

Masks and Respirators During COVID-19

- Masks and respirators
 - Risk assessment, functions and limitation
- Approvals and regulations: FDA, NIOSH, and CPSC
- Worker PPE use versus the public
 - NPPTL, OSHA and ASTM
- How masks and respirators are constructed
- How particles travel: droplets vs aerosols

Healthcare Workers

- More than 18 MM workers are employed in the healthcare industry
- PPE used to protect disease transmission to HC workers and to patients
- Standard precautions
- Bloodborne pathogens
- Influenza, Tb and COVID-19

Masks

- Face masks are terms used to describe a loose fitting device worn over the nose and mouth



- Masks are designed to reduce transfer of infectious fluids among individuals not small virus aerosols
- There are surgical, procedural and other types

Examples of Masks and Facial Coverings



Comfort mask



Face mask, non-surgical (FDA)
Procedure mask



Facial
covering



Facial
covering

Masks and Face Coverings

- Surgical masks are sterile and have ties that go over a surgical cap.
- Procedure masks have ear loops
- There are dental masks and masks for children
- There are homemade face coverings
- Masks are designed to reduce contamination from the wearer to the environment.
- Masks with exhalation valves are an oxymoron
- Masks and face coverings keep the wearer from touching nose and mouth

Some Newer Mask Concepts

- LG powered air mask

South Korean electronics company LG has integrated electronic fans and HEPA filters into a face mask



Some Newer Mask Concepts

- the SEEUS95 mask



Some Newer Mask Concepts

SEEUS95 mask claims better protection than market leading masks made from non-woven polypropylene or cloth. the clear, earloop free, self-adhesive and kind to your skin mask features a sustainable design made from all-natural, environmentally safe materials. for example, bamboo has more tensile strength than steel and is naturally anti-bacterial and anti-microbial, absorbing moisture in the air which carries viruses. the silk fiber is strong, also anti-bacterial and carries an electrostatic charge that attracts viruses. the nano silver (AgNPs) purifier.

This is a HEPA filter face mask with a built-in, two-speed micro electric fan that provides boosted airflow compared to a typical mask.



Convertible Mask



Cambridge Mask Accessories

Optional head strap and nose foam accessory pack to help improve mask fit. This mask comes in four sizes. Meets EU respirator requirements for fit and filter performance

Respirators

- Respirators are designed to protect the respiratory tract from airborne hazards
- Most respirators require a tight seal to the face
- Respirators were not intended to reduce the spread of contamination from the wearer
- Most respirators have exhalation valves
- Controversy of elastomeric respirators in healthcare

N95 Respirators

- The term N95 is frequently used to describe a filtering facepiece respirator w/N95 filter
- There are many models and these are generally designed to be disposable



Chinese KN95 Respirators

KN95-Chinese standard similar to NIOSH N95

The FDA has removed respirators made by 60 companies in China from its emergency use authorization (EUA) list for COVID-19 over concerns that they may be “sub-standard.”

NIOSH has completed more than 60 assessments of respirators from China that were on the April 3 list and has found a greater than 60% failure rate.

Counterfeit N95 Respirators

No markings at all on the filtering facepiece respirator

No approval (TC) number on filtering facepiece respirator or headband

No NIOSH markings

NIOSH spelled incorrectly

Presence of decorative fabric or other decorative add-ons (e.g., sequins)

Claims for the of approval for children (NIOSH does not approve any type of respiratory protection for children)

Respirator has ear loops instead of headbands

Elastomeric Respirators

- Elastomeric respirators are those designed to be cleaned and disinfected.
- They are more robust respirators with better head straps and frequently come in three sizes.






envomask

NIOSH N95
TC-84A8448
Sleepnet
39827

this side
out

Sleepnet 73950

envo

Powered Air-Purifying Respirators

- PAPRs have a motor that blows air through filters and into the facepiece.
- Many models do not require a tight seal
- Used for high aerosol generating procedures



The Transition of Masks and Respirators

- Covid 19 is creating a unique situation where the design/intention of masks and respirators are beginning to merge
- Examination of exhalation valves as sources of transmission on respirators
- Development of better fitting masks and better filtration materials

Reusing “Disposable Respirators”

- Most filtering facepiece respirators were not intended to be cleaned, disinfected and reused.
- Enormous numbers of these respirators are required during the pandemic.
- Shortages have led to reuse with various disinfecting methods: e.g. vaporous HP
- However, these were never meant to be reprocessed: thin elastic straps and thin foam nose pieces.

The Economics of “Disposable Respirators”

- Normally, FF respirators cost \$1.25 each
- Reprocessing with vaporous HP can cost \$4-5 each (Boston experience with Battelle unit)
- Why not invest in better FF if reprocessing is going to occur with cotton adjustable straps and better nose padding?
- Reprocessing methods don't clean respirator, just disinfect them.

