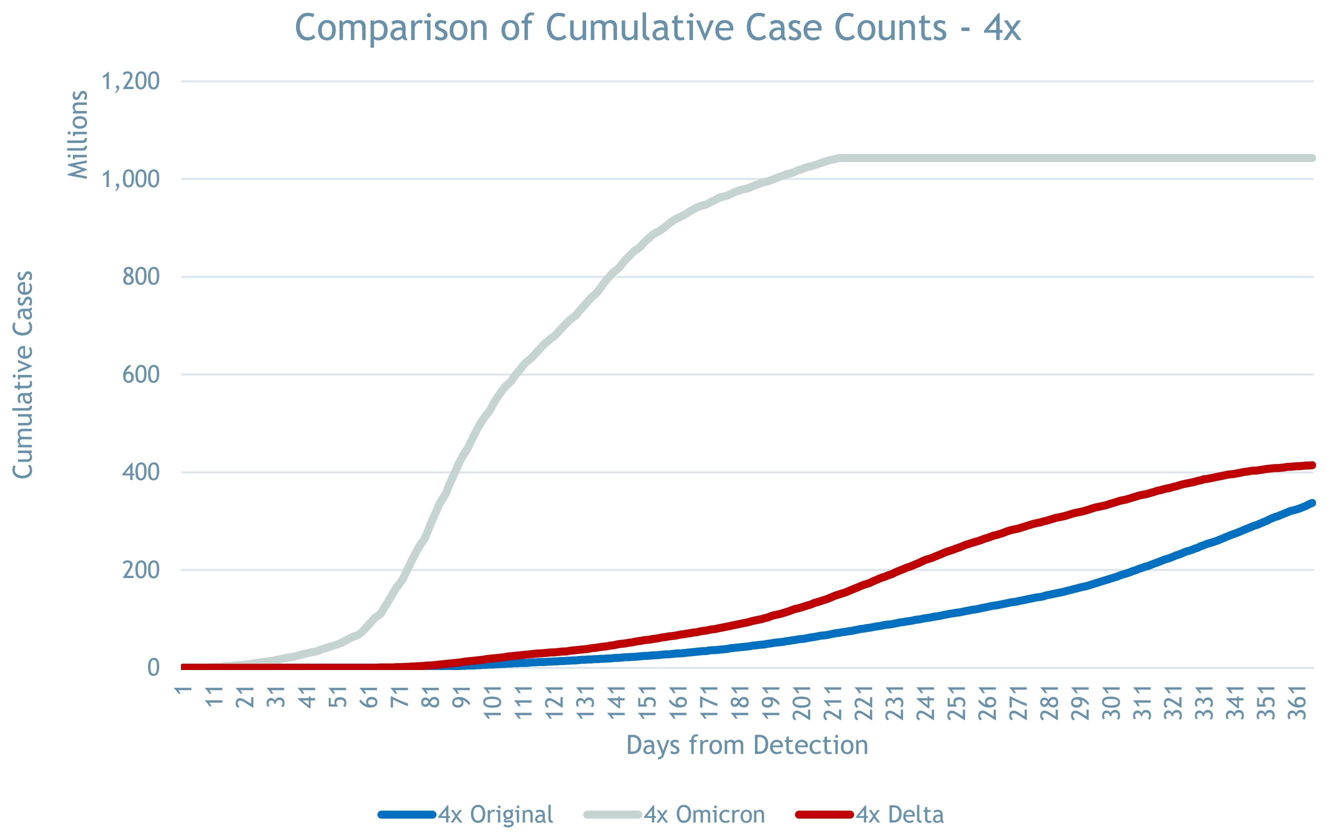
World Vital Worker Total Population is 1.9 billion, of which 1 billion are in agriculture and 250M are in healthcare

SARS-CoV-2 Omicron Variant: A Bad Case Scenario

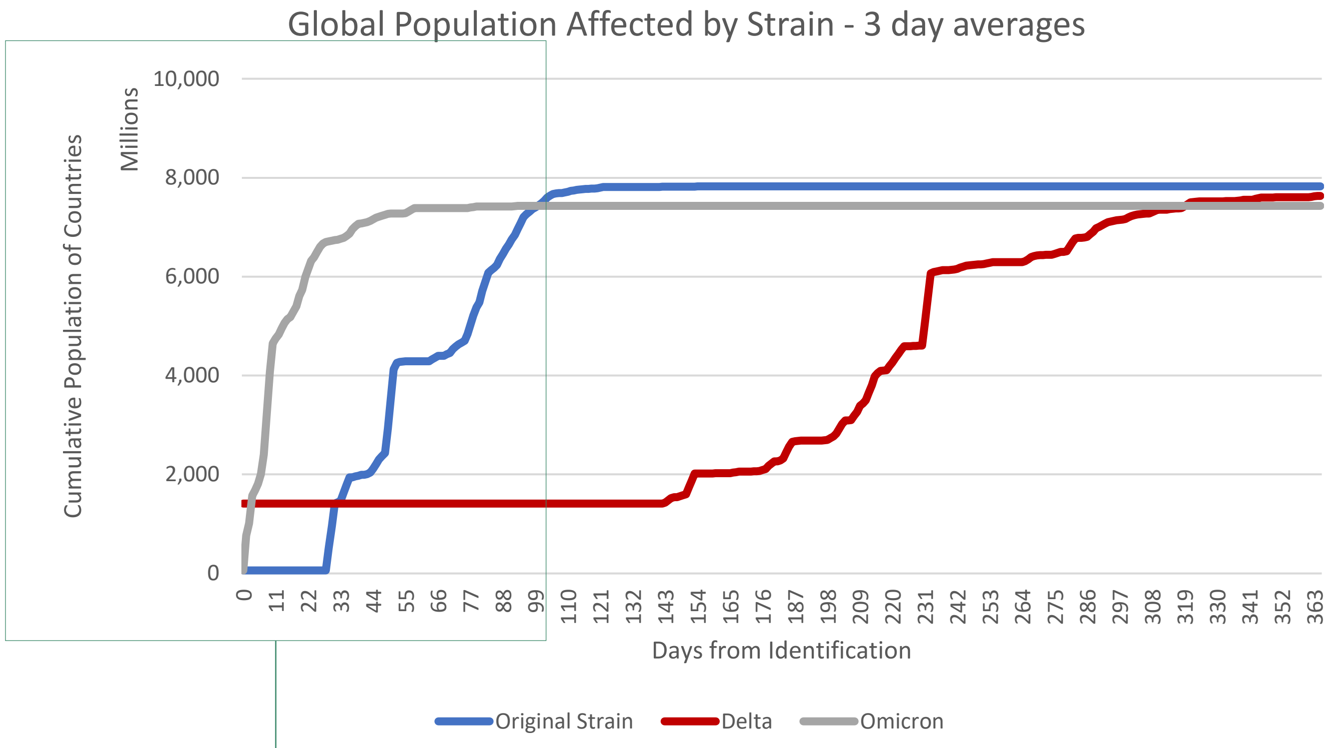
- The Omicron variant was detected in 32 countries within 7 days of its announcement, indicating it was likely spreading before detection.
- Within 90 days of detection, Omicron made up >99% of global COVID-19 samples sequenced.
- By November 2021, many countries had loosened travel restrictions and public acceptance of mitigation measures was falling
  - Its spread wasn't completely unmitigated but may be a good proxy for the spread of a novel highly transmissible, emerging infectious disease
- We used SEIR models to examine potential worst-case scenarios using shorter serial intervals
  - These were no worse than the spread of the Omicron variant except for extreme combinations of serial interval and transmissibility

Cumulative Cases for COVID Waves

Omicron wave reached its maximum within 200 days—providing PPE after this point is of no use to prevent further spread



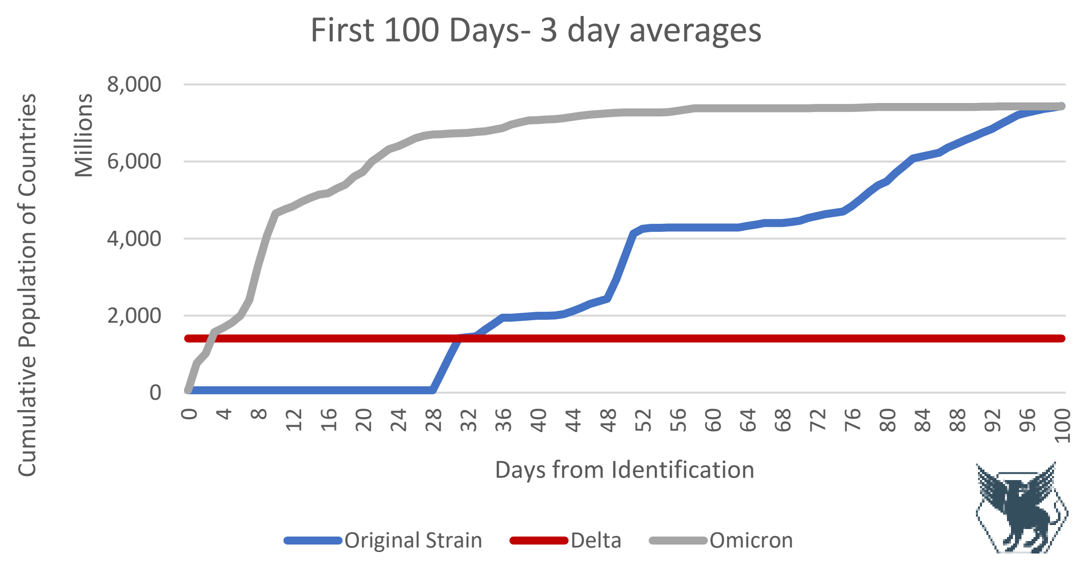
Global Population Affected



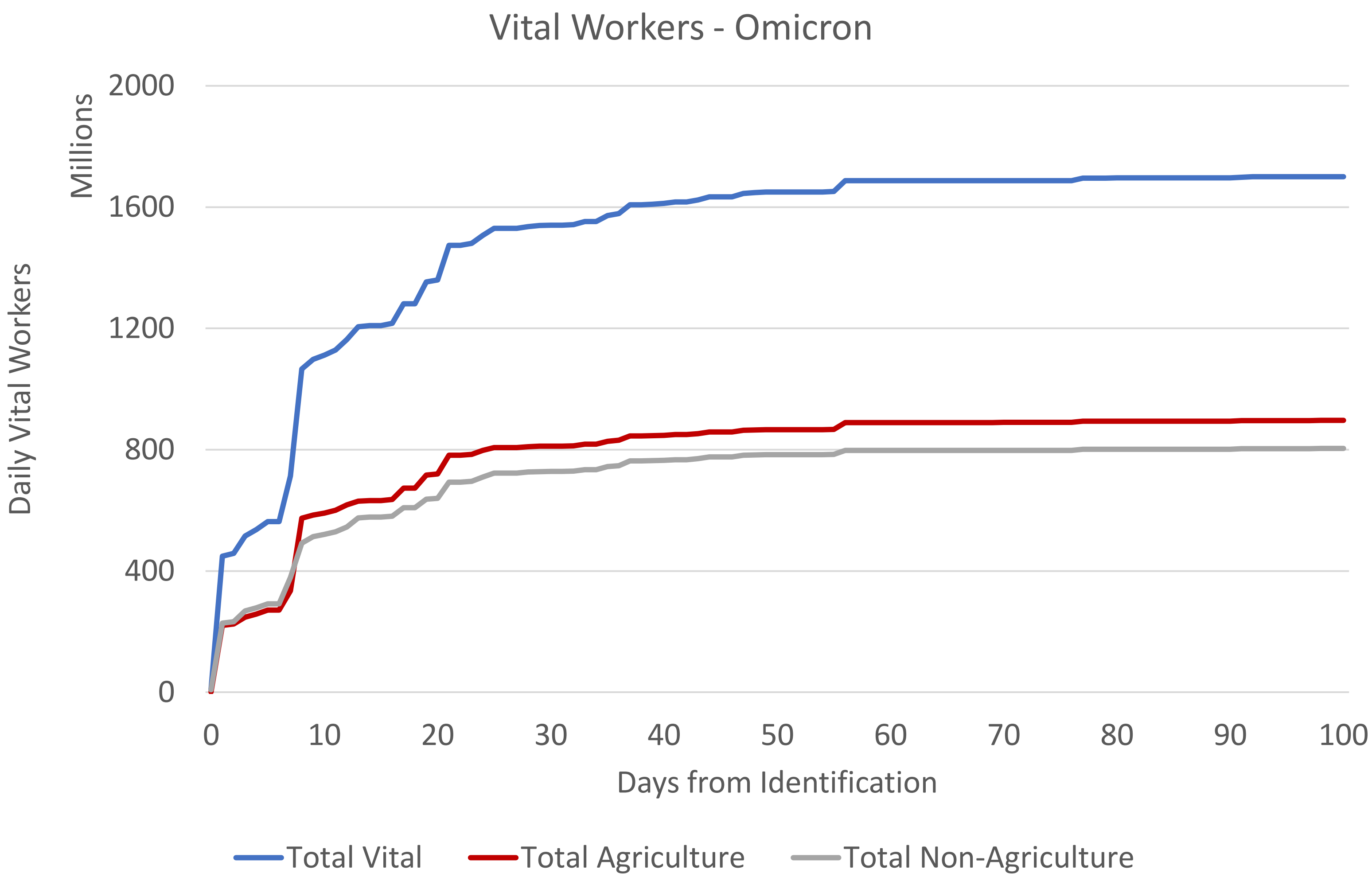
Omicron and original variant reached almost all countries in 100 days

Demand will rapidly explode during this time as workers in each country with cases demand protection

