CORONAVIRUS:
THINGS YOU NEED TO KNOW AS A LAWYER

April 22, 2020

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CORONAVIRUS: THINGS YOU NEED TO KNOW AS A LAWYER

Agenda

12:15 P.M. Program Begins

1:15 P.M. Program adjourns

Faculty

Ms. Linda L. Chezem
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Martinsville, IN 46151
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Linda Chezem

Of Counsel

Linda Chezem has 44 years of legal experience, including 22 years as a trial and appellate court judge.

She is a professor at Purdue University in the Department of Youth Development and Agriculture Education.

She holds an adjunct appointment at the IU School of Medicine, Department of Medicine, with the Indiana Alcohol Research Center.

Linda Chezem's Background

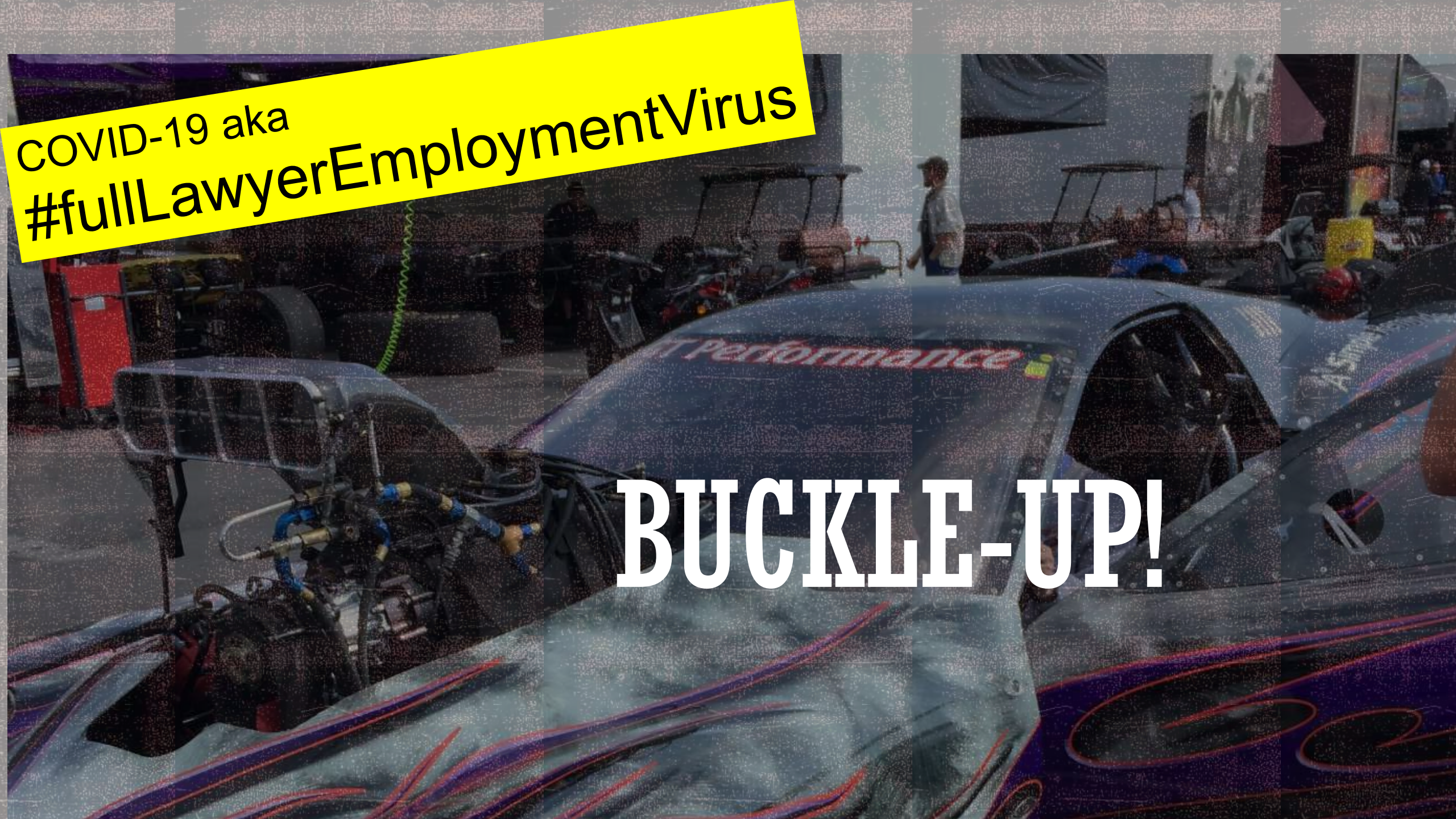
Linda graduated from Indiana University School of Law in 1971. She worked in private practice in Paoli, Indiana. She became a Lawrence County Court judge and later a Lawrence Circuit Court judge. She spent 10 years as a judge at the Indiana Court of Appeals.

Her jurisdiction at trial court level included all crimes and misdemeanors, from traffic to felony-murder, marriage dissolution, probate, juvenile, and unlimited civil docket.

Linda has received multiple awards throughout her career. These awards have included Sagamore of the Wabash honors from three governors, a Distinguished Hoosier Award, Hoosier Hero, and Distinguished Barrister.

Covid-19

Linda L. Chezem
Foley Peden & Wisco
Martinsville, IN


COVID-19 aka
#fullLawyerEmploymentVirus
BUCKLE-UP!

Who are you going to call? For what?

What is the role of homeland security?

What is law enforcement supposed to do?

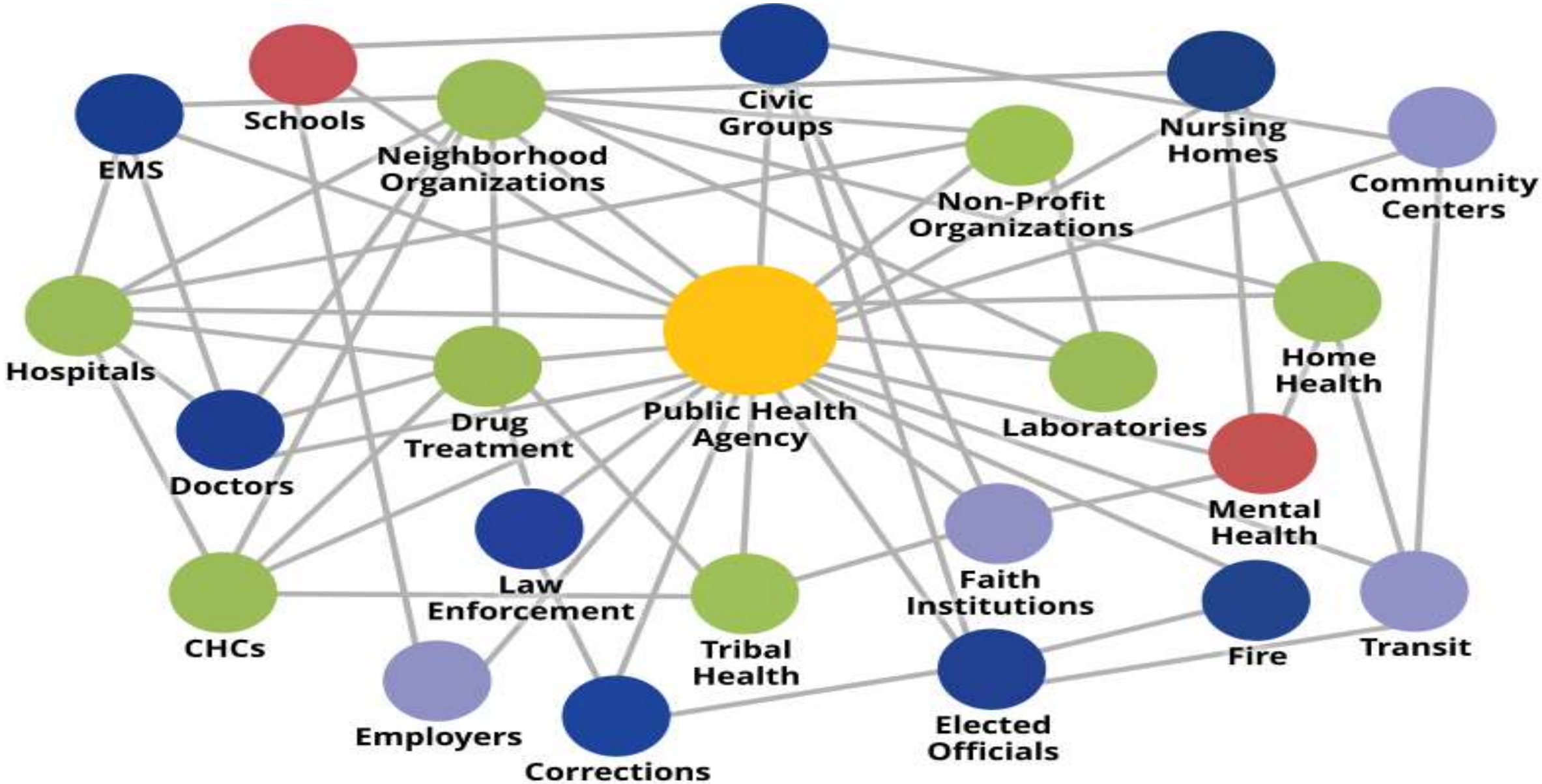
National Guard?

Public Health- aren't those the measles and mumps guys?

Lawyers- whose?

Emergency Management

- The Constitution tasks the States with responsibility for public health and safety—hence, they are responsible for public risks, while the Federal Government's ultimate obligation is to help when State, local, or individual entities are overwhelmed.
- The overall goals of emergency management at all levels are:
  - First, to reduce the loss of life;
  - Then, to minimize property loss and damage to the environment;
  - And finally, to protect the jurisdiction from all threats and hazards.



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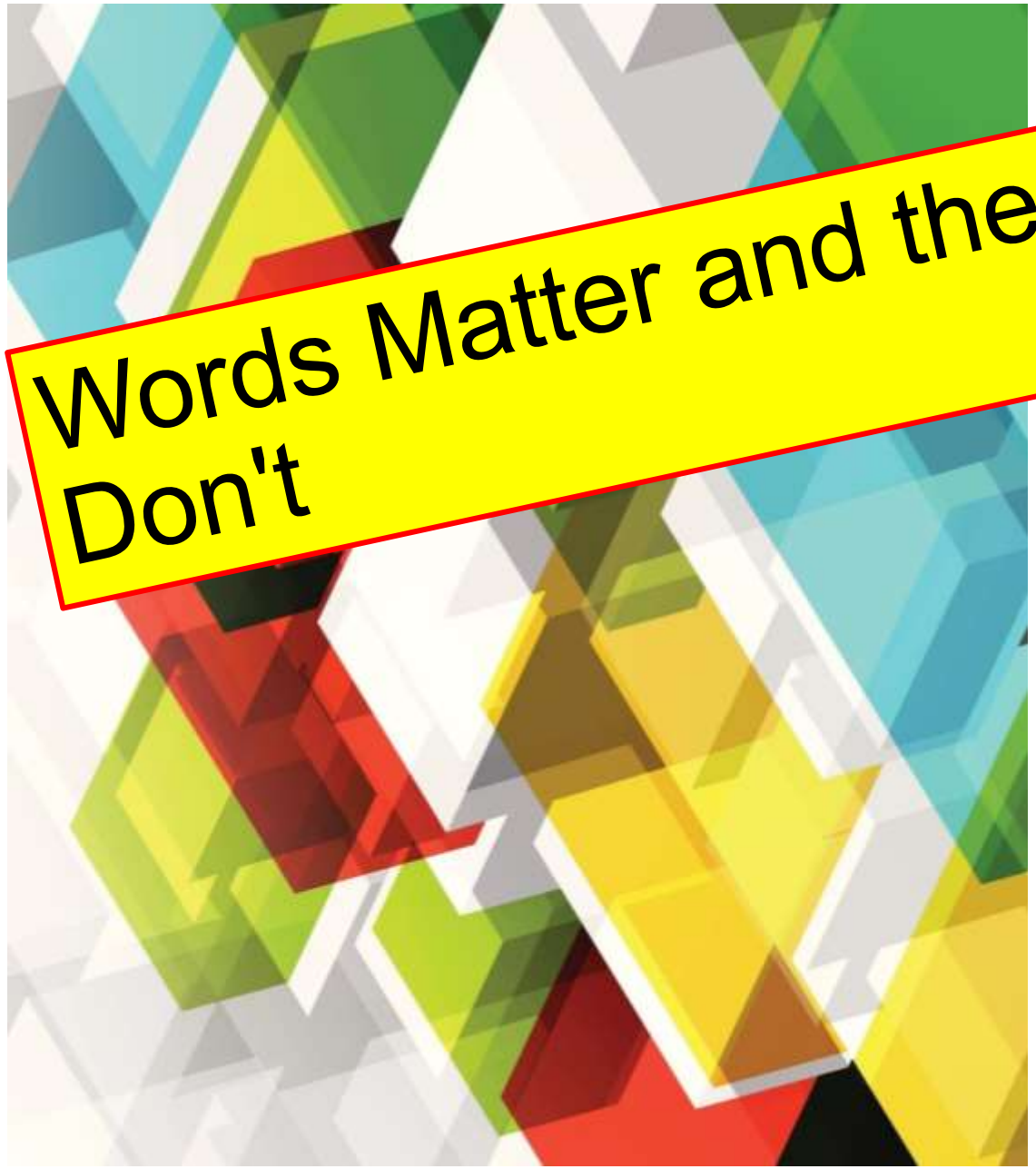


Words Matter and the Numbers Don't

- Public Health Keys
  - Isolation
  - Quarantine
  - Tests –for what? Which is worse? A false negative or a false positive?
  - Numbers are meaningless. People are comparing unicorns to squirrels and changing the unicorn description every day.

