



Towards a Theory of Pandemic-Proof PPE

Industry Working Group

September 19, 2023



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Agenda

1. Welcome/Introduction
2. Background, Purpose, Recap of Requirements
3. Boosting Surge Capacity
4. *Break*
5. Resiliency in the Supply Chain and Increasing Manufacturing Base
6. *Lunch*
7. Recap of TPPs, Creating Market Demand for Innovative Products
8. Building a Sustainable Marketplace
9. *Break*
10. Lowering Barriers to Novel and Existing Products
11. Improving PPE Post-Market
12. Industry Support for Innovative Research
13. Wrap-up and Next Steps



Welcome & Introduction

Rocco Casagrande, PhD



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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
- The solutions were drawn from several sources:
 - They were elaborated in the literature
 - They became apparent from our analysis
 - They were suggested by industry stakeholders in our structured discussions
- The purpose of the meeting today is to obtain industry feedback if these solutions are actually:
 - Feasible
 - Sustainable
 - Compatible with industry business models
- I.E. We want you to throw rocks at the solutions we propose
 - Some rocks will knock a solution out (so we have fewer to consider at the end)
 - Some will dent the idea and reshape it



Workshop Rules

- Be respectful
 - Although participants today are all from industry, many different perspectives are represented
 - Established vs upstarts
 - Small vs large
 - Gloves, gowns, respirators (and disposables vs reusables)
 - If you disagree, just state your opinion from your perspective instead of stating that the other speaker is incorrect
 - You're probably both right given your own companies' positions
- 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 industry 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 company and the part of the PPE industry you represent
 - For example....



Workshop Rules

- This workshop is non-attributional
 - No one should attribute anything said in this workshop to a person or the company 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...”
- Government and philanthropic representatives are observers
 - We will not be seeking their input during the discussion
 - Of course, they are welcome to share their opinions during the breaks and with us and workshop participants after the workshop
- Network
 - Many people have mentioned that they have few opportunities to talk to their private- and public-sector colleagues to exchange ideas
 - We have created this workshop with longer breaks, a non-working lunch, and two receptions





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
- Impacts vital workers similarly to the 1918 influenza pandemic.

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.






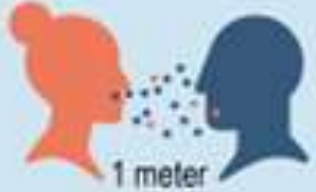













Model Results for Respiratory PPE

Scenario	Type of PPE				
	No mask	Surgical	Disposable N95	N99	PAPR
	Time to Infection				
 1 (Room)	 18 min	 30 min	 227 min		
 2 (Visit)	 6 min	 14 min			
 3 (Cloud)	 32 min	 73 min			



Model Results for Barrier PPE

<p>90th Percentile of Measles Emission</p> <p>In this scenario, 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.</p>	 Hands	 Mouth	 Nose	 Eyes	 Face (eyes + nose + mouth)
Scenario	Time to Infection				
 1 meter	 17 min	 165 min			 69 min
 1.8 meter	 54 min	 535 min			 223 min



Gap Identification & Prioritization

- Gap identification based on research into past pandemics
- Gaps presented to working group of government, NGO, and industry representatives
- Participants ranked gaps for importance to future PPE

- 1 National and regional stockpiles were inadequate (11 votes)
- 2 Respirator fit standards do not capture the facial diversity of all users (8 votes)
- 3 Geographic concentration of PPE production (6 votes)
- 4 Public communication about PPE and combating mis-/dis-information (6 votes)
- 5 FFRs lose fit and performance over time (5 votes)
- 6 No PPE standards for the public, including children (4 votes)
- 7 PPE reimbursement structure stifles innovation (4 votes – no government stakeholders prioritized this gap)





Target Product Profiles



Respiratory Protection | Common Requirements

	Desired	Required
Design Feature	Must not require fit	If fit is required: <ul style="list-style-type: none"> • Must achieve fit and fit be apparent • Must not lose fit over time (and be apparent if lost)
	Use human factors design for size and comfort including accommodating: <ul style="list-style-type: none"> • facial hair • cultural headwear • assistive devices • head shapes 	
	Enable easy communication	
	No interference with occupational duties	Minimal interference with occupational duties
	Prolonged usage must not cause adverse reactions	Prolonged usage must have minimal adverse reactions



Respiratory Protection | Responders

	Desired	Required
Material Performance		Inward penetration of 0.5-1um particles must be less than 2%
Use Desirability		Able to withstand repeated disinfection (non-disposable elements) or sufficiently cheap and plentiful to allow disposal
	Comfortable to wear for an entire shift without requiring replacement or removal	Comfortable for long periods and can be doffed and re-donned without damage
	Simple donning and doffing requiring minimal training and minimizes opportunities for cross contamination	
	For those with direct contact with potentially infected only: should prevent fluid penetration	



Respiratory Protection | All Other Workers

	Desired	Required
Material Performance		Inward penetration of 0.5-1um particles must be less than 6%
Use Desirability		Able to withstand repeated disinfection (non-disposable elements) or be cheap and plentiful to allow disposal
	Must continue to protect in host, cold or humid environments during prolonged use	
	Simple donning and doffing requiring minimal training and minimizes opportunities for cross contamination	



Barrier Protection | Responders

	Desired	Required
Design Feature	Must continue to protect in hot and cold environments and not overheat and overcool during prolonged use	Must continue to protect in hot environments and not overheat during prolonged use
	Use human factors design for size and comfort including accommodating: <ul style="list-style-type: none"> • Facial hair, cultural headwear, head shapes • Various body types • Access to body for biological needs of all workers 	
	No interference with occupational duties	Minimal interference with occupational duties
	Prolonged usage must not cause adverse reactions	Prolonged usage must have minimal adverse reactions
Material Performance	Comfortable to wear for an entire shift without requiring replacement or removal	Comfortable for long periods and can be doffed and re-donned without damage
Use Desirability	Simple donning and doffing requiring minimal training and minimizes opportunities for cross contamination.	