This is the critical window for PPE supply

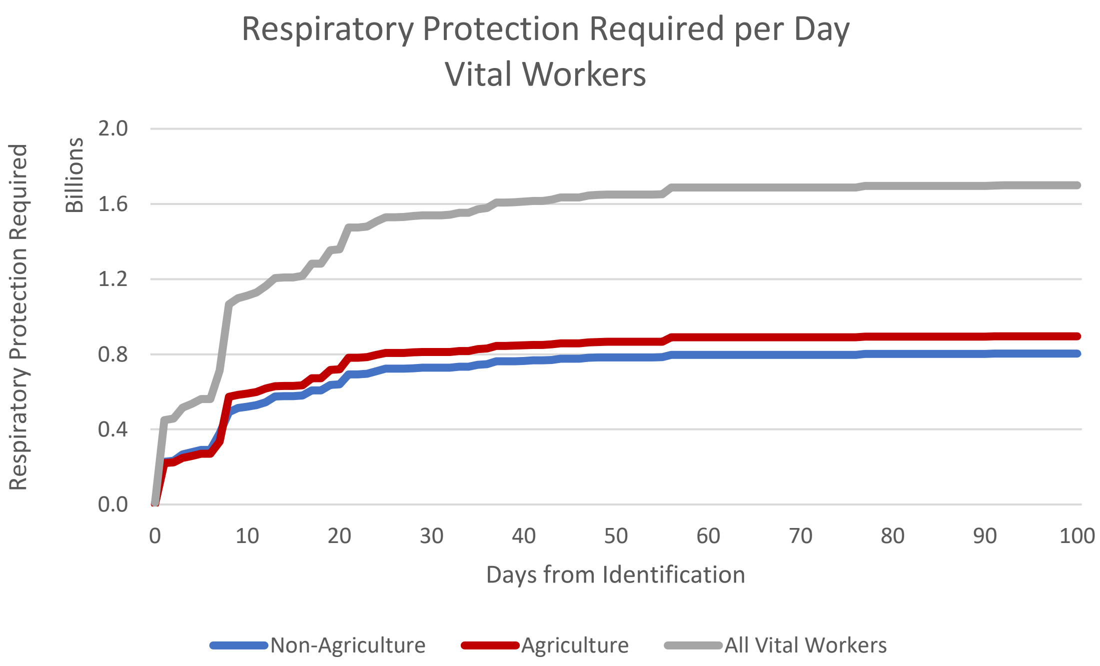


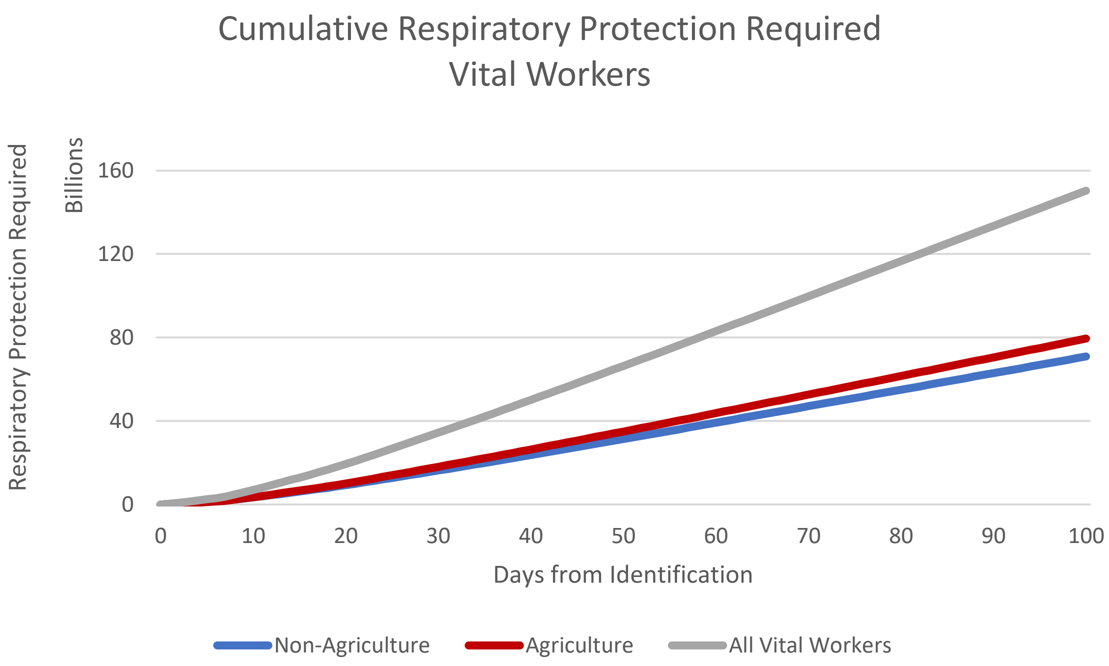
Vital Workers Affected



Respiratory PPE Needed Over Time - Vital Workers

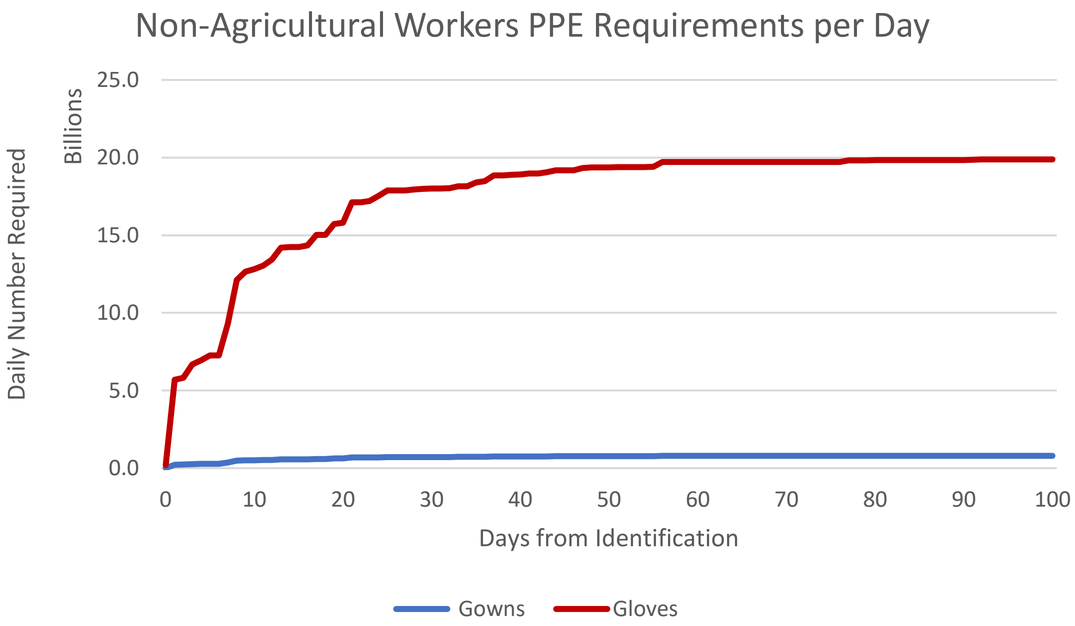
- Masks, gowns gloves for vital workers based on demand curve and number used per day

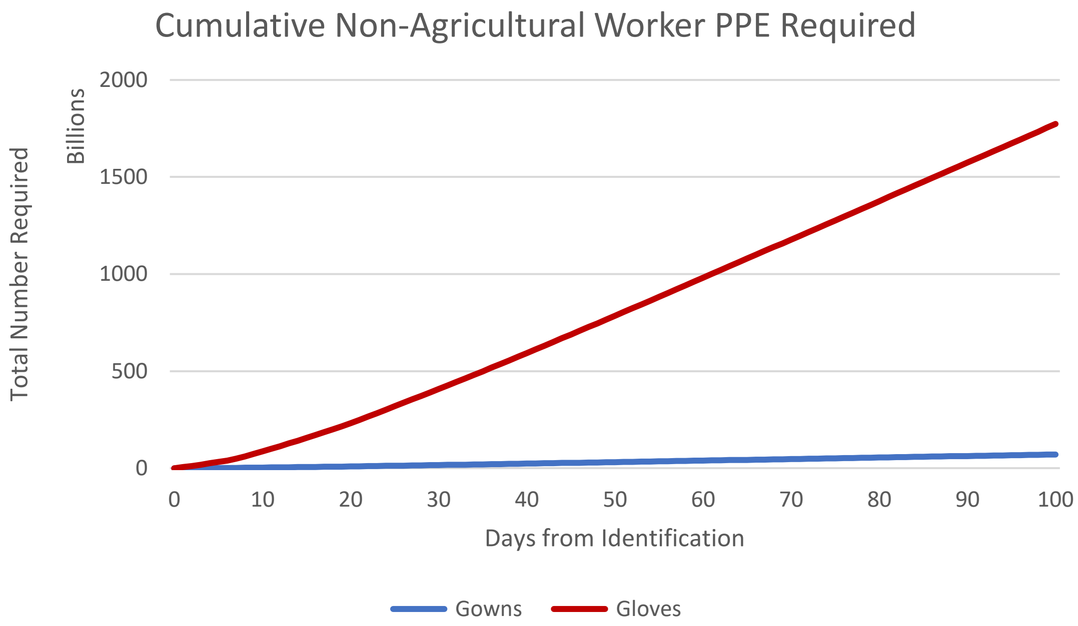




Peak demand of roughly 1.5Bn units of respiratory protection per day is needed to protect vital workers
Approaches 90% of peak demand in 20 days

Barrier PPE Needed Over Time - Vital Workers





- This gown and glove demand presumes that all vital workers need barrier protection
- Perhaps engineering controls can be used to remove much of demand except for workers that must touch others (healthcare)
  - If only healthcare workers need barrier protection 6Bn gloves and 250M gowns needed per day

Conclusions for Demand Analysis

- 1.6Bn units of respiratory PPE per day will be needed within the first 100 days
    - As discussed later, this is probably 100x more than the number of N95s produced globally
- Barrier protection (gloves, gowns, face shields) needs can be moderated if engineering controls can be used to isolate workers
    - Focused just on healthcare workers who must touch patients
        - In this case, roughly 6Bn gloves are needed per day
    - If true, even 2021 glove production may fall short by a few fold (shown later)
    - If false, glove production must increase by more than 10x

Overall conclusions from parametric analysis

- A pandemic as transmissible as measles, as aggressive as the Omicron variant of COVID and as pathogenic as pandemic flu would require high levels of respiratory protection in large quantities
  - N95-type respirators would barely protect vital workers IF:
    - Fit could be assured
    - Engineering controls were enhanced
    - And social distancing were enforced
  - 50Bn/per month would need to be provided during peak demand
  - This enhanced PPE must be widely available within 100 days of the emergence if the population and workforce is to be protected
- Barrier protection (esp of hands) may be necessary to prevent self-inoculation after contamination
  - If engineering controls could physically separate all workers except those in healthcare, current glove supply must increase by a few fold
  - If all vital workers need gloves, then supply must increase dramatically

Discussion

Any suggestions to improve the data sources or methodologies used?

Are these scenarios sufficiently reflecting a possible future pandemic?

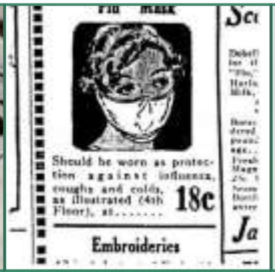
Are these reasonable requirements to shoot for so that we are not slow-footed by the next pandemic?

Designing PPE for End Users

Mindy James, PhD

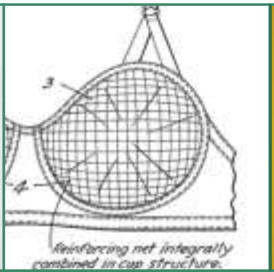
Case Study: Historical Highlights in Respirator Design

1910:
Cloth and gauze face masks created to slow Manchurian plague in China



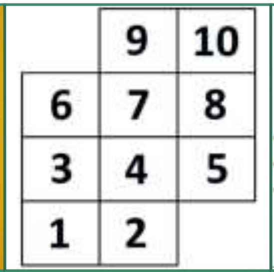
1918:
Cloth and gauze face masks become widely used due to the Spanish flu

1917-1945:
WWI & WWII militaries develop fiberglass gas masks for soldiers & general public

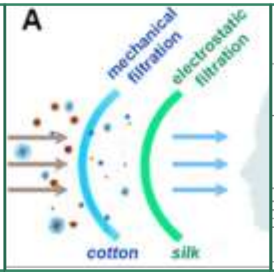


1961:
3M develops stretch broken fiber mask based on bra cup shapes

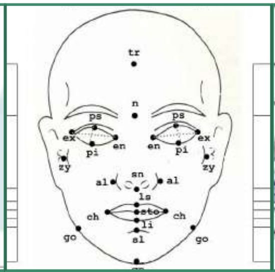
1972:
3M's first single use N95 respirator is approved by NIOSH



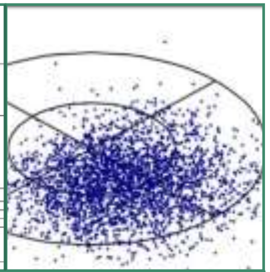
1978:
LANL Panel is created using US military facial measurements; used as a standard for FFR testing and sizing



1992:
Electrostatic technology is applied to mask materials - increasing filter efficiency by 10x



2007:
NIOSH Panel created to update LANL Panel; based on US working population



2009:
China uses population measurements to create fit panel; apparently not widely used to date

The history of respirator design is reactive, and data inputs, when used, are largely derived from a homogeneous population

“

Despite drawbacks in terms of comfort and fit, the ubiquitous disposable masks and disposable N95 respirators used by the vast majority of healthcare workers have not appreciably improved since the mid-1990s.

- *Masks and Respirators for the 21st Century: Policy Changes Needed to Save Lives and Prevent Societal Disruption*
JHU Center for Health Security 2021

Gaps in Design of PPE

Filtering facepiece respirators lose fit and performance over time

Respirators are not designed to accommodate facial diversity

Some PPE is not designed to meet religious and cultural needs

PPE is not designed to meet body diversity or biological requirements

Some PPE is not designed for use in hot environments

Case Study: The Importance of Fit Testing

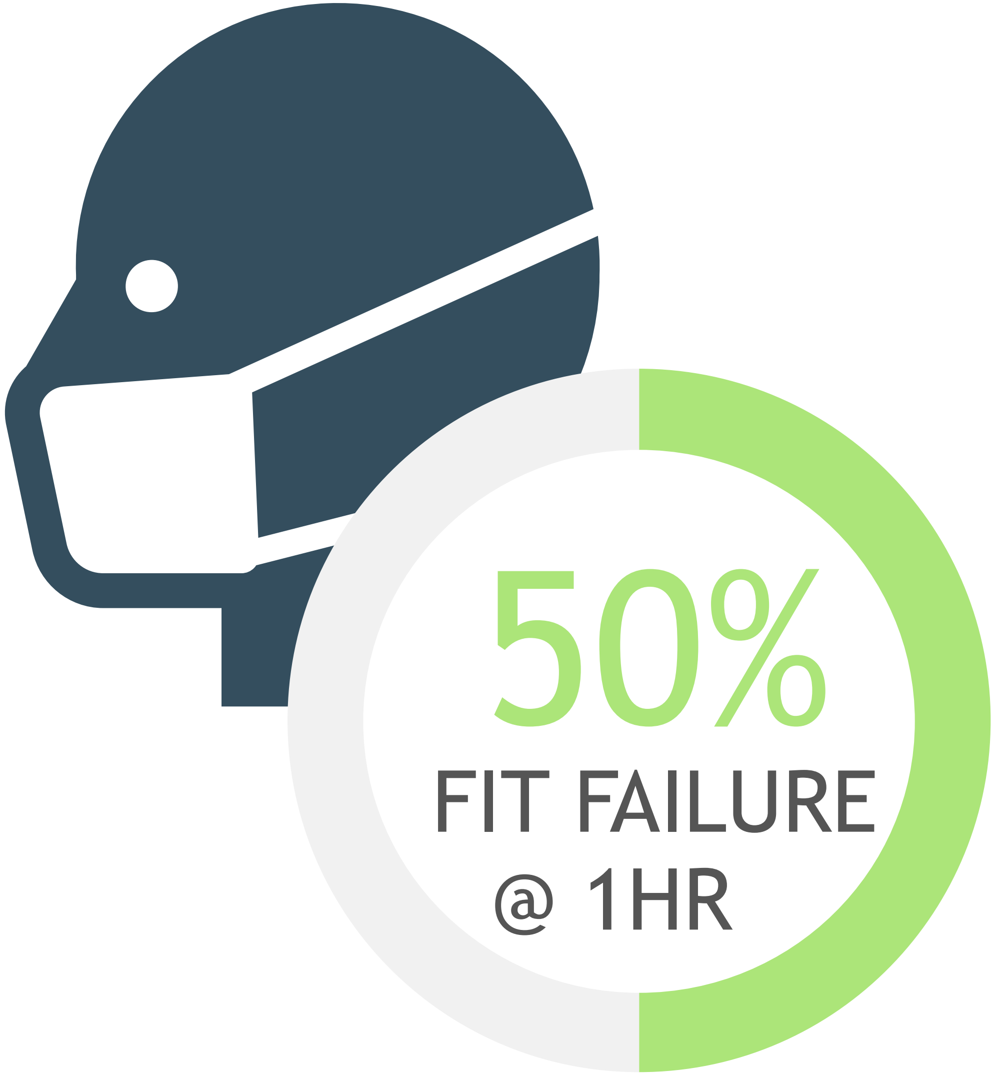
Milosevic 2022 performed a FFR fit test study with Australian health care workers (HCW):

- 55% of Australian HCWs passed a fit test on the first selection
- By the 3rd FFR, 93% were successfully fitted

Fit testing is not available to the general public or some front-line workers

Case Study: FFRs Lose Fit Over Time

- *Jung et al., 2021* assessed fit failure of N95 FFRs for 10 individuals during routine activities (office work, phone calls, talking, walking) for one, two, or three hours
- At all three intervals, significant failures in fit were found
- While a small sample size, these results are striking; the test should be repeated



Case Study: FFRs Lose Filtration Over Time

- FFRs lose filtration capability over time as particles build up on the material
  - Probably due to loss of charge on electret
- The graph on the right shows degradation of performance over a few hours
  - However, the rate of inhalation was unrealistically high