Isolation

- the physical separation, including confinement or restriction, of an individual or a group of individuals from the general public if the individual or group is infected with a dangerous communicable disease, in order to prevent or limit the transmission of the disease to an uninfected individual.

- TREATMENT is not a statutory reason.

Quarantine

- **Range of community containment strategies for infectious diseases**
- **Applied to persons exposed but *not ill*, i.e., contacts (not cases)**
- **Designed to meet two objectives**
  - **Facilitate early recognition of symptoms of a contagious disease, should they develop**
  - **Reduce risk of transmission before progression to disease has been recognized**

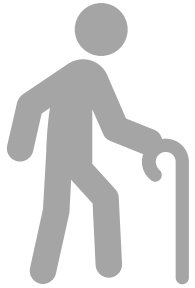
Known characteristics of this virus:	What is unknown:	What is needed NOW:
✓ **Contagious**	✓ Accurate rate of transmission	✓ Adequate testing with RAPID on-site results
✓ **Can live on surfaces for periods of time**	✓ Accurate rate of infection	✓ Vaccine
✓ **High lethality risk to vulnerable populations**	✓ Accurate mortality rate	✓ A proven cure
✓ **Exhausts current medical capacity and resources if it becomes widespread**	✓ Immunity duration, if any	✓ Less gaslighting

How Do We Keep Our Favorite Lawyers, Staff, And Clients Safe?

Basic sanitary precautions

Floors, Surfaces, and Office Objects Contamination

Don’t give advice that is not scientifically supported.



Workforce Issues

Vulnerable preconditions

ADA reasonable accommodations

Family Care

MECHANICS

Communications

Vocabulary,

Physical Layout

Technology

Mental

Keeping the Law Firm Doors Open

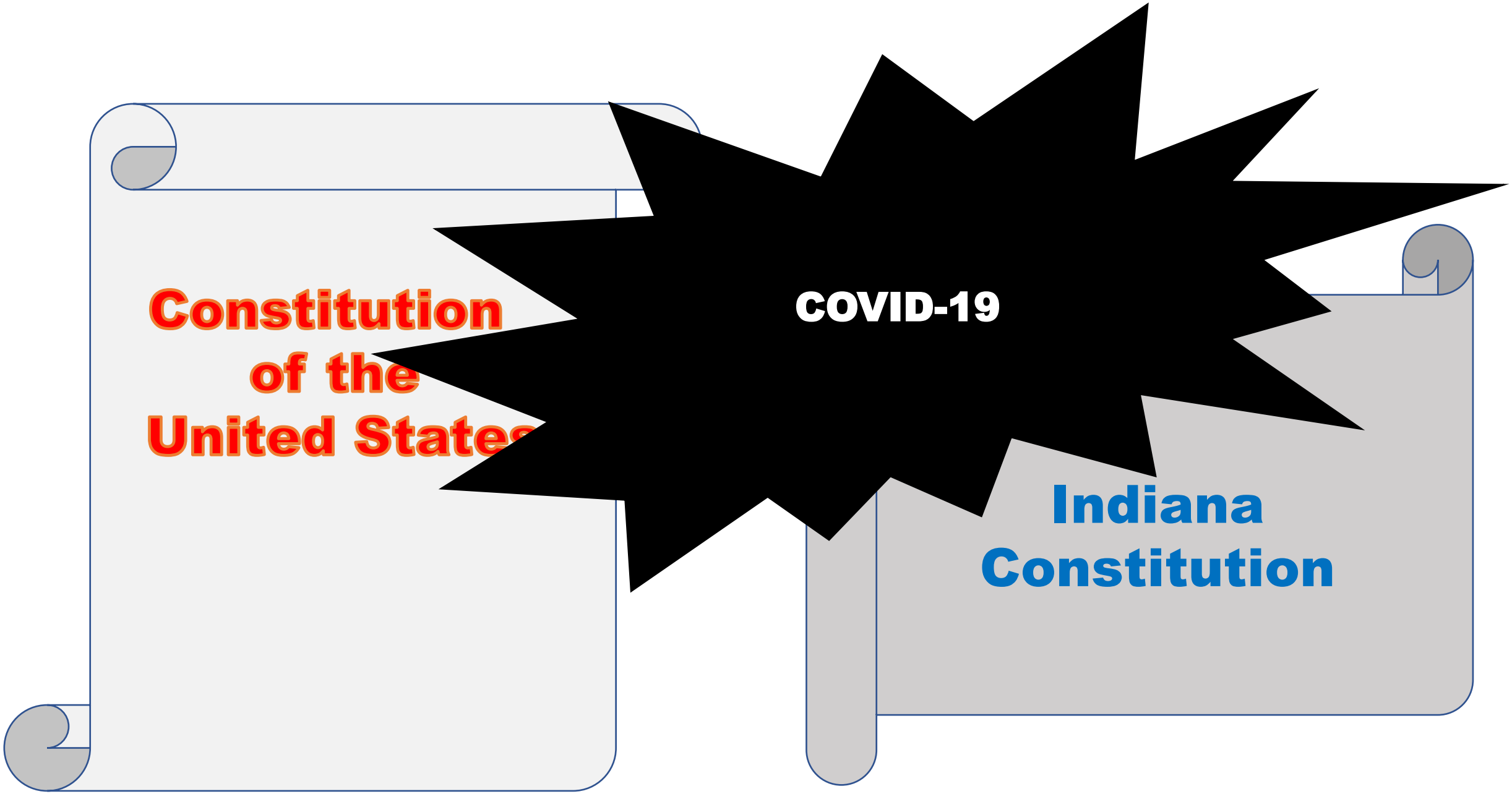
Financially

Virtually - Communications

- Physically
  - Plexiglass shields
  - Give away ink pens
  - Give away masks and gloves

Technology

- Access –check with providers
- Speed
- Security helps assure confidentiality. That is an ethical requirement.
- Security
- Security


Constitution of the United States
COVID-19
Indiana Constitution

LINES OF AUTHORITY

- 10th Amendment
- 11th Amendment
- 14th Amendment- The Fourth Amendment applies to the acts of all state officials, including both civil and criminal authorities. See New Jersey v. T.L.O., 469 U.S. 325, 335 (1985).

- Rights Considerations Including:
  - Notice
  - Rights to Personal Autonomy
  - Privacy - Emerging Questions
  - Freedom of Movement
  - Takings

- A particular action must be based on statute, regulation, or other legal precedent.
- Authority does not necessarily equal policy.
- Important tool, but not a substitute for
  - Planning
  - Resources
  - Communication.

Massachusetts vs Jacobson

Compagnie Francaise de Navigation à Vapeur v. State Board of Health,

186 U.S. 380 (1902) (recognizing power of states to institute quarantine

to protect their citizens from infectious diseases).

Public Health uses legal words with different meanings.

Medical and research terms that you may need to know.

Knowledge base for medical and scientific information you may need for your client.

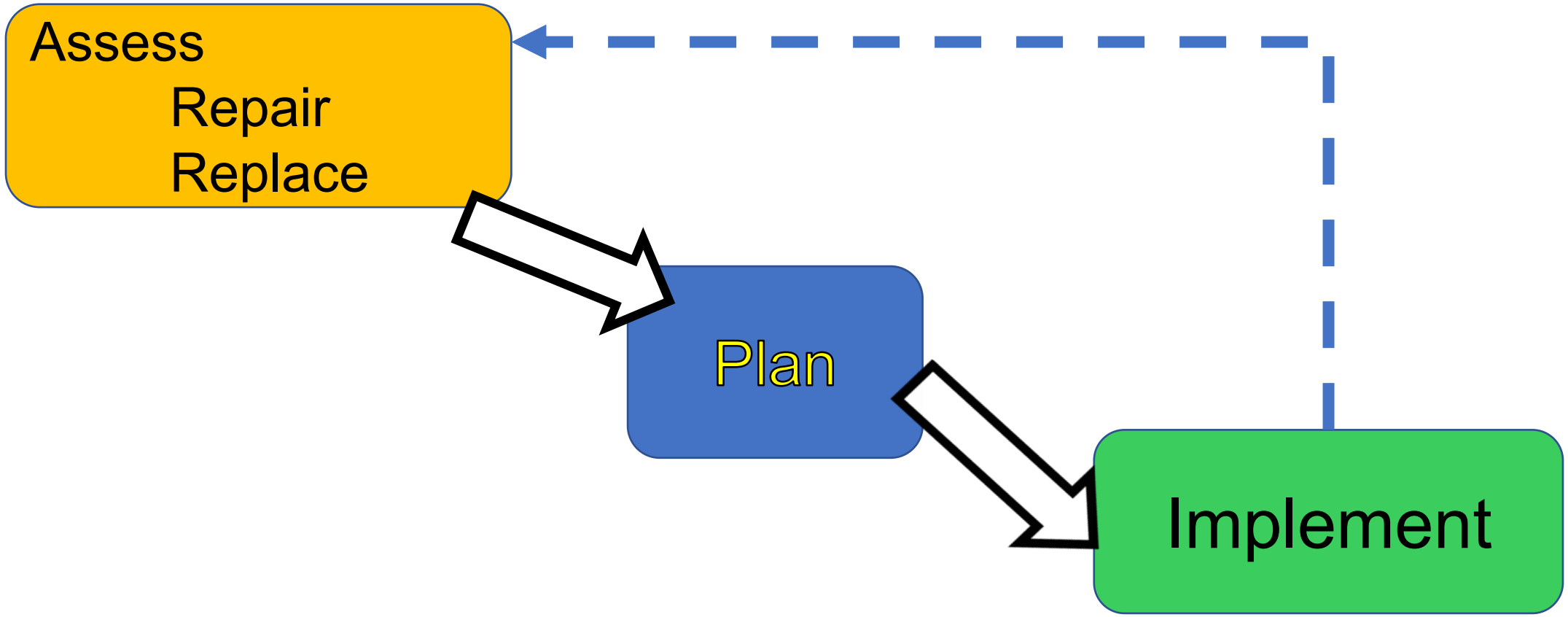
Public Health Law Bench Books

https://www.cdc.gov/phlp/publications/topic/benchbooks.html

Martial Law and Public Health

- Martial law has been federally imposed only a few times, although various state governors have declared it on numerous occasions.
- Scheiber and Scheiber
- Dames & Moore v. Regan
- Youngstown

After- Action:
Getting Ready For The Next Time



Bayonets in Paradise : Martial Law in Hawai`i during World War II

- Recounts the extraordinary story of how the army imposed rigid and absolute control on the total population of Hawaii during World War II.
- Duncan v. Kahanamoku, in which the U.S. Supreme Court heard argument on the martial law regime—and ruled in 1946 that provost court justice and the military's usurpation of the civilian government had been illegal.

Panic In the Streets

Film shot in New Orleans in 1950. This is the story of a public health worker (Richard Widmark) and a police detective (Paul Douglas) who have only a few hours in which to capture some fleeing felons who may be infected with the plague.

http://www.amazon.com/exec/obidos/ASIN/6301863208/qid=1028651532/sr=1-1/ref=sr_1_1/002-1546438-4826408

It Is Not Easy Being Healthy

- Individuals
  - Lack of understanding
  - Fear of costs
  - Government Interference with Rights

- Elected Officials
  - Lots of Noise
  - No Background
  - Low Budgets and Squeaky Wheels
  - Who can they trust?
  - State & Feds are not seen as helpful but source of unfunded mandates

Rapid Expert Consultation on the Effectiveness of Fabric Masks for the COVID-19 Pandemic (April 8, 2020)

Rapid Expert Consultation on the Effectiveness of Fabric Masks for the COVID-19 Pandemic (April 8, 2020) (2020)

DETAILS

8 pages | 8.5 x 11 | PDF
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National Academies of Sciences, Engineering, and Medicine

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The National Academies of
SCIENCES • ENGINEERING • MEDICINE

April 8, 2020

Kelvin Droegemeier, Ph.D.
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, DC 20504

Dear Dr. Droegemeier:

Attached please find a rapid expert consultation that was prepared by Rich Besser and Baruch Fischhoff, members of the National Academies' Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats, with input from Sundaresan Jayaraman and Michael Osterholm. Details on the authors and reviewers of this rapid expert consultation can be found in the Appendix of the attachment.

The aim of this rapid expert consultation is to respond to your request concerning the effectiveness of homemade fabric masks worn by the general public to protect others, as distinct from protecting the wearer. The request stems from an interest in reducing transmission within the community by individuals who are infected, potentially contagious, but asymptomatic.

Overall, the available evidence is inconclusive about the degree to which homemade fabric masks may suppress spread of infection from the wearer to others. For as long as homemade fabric masks are in use by the public, the investigations outlined at the end of the rapid expert consultation could reduce uncertainty about the effectiveness of these masks.

My colleagues and I hope this input is helpful to you as you continue to guide the nation's response in this ongoing public health crisis.

Respectfully,

Harvey V. Fineberg, M.D., Ph.D.
Chair
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

April 8, 2020

This rapid expert consultation responds to your request concerning the effectiveness of homemade fabric masks worn by the general public to protect others, as distinct from protecting the wearer. The request stems from an interest in reducing transmission within the community by individuals who are infected, potentially contagious, but asymptomatic or presymptomatic. As discussed below, the answer depends on both the masks themselves and how infected individuals use them.

The following analysis is restricted to the effectiveness of homemade fabric masks, of the sort illustrated in recommendations[1] directed at the general public, in terms of their ability to reduce viral spread during the asymptomatic or presymptomatic period. It does not apply to either N95 respirators or medical masks.