Variations in FF Respirators



PPE

- Respirators and masks are a form of personal protective equipment
- PPE requires a risk assessment be conducted to select the type that is appropriate
- Face masks are rated: Level 1,2,3 with respect to fluid resistance and filter penetration
- Respirators are given ratings based on filter efficiency (95,99 and 100) and also APFs for facepiece leakage.

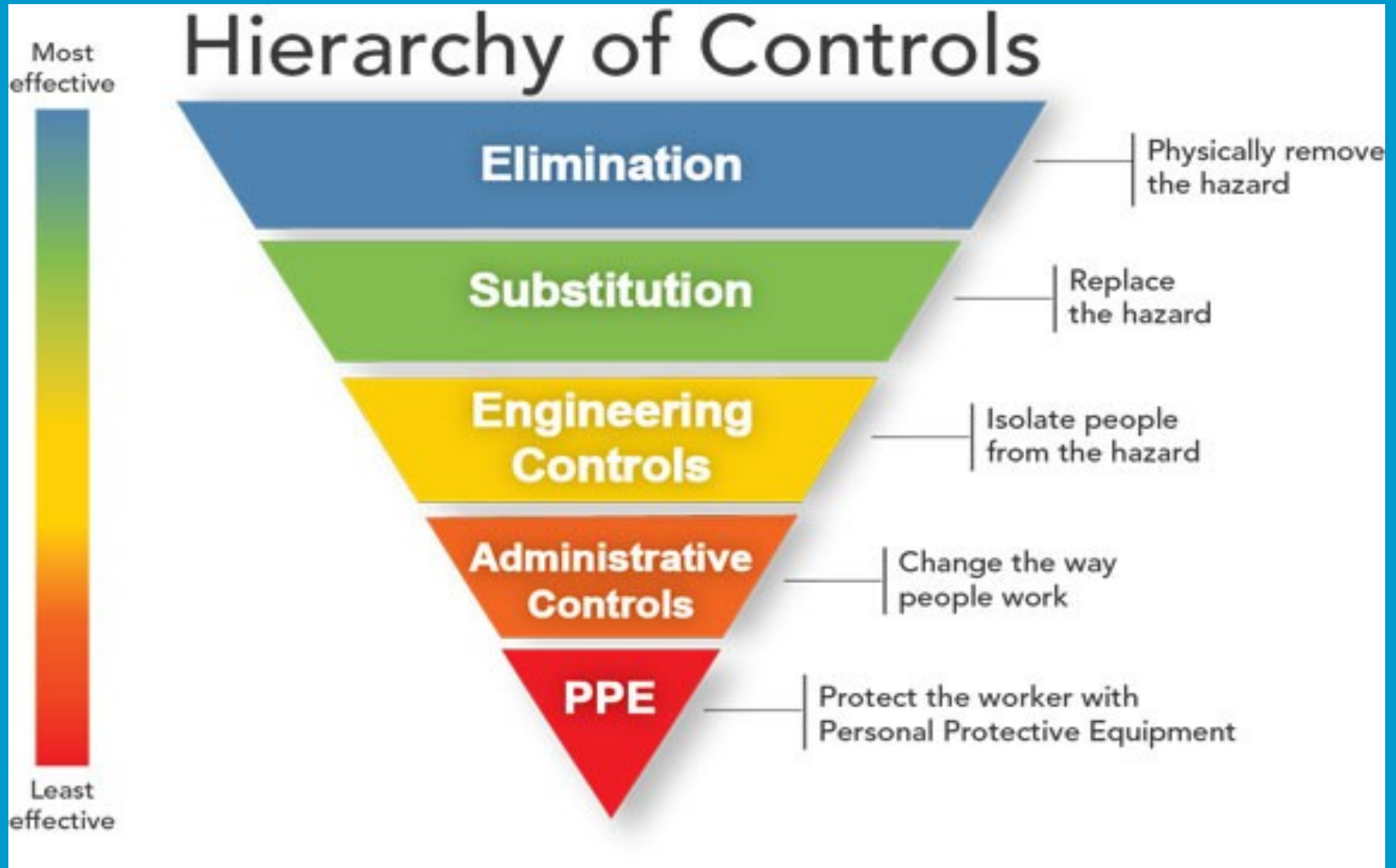
PPE (2)

- Homemade masks using cloth material have a much higher breathing resistance for the same filter efficiency used in medical masks and respirators.
- Studies of cloth masks indicated penetrations of 4 - 90% of particles challenged compared with less than 5% for N95 respirators

PPE (3)

- Face shields and goggles are also important protection for airborne exposure
- The eyes are a source of entry for virus and masks and N95 respirators only cover the nose and mouth.
- These devices must be cleaned and disinfected after each use.

