Towards a Theory of Pandemic-Proof PPE

Final Meeting

29 November 2023

GRYPHON SCIENTIFIC

Welcome

Background, Purpose, & Requirements

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

Project Approach Overview

This is the last quarter 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?

Purpose of Today's Workshop

- Today, we will present some solutions to close critical gaps in achieving Pandemic Proof PPE
  - We present an Analysis of Alternatives to make a recommendation
- The solutions were drawn from several sources:
  - They were elaborated in the literature
  - They became apparent from our analysis
  - They were suggested by stakeholders in our structured discussions
    - These solutions were reviewed in an industry workshop to ensure that they are actually:
      - Feasible
      - Sustainable
      - Compatible with industry business models
- Today, we'd like the feedback of a broader audience (governments, NGOs)

Workshop Rules

- Pictures of PPE in the presentation are for illustration only, and not an endorsement
- Introduce yourself when speaking
  - We are very happy at the level of engagement in this workshop, but we have too many people for a round-robin introduction
  - To signal you want to speak during discussion stand up your table card on end.
    - I'll call on you in order
  - When you start to talk, say your name, the entity you represent
  - For example….
- This workshop is non-attributional
  - No one should attribute anything said in this workshop to a person or the entity that person is representing
  - We will use information shared in this workshop to inform our findings, and may quote from this workshop, but not attribute it to you
    - "Workshop participants said…." instead of "BestCo Rep Jane Smith said…"

What PPE Do We Need?

Problem Statement

In this study, we modeled a scenario where a virus emerges that is:

- As infectious and hardy as measles,
- Spreads as rapidly as SARS-CoV-2, and
- Harms vital workers similarly to the 1918 influenza pandemic.

A virus like this has evolved, luckily it infects cattle and not people, but it does share a common ancestor with measles virus—a historical near miss for a worst-case scenario

How can we pandemic-proof the PPE enterprise to defend against a threat like this?

Modeling Scenarios

Scenario 1, Model A

Two people occupying a room facing away from each other (or a physical barrier is between them), as in a shared office space. This scenario excludes spray and the particle cloud produced by speaking and the infected person is exposed to virus particles suspended in the air. Both people enter the room at the same time, for example, at the start of a work shift. The infected person is unmasked.

Scenario 2, Model A

An uninfected person visiting a room in which an infected person has been present for a long period. This scenario simulates a worker temporarily visiting an infected individual as part of their job duties.

Scenario 3, Model A

An unmasked infected person speaking to an uninfected person and they are not separated by a physical barrier. This scenario focuses on virus particles inhaled by the uninfected person inside the cloud immediately in front of the infected person who is speaking. This scenario can simulate the hazard encountered when working indoors or outdoors.

Scenario 3, Model B

An unmasked infected person speaking to an uninfected person. This scenario focuses on the potential for infection from the spray produced by an infected person landing in the eyes, nose, mouth or fingertips of the uninfected person. This scenario can simulate the hazard encountered when working indoors or outdoors.

The protection needed by a worker is defined by the hazard and the environment in which the hazard is encountered

Model Results for Respiratory PPE

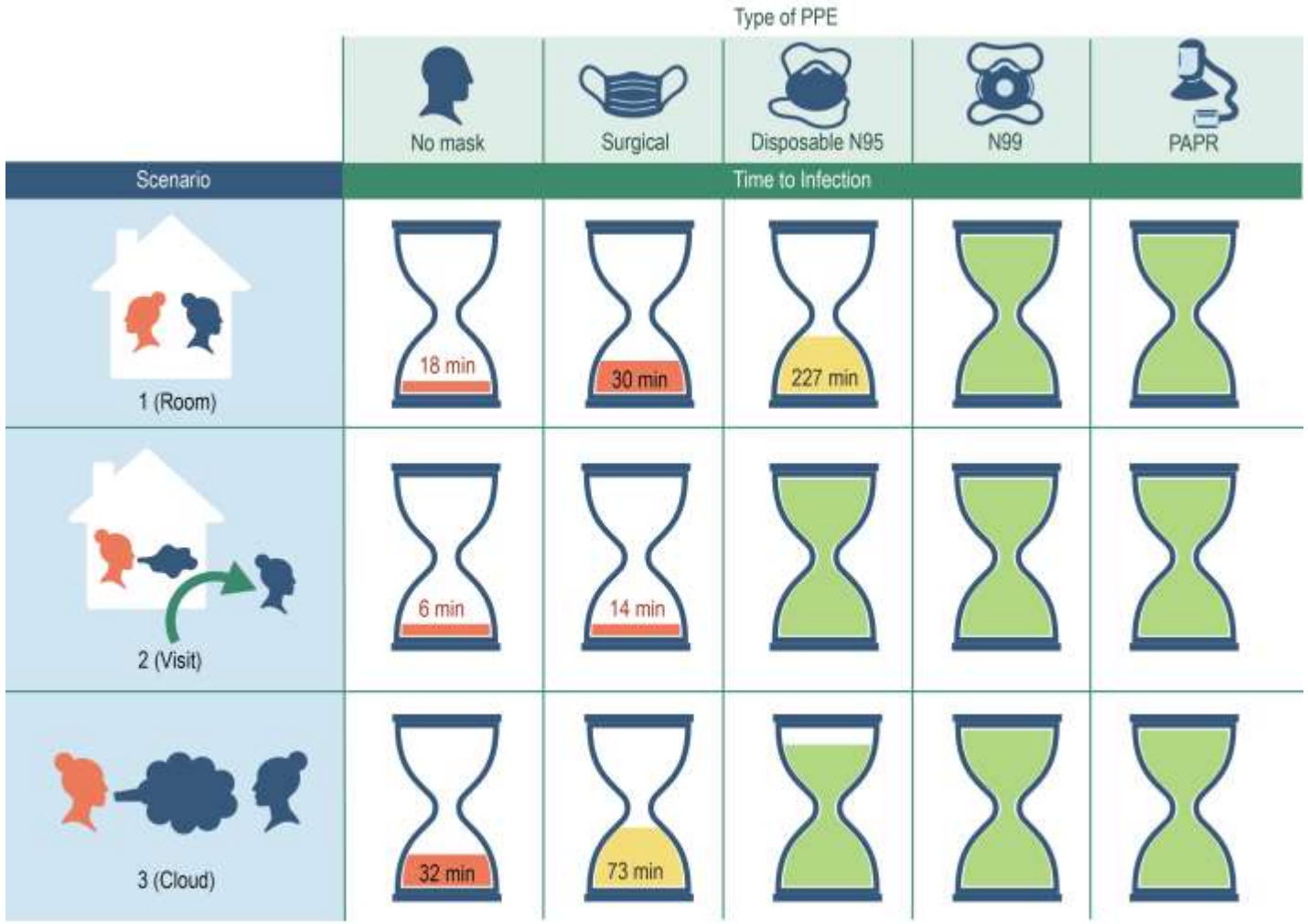


Figure inspired by similar figure in Brosseau, L et al, 2021

Our model assumes an encounter with an individual who drives the force of the pandemic

We assume that they are encountered while speaking, and in the stage of their disease course where they are shedding the most virus

We assume that this exposure lasts only one workday

Difference in protection shown between N95 and N99s in this figure are due to leakage around the respirator, not penetration through the filter

Model Results for Barrier PPE

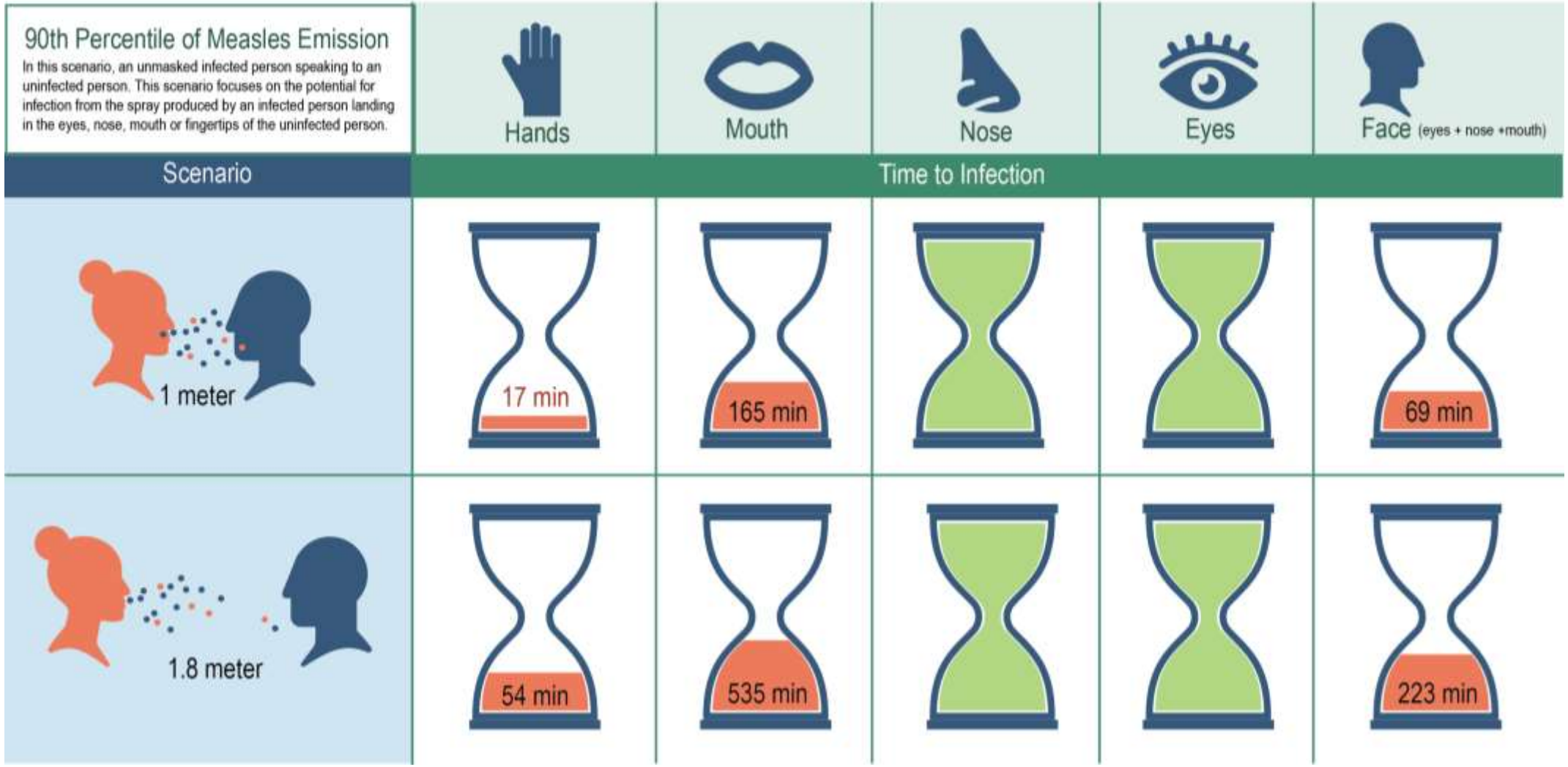


Figure inspired by similar figure in Brosseau, L et al, 2021

Target Product Profiles

Respiratory Protection

	Characteristic	Description
Design Features	5.1.1. Fit	Fit not required, or if fit is required: • Must achieve fit and fit be apparent. • Must not lose fit over time (and fit be apparent if lost).
	5.1.2. Human Factors Design	Use human factors design for size and comfort including accommodating: • Facial hair • Cultural headwear • Assistive devices • Head shapes
	5.1.3. Communication	Enable easy communication.
	5.1.4. Adverse Reactions	Reduce/Eliminate adverse reactions with prolonged use.

Respiratory Protection

	Characteristic	Description
Material Performance	5.1.5. Inward Penetration	Sufficiently low inward penetration of 0.5-1µm particles • For workers indoors: <2% • For workers outdoors or alone: <6%
	5.1.6. Disinfection	Able to withstand repeated disinfection (non-disposable elements) or sufficiently cheap and plentiful to allow disposal.
Use Desirability	5.1.7. Comfort/Adverse Reactions	Must be comfortable to wear for an entire shift, without replacement or removal; if not comfortable for an entire shift, must allow for doffing and re-donning without damage.
	5.1.8. Adverse Environments	Must continue to protect and work in adverse environments.
	5.1.9. Easy Donning and Doffing	Simple donning and doffing that requires minimal training and minimizes opportunities for cross contamination.
	5.1.10. Fluid Penetration	Prevents fluid penetration for those with direct contact with potentially infected people.

Barrier Protection

	Characteristic	Description
Design Features	5.2.1. Adverse Environments	Must not cause thermal discomfort.
	5.2.2. Human Factors Design	Use human factors design for size and comfort including accommodating: • Facial hair • Braided hair • Cultural headwear • Various body types, including presence of breasts • Access to the body for the biological needs of all workers
	5.2.3. Interference with Occupational Duties	No/minimal interference with occupational duties.
	5.2.4. Adverse Reactions	Reduce/eliminate adverse reactions with prolonged use.
Material Performance	5.2.5. Disinfection	Able to withstand repeated disinfection or be sufficiently cheap and plentiful to allow disposal
Use Desirability	5.2.6. Comfort	Must be comfortable to wear for an entire shift without replacement or removal; if not comfortable for an entire shift, must allow for doffing and re-donning without damage.
	5.2.7. Easy Donning and Doffing	Simple donning and doffing that requires minimal training and minimizes opportunities for cross contamination.