In considering the evidence about potential effectiveness of homemade fabric masks, it is important to bear in mind how a respiratory virus such as SARS-CoV-2 spreads from person to person. Current research supports the possibility that, in addition to being spread by respiratory droplets that one can see and feel, SARS-CoV-2 can also be spread by invisible droplets, as small as 5 microns (or micrometers), and by even smaller bioaerosol particles.[2] Such tiny bioaerosol particles may be found in an infected person's normal exhalation.[3] The relative contribution of each particle size in disease transmission is unknown.

There is limited research on the efficacy of fabric masks for influenza and specifically for SARS-CoV-2. As we describe below, the few available experimental studies have important limitations in their relevance and methods. Any type of mask will have its

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[1] Centers for Disease Control and Prevention (CDC) Recommendation Regarding the Use of Cloth Face Coverings, Especially in Areas of Significant Community-Based Transmission in response to COVID-19 https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover.html

[2] Gralton and colleagues (2011) noted the following in regards to particulate size and the importance of airborne precautions whenever there is a risk of both droplet and aerosol transmission: "Regardless of the complexities and limitations of sizing particles and the contention of size cut-offs, it remains that particles have been observed to occupy a size range between 0.05 and 500 microns. Even using the conservative cut-off of 10 microns, rather than the 5 micron to define between airborne and droplet transmission, this size range indicates that particles do not exclusively disperse by airborne transmission or via droplet transmission but rather avail of both methods simultaneously. This suggestion is further supported by the simultaneous detection of both large and small particles. In line with these observations and logic, current dichotomous infection control precautions should be updated to include measures to contain both modes of aerosolised transmission. This may require airborne precautions to be used when at risk of any aerosolized infection, as airborne precautions are considered as a step-up from droplet precautions." Gralton, J., et al. 2011. The role of particle size in aerosolised pathogen transmission: A review. J Infect 62(1):1-13.

[3] National Research Council. 2020. *Rapid Expert Consultation on the Possibility of Bioaerosol Spread of SARS-CoV-2 for the COVID-19 Pandemic (April 1, 2020).* Washington, DC: The National Academies Press. https://doi.org/10.17226/25769.

own capacity to arrest particles of different sizes. Even if the filtering capacity of a mask were well understood, however, the degree to which it could in practice reduce disease spread depends on the unknown role of each particle size in transmission.

Asymptomatic but infected individuals are of special concern, and the particles they would emit from breathing are predominantly bioaerosols. To complicate matters further, different individuals vary in the extent to which they emit bioaerosols while breathing. Because of the concern with spread from asymptomatic individuals, who, unlike symptomatic persons, may be out and about, this rapid expert consultation includes the effects of fabric masks on bioaerosol transmission.

Impact of Mask Design and Fabrication on Performance

Any effects of fabric masks will depend on how and how well they are made. In an unpublished study whose raw data are not currently available, Jayaraman[4] and colleagues examined a range of fabric-based filtration systems, in terms of how well they stopped particles (filtration efficiency) and how much they impeded breathing (differential pressure, Delta-P, the measured pressure drop across the material, which determines the resistance of the material to air flow).[5] The study varied fabric type (woven, woven brushed, knitted, knitted brushed, knitted pile), material type (cotton, polyester, polypropylene, silk), fabric parameters (fabric areal density, yarn linear density, fabric weight), and construction type (number of layers, orientation of the layers). The study found wide variation in filtration efficiency. A mask made from a four-layer woven handkerchief fabric, of a sort that might be found in many homes, had 0.7 percent filtration efficiency for 0.3 micron size particles and a Delta-P of 0.1". Much higher filtration efficiency was observed with filters created specifically for the research from a five-layer woven brushed fabric (35.3 percent of the particles were trapped) and from four layers of polyester knitted cut-pile fabric (50 percent of the particles were trapped with a Delta-P of 0.2").

The greater a mask's breathing resistance, which is reflected in a higher Delta-P, the more difficult it is for users to wear it consistently, and the more likely they are to experience breathing difficulties when they do.[6] Although Jayaraman and colleagues did not measure breathing resistance directly, almost all the masks that they tested would be expected to have breathing resistance within the range of commercial N95 respirators. One mask that used 16 layers of the handkerchief fabric, in order to increase filtration efficiency (63% efficiency with Delta-P of 0.425"), had breathing resistance greater than that of commercial N95 respirators, which would cause great discomfort to many wearers and cause some to pass out.

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[4] Jayaraman, S. *Pandemic Flu – Textile Solutions Pilot: Design and Development of Innovative Medical Masks,* Final Technical Report, Georgia Institute of Technology, Atlanta, Georgia, submitted to CDC, February 14, 2012.

[5] The tests were conducted according to ASTM F2299-3 test method using poly-dispersed sodium chloride aerosol particles with an airflow rate of 30L/min and airflow velocity of 11 cm/s. Aerosol sizes measured: 0.1, 0.2, 0.3, 0.4, 0.5, 0.7, 1 and 2 microns.

[6] 3M™ Health Care Particulate Respirator and Surgical Masks, Healthcare Respirator Brochure, 3M Company, MN.

An additional consideration in the effectiveness of any mask is how well it fits users. [7] Even with the best material, if a mask does not fit, virus-containing particles can escape through creases and gaps between the mask and face. Leakage can also occur if the holding mechanism (e.g., straps, Velcro®) is weak. We found no studies of non-expert individuals' ability to produce properly fitting masks. Nor did we find any studies of the effectiveness of masks produced by professionals, when following instructions available to the general public (e.g., online). Given the current Centers for Disease Control and Prevention (CDC) recommendation to wear cloth face coverings in public settings in areas of significant community-based transmission, additional research should examine the ability of the general public to produce properly fitted fabric masks when following communications and instructions.

Role of the Wearer

The effectiveness of homemade fabric masks will also depend on wearers' behavior. Even if a mask could fit well, its effectiveness still depends on how well wearers put it on and keep it in place. As mentioned, breathing difficulty can impede effective use (e.g., pulling a mask down), as can moisture from wearers' breath. Moisture saturation is inevitable with fabrics available in most homes. Moreover, moisture can trap virus and become a potential contamination source for others, after a mask is removed.

Effectiveness of Homemade Fabric Masks in Protecting Others

Several experimental studies have examined the effects of fabric masks on transmission of droplets of various sizes.

Anfinrud and colleagues[8] shared via email that they used sensitive laser light-scattering procedures to detect droplet emission while people were speaking. The authors found that "a damp homemade cloth facemask" reduced droplet emission to background levels (when users said "Stay Healthy" three times). However, when a fabric is dampened, the yarns can swell over time, potentially altering its filtering performance. That swelling will depend on the fabric: cotton swells readily, synthetics less so. In an unpublished follow-up experiment, Anfinrud and colleagues repeated their study with a variety of dry (not moistened) cloths, including a standard workers dust mask (not certified N95) and a mask rigged from an airline eye covering. They found that all of these masks reduced droplet emission generated by speech to background level. [9]

Bae et al., 2020 evaluated the effectiveness of surgical and cotton masks in filtering SARS–CoV-2.[10] They found that neither kind of mask reduced the dissemination of

[7] Davies and colleagues (2013) noted that, "Although any material may provide a physical barrier to an infection, if as a mask it does not fit well around the nose and mouth, or the material freely allows infectious aerosols to pass through it, then it will be of no benefit."
[8] Anfinrud, P., et al. New England Journal of Medicine, In Press. Could SARS-CoV-2 be transmitted via speech droplets?
[9] Personal communication, Adriaan Bax, National Institutes of Health, 4/4/2020.
[10] Bae, S., et al. 2020. Effectiveness of surgical and cotton masks in blocking sars–cov-2: A controlled comparison in 4 patients. Annals of Internal Medicine.

SARS–CoV-2 from the coughs of four symptomatic patients with COVID-19 to the environment and external mask surface. The study used disposable surgical masks (180 mm × 90 mm, 3 layers [inner surface mixed with polypropylene and polyethylene, polypropylene filter, and polypropylene outer surface], pleated, bulk packaged in cardboard; KM Dental Mask, KM Healthcare Corp) and reusable 100% cotton masks (160 mm × 135 mm, 2 layers, individually packaged in plastic; Seoulsa). The median viral loads of nasopharyngeal and saliva samples from the four participants were 5.66 log copies/mL and 4.00 log copies/mL, respectively. The median viral loads after coughs without a mask, with a surgical mask, and with a cotton mask were similar: 2.56 log copies/mL, 2.42 log copies/mL, and 1.85 log copies/mL, respectively. All swabs from the outer mask surfaces of the masks were positive for SARS–CoV-2, whereas swabs from three out of the four symptomatic patients from the inner mask surfaces were negative. Note that this study focused on symptomatic patients who coughed.

Rengasamy et al. (2010)[11] tested the filtration performance of five common household fabric materials: sweatshirts, T-shirts, towels, scarves and cloth masks (of unknown material) in a laboratory setting. These fabric materials were tested for sprays having both similar and diverse particle sizes (monodisperse and polydisperse). The range of sizes used in the study (.02 – 1 micron) includes that of potential virus-containing droplets.[12] The study projected the particles at face velocities, typical of breathing at rest and during exertion (5.5 and 16.5 cm/s). The test also examined N95 respirator filter media. At the lower velocity, 0.12 percent of particles penetrated the N95 respirator material; at the higher velocity, penetration was less than 5 percent. For the five common household fabric materials, across the tests, penetration ranged from about 40 to 90 percent, indicating a 10-60 percent reduction. The authors concluded that common fabric materials may provide a low level of protection against nanoparticles, including those in the size ranges of virus-containing particles in exhaled breath (.02 – 1 micron). However, Gralton et al. (2011) found particles generated from respiratory activities range from 0.01 up to 500 microns, with a particle size range of 0.05 to 500 microns associated with infection. They stress the need for airborne precautions to be used when at risk of any aerosolised infection, as airborne precautions are considered as a step-up from droplet precautions.

Davies and colleagues (2013)[13] had 21 healthy volunteers make their own facemasks from fresh, unworn cotton t-shirts. This is the only study we found with user-made masks. Participants then coughed into a box, when wearing their own mask, a surgical mask, or no mask. They received no help or guidance from the researcher in making or fitting their masks. The researchers took samples of particles settling onto agar plates and a Casella slit sampler in the box. Under the baseline conditions of no mask, only a small number of colony-forming units (indicative of bacteria) were detected, limiting the

[11] Rengasamy, S., et al. 2010. Simple respiratory protection--evaluation of the filtration performance of cloth masks and common fabric materials against 20-1000 nm size particles. Ann Occup Hyg 54(7):789-798.

[12] According to Gralton et al (2011), particles generated from respiratory activities range from 0.01 up to 500 microns, with a particle size range of 0.05 to 500 microns associated with infection.

[13] Davies, A., et al. 2013. Testing the efficacy of homemade masks: Would they protect in an influenza pandemic? Disaster Med Public Health Prep 7(4):413-418.

opportunity to demonstrate reductions. Still, the investigators reported that both homemade and surgical masks reduced the number of large-sized microorganisms expelled by volunteers, with the surgical mask being more effective.

van der Sande and colleagues (2008)[14] examined the extent to which respirator masks, surgical masks, and tea-cloth masks made by the researchers would reduce tiny (0.02-1.0 micron) particle counts on one side of the mask compared to the other. They used burning candles in a test room to generate particles. Two of the study's three experiments examined the protection afforded the wearer (reduced particle counts inside the masks compared to outside). Although not directly germane to the question of protecting others, the study found a modest degree of protection for the wearer from cloth masks, an intermediate degree from surgical masks and a marked degree with equivalent of N95 masks. For example, among adults, N95 masks provided 25 times the protection of surgical masks and 50 times the protection of cloth masks. The study's third experiment tested the effectiveness of the three masks at reducing emissions from a simulation dummy head that produced uniform "exhalations." It found that cloth masks reduced emitted particles (leakage) by 1/5, surgical masks reduced it by 1/2, and N95-equivalent masks reduced it by 2/3.

MacIntyre et al. (2015)[15] conducted a randomized control trial (RCT) comparing infection rates of 1,607 hospital healthcare workers, wearing cloth (two layers, made of cotton) or medical masks (three layers, made of non-woven material), while performing their normal tasks. Workers who used cloth masks experience much higher rates of influenza-like illness (relative risk = 13.00, 95% CI 1.59 to 100.07). This study measured the protective effect for the wearer, rather than the protection of others from the wearer, and did not include a condition with individuals wearing no masks.

Effect on Users' Risk Behavior

In our rapid review, we found no studies of the effects of wearing masks on users' behavior. Speculatively, for some users, masks could provide a constant reminder of the importance of social distancing, as well as signal its importance to others, strengthening the social norm of social distancing. Conversely, for some users, masks might "crowd out" other precautionary behaviors, giving them a feeling that they have done enough to protect themselves and others. Prior research, conducted in less intense settings, could support either speculation. Focused research could help determine when precautionary behaviors reinforce or displace one another.

It is critically important that any discussion of homemade fabric masks reinforce the central importance of physical distancing and personal hygiene (frequent hand-washing) in reducing spread of infection.

Conclusions

[14] van der Sande, M., et al. 2008. Professional and home-made facemasks reduce exposure to respiratory infections among the general population. PLoS One 3(7):e2618.
[15] MacIntyre, C., et al. 2015. A cluster randomised trial of cloth masks compared with medical masks in healthcare workers. BMJ Open 5(4):e006577.