Hierarchy of Controls



Respirator Risk Assessment

- Respirators are chosen based on the type and severity of the airborne hazard
- “Protection Factor” indicate the level of protection a respirator is expected to provide when used in an acceptable program
- N95 FFR and elastomeric half-facepiece: 10
- PAPRs: 1000
- SCBA: 10,000

Respirator Risk Assessment (2)

- Acceptable level of exposure (OEL)
- Actual exposure/protection factor \leq OEL
- Example benzene has OEL of 1 ppm
- If we have 100 ppm in workplace, we need a respirator with protection factor \geq 100
- N95 FFR and half-facepiece: 10
- FF w/N95: 20, FF w/ P100: 50
- PAPRs: 1000

Respirator Risk Assessment (3)

We cannot measure virus in real time

We do not have an OEL for COVID-19

History of Regulations Governing Masks and Respirators

- US BOM began approving respirators in 1920
- Regulations applied to workplaces

The Bureau applied guiding principles establishing basic requirements for all types of respiratory equipment. (1) they must give adequate protection; (2) they must be reasonably comfortable and physically convenient to wear; (3) they must provide protection for an acceptable time period; and, (4) they must be constructed of durable materials.

History of Regulations Governing Masks and Respirators (2)

- BOM began approving filtering respirators in 1934
- At that time, there were no national requirements such as OSHA (established in 1970) requiring the use of BOM-approved respiratory protection equipment in workplaces. Despite the absence of a regulatory requirement, reputable manufacturers voluntarily sought the Bureau's approval.

History of Regulations Governing Masks and Respirators (3)

- The first respirator approved was the MSA Gibbs respirator for mining rescues
- Miners Wearing The Gibbs Respirator



History of Regulations Governing Masks and Respirators (4)

1917 MSA Dust mask



History of Regulations Governing Masks and Respirators (5)

- 1940's BOM conducted human subject wearing inspections and lab testing to assess conformance to requirements.
- Dust respirators were tested against relatively high concentrations of quartz dust, lead dust, chromic acid mist, siliceous mist, lead paint mist, or lead fume, depending on the purpose for which the device was designed.

History of Regulations Governing Masks and Respirators (6)

- 1970 OSH Act created OSHA and NIOSH
- OSHA created regulations governing employers that required the use of respirators: medical clearance, training, fit testing and proper selection including only approved respirators.
- NIOSH (part of CDC) took over testing and approval of respirators from BOM

NIOSH Certification of Respirators

- NIOSH is the only US agency that has authorization to approve respirators
- NIOSH has different requirements for a variety of respirators: N95s to SCBAs
- NIOSH requires that mfg. supply quality control program and test data during submission.
- NIOSH performs its own tests on respirators submitted by manufacturers

NIOSH N95 Certification (2)

- Has standards for:
 - breathing resistance
 - filter efficiency: 95,99, and 100
 - use in oil environments: N, R, and P
- Approves mfg. instructions, labels and modifications
- Will audit mfg. and their quality assurance program every other year
- Assigns TC number and information is online
- Performs random testing from respirators in the marketplace

FDA Regulations

- FDA considers masks and respirators used by healthcare workers to be Class II medical devices.
- FDA must “clear” these devices before they are sold. FDA does not regulate their use only their sale by manufacturers
- FDA does no testing but relies on data provided by manufacturer from ASTM

FDA Regulations (2)

- FDA identifies surgical masks that must be sterile and have ties
- Procedural masks used by healthcare workers in non-surgical situations with ear loops
- Other masks that make claim of protecting workers or patients may require FDA clearance

FDA 510-K

N95 respirators and facemasks

- filter efficiency
- resistance to airflow
- flammability
- biocompatibility
- fluid resistance

ASTM F2100-11

TEST	LEVEL 1	LEVEL 2	LEVEL 3
BFE (Bacterial Filtration Efficiency) at 3.0 micron ASTM F2101	≥ 95%	≥ 98%	≥ 98%
PFE (Particulate Filtration Efficiency) at 0.1 micron ASTM F2299	≥ 95%	≥ 98%	≥ 98%
Delta P (Differential Pressure in mm H₂O/cm²)	< 4.0	< 5.0	< 5.0 (<0.04 inches/cm ²)
Fluid Resistance to Synthetic Blood ASTM 1862, mm Hg	80	120	160
Flame Spread	Class 1	Class 1	Class 1

ASTM F23.65 Barrier Face Covering

- New standard chaired by NIOSH
- Testing:
 - filter efficiency (bacteria and inert aerosols, breathing resistance, impact of cleaning)
- Will prohibit vents w/o filters
- Labeling: correct sizing, placement on the face, maintenance

AATC M14-2020

Guidance and consideration for General Purpose Textile Face Coverings: Adults

- American Association of Textile Chemists and Colorists
- Voluntary guidance for design, construction, and labeling of reusable textile face coverings for adults
- Seven page document with extensive information

A Fabric Mask for Enhanced Effectiveness, Comfort, and Compliance

Produced a mask that was form-fitting, customizable, washable, and could be worn continuously and routinely over extended periods of time by individuals and therefore could serve as an effective means to reduce the harm from SARS-CoV-2.