A few recurring themes

- In the last pandemic, we required that our workforce adapt to the PPE on hand
  - Mismatches between faces/bodies and PPE
  - Inflexibility to meet cultural, ethnic and functional needs
  - Uncomfortable and often unsuited to the demands of the working environment
- Because we have time before the next pandemic, we should strive to have our PPE system be adapted to the needs of the workforce
  - PPE should meet the physical and operational needs of a diverse workforce

- To be effective, a wearer of respiratory PPE must be able to:
  - Obtain a good fit
  - Maintain a good fit throughout their workday
  - Ascertain if a good fit has been achieved and when it has been lost

    OR
  - Have access to respiratory PPE that does not require a fit

Foreshadowing

- There are no shortcomings with face shields that need addressing
- The only shortcomings with gloves is insufficient supply and geographic concentration of production
- Body covering PPE must be redesigned to fit the needs of female workers
- Respiratory PPE should involve a mix of elastomeric and PAPRs (to suit workers who cannot easily wear a tight-fitting respirator)
  - Although disposable N95s offer sufficient protection for many vital workers, elastomerics are:
    - More cost effective when you consider the entire lifecycle cost
    - Offer greater levels of protection
    - Are easier to obtain and maintain a fit
    - Are considered more desirable by workers in head-to-head comparison studies
- Further innovation could lead to the development of body covering PPE that is better suited to extreme environments and respirators that are MORE comfortable and have superior fit characteristics

How much PPE do we need?

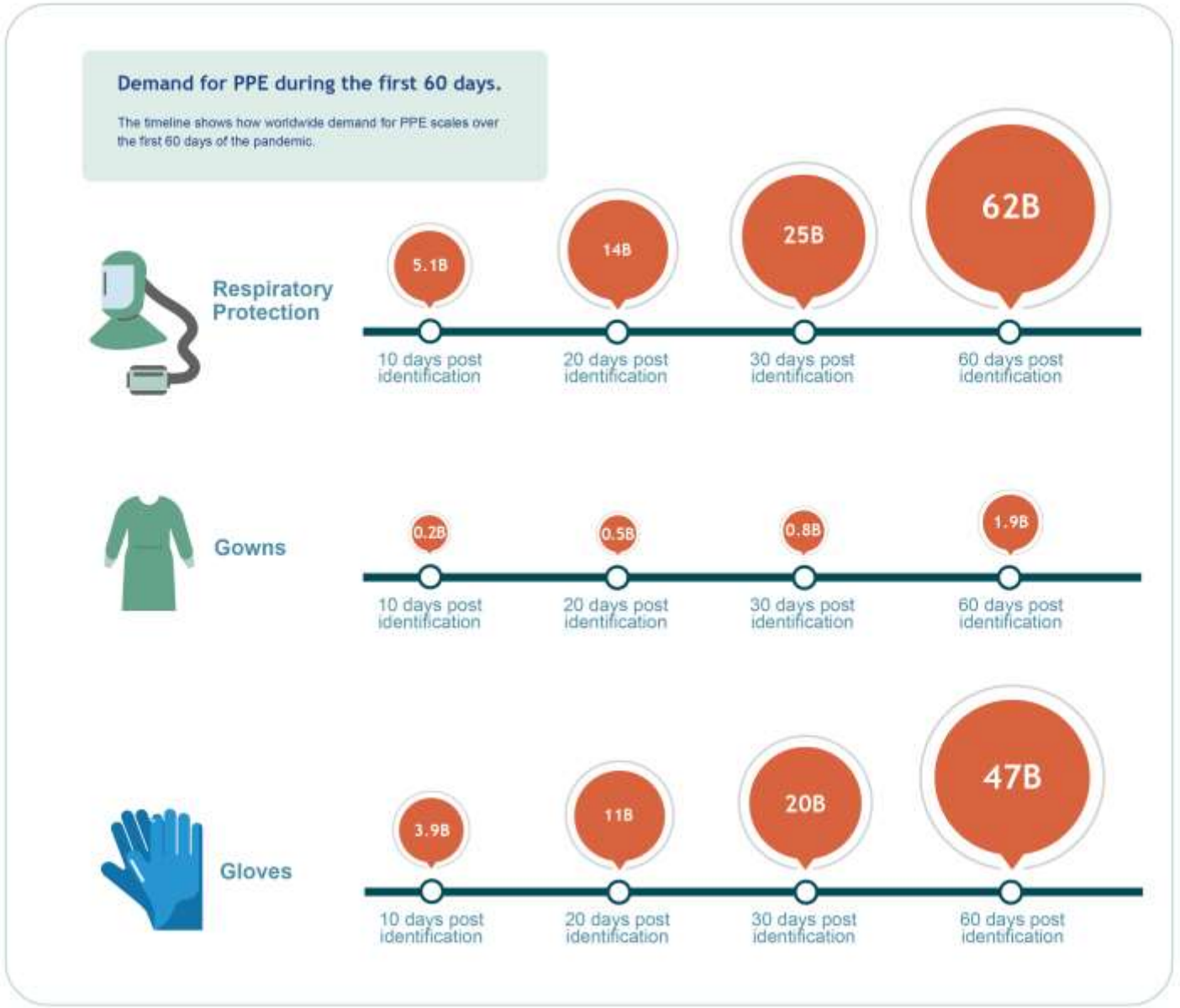
The PPE supply gap we see

Maximum Daily Vital Workers

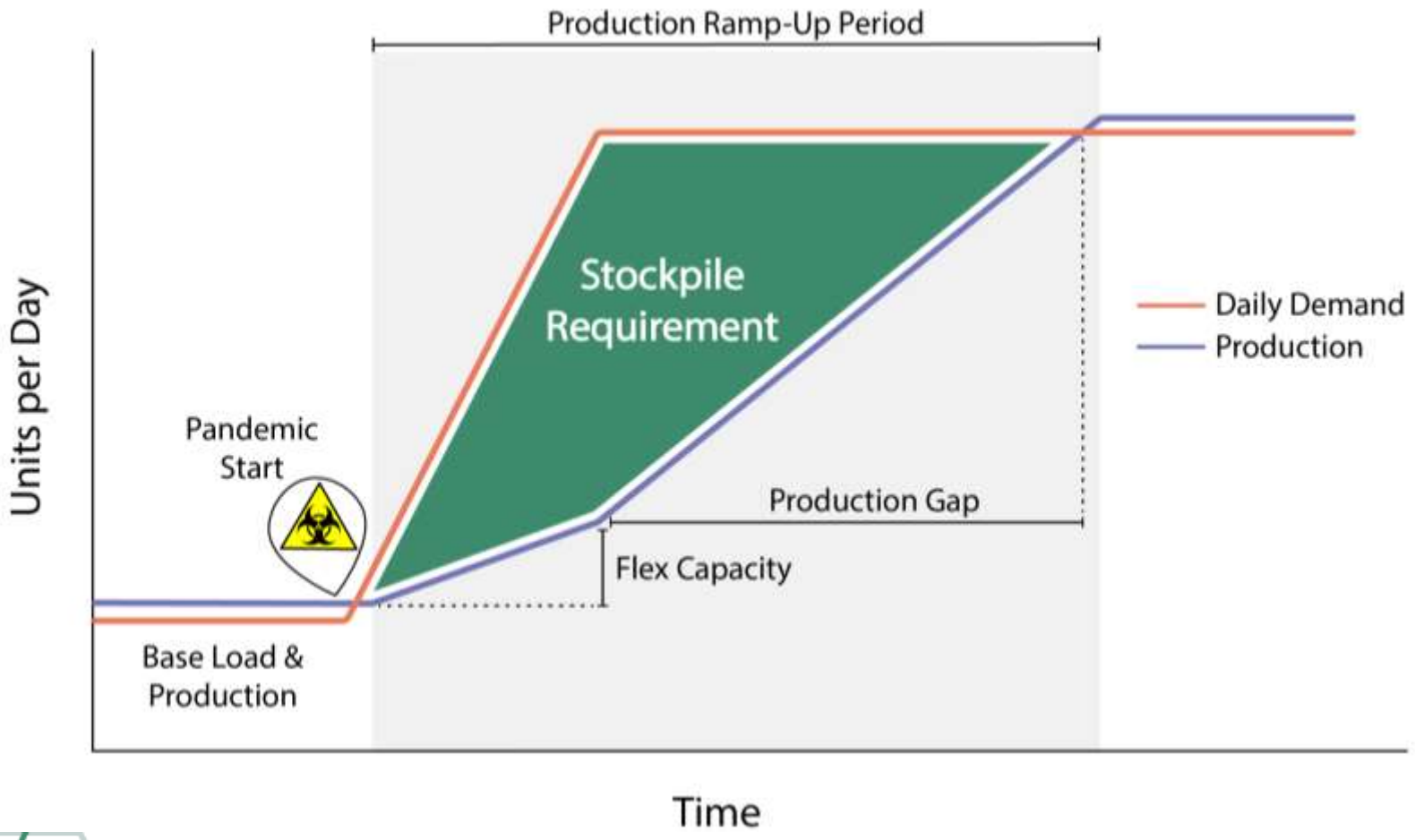
Country	Responders	Indoor Accompanied	Others
USA	4.7 million	40 million	2.4 million
EU	4.8 million	53 million	6.2 million
India	3.3 million	120 million	100 million
All Others	26 million	650 million	360 million
Global	**39 million**	**860 million**	**470 million**

- This figure illustrates the number of vital works that will need daily protection for a Pandemic
- These vital workers include most workers necessary for the continued function of society
  - Less numerous than “essential” workers as defined in the last pandemic
- These numbers indicate peak daily demand, and do not represent the full scale of a stockpile

Rapid PPE Demand Growth



Illustrating the Production Gap



We tried to re-think each part of this figure to see where changes in the PPE enterprise could improve preparedness

Questions?

Ensuring Sufficient Supply

Part 1

Presented by: Dr. Rocco Casagrande

Production & Ramp Up

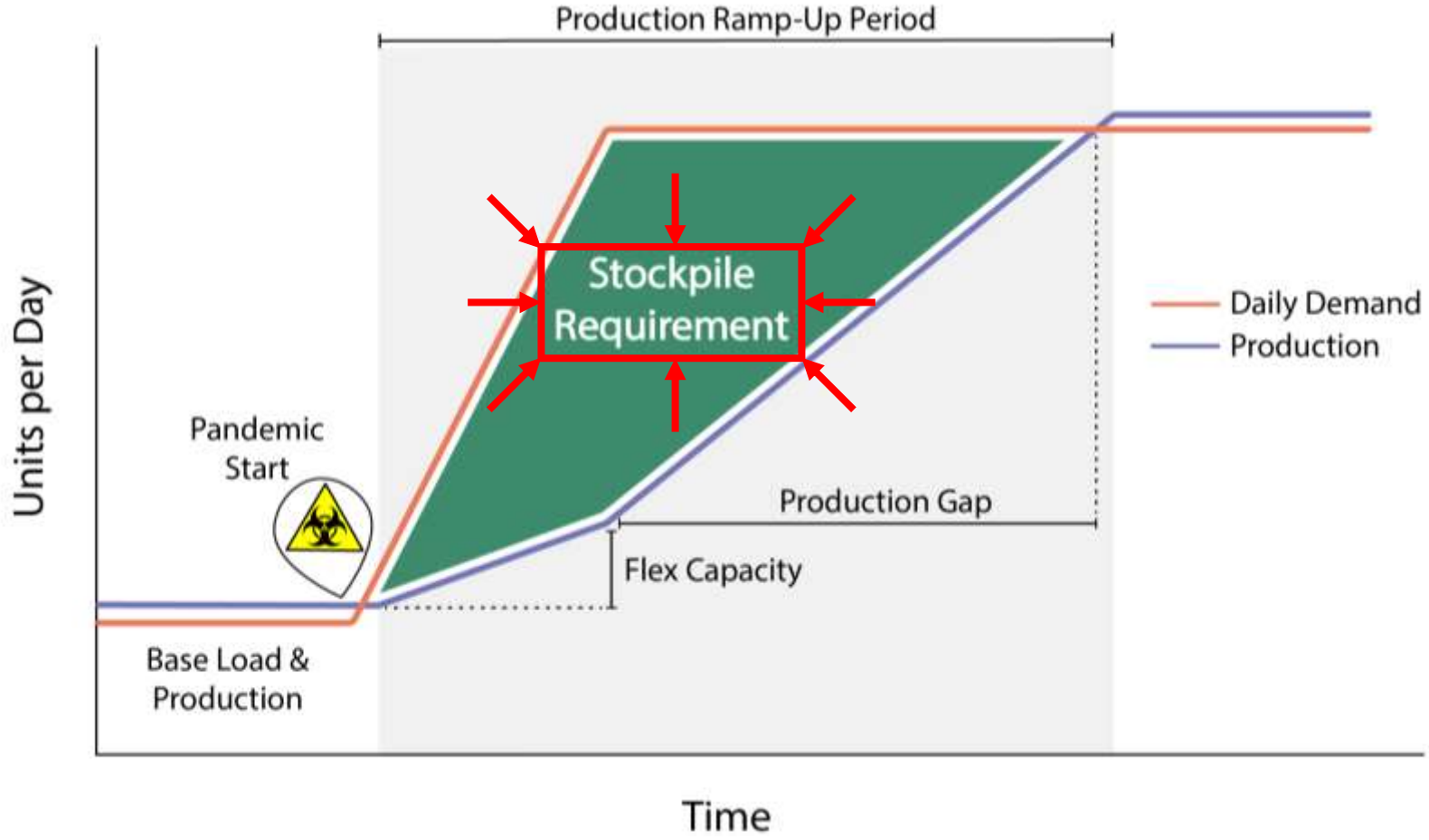
Reducing the production gap

Minimizing the Stockpile Requirement

Country	Disposable Respirators		Elastomeric Units
USA	8.8 billion	Or	58 million
EU	12 billion		81 million
India	41 billion		280 million
All Others	190 billion		1.3 billion
Global	**260 billion**		**1.7 billion**