Loss of Filtration Capability as a Function of Time in Use

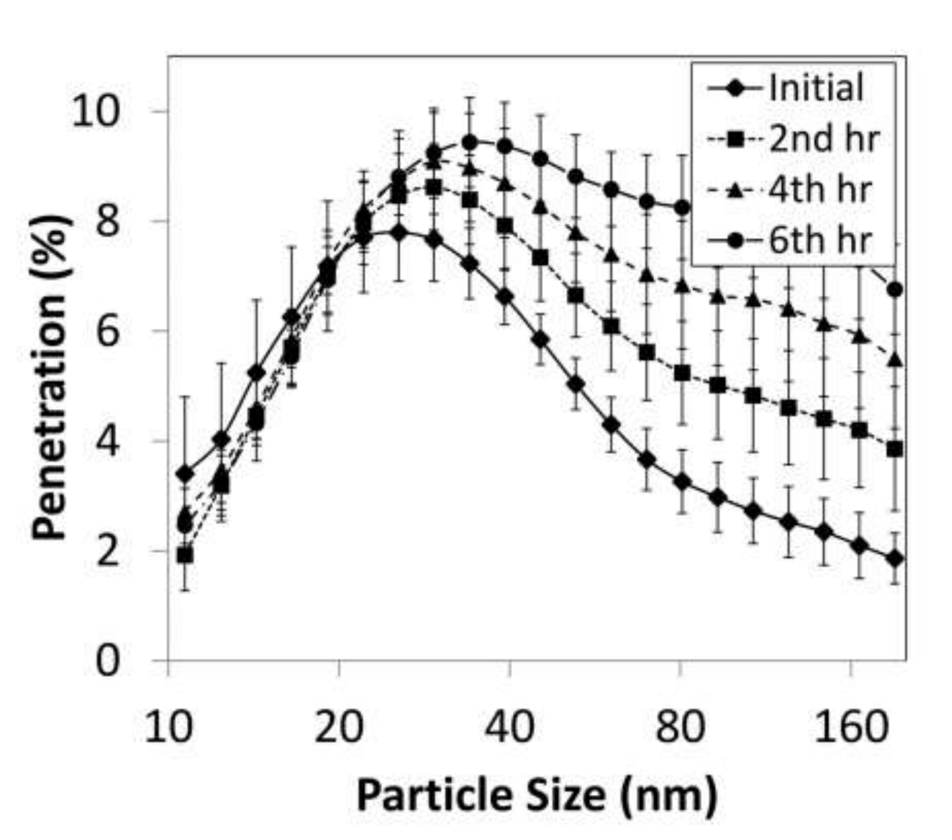


Figure from Mahdavi et al., 2015

Case Studies: PPE is Not Designed for Facial Diversity

65%

Less than 65% of Chinese subjects passed fit tests on N95 & FFP3 respirators
(Zhang 2020)

45%

Less than 45% of Chinese subjects passed fit tests on Chinese Certified (GB 2626-2006) respirators
(*Jiang 2013*)

60%

Less than 60% of French HCW's passed fit tests on FFP2 respirators
(Ciotti 2012)

PPE is Not Designed for Religious & Cultural Needs

- Facial hair diversity – facial hair varies by ethnicity, gender, and culture
  - Example: Some religions require men to maintain facial hair
  - PAPRs provide respiratory protection for individuals with facial hair
    - Expensive to purchase & maintain
    - Restricts hearing & peripheral vision
    - Physiologic/ergonomic impacts
- Cultural clothing requirements
  - Example: Jewish, Islamic, Sikh, and Christian religious groups require clothing that impact PPE Fit

Zanub Hygienic Hijab by Mawadda
Image from www.usmawadda.com
Under mask beard cover to create a smooth surface.
Image from Bhatia et al. 2022

PPE is Not Designed for Body Diversity

- PPE is not designed to fit the diversity of shapes of all human bodies
- Most PPE is designed for the bodies of European and American men
  - Standard sizes of PPE (i.e., medium/large) may not fit non-western men who are smaller in stature
  - PPE is not sized for the anthropometric ratios of the female body (e.g., breasts, narrower shoulders, wider hips, etc.)
    - Women often need to “size up”

PPE is Not Designed for Human Biological Requirements

PPE is not designed to fit the biological needs of women

- PPE does not accommodate the different stages of pregnancy
- PPE does not allow for easy restroom access
  - A Women in Global Health survey of female HCWs in over 50 countries found that menstruating women adapt to limited restroom access by:
    - Manipulating birth control medication dosing to skip their periods
    - Wearing adult diapers

70%

Globally, most healthcare workers are female

57%

Women said that their PPE hindered their work

in a 2016 survey of 3,000 women

PPE is Not Designed for Hot Environments

- The impermeability of PPE prevents sweat evaporation, leading to increased body temperature
- Thermal effects are exacerbated in hot environments resulting in:
  - Dehydration
  - Shortness of breath or chest tightness
  - Reduced professional judgement
  - Exhaustion
  - Shortened work time

Case Study

81% of participants reported a productivity loss related to heat stress, despite 79% of them working in an indoor and air-conditioned environment.

Gaps in PPE Use

PPE may interfere with job duties & impacts are exacerbated by poor fit

PPE use is linked to adverse physical reactions

GRYPHON SCIENTIFIC

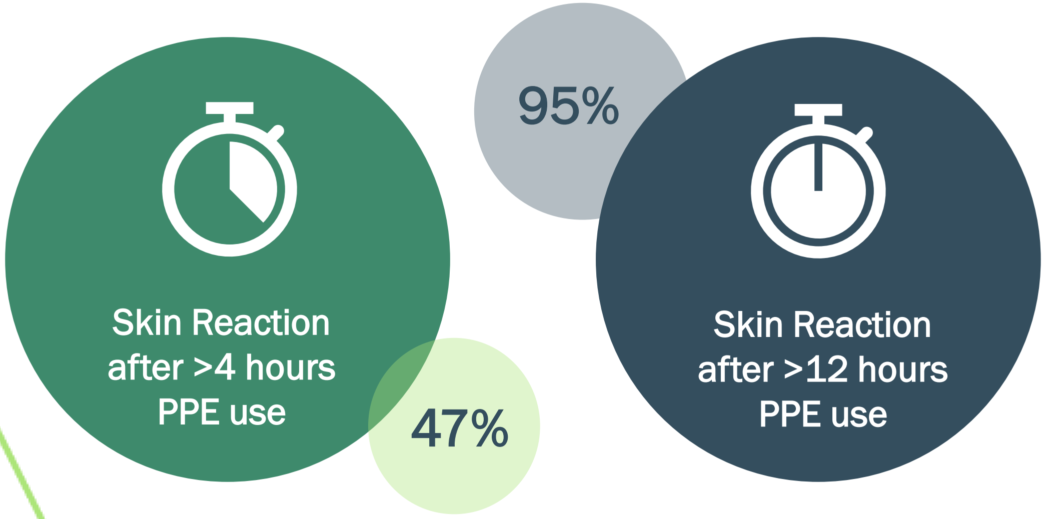
PPE May Interfere with Job Duties

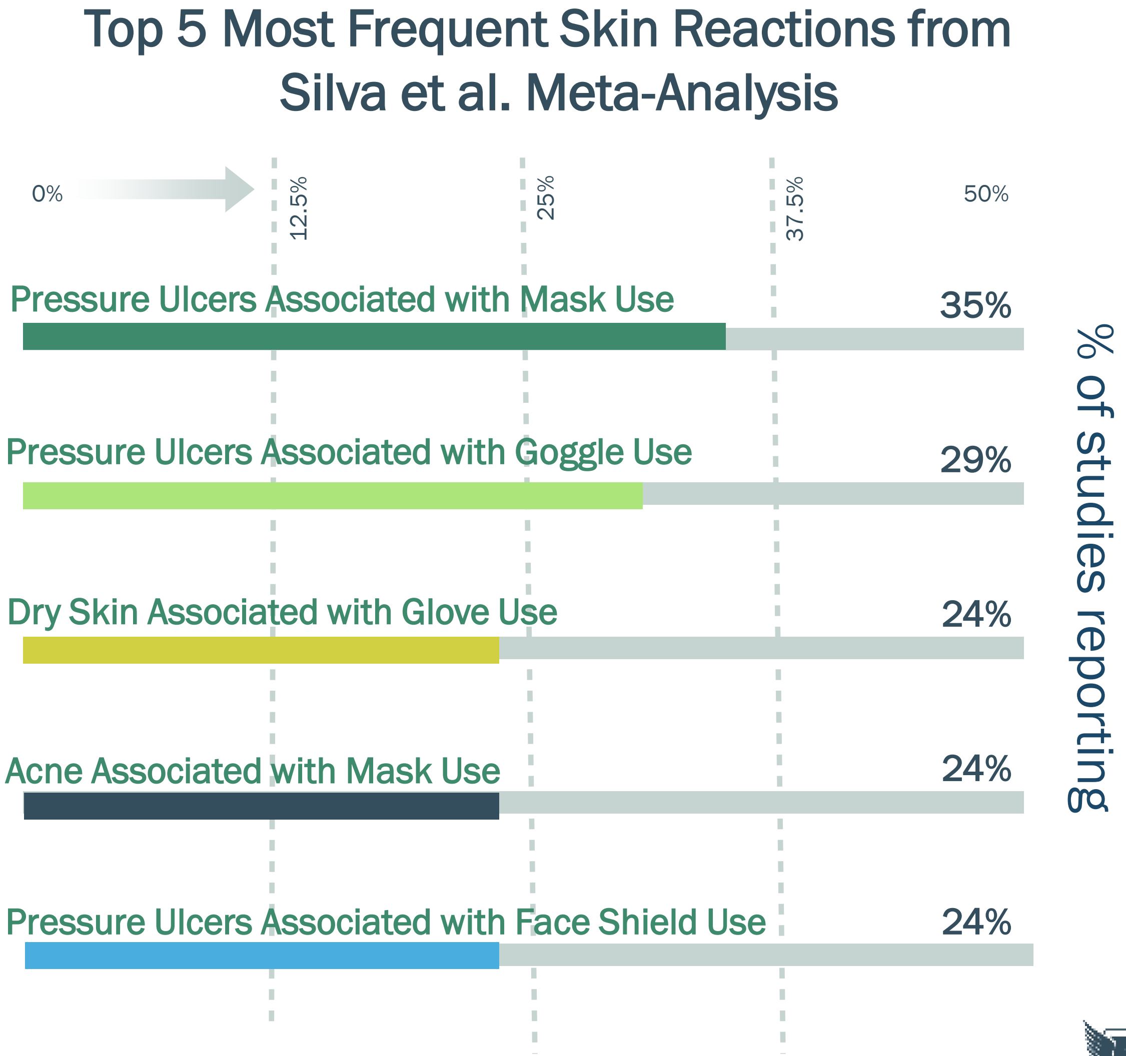
PPE Type	Challenges with Good Fit	Additional Challenges with Poor Fit
Eye Protection	Fogging	Adjustment/Contamination
Gowns/Coveralls	Heat, range of motion	Mobility, fit of other PPE
Gloves	Decreased dexterity/tactility	Moisture/Slippage, perforation
PAPR	Communication, hearing, vision	Adjustment/Contamination
Respirators	Communication, fatigue	Adjustment/Contamination

Poor Fit issues are more prevalent in Female, Minority, or Ethnic groups, as anthropometry varies greatly between these groups- making fit harder to achieve.

PPE-Associated Adverse Skin Reactions

- Surgical or N95 masks, goggles, face shields, and gloves are associated with adverse skin reactions
- Pressure ulcers (stage 1 and 2) were the most frequently reported adverse reaction followed by acne, skin depression, and dry skin





PPE-Associated Headaches

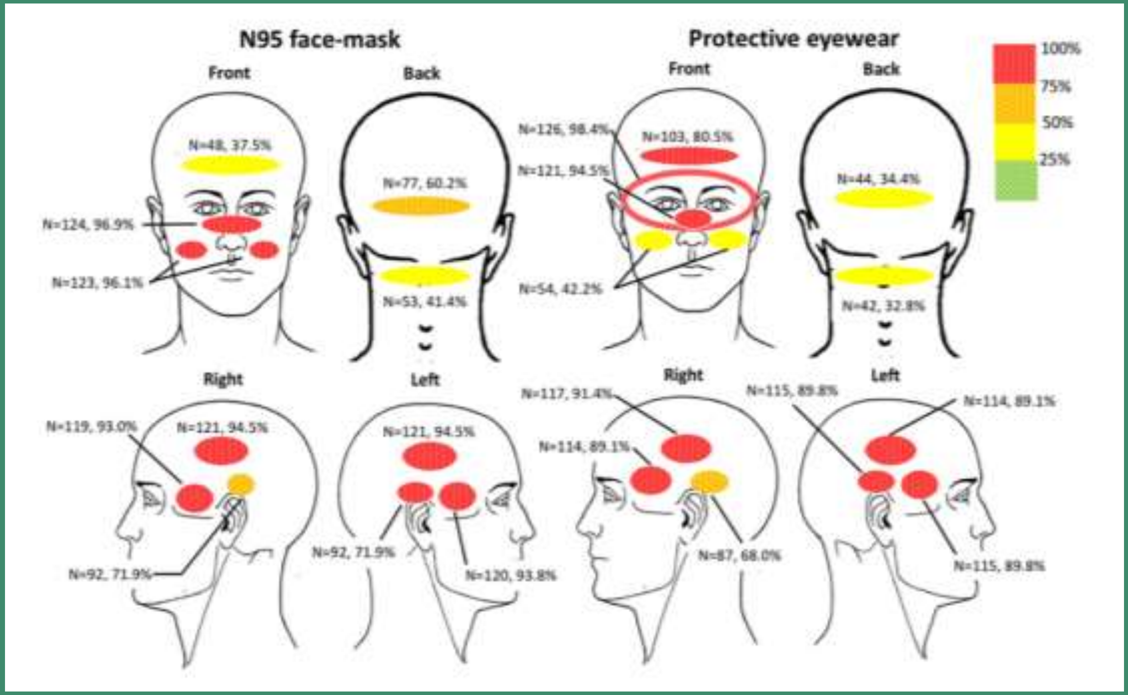
Multiple studies have suggested many types of PPE worn on the head may cause headaches

50%

Prolonged PPE use increased prevalence of headache

Meta-analysis of 26 studies, *Sahebi 2022*

Case Study: Ong 2020



PPE-associated headaches are likely caused by external compression of the head and/or neck

Wrap-Up: Designing PPE for End Users

Discussion

Are there any gaps we did not discuss that are important?

How should the gaps we listed here be prioritized?