Positioning Component

Positioning Component

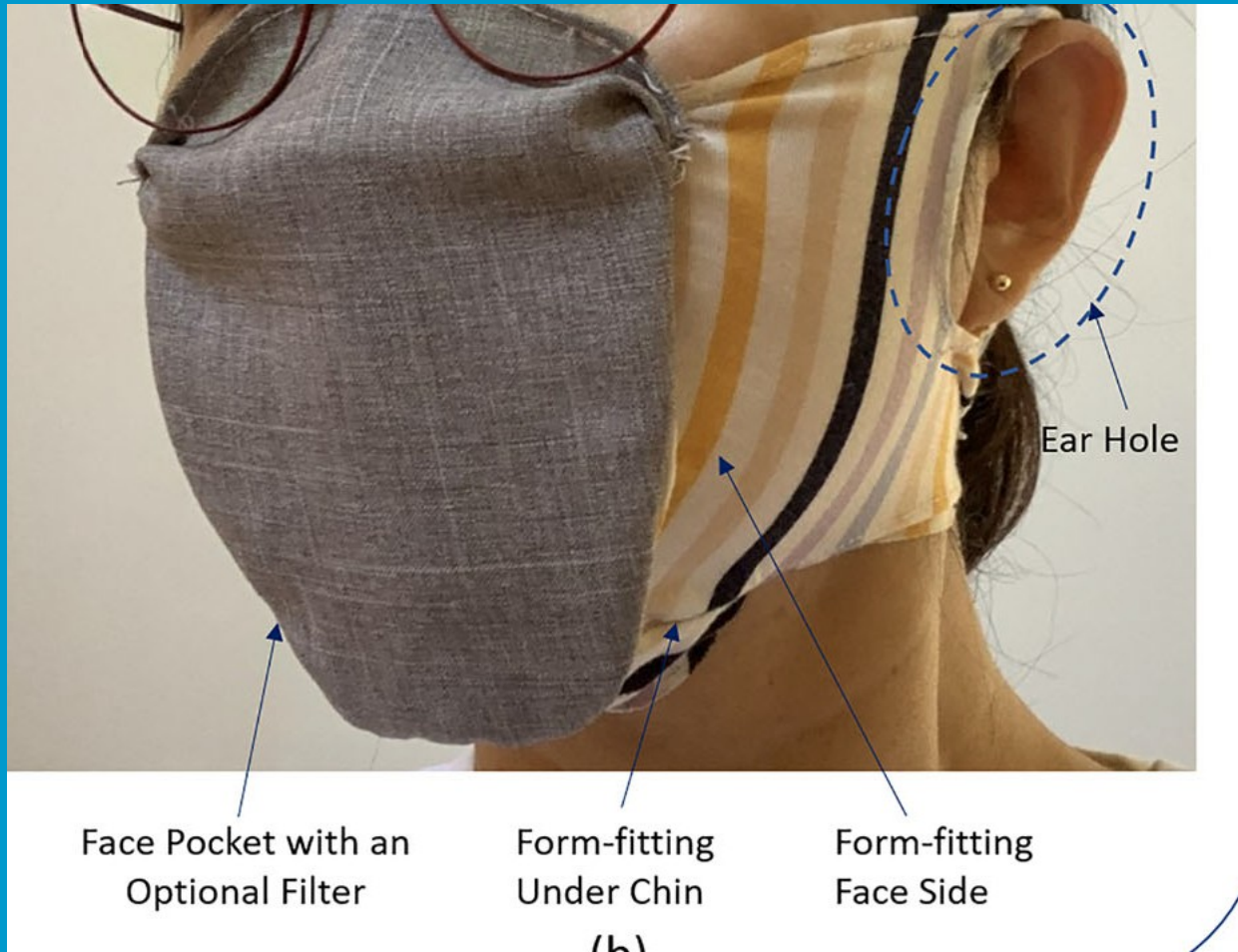
Barrier Component

Form-fitting Component

Form-fitting Component

Fastening Component

Fastening Component



Face Pocket with an
Optional Filter

Form-fitting
Under Chin

Form-fitting
Face Side

Ear Hole

(b)

Healthcare N95 Respirators

- FDA originally required that respirators in healthcare be approved by NIOSH and meet ASTM standards and be cleared by FDA. They were called Surgical N95s.
- 2018 FDA agreed that NIOSH would do approval. NIOSH now has N95-F respirator standard
- OSHA which governs use of respirators has never required FDA clearance.