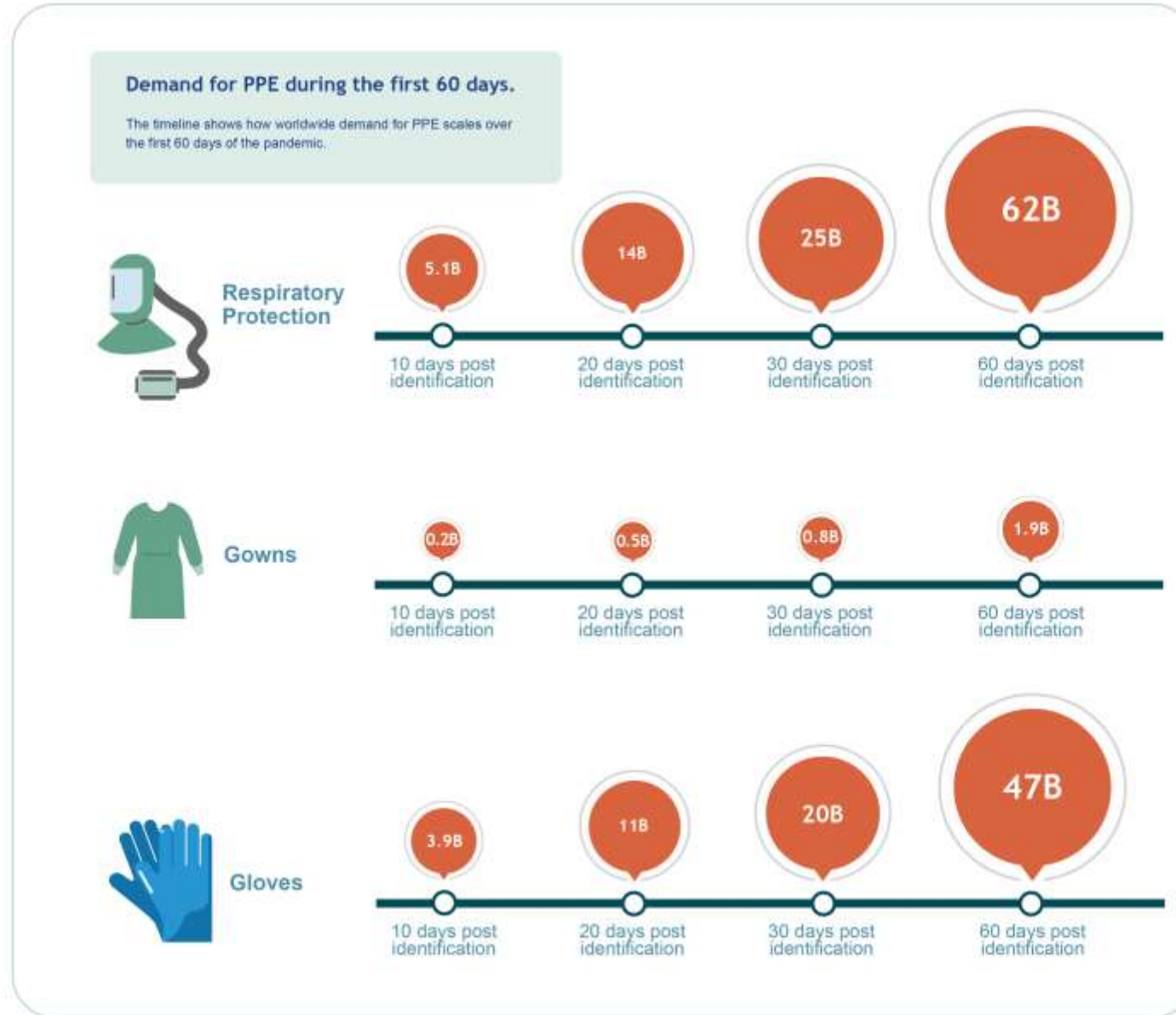




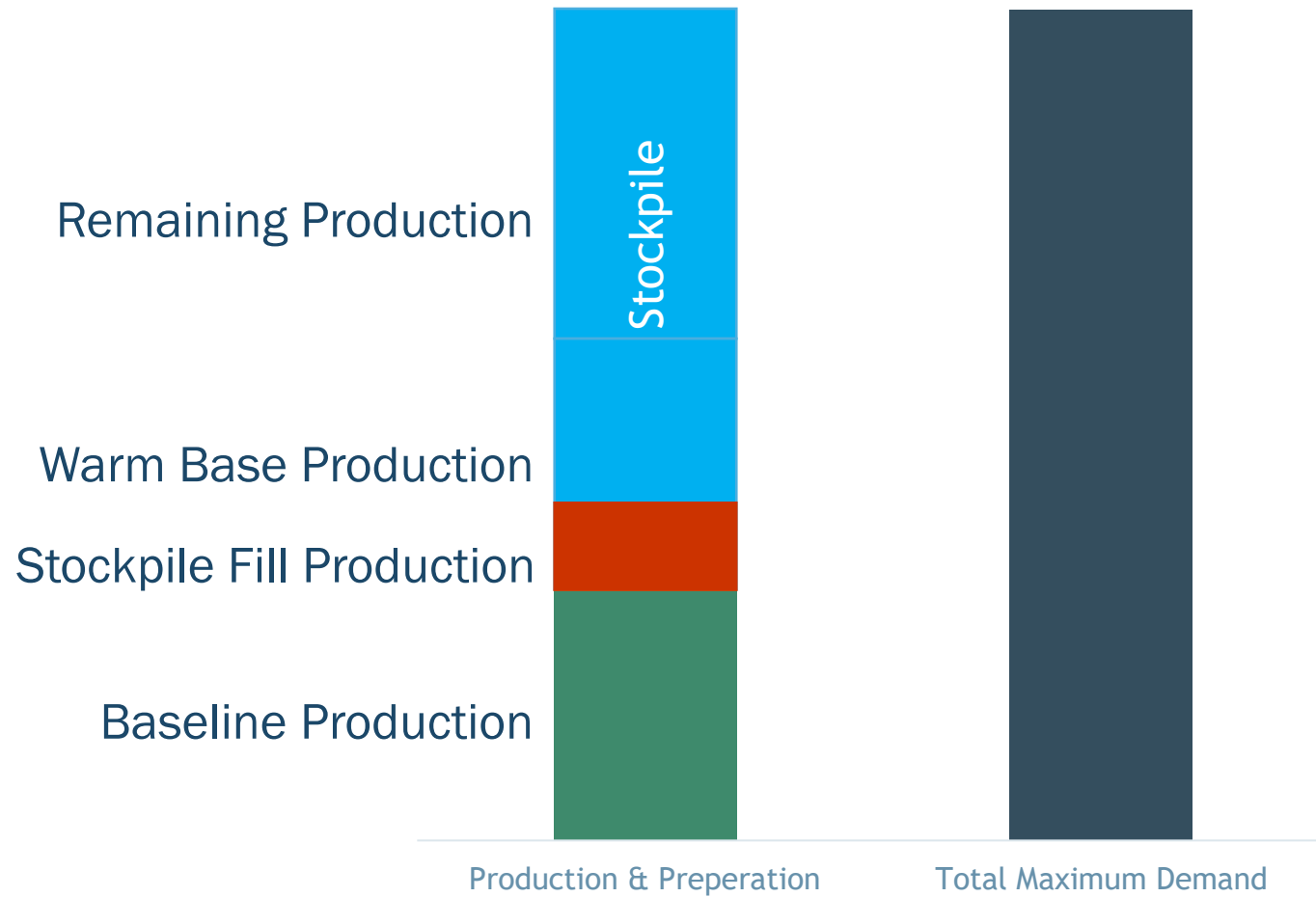
How much PPE do we need?