Gaps

- PPE is not designed for diverse users & environments
- FFRs lose fit & efficacy over time
- PPE may interfere with job duties
- PPE use is linked to adverse physical reactions

INITIAL PPE SUPPLY CHAIN REVIEW

Theory of Pandemic-proof PPE

Sage Analysis Group

3 Mar 2023

Initial observations from information available in Phase 1
Findings will evolve with further research and analysis

Agenda

1. Context & Overview of Phase 1 Work
2. Overall Observations
   - Data Availability
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   - Gloves
   - Masks (Surgical & N95)
   - PAPRs
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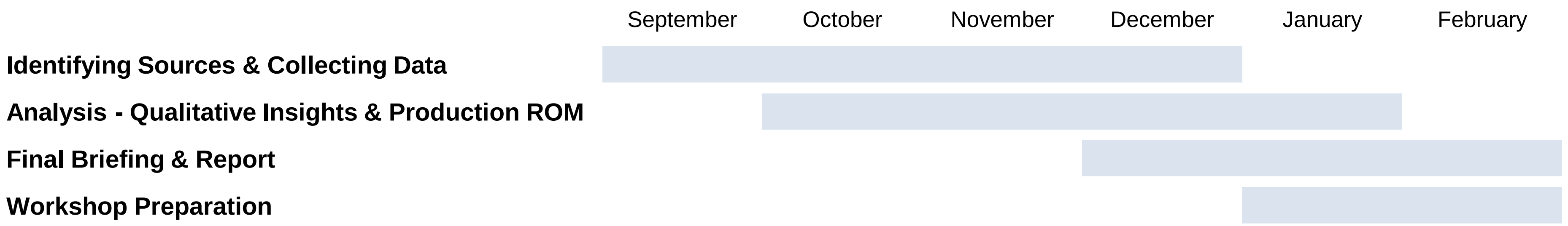
Sage Analysis Group

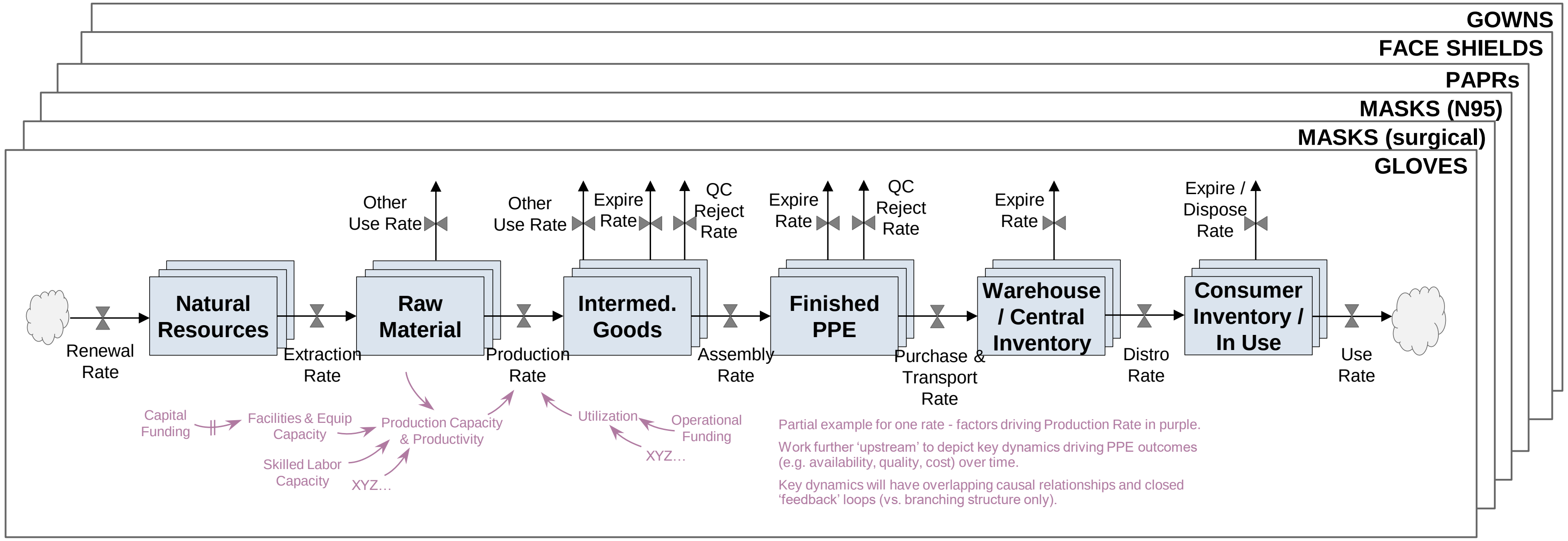
Overview of Sage's Phase 1 PPE Supply Chain review



- As part of the broader P4E effort, Sage conducted an **initial review of the supply chain** for critical PPE categories to ultimately support developing strategies to improve resiliency
- We conducted a **high-level survey** of information available in the **public domain**
- From our research, we made initial **rough order of magnitude estimates** for production capacity as well as some other qualitative insights and conclusions
- **Quality data was scarce in most areas.** We identified data gaps, explored options, and highlighted initial rough assumptions used to fill gaps.
- There are far more sources than we could explore in Phase I (good sources welcomed!)

Brief background on Sage Analysis Group on final slide for reference

Context: Considering all the different elements in each supply chain is important to help prioritize interventions to improve future resiliency.



Each PPE Supply Chain is **Unique** and **Evolving**

Integrating information enables more holistic analysis of options and tailoring to the specifics of each PPE category to achieve the most leverage.

Integrated view can help different groups who typically focus on part of the overall system to better see how initiatives outside their area will impact them.

What information exists?

Where are the data gaps?

Where are the bottlenecks?

What are the long-lead items?

What are the key risks?

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Summary Observations: Reliable and consistent quantitative data is not readily available for most elements of the PPE supply chain (1 of 2)

- We explored a wide range of potential sources seeking data across the whole value chain – primary inputs, manufacturing, distribution – for each type of PPE examined.
- Despite intense interest in PPE manufacturing since early 2020, consistent and comprehensive quantitative data is not readily available in the public domain
- There are of course many potential sources. We weren't able to investigate all in Phase I and we continue to seek better sources of data – ideas welcomed!
- To support making rough estimates of capacity we used different approaches to assemble information on different parts of the supply chain. Approaches included:
  - Primary source (e.g., company or trade association annual reports, press releases, etc.)
  - Secondary source (e.g., news articles, other government / private reports)
  - SME / industry interviews
  - Commercial market research reports
  - Trade flows from UN COMTRADE database
  - Triangulation (i.e., assumptions and structured deductions)

Summary Observations: Reliable and consistent quantitative data is not readily available for most elements of the PPE supply chain (2 of 2)

All sources reviewed in Phase I had shortcomings, some glaring. Common issues:

- Most Western companies view production capacity data as competitive information and share only highly aggregated data, if any at all
- Most Chinese companies (critical for most PPE) share even less information
- Anecdotal information from news articles and interviews was sparse and, of course, has uncertain sourcing, reliability, or broad applicability
- All the commercial (paid) market research reports we sampled in Phase I suffered from these same issues and did not add much value. There are a lot of companies offering reports and we welcome suggestions of high-quality sources that are worth the expense.
- Trade flow data sampled doesn’t differentiate between domestic use or re-export, and data is too aggregated to be useful in the case of most finished goods
- Different PPE types had different issues, but all of these were issues for all PPE types

For most PPE types, we used a ‘triangulation’ approach to cross-check estimates from the limited and sparse information of different types

Summary Observations: A few high-level points apply to all PPE categories

There were significant differences across PPE types that are covered later in these materials, but some commonalities include:

- Even the limited quantitative data highlights how much of global PPE manufacturing capacity is clustered in East / Southeast Asia
- Most PPE types (PAPRs a notable exception) have few but complicated manufacturing steps
  - Tooling and production equipment is often capital-intensive
  - Process often requires expertise, IP, or specialized labor to enable high volume low-cost production
- Several PPE types use similar primary inputs (e.g., Specialized nonwoven fabrics are the primary inputs for masks, gowns, and PAPR filters)
- Supply chains and markets have seen major and ongoing changes due to COVID-19
  - Market "failures" in beginning of pandemic (new manufacturers struggled to connect w/ existing customers; governments-imposed export restrictions; hoarding; theft / black markets)
  - Large price fluctuations. Initial major increases in price due to short supply, followed by price drops below pre-pandemic norms as COVID surge capacity came online and initial spike in demand moderated. This dynamic impacted different points in the supply chain differently at different times.
  - Strategic on-shoring as governments adopt "protectionist" policies to prevent shortages in the future
  - New entrants, major facility changes, some use of alternate materials, many adjacent industries temporarily filling gaps, questions about sustainability of some companies and facilities
    many PPE manufacturers (notably China but many) who entered the market during COVID-19 are no longer in business

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Gloves: better data availability due to manufacturing concentration

Key Findings

- Extreme concentration of value chain in Southeast and East Asia
- Gloves appear to be relatively minor draw on global natural latex / NBR production
- Though lower-value, glove manufacturing is labor-intensive and requires capital-intensive equipment
- Tooling and process mostly similar between latex / NBR

Production Landscape

ROM Annual Global Production*:

350-400 B units

- ~65% manufactured in Malaysia
- ~30% manufactured in China & Thailand
- ~5% other

**Most data is from 2021*

Data and Analysis Challenges

- Available production data did not distinguish between types of glove (material, use, etc.)
- Unclear whether manufacturing outside of Asia is for specialized gloves
- There was extremely limited information on upstream (e.g., latex) producers and Chinese manufacturers
- Available trade data that was analyzed comes with inherent challenges / is of limited utility
- Market share data was self-reported, with limited insight into assumptions or calculations

Gloves: examination of the whole value chain

Raw materials

- Primary inputs concentrated in Asia. There are 2 options for raw material used:

1. Latex

- Supply clusters in Southeast Asia
- Latex mostly produced by small suppliers

2. NBR

- Supply concentrated in East Asia
- Supply constrained during COVID

Manufacturing

- Geographic concentration in Asia
- "Big 4" in Malaysia supplies more than 50% of global supply
- Good production reporting from trade organizations (e.g. MARGMA)
- Initial investment is capital intensive
- Labor intensive removal of gloves from tooling
- History of labor violations

Shipping and Distribution

- Shipping primarily via ocean freight
- Shelf life: 3-5 years depending on type

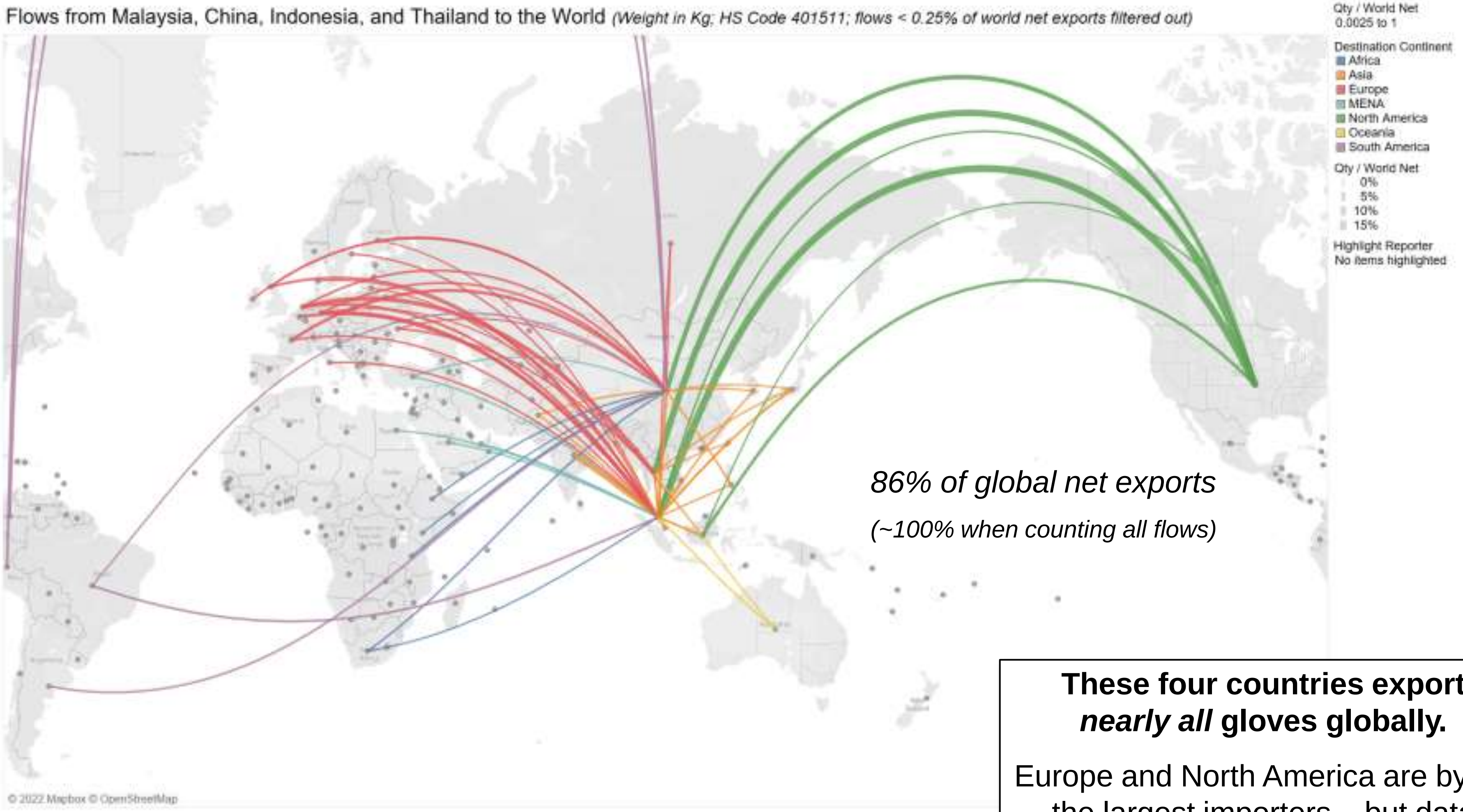
Gloves: The Malaysian “Big 4”

- Within Malaysia, manufacturing is dominated by the “Big 4”, who together produce roughly half of the world’s medical gloves
- These companies generally have multiple production lines (rather than one or two large facilities), and some have operations in other countries like Thailand, China, and Vietnam
- Data sources are often not clear on production location within each firm so there are bands of uncertainty around these estimates
- These firms also provide fairly detailed data in their annual reports about their total production capacity and market share

Manufacturer	2021 Production Capacity* *(B pieces)* (*From various sources*)	Implied Share of Malaysian Production *(240B**)* (*Extrapolated figure*)	Implied Share of Global Production *(370B***)* (*Extrapolated figure*)
Top Glove	90	38%	25%
Hartalega	43	18%	12%
Kossan Rubber	33.5	14%	9%
Supermax Corp	26	11%	7%
Sum of Big 4	**193**	**80%**	**52%**
Implied Remainder (Malaysia)	*47*	*20%*	*13%*

**Taken from company annual reports and press releases*
***240 billion pieces from Malaysia, or 65% of global production, per MARGMA (https://www.theedgemarkets.com/article/margma-expects-global-glove-demand-resume-growth-next-year-after-19-drop?type=corporate)*
****370 billion pieces worldwide, extrapolated if 240B is 65% of market*

2021 Export Flows as % of Global *Net* Exports: Gloves from **Malaysia, China, Thailand, Indonesia**



86% of global net exports

(~100% when counting all flows)

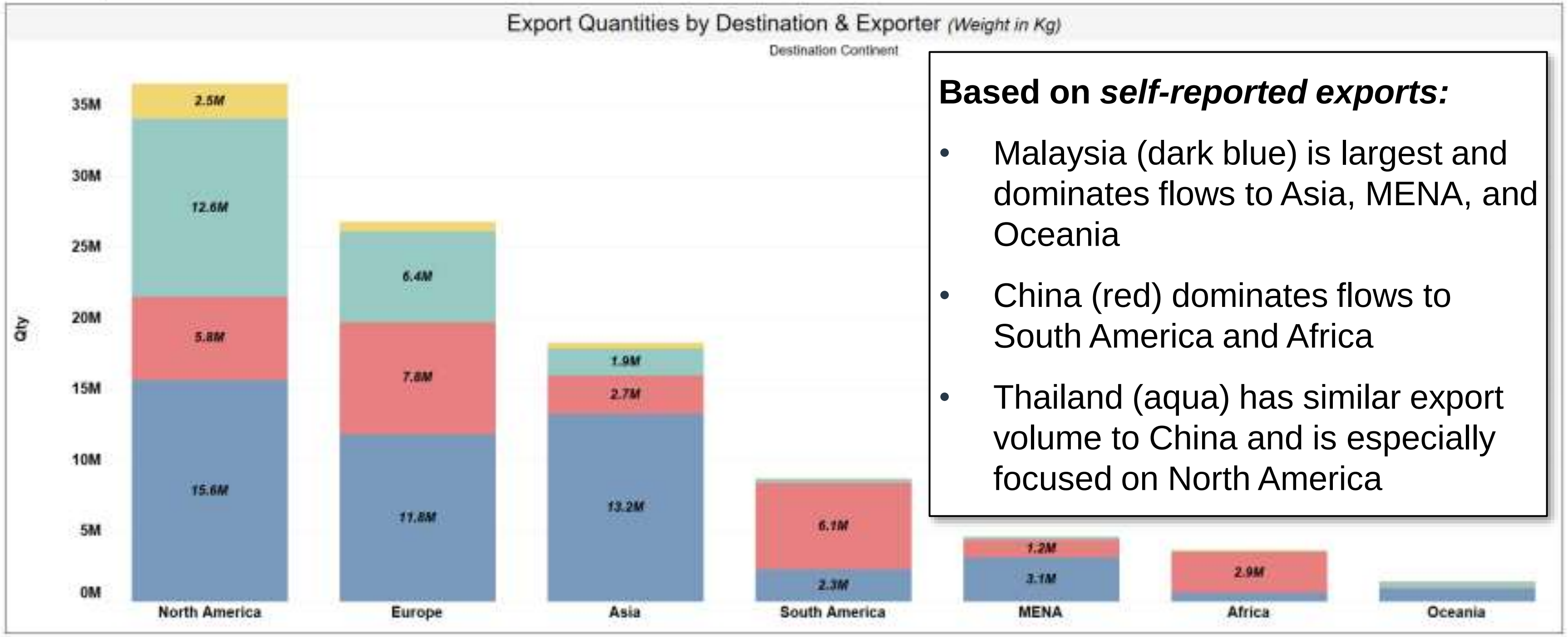
These four countries export *nearly all* gloves globally.