Consumer Product Safety Commission

- CPSC has responsibility for masks and respirators that are not worn in workplaces
- CPSC gets involved when imports claim fraudulent approvals
- Otherwise, product liability laws govern the use of these respirators if they were to result in an injury

Public vs Worker Masks and Respirators

- Respirators developed from the need of workers to have airborne protection
- There are OSHA regulations, Worker's Compensation laws
- Mask development was the result of FDA regulations focused on healthcare workers
- FDA has been involved when mfg. make claims of viral protection for public use

Public vs Worker Masks and Respirator (2)

- There are needs to produce respirators that protect the public:
 - Smoke from wildland fires
 - patients that are immunocompromised
 - family members taking care of COVID-19 patients
- There are countries that approve respirators for the public including children: e.g. China and Israel
- 3M sells respirators for children in China

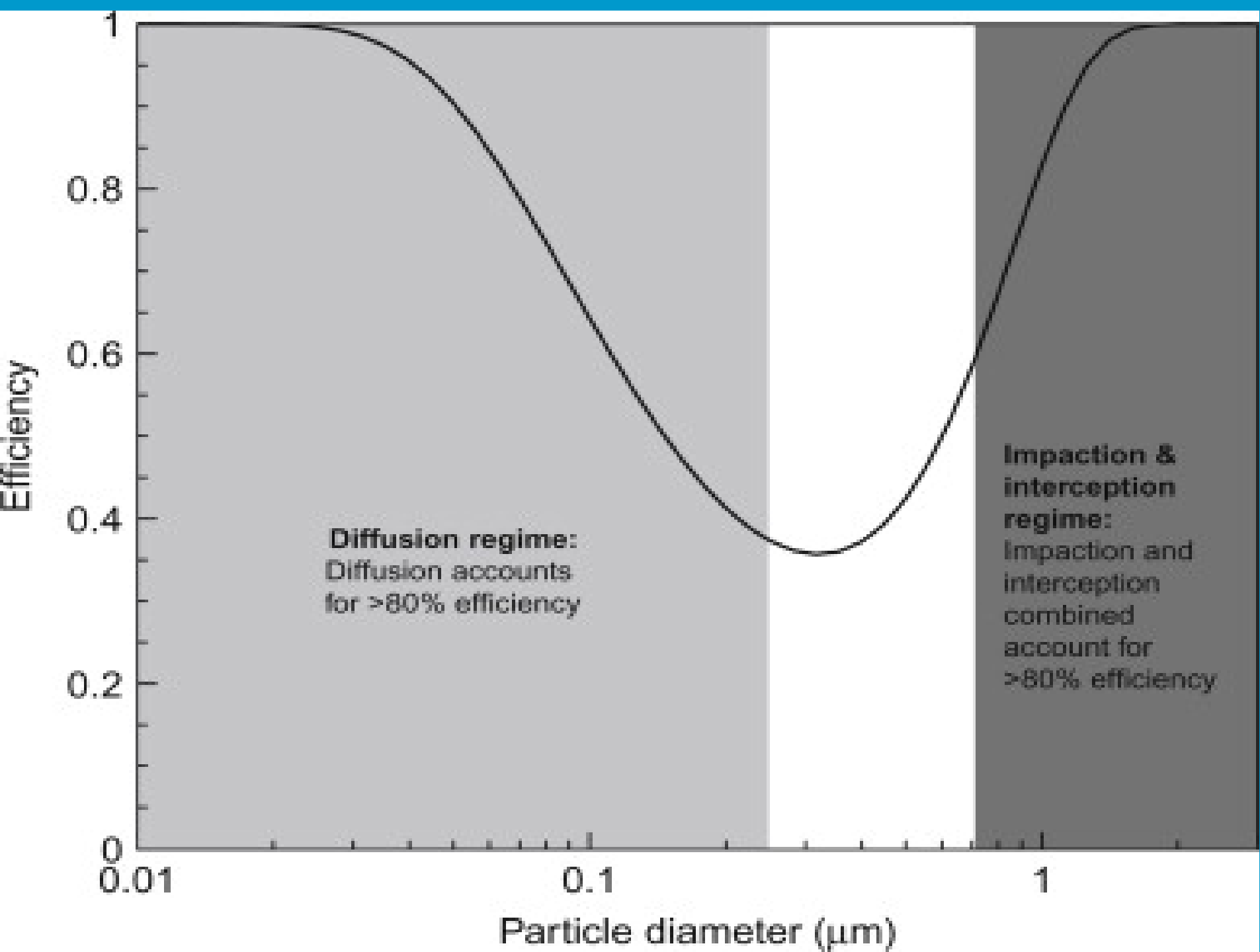
Public vs Worker Masks and Respirator (3)

- NIOSH is the only agency with expertise in respiratory protection in U.S.
- NIOSH's congressional mandate limits its research and regulations to workplaces
- They have become increasingly called upon to provide guidance to state public health agencies
- Respirator mfg have stated they will not develop respirators for the public without NIOSH approval.
- NAM is/will conduct a study of this issue

Basic Filtration Mechanisms

- Gravitational settling-only relevant for large particles >10 μm
- Impaction-velocity and size 1-10 μm
- Interception-particles get stuck on fibers 0.3-1 μm particle. Where particles are as large as diameter of fibers.
- Diffusion-smaller the particle the better <0.3
- Electrostatic attraction-small particles <0.3

Corona virus particle is about 0.12 μm



How Are Healthcare Masks Constructed

- Medical masks are made with non-woven fabric, which has better bacteria filtration and air permeability while remaining less slippery than woven cloth. The material most commonly used to make them is polypropylene.
- Medical masks have three layers: outer is non-woven liquid resistant thermally bonded polypropylene, middle layer is non-woven liquid resistant melt blown polypropylene and inner is non-woven paper that is soft and liquid resistant.
- The filtration level of a mask depends on the fiber, the way it's manufactured, the web's structure, and the fiber's cross-sectional shape.