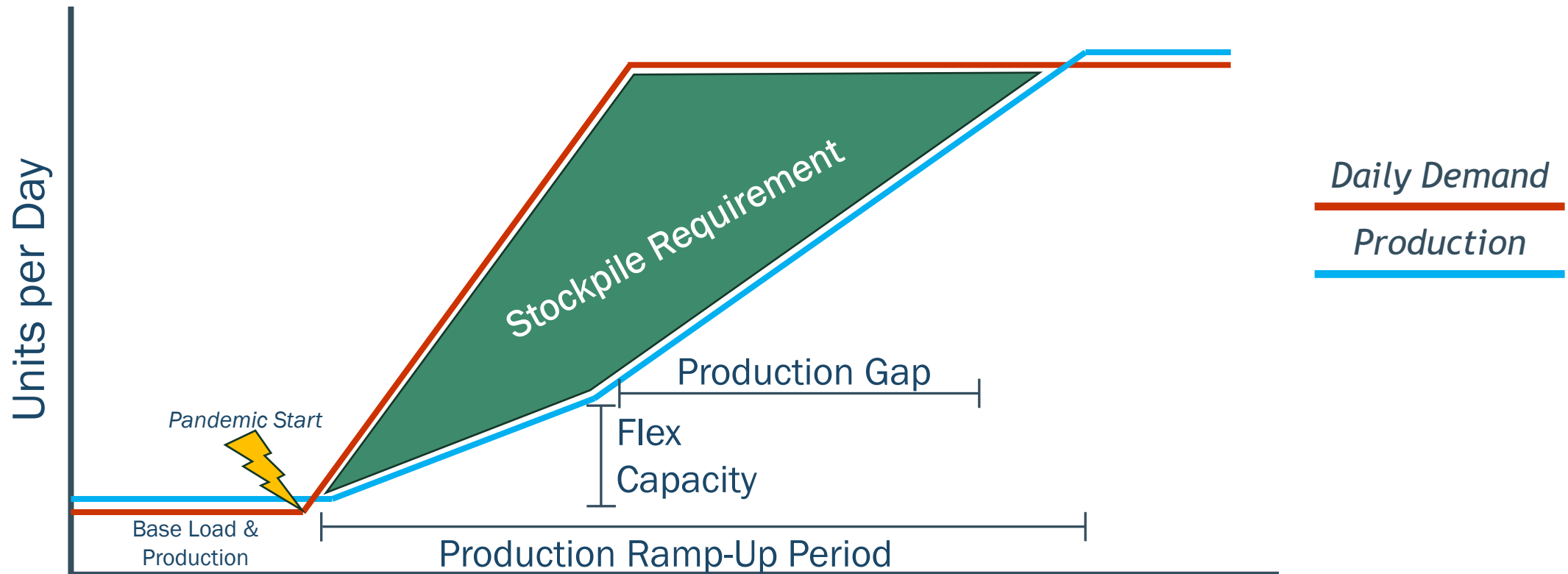
Rapid PPE Demand Growth



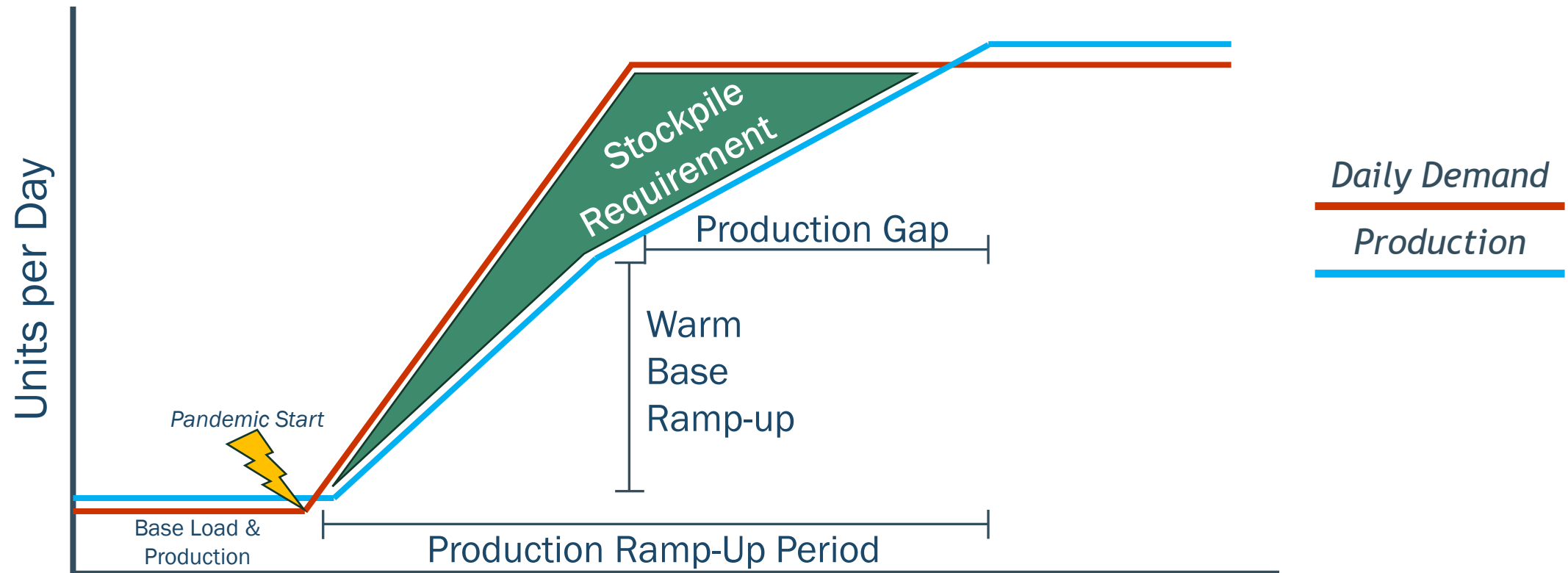
Meeting Pandemic Demand



Pandemic Supply-Demand Dynamics



Warm Basing Supply-Demand Dynamics



Surge Capacity

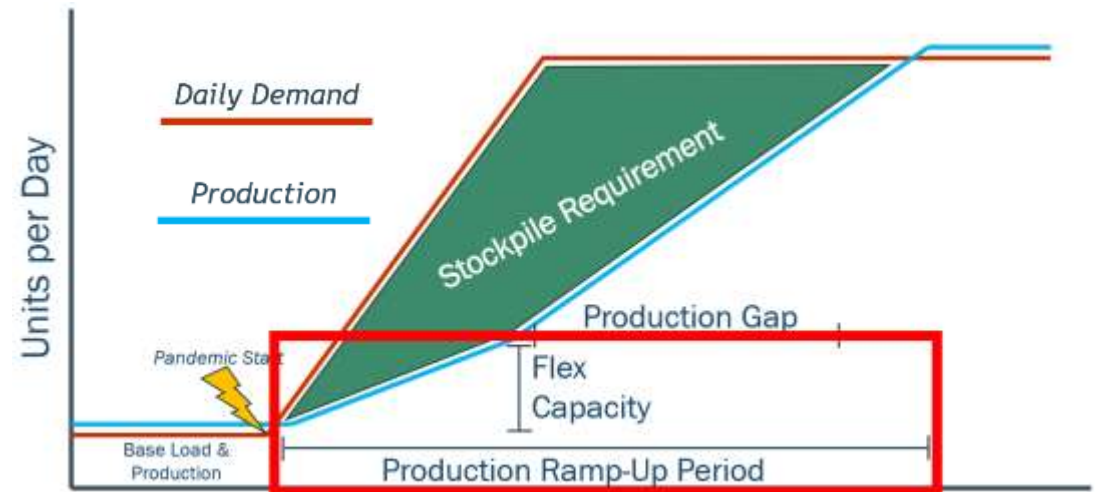
Dan Greene, PhD



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Surge Capacity: The Problem

- Routine PPE production is far below what is required during a catastrophic pandemic
- COVID-19 was not a “worst-case” disease and PPE availability in the first 6 months was still inadequate
- Manufacturers must rapidly surge production capacity to meet spiking demand in the ramp-up period



Surge Capacity Topics

1. Early Detection & Production
2. Warm-Basing Methods
3. Scaling Staffing





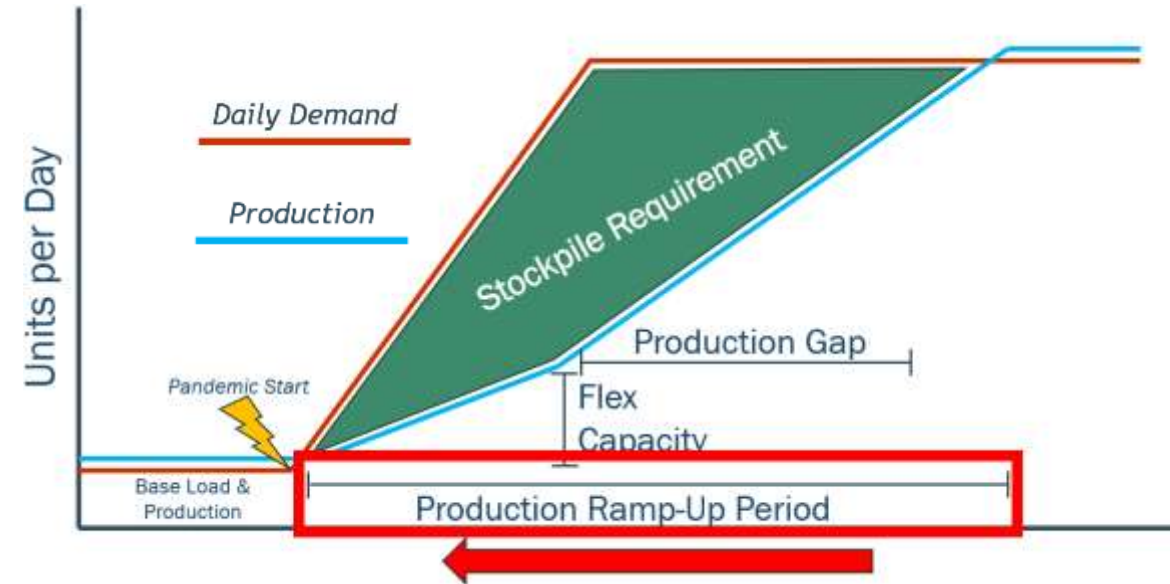
Early Detection & Production

Get ahead of the outbreak, reduce spin up time



Early Detection & Production

- 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
- Risk of overproduction and wasted inventory if the outbreak fails to materialize or is contained quickly
 - Governments could commit to purchase unsold inventory
 - Governments could pay industry a “readiness fee”



Questions

- Would private industry be willing to act on early-warning signals from government without additional incentives?
- If not, what type of guarantees (from governments) are needed for industry to act on early warnings?
- How often would “false alarms” need to be avoided for early production to be tenable?
- Would smaller companies be interested in early production efforts?