This table considers the PPE needed just for the 5-month period before production can scale up
It includes a 25% factor for loss/damage of elastomerics during this period

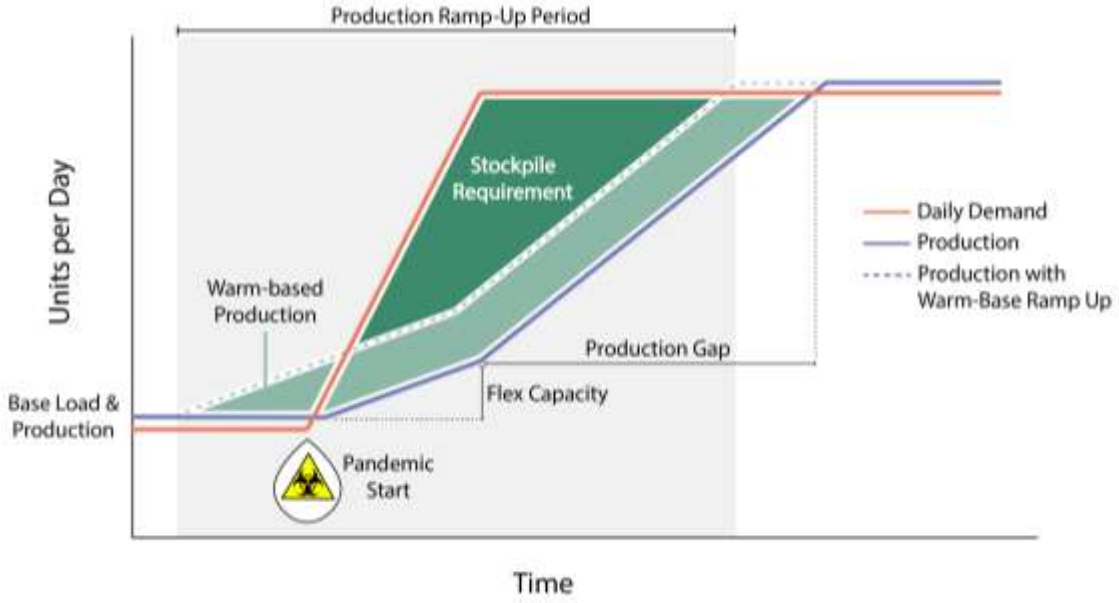
Minimizing the Stockpile Requirement



Early Detection & Production

- Concept: Governments and public health entities closely track potential outbreaks and could notify industry of concerning situations

- Early detection would allow companies to:
  - Spin up production
  - Begin hiring and training staff
  - Purchase raw materials before crisis demand begins
- At least one company we spoke with already tracks emerging outbreaks and begins to surge production



- Risk of overproduction, over-hiring and wasted
- inventory if the crisis fails to materialize
  - Governments could commit to purchase unsold inventory
  - Governments could pay industry a “readiness fee”
  - Government provide tax breaks to compensate for unemployment costs or allow labor flexibility in countries with restrictive labor markets

Early Detection & Production Costs

- If a Government detects a virus of pandemic potential before it spreads, how much would it cost to preemptively purchase a two-month supply of PPE for Responders?
- Modeled for USA Responders (HCW and military only)
  - Only purchase cost considered (no storage or distribution costs)
  - For a 2 month supply, some examples

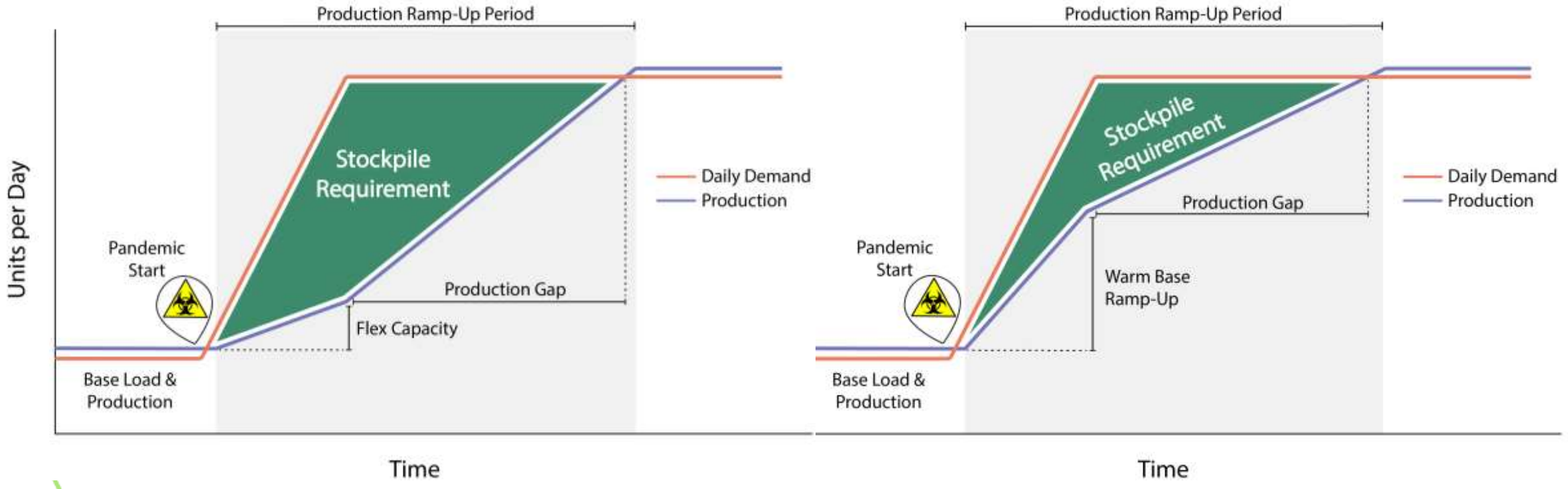
PPE Produced	Low Bound Cost	High Bound Cost
Disposable N95s	$89 Million	$530 Million
Gowns + Gloves	$400 Million	$2.3 Billion

We assume a potential pandemic pathogen is detected every 5 years- incurring these costs.

If only 1 in 4 of these pathogens becomes a pandemic, $1.5 to $8.4 Billion would be wasted on false alarms

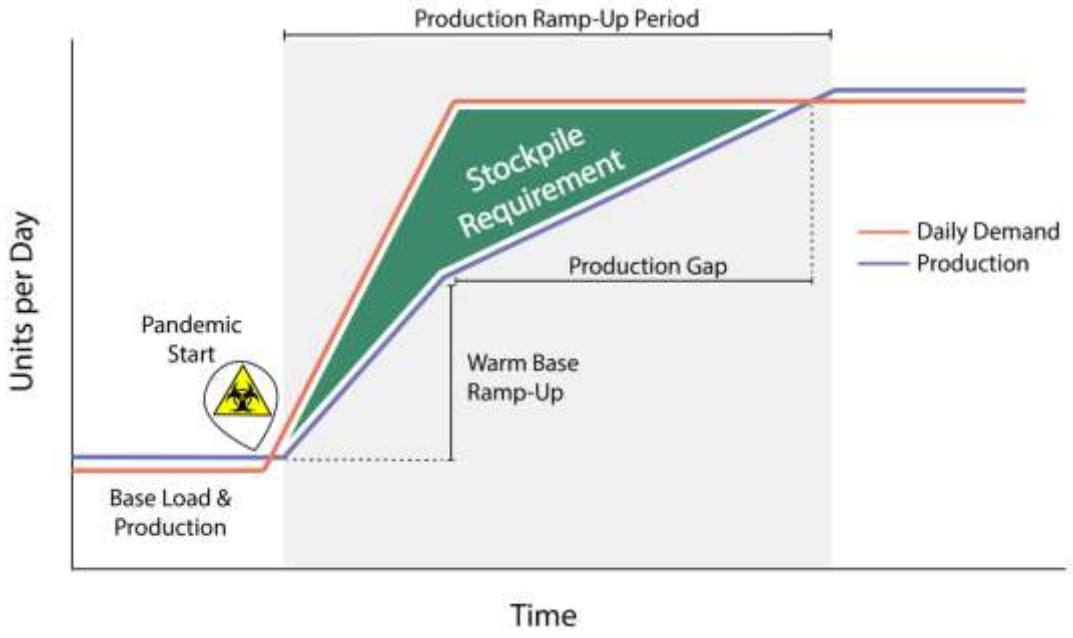
Though this production could be put to good use in foreign aid or stockpiling

Warm-basing


Production Ramp-Up Period
Stockpile Requirement
Daily Demand
Production
Pandemic Start
Production Gap
Flex Capacity
Base Load & Production
Units per Day
Time
Production Ramp-Up Period
Stockpile Requirement
Production Gap
Daily Demand
Production
Pandemic Start
Warm Base Ramp-Up
Base Load & Production
Time

Warm-basing

- Government pays for standby production capacity that can be activated in an emergency
  - Frequently used by the Defense Logistics Agency
- Best for larger companies that can quickly activate large amounts of additional capacity
  - Especially by switching the types of products made
- Must consider costs of raw materials, machinery, storage space, maintenance, and labor



Warm-basing: Options

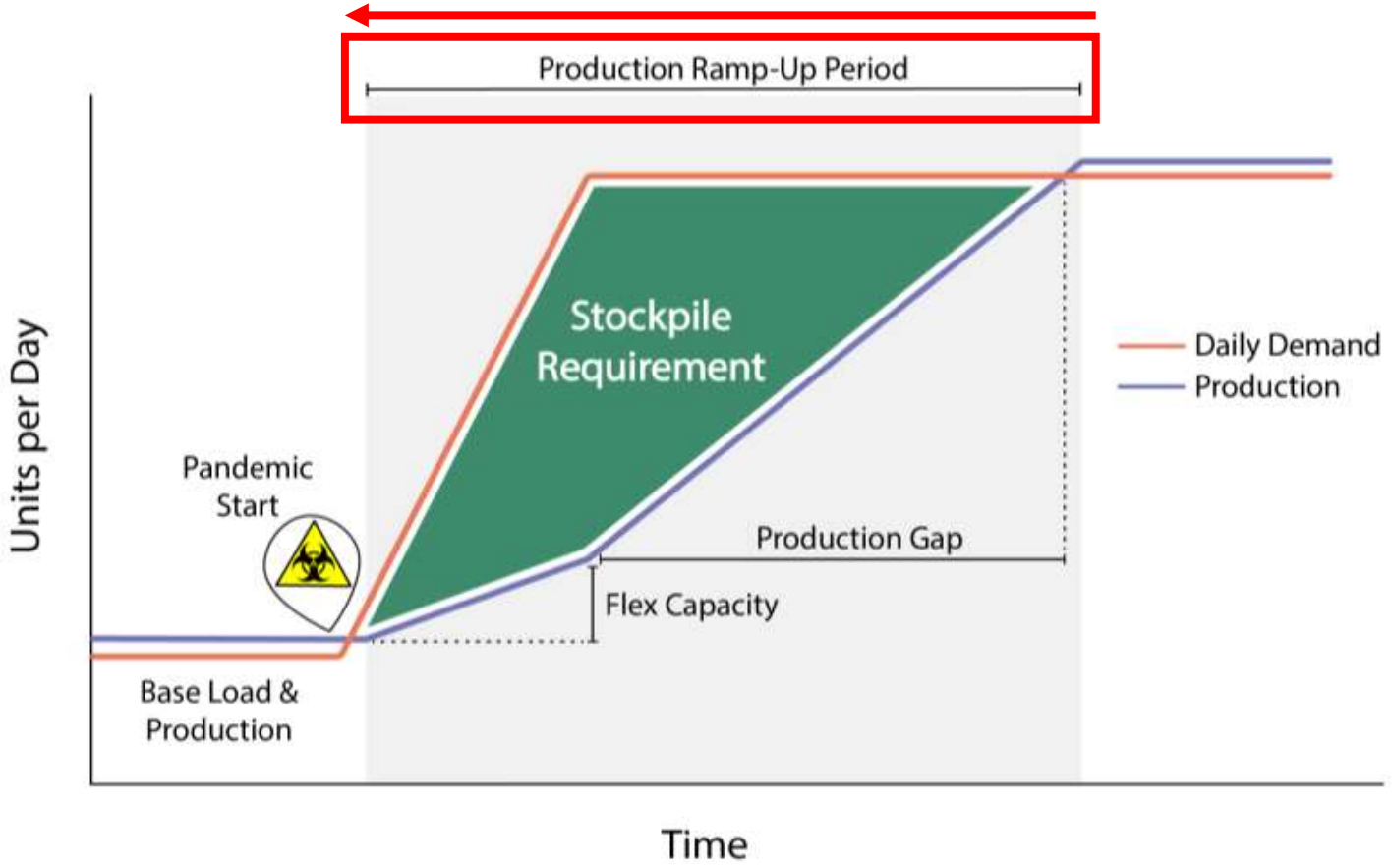
- Subsidize equipment loans if manufacturers agree to run fewer shifts and conserve labor surge capacity
- Buy additional manufacturing lines and mothball them for a fee
- Pay manufacturers to store extra buffers of precursor materials
- Plans to shift workers and equipment from the production of less necessary items to pandemic-ready PPE

Scaling Staffing

Employing enough skilled and trained labor

Scaling Staffing: Background

- Several companies noted difficulty increasing the number of shifts or staffing additional lines due to a lack of trained and available workers



Scaling Staffing: Background

- To ramp up production, both skilled and unskilled labor is required.
  - Several companies operating during the pandemic noted difficulty increasing the number of shifts or staffing additional lines due to a lack of trained and available workers
- The faster labor and machinery is available, the shorter the production ramp up period
- Some companies freed up skilled labor by utilizing volunteers to provide unskilled labor such as packing or sorting.

