Roadmap to Deliver eN95s to HCW and High-Filtration Masks to the Public Flatten The Curve In 3 Weeks

WITH POLITICAL WILL, AN 8 WEEK ACCELERATED PUSH CAN YIELD
HIGH-FILTRATION MASKS FOR 100 MILLION+ PEOPLE IN FEBRUARY 2021

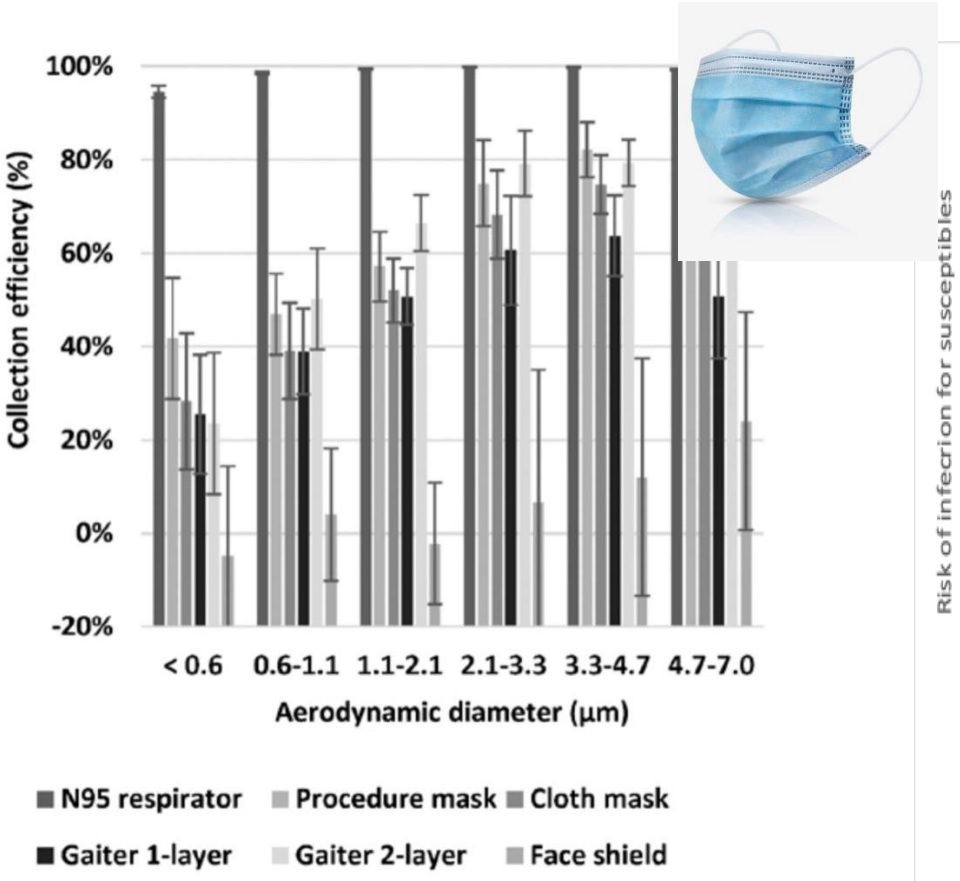
Agenda

- Need for High Performing Masks
- Finally, a Measurement Standard, Sealing Face Coverings
- Filter Media & Filter Fabrication
- Industrially Viable Short Term Solutions
- Scaling Elastomeric N95s for HCW - Synergy & Alignment
- Federal Will, Leadership, Capital Expense
- CDC, Administration