There are no studies of individuals wearing homemade fabric masks, in the course of their typical activities. Therefore, we have only limited, indirect evidence regarding the effectiveness of such masks for protecting others, when made and worn by the general public on a regular basis. That evidence comes primarily from laboratory studies testing the effectiveness of different materials at capturing particles of different sizes.

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 transmission of small aerosolized particulates of the size potentially exhaled by asymptomatic or presymptomatic individuals with COVID-19. The extent of any protection will depend on how the masks are made and used. It will also depend on how mask use affects users' other precautionary behaviors, including their use of better masks, when those become widely available. Those behavioral effects may undermine or enhance homemade fabric masks' overall effect on public health. The current level of benefit, if any, is not possible to assess.

Research could provide firmer answers by assessing the effectiveness of such fabric masks, as made and used by the general public. That research would have the goals of providing the public with (1) usable instructions on how to make, fit, use, and clean homemade fabric masks; (2) estimates of the protection that such masks afford users and others in different environments (e.g., where the likelihood of contact is higher, like grocery stores, compared to wearing masks all of the time); and (3) effective reinforcement of other precautionary behaviors. That research could provide policy makers with estimates of the net effect of encouraging use of homemade fabric masks on public health, with realistic estimates of how such masks will be made and used, as well as how they will affect other precautionary behaviors of users and others who observe and interact with them.

My colleagues and I hope this input is helpful to you as you continue to guide the nation's response in this ongoing public health crisis.

Respectfully,

Richard Besser, M.D.
Member
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Baruch Fischhoff, Ph.D.
Member
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

APPENDIX

Authors and Reviewers of this Rapid Expert Consultation

This rapid expert consultation was prepared by staff of the National Academies of Sciences, Engineering, and Medicine, and members of the National Academies' Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats: Richard Besser, Robert Wood Johnson Foundation; and, Baruch Fischhoff, Carnegie Mellon University. The following subject matter experts also provided input: Sundaresan Jayaraman, Georgia Tech; and Michael Osterholm, University of Minnesota.

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Rapid Expert Consultation on SARS-CoV-2 Laboratory Testing for the COVID-19 Pandemic (April 8, 2020)

Rapid Expert Consultation on SARS-CoV-2 Laboratory Testing for the COVID-19 Pandemic (April 8, 2020) (2020)

DETAILS

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April 8, 2020

Kelvin Droegemeier, Ph.D.
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, DC 20504

Dear Dr. Droegemeier:

Attached please find a rapid expert consultation on the uses, interpretation and future directions of laboratory tests that was prepared by David Relman, David Walt, and Kristian Andersen, members of the National Academies' Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats. Details on the authors and reviewers of this rapid expert consultation can be found in the Appendix of the attachment.

The aim of this rapid expert consultation is to provide scientifically grounded principles that are relevant to decision-making about the interpretation of laboratory tests.

This rapid expert consultation covers the current, pertinent studies and points the way to specific research needs in the days and months ahead. We hope this document proves useful to you and your colleagues.

Respectfully,

Harvey V. Fineberg, M.D., Ph.D.
Chair
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

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April 8, 2020

This rapid expert consultation responds to your request for information on the interpretation of laboratory tests, future developments and research needs.

Laboratory confirmation with reliable, standardized testing is the gold standard for determining disease rates. However, especially early after recognition of a new infectious disease, tests with high sensitivity[1] and specificity[2] may not be available that can accurately and consistently separate individuals with the infection from individuals without the infection. It is important to note that clinical judgment, which usually takes into account the probability of infection based on exposure risk and a review of clinical signs and symptoms, is crucial in understanding an infectious disease such as COVID-19 and who may have it.

There are two general types of infectious disease tests – those that detect the disease agent directly (e.g., PCR tests for viral RNA) and those that detect a host response to the disease agent (e.g., serology tests that detect specific antibodies). An increasing number of purveyors now offer COVID-19 tests of each type.

Detection of viral RNA

Most COVID-19 tests in current use detect the disease agent directly and measure viral RNA. Viral RNA indicates current infection and suggests infectivity and transmission risk for others; however, the presence of viral RNA in an individual, especially late in infection, may represent viral remnants rather than intact virus particles capable of transmission. Additional studies on the temporal dynamics of viral RNA in infected persons, across body sites and fluids, and correlations of these measurements with risk of transmission to other individuals, are sorely needed—as is a much greater capacity to perform these tests nationwide.

Current clinical tests for SARS-CoV-2 rely on the detection of viral RNA, using reverse-transcriptase polymerase chain reaction (RT-PCR) or loop-mediated isothermal amplification (LAMP), in nasopharyngeal (NP), oropharyngeal (OP), sputum or saliva samples. RT-PCR tests have been widely used for the diagnosis of COVID-19. A retrospective study suggested that these tests may be less sensitive in identifying the early phases of disease than computerized tomography (CT) scans of the chest, and other clinical and laboratory findings.[3] One study of 51 patients with COVID-19, diagnosed on the basis of a positive RT-PCR at any time during the course of their illness, found that only 35 of the 51 had a positive RT-PCR at the time of clinical

[1] Sensitivity: The probability of a positive test result in a patient who has the disease. An error in sensitivity produces a false negative result.
[2] Specificity: The probability of a negative test result in a patient who does not have the disease. An error in specificity produces a false positive result.
[3] Xu, H., L. Yan, C. Qiu, B. Jiao, Y. Chen, X. Tan, Z Chen, et al. 2020. Analysis and prediction of false negative results for SARS-CoV-2 detection with pharyngeal swab specimen in COVID-19 patients: A retrospective study. https://doi.org/10.1101/2020.03.26.20043042 (accessed April 4, 2020).

presentation, while 50 of the 51 had abnormal CT findings at the time of presentation.[4] Neither this nor other studies we have found pinpoint the reasons for false negative results on initial PCR tests, but the reasons may include stage of illness, lower amounts of virus in certain anatomic sites and in certain patients, and suboptimal sample collection methods.

LAMP testing methods developed for SARS-CoV in 2004 were found to be more rapid, more simple to perform, and cheaper than conventional methods.[5] LAMP also appears to be sensitive and specific for SARS-CoV-2 when compared to RT-PCR, using spiked non-patient samples.[6] Large cohort studies are now underway to test whether these advantages hold up.

Rapid tests that detect viral RNA include Cepheid's SARS-CoV-2 cartridge[7] for use on their rapid PCR Xpert platform with a 45 minute turn-around, and Abbott's ID NOW COVID-19 isothermal amplification test[8] for use on its ID NOW platform with results in less than 15 minutes. Both of these tests are helpful toward building local capacity, but at the time of this report (6 April), neither had achieved levels of production that come close to meeting national needs. Their use will be limited to sites that have invested in those instrument platforms; in addition, the robustness of their supply chains has not been adequately confirmed. Rapid tests like these will be most valuable in assessing patients for whom emergency procedures such as surgery, if undertaken without a test result, might pose a high risk of disease transmission.

Although not yet in the clinical workplace, a CRISPR-Cas12 or -Cas13 based diagnostic test for SARS-CoV-2 might offer advantages over current technologies. CRISPR-Cas12/Cas13 provides for high sensitivity (can detect as few as 10 gene copies), specificity, portability, easy read-out

[4] Fang, Y., H. Zhang, J. Xie, M. Lin, L. Ying, P. Pang, and W. Ji. 2020. Sensitivity of chest CT for COVID-19: Comparison to RT-PCR. *Radiology*, https://doi.org/10.1148/radiol.2020200432 (accessed April 4, 2020).
[5] Thai H., M. Le, C. Vuong, M. Parida, H. Minekawa, T. Notomi, F. Hasebe, and K. Morita. 2004. Development and evaluation of a novel loop-mediated isothermal amplification method for rapid detection of severe acute respiratory syndrome coronavirus. *J Clin Microbiol*; 42(5):1956-1961.
[6] Lamb, L., S. Bartolone, E. Ward, and M. Chancellor. 2020. Rapid detection of novel coronavirus (COVID-19) by Reverse Transcription-Loop-Mediated Isothermal Amplification. https://doi.org/10.1101/2020.02.19.20025155 (accessed April 4, 2020).
[7] Cepheid. 2020. Xpert Xpress SARS-CoV-2 has received FDA Emergency Use Authorization. https://www.cepheid.com/coronavirus (accessed April 2, 2020).
[8] Abbott. 2020. Detect COVID-19 in as little as 5 minutes. https://www.abbott.com/corpnewsroom/product-and-innovation/detect-covid-19-in-as-little-as-5-minutes.html (accessed April 2, 2020).

(e.g., colorimetric with paper strips), speed (~45 min), and low cost (few dollars per sample).[9,10,11]

A recent report indicates that viral RNA can be detected by RT-PCR directly in NP swab samples without the need for an RNA extraction step, presumably due to the high burden of infection at this body site and the shedding of viral RNA from dead and lysed host cells.[12] In this report, there was only a 20-fold decrease in sensitivity of viral detection; other reports suggest ~100-fold loss in sensitivity. This is an important finding in the event that current shortages of RNA extraction kits continue or worsen.

One approach for increasing the scale of PCR testing relies on pooling samples for initial screening, with follow-up testing of subsets of the original pool if the initial screen produces a positive result.[13] While early tests of this approach are promising and this type of multiplexing strategy has worked in other disease screening scenarios, it will require further validation. If pooled samples prove feasible, pooling could multiply the throughput of test facilities by five- or ten-fold, depending on the prevalence of positive results in the sampled population.

Detection of host immune response

Tests of the second type, i.e., those that detect a host response to the disease agent, typically measure specific antibodies to the agent, and a number of these so-called serological tests for SARS-CoV-2 are coming online as well. These tests also offer useful information, but the utility and meaning of serological information is quite distinct from the utility and meaning of viral RNA diagnostic test results. Serological tests measure whether an individual has been previously exposed to the agent; however, they have also been used to complement RT-PCR results in establishing a diagnosis later in the course of illness (see also Rapid Expert Consultation on Viral Shedding and Antibody Response (April 8, 2020)). IgM antibodies typically appear within days to about a week after the onset of symptoms, and persist for weeks to a month or two. They appear earlier than IgG antibodies but are less specific. IgG antibodies typically first appear in the bloodstream two weeks after infection and last for months and in

[9] Kellner M.J., J.G. Koob, J.S. Gootenberg, O.O. Abudayyeh, and F. Zhang. 2019. SHERLOCK: Nucleic acid detection with CRISPR nucleases. *Nat Protoc* 14:2986-3012.
[10] Lucia C., P. B. Federico, and G. C. Alejandra. An ultrasenstitive, rapid, and portable coronavirus SARS-CoV-2 sequence detection method based on CRISPR-Cas12. 2020. https://doi.org/10.1101/2020.02.29.971127 (accessed 2 April 2020).
[11] Metsky H., C.A. Freije, F. Tinna-Solveig, Kosoko-Thoroddsen, P.C. Sabeti, and M. Cameron. 2020. CRISPR-based surveillance for COVID-19 using genomically-comprehensive machine learning design. https://doi.org/10.1101/2020.02.26.967026 (accessed April 2, 2020).
[12] Bruce E., T. Scott, J. Hoffman, P. Laaguiby, D. Gerrard, S. Diehl, D.G.B. Leonard, et al. 2020. https://biorxiv.org/content/10.1101/2020.03.20.001008v1 (accessed April 2, 2020).
[13] Yelin, I., N. Aharony, E.S. Tamar, A. Argoetti, E. Messer, D. Berenbaum, E. Shafran, et al. 2020. Evaluation of COVID-19 RT-zPCR test in multi-sample pools. https://doi.org/10.1101/2020.03.26.20039438 (accessed April 5, 2020).

some cases, years. Anti-SARS-CoV-2 antibodies of various types have been detected in COVID-19 patients a median of 5 to 14 days following symptom onset (see also Rapid Expert Consultation on Viral Shedding and Antibody Response (April 8, 2020)). Within a few weeks of infection, SARS-CoV-2 antibodies and viral RNA can both be present in the same individual. In general, serological results, especially IgM measurement, may be less specific than molecular tests. All SARS-CoV-2 serological study results should be viewed as suspect until rigorous controls are performed and performance characteristics described, as antibody detection methods can vary considerably, and most so far have not described well-standardized controls. Samples from patients with seasonal (non-SARS-CoV-2) coronavirus infections are especially important as negative controls (see below).

The presence of antibodies against an infectious agent can be a valuable marker for past infection in population-based epidemiologic studies, and they enable assessments of the efficacy of various public interventions in preventing disease spread. Antibodies can also indicate host immunity against the agent. However, in the case of SARS-CoV-2, it is not known whether the presence of antibodies indicates protection from illness.

A consideration of the human immune response to the four seasonal coronaviruses, and to previous emerging coronaviruses, is important to note here. By adulthood, almost everyone has antibodies against these common viruses (hCoV-OC43, hCoV-229E, hCoV-HKU1 and hCoV-NL63); however, people still get infected with these viruses each winter. There are limited data on how this happens, what the antibodies in our blood actually recognize on these viruses, why naturally-occurring antibodies do not protect us, how the seasonal coronaviruses mutate each year, and why we see them in the winter but not in the summer.

In analyses of antibody responses in individuals exposed to MERS-CoV, commercial ELISA kits in general exhibited good specificity but poor sensitivity compared to a plaque reduction/neutralization titer assay used in a research laboratory.[14] Establishing standards with high sensitivity and specificity that are accepted and followed by all laboratories will be key to determining true exposure to SARS-CoV-2 and potential immunity and for obtaining validated results. In addition, in the case of MERS, as with SARS-CoV-2 (see above), high levels of antibody and of virus are often found in the same patient.[15] Measurements of T cell responses to SARS-CoV-2 may be useful as a complement to antibody assays, in the same fashion as with MERS-CoV.[16]

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[14] Alshukairi A., J. Zheng, J. Zhao, A. Nehdi, S. Baharoon, L. Layqah, A. Bokhari, et al. 2018. High prevalence of MERS-CoV infection in camel workers in Saudi Arabia. *mBio* 9. pii: e01985-18.