Europe and North America are by far the largest importers – but data doesn't reveal final destination (e.g., re-exported within Europe)

Source: UN COMTRADE Database

Sage Analysis Group

2021 Export Flows: Gloves from **Malaysia, China, Thailand, Indonesia**



Based on *self-reported exports:*

- Malaysia (dark blue) is largest and dominates flows to Asia, MENA, and Oceania
- China (red) dominates flows to South America and Africa
- Thailand (aqua) has similar export volume to China and is especially focused on North America

Source: UN COMTRADE Database

By weight in Kg; HS Code 401511

Sage Analysis Group

Masks: limited data despite intense focus on face coverings

Key Findings

- Indications of manufacturing concentration in China, though new capacity came online in numerous other countries in response to shortage during COVID-19
- Process is highly automated with some manual labor input
- Heavy reliance on nonwoven fabrics, especially meltblown, which is an effective filter
- Specialized machinery, technical expertise and IP needed in nonwovens likely to result in bottlenecks

Production Landscape

N95 ROM Annual Global Production*:
1-5 B units

Surgical Mask ROM Annual Global Production*:
7-35 B units

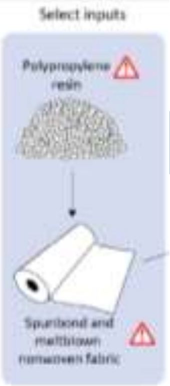
**Most data is from 2021*

Data and Analysis Challenges

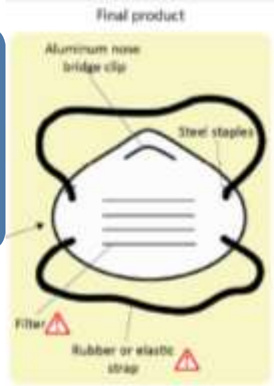
- Lack of authoritative high-quality data from international agencies or trade organizations
- A wide range of production estimates from various sources (e.g., NY Times, OECD, Ocean Asia)
- Minimal disclosure on production from individual manufacturers due to competition concerns
- Available trade data that was analyzed comes with inherent challenges / is of limited utility
- Dynamic production landscape due to high demand and public attention
- Commercial market research report we acquired had obvious shortcomings and thus questionable reliability

Masks: examination of the whole value chain

Raw materials



Manufacturing



Shipping and Distribution

Raw materials

- High demand of meltblown non-woven filter, requiring expensive facilities
- **N95s** require denser meltblown for filtration layer than other applications
- Discussions w/ SMEs shows potential to use other material with similar filtering properties to reduce potential bottleneck

Manufacturing

- Geographic concentration in China (1/2 of all masks pre-COVID). Very limited data from Chinese firms.
- High investment cost for **N95** masks (thermoforming & die stamping tools)
- **Surgical** masks easier to produce despite similar inputs
- Shortages during COVID-19 brought wave of new entrants who now see declining demand and are high cost
- NOISH / similar approvals required in most markets (barriers to entry)

Shipping and Distribution

- Export restriction in multiple countries during Covid-19
- Mostly distributed via ocean freight with some via air due to high demand during Covid-19
- Possible shelf life beyond manufacturing suggested date

Nonwovens: a critical input to surgical and N95 masks

Albert Shih (University of Michigan), April 2020:

*"**The outer two layers, there are plenty of supplies**, but [meltblown] is not easy to obtain or make, and you cannot just start a new line. You have to show that the microbes won't penetrate it and get into the lungs."*

Dave Rousse (INDA), April 2020:

*Even established companies are having trouble boosting production because **they can't simply buy more machines**, according to Dave Rousse, president of INDA, the Association of the Nonwoven Fabrics Industry.*

*"**There are only five or six companies across the globe that make these machines**, and they're not inexpensive. These are sizable machines, a lot of technology, a lot of air handling, a lot of electronics, a lot of precision moving parts," Rousse said. "**Normally it's nine to 12 months before you could get a machine delivery**."*

Global Nonwovens Production (pre-COVID)

- ~16 M tons globally
- ~45% in Asia
- ~33% in China alone
- ~5% meltblown

Dealing with Increased Demand (COVID)

- 2019: ~7% of meltblown went to masks*
- 2020: ~33% of meltblown went to masks*
- Surge achieved by:
  - **New** market entrants
  - **Expanding** existing lines
  - **Converting** other non-woven lines to meltblown
- Factors gating response:
  - Technical **feasibility** (e.g., quality standards applied and condition of existing facilities)
  - Perceived **sustainability** (e.g., duration of increased demand); Meltblown oversupply began in 2022

PAPR: limited data though high interest for high-quality respiratory protection

Key Findings

- PAPRs are the most complex and highest-value forms of PPE we examined
- The multiple uses for many of their components (fans, filters, batteries, etc.) means there is more capacity in adjacent industries that could possibly be tapped into (e.g., Ford-3M partnership)
- The more complicated inputs (intermediate, rather than raw, goods) and functionality makes it more likely that they would be manufactured by firms in developed countries

Production Landscape

ROM Annual Global Production*:

2-5 M units

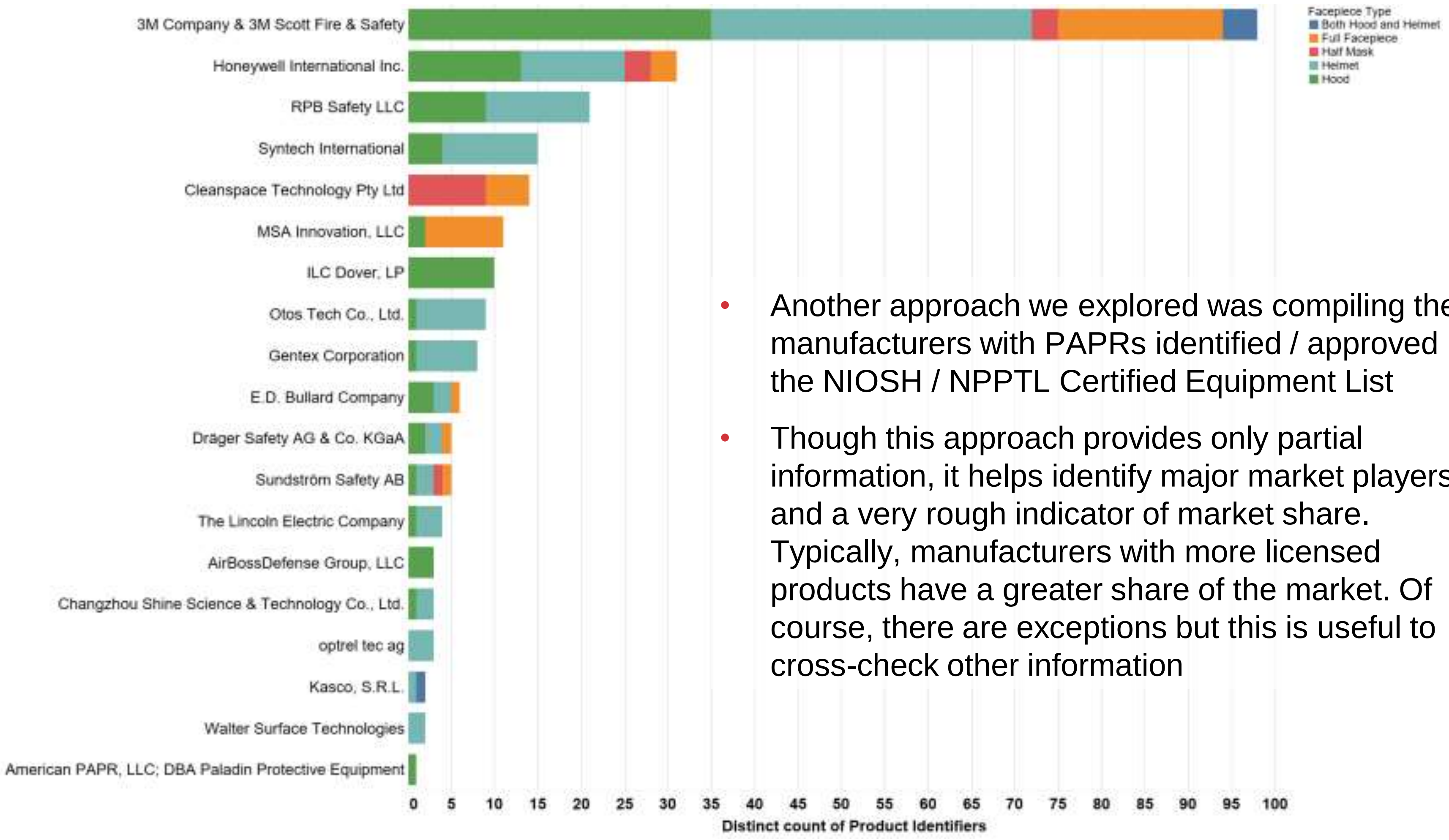
- Mostly produced in Asia Pacific and the United States^

**Most data is from 2021*
VMR Market Research

Data and Analysis Challenges

- Limited public data is available on PAPR production
- Some demand-side data, such as high-level global market values and scale of hospital purchases of PAPRs in the United States, are available but provide limited insight on production
- Bigger, Western players like 3M appear to have a much higher share of PAPR market than they do for lower-value PPE, but they do not share production or market share data publicly
- Available trade data that was analyzed has key limitations on usefulness (granularity, domestic use, cross-shipment)

PAPRs: example of alternative, limited approach



- Another approach we explored was compiling the manufacturers with PAPRs identified / approved in the NIOSH / NPPTL Certified Equipment List
- Though this approach provides only partial information, it helps identify major market players and a very rough indicator of market share. Typically, manufacturers with more licensed products have a greater share of the market. Of course, there are exceptions but this is useful to cross-check other information

Source: https://www2a.cdc.gov/drds/cel/cel_form_code.asp

PAPRs: review of an example commercial market research report

- To test whether independent market research firms have comprehensive information, we purchased a report from a firm (Verified Market Research (VMR))
- On reviewing the report, we found they also were not able to identify detailed production data – e.g., their by-company production capacity would only seem to cover ¼ to ½ of what VMR itself estimates is the global market
- To reach our ROM conclusions, we took a range of market size estimates and made unit price assumptions to triangulate a global production capacity

Limited Quantitative Data → Our Resulting Approach

TABLE 63 COMPANY PRODUCTION OF PAPR (UNITS)

Company	2019	2020	2021
3M	139 K to 140 K	177 K to 178 K	179 K to 180 K
Avon Rubber PLC	10 K to 12 K	13 K to 14 K	15 K to 16 K
Honeywell International Inc.	45 K to 55 K	50 K to 60 K	60 K to 70 K
Dragerwerk AG & Co. KGaA	202 K to 203 K	215 K to 216 K	246 K to 247 K
Mine Safety Appliances (MSA) Company	22 K to 22.5 K	27 K to 27.8 K	24 K to 24.3 K
GVS Group	33 K - 34 K	210 K - 211K	126 K - 127 K

		Market Size (from market research reports)	
		Lower Bound	Upper Bound
Price (assumptions)	Lower Bound		Most units
	Upper Bound	Least Units	

Face Shields: broad range of definitions and production methods

Key Findings

- Face shields are relatively simple in their primary inputs and production
- Comparatively easy for adjacent industry capacity to pivot / manufacture face shields
- Wide application of 3D printing and DIY during COVID-19
- High percentage of reusable face shields on the market

Production Landscape

ROM Annual Global Production*:

650-875 M units

(20-25% medical)

- Roughly 50% in China and 20% in the United States

**Most data is from 2021*

Data and Analysis Challenges

- Limited public data is available on face shields production
- Some high-level demand-side market data are available but provide limited insight on production
- The varying definitions of “face shield” made apples-to-apples comparison and corroboration of data difficult
- Available trade data that was analyzed comes with inherent challenges / is of limited utility

Face Shields: examination of the whole value chain

Raw materials → **Manufacturing** → **Shipping and Distribution**

Raw materials

- Common raw materials (e.g., plastic, foam, elastic, tape)

Manufacturing

- Majority produced in China, but a fair capacity in U.S. and other countries
- Broad utilization of 3D printing and DIY during Covid-19 globally
- Relatively easy for non-medical manufacturers to produce

Gowns: diverse market and limited data availability

Key Findings

- Gowns are among the most diverse form of PPE in terms of their intended use, material, type, and method of construction
- Many gowns use the same primary inputs (e.g., SMS or other nonwovens) as masks in their production, making the production vulnerable to surge in mask production
- Gowns are quite labor intensive to produce with relatively limited opportunities for automation compared to other PPE such as masks

Production Landscape

ROM Annual Global Production*:

1-8 B

- China and other parts of Asia

**Most data is from 2021*

Data and Analysis Challenges

- Limited public data is available on medical gown production
- Some high-level demand-side market data are available but provide limited insight on production
- The varying definitions of “gown” made apples-to-apples comparison and corroboration of data difficult
- Available trade data that was analyzed comes with inherent challenges / is of limited utility

Gowns: examination of the whole value chain

Raw materials → **Manufacturing** → **Shipping and Distribution**

Raw materials

- Competes with masks and other industrial applications of nonwoven fabric for primary inputs
- Discussions w/ SMEs suggest potential for using alternate materials that have similar characteristics and could mitigate a bottleneck in a surge scenario

Manufacturing

- Manufacturing varies depending on kind of gown (e.g., coveralls, aprons, gowns; method of sealing, etc.)
- Labor intensive
- Geographic concentration in East Asia
- Limited reporting from East Asian manufacturers

Shipping and Distribution

- Export restriction in multiple countries during Covid-19

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Potential next steps

- Given the criticality of PPE, ***it would help to have better and more comprehensive data*** on the global supply chain. Phase I review highlights lack of quality data (consistent, comprehensive, time-series). Commercial market research reports also have these issues.
- Though ***even perfect data has limited value in such a dynamic situation***. COVID-19 drove massive changes in the supply chain. The supply chain today is different from a year ago, and vastly different from 3 years ago. For future resiliency, ability to surge and long-term sustainability are at least as important as steady-state capacity. Example changes:
  - *New market entrants began producing PPE, while major manufacturers surged capacity.*
  - *Some companies (especially in China but globally) 'appeared' during COVID and already disappeared*
  - *Governments imposed export restrictions, disrupting reliance on "global" production capacity*
  - *Disruption in adjacent markets impacted PPE (e.g., limited ocean freight capacity for PPE shipment due to global economic slowdown)*
- With limited data and many dynamics, ***integrating information of many types and putting it in context of supply chain structure*** can help identify and compare leverage points, e.g.:
  - *Where are there key information gaps? Is qualitative information sufficient for decisions to be made?*
  - *Who in industry might have important information that could be obtained via interviews to fill gaps?*
  - *How will system behave over time in different scenarios? What are second-order impacts of actions?*
- This approach can provide a framework to integrate available information, ***prioritize where on the supply chain to focus for each PPE type***, and help narrow the range of uncertainty on where there is the greatest leverage to improve resiliency in scenarios of interest

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Comparison to demand

Gloves: 400Bn made in 2021 vs projection of 2,000 Bn needed

Respiratory protection: Need 600Bn of high protection respirators

Compare to 5Bn of N95 level and a few million PAPRs

Body protection: >8Bn made in 2021 vs projection on 90Bn needed

Topics for discussion

Shortcomings:

- Lack of quality data in public domain
- Geographic concentration of production
- Long lead times associated with capacity stand-up
- Manufacturer sensitivity to price fluctuations / expectation of future demand
- Ongoing changes in supply chain
- Fragility *(transit bottlenecks, just-in-time manufacturing, inadequate stockpiling, etc.)*
- Limited ability to coordinate and efficiently / equitably allocate scarce goods *(e.g. export restrictions, bidding wars, black markets, new market entrants unable to connect to customers, etc.)*
- *Other…*

Opportunities:

- Alternative materials (how to incentivize and gain approvals?)
- Rotating safety / buffer stock
- Surge capacity *(e.g. extra shifts)*
- Pre-arranged surge capacity from adjacent industries *(production lines, shipping, …)*
- Demand guarantees / long-term contracts
- Market infrastructure / mechanism to connect new / surge suppliers with existing large customers
- Regulatory standard coordination
- Accelerating approval processes
- Design for re-use / reusable PPE (PAPR)
- *Other…*

Thank you!