Technical School Model

- The German automotive industry creates partnerships with community colleges or vocational schools to create “Technical Schools”
- Industry creates training programs and provide access to relevant equipment in the technical schools
- The net effect is increasing the availability of skilled labor and widening industry familiarity/accessibility
  - Also improves job opportunities

National Guard Model

- Government funds training of individuals at regular intervals with contracts to hire for those skills in emergency scenarios.
  - This could easily be applied across the PPE manufacturing sector
- Targets for a PPE National Guard Model would be adjacent manufacturing industries
  - This would address labor shortages in time of surge production or surge capacity
- Funding, Training, and Work agreements would be required to maintain this program

Break

Ensuring Sufficient Supply

Part 2

Presented by: Dr. Rocco Casagrande

Immediate Supply and Stockpiling

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Immediate Supply Topics

1. Scope & Overview of the Supply Methodologies

2. The Inventory Management Systems
   - Vendor Managed Inventories
   - Distributor Managed Inventories
   - User Managed Inventories
   - Governmental Stockpiles

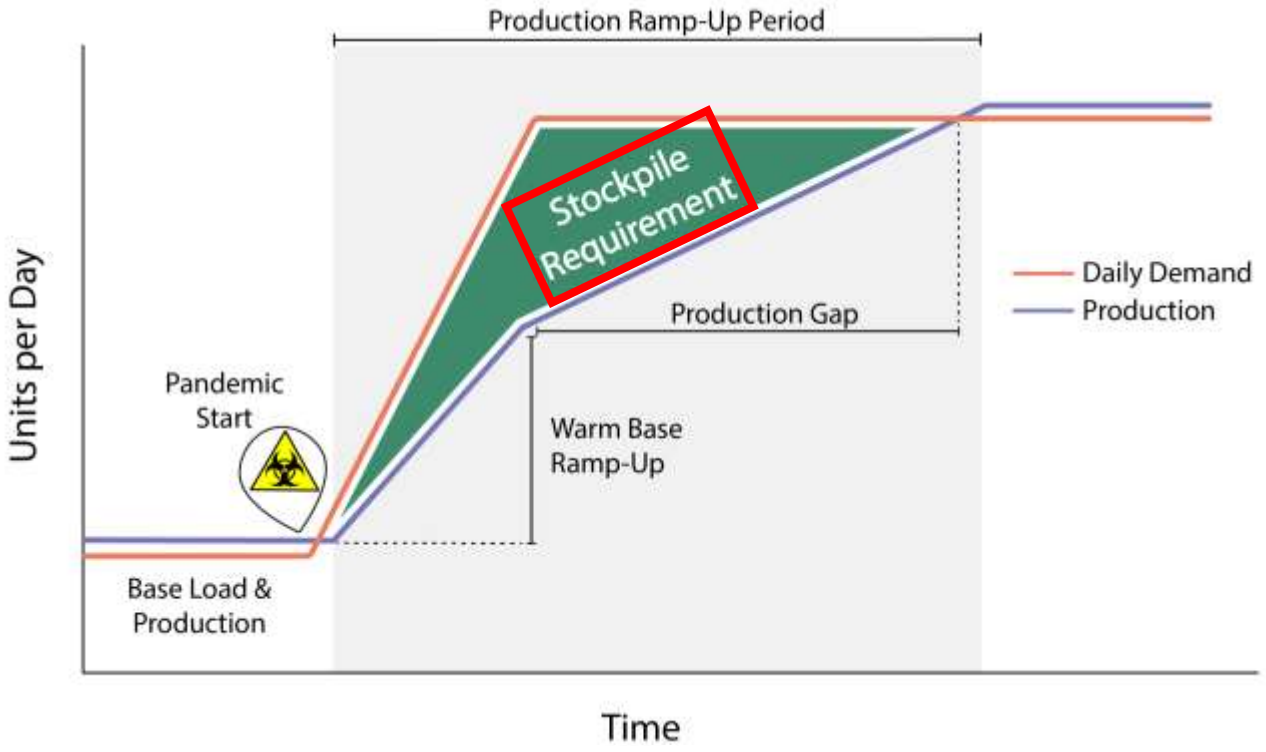
3. System of Systems

4. The Recommended Stockpile

Supply Methodologies Scope & Overview

Period of Immediate Supply

- During the production ramp-up period, demand will exceed supply
- This will occur regardless of any production ramp up capabilities
- Stockpiling methodologies provide an immediate injection of PPE to vital workers until production catches up



Shortcomings of “stockpiling”

- Traditional stockpiles experienced significant failures during COVID-19
  - Expired or damaged inventory
  - Inadequate stocking to address early crisis
  - Distribution debates and conflicts

- Traditional stockpiles suffer from expiry waste in the decades between pandemics

- Methods to supply PPE and ensure back-up stock can be more varied than traditional government stockpiling
  - ‘Stockpiles’ are just intended to provide the immediate supply boost to buy time until production can catch up. Other mechanisms can serve the same function.

Immediate Supply Methods

- Methods to spread PPE supply stocks across supplier and user types require several elements:
  - Purchase of original stock (respirators, gloves, gowns) in a quantity no more than would be sold/shipped/used before the materials in the stock expire
  - Regular rotation to avoid expiration of existing stocks
  - A fee to maintain the inventory

- The four types differ primarily in who holds the PPE stock, but require similar infrastructure
  - Vendor Managed Inventories
  - Distributor Managed Inventories
  - User Inventories
  - Government inventories that rotate stocks through foreign aid

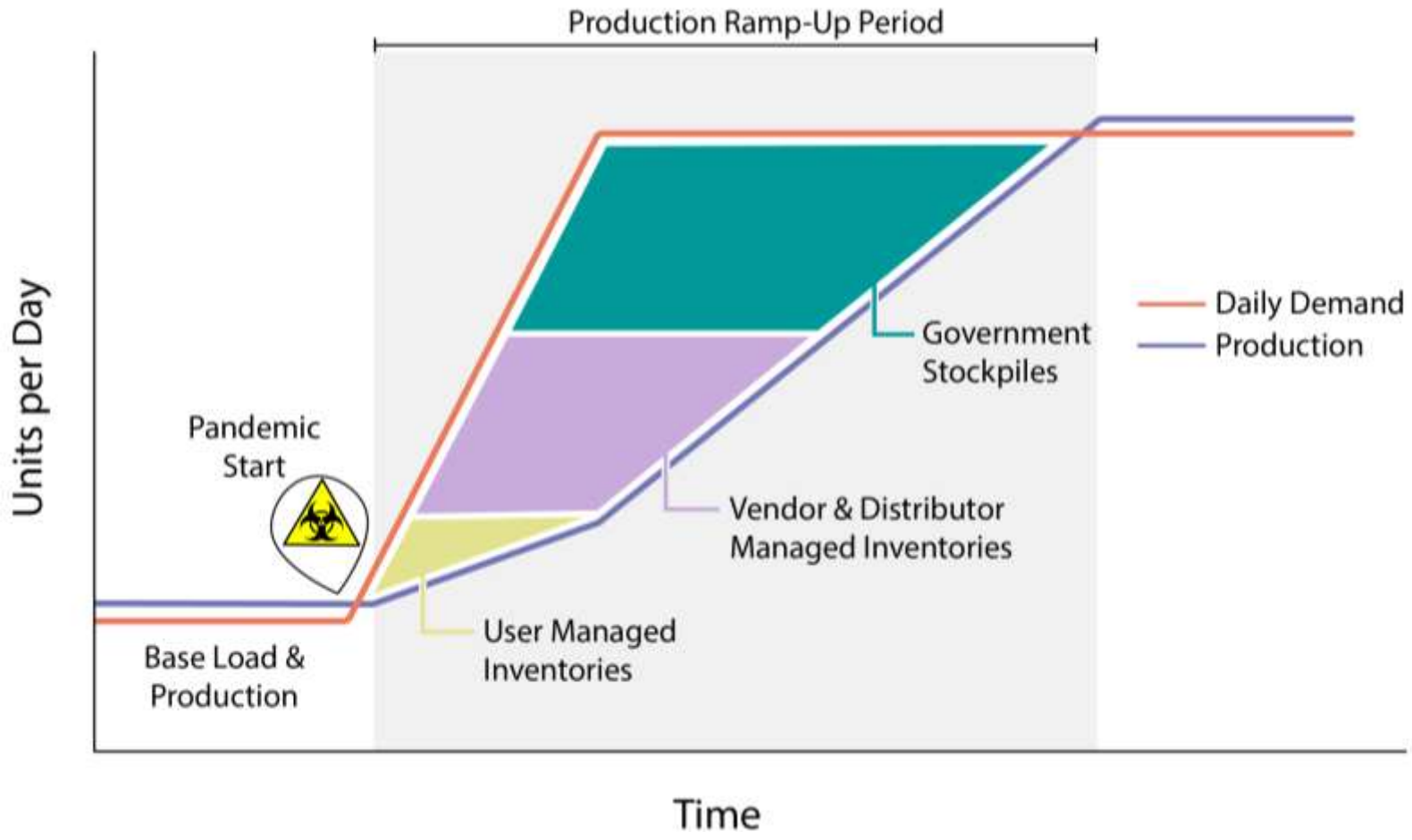
What is an acceptable fee?

Unit	High Bound Fee	Low Bound Fee
Disposable N95	39.37%	6.56%
Elastomeric Unit	1.66%	0.37%
Elastomeric Filter	2.78%	0.28%
PAPR Units	0.57%	0.06%
PAPR Filters	110.73%	110.73%
PAPR Hoods	2.50%	2.50%
Gloves	33.01%	4.79%
Disposable Gowns	2.40%	0.64%

- Management Fees are meant to cover the cost of storing and managing PPE
  - This helps cover warehousing space, equipment costs, labor, etc.
  - Storage fee can be represented as a percentage of the products value
- The overhead costs to manage goods can be calculated as storage costs divided by unit price
  - The table shows an example of this ratio as determined by our model's warehousing costs
- Generally, a higher value density indicates a lower management fee
- Currently, there is limited opportunity for reusables to enter a managed inventory
  - Their high value density suggests that a managed inventory of reusables could be VERY cost effective

Inventory Management Methodologies

A System of Systems



Vendor Managed Inventories (VMIs)

- Vendors (e.g., manufacturers) have the infrastructure, capacity, and expertise to manufacture and store PPE
- As an added benefit, waste could be reduced through stock rotation to avoid expiration of products
  - However, VMIs would likely be limited by the rate of PPE sales
- Payments or incentives could cover overhead costs associated with building and maintaining VMIs to make them feasible for vendors
- The government would purchase the supply bubble and receive it in times of emergency
- Currently, a VMI of reusable PPE would be challenging because holding materials back reduces it's useful lifetime for customers

Distributor Managed Inventories (DMIs)

- Distributors hold the logistics capacity and warehouse space necessary for large scale inventory management while understanding the consumption rates of their clientele
- Mixed product inventories could be stockpiled and efficiently distributed to vital workers
- As with VMIs, waste could be reduced by rotating through inventory
- Distributors would be well positioned to supply existing customers, though they may face difficulties supplying and releasing stocks to new stakeholders
  - The government would purchase the supply bubble and receive it in an emergency

User Managed Inventories (UMIs)

- Users are those who use the PPE day-to-day, such as healthcare facilities and emergency responders
- Having these users stockpile goods ensures that vital goods are already in the right place when a pandemic emerges
  - Resilient to transportation shocks
- Users that consume significant quantities of PPE, such as large hospitals, should stockpile necessary PPE
  - Rate of usage is a limiting factor for stockpiling, so it may not be feasible for smaller users
- Management fees for UMIs would allow users to build and maintain PPE inventories

UMI Options

Government healthcare facilities and hospitals gradually build up a 90-day supply of PPE for all locations and rotate stock

Emergency response agencies fund 90-day PPE UMI stockpiles, with rotation at fire stations and EMS bases

Government funds 90-day PPE UMI stockpiles with rotation at private healthcare facilities

Government Stockpiles

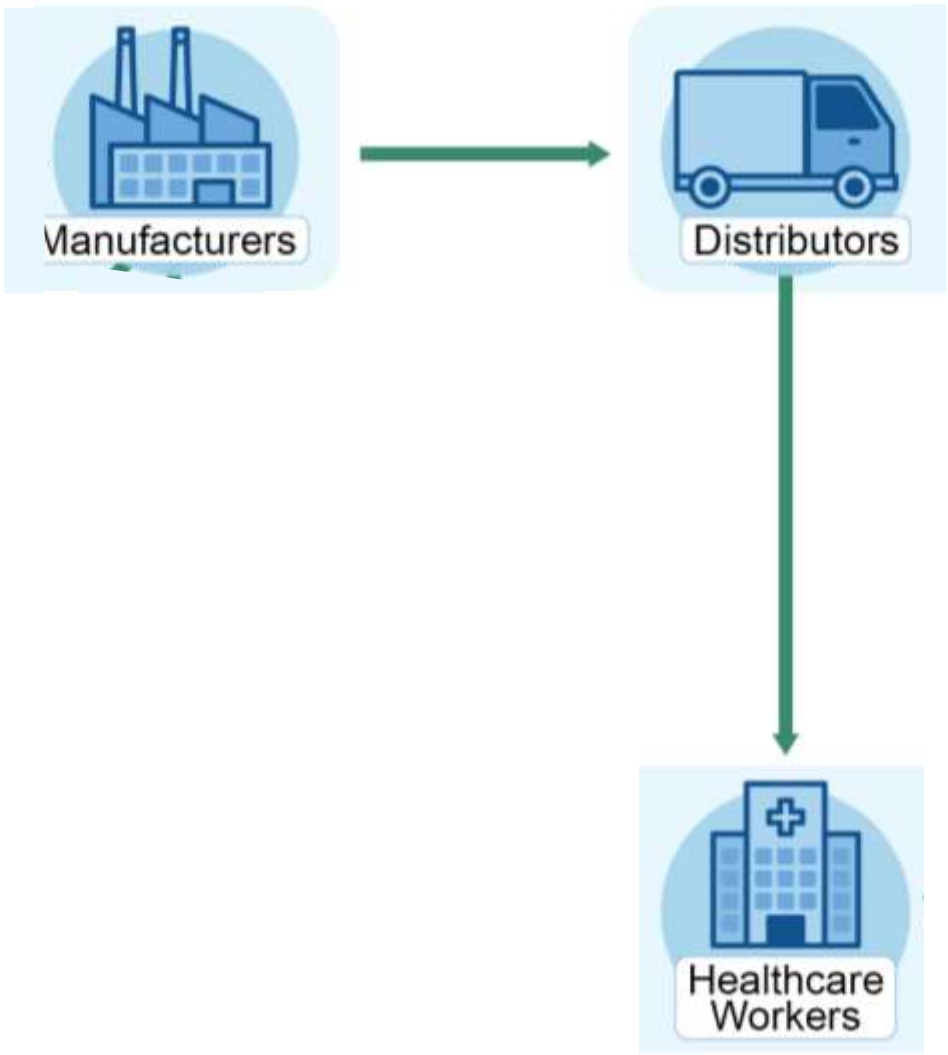
- Government stockpiles exist to mitigate the public health impacts of disasters such as pandemics or hurricanes through distribution of vital goods to those in need