[15] Corman V.M., A.M. Albarrak, A.S. Omrani, M.M. Albarrak, M.E. Farah, M. Almasri, D. Muth, et al. 2016. Viral shedding and antibody response in 37 patients with Middle East Respiratory Syndrome coronavirus infection. *Clin Infect Dis* 62(4):477-483.

[16] Zhao, J., A.N. Alshukairi, S.A. Baharoon, W.A. Ahmed, A.A. Bokhari, A.M. Nehdi, L.A. Laygah, et al. 2017. Recovery from the Middle East respiratory syndrome is associated with antibody and T cell responses. *Sci Immunol* 2:eaan5393.

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Determination of infectivity

Current molecular tests for RNA do not determine whether there is viable virus in the specimen. For example, high levels of viral RNA can be found in stool samples, but infectious virus is typically not isolated from these samples.[17] Some types of viral RNA intermediates may be indicative of active replication in, or proximal to, the specimen. These RNAs are produced during the viral life cycle in a human cell but are not incorporated into the mature virus particle; thus, the presence of these RNAs indicates active replication, rather than previously-assembled viable virus. The identification and development of assays for these non-packaged replicative RNA intermediates may have clinical utility in predicting an increased likelihood of the presence of infectious virus. Protein-based tests for virus are more likely to be superior in detecting infectivity than genomic tests as proteins are degraded more rapidly than viral RNA.

Research needs

There are several important unmet needs, some of which are now the subject of ongoing research.

- It would be quite helpful to have a test that identifies infected individuals before they are symptomatic and before they shed virus and become infectious for others. One promising approach is to identify human genes that are expressed early in infection, perhaps in blood or saliva, with some specificity for the infection of interest. Work on broad classes of viral and bacterial infections suggests that this may be possible,[18,19] and groundwork on SARS-CoV-2 has begun.[20]
- A comprehensive mapping of antibody specificity during the course of SARS-CoV-2 infection, i.e., a survey of antibody reactivity and function, would greatly help in understanding variability in the outcome of infection in different individuals, risk stratification, the relationship of pre-existing antibody profiles with SARS-CoV-2 outcome, and the identification of optimal vaccine antigens. An interesting preprint by Khan, et al. describes the creation of a microarray with 67 antigens from all known coronaviruses and other known respiratory viruses that will help elucidate whether baseline anti-coronavirus antibodies might influence the clinical course of COVID-19, and help to describe the evolution of the immune response during the course of SARS-

[17] Wölfel, R., V. Corman, W. Guggemos, M. Seilmaier, S. Zange, M. Muller, D. Niemeyer, et al. 2020. Virological assessment of hospitalized patients with COVID-2019. *Nature* https://doi.org/10.1038/s41586-020-2196-x (accessed April 4, 2020).
[18] Mayhew M.B., L. Buturovic, R. Luethy, U. Midi, A.R. Moore, J.A. Roque, B.D. Shaller, et al. 2020. A generalizable 29-mRNA neural-network classifier for acute bacterial and viral infections. *Nat Commun* 11:1177. https://www.nature.com/articles/s41467-020-14975-w (accessed April 4, 2020).
[19] Warsinske H., R. Vashisht and P. Khatri. 2019. Host-response-based gene signatures for tuberculosis diagnosis: A systematic comparison of 16 signatures. 2019. *PLoS Med* 16(4):e1002786.
[20] Blanco-Melo D., B.E. Nilsson-Payant, W, Liu, R. Møller, M. Panis, D. Sachs, R.A. Albrecht, and B.R. tenOever. 2020. SARS-CoV-2 launches a unique transcriptional signature from in vitro, ex vivo, and in vivo systems. https://doi.org/10.1101/2020.03.24.004655 (accessed April 2, 2020).

CoV-2 infection.[21] Other, more comprehensive antibody profiling technology already exists, and awaits application to COVID-19 patient serum samples.[22]

- Well-controlled longitudinal studies are critically needed as they can determine the relationship between different types of SARS-CoV-2-specific antibodies and the likelihood of an individual becoming re-infected. A critical goal is identification of antibodies that neutralize and block SARS-CoV-2 viral infection, as well as the determination of how much neutralizing antibody is needed for protection. As a technical note, proper identification of neutralizing antibodies will require not only pseudotyped virus with the appropriate epitopes, but fresh clinical isolates of SARS-CoV-2 virus as well.

Summary

The two general classes of diagnostic tests, one to detect viral RNA and the other to detect human antibodies directed against the virus, each provide a distinct set of benefits and weaknesses. Detection of viral RNA generally indicates active, ongoing infection and suggests infectiousness for others, especially early in the course of infection, although the persistence of detectable viral RNA weeks after infection may no longer be synonymous with virus capable of causing infection. Antibody tests provide evidence of past exposure and possible immunity; however, the relationship between antibody and protection has not been established for this virus. Both types of tests will require proper validation and new longitudinal studies of infected individuals before they can be properly interpreted.

My colleagues and I hope this input is helpful to you as you continue to guide the nation's response in this ongoing public health crisis.

Respectfully,

David A. Relman, M.D.
Member
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

[21] Khan S., R. Nakajiima, A. Jain, R. Ramiro de Assis, A. Jasinskas, J.M. Obiero, O. Adenaiye, et al. 2020. Analysis of serological cross-reactivity between common human coronaviruses and SARS-CoV-2 using coronavirus antigen microarray. https://doi.org/10.1101/2020.03.24.006544 (accessed April 2, 2020).
[22] Xu G. J., T. Kula, Q. Xu, M. Z. Li, S. D. Vernon, T. Ndulng'u, K. Ruxrungtham, et al. 2015. Comprehensive serological profiling of human populations using a synthetic human virome. *Science* 348(6239):aaa0698.

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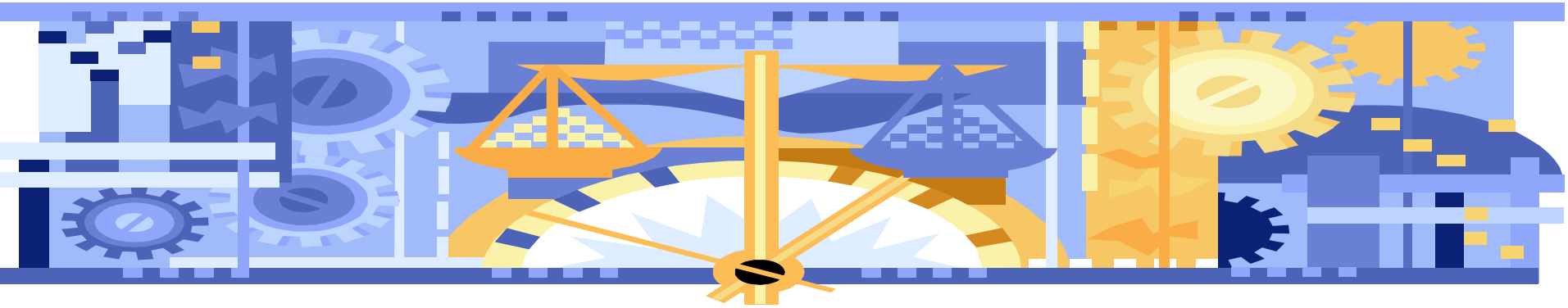
APPENDIX

Authors and Reviewers of this Rapid Expert Consultation

This rapid expert consultation was prepared by staff of the National Academies of Sciences, Engineering, and Medicine, and members of the National Academies' Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats: David Relman, Stanford University; David Walt, Brigham and Women's Hospital, Harvard Medical School; and Kristian Andersen, The Scripps Research Institute.

Harvey Fineberg, chair of the Standing Committee, approved this document. The following individuals served as reviewers: Linsey Marr, Virginia Tech; Matthew Frieman, University of Maryland School of Medicine; Stanley Perlman, University of Iowa; Michael Diamond, Washington University; Mark Denison, Vanderbilt University Medical Center; Jim Chappell, Vanderbilt University Medical Center, and Michael Osterholm, University of Minnesota. Ellen Clayton, Vanderbilt University Medical Center, and Susan Curry, University of Iowa, served as arbiters of this review on behalf of the National Academies' Report Review Committee and its Health and Medicine Division.

Preparedness, Public Health, and the Law



Preparedness, Public Health, and the Law

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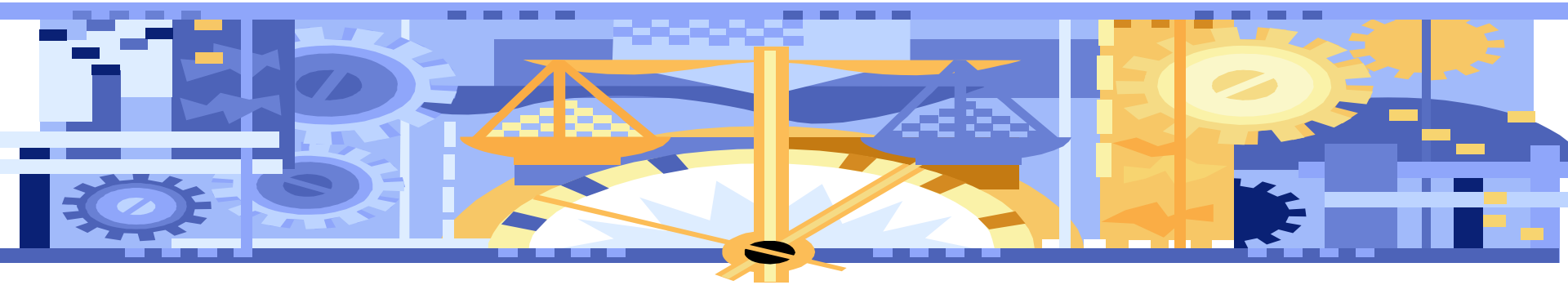


What are we doing here?

- Who are these people?
- Planning?
- Legal Overview
- Review of the Hypothetical case
- Next Steps

Who are you going to call? For what?

- What is the role of homeland security?
- What is law enforcement supposed to do?
- National Guard?
- Public Health- aren't those the measles and mumps guys?
- Lawyers- whose?

Public Health Systems

- Monitor health status to identify and solve community health problems.
- Diagnose and investigate health problems and health hazards in the community.
- Inform, educate, and empower people about health issues.
- Mobilize community partnerships and action to identify and solve health problems.
- Develop policies and plans that support individual and community health efforts.

- Enforce laws and regulations that protect health and ensure safety.
- Link people to needed personal health services and assure the provision of health care when otherwise unavailable.
- Assure competent public and personal health care workforce.
- Evaluate effectiveness, accessibility, and quality of personal and population-based health services.
- Research for new insights and innovative solutions to health problems.

The Core Public Health Functions

- Core Function 1—Assessment
  - Assessment, monitoring, and surveillance of local health problems and needs, and of resources for dealing with them
- Core Function 2—Policy Development
  - Policy development and leadership that fosters local involvement and a sense of ownership that emphasizes local needs and that advocates equitable distribution of public resources and complementary private activities commensurate with community needs
- Core Function 3—Assurance
  - Assurance that high-quality services, including personal health services, needed for protection of public health in the community are available and accessible to all persons; that the community receives proper consideration in the allocation of federal, state and local resources for public health; and that the community is informed about how to obtain public health, including personal health services, or how to comply with public health requirements

Emergency Management

- The Constitution tasks the States with responsibility for public health and safety—hence, they are responsible for public risks, while the Federal Government's ultimate obligation is to help when State, local, or individual entities are overwhelmed.
- The overall goals of emergency management at all levels are:
  - First, to reduce the loss of life;
  - Then, to minimize property loss and damage to the environment;
  - And finally, to protect the jurisdiction from all threats and hazards.

National Preparedness System

- Functions for National Preparedness Goal.
  - Identifying and Assessing Risk
  - Estimating Capability Requirements
  - Building and Sustaining Capabilities
  - Planning to Deliver Capabilities
  - Validating Capabilities
  - Reviewing and Updating

- https://emilms.fema.gov/is1a/EMOPsummary.htm

http://www.phe.gov/about/aspr/strategic-plan2014/Pages/default.aspx

- Mission, Vision, Values
- Goal 1: Promote resilient communities by fostering a nation able to withstand and recover from public health emergencies.
- Goal 2: Strengthen leadership and capabilities within public health and medical emergency management to include prevention, preparedness, mitigation, response, and recovery.
- Goal 3: Promote an effective medical countermeasures enterprise.
- Goal 4: Lead, coordinate, and develop proactive and forward thinking policies that support national and international public health and medical preparedness, response, and recovery capabilities.
- Goal 5: Improve health outcomes from disasters by strengthening the ability of our nation's health care system to effectively respond and recover.
- Goal 6: Improve ASPR adaptability and resilience by maximizing workforce potential, developing leadership, and encouraging a continuous learning culture.

Derivation of legal authority for government action

- **A particular action must be based on statute, regulation, or other legal precedent.**
- **Authority does not necessarily equal policy.**
- **Important tool, but not a substitute for**
  - **Planning**
  - **Resources**
  - **Communication.**

Legal Framework of Government

- United States Constitution
  - Federal Legislation
    - Regulations
- State (Michigan) Constitution
  - State Laws
    - State Regulations
  - Local Ordinances

U.S. Constitution

- Preamble:
- We the People of the United States, in Order to form a more perfect Union, establish Justice, insure domestic Tranquility, provide for the common defence, promote the general Welfare, and secure the Blessings of Liberty to ourselves and our Posterity, do ordain and establish this Constitution for the United States of America.