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Sage Analysis Group prepared this document.
It is not a commitment or recommendation.

PPE Production and Distribution Gaps

John Baggett, PhD

PPE Demand Spiked During the COVID-19 Pandemic

Between the years of 2019 and 2020, the demand for PPE spiked significantly, placing strain on every aspect of the supply chain – be it raw materials, manufacturing, or distribution

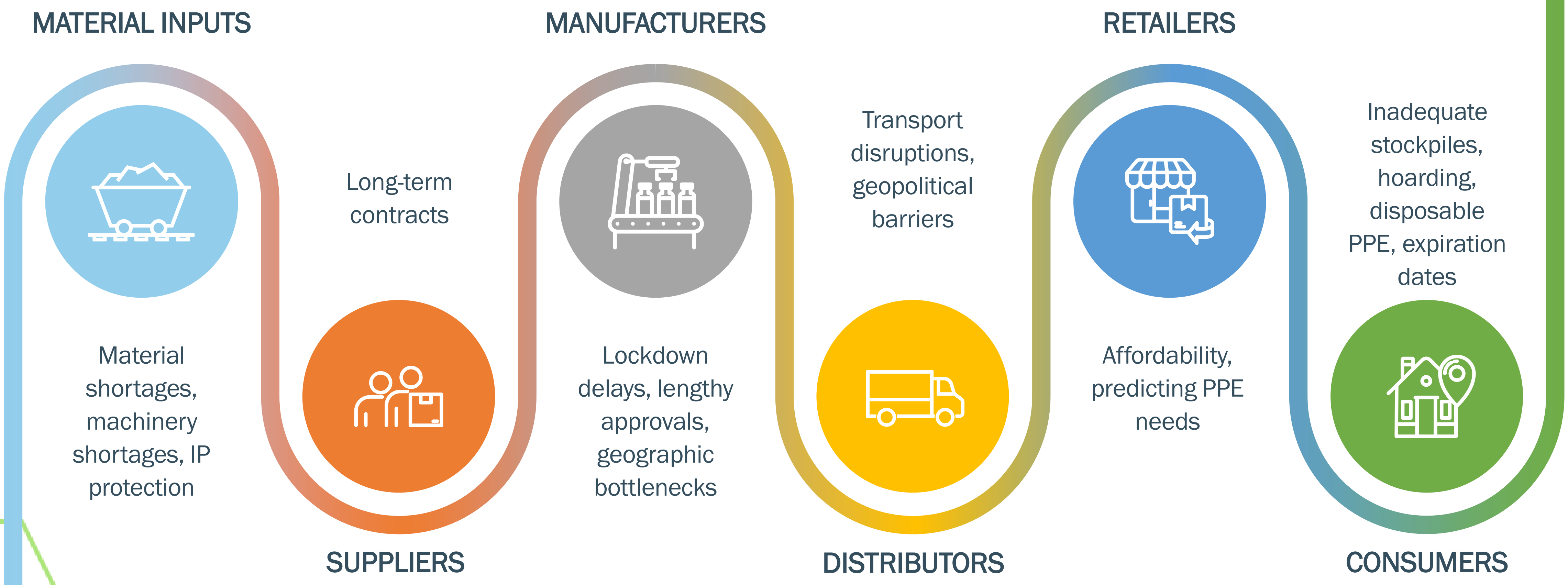
15 Billion
HCW Respirators
300% Demand Increase

159 Billion
Surgical Masks
16,000% Demand Increase

445 Billion
Gloves
318% Demand Increase

5 Billion
Gowns
16% Demand Increase

Gaps in the PPE Supply Chain (SC) during COVID-19



Gaps in Supply Chain Material Inputs

Competition for material inputs limited PPE supply

- Material inputs are highly specialized
- Long-term contracts for raw materials are common

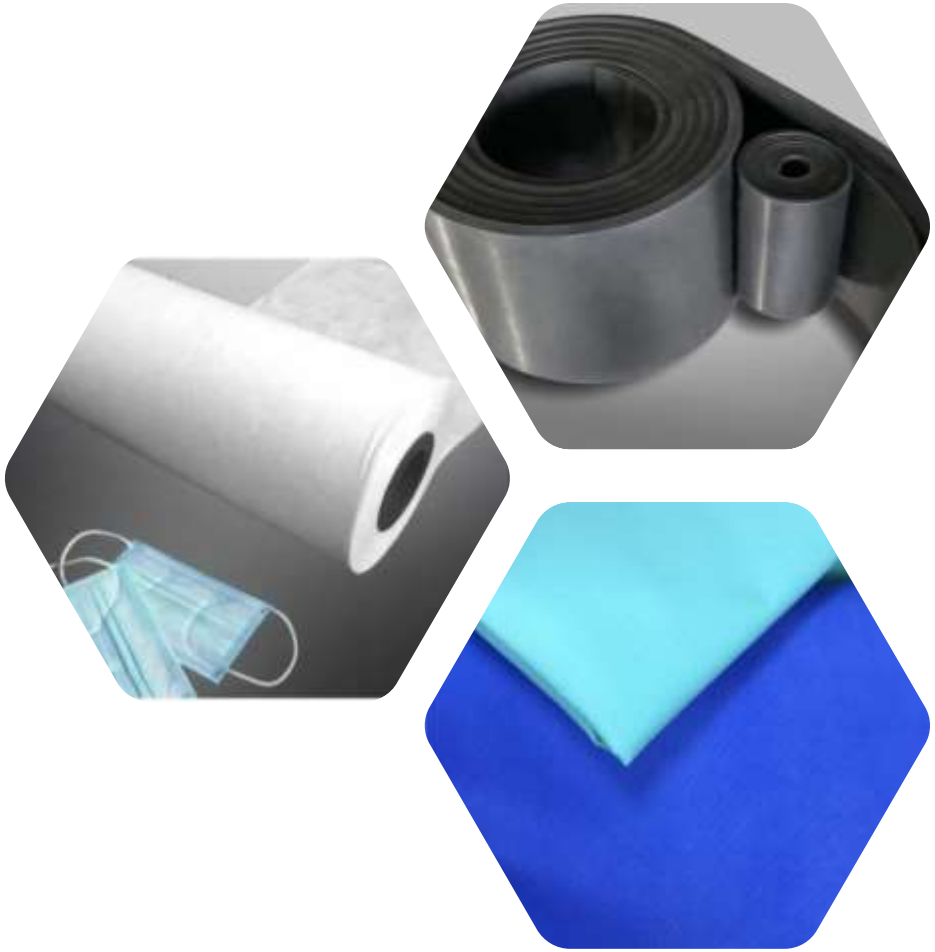
Specialized machinery for producing material inputs was lacking

Intellectual property constraints limited material input production

GRYPHON SCIENTIFIC

Competition for Material Inputs Limited PPE Supply

- Key material inputs:
  - Nitrile butadiene rubber (NBR)
  - Natural latex
  - Meltblown fabric
  - Spunbond + meltblown + spunbond (SMS) fabric
- SMS fabric manufacturers diverted production to focus on meltblown production
- Competition increased prices for SMS fabric **4- to 7-fold** from 2019 to 2020



Specialized Machinery for Producing Material Inputs was Lacking

$

New facilities are expensive to set up

≥ $10 million

Setup is slow

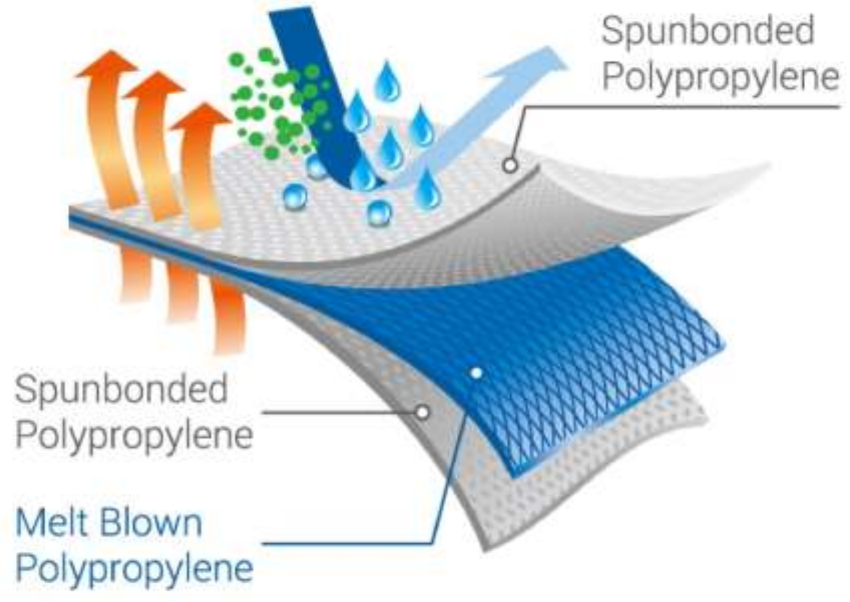
≥ 9 months

- Few companies produce necessary machinery
  - esp. extrusion dies & electrostatic generators for meltblown

- This makes the machinery expensive and slow to obtain

Intellectual Property (IP) Constraints Limited Material Input Production

- Specialized material-bonding patterns for creating SMS are proprietary information
- Hinders the entrance of new manufacturers
- Barrier for low- and middle-income nations (LMICs) due to the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement between World Trade Organization members



Gaps in Supply Chain due to Supplier Issues

Long-term contracts create barriers for new manufacturers to obtain material inputs

*Geopolitical issues impacting trade influenced the ability of raw materials to move between countries**

**Gaps similar to those covered in the Distribution section; discussed there in detail*

GRYPHON SCIENTIFIC

Long-term contracts create barriers for new manufacturers to obtain material inputs

- Long-term contracts ensure sales and provide consistent inputs for manufacturers on the receiving end
- Contracts make pivoting to new production difficult
- Barrier is severe for meltblown fabric because of contracts with other industries:
    - Filtration
    - Absorbent hygiene
    - Apparel
    - Sorbents

Gaps in Supply Chain Manufacturing

Delays from lockdowns and social distancing requirements

Lengthy approval processes for PPE certification

Geographically concentrated production

Specialized equipment

IP constraints for PPE assembly

** Gaps like the issues described for Raw Materials, discussed there in detail*

Delays due to Lockdowns and Social Distancing

- Factory Shutdowns
  - Factories were shut down at the start of the pandemic due to uncertainty
  - Workforce outbreaks shut down factories

- Changes to Manufacturing Practices
  - Social distancing requirements reduced factory production capacity
  - Policies such as China's "zero-COVID" impacted production schedules

Complex Approval Processes for PPE Certification

- Industry standards and the US federal certification process were reported as barriers to entry for new firms wanting to produce N95 masks in a study by the United States International Trade Commission

- In the US, NIOSH approves all FFRs for occupational use while the FDA is charged with approving FFRs designed for use in healthcare settings
  - FDA requires fluid resistance, flammability and biocompatibility for N95 respirators used in healthcare settings (surgical N95s). Prior to 2018 these products were also cleared by FDA.
  - A 2018 MOU between the FDA & NIOSH exempts N95 FFRs designed for use in healthcare from the FDA approval process if they meet agreed upon evaluation criteria and receive NIOSH approval
  - NIOSH approval takes an average of three months (longer for surgical N95s)
  - If a product exceeds the standard threshold, FDA clearance via the 501(k) premarket notification process may be required and takes an additional 90 days if required

Geographically Concentrated PPE production

- China and the US make the majority of every PPE type except gloves
  - Medical masks: 50-60% China, 20-25% US
  - Medical gloves: 65% Malaysia, 20% Thailand
  - Other: ~40% China, ~20% US

- Exacerbated risks to global supply chains from individual state policies

> A combination of widespread supply chain disruptions and a 280% surge in demand in 2020 denied entire populations access to high-quality PPE. In the medium term, production capacity should be established in under-served regions, with support for select players who can achieve the scale required to be commercially viable and compete sustainably in the global market.

- Transforming the Medical PPE Ecosystem, Global Fund 2021

Gaps in Supply Chain Distribution

Pandemic measures caused transport disruptions

Geopolitical issues impacting trade influenced the ability of PPE to move between countries

Transport disruptions for PPE

- Cargo shipping by water was not fast enough to meet demand
  - Shipping from China to U.S. takes ~ 1 month
  - Port delays further extended transit time

- Flights were limited due to travel restrictions
  - 45-50% of air freight is transported in passenger planes
  - Air freight capacity in passenger planes was at 25% of typical in April 2020

- Quarantines and roadblocks slowed ground travel

Geopolitical Issues Impacting Trade Influenced the Ability of PPE to Move Between Countries

Export

During the COVID-19 pandemic, **50+ countries** had some sort of PPE export control, including some top PPE suppliers

Import

Withhold release orders (WRO) issued by US Customs and Border protections halted the import of PPE into the US

Regulation

In response to widespread issues with counterfeiting, China imposed internal regulations on exported masks that affected availability

Gaps in Supply Chain due to Retail Issues

Some LMICs struggled to access and afford PPE

Difficulties predicting PPE needs to place accurate orders

Some LMICs Struggled to Access and Afford PPE

- PPE availability issues were compounded in many countries due to previous political issues
  - Nations experiencing significant armed conflicts (e.g. Libya, Syria, Yemen), political instability (Myanmar), and international isolation (Eritrea, North Korea) experience severe lack of PPE availability

- PPE was unaffordable for some LMICs
  - High demand and low supply priced out some LMICs
  - Some LMICs relied on HICs and philanthropic funds

Fragmented demand led countries with limited resources to be locked out of supply agreements. PPE export restrictions imposed at the start of the pandemic to maintain local access severely constrained the supply [...] Manufacturers prioritized those procurers who were prepared to purchase very large volumes or pay a premium [...] Large PPE manufacturers concentrated in Asia required upfront cash payments and large volumes to secure supply, which made it difficult for many LICs/LMICs to obtain access (beyond arrangements through UN agencies).

- *Transforming the Medical PPE Ecosystem, Global Fund 2021*

Difficulties Predicting PPE Needs to Place Accurate Orders

- Changing guidance on PPE requirements (e.g., mask recommendations)
- Fluctuations in COVID-19 patient numbers
- Some essential workers are not included in demand calculations
  - e.g. cleaning staff and community health workers
- Limited national administrative capacities to forecast demand

Gaps in Supply Chain due to Consumer Issues

National and regional PPE stockpiles were inadequate

Consumer hoarding and panic buying

Disposable PPE is more sensitive to supply chain disruptions

PPE expiration dates create confusion

National and Regional PPE Stockpiles were Inadequate

- HHS found that the U.S. SNS had only about 1% of the masks needed

- The UK's PIPP and a smaller 'no deal' EU exit stockpile containing ~ 2-weeks' worth of supplies needed by the NHS

- Nordic countries such as Sweden, Denmark, and Norway had abandoned their stockpiles prior to COVID-19
    - The EU commissioned a strategic rescEU stockpile of medical equipment such as ventilators and PPE to help EU countries in the context of the COVID-19 pandemic.