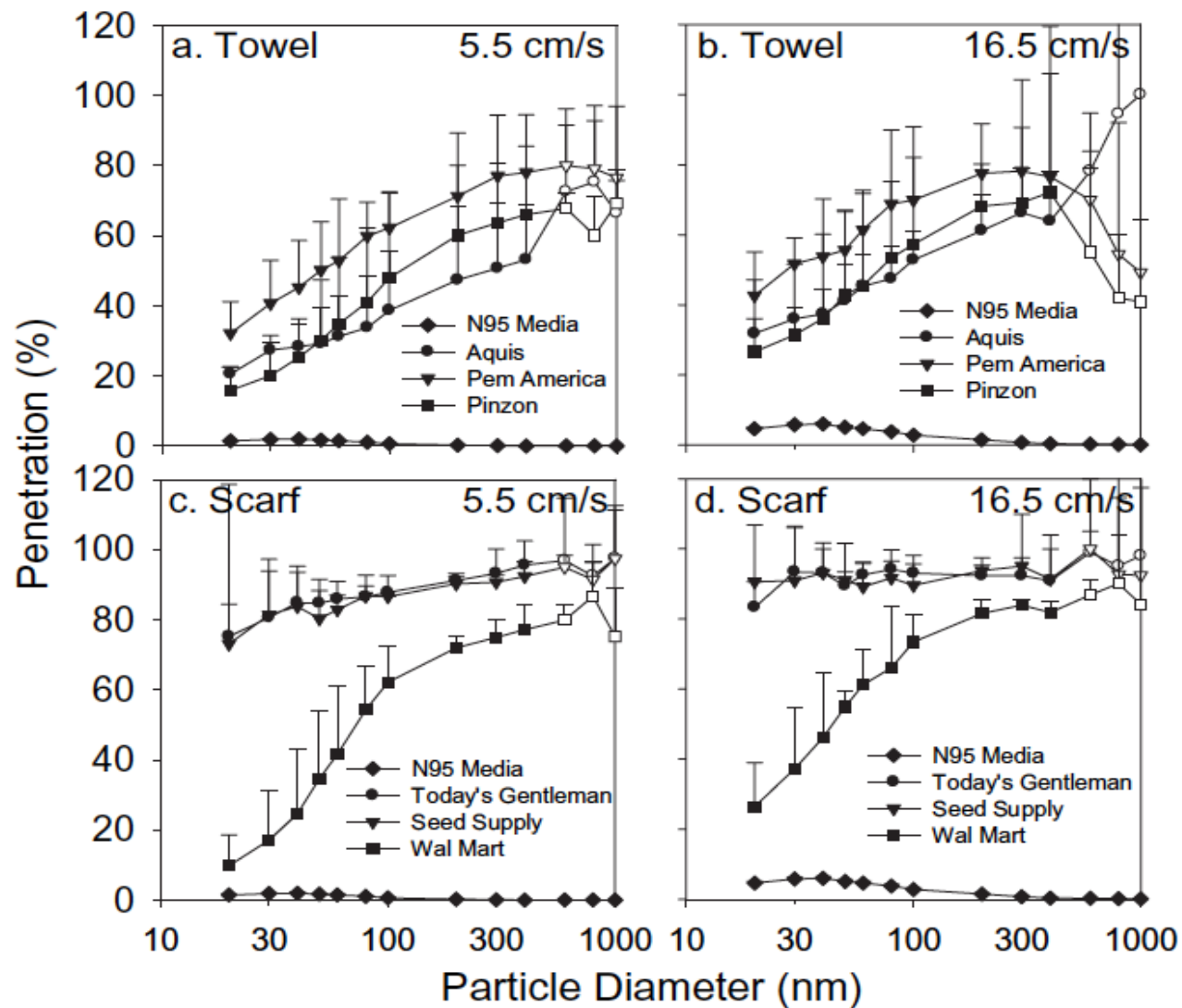
How Are N95 Respirators Constructed

- The respirator is comprised of up to four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene.
- Respirator are more robust based on their design
 - biocompatibility
 - durable to last for a medium-long time
 - work in variety of environmental conditions
 - must fit tightly a variety of face sizes: protection factor