State and Federal

- Federal courts and agencies have jurisdiction when an act of terror is involved.
- States have all public health responsibility by reason of the 10th Amendment.
- The Constitution of Michigan establishes the framework of courts and law for Indiana.

10th Amendment to the U.S. Constitution

- **Powers of the States and People.** The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.
- **Ratified 12/15/1791.**

Article 1. Bill of Rights

Section 1. WE DECLARE, That all people are created equal; that they are endowed by their CREATOR with certain inalienable rights; that among these are life, liberty, and the pursuit of happiness; that all power is inherent in the people; and that all free governments are, and of right ought to be, founded on their authority, and instituted for their peace, safety, and well-being. For the advancement of these ends, the people have, at all times, an indefeasible right to alter and reform their government.

(History: As Amended November 6, 1984).

Case Law

- Few cases are tried
- Fewer are appealed
- Fewer are published

- In political terms, Understand the SWAP
- In economic terms, do a cost benefit analysis

Isolation

- the physical separation, including confinement or restriction, of an individual or a group of individuals from the general public if the individual or group is infected with a dangerous communicable disease, in order to prevent or limit the transmission of the disease to an uninfected individual.

- TREATMENT is not a statutory reason.

Quarantine

- **Range of community containment strategies for infectious diseases**
- **Applied to persons exposed but *not ill*, i.e., contacts (not cases)**
- **Designed to meet two objectives**
  - **Facilitate early recognition of symptoms of a contagious disease, should they develop**
  - **Reduce risk of transmission before progression to disease has been recognized**

Panic In the Streets

- Film shot in New Orleans in 1950. This is the story of a public health worker (Richard Widmark) and a police detective (Paul Douglas) who have only a few hours in which to capture some fleeing felons who may be infected with the plague.
- http://www.amazon.com/exec/obidos/ASIN/6301863208/qid=1028651532/sr=1-1/ref=sr_1_1/002-1546438-4826408

From the Streets to the Courts

Martial Law and Public Health

- Martial law has been federally imposed only a few times, although various state governors have declared it on numerous occasions.
- Scheiber and Scheiber, supra note 93, at 478, 480.
- Dames & Moore v. Regan, 453 U.S. 654, 661 (1981).
- Youngstown, 343 U.S. 579 (1952).

Martial Law

- Justice Jackson mentioned that "[a]side from the suspension of the privilege of habeas corpus," the framers made "no express provision for exercise of extraordinary authority because of a crisis." Youngstown, 343 U.S. at 650. In a footnote to that comment, he wrote: "I exclude, as in a very limited category by itself, the establishment of martial law." Id. n.19 (citing Ex parte Milligan, 71 U.S. (4 Wall.) 2 (1866) and Duncan v. Kahanamoku, 327 U.S. 304 (1946) (citations omitted), (see infra Parts III.B and III.C for a discussion of these cases).
- 28. . Ex parte Milligan, 71 U.S. (4 Wall.) 2 (1866).
- 29. . REHNQUIST, supra note 106, at 60 (citations omitted). See generally Hasday, supra note 91, at 130-32 (discussing President Lincoln's actions relating to the suspension of the writ of habeas corpus during the Civil War.).

Bayonets in Paradise : Martial Law in Hawai`i during World War II

- Recounts the extraordinary story of how the army imposed rigid and absolute control on the total population of Hawaii during World War II.
- Duncan v. Kahanamoku, in which the U.S. Supreme Court heard argument on the martial law regime—and ruled in 1946 that provost court justice and the military's usurpation of the civilian government had been illegal.

Law of Populations

- Population-based legal analysis is the theoretical foundation of public health law. The law of populations is a relatively new theoretical framework in jurisprudence that seeks to analyze legal problems using the tools of epidemiology. Population-based legal analysis can be applied to traditional public health problems but also has application in environmental law, zoning, evidence, and complex tort.

SUMMARY

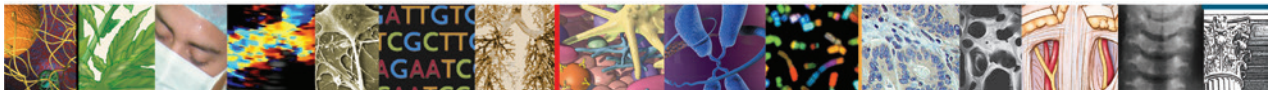
- United States Constitution
  - Rights guaranteed to citizens cannot be violated by the states
  - 14th Amendment
  - Section 1983
- Michigan Constitution
  - Provides framework for the actions of state and local governments
  - Provides due process protections for those who live in Indiana
  - Laws and Writ of habeas corpus may not be suspended

It Is Not Easy Being Healthy

- Individuals
  - Lack of understanding
  - Fear of costs
  - Government Interference with Rights

- Elected Officials
  - Lots of Noise
  - No Background
  - Local Budget and Squeaky Wheels
  - Who can they trust?
  - State is not seen as helpful but source of unfunded mandates

COVID-19
The Law and Limits of Quarantine



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Perspective

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Covid-19 — The Law and Limits of Quarantine

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As Covid-19 spreads around the globe, governments have imposed quarantines and travel bans on an unprecedented scale. China locked down whole cities, and Italy has imposed draconian restrictions throughout the country. In the United States, thousands of people have been subjected to legally enforceable quarantines or are in "self-quarantine." The federal government has also banned entry by non–U.S. nationals traveling from China, Iran, and most of Europe and is screening passengers returning from heavily affected countries. Still, the numbers of cases and deaths continue to rise.

Quarantines and travel bans are often the first response against new infectious diseases. However, these old tools are usually of limited utility for highly transmissible diseases, and if imposed with too heavy a hand, or in too haphazard a manner, they can be counterproductive.[1] With a virus such as SARS-CoV-2, they cannot provide a sufficient response.

In public health practice, "quarantine" refers to the separation of persons (or communities) who have been exposed to an infectious disease. "Isolation," in contrast, applies to the separation of persons who are known to be infected. In U.S. law, however, "quarantine" often refers to both types of interventions, as well as to limits on travel. Isolation and quarantine can be voluntary or imposed by law.

Inside the country, isolation and quarantine orders have traditionally come from the states. Courts have typically upheld these orders in deference to the states' broad powers to protect public health. Nevertheless, courts have occasionally intervened when a quarantine was unreasonable or when officials failed to follow necessary procedures. For example, in *Jew Ho v. Williamson* (1900), a federal court struck down a quarantine imposed by San Francisco in response to an outbreak of bubonic plague because it was racially motivated and ill-suited to stop the outbreak.

Although isolation and quarantine orders have been less common in recent decades, many states have isolated patients with tuberculosis who did not adhere to medication regimens.[2] At least 18 states quarantined people returning from West Africa during the 2014 Ebola outbreak.[3] In March 2019, Rockland County, New York, prohibited all minors who were unvaccinated against measles from entering any place of public assembly. In *W.D. v. County of Rockland* (2019), a New York State judge struck down that order, ruling that there was no emergency. Most states, however, do not require an emergency declaration in order to issue a quarantine.

The federal quarantine power is limited to preventing the spread of communicable diseases into the

country or across state lines. Section 361 of the Public Health Service Act grants the Surgeon General the power (since delegated to the Centers for Disease Control and Prevention [CDC]) to apprehend, detain, or issue a conditional release for the purpose of preventing the introduction into the country, or the spread across state lines, of a quarantinable disease, as designated by executive order (see box). The current list includes "severe acute respiratory syndromes," which encompasses Covid-19.

Quarantinable Diseases.*

Cholera
Diphtheria
Infectious tuberculosis
Plague
Smallpox
Yellow fever
Viral hemorrhagic fevers
Severe acute respiratory syndromes
Influenza that can cause a pandemic

* From the Centers for Disease Control and Prevention. Legal authorities for isolation and quarantine. www.cdc.gov/quarantine/aboutlawsregulationsquarantineisolation.html.

Despite the breadth of its powers, the CDC has generally focused on providing expert guidance to states during outbreaks. In 2017, however, the agency issued new quarantine regulations (codified in 42 Code of Federal Regulations [CFR], parts 70 and 71) suggesting that it would no longer defer to the states. These regulations make clear that, independent of state action, the CDC may isolate, quarantine, examine, or bar travel of anyone within the country who CDC officials reasonably believe may bring a communicable disease into the country or spread it across state lines. When the secretary of health and human services declares a public health emergency, as Secretary Alex Azar did on January 31, these orders can be issued against persons in the precommunicable stage, which begins at a person's earliest opportunity for exposure to an infection and ends on the latest date at which the person could reasonably be expected to become contagious.

The regulations also commit the CDC to providing medical care for people who are detained, but they may charge insurers for that care. In addition, they establish a multilevel internal administrative review process. But they do not ensure expeditious or independent review of detention orders or travel bans. Moreover, although the CDC stated that it would "seek to use the least restrictive means necessary to prevent the spread of communicable diseases," the regulations do not require the agency to adhere to that standard. Though the CDC's quarantine powers permit it to deny entry into the United States for a quarantinable disease, President Trump relied on Sections 212(f) and 215(a) of the Immigration and Naturalization Act to ban Chinese and Iranian nationals from entering the country.

Despite their breadth, the federal and state quarantine powers are subject to important constitutional limitations.[2] First, as *Jew Ho* affirmed, quarantines cannot be imposed in a racially invidious manner. Second, governments must have a strong basis for the restrictions. Looking to case law regarding civil commitment, many scholars and some lower courts have concluded that isolation and quarantine are constitutional only when the government can show by clear and compelling evidence that they are the least restrictive means of protecting the public's health. However, at least two federal courts reviewing postdetention challenges to Ebola quarantines held that the standard was not sufficiently well established to allow the claims to go forward.[3] Third, persons who are detained, or whose liberty is otherwise restricted, are entitled to judicial review — traditionally under the writ of habeas corpus.[3] Finally, when governments detain people, they must meet those people's basic needs, ensuring access to health care, medication, food, and sanitation. Such standards are not only constitutionally compelled: they are critical to ensuring that detained persons comply with orders.

Although we are likely to see greater use of robust social distancing measures, such as school closures or the cancellation of public meetings, broad sanitary cordons — in which geographic areas are quarantined — would raise serious constitutional questions. They also can present numerous logistical challenges and can increase the risk to those living in the restricted zone. Such measures may also have limited efficacy with a highly contagious disease such as Covid-19.[4]

With community transmission occurring in several parts of the United States, it is time to recognize that travel bans and mandatory quarantines alone cannot end the outbreak. In a public letter to the Trump administration, we (along with more than 800 other public health and legal scholars and organizations) argue that more constructive tools are needed.[5]

Flattening the curve — slow-

ing the spread of Covid-19 across space and time — is critical. The health care system cannot sustain a massive influx of infectious cases to emergency departments and hospitals. Patients with mild symptoms should stay home when possible. To facilitate this step, workers should be allowed to telecommute wherever it's feasible to do so. But many low-wage and gig workers cannot afford to stay home. Nor can they handle the economic impact of other social distancing measures that may help to slow transmission. On March 13, the House of Representatives, with President Trump's support, took the first step by passing the Families First Coronavirus Response Act, which includes provisions for paid sick leave and unemployment insurance for many, but unfortunately not all, workers. As of mid March, the Senate has yet to take up the bill.

We must also reduce hurdles to testing and care. The House bill would provide free testing, but more needs to be done to ensure that testing kits are available. Furthermore, noncitizens must be protected from adverse immigration consequences for seeking testing or care or for complying with contact tracing. Finally, emergency guidance or regulations can be issued to limit the financial impact of high-deductible health plans and "surprise bills" from out-of-network providers for Covid-19 diagnosis or treatment.

Despite the breadth and allure of travel bans and mandatory quarantine, an effective response to Covid-19 requires newer, more creative legal tools. With Covid-19 in our communities, the time has come to imagine and implement public health laws that emphasize support rather than restriction.

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Jacobson v. Massachusetts: It's Not Your Great-Grandfather's Public Health Law

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Jacobson v Massachusetts: It's Not Your Great-Great-Grandfather's Public Health Law

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Abstract

Jacobson v Massachusetts, a 1905 US Supreme Court decision, raised questions about the power of state government to protect the public's health and the Constitution's protection of personal liberty. We examined conceptions about state power and personal liberty in *Jacobson* and later cases that expanded, superseded, or even ignored those ideas.

Public health and constitutional law have evolved to better protect both health and human rights. States' sovereign power to make laws of all kinds has not changed in the past century. What has changed is the Court's recognition of the importance of individual liberty and how it limits that power. Preserving the public's health in the 21st century requires preserving respect for personal liberty.

> *"The case before us must be considered in the light of our whole experience and not merely in that of what was said a hundred years ago."*
>
> *—Missouri v Holland*[1]

ONE HUNDRED YEARS AGO, in *Jacobson v Massachusetts*, the US Supreme Court upheld the Cambridge, Mass, Board of Health's authority to require vaccination against smallpox during a smallpox epidemic.[2] *Jacobson* was one of the few Supreme Court cases before 1960 in which a citizen challenged the state's authority to impose mandatory restrictions on personal liberty for public health purposes. What might such a case teach us today? First, it raises timeless questions about the power of state government to take specific action to protect the public's health and the Constitution's protection of personal liberty. What limits state power? What does constitutionally protected liberty include? Second, answers to these questions can change as scientific knowledge, social institutions, and constitutional jurisprudence progress. A comparison of answers to these questions 100 years ago and today shows how public health and constitutional law have evolved to better protect both health and human rights.