- Centralized stockpiles may be costly and difficult to manage, given the lack of stock rotation, expiry waste, and large space requirements
  - Though, governments can operate at a loss, unlike the other inventories discussed
  - As you'll see, for long-lived items, the cost can be lower than originally conceived

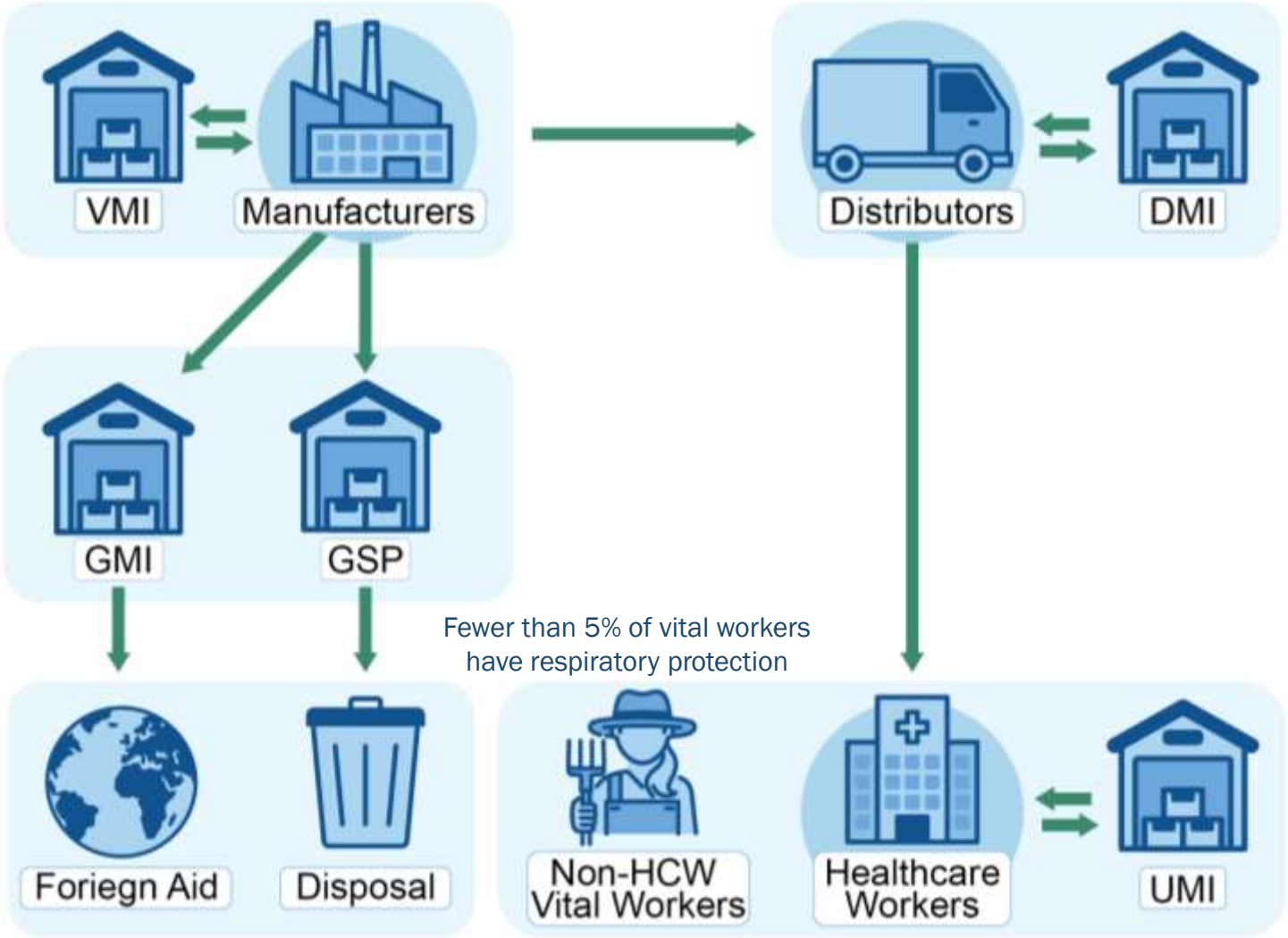
- Despite these challenges, government stockpiles can effectively distribute stock (especially to new stakeholders) and can create sustained demand for the PPE market

A System of Systems

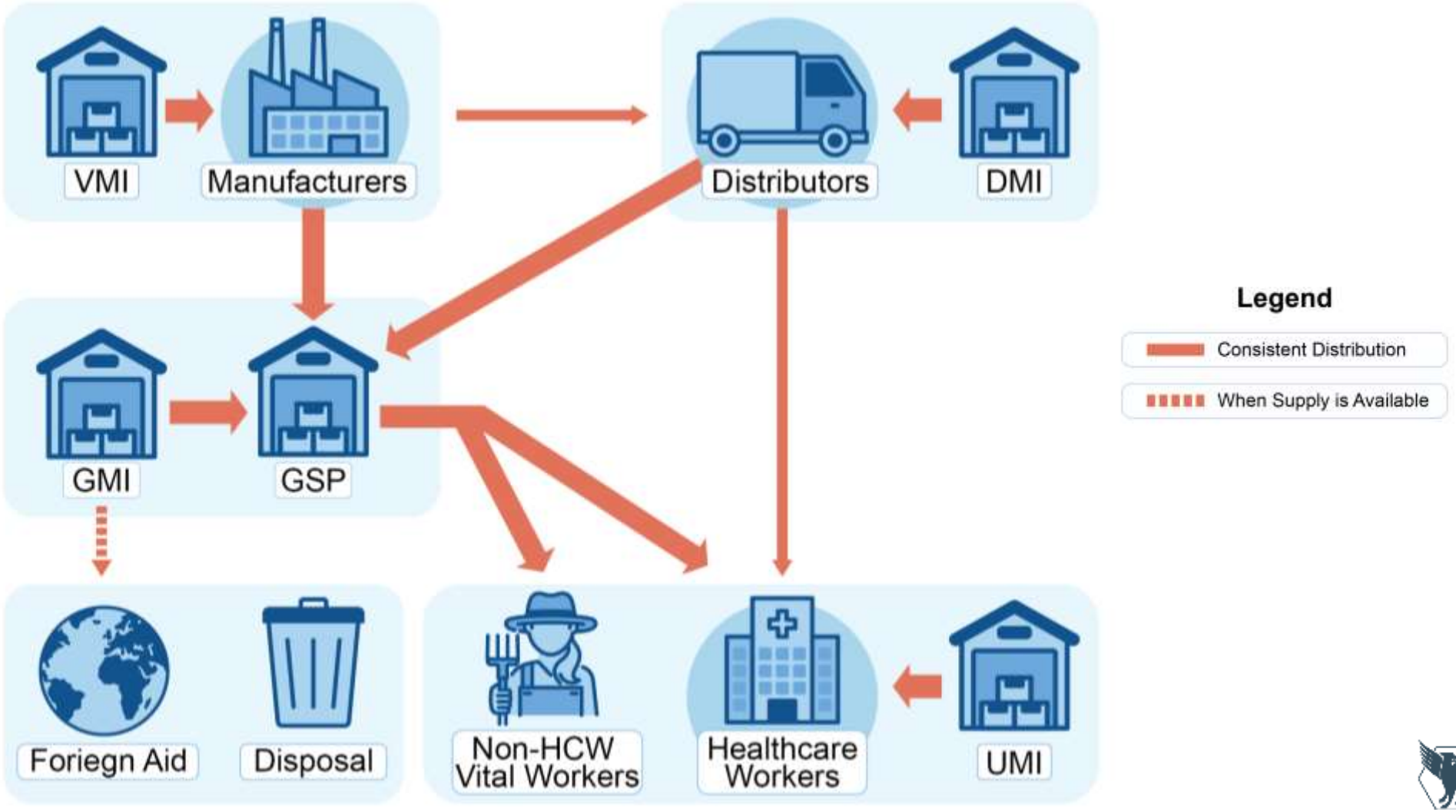
Normal Medical PPE Distribution System



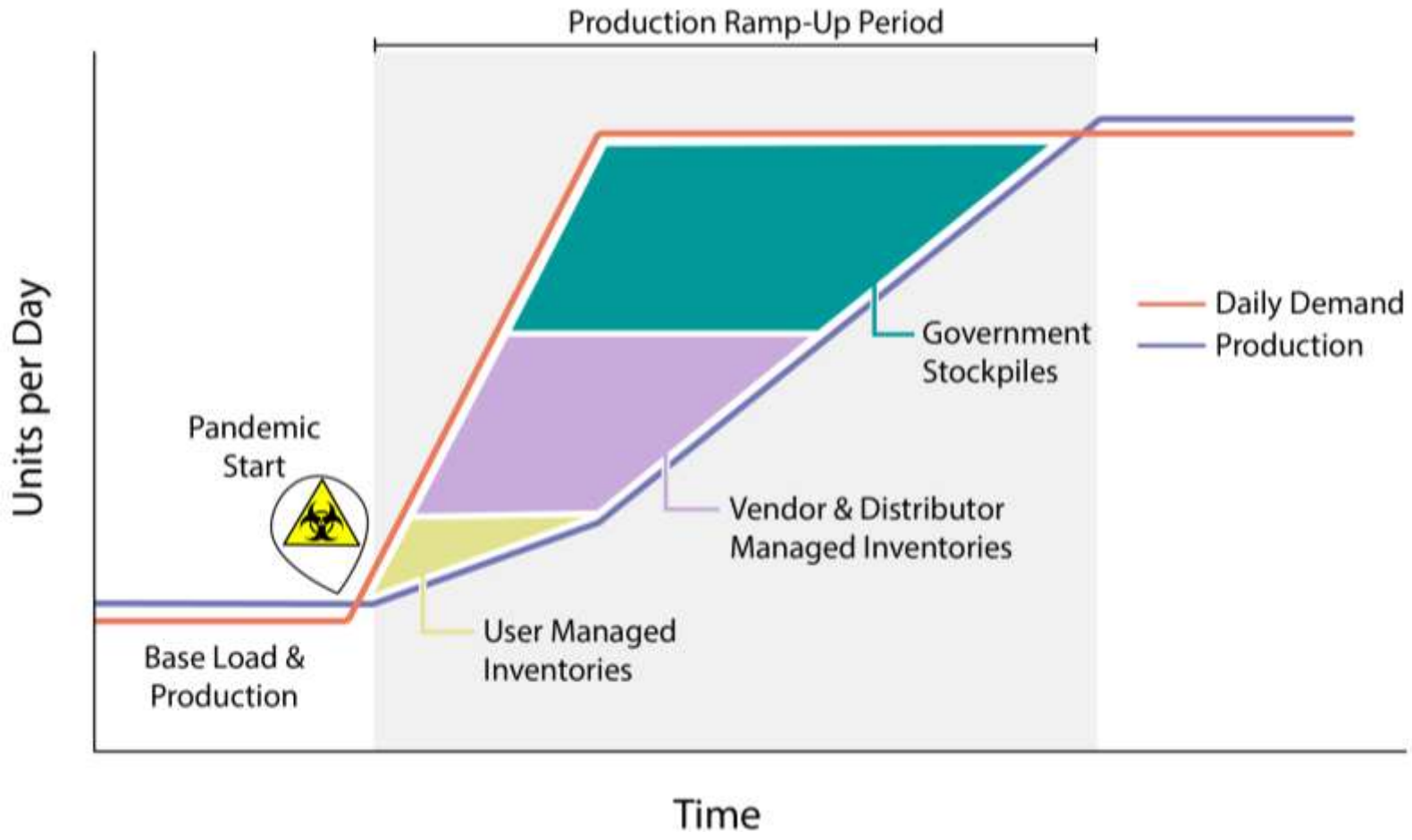
Normal Times: System of Systems



Pandemic Times: System of Systems



Distributed Stockpile Method



*Not to scale

Distributed Stockpile

- Each type of organization for inventory management has their own relative strengths and challenges
- Placing the burden of the entire global demand on one group (governments, vendors, etc.) would be unreasonable
- Spreading both the burdens and the benefits of global PPE demand would reduce expiry waste, enable efficient regional distribution, and create a resilient PPE supply
- Inventory tracking and distribution, however, would be made more complex

For a Functional Distributed Stockpile

- Data would need to be shared between systems to create a complete understanding of national stock levels
- Quality Assurance should become a regular feature of all inventories to ensure the long-term viability of the goods.
- A platform for inventories and producers to share data and test results would need to be developed and/or implemented

Questions on components?