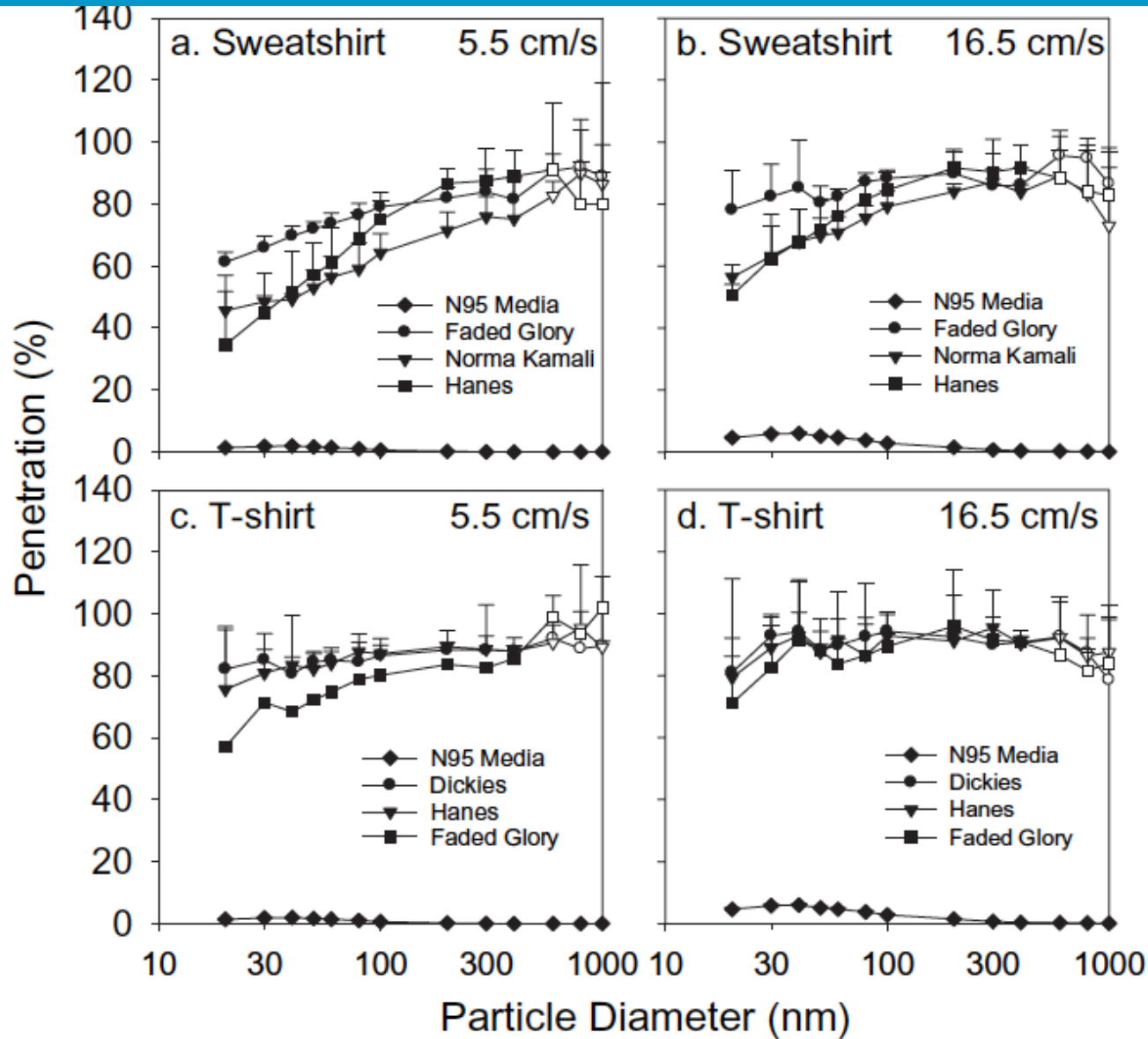
How Are Homemade Masks Made

- A variety of materials (mostly cloth) and mostly using ear loops
- Shakya et al. (2017) examined three types of cloth masks. The cloth masks had the filtration efficiency 15-90%.
- Konda et al. (2020) evaluated several common fabrics including cotton, silk, chiffon, flannel, and various synthetics. When the fabrics were tested as a single layer, the filtration efficiencies were 5 to 95%