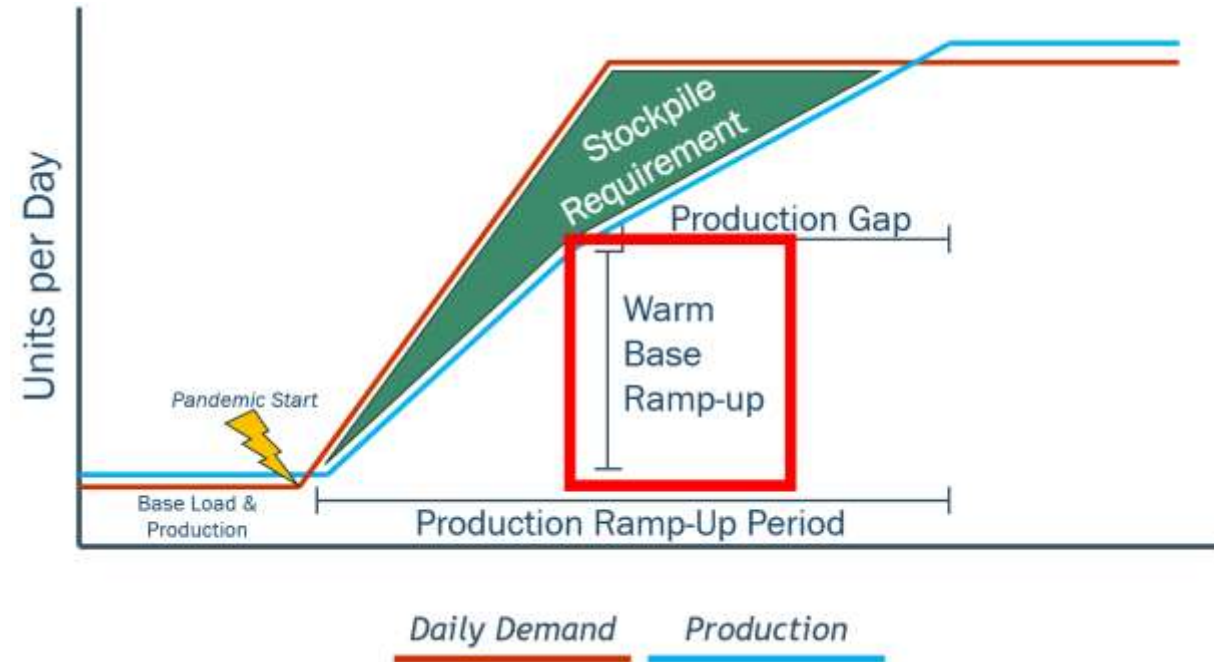
Warm-Basing Methods

Maintaining standby production capacity



Warm-basing: Background

- 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
- 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



Questions

- What warm-basing arrangements would be most effective?
- What level of fee is required to maintain equipment?
- How feasible is warm-basing for smaller companies with fewer production lines?
- What overlooked cost elements should be integrated into warm-basing options?
- Are other mechanisms to establish a warm base viable?





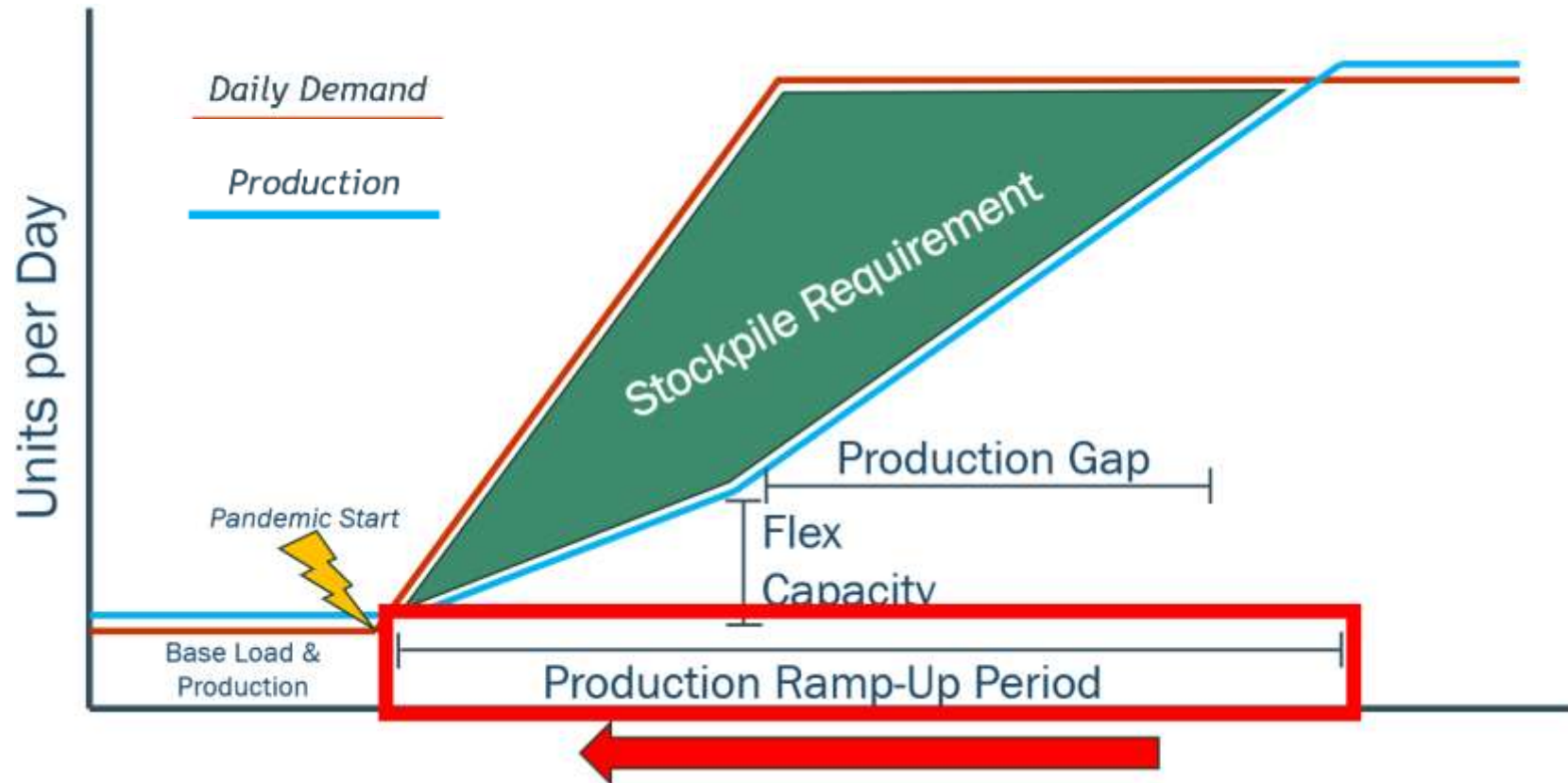
Scaling Staffing

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



German Technical School Model

- Partnerships between industries and vocational schools or community colleges to increase the workforce over time
- Companies create training programs and provide access to relevant equipment
- Schools implement the training programs to provide a more skilled workforce



National Guard Model

- Engage personnel that currently produce similar non-PPE products to instead produce PPE for a set amount of time regularly
 - Training would occur in PPE facilities
 - Training must be kept current
 - Would target similar industries
- When PPE need is high, called to active duty to produce PPE full time (or to a set capacity)
 - Reduces time needed to ramp up production to meet PPE demand
- Funding must be available for the training and maintenance of this program



Questions

- Are staff shortages enough of a problem to deserve focus?
- Is there enough present-day demand for PPE manufacturing to make technical school an appealing choice?
- Is the “National Guard model” attractive to PPE manufacturers if it were funded?
 - Concerns with IP or down time of lines
 - Is there a sufficient manufacturing base nearby that this even makes sense
- Are there other options to reduce training needs or time to full staffing for surge production?