The recommended final state is next

The Recommended Stockpile

The Recommended Stockpile

A stockpile of PPE to cover the first 5 months of need (150 days)

90% of Respiratory PPE are Elastomeric Respirators

10% of Respiratory PPE are PAPRs

100% of Respiratory PPE is Centrally Stockpiled

- PPE purchases occur yearly to resupply the stockpile and build recurring PPE demand

Responder Barrier Protection is in Managed Inventories and Centralized Stockpiles

- Users stockpile 3 months of normal use
- Vendors & Distributors each stockpile 3 months of PPE for their customers' regular use
- Centralized Stockpiles hold remainder of PPE

Respiratory Protection

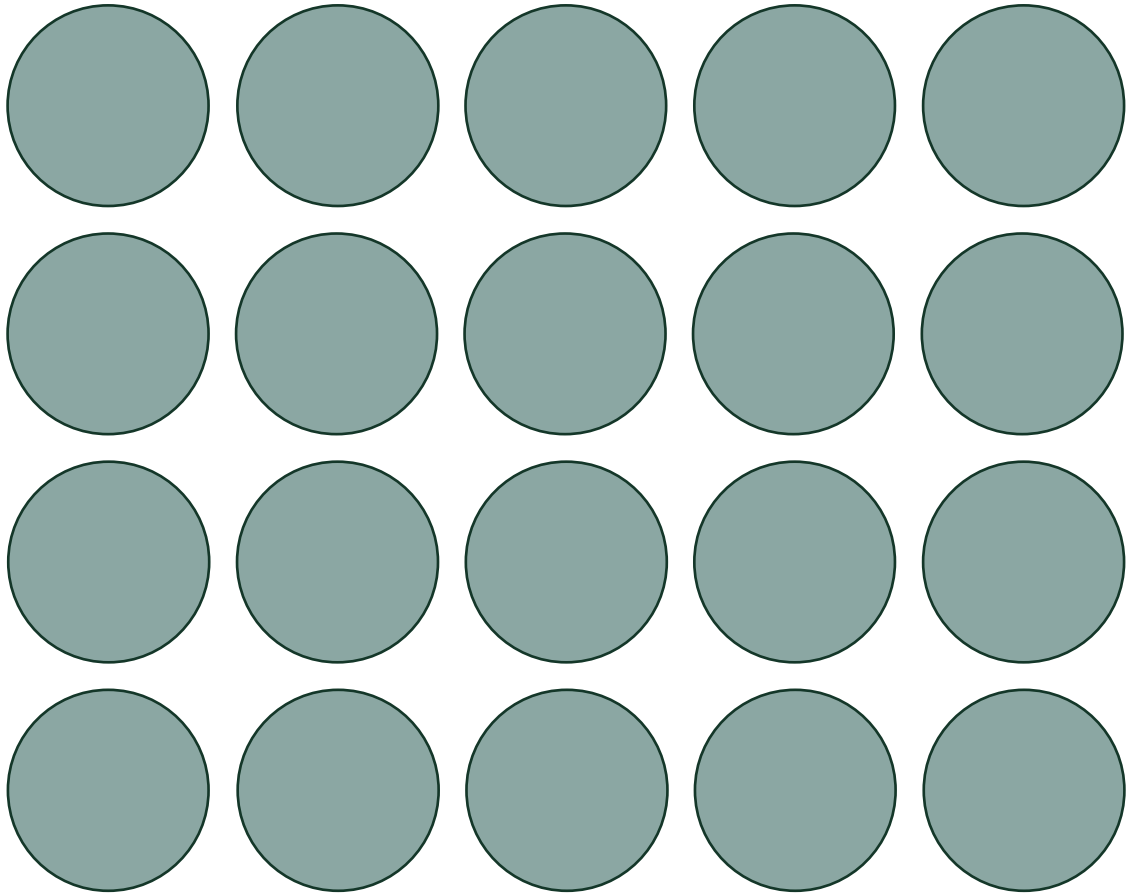
The 150 Day Stockpile Requirement

Country	Elastomeric Units		Disposable Respirators
USA	58 million	Or	8.8 billion
EU	81 million		12 billion
India	280 million		41 billion
All Others	1.3 billion		190 billion
Global	**1.7 billion**		**260 billion**

This table considers the PPE needed just for the 5-month period before production can scale up
It includes a 25% factor for loss/damage of elastomerics during this period

Relative Global Stockpile Sizes

0.32 Million Pallets for a global stopgap supply Elastomeric Respirators and Filters



20+ Million Pallets for an equivalent supply of Disposable N95’s

Relative Global Stockpile Sizes

0.13 Square Miles
Warehouse Space for
Equivalent # of Elastomeric
Respirators & Filters

Relative Global Stockpile Costs

Disposables and other short shelf-life goods benefit from Managed Inventory practices

20-year Disposable N95 Managed Inventory

$190 - $1,200 Billion USD

Assuming a 10% Management Fee

20-year Disposable N95 Centralized Stockpile

$360 - $1,700 Billion USD

20-year Elastomeric Managed Inventory

$130 - $670 Billion USD

Assuming a 10% Management Fee

20-year Elastomeric Centralized Stockpile

$19 - $100 Billion USD

Relative Global Stockpile Costs

Reusables and other durable goods benefit from Centralized Stockpiles

20-year Disposable N95 Managed Inventory

$190 - $1,200 Billion USD

Assuming a 10% Management Fee

20-year Disposable N95 Centralized Stockpile

$360 - $1,700 Billion USD

20-year Elastomeric Managed Inventory

$130 - $670 Billion USD

Assuming a 10% Management Fee

20-year Elastomeric Centralized Stockpile

$19 - $100 Billion USD

Why 10% PAPR's

- Because filtration technology is highly depended on an unbroken seal with skin to prevent leakage.
- People with beards, cultural headwear and assistive devices are not able to acquire adequate fit with tight fitting half mask respirators.
- Seeing the face is desired for some job roles
- To help accommodate this diversity, we assume that 10% of purchased respiratory protection are PAPRs

PAPR Tradeoffs

The main tradeoff for this option is the high cost associated with PAPRs

- PAPR costs will range from $26 to $180 million USD
- Elastomeric costs will range from $38 to $200 million USD
- **10% PAPR respiratory protection represents 40% to 50% of total respiratory protection costs**
- Exact proportion of costs depends highly on the type of PAPR stockpiled
    - Some have longer shelf-lives than others, some have parts that are less durable, some have replaceable batteries that expire

Despite the high costs – PAPR's also represent a much higher level of protection than tight fitting half mask respirators

Barrier Protection

The 150 Day Stockpile Requirement

Country	Gowns		Gloves
USA	890 million	And	22 billion
EU	900 million		23 billion
India	620 million		16 billion
All Others	5.0 billion		124 billion
Global	**7.4 billion**		**180 billion**

We presume that barrier protection is needed only for workers that must closely encounter other people (e.g. HCW and soldiers)

Relative Global Stockpile Costs

20-year Glove & Gown Managed Inventory

$25 - $140 Billion USD

Assuming a 10% Management Fee

20-year Glove & Gown Centralized Stockpile

$41 - $200 Billion USD

Could likely reduce fee for gowns

Why not reusable gowns?

Reusable gowns were considered and excluded to the vast increases in storage requirements, laundering costs, purchase cost, and weight.

Reusable gowns in their current state are not feasible for stockpiling when compared to disposable gowns.

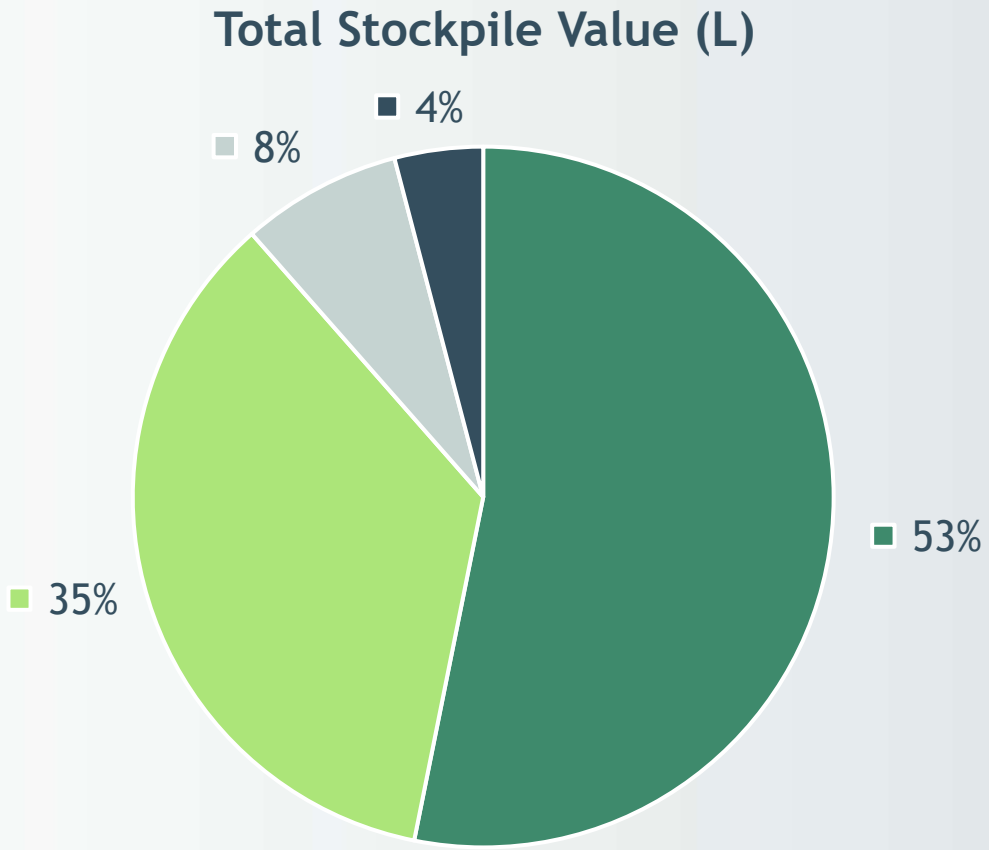
Recommended Global Stockpile Breakdown

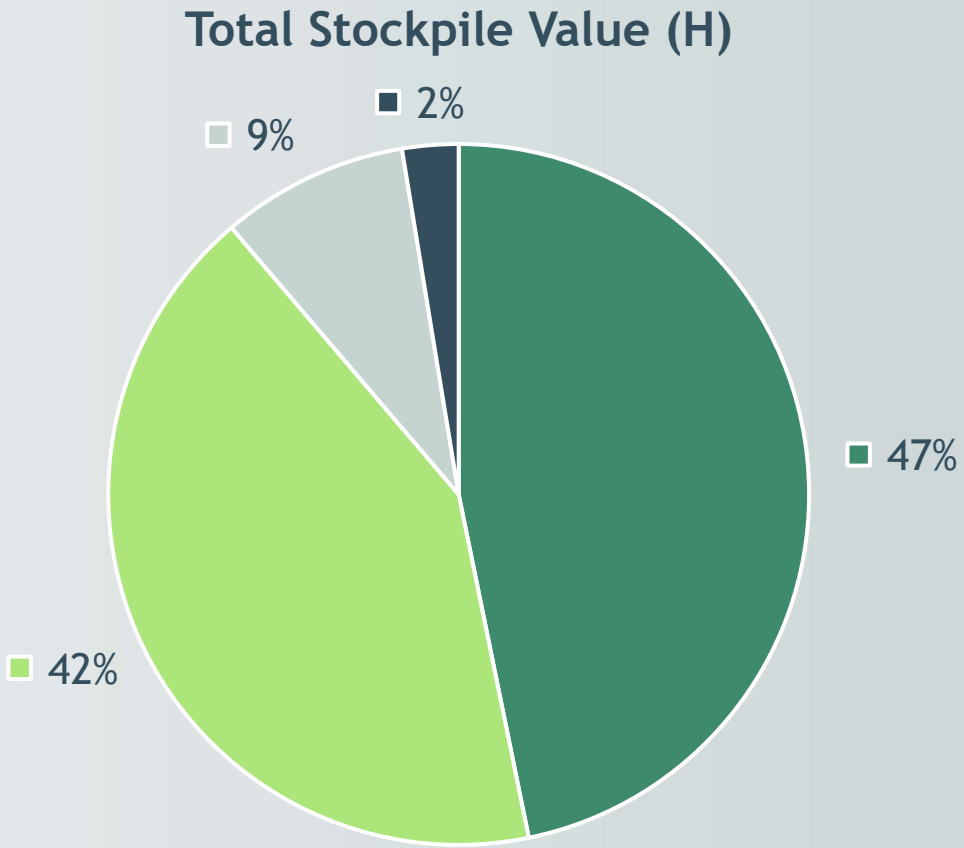
Manager	Regular Use Supply	Surge Use Supply
Users	3 months	18 days
Vendors	3 months	18 days
Distributors	3 months	18 days
Government		96 days

- We recommend that Users, Vendors, and Distributors stockpile 3 months of regular PPE consumption
  - Equivalent to 18 days of surge use each
  - Government stockpiles will cover 64% of the stockpile requirement
- If various stakeholders could be convinced to carry 6 months of regular PPE consumption, costs and expiry waste would be reduced further