Jacobson was decided in 1905, when infectious diseases were the leading cause of death and public health programs were organized primarily at the state and community levels. The federal government had comparatively little involvement in health matters, other than preventing ships from bringing diseases such as yellow fever into the nation's ports.[3] Few weapons existed to combat epidemics. There was no Food and Drug Administration (FDA), no regulation of research, and no doctrine of informed consent. The Flexner Report was 5 years in the future, medicine would have little to offer until sulfonamides were developed in the 1930s, and most vaccines would not be available for almost half a century. [4,5] Hospitals were only beginning to take their modern form,[6] and people who had mental illnesses were often shut away in asylums.[7,8] Contraception and interracial marriage were crimes,[9] women did not have the right to vote, and Jim Crow laws prevented African American men from exercising constitutional rights that it took the Civil War to win.[10]

Today, smallpox has been eradicated. The major causes of death are chronic diseases and trauma, which are influenced by multiple factors, including environment, occupation, socioeconomic status, race/ethnicity, diet, behavior, and political inequality.[11,12] Immunizations prevent many infectious diseases, and new outbreaks are most likely to result from global travel, laboratory accidents, or even criminal acts.[13] Scientific advances have produced an array of health care facilities, drugs, vaccines, and technologies to prevent and treat health problems. Much of the responsibility for regulating the safety of the workplace, air, water, food, and drugs has shifted to the federal government.[14] Women have the right to vote and to decide whether to have children. Patients have the right to refuse medical treatment,[15] and everyone has the right to be free from arbitrary or discriminatory detention.[16]

The states' sovereign power to make laws of all kinds has not changed during the past century. What has changed is the US Supreme Court's recognition of the importance of individual liberty and how it limits that power. Additionally, states have changed how they use their power and what they regulate as new health problems and solutions emerge. In this article, we discuss these changes by examining (1) the conceptions of state power and personal liberty discussed in *Jacobson* and (2) 20th-century cases that expanded, superseded, or even ignored those concepts. Finally, we speculate about how challenges to analogous public health laws would be decided today in light of the evolution of science and constitutional law.

JACOBSON V MASSACHUSETTS

As the 20th century began, epidemics of infectious diseases such as smallpox remained a recurrent threat. A Massachusetts statute granted city boards of health the authority to require vaccination "when necessary for public health or safety."[17] In 1902, when smallpox surged in Cambridge, the city's board of health issued an order pursuant to this authority that required all adults to be vaccinated to halt the disease. The statutory penalty for refusing vaccination was a monetary fine of $5 (about $100 today). There was no provision for actually forcing vaccination on any person.

Henning Jacobson refused vaccination, claiming that he and his son had had bad reactions to earlier vaccinations. The Massachusetts Supreme Judicial Court found it unnecessary to worry about any possible harm from vaccination, because no one could actually be forced to be vaccinated: "If a person should deem it important that vaccination should not be performed in his case, and the authorities should think otherwise, it is not in their power to vaccinate him by force, and the worst that could happen to him under the statute would be the payment of $5."[18] Jacobson was fined, and he appealed to the US Supreme Court.

The Supreme Court had no difficulty upholding the state's power to grant the board of health authority to order a general vaccination program during an epidemic. No one disputed, and the Constitution confirmed, that states retained all the sovereign authority they had not ceded to the national government in the Constitution.[19–23] There had never been any doubt that, subject to constitutional

limitations, states had authority to legislate with respect to all matters within their geographic boundaries, or to police their internal affairs, which Chief Justice Marshall referred to as the "police power."[24–26] During the 1800s, the Supreme Court confirmed that this power included the power to pass laws that promote the "health, peace, morals, education and good order of the people."[27–29] Most early Supreme Court cases that involved state police powers, however, were disputes over which level of government—state or federal—had jurisdiction to regulate or tax a commercial activity.[30–37] *Jacobson* was the rare case in which a state's jurisdiction was not questioned—because no one claimed that the federal government should control a local smallpox epidemic. Instead, the question was whether the state had overstepped its own authority and whether the sphere of personal liberty protected by the Due Process Clause of the 14th Amendment[38] included the right to refuse vaccination.

Justice Harlan stated the question before the Court: "Is this statute . . . inconsistent with the liberty which the Constitution of the United States secures to every person against deprivation by the State?"[2(p25)] Harlan confirmed that the Constitution protects individual liberty and that liberty is not "an absolute right in each person to be, in all times and in all circumstances, wholly free from restraint":

> *There is, of course, a sphere within which the individual may assert the supremacy of his own will and rightfully dispute the authority of any human government, especially of any free government existing under a written constitution. But it is equally true that in every well-ordered society charged with the duty of conserving the safety of its members the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand.*[2(p29)]

Thus, the more specific questions were whether the safety of the public justified this particular restriction and whether it was enforceable by reasonable regulations. The Court answered *yes* to both questions. It noted that the vaccination law applied "only when, in the opinion of the Board of Health, that was necessary for the public health or the public safety."[2(p27)] The board of health was qualified to make that judgment, and, consistent with its own precedents, the Court said that it was the legislature's prerogative to determine *how* to control the epidemic, as long as it did not act in an unreasonable, arbitrary or oppressive manner.[2,39,40] Vaccination was a reasonable means of control: "The state legislature proceeded upon the theory which recognized vaccination as at least an effective if not the best known way in which to meet and suppress the evils of a smallpox epidemic that imperiled an entire population."[2(p31)]

The Court nonetheless concluded with a note of caution:

> *The police power of a State, whether exercised by the legislature, or by a local body acting under its authority, may be exerted in such circumstances or by regulations so arbitrary and oppressive in particular cases as to justify the interference of the courts to prevent wrong and oppression.*[2(p38)]

For example, it noted that the law should not be understood to apply to anyone who could show that vaccination would impair his health or probably cause his death.

In most respects, *Jacobson* was an easy case.[41] The decision held that a state may require healthy adults to accept an effective vaccination when an existing epidemic endangers a community's population. As with all court decisions, what this "means" is a matter of interpretation. *Jacobson* may be what Sunstein called a narrow and shallow decision—narrow because it is not intended to apply to a broad range of legislation, and shallow because it does not explicitly rely on a general theory of

constitutional interpretation to justify its result.[42] People who have quite different world views or philosophies can accept the decision because it need not require the same result for different laws or in different circumstances. Not surprisingly, judges and scholars emphasize different language in the opinion to support different interpretations.[43–46]

JACOBSON'S INFLUENCE DURING THE FIRST HALF OF THE 20TH CENTURY

The Court described police power as essentially unlimited except by provisions of the Constitution and the state's own constitution. The federal Constitution created federal powers; it did not create state powers. The Court did not attempt to specify what the police power covers, because it is essentially the power of a sovereign state to make and enforce laws.[21] Thus, the real question was, and continues to be, what limits sovereign state power?

The Court confirmed that the 14th Amendment protected individual liberty, which limits state power. It did not attempt to specify everything included in the definition of liberty, because liberty is a broad concept. Beyond freedom from physical restraint or bodily invasion, it includes freedom of thought, belief, expression, and decisionmaking. The constitutional question was whether the state could justify restricting 1 aspect of liberty (the liberty to refuse vaccination). Without justification, the law is unconstitutional. With justification that meets constitutional standards, the restriction on liberty does not violate the Constitution.

The Court mentioned 2 justifications for the Massachusetts law. First, it found that the state may be justified in restricting individual liberty "under the pressure of great dangers" to "the safety of the general public." The statute, by its terms, encroached on liberty only when "necessary for the public health or safety."[2(p29)] The smallpox epidemic proved the danger to the public. Second, by using the language of earlier decisions, the Court said that laws should not be arbitrary or oppressive. It also suggested that the state should use means that have a "real or substantial relation" to their goal.[2(p31)] In this case, vaccination was a reasonable means to achieve the goal of controlling the epidemic. It was not an arbitrary choice; it had a real and substantial relation to preventing the spread of smallpox.

These standards reflect the classic principle *sic utere tuo ut alienum non laeda*—so use your own that you do not injure another man's property—that the Court had applied in earlier cases.[23,26] One might have expected that these standards would be used to judge the validity of laws that restrict personal liberty. In later cases, however, the Court did not necessarily require states to meet these standards. Instead, it sometimes ignored the standards in favor of a more general principle that permitted more discretionary use of state power. For example, in 1922, in *Zucht v King*, the only other US Supreme Court decision that addressed immunizations, the Court upheld a city ordinance that prohibited anyone from attending a public or private school without a certificate of smallpox vaccination.[47] Rosalyn Zucht, who refused vaccination, challenged the ordinance as unnecessary after she was excluded from school. The Court did not mention the questions of whether smallpox posed any danger, whether vaccination was necessary, or whether the ordinance was arbitrary or oppressive. Its 3-paragraph opinion noted simply that states can grant cities broad authority to decide when to impose health regulations.

In 1927, in *Buck v Bell*, the US Supreme Court upheld a Virginia law that authorized the involuntary sterilization of "feeble minded" persons in state institutions.[48] Theories of eugenics enjoyed some medical and scientific support during the 1920s and 1930s.[49] The Court found that the law served the public health and welfare because "mental defectives" would produce degenerate criminal offspring or imbeciles who "sap the strength of the state."[48(p207)] In a chilling opinion, Justice Oliver Wendell Holmes concluded:

> *Society can prevent those who are manifestly unfit from continuing their kind. The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes. Jacobson v Massachusetts, 197 US 11. Three generations of imbeciles are enough.*[48](p207)

Jacobson was cited as support for the general principle that public welfare was sufficient to justify involuntary sterilization. The decision extended the police power's reach from imposing a monetary penalty for refusing vaccination to forcing surgery on a young woman against her will and depriving her of the ability to have children.[50] The Court did not require the state to demonstrate that sterilization was necessary and not arbitrary or oppressive. This suggests that the Court did not view *Jacobson* as having required any substantive standard of necessity or reasonableness that would prevent what today would be considered an indefensible assault. The Court did not even consider that Carrie Buck might have any right to personal liberty. With the Court's imprimatur of involuntary sterilization laws, more than 60 000 Americans, mostly poor women, were sterilized by 1978.[51]

Such cases diluted the reasons that justified restrictions on personal liberty. The Court did not always say that danger meant an immediate threat to the public at large, and it accepted a broader range of means as reasonable. The Court generally accepted, with little analysis, the legislature's judgment of what should be done to protect public health and safety, at least where only individual liberty was affected.[52–54] In contrast, when state laws regulated commercial businesses and economic relationships, the Court typically required a close fit between goals and means.[55] In *Lochner v New York*, which was decided 2 months after *Jacobson,* the Court struck down a New York state statute that limited the working hours of bakers to 60 hours per week, because it was "an unreasonable, unnecessary and arbitrary interference with the right and liberty of the individual to contract in relation to his labor." [56] The period between 1905 and 1937 is sometimes called the *Lochner* era, because the Court struck down many laws that regulated private economic relationships, such as labor laws, as a violation of property rights (also protected by the Due Process Clause) and freedom of contract.[43] These decisions reflected a prevalent belief that private property and a laissez-faire economic order were essential to preserve individual liberty and economic opportunity.[22,23,26,57]

By 1937, the Depression had shattered the belief that individuals could always take care of themselves, and the Roosevelt Administration pressed for reform legislation.[58] An increasing number of justices and scholars recognized that economic survival and personal freedom required some affirmative government action to provide services and to regulate private industry.[59] Thus, even seemingly private decisions could be viewed as affected by the public interest and subject to regulation.[60] The Court abandoned its *Lochner* jurisprudence and ultimately overruled or ignored decisions from that era.[61–63] The Court began to routinely uphold state and federal legislation, and it accepted any plausible means a legislature chose to pursue legitimate ends, unless the law violated the Constitution.[64–66]

The Court then faced the problem of deciding how constitutional provisions limited government action. The Bill of Rights describes individual rights in broad terms, such as freedom of speech and due process of law. In a democracy that has no official religion or ideology, any interpretation of such abstract concepts could be attacked as merely the justices' personal philosophy.[67] Yet, if they upheld all laws that are purported to serve the common good, such as involuntary sterilization, government power would be unlimited—the definition of tyranny.[68] There was agreement that the Constitution was intended to prevent tyranny by government and that the Bill of Rights (and later amendments) were added to forbid majority rule on matters of fundamental importance.[69] Thus, the Court began to recognize a carefully limited hierarchy of individual rights that deserved protection from government invasion.[70,71] The Court still struggles with the problem of finding legitimate bounds on government powers. Nevertheless, it has consistently relied on constitutional rights to limit state power.

MODERN CONSTITUTIONAL LAW: RECOGNITION OF HUMAN AND CIVIL RIGHTS

During the second half of the 20th century, the US Supreme Court recognized that the liberty protected by the 14th Amendment included most of the rights guaranteed by the Bill of Rights.[43] Individuals were protected from an abuse of state and federal power. World War II and the Nazi atrocities spurred recognition of human rights, as exemplified by the Nuremberg Code.[72] In the United States, the civil rights movement of the 1950s challenged the assumption that state legislatures could be presumed to act in the best interests of all their citizens in a way that had not been seen since the Civil War. The civil rights movement changed the social structure with as much force as the New Deal changed the economic structure. *Brown v Board of Education*,[73] which struck down state-imposed school segregation, marked a turning point when it signaled the Court's new willingness to look closely at what state laws require or forbid and to strike down laws that invidiously discriminated against African Americans.[74] During the next 2 decades, women, people with mental illnesses, and prisoners followed the example of African Americans and challenged laws that treated them unfairly.