Break

20 minutes



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Resilience in the Supply Chain

Dan Greene, PhD



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The Problem(s)

- PPE and precursor materials are produced in only a few countries
- During the COVID-19 pandemic, many countries had little situational awareness of their PPE supply chains, allocation, and demand



Supply Chain Topics

1. Domestic/regionalized production of PPE and precursor materials
2. Stockpiles of precursor materials
3. Government supply chain tracking

Covered later:

- Creating sustainable domestic markets
- Implementation details for stockpiles



Domestic/Regionalized Production of PPE and Precursor Materials

- Governments should fund and otherwise support domestic/regionalized production of PPE and precursor materials
 - *Example: HHS/ASPR awarding major contracts to US N95 and NBR manufacturing*
- Domestic vs. regional coordination will depend on country sizes and budgets
- May require foreign aid to stand up in some countries (see financing options later)



Stockpiles of Precursor Materials

- Some manufacturers currently maintain small stocks of precursor materials in case of emergency
- National, regional, or manufacturer stockpiles of precursor materials would create a buffer to allow manufacturing to continue while issues with foreign production or imports are resolved



Government Supply Chain Tracking

- Governments should regularly collect key supply chain data from manufacturers
 - Aligned with White House July 2021 “National Strategy for a Resilient Public Health Supply Chain”
- Integrate private-sector and state-level resources
- Include cybersecurity protections for business-sensitive or proprietary data
- Track to anticipate shortages and pay for buffers of precursors as needed



Questions

- Where would money go farthest in foreign aid for domestic PPE and precursor materials?
- Would it be cost-effective to pay domestic manufacturers to store buffers of precursors?
- What data are not worth collecting for government supply chain tracking (highly sensitive and not informative)?
- What examples of successful national PPE supply chain tracking can be followed?



Immediate Supply and Stockpiling

Evan Turner, MS



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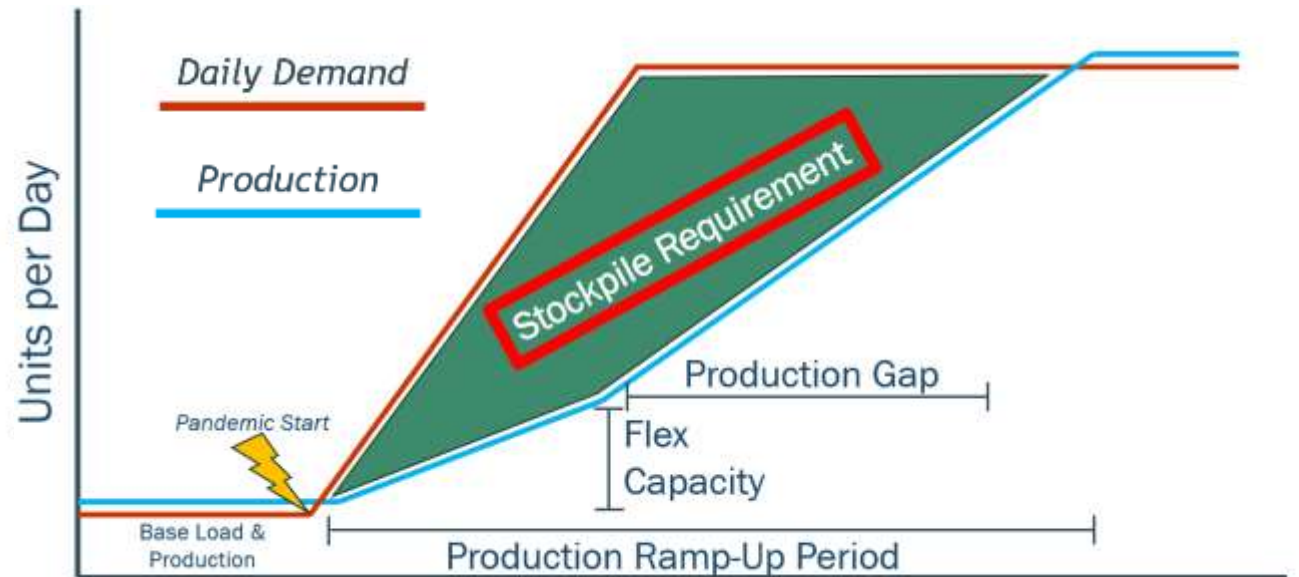
Immediate Supply Topics

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



Period of Immediate Supply

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



Why Not “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 intended to provide the immediate supply boost to buy time until production can catch up.



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
 - Governments





Inventory Management Methodologies



Vendor Managed Inventories (VMIs)

Vendors (e.g., manufacturers) have the infrastructure, capacity, and expertise to manufacture and store their PPE, with the added benefit of being able to rotate their stock to avoid expiration

The Pros:

- Vendors have experience/ expertise with inventory management creating lower associated costs with stockpiling
- Vendor stockpiles would link production capacity directly to stockpiles
- Waste could be reduced through stock rotation

The Cons

- Inventory turnover may not match required quantities of PPE
- Unclear what impact these inventories have on vendor operations
- May have limited space for storage of large stocks



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

The Pros:

- Distributors have greater experience/expertise with inventory management
- Distributors can stockpile & distribute mixed product inventories
- Distributors understand consumption rates of clientele
- Waste could be reduced through stock rotation

The Cons

- Inventory turnover may not match required quantities of PPE
- Distributors may be unsuited to manage stocks of products that are not purchased by their usual clientele
- Distributors may face difficulty releasing stocks to new stakeholders during an emergency



User Managed Inventories (UMIs)

Users are those who use the PPE day-to-day. By having these users stockpile goods, we would ensure that vital goods are already in the right place when a pandemic emerges.

The Pros:

- Onsite inventory grants immediate access in emergency situations
- Prevents stockout situations for frequent users
- Users might have the best insight into consumption rates
- Distributed storage builds resilience to multiple hazards
 - E.g., a hurricane in a pandemic

The Cons

- Increases costs on users
- Most are not used to stock rotation
- Very limited storage space
- May be more difficult for smaller users (e.g., small hospitals)
- Users may not participate willingly/enforcement may be required
- Not all users utilize PPE at a rate that could represent a crisis stockpile



UMI Options



Government healthcare facilities and hospitals gradually build up a 60-day supply of PPE for all locations and rotate stock



Emergency response agencies fund 60-day PPE UMI stockpiles, with rotation at fire stations and EMS bases



Government funds 60-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

The Pros:

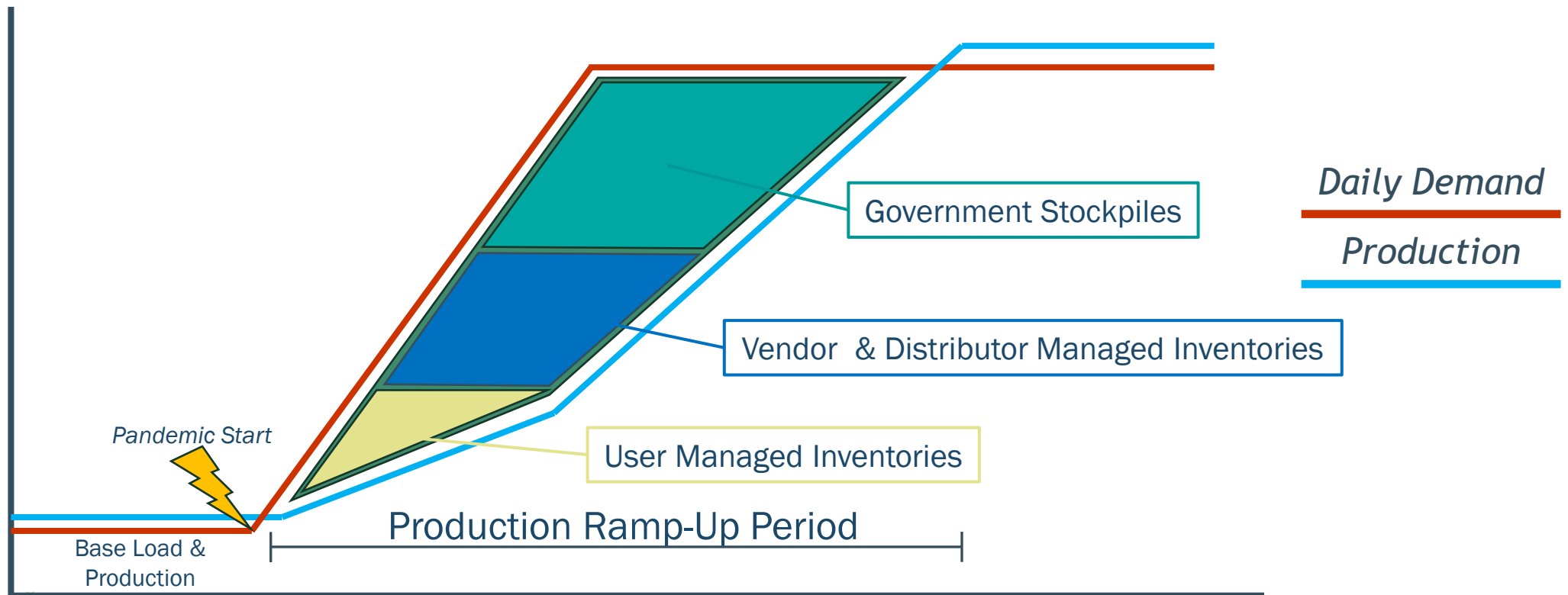
- Government stockpiles can operate at a loss (do not have to be profitable)
- Governmental control of supply could lead to more rapid hub & spoke distribution
- Government stockpiles can create more sustained demand for the PPE market