The cost of a 20 year Global Stockpile $290 Billion to $1.8 Trillion

Total Global Stockpile Value





Elastomeric PAPR Gloves Gowns

$72 Billion **$430 Billion**

GRYPHON SCIENTIFIC

Lunch

Creating Market Demand & Building a Sustainable Marketplace

Presented by: Dr. John Baggett

Comparing Respirator Types

	N95 FFR	EHMR
Upfront Cost	X	
Cost over time		X
Initial Fit		X
Long-term Fit		X
Respiratory Protection		X
Accessibility	X	
Waste Generated		X
User Preference		X

Initial Fit of Respirators

- Obtaining Fit
  - FFRs
    - In fit testing of more than 6,000 HCWs:
      - 55% passed on the first N95 FFR selection
      - By the 3rd FFR selection, 93% were successfully fitted
  - EHMRs
    - In fit testing of 150 HCWs:
      - 92% passed on the first EHMR selection

Long-term Fit of Respirators

- Maintaining Fit:
  - FFRs
    - In fit testing of 10 individuals during routine office work for one, two, or three hours:
      - 50% of participants experienced fit failure after one hour
    - In fit testing of 64 HCWs during simulated CPR chest compressions:
      - 18/64 (28%) experienced fit failure
  - EHMRs
    - In fit testing of 36 HCWs during simulated CPR chest compressions:
      - No participants experienced fit failure

Respiratory Protection of EHMRs

- Total inward leakage (TIL)
  - An estimation of a respirator's performance, measured as leakage of contaminants via:
    1. Filter media
    2. Face seal

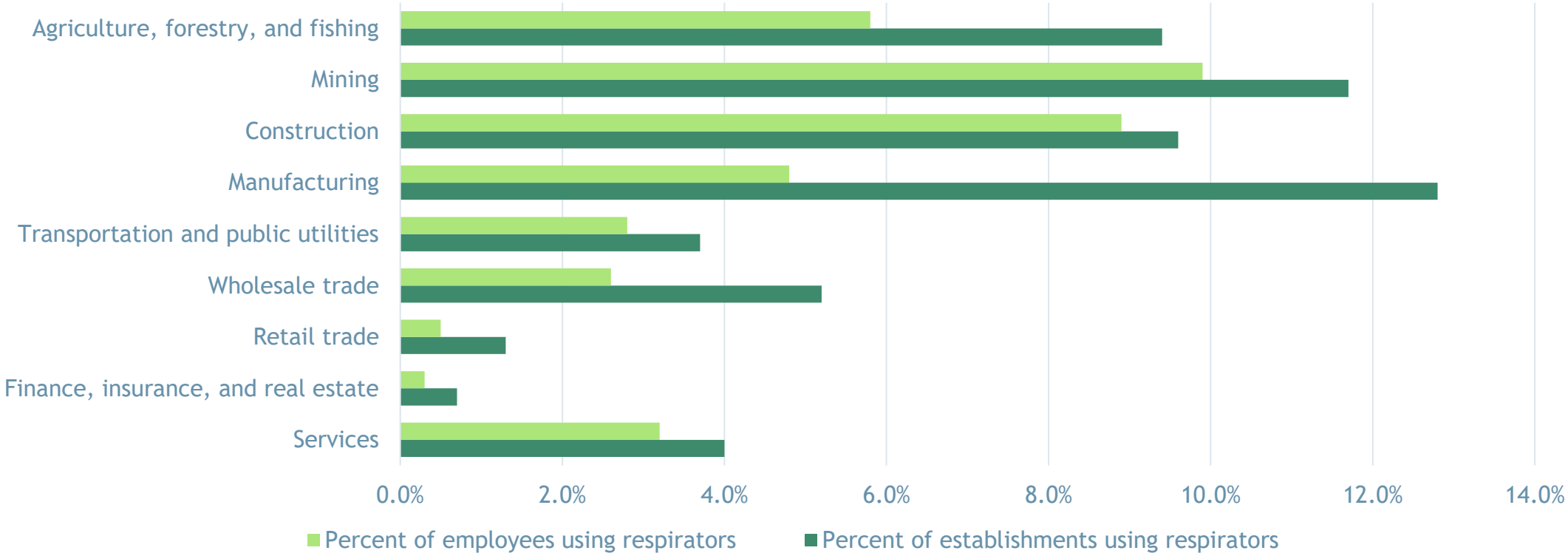
- Significant decrease in EHMR TIL compared to N95
  - Well Fit Respirator: 60–97% decrease compared to an N95
  - Poorly Fit Respirator: 78–95% decrease compared to an N95

Sustainability of EHMRs

- Use of disposable FFRs creates excess waste and may present supply issues
- EHMRs are more sustainable than FFRs:
  - Durable respirator components can be decontaminated and reused for months to years
  - Only filters are replaced
  - Filters may last up to one year before replacement

EnvoMask: *www.envomask.com*
ElastoMaskPro: *www.reusable-respirators.com*
FloMask: *www.flomask.com*

Respirator Usage in Industrial Workplaces



A 2001 survey by the Bureau of Labor Statistics and NIOSH concluded that fewer than 5% of industrial workplaces utilize respirator

NIOSH is currently surveying industrial workplaces to provide updated statistics

PPE Production is Geographically Concentrated

- China and the US make the majority of every PPE type except gloves
- While the production based on country has shifted recently, production is still heavily concentrated
- Exacerbates risks to global supply chains from individual state policies and transportation issues
- Forced labor concerns are still an issue with shifting locations of production
- On-shoring and friend-shoring PPE manufacturing secures supply chains against trade interruptions

Questions?

Inducing Regional/Domestic Demand

Regional/Domestic Demand: The Problem

- There is currently not enough demand for regional/domestic PPE to sustainably support the industry.

- Without demand signal, businesses are resistance to investing in increased production or new products.

- Reasons demand favors existing foreign manufacturers:
  - Price
  - Established distribution relationships and markups of branded PPE
  - Training and fit testing requirements of new products
  - Volume of units needed

Goals

- Induce sustainable demand to support and expand the domestic/regional **industry that makes PPE that meets the TPPs**

- Important considerations:
  - Manufacturers and distributors told us they would make or carry novel products if demand signals existed to support them

  - Inducements should both create initial demand and help manufacturers and distributors build long-term markets

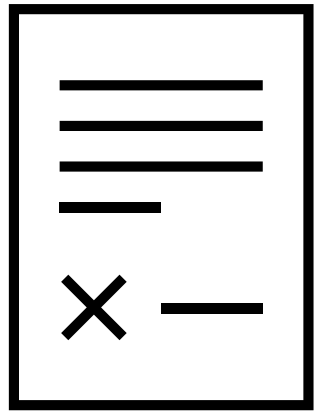
Sustainable Market Topics

1. Government Purchasing
2. Domestic Purchasing Requirements
3. Volume Guarantees
4. PPE Reimbursements to Healthcare
5. Labor Union Requirements for High-Quality PPE
6. Pilot Programs

Government Purchasing

- National and regional agencies can purchase PPE preferentially or exclusively that meets the TPPs

- Government facilities such as hospitals and fire stations can be required to purchase PPE that meets the TPPs only
  - This may be more effective in countries with national health systems that can drive significant demand
  - May require additional budget allocation if domestic/innovative PPE is more expensive



Domestic Purchasing Requirements

- Government could require agencies, contractors, and/or private businesses to purchase a fraction of PPE domestically
- Government contract clauses can be powerful drivers of policy
- *Example: Canadian effort to boost domestic PPE manufacture*
- *Example: Make PPE in America Act*
  - *Example agencies: Security, Health, Defense, Energy, Veterans Affairs*
  - *Current limitations: Small contracts are exempt, implementation language is unclear*

Volume Guarantees for Novel Products

- Volume Guarantee contracts based on meeting TPPs and specific price points can incentivize the creation of new PPE
  - If the manufacturer cannot meet their volume targets with their customer base, the guarantor buys the rest
- An ideal program includes support for entering new markets
  - Local knowledge of systems and set-up
  - Government connections
  - Market/business advising
- This model has proven success encouraging novel product creation and entrance into underserved markets
  - MedAccess has used this model to bring novel therapeutics and vaccines to the market

Volume Guarantees: MedAccess Example

- Goal: expand access to medical interventions by reducing cost, increasing supply, and increasing availability
- How: volume guarantee agreements with manufacturers
  - Manufacturer agrees to meet a set demand for the product at or below an agreed upon maximum price for the length of the agreement
  - Individual buyers (countries) enter into separate agreements with the manufacturers to purchase the product at or below the maximum price
  - If the sales are below the guaranteed volume, the company is compensated the difference
- Benefits: a mutually beneficial partnership is developed
  - Manufacturers have reduced risk and stable demand
  - Countries receive stable supply at a predictable price
  - MedAccess fulfils their goal of expanded access to medical interventions

PPE Reimbursements to Healthcare

- Nations with national health systems can include payments or facility fees (this works uniquely in each country)
- In nations with combinations of private and public insurance, public insurance programs can reimburse PPE per-patient or per-facility
  - *Example: US Centers for Medicare and Medicaid Services will reimburse a percentage of the cost of domestic PPE for each Medicare patient*
  - This program could be improved:
    - The burden of paperwork is significant – bi-weekly submission of cost sheets
    - Reimbursements are below the actual cost difference to purchase domestic PPE
    - Could include other incentives like cost premiums for body-covering PPE that accommodates female bodies

- Well-designed programs could improve adoption of innovative/domestic PPE **if** they reimburse appropriately for the cost differential

Reimbursements: CMS Example

- Current US reimbursements cover part of the cost of moving to domestic PPE
- Final product and all components must be made in the US
  - The actual wording of this requirement is confusing for hospitals

Excerpt from CMS example table 70: Mock N95 Supplemental Cost Reporting Form

Line 11: Total cost differential for purchasing domestic NIOSH-approved surgical N95 respirators.	Calculation: Line 1 * Line 10.	$30,000
Line 12: Medicare Part A hospital inpatient cost share.	Calculation: Line 6 / Line 5.	0.20
Line 13: Medicare Part B hospital outpatient cost share.	Calculation: Line 7 / Line 5.	0.10
Line 14: IPPS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators.	Calculation: Line 11 * Line 12.	**$6,000**
Line 15: OPPS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators.	Calculation: Line 11 * Line 13.	**$3,000**

Labor Union Requirements for High-Quality PPE

- Major associations of hospital staff can combine forces with an increasingly organized workforce
- Include requirements for protective, comfortable and desirable PPE in labor contracts
- Would require long-term work and negotiation
- Will work in locations with a preponderance of organized labor

Pilot Programs for Innovative PPE in Healthcare

- Pilots of elastomerics have been popular with HCW
- Demonstrate to hospitals that they work, are comfortable and are cost-effective long-term
  - Test in emergency departments and isolation wards where enhanced PPE is worn
- NIOSH pilots of adapters for exhalation valves and comparative studies of novel products

Design of a Good Pilot—Engagement of Subjects

- To engage subjects, we suggest a PPE Fair during the recruitment phase
  - We first heard about this approach from Molly Stitt-Fischer at U. of Pittsburgh
    - She has a day in which lab workers can try out all the different types of PPE that are available to them
      - Workers can try the PPE on, and use it while manipulating lab equipment and stuffed animals standing in for model animals
  - In a PPE pilot, the subjects can try on various types of respiratory and body covering PPE and use their instruments while wearing it
    - Only PPE that meets the TPPs would be part of the fair
    - Occupational health can be present to make sure a good fit can be achieved while wearing the desired PPE
    - Subjects will feel more incentivized to pilot the PPE they liked

Design of a Good Pilot—Study Design

- Controls:
  - Suggest that the study be divided into two phases, in one phase half the subject wear conventional PPE and half wear the enhanced PPE they chose.
  - In the second phase they switch
  - This approach allows control over temporal, role, and interpersonal variability
- Outcomes to measure:
  - Perceived logistical/administrative burden of reusable PPE
  - Perceived comfort/wearability differences amongst HCWs
  - Real-world protection factors achieved during workday
  - Real-world data on loss/durability of reusable PPE
  - Number of sick days taken by HCW in study
    - The statistical power of this study must be carefully designed accounting for natural variance in sick time
- Other pilots can be done in other workplace settings to gather important data on real-world efficacy of PPE in workplaces without dedicated occupational health expertise

Discussion Questions

- Are there any new demand induction programs currently being discussed by your organization?
  - Preferential purchasing
  - Guaranteed purchasing
  - Insurance incentives
  - Worker mobilization
  - Pilot Programs

- Do you have experience/examples of programs of these types that have or have not been successful?