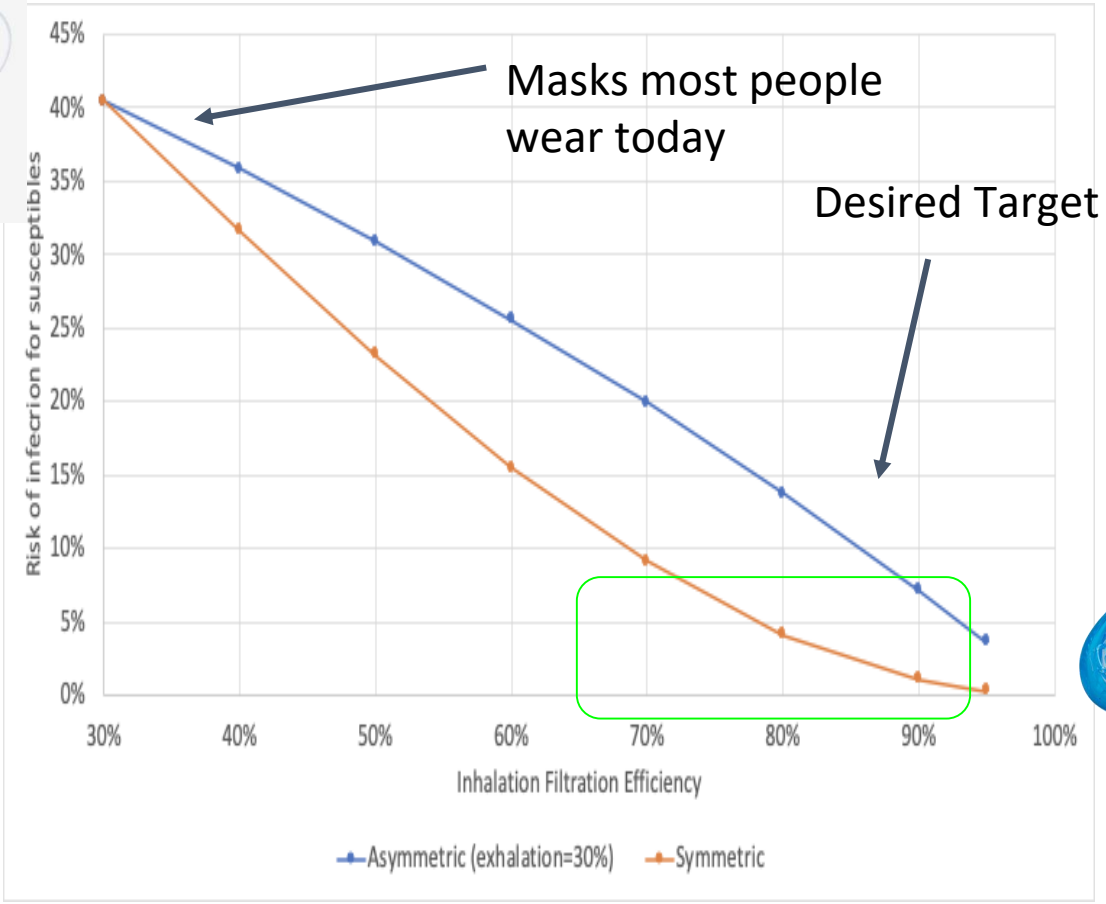
Evidence that higher-filtration masks are needed

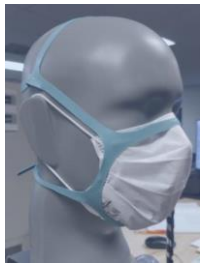
Study	Result
DANMASK-19 study,	Randomized Control Trial (RCT) showed wearing surgical masks in the community did not protect wearers https://www.acpjournals.org/doi/10.7326/M20-6817
Finnish study of healthcare workers	Healthcare workers in units provided with N95 respirators showed superior protection when N95 respirators were worn continuously compared to those provided with surgical masks https://www.medrxiv.org/content/10.1101/2020.08.17.20176842v1
Argentinian cruise ship	Widespread transmission of SARS-CoV-2 even though surgical masks were provided. https://thorax.bmj.com/content/75/8/693
Long-haul Airplane Flight (Boeing 777)	Transmission on airplanes appears to have been mitigated but not eliminated by universal mask wearing, suggesting that improved source control and personal protection could make important contributions https://www.washingtonpost.com/travel/2020/11/20/new-zealand-flight-covid/ https://research.esr.cri.nz/articles/preprint/A_case_study_of_extended_in-flight_transmission_of_SARS-CoV-2_en_route_to_Aotearoa_New_Zealand/13257914

Take-away: High filtration Masks = Near Zero Infection Risk



CDC Source Control Study, Oct 2020



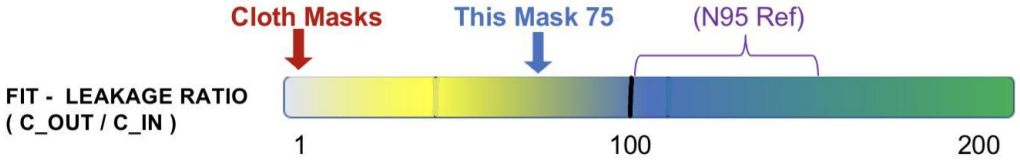


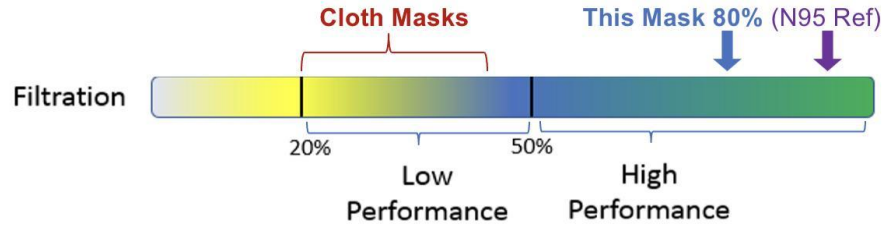
Based on Dr. Jose Jimenez's aerosol model http://tinyurl.com/covid-estimator
https://www.medrxiv.org/content/10.1101/2020.11.10.20227710v1

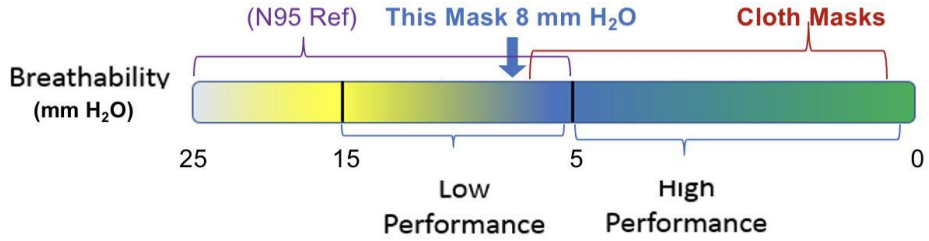
General Public Mask Standard (ASTM WK73471)