The Cons

- With no rotation of stock through normal use, expiry waste can be significant
- Trust in government stockpiles is low after the previous pandemic
- Total space requirements exceed the capacity of current government stockpiles
- Low- and middle-income countries might not have the infrastructure or funding for similar stockpiles



Distributed Stockpile Method



Distributed Stockpile

Placing the burden of the entire global demand on one group (governments, vendors, etc.) is unreasonable. Spreading both the burdens and the benefits of this global demand is likely the most reasonable method for sustaining the PPE supply

The Pros:

- Distributed stockpiles create inventory resilience
- Distributed stockpiles create new markets/revenue streams
- Will generate less waste than traditional stockpiling methods
- Reduces the amount managed by any one group

The Cons:

- Tracking multiple inventories could be complex
- Diverse storage locations of PPE can make distribution more complex
- Some methods may be price exclusive to certain regions
- Updating stocks for new PPE technology becomes difficult and tied to contracts



For a Functional Distributed Stockpile

- Data would need to be shared between systems in order 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

- What are other drawbacks of these systems?
- How much inventory could distributors hold as a buffer?
- If the fee to manage the inventory is high, management fees exceed expiry waste fees. What minimum level of fee would be acceptable?
 - Our estimates place warehousing costs of these goods *up to* 6.6% for N95's and 1.6% for EHMR's
 - If fee is too high, it becomes equivalent to expiry waste
 - A fee of 10% is equivalent to expiry waste for a product with a 10-year shelf life
- What quantity of PPE would manufacturers be able to rotate?
- Besides users, distributors, and manufacturers, are other organizations suitable for this type of stock rotation scheme (aid organizations perhaps)?





Lunch

1 hour



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Demand Signals

Barrier and Respiratory PPE for Vital Workers

Mindy James, PhD



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How are TPPs useful?

- Current PPE individually meets some of the targets, but no single product currently on the market satisfies all requirements
- The goal of targets is to create discussion of how to best protect vital workers while providing PPE that satisfies the users
- Novel products can be incentivized to meet the targets through subsidization or contract vehicles





Designing for TPPs

Solutions for Barrier and Respiratory PPE



Designing for TPPs

1. Barrier Protection

- Fit
- Protection
- Comfort
- Sustainability

2. Respiratory Protection

- Fit
- Protection
- Comfort
- Usability
- Sustainability



Barrier PPE - Fit

- Gaps
 - Currently available barrier PPE does not meet body diversity and biological requirements
- Proposed Solutions
 - Design adjustable body coverings (e.g., inclusion of pleats, elastics, etc.) for diverse bodies & functions
 - Body diversity (e.g., height, weight, body ratio, etc.)
 - Sex-specific characteristics (e.g., breasts, pregnancy, etc.)
 - Restroom access
 - Baseline body covering design can accommodate biological needs of women but also be appropriate for men
 - Design gloves to fit diverse hands
 - Anthropometry in addition to size
 - Product-as-service model of reusable gowns to enable larger range of sizes
 - Procurers ensure that PPE fits the bodies of their entire user population



Barrier PPE - Protection

- Gaps
 - PPE may become contaminated during use and serve as a source of self-contamination to the wearer
- Solutions
 - Use of graphene-modified fabrics to inactivate microbial contaminants
 - Inclusion of other biocidal agents (e.g., metals, quaternary ammonium, nanostructures, etc.) in barrier PPE



Graphene Isolation Gown: www.rhycommedical.com



Barrier PPE - Comfort

- Gaps
 - Impermeable body coverings trap body heat and sweat
 - Wearers need frequent breaks and PPE must be replaced
- Solutions
 - Heat:
 - Integration of phase-change materials (PCMs) into textiles
 - Use of infrared-transparent visible-opaque (ITVO) fabrics
 - Use of thermal conductive textiles
 - Moisture:
 - Use of Janus textiles
 - Incorporation of super absorbent polymers (SAPs)



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

Barrier PPE - Sustainability

- Gap
 - Use of disposable body coverings generates excess PPE waste and may present supply issues
- Proposed Solution
 - Where possible (e.g., in non-surgical settings) body covering PPE should be transitioned to reusable products



Image from: Kelman, 2022



Respiratory PPE - Designing for Fit

- Gap: Fit panels used in the design & testing of respirators are based on facial measurements from ~4,000 American workers
 - Underrepresentation of women and non-white ethnic groups hinders fit in these populations
- Proposed Solutions
 - Conduct research into anthropometry of the diverse human population
 - Utilize global anthropometric data in the initial design of respiratory PPE

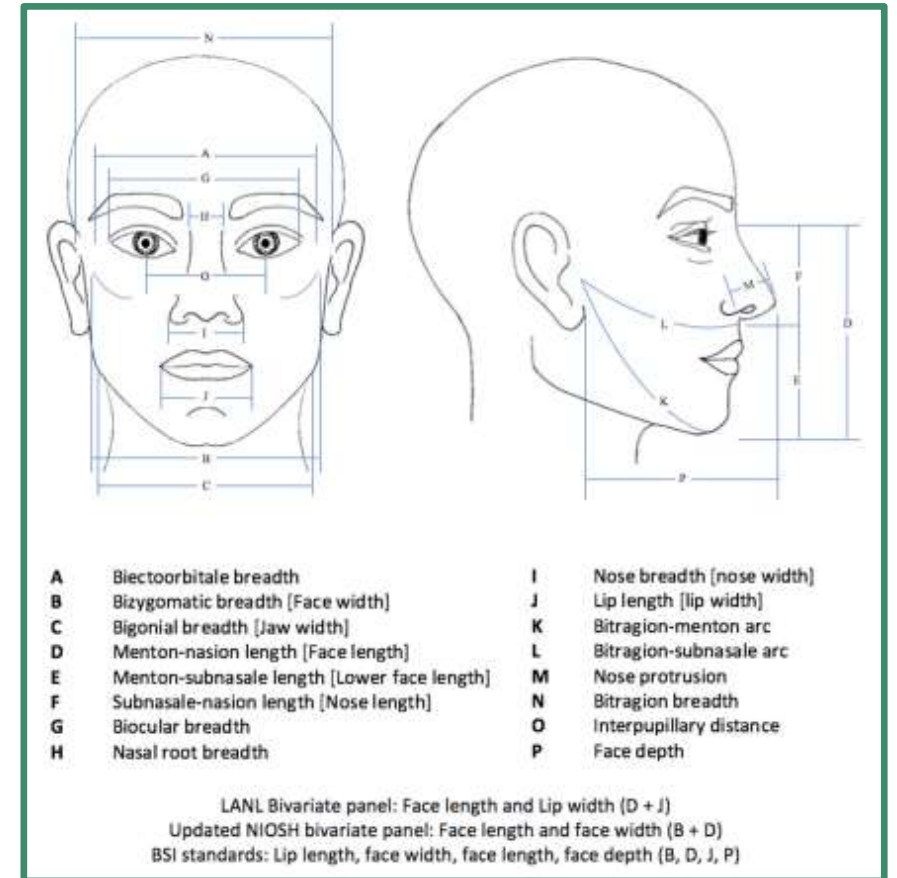


Figure from: Chopra et al., 2021



Respiratory PPE - Improving Fit

- Gaps
 - Low fit test passage rate for filtering facepiece respirators (FFRs)
 - Lack of respirator options for individuals with facial hair
 - FFR users may experience fit failure during use
- Proposed Solutions
 - Use of a novel face seal device designed to enhance FFR fit
 - Use of the Singh Thattha Technique to accommodate bearded individuals
 - Switch from FFRs to elastomeric respirators with moldable edges for improved fit