Building a Sustainable Marketplace

Sustainable Marketplace: The Problem

- Domestic PPE manufacturers in many countries lack sustainable demand to stay in business and produce innovative products
  - Being undercut by foreign competition
  - Being undercut by minimally-effective PPE

- Funders and governments can arrange **contracts** themselves and **induce demand** through policy and outreach

Contract Vehicle Topics

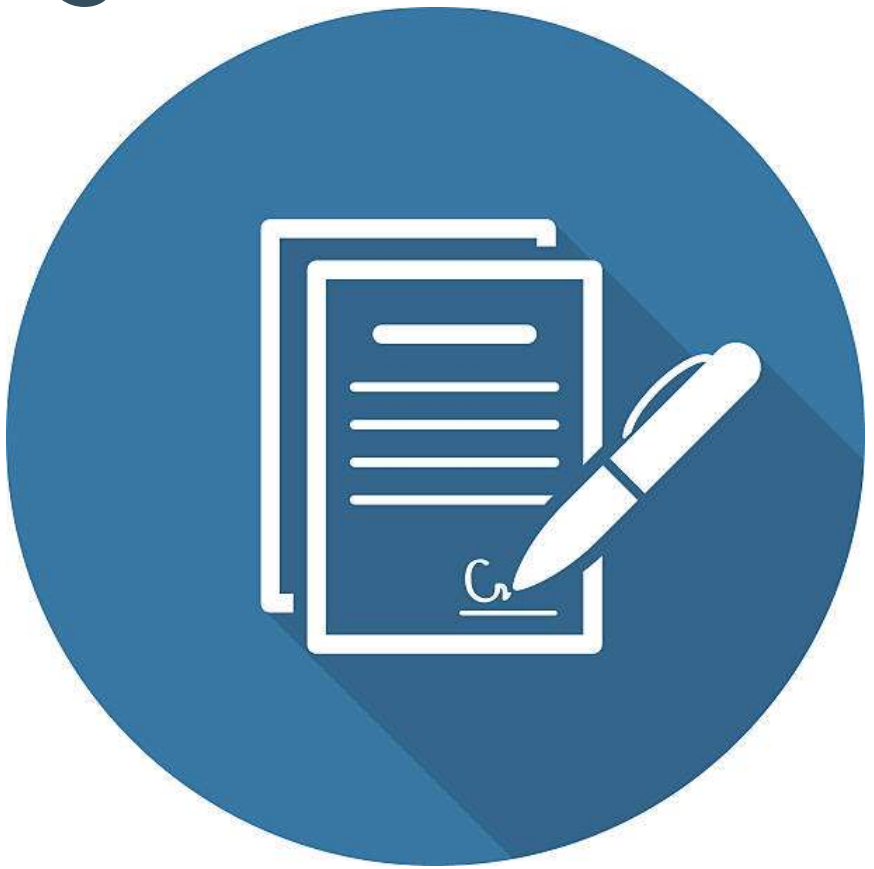
1. Advance Manufacturing Contracts for existing products

2. Advance market commitment for novel products

3. Volume Guarantees to distribute production

Multi-year Government Contracts for Immediate PPE Purchasing

- Immediately useful for filling stockpiles
  - Using the morning's recommendations as an example:
    - Stockpiles that are rotated (e.g. UMI) would be filled first
    - For those stockpiles that are not rotated, they would be filled over a time matching the shelf life
      - E.g. 10 years for EHMRs
      - This way, the stockpile creates a permanently sustainable demand signal
- Helps build manufacturing capacity as stocks are developed
  - I.e. if the manufacturing to fill the stocks in time is twice baseline, the industry has twice as much capacity for emergencies
- 5–10-year contracts were preferred by many manufacturers in discussions
  - *Example: $385 in recently-announced HHS/ASPR contracts for PPE*



Contract Vehicle Options for Future PPE Purchasing

- **Advance contract:** If external geopolitical conditions are met (e.g. novel pandemic), government buys X amount of PPE (with/without guarantee)
  - This approach was considered less desirable

- **Advance market commitment:** If manufacturers develop a novel PPE product that meets target product profile at an agreed upon price, government will buy X amount

- **Volume guarantee:** Funder assists in connecting PPE manufacturer with a new market and guarantees that X amount will be purchased, by funder itself if normal customer base fails to buy the amount
  - MedAccess model

Definition of Domestically Produced PPE Should be Consistent Between Funding Mechanisms

- Industry representatives noted that the definition of “domestically produced PPE” often changes from one funding mechanism to the next
- These changes increase the effort of compliance for manufacturers and reduces participation
- To alleviate this issue, the definitions used for domestic or regional production should stay consistent from one funding mechanism to another as much as possible

Quantitative Refinement of the TPPs

- Once innovative TPPs have begun to be incorporated into stockpiles, requirements in the TPP should be refined to spur continued improvement and innovation
- Examples:
  - Body covering PPE that allows female workers access to their bodies
    - Defined by time to access? Surface area? Location?
  - Respirators should maintain fit over an entire workday
    - Fit should be maintained in real workplace settings for eight hours in 95% of workers, 99%, 99.9%? 100% is infeasible.
  - Body covering PPE should accommodate breasts
    - How should comfort of the wearer be defined?
- More real-world data and user experience is needed to define these requirements and define trade offs—as described in post-market surveillance, below
  - Is a respirator that loses fit in only 1% of wearers but is less comfortable superior to a respirator that loses fit in only 2% of wearers but is more comfortable?
  - Weighted score sheets could be created using concurrent engineering approaches

Questions

- What are the pros and cons of these various options from the perspective of government?
- Has any been tried and failed? Why?
- Should scale-up capacity (e.g. warm-basing) be included as a condition for multi-year contracts, or should it be kept separate?
- Should governments buy the designs of PPE products that meet a TPP and then distribute them among domestic manufacturers to facilitate competition and avoid redundant R&D?

Break

Lowering Barriers to Novel and Existing Products

Presented by: Bryn O’Meara

Reducing Product Barriers Topics

1. PPE Nomenclature & Standards
2. Worker Protection Agency Regulations
3. Regulatory Advisory Networks

PPE Nomenclature & Standards

Nomenclature

- There is currently no standardized nomenclature for PPE internationally
- Labeling and information requirements in native languages may be a barrier
- Development and implementation of a common global nomenclature and sheet formats for PPE would allow:
  - Easier stockpiling
  - Cross-linking of global inventory databases

Standards

- Regulatory standards vary for the same PPE across countries & regions
- Aligning international PPE standards would simplify product lines and enable global PPE sharing
- Preferably standards would be freely available

U.S. N95

European FFP2

Japanese DS2

3M Aura 9211+ N95: *www.3m.com*
3M Aura 9322+ FFP2: *www.3m.com*
3M Aura 9322J+ DS2: *www.3mcompany.jp*

Worker Protection Agency Regulations

- Regulations set forth by worker protection agencies are inflexible and may not allow for use of innovation solutions
  - *Example: U.S. OSHA regulations require contact of a respirator with the user's skin, thereby preventing the use of fit solutions such as the Singh Thattha technique*

- Increased the flexibility of regulations for PPE would allow innovative solutions to be used without the need for full revision of regulations

Singh Thattha Technique: *Bhatia et al., 2022*

Regulatory Advisory Networks

- Navigation of the regulatory landscape is difficult for new market entrants, impeding innovation and wasting money

- Establishment of PPE product development advisory networks to aid in navigating the regulatory landscape and product approval process
  - Network of individuals with expertise in product development providing low to no cost advisement for novel PPE producers
  - Compensation for advisors paid by governments or NGOs
  - Application process to access advisory network to focus resources on products that improve PPE on the market

Questions

- Would internationally accepted nomenclature and standards minimize time to market for new product?
  - Would there be acceptance or resistance from industry to adopt such changes?

- Where should regulatory flexibility be implemented to ensure safe products while still supporting innovation?

- What would it take to have the Singh Thattha technique be acceptable in occupational health programs?

Improving PPE Post-Market

Presented by: Bryn O’Meara

Post-Market Topics

Gap: Post-market surveillance was shown to be inadequate during the COVID-19 pandemic, resulting in counterfeit and inadequate products on the market

1. Post-Market Surveillance
2. Imperfect Use Index
3. Combatting Counterfeits

Post-market Surveillance

- Medical devices, pharmaceuticals, and other products track effectiveness and adverse event information

- Tracking information on aspects of PPE performance could improve:
  - Understanding and frequency of fit failures
  - Adverse reactions caused by mask usage (e.g. facial wounds, headaches)
  - Design aspects that are most likely to cause problems

Imperfect Use Index

- Collect and report additional evidence for respiratory PPE effectiveness considering imperfect and ideal use
  - Example: the Pearl Index for contraception
  - Including protection of respirators without fit testing or used with minimal training

- Products that require proper use should be evaluated in real-world circumstances for effectiveness and patterns in user errors and consequences

Gaps in Combatting Counterfeits

- Counterfeiters and knock-off producers took advantage of the rapid rise in demand of N95 respirators
- While DHS and other agencies intercepted millions of counterfeit respirators, significant volumes of counterfeit respirators flooded U.S. markets (including healthcare settings) during the COVID-19 pandemic
- Certified N95 respirators contain a NIOSH Testing and Certification approval number, (e.g., TC-84A-XXXX), but this can be copied by counterfeit products
- Some companies have incorporated additional verification measures

Verification Solutions

- Label individual respirators or respirator boxes with scannable QR code:
  - We identified one large company providing QR on their respirator boxes (unclear if code can only be scanned once)
  - Anecdotal evidence of individual KN95 respirators labeled with unique QR code (on tag)
  - Implementing a single-use, unique QR code linked to manufacturing database could help ensure respirator is genuine
- Implement RFID chips into respirator boxes:
  - Social acceptability, cost, and manufacturing disruptions may limit RFID implementation into single respirator
  - At ~$0.10 per chip, passive RFIDs may be incorporated into boxes of respirators and read by cell phone and used as a verification system
- These solutions are much easier to implement for elastomeric respirators
  - Also less necessary due to increased difficulty of making counterfeits

Questions

- What are reasonable and affordable post-market surveillance solutions to:
  - Identify counterfeit products?
  - Remove them from the marketplace?
  - Stop their production?

- How could monitoring of imperfect use be incorporated into approval and product data?

- Should authenticity verification solutions be utilized at the import, distribution, or user level?

Support for Innovative Research

Presented by: Dr. Rocco Casagrande

Innovative Research

Researchers need support to continue developing innovative products and technologies to improve PPE

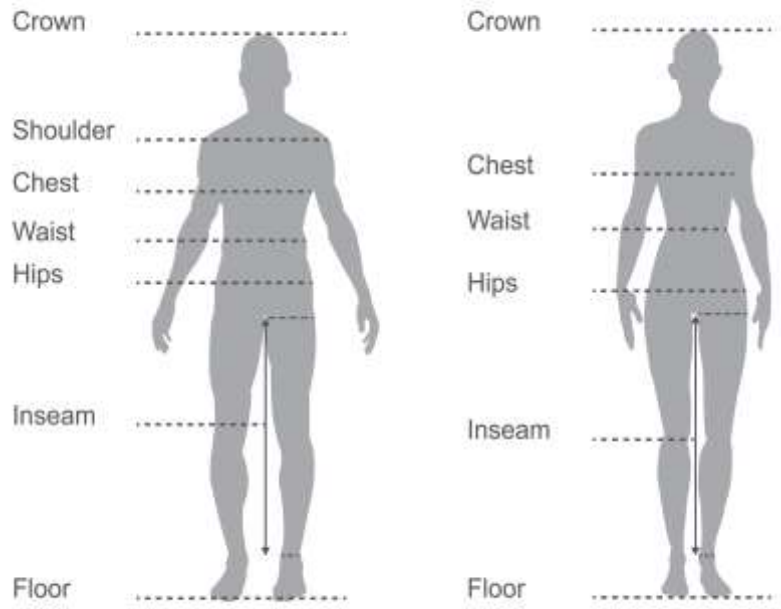
1. Anthropometry for better fit
2. Advanced materials for thermal comfort
3. Real-time fit assurance
4. PAPRs with low lifecycle costs

Using Anthropometry for Better Fit

Gap: PPE products do not fit the diverse workforce

Solution: Development of technical tools for land-marking human bodies

1. Improved anthropometry databases
2. Accurate and impartial landmarking software
3. Data on mask shape
4. Apps to choose fit for workers not covered by RPPs



Advanced Materials for Thermal Comfort

Gap: Impermeable PPE items trap heat and moisture leading to frequent breaks for PPE wearers

Solution: Utilize advanced materials in the construction of PPE

- Phase-change materials
- Infrared-transparent visible-opaque fabrics
- Thermal conductive textiles
- Janus textiles
- Super absorbent polymers

Some materials have been incorporated into PPE for low-risk conditions, but support is needed for additional research and implementation

ITVO fabrics, Photo from: Cai et al., 2019

Real Time Respirator Fit Assurance

Gap: Respirator fit may not be apparent, and users may lose respirator fit during wear

Solution: Use of a wearable quantitative instrument for real-time fit assurance

- Dual-channel condensation particle counter (DC-CPC) can be worn to continuously measure respirator fit during occupational activities
- DC-CPC can be worn for an extended period after annual fit testing to measure fit during occupational activities

Technology is being tested for military applications but is not yet available for civilian use

Use of DC-CPCs for real-time fit assurance requires the manufacture of respirators with permanent fit testing ports

Could cost-effective kiosks that measure fit, placed outside of critical areas (schools, hospital wards, auditoriums) be used to ensure that people entering are properly protected?

PAPRs with low lifecycle costs

- Our best estimate for generic PAPRs and elastomerics suggests that protecting 10% of workers with PAPRs costs about the same as protecting 90% of workers with EHMRs
- The total lifecycle cost of PAPRs depends on:
  - The shelf life of the durable components
  - The shelf life of the hood and durability during re-use
  - The shelf life of filters and extent of reusability
  - The shelf life of batteries
- There are no PAPRs on the market today that have a low total cost of ownership because cheap PAPRs often have less reusable components
- Research is needed to create a PAPR with the entire cost of ownership is lower than today

Questions

- Where would additional funding from governments or NGOs be the most effective at supporting innovation and boosting supply?
  - Funding for pre-emptive licensing of new facilities
  - Funding for regulatory advisors

Wrap-Up & Next Steps

Next Steps

- Your feedback today will be incorporated into our final report
- We expect to deliver a final report by the end of the year
- Our sponsors have provided resources to continue our work into 2024
  - Let us know if additional briefings would be helpful
  - Introduce us to stakeholders who should hear this message
  - Tell us about meetings/conferences that are complementary to our work
  - Ask for specific results from this study that would be useful for you to take action, we can provide tailored outputs
  - Contact either me at rocco@gryphonscientific.com or anna at amuldoon@gryphonscientific.com

Let’s eat!

- Please let us thank you by having some final food/drinks on us up the street!
  - Circa Foggy Bottom is located at 2221 I St NW