- ASTM – Respected Industrial Standard Body
- Essence:
  - Allows use of widely available materials that provide high performance filtration without impacting N95 supply to frontline responders.
  - New and Existing Mask Fabricators Can Scale Supply within 6 Weeks
- Performance Measures
  - Sub-micron Particle Filtration (i.e. 95%)
  - Breathability
  - Inward Leakage Assessment
- Eliminates Lengthy Testing / Approval Process
- Chaired by CDC Deputy Director Jonathan Szalajda
- Impact: Immediately contrasts surgical and cottage industry non-sealing masks with a high performing masks made to measurable standard.
- Jan 4 Vote Jan 12 Special Meeting Feb 12 Release

- NOTE: Establishes measurement method, defines ranges.
- Exact performance of a point design can vary within the range.



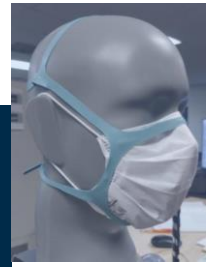




ESTABLISHES A MEASUREMENT FRAMEWORK - DOES NOT STIPULATE EXACT PERFORMANCE LEVELS PER USE CASE

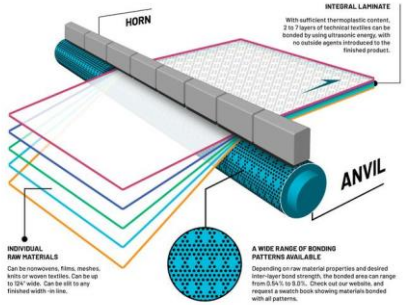
Which Styles Scale Fast

- US Scaled Disposable N95 Capacity Only to Front Line Responder Level - Long Lead & High Capital Expense
- Manufacturability of Flat Filters vs. Complex Formed Shapes
  - Flat is readily producible using existing equipment with capacity.
  - Avoids lengthy / expensive capital equipment procurement
- Additional Benefits
  - Durability of Elastomeric Mask and Filter
  - Comfort (Soft Seal, Minimal Steam to Eye Glasses)
  - Quality of Seal / Level of Protection
  - Filters last longer and potentially reusable after drying out (CDC)

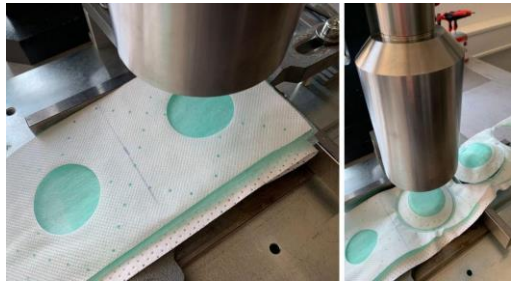


Flat Filter Fabrication

Step 1: Create Filter Layer



Step 2: Assemble Layers



Step 3: Weld / Cut

- Filter Layer Creation
  - New Non-woven Filter @ N95 level
  - Excess Meltblown @ N95 Level (if available)
  - Many High Availability Non-N95 Materials that Approach N95 (i.e. N80)

- Layering to Create Laminate Stack
  - Numerous Existing Manufacturing Lines Currently Running Below Capacity(i.e. Upholstery)
- Welding / Die Cutting
  - Inexpensive, Custom Shape Equipment within 6
- NOTES
  - Equipment for formed shape disposable N95s is long lead / $$$$
  - Pleated surgical mask equipment is available to support elastomeric harness approach.

Elastomeric Mask Fabrication




- Injection Molded Piece Parts
  - Tooling: Accelerated Production in 6-8 Weeks
  - Production: Enormous National Capacity
- Resin Availability
- For Existing Masks that May Already Meet NIOSH or FDA Requirements, Tool Designs Already In Use. Simply Scale Existing Designs

Injection Molding Tool

Injection Molding Machine

Polymer Resin

Elastomeric N95s for Frontline Workers

Elastomeric Masks

Reduced N95 Material Demand

Extended Life

Short-term Strategy:

Scale Existing eN95 Tooling Frontline Workers (N95) & Public (ASTM)

Recent Approval of Valveless Respirator (MSA Safety)

EUA for Sealing Valves ?

Dedicate N95 Filter Capacity to Frontline Responders

Dedicated ASTM Level Filter Capacity to General Public

Messaging / Communication

- CDC Recommend Public Use ASTM Standard Masks to Highest Available Performance Level
  - This will create instant demand.
- President Elect Coronavirus Task Force
  - Title III Funding Support to Rapidly Scale
  - Decision: Federal Funding of Mask Cost for Citizens
  - Public Advocacy, 100 Days of Masking
- Motivate via Public Messaging:
  - Convene Working Group of Health Communications Experts to Drive Adoption

Biden Asking for “100 Days of Masking”