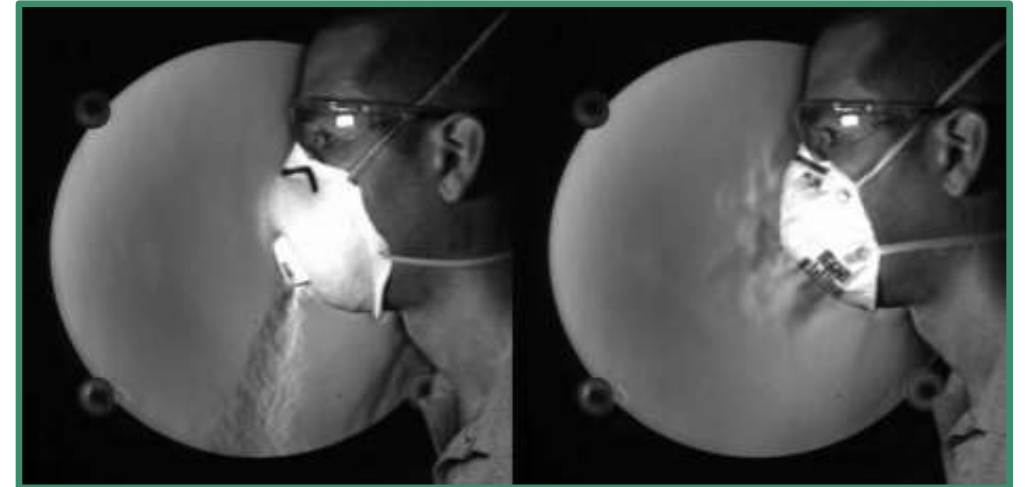
Respiratory PPE - Fit Assurance

- Gaps
 - Respirator fit may not be apparent
 - Users may lose respirator fit during wear
- Proposed Solutions
 - Design EHFRs with permanent fit testing ports
 - Provide fit assurance kiosks for rapid quantitative fit testing at entry to infectious areas
 - Include sensors in reusable respirators to sense and report on loss of fit



Respiratory PPE - Protection

- Gaps
 - Respirators with exhalation valves introduce unfiltered exhaust into the environment
 - PPE may become contaminated during use
 - Respirators often require detailed training for **proper** use
- Proposed Solutions
 - Design respirators with two-way filtration for user comfort and source control
 - Utilize biocidal fabrics to inactivate microbial contaminants
 - Design respirators so that minimal to no training is required for proper use



Exhalation images from: *Staymates*, 2020



Respiratory PPE - Comfort

- Gaps
 - Respirator users may find it difficult to breathe
 - Materials trap heat and moisture from exhaled air
- Solutions
 - Difficulty breathing
 - Use of polymer-based nanofibers to decrease breathing resistance while maintaining filtration
 - Heat & Moisture
 - ITVO fabrics to produce radiative cooling
 - Super absorbent polymers (SAPs) to absorb exhaled moisture
 - Janus textiles for unidirectional moisture transport

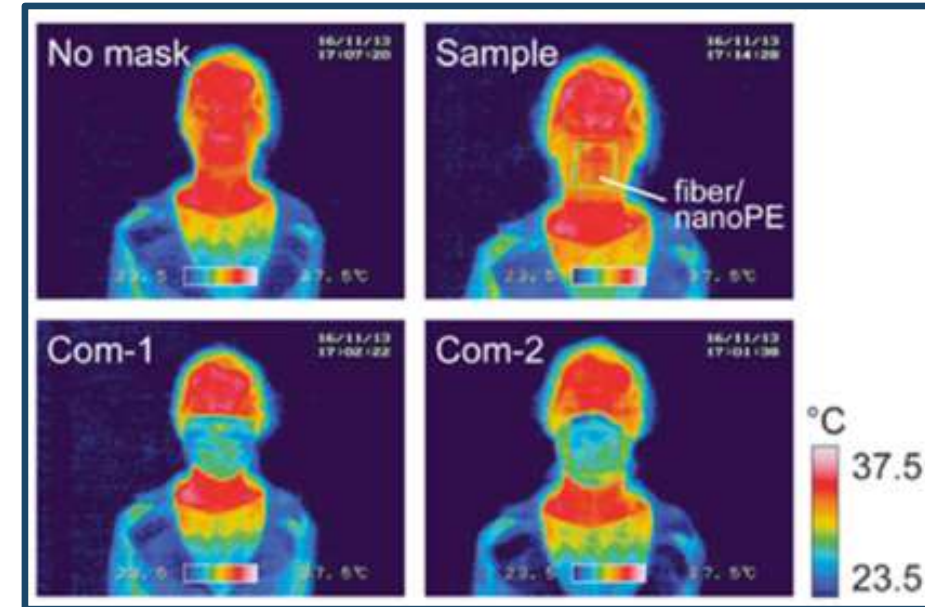
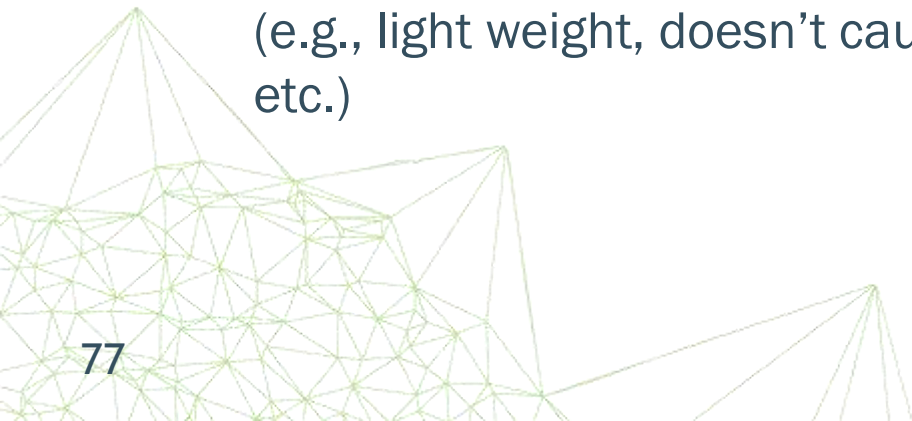


Figure from: Yang et al., 2017



Respiratory PPE - Enhanced Usability

- Gaps
 - PPE may hinder communication
 - Respiratory protection may not be suitable for long periods of use
- Proposed Solutions
 - Design respiratory PPE allows for communication:
 - Does not muffle speech
 - Provides a view of the user's mouth (e.g., clear front or hood)
 - Does not impair user's hearing (e.g., quiet PAPR motor)
 - Design respiratory PPE that remains comfortable over long periods (e.g., light weight, doesn't cause pressure sores or headaches, etc.)



Respiratory PPE - Sustainability

- Gap: Use of disposable respirators creates excess waste and may present supply issues
- Proposed Solution
 - Use of innovative reusable respirators:
 - Only filters are replaced
 - Filters may last up to one year and are interchangeable
 - Stockpiling of filters requires less space
 - Base portion of respirators can be decontaminated easily



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



Questions

- Which of these aspects is the most feasible to adjust? Which is the hardest?
- Can you see ways to move toward these targets quickly?
- What are the barriers to industry working directly with innovators and how can those barriers be reduced?
- What are the barriers to the product-as-service model for reusable gowns?