Consumer Hoarding and Panic Buying

- Consumer hoarding and panic buying of masks and gloves surged during the COVID-19 pandemic

- Two distinct groups of non-healthcare buyers (*Cohen and Rodgers, 2020*):
  1. Individuals purchasing PPE to profit from reselling at inflated prices
  2. Panicked consumers who were afraid they would not have the PPE needed for them to protect themselves while working

Disposable PPE is More Sensitive to Supply Chain Disruptions

- In the 1980s, the U.S. medical device industry transitioned to a "single-use disposable" manufacturing standard to reduce costs

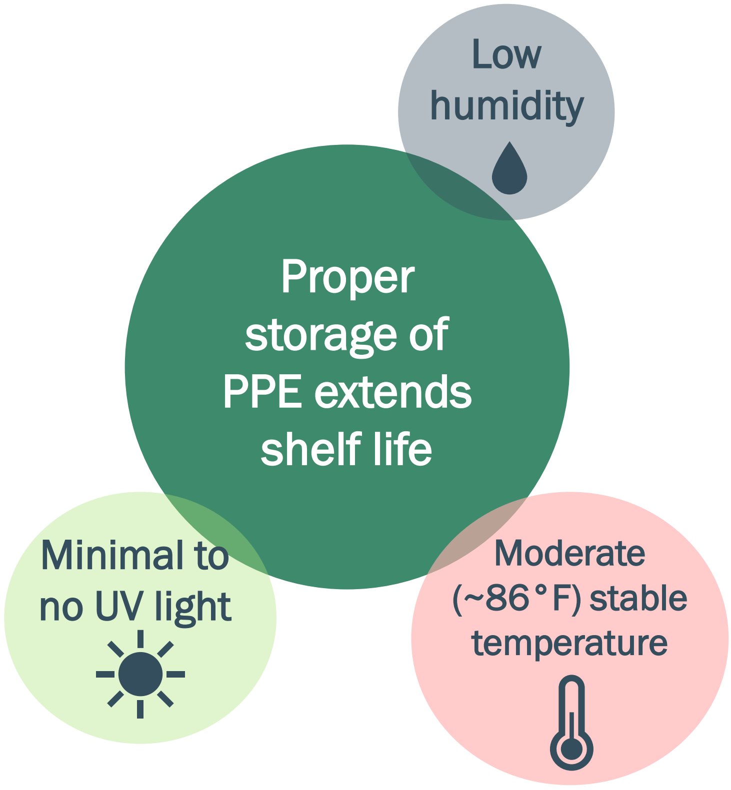
- Reusable PPE can meet demand when supply chains are broken

PPE Expiration Dates Create Confusion

- FFRs and medical gloves are not required to have expiration date labeling in the U.S.

- A generic shelf-life of **5 years** from the date of manufacturing is typically used

- Studies have shown that FFRs and medical gloves can be effective past the 5-year expiration date if proper storage conditions are met



Wrap-Up: Production and Distribution

Discussion

Are there any gaps we did not discuss that are important?

How should the gaps we listed here be prioritized?

Gaps

Material inputs:
- Material/machinery shortages
- IP issues

Suppliers:
- Long-term contracts

Manufacturers:
- Lockdown delays
- Lengthy approvals
- Geographic bottlenecks

Distributors:
- Transport disruptions
- Geopolitical barriers

Retailers:
- Affordability
- Predicting PPE consumption

Consumers:
- Inadequate stockpiles
- Hoarding
- Disposable PPE
- Expiration dates

Additional Gaps

Anna Muldoon, MPH

Gaps in Quality Management

- Recalls Reduced Available Supply of PPE Before and During the COVID-19 Pandemic
- Certifying performance relative to standards and detecting counterfeits during manufacturing, procurement, distribution, and usage
- Sharing certification results among stakeholders to redistribute PPE as needed

Case Studies: Recalls Reduced Available Supply of PPE Before and During COVID-19

In January 2020, 9.1 million gowns (level 3) were recalled by Cardinal Health due to production at an unauthorized production site. Due to this recall the U.S. entered the pandemic with a shortage of gowns.

Multiple recalls in face masks produced in China as well as other countries exasperating the global shortages in masks

- Reasons for recalls in masks during early 2020:
  - **Product malfunctions** where the product is not compliant with required standards
  - **Counterfeits** where the product is a fake version of a legitimate product
  - **Misleading descriptions** where the labeling has unsupported claims of protection

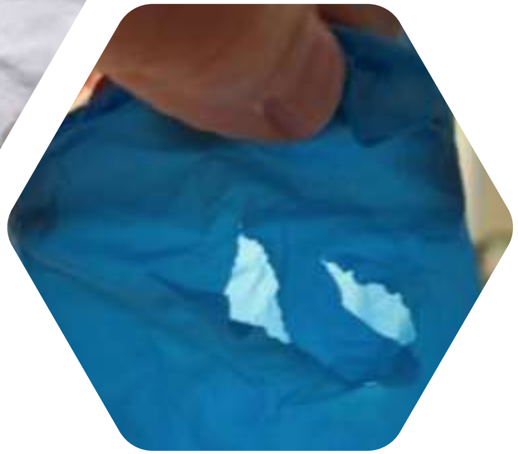
Last month, companies that make or sell masks of dubious quality racked up almost $34 million in sales.

“It’s really the Wild West out there with so many bad actors ripping people off,” said Anne Miller, executive director of Project N95, a nonprofit that connects people to bona fide personal protective equipment.

Counterfeit Covid Masks Are Still Sold Everywhere, Despite Misleading Claims
New York Times, 2021

Certifying Performance and Detecting Counterfeits

- NIOSH: “The COVID-19 global pandemic has unleashed an overwhelming flood of counterfeit respirators into the marketplace”
  - 60% of tests of international respirators performed below N95 standard (Andrews et al., 2020)
- Also need to assess PPE in the field as it degrades (e.g. hospitals, stockpiles)
- NIOSH was overwhelmed with demand for certification during COVID-19; likely true of other national agencies as well



Certifying Performance and Detecting Counterfeits

- Key bottlenecks:
  - Time/resources (staff)
  - Expensive testing equipment (e.g., TSI 8130)
  - Technical expertise for testing and completing paperwork

- As a result:
  - Limited rate of testing, long wait times, high cost ($2,000+ depending on product)
  - Repeated failures for products that are ultimately compliant
  - Manufacturers disincentivized or unable to certify
  - Performance testing is impractical for users and stockpiles

Sharing Certification Results

- PPE providers & regulators need to inform consumers about counterfeits and recalls
  - E.g., NIOSH Counterfeit N95 Challenge

- Consumers need to inform providers & regulators about their inventory and its performance

- Potential need for an IT platform for PPE ecosystem stakeholders to share information about PPE quantity, quality, and location
  - But need to verify accurate data

Gaps in Communication & Training

- Public communication about PPE and combating mis/disinformation
- Tailoring training materials for languages and low literacy/numeracy

Public Communication about PPE

- During COVID-19, the combination of misinformation, disinformation, and polarization reduced adherence to PPE recommendations and sowed confusion
  - By September 2021, mask-wearing reached a high-point of polarization, with 71% of Democrats and 30% of Republicans wearing masks.
  - Inconsistent guidance reduced worker trust in PPE recommendations and effectiveness early in the COVID pandemic.
- Coordinated disinformation campaigns targeted public health interventions, government trust, and polarization in multiple countries.
- The World Health Assembly has cited misinformation as one of the key unaddressed problems of the COVID-19 pandemic.
- Misinformation appears in most outbreaks and pandemics (Zika, ebola, flu, COVID-19, etc) and should be expected in future pandemics.
  - In the scenario envisioned, misinformation must be combatted to build confidence that PPE is working to prevent infection

Public Communication about PPE

- Repeated changes and unclear guidance on public masking during COVID caused lasting mistrust of government communication, particularly in the US (Muller, 2021)

- Clear communication and “defensive pessimism” can preserve public trust in government communication (Wong & Jensen, 2020)

User-tailored Training Materials

- Workplace PPE training materials are inadequate for low-literacy adults
  - 18.9% of adults in OECD countries have low literacy skills; 23.5% have low numeracy skills (OECD, 2019)
  - Safety education for those with low-literacy is a cross-sectoral problem
- PPE and safety information is often available in only majority languages, leading to gaps in training, communication, and compliance among minority-language speakers

Wrap-Up: Additional Gaps

Discussion

Are there any gaps we did not discuss that are important?

How should the gaps we listed here be prioritized?

Gaps

- Recalls reduce available supply of PPE before and during the COVID-19 pandemic
- The world is not meeting demand for PPE certification, testing, and related research
- Information about PPE quantity, quality, and counterfeiting is not being shared efficiently
- Mis- and disinformation that can undermine workers' confidence in PPE must be combatted more effectively
- PPE training materials need adapting for more languages and low literacy/numeracy

Scoring Gaps in PPE

Meg Rush, PhD

Gaps	Gov't Votes	Mfg Votes	NGO Votes
Intellectual property constrains limited material input production		1	
Long-term contracts create barriers for new manufacturers to obtain material inputs			
Delays from lockdowns and social distancing requirements			
Lengthy approval processes for PPE certification			1
Geographic concentration of production	2	2	2
Specialized equipment for production	1		
IP constraints for PPE assembly			
Pandemic measures caused transport disruptions			
Geopolitical issues impacting trade influences the ability of PPE to move between countries			
Some LMICs struggled to access and afford PPE			1
Difficulties predicting PPE needs to place accurate orders			
National and regional PPE stockpiles were inadequate	3	1	7
Consumer hoarding & panic buying strained supply			
Public communication about PPE and combating mis-/dis-information	2		4
Tailoring training materials for languages and low literacy/numeracy			
Providing occupation-specific PPE recommendations for non-medical critical industries	1		
PPE is not designed for the diversity of functional needs		1	
PPE reimbursement structure stifles innovation		2	2
Consumer preferences and affordability	1		1

Gaps	Gov't Votes	Mfg Votes	NGO Votes
Marketing Limitations			
No PPE standard for the public, including children	3		1
PPE with the same purpose has different nomenclature			1
Regulatory standards are different by country for the same PPE			
Respirator fit standards do not capture the facial diversity of all users (AKA fit testing issues)	2	2	4
PPE is not designed for the diversity of shapes of all human bodies			2
PPE is not designed for the diversity of biological requirements of all human bodies			2
Some PPE is not designed for religious & cultural needs			
Some PPE is not designed for hot environments			
FFRs lose fit & performance over time	2		3
PPE may interfere with job duties			1
PPE use is linked to adverse physical reactions			1
Competition for material inputs limited PPE supply			
Specialized machinery for producing material inputs was lacking			
Intellectual property constrains limited material input production			

Next Steps

Rocco Casagrande, PhD

Project Approach Overview

- This is the midpoint of a 1-year, 4-phase project

1.
Characterize PPE gaps that hampered responses to previous pandemics

2.
Parametrically analyze PPE performance and demand against next-generation pandemic threats

3.
Use data from Phase 1 and 2 to describe requirements for effective PPE

4.
Identify opportunities for funding to reach PPE goals set in Phase 3

What are gaps? → What are goals? → How are goals achieved?

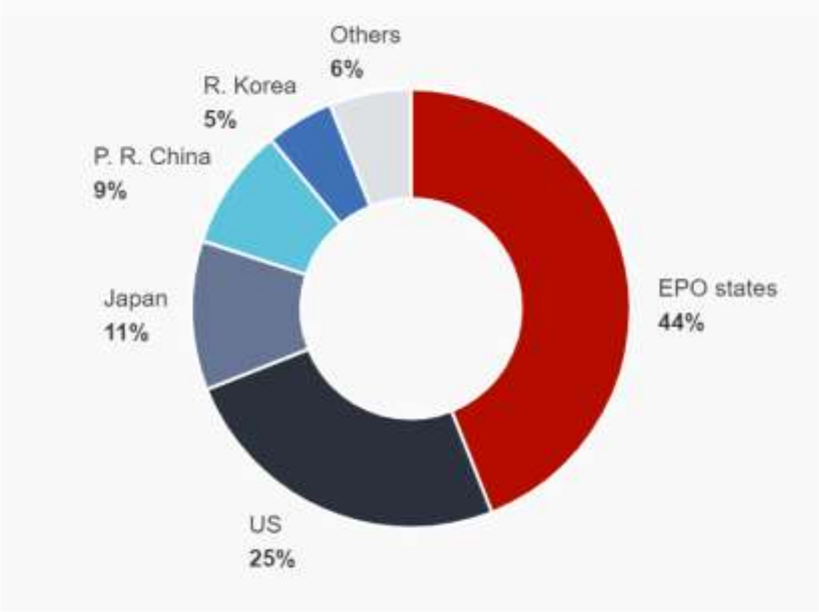
Developing Requirements

- Via analysis of the highest priority gaps, a vision of what Pandemic-Proof PPE should come into focus
- Some of the requirements could be lofty
- Some of the requirements could be conflicting
- Our goal is to set a single set of consistent, achievable requirements to most improve the PPE enterprise

- These steps will require more primary data collection—we may reach out for your help to talk to key stakeholders
- This step will also require more in-depth analysis of the evidence behind some gaps

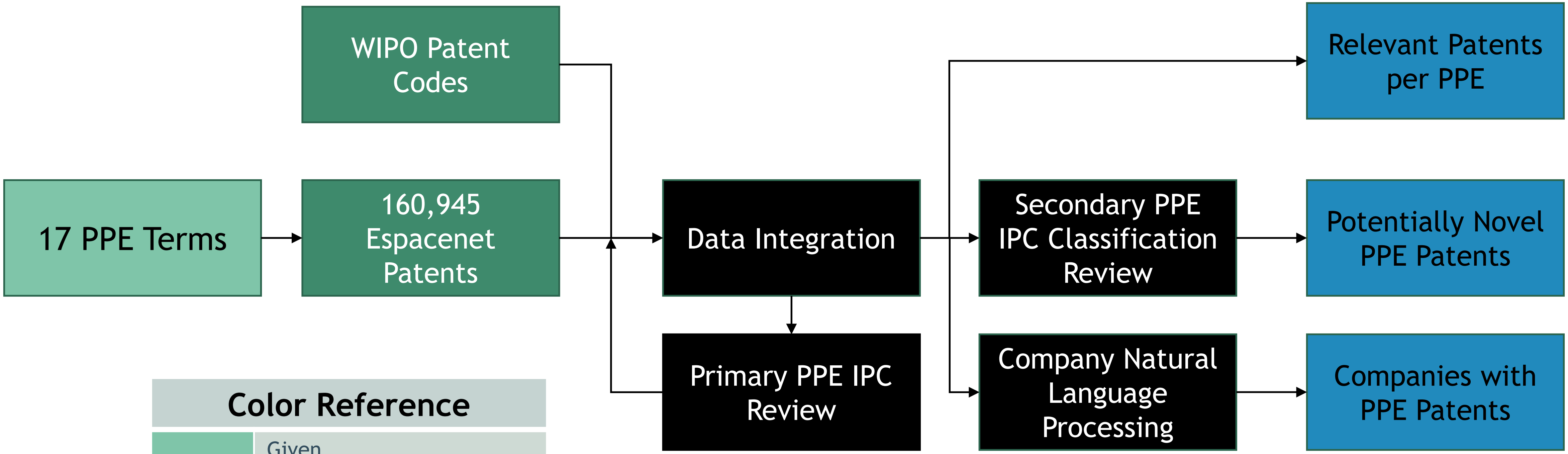
Example Deep Dive: Analysis of Entangling IP

- The European Patent Office (EPO) runs a patent search platform called Espacenet.
  - The EPO receives patents from countries both within and outside geographical Europe
  - In our experience, has the best source for accessing and programmatically manipulate data
  - Provides an interesting, but incomplete, dataset for IP analysis



All Patents by Geographic Origin of Application in EPO

Pilot Project Approach: 2020-2022 PPE Patents



Color Reference	
(light green)	Given
(dark green)	Pulled From Online Source
(black)	Code-Based Work
(blue)	Outputs

Preliminary: Top Patent Holders for 4 PPE Types

Electret Meltblown Masks	Count
Kingfa Science & Technology Co., Ltd	47
3M Innovative Properties Co.	18
Toray Advanced Materials Korea Inc.	14
Beijing University of Chemical Technology	9
Jiangsu Kingfa Science & Technology Advanced Materials Co.	9
Guangdong Jiasiwei New Material Technology Co.	7
Fudan University	5
Nantong University	5
Guangxi Defulai Medical Equipment Co.	5
Anhui Yuanchen Environnemental Protection Polytron Technology	4

Nitrile Gloves	Count
LG Chemical Ltd.	25
Liaoning Hongen Medical Equipment Co., Ltd.	19
Top Glove International SDN BHD	16
Shandong Xingyu Gloves Co., Ltd.	13
Zeon Corp.	13
Midori Anzen Co., Ltd.	12
Ansell Ltd.	11
Zhangjiagang Dayu Rubber Products Co., Ltd.	11
Hebei TitanFine Medical Technology Co., Ltd.	10
Niujian Technology Co., Ltd.	10

Polypropyelene Non-Woven Fabric Masks	Count
Kobayashi Pharmaceutical Co., Ltd.	27
Toray Advanced Materials Korea Inc.	22
Kingfa Science & Technology Co., Ltd	21
Daio Seishi KK	14
Kao Corp.	14
Mitsui Chemical Inc.	10
Unicharm Corp.	10
Shanghai Hulijia Independent Co., Ltd.	9
Inoue MTP KK	8
Dongying Jofo Purification Technology Co., Ltd.	6

SMS Masks	Count
Proctor & Gamble	49
Unicharm Corp.	28
ResMed Inc.	28
Kobayashi Pharmaceutical Co., Ltd.	24
Samsung Electronics Co., Ltd.	23
Kimberly-Clark Corp.	9
Toray Advanced Materials Korea Inc.	9
Shanghai Hulijia Independent Co., Ltd.	8
Kao Corp.	7
Viz AI Inc.	7

Determining how Requirements Should be Reached

- After the requirements are set, we will analyze various means of achieving those requirements, involving:
  - Researching the various solutions proposed to close gaps already recognized
  - Searching through the engineering and scientific literature for advanced PPE
  - Investigating companies forming to address gaps
  - Modeling supply/demand dynamics in the context of epidemiology

Example Option to Close Gaps: UMI

- More than a decade ago, a scheme to increase availability of medical supplies was proposed that leverages the flexibility afforded by long shelf lives: the User Managed Inventory (UMI)
  - Those that hold critical medical supplies are incentivized to increase their stocks and perform stock rotation up to the point where all can be used prior to expiration
- For example, consider a PPE item with a five-year shelf life
  - Normally, a distributor (e.g. Cardinal Health) has a one-month stock of this PPE
  - Healthcare centers each hold a two-week stock of this PPE
  - If distributors and healthcare centers were each incentivized to hold a 1-year stock:
    - None would ever expire
    - Stocks in the system would be increased from 6 weeks to 104 weeks of normal usage
    - Cost is equivalent to necessary incentive plus a ONE-TIME purchase of the increase in stock
      - If stock is increased gradually, also extends demand from manufacturers

Next Steps

- We will produce a written report based on our research and your feedback from today
  - We would love to get feedback on this report from you
- We will perform additional outreach to key stakeholders and innovators
  - We will ask your support to reduce the number of cold-calls
- We will ask you to provide us any information you have on methods you favor to close these key gaps
- We will hold a final workshop (approx. six months from now) to discuss requirements and proposals to meet the requirements
  - We will probably schedule that workshop in the next two months

Thank you!