Simple Respiratory Protection—NIOSH 2010



Simple Respiratory Protection—NIOSH 2010



Do Fabric Masks Prevent Transmission of COVID-19

NAM letter to President dated 4-8-2020

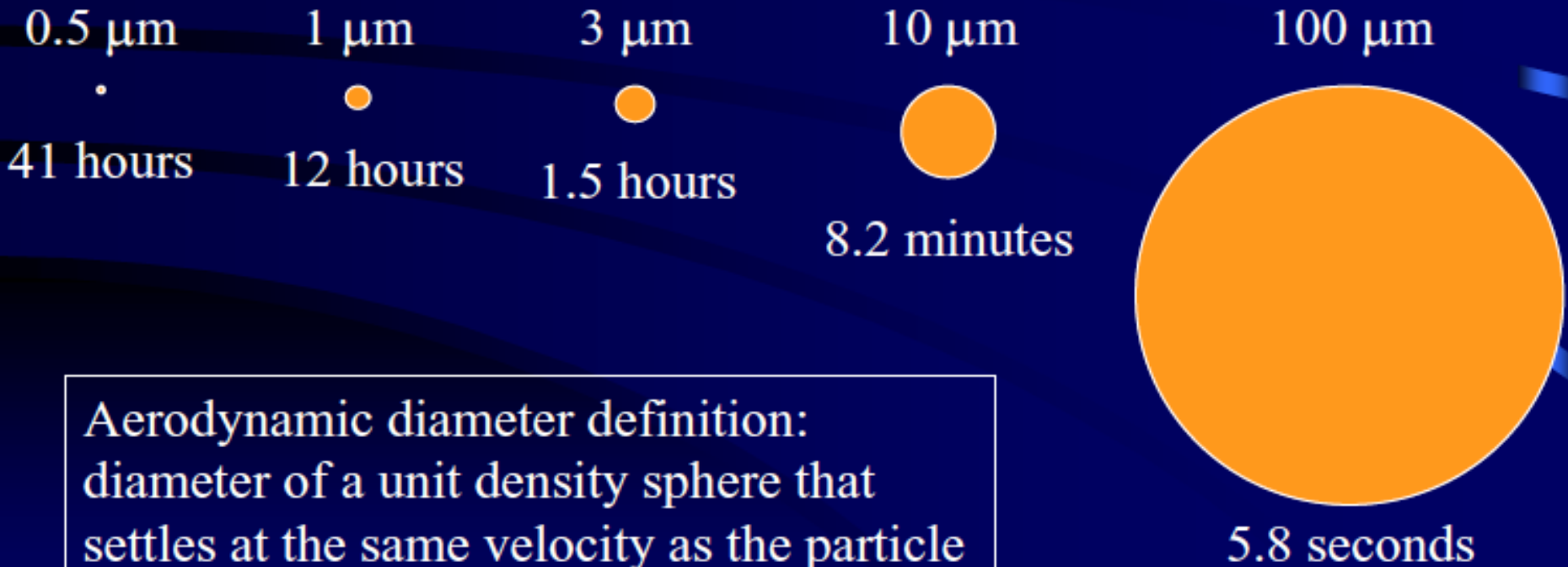
“The evidence from these laboratory filtration studies suggests that such fabric masks may reduce the transmission of larger respiratory droplets. There is little evidence regarding the transmission of small aerosolized particulates of the size potentially exhaled by asymptomatic or presymptomatic individuals with COVID-19.”

How Viruses Travel in Air

- Viruses are particles and they travel in air like any other particle
- Particles travel based on: size, density, velocity, humidity, air currents
- Droplets 5-10 μm and they travel maybe up to 6 feet
- Aerosols smaller particles that can stay suspended and travel further.

Particle Settling in Still Air

Time to settle 5 feet by unit density spheres



Aerodynamic diameter definition:
diameter of a unit density sphere that
settles at the same velocity as the particle
in question

Coughing, Sneezing & Breathing



Coughing, Sneezing & Breathing

- A cough produces respiratory droplets of varying sizes. Larger droplets fall to the floor, or break up into smaller droplets.
- CDC: keeping at least six feet away from others can help you avoid contact with these respiratory droplets and lower the risk of infection. That guidance is based on the assumption that transmission mainly occurs through large droplets that fall in close proximity

Coughing, Sneezing, Breathing (2)

- Scientists have argued, droplets can travel farther than six feet. And small droplets known as aerosols can remain suspended or travel through the air before they eventually settle on surfaces.
- It's not like, 'Oh, it's six feet, they've all fallen and there's nothing,'" said Donald K. Milton, an infectious aerosols scientist at the University of Maryland's School of Public Health. "It's more like it's a continuum." The farther you get away, the more diluted it is," Dr. Milton said of the aerosol.

Coughing, Sneezing, Breathing (3)

- In fact, researchers at M.I.T. studying coughs and sneezes observed particles from a cough traveling as far as 16 feet and those from a sneeze traveling as far as 26 feet.
- Studies of influenza have shown that infected people with mild or no symptoms may also generate infectious droplets through speaking and breathing.
- An infected person talking for five minutes in a poorly ventilated space can produce as many viral droplets as one infectious cough.

Coughing, Sneezing, Breathing (4)

- A mask disrupts the trajectory of a cough, sneeze or breath and captures some respiratory droplets before they can spew out.
- Wearing a mask can help protect yourself and others.

Important Questions:

- Can small aerosols contain enough virions to cause infection?
- How long can small aerosols that remain suspended remain infectious?

How Does COVID-19 Spread

- **NAM Report to President April 1, 2020**

“However, for no respiratory virus is the exact proportion of infections due to air droplet, aerosol, or fomite transmission fully established”

“While the current SARS-CoV-2 specific research is limited, the results of available studies are consistent with aerosolization of virus from normal breathing.”

Upcoming NAM Study

- Current respiratory protection guidance and recommendations to outdoor workers and the general public dealing with natural disasters and accidents, as well as coordination of that guidance.