Sustainable Marketplace

Rocco Casagrande, PhD



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Inducing Regional/Domestic Demand



Goals

- 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



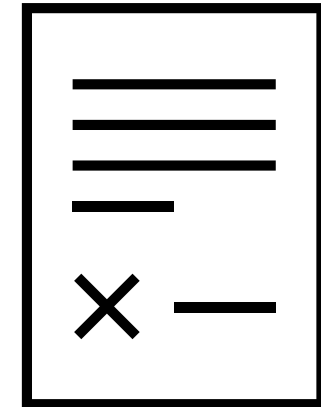
Sustainable Market Topics

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



Government Purchasing

- National and regional agencies can purchase PPE preferentially exclusively from domestic or regional manufacturers
- Government facilities such as hospitals and fire stations can be required to purchase only domestic PPE
 - This may be more effective in countries with national health systems that can drive significant demand
 - May require additional budget allocation if domestic 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*



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*
 - The burden of paperwork is significant – bi-weekly submission of cost sheets
 - Reimbursements are below the actual cost difference to purchase domestic PPE
- Well-designed programs could improve adoption of domestic or regional 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



Questions

- We heard from many participants that domestic purchasing rules are not working as intended. What isn't working?
- Would domestic PPE purchasing requirements cause buyers to evade requirements or underbuy PPE?
- What would be more effective: domestic PPE purchasing requirements or subsidizing domestic PPE?
- In the US, are government buyers a large enough market to sustain a domestic industry?



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



Labor Union Requirements for High-Quality PPE

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



Pilot Programs for Innovative PPE in Healthcare

- Pilots of elastomerics have been popular
- Demonstrate to hospitals that they work, are comfortable and are cost-effective long-term
 - Test in emergency departments and isolation wards
 - Evaluate popularity among HCWs, effective infection rates, logistics, cost savings
 - Evaluate logistical burden of maintaining a reusable PPE program
- NIOSH pilots of adapters for exhalation valves and comparative studies of novel products



Government Promotion of TPPs

- National governments can tie purchasing to movement to TPPs over time
- This could include long-term contracts that can only be renewed if models consistently move more into alignment with TPPs
- Governments can set a cut-off date after which they will not purchase PPE failing to meet a standard higher than the current one



Questions

- What is more effective to convince manufacturers to produce products in alignment with the TPPs:
 - Guaranteed purchasing
 - Insurance incentives
 - Support for entering new markets
- What level of financing is necessary to develop production capacity in underserved regions?





Financing Products



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



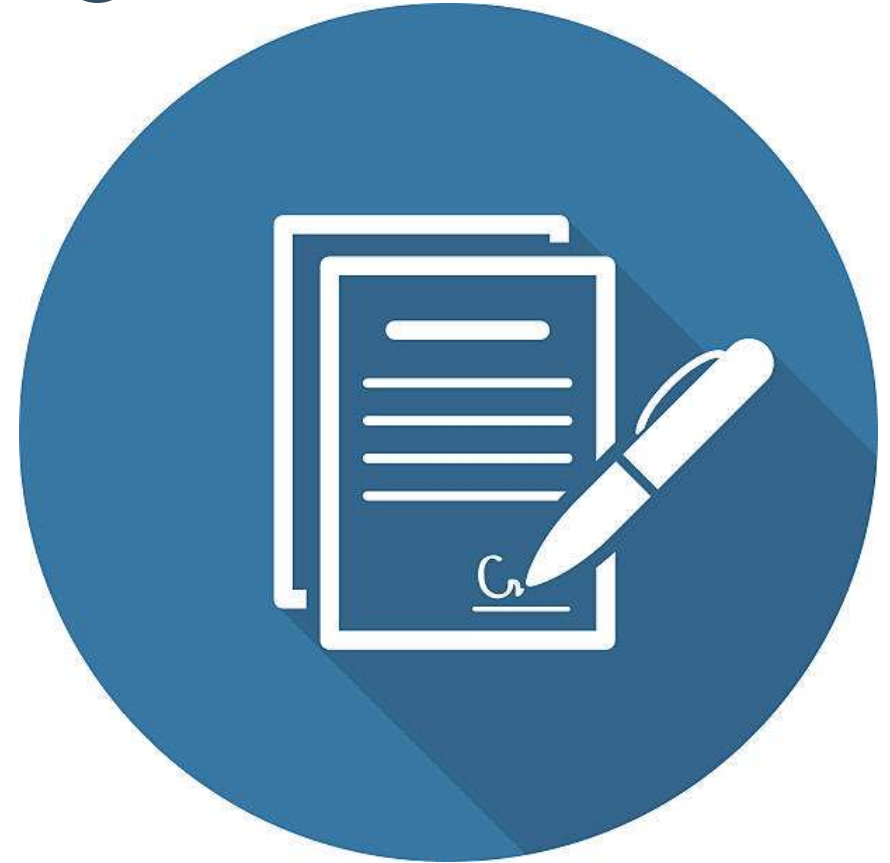
Contract Vehicle Topics

1. Advance Manufacturing Contracts for existing products
2. Volume Guarantees to distribute production
3. Contract Structures



Multi-year Government Contracts for Immediate PPE Purchasing

- Immediately useful for filling stockpiles
- Awarded to company/companies that can deliver the most PPE per dollar
- Helps build manufacturing capacity as stocks are built
- 5-year contracts were preferred by many manufacturers in discussions



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)



- **Advance market commitment:** If manufacturers develop a novel PPE product that meets target product profile, 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



Questions

- What are the pros and cons of these various options from the perspective of industry?
- 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

20 minutes



Reducing Product Barriers

John Baggett, PhD



Reducing Product Barriers Topics

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



PPE Nomenclature & Standards

- Gaps:
 - There is no standardized nomenclature for PPE internationally
 - Regulatory standards vary for the same PPE across countries & regions
 - Labeling and information requirements may be a barrier
- Proposed Solutions
 - Develop and implement common global nomenclature and data sheet formats for PPE
 - Align international PPE standards (single global standard, preferably not ISO)



U.S. N95



European FFP2



Japanese DS2



Worker Protection Agency Regulations

- Gap: Regulations set forth by worker protection agencies are inflexible and may not allow for use of innovation solutions
 - *Example: U.S. regulations require contact of a respirator with the user's skin, thereby preventing the use of fit solutions such as the Singh Thattha technique*
- Solution: Increase the flexibility of regulations for PPE so that innovative solutions can be used without the need for full revision of regulations
 - *Example: U.S. OSHA has agreed to adjust regulations pending NIOSH study of technique*



Singh Thattha Technique: Bhatia et al., 2022





Regulatory Advisory Networks

- Gap: Navigation of the regulatory landscape is difficult for new market entrants, slowing down new products and wasting money
- Solution: Establishment of PPE product development advisory networks
 - Network of individuals with expertise in product development providing low to no cost advisement for novel PPE producers
 - Aid in navigating the regulatory landscape and product approval process
 - 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?
- 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
- What would it take to have the Singh Thattha technique be acceptable in occupational health programs?



Post-Market Surveillance

John Baggett, PhD



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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



Improper Use Index

- Collect and report additional evidence for respiratory PPE effectiveness considering imperfect and ideal use
 - Similar to the Pearl Index for contraception,
 - Including protection of respirators without fit testing.
- 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



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?



Wrap-Up & Next Steps



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Thank you!

- Thank you very much for your time and input today
- We were cheered by how much interest there was in this study and how many of you sent extra representatives to this meeting



Next steps

- Your feedback today will reduce the number of possible solutions to finally evaluate and reshape even more solutions
- Our final cost-benefit evaluation will be used to chart a path forward to obtain PPE that is:
 - effective against the next pandemic
 - available in the quantities needed at the time it is needed
- Our final workshop will be held in late November
 - We will review final proposed solutions for refinement and feedback with a group that includes government, industry, funders and NGO
 - We are limited in space and resources with the number of people who can attend and, once again, enthusiasm for attending is unexpectedly high
- Our final report will be issued by the end of 2023

What are the gaps?

What are the goals?

How are the goals achieved?



Next steps

- If you had feedback that you didn't get a chance to share with us today, please email me with it
 - Rocco@gryphonscientific.com
 - This request applies to industry AND government/philanthropic observers
- We will specifically reach out to other (non-industry) stakeholders for feedback on specific solutions over the next two months
- Please let us thank you by having some final food/drinks on us up the street!