- Thank you once again for your engagement and candor today
  - Many of you traveled far for this
- Thanks again to Effective Giving for their support on this effort
- Safe travels home

- Please be in touch with any further comments or questions:
  - Rocco@gryphonscientific.com

Additional slides

Notes on Cochrane Study (Jefferson et al., 2023)

Primary finding:

- Medical/surgical masks indistinguishable from nothing in RCTs of resp. illness community spread
- N95/P2 respirators mostly indistinguishable from medical/surgical masks in resp. illness spread in healthcare settings

Limitations noted by authors:

- “The high risk of bias in the trials, variation in outcome measurement, and relatively low adherence with the interventions during the studies hampers drawing firm conclusions.”

Notes on Cochrane Study (Jefferson et al., 2023)

Additional points by MacIntyre et al. (2023):

- Studies varied in expectations of partial vs. full-time usage
- Studies held unrealistic expectations for compliance
- Studies failed to examine source-control effects
- Studies failed to include non-RCT and lab studies showing protective effects of masks

Aligning PPE Standards

- Recommendation: Fund key players to articulate a common set of international baseline standards for PPE performance and a common nomenclature for identifying PPE products

- ANSI or ISO are well-positioned to prototype common standards
  - ANSI/ISO standards are already a basis for national standards
  - Experience developing standards for an international audience
  - Potential for faster action and more international legitimacy than a national government developer

- WHO is well-positioned to convene standards developers, manufacturers, regulators, and procurers
  - WHO could also include PPE standards in its International Health Regulations

"

PPE standards currently vary across regions and create confusion, while testing capacity is often insufficient to ensure standards have been met. Going forward, standards for critical PPE should be harmonized, with a concerted effort to scale-up testing capacity in LMICs and globally.

- Transforming the Medical PPE Ecosystem, Global Fund 2021

Gap: FFRs Lose Fit Over Time

"In conclusion, the donning and extended use (>1 hour use) of N95 respirators led to higher fit failure rates. The reuse and extended use of N95 respirators should be done with caution in high-risk exposure setting[s] such as those involving aerosol-generating procedures.

– *Jung et al., 2021*

PPE is Not Designed for Facial Diversity

- Respirators are judged based on filtration efficiency
- Filtration efficiency relies on a fitted respirator
- Facial anthropometry plays a major role in the fit of respirators

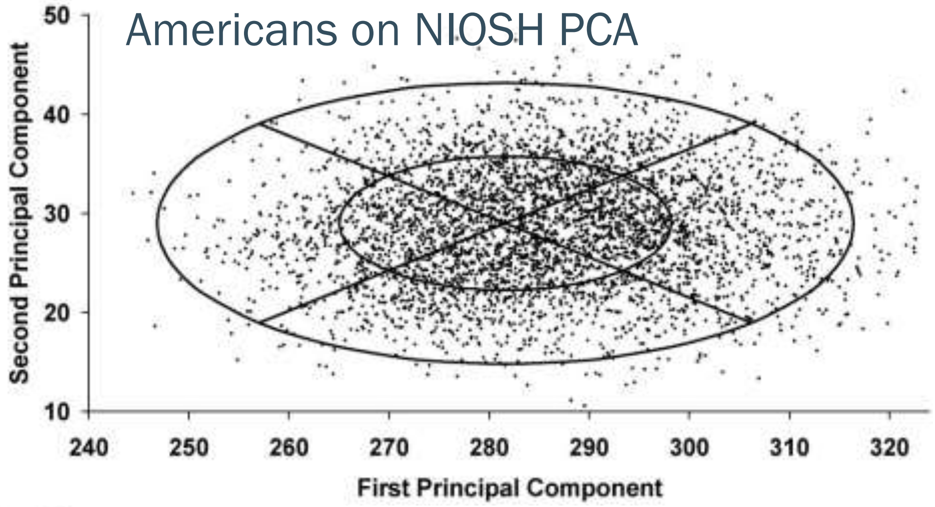
What America did in response

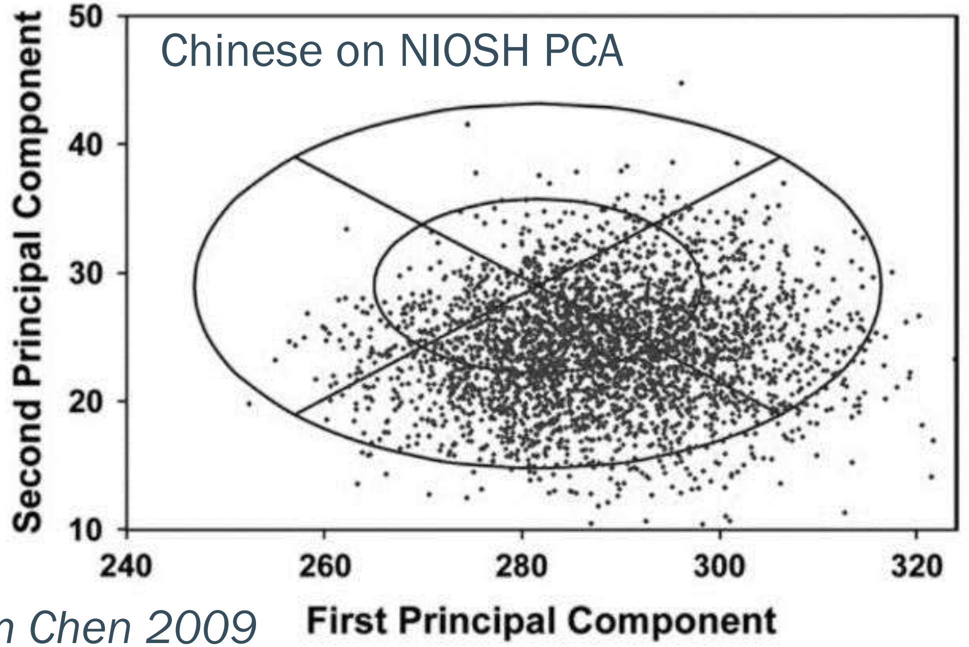
- NIOSH created standards for filtration efficiency
  - Most other countries have similar standards for filtration
- NIOSH created a Panel to test respirators against the face sizes of the US workforce
  - A Bivariate Panel was selected, and proven efficacious with a PCA Panel
  - Few countries have similar testing requirements and anthropometry data on their workforce

Case Study: PPE is Not Designed for Facial Diversity

Where does the NIOSH Panel fail?

- The NIOSH panel contributes to N95 respirator sizes
- The NIOSH panel is NOT representative of global ethnic breakdowns
  - ~75% of the US workforce is white
- The Chinese illustrate this in 2008 by fitting their population to the NIOSH Panel
  - These demonstrated the differences in ‘average’ Facial Anthropometry between ethnic groups



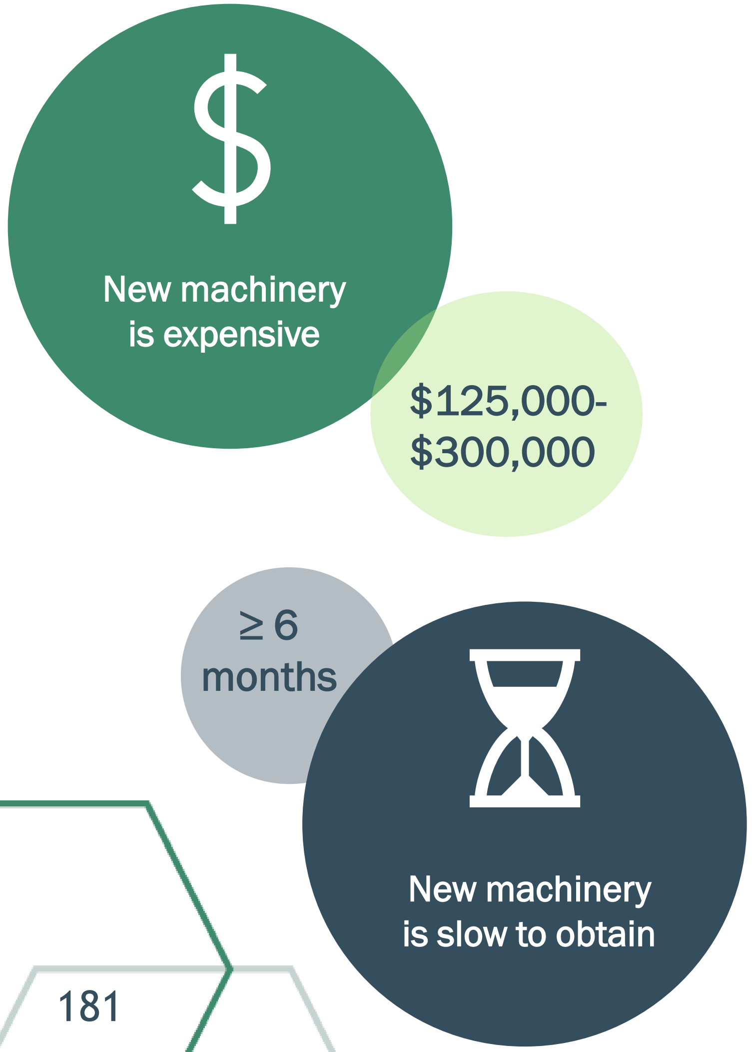


Figures from Chen 2009

In 2020, during the COVID-19 pandemic, the U.S. respirator supply chain demonstrated an inelasticity in relation to a limited surge production capacity for respirators and other PPE types, such as gowns. Further, international manufacturers often serve as primary suppliers of PPE for the U.S. market. Obtaining needed PPE in 2020, especially respirators, proved to be difficult due to limited exports of raw materials and NIOSH-approved respirators produced outside of the United States.

- Draft NIOSH Healthcare Personal Protective Technology (PPT) Targets for 2020 to 2030

Manufacturing PPE Requires Specialized Equipment



Equipment from other sectors was not able to quickly transition to PPE manufacturing

- Roller spacing is particular to manufacturing process
- Electrostatic properties are required in FFR manufacturing

The creation of new manufacturing facilities/lines is limited by:

- Machinery is expensive to purchase
- Machinery takes a long time to obtain
- Technical expertise is required to set up and run the equipment

IP constraints in PPE assembly

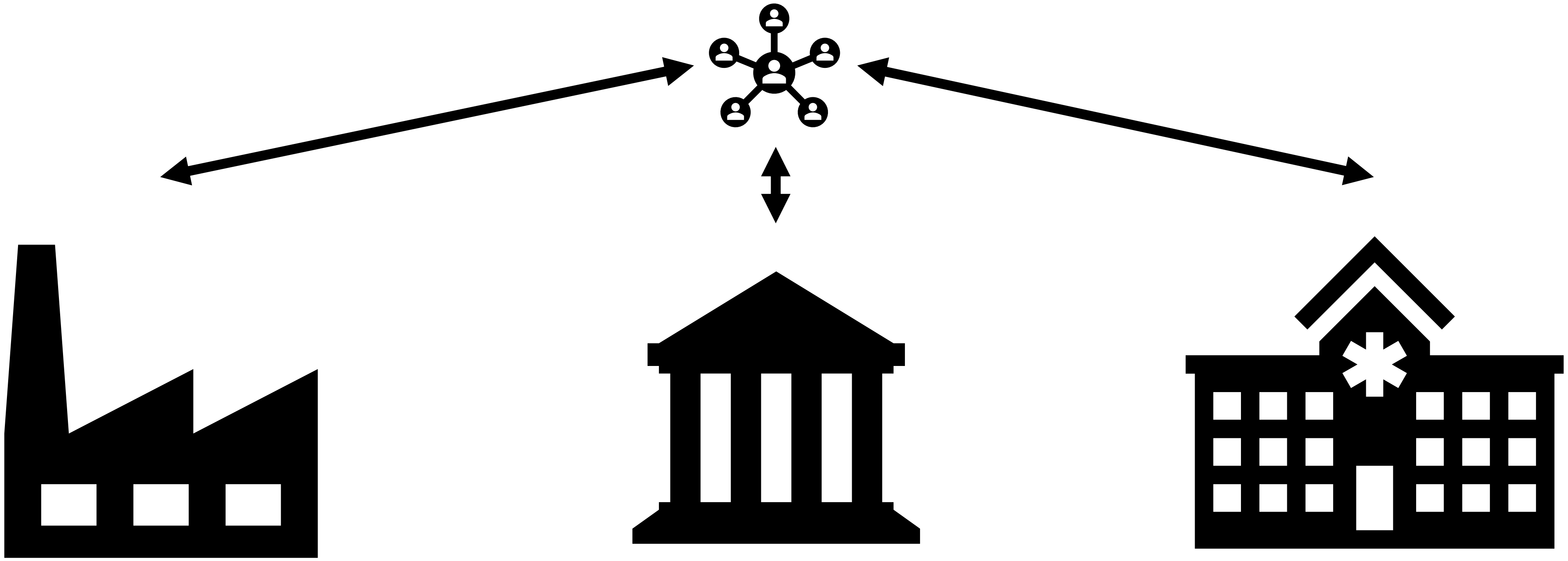
- The optimal processes to produce N95 respirators may also be covered by IP rights.
- This would require new entrants to create their own design that can meet the required filtration levels (or acquire a license from the IP rights owner).
- Bonding patterns used in thermoforming and die-cutting is very important as the wrong settings could affect the uniform porosity.
- Patented bonding patterns are also available to license out (contains temperature, pressures and line speed settings.

Special Considerations for Domestic Manufacturing of PPE

- Current facilities (do they exist or not)
- Technical Expertise
    - Barrier to entry due to understanding manufacturing process and standards
    - Ambiguity in government contracting requirements
- Labor Costs
    - Domestic labor is more expensive
    - Resulting in increased costs for end users
        - Gown made in Asia: $4-7
        - Gown made in U.S. $17-20
- Concern that demand would not last past the pandemic

PPE Quality Control Challenges

Stakeholders share credible PPE quality information to coordinate production, distribution, and use



PPE producers verify quality at point of manufacturing

PPE regulators detect counterfeits and check compliance with standards

PPE users verify quality as it is used and degrades