The Court created an explicit hierarchy of rights and tests for determining whether laws justifiably restricted different constitutionally protected rights, such as freedom from self-incrimination[75] and unreasonable search and seizure.[76] For constitutionally protected liberty, the Court recognized that some aspects of liberty, such as freedom from arbitrary detention and bodily intrusion, are more important than others, such as freedom to use property or money.[77–79] The most important, which were deemed "fundamental," were subjected to the "strict scrutiny" test: the Court determined (1) whether the government could prove that challenged law served a purpose so "compelling" that it was justified in taking action and (2) whether what the law required or forbade was "narrowly tailored" to achieve that purpose and did so with as little interference with individual liberty as possible.[14] Few rights qualify as fundamental. They include freedom of speech and association,[80,81] voting,[82] freedom from arbitrary physical restraint,[83] and decisions about marriage,[84,85] contraception,[86–88] procreation,[89] family relationships,[90,91] child rearing, and education.[92,93] For example, a Virginia law that made interracial marriage a felony was struck down in 1967 because "the freedom to marry, or not marry, a person of another race resides with the individual and cannot be infringed by the State."[84]

Aspects of liberty that do not qualify as fundamental are subjected to "rationality review," a test that continues the Court's earlier deference to the legislature. Laws that restrict nonfundamental liberty rights need only be "rationally related" to any "legitimate state interest," and the Court continues to accept almost any plausible reason as justification. Laws that regulate industry to reduce risks to health or safety are easily justified under this test. Some justices and scholars have criticized this 2-tiered view of rights, because it is not sensitive to the importance of some aspects of personal liberty that do not qualify as fundamental.[94,95] In some circumstances, the Court has demanded that the state provide a higher level of justification for limiting personal liberty, even when it does not explicitly call the right fundamental.[96,97] For example, in cases that involve civil commitment or involuntary hospitalization for mental illness, the Court has required the state to prove—by clear and convincing evidence—that a person is mentally ill *and* that the illness renders the person dangerous to others.[83,88,98–100] Similarly, the Court has generally recognized the rights of individuals to make decisions about medical treatment, including the right to refuse life-saving treatment.[101–104] Today, decisions to participate in research or to use experimental and investigational drugs or "therapies" also require the individual's informed consent, even in the military.[105] Most recently, the Court found that states cannot justify restricting personal liberty solely on moral grounds. In *Lawrence v Texas*, the Court struck down a Texas statute that made private anal sex between consenting same-sex adults a crime because the law served no legitimate state purpose.[91]

At the same time, the ways in which government achieves its goals has been changing. Modern biomedical and behavioral sciences, epidemiological research, and information technology offer tools for protecting health that were not available during the first half of the 20th century. Public health programs have drawn upon scientific advances to create more voluntary services for a more diverse population and new and different health problems.[106,107] Responsibility for public health has spread from local community officials to cooperation with private organizations, the federal government, and even international organizations. As similar health problems increasingly affect people all across the country, the federal government has assumed substantial regulatory authority, just as it did for civil rights protection during the 1960s and environmental protection during the 1970s.[108–112]

During the past decade, the US Supreme Court has recognized some limits to the federal government's constitutional authority to regulate interstate commerce when it intrudes on matters traditionally considered part of the police power.[113–116] But, despite rhetoric about the importance of state sovereignty, its decisions have not expanded state power.[43,117] The power of a sovereign state can hardly be increased. Instead, the Court has struck down federal remedies for individuals who suffer from abuses of state power.[118,119]

Even with this caveat, the federal government remains a major player in national public health matters. In addition to direct regulation under the Commerce Clause, it wields considerable influence over state and local public health activities with its power of the purse. In practice, therefore, the states' power is exercised in a somewhat more restricted sphere of human and commercial activity. Yet within this sphere, current constitutional law recognizes few limits on the states' police power, except in the rare circumstances when it unjustifiably restricts important personal liberties.

APPLYING MODERN CONSTITUTIONAL LAW

Given the changes in constitutional law, public health, and government regulation, what kinds of public health laws that address contagious diseases might be constitutionally permissible today? A law that authorizes mandatory vaccination during an epidemic of a lethal disease, with refusal punishable by a monetary penalty, like the one at issue in *Jacobson*, would undoubtedly be found constitutional under the low constitutional test of "rationality review." However, the vaccine would have to be approved by the FDA as safe and effective, and the law would have to require exceptions for those who have contraindications to the vaccine. A law that authorizes mandatory vaccination to prevent dangerous contagious diseases in the absence of an epidemic, such as the school immunization requirement summarily upheld in 1922, also would probably be upheld as long as (1) the disease still exists in the population where it can spread and cause serious injury to those infected, and (2) a safe and effective vaccine could prevent transmission to others.

The legitimacy of compulsory vaccination programs depends on both scientific factors and constitutional limits. Scientific factors include the prevalence, incidence, and severity of the contagious disease; the mode of transmission; the safety and effectiveness of any vaccine in preventing transmission; and the nature of any available treatment. Constitutional limits include protection against unjustified bodily intrusions, such as forcible vaccination of individuals at risk for adverse reactions, and physical restraints and unreasonable penalties for refusal.

Ordinarily, there would be no justification for compulsory vaccination against a disease like smallpox that does not exist in nature. The Centers for Disease Control and Prevention's recent attempt to persuade health care workers to voluntarily accept smallpox vaccination failed, largely because of concerns about the risks of vaccination in the absence of a credible threat of disease.[120] Protecting the country against a terrorist's introduction of smallpox would fall within federal jurisdiction over national security. The intentional introduction of smallpox also could be a crime under both federal and state law. Assuming that an FDA-approved vaccine were available, there would be little, if any, practical

need for a mandatory vaccination law. People at risk would undoubtedly demand vaccine protection, just as they clamored for ciprofloxacin after the (non-contagious) anthrax attacks in 2001.[121] The real problem in such cases is likely to be providing enough vaccine in a timely manner. The same may be true for a natural pandemic caused by new strains of influenza, for example. On the other hand, if a vaccine were investigational, compulsory vaccination would not be constitutional, and people would be less likely to accept it voluntarily.[122,123]

Likewise, a state statute that actually forced people to be vaccinated over their refusal, such as Florida's new "public health emergency" law, would probably be an unconstitutional violation of the right to refuse treatment.[124] In the case of Nancy Cruzan, the Court assumed, without having to decide, that competent adults have a constitutionally protected right to refuse any medical treatment, including artificially delivered care such as nutrition and hydration.[102] Even the state's legitimate interest in protecting life cannot outweigh a competent adult's decision to refuse medical treatment.[104,125] Today, a general interest in the public's health or welfare could not justify sterilizing Carrie Buck against her will. Since *Griswold v Connecticut*, the Court has repeatedly struck down state laws that interfere with personal reproductive decisions. All competent adults have the right to refuse surgical sterilization. The Court also said that people who cannot make decisions for themselves because they are legally incompetent are entitled to have their wishes respected and carried out.[102] If their personal wishes are unknown, they must be treated in accordance with their own best interests, not the interests of the state.

Such cases underscore an important difference between laws that are intended to prevent a person from harming other people, which can be a justified exercise of police power, and laws that are intended to protect only the health of the individual herself, which are unjustified violations of liberty. A committee appointed by the British government is reportedly considering a proposal to vaccinate children with vaccines that block the highs produced by cocaine, heroin, and nicotine.[126,127] Which category might this proposal fit? Drug addiction is a public health problem[128] but not a contagious disease. It is unlikely that the possibility of a person becoming addicted to drugs in the future would be sufficient to warrant compulsory vaccination, even if it is assumed that the vaccine would not affect ordinary intellectual or emotional function. The modern public health approach would be to provide education about drug abuse or to offer safe and effective medications in a voluntary treatment program.

Even in an emergency, when there is a rapidly spreading contagious disease and an effective vaccine, the state is not permitted to forcibly vaccinate or medicate anyone. The constitutional alternative is to segregate infected and exposed people separately to prevent them from transmitting the disease to others. Here again, modern constitutional law demands a high level of justification. The Supreme Court has long recognized that "involuntary confinement of an individual for any reason, is a deprivation of liberty which the State cannot accomplish without due process of law,"[98] and some justices have called freedom from such confinement fundamental in nature.[83] While it has not decided a case that involved isolation or quarantine for disease, it has held that civil commitment for mental illness is unconstitutional unless a judge determines the person is dangerous by reason of a mental illness.[83,98] Assuming, as most scholars do, that the law governing commitment to a mental institution also applies to involuntary confinement for contagious diseases, the government would have the burden of proving, by "clear and convincing evidence," that the individual actually has, or has been exposed to, a contagious disease *and* is likely to transmit the disease to others if not confined.[129,130]

When the HIV epidemic began in 1981, these principles from the 1970s reminded legislators at both the state and federal levels that people could not be involuntarily detained simply because they had HIV infection.[131] Only a few individuals who imminently threatened to infect other people by deliberate or uncontrollable behavior would meet the constitutional test. More recently, the same approach has been used by lower courts in some cases that involved people who had active, contagious tuberculosis.[132,133] Involuntary commitment has been used for a small number of people who were

unable to avoid contact with others, typically because of mental illness, substance abuse, or homelessness.[134–137] In practice, people who can stay in their own homes and have access to adequate care are virtually never subjected to involuntary commitment. They do not need to be committed for effective public health protection. The need for coercive measures like compulsory isolation can be seen as evidence of a failure to provide the public health programs that could have prevented or treated disease.[138–140] For example, the rise of tuberculosis in New York City during the 1980s, and the city's increased use of involuntary isolation for people who had untreated tuberculosis, owes more to the collapse of the city's treatment programs than to the value of involuntary commitment.[141,142]

Today, involuntary isolation and quarantine should be needed and used only in extremely rare cases. The most likely is where a new airborne infectious disease, such as severe acute respiratory syndrome (SARS), for which no treatment yet exists, enters the country. Yet, even with the SARS epidemic, there proved to be almost no need to compel isolation, and quarantine was almost exclusively done in the individual's home.[143,144] After all, laws that compel detention necessarily apply to the exceptional person, just as Henning Jacobson was in 1905. Most people were eager to take precautionary measures voluntarily. In Beijing, China, however, where the government was rumored to be planning a large-scale quarantine, almost 250 000 people fled, which increased the risk of spreading the disease. Indeed, historically, large-scale quarantines have had little positive effect on epidemics.[145]

As a practical matter, major new epidemics or terrorist attacks are likely to be considered national emergencies. In such circumstances, overreactions are likely and constitutional rights may be trampled, regardless of established law, which is what happened when the military forced Americans of Japanese descent into internment camps during World War II. In 1944, Fred Korematsu's detention in such a camp was upheld by the US Supreme Court in a decision that has been regretted ever since.[146] In an amicus curiae brief in the cases against the Bush Administration by individuals detained without charges at Guantánamo Bay in connection with the "war on terror," Korematsu reminded the Supreme Court:

> *History teaches that, in time of war, we have often sacrificed fundamental freedoms unnecessarily. The Executive and Legislative Branches, reflecting public opinion formed in the heat of the moment, frequently have overestimated the need to restrict civil liberties and failed to consider alternative ways to protect the national security.[147]*

In 2004, however, the Court was no longer willing to give government "a blank check."[148] It found that even individuals who were being held as presumed terrorists were entitled to constitutional due process protections.[148,149]

LESSONS FOR MODERN PUBLIC HEALTH

One hundred years after *Jacobson*, neither public health nor constitutional law is the same. Programs essential to today's public health, such as those that regulate hazardous industries and products and that provide medical care, which would have been struck down in 1905, are routinely upheld today because they serve a legitimate public purpose and do not interfere with personal liberty. In contrast, deprivations of liberty that might have been upheld in 1905 would be struck down today. Public health now has better tools at its disposal: better science, engineering, drugs and vaccines, information, and communication mechanisms for educating the public.

The history of US Supreme Court decisions about states' power to restrict personal liberty shows the different ways in which states' power can be characterized. At bottom, however, all doctrinal interpretations begin with 1 of 2 presumptions: (1) the state has complete power to do anything that is not expressly prohibited by the federal or its own state constitution, or (2) the state has only those

powers granted to it by the people or that constitute an essential aspect of sovereignty for which governments are formed.[150,151] Although traces of both views can be seen in the opinions of different justices, the Court has generally adopted the first view: the Constitution provides the only limit on state power. Thus, the Court's interpretation of what counts as a constitutional right assumes extraordinary importance. As Justice Charles Evans Hughes noted, "We are under a Constitution, but the Constitution is what judges say it is. . . ."[152](p199)

During the past decade, the Court has been reluctant to recognize constitutional protection for new aspects of liberty. Some scholars and conservative justices have argued that the Due Process Clause does not or should not protect personal liberty, such as the freedom to use contraception, and that states should have freer reign to impose restrictions on people.[153–156] Others argued that, without such protection, we might as well not have a Constitution.[157] Although the Court is not likely to soon abandon what it has already recognized, the renewed debate makes clear how fragile constitutional rights might be.

At a time when terrorism threatens the entire world, people may be easily convinced that their security depends upon giving up their liberty. People also may believe laws that restrict personal freedom will not apply to them. History supports the view that coercive laws have largely targeted disadvantaged minorities. Quarantine laws were most often directed at disfavored immigrant groups.[39,138] During the 19th and early-20th century, people who were poor, non-white, or recent immigrants were widely believed to live in filth, intoxication, violence, and debauchery or were often blamed for harboring and spreading disease.[158,159] Such attitudes may have surfaced when the Boston Board of Health sent police officers to inoculate "tramps" against smallpox. Police reportedly held some men down and beat others to accomplish their task.[160] Although we may believe we are more enlightened today, similarly disfavored groups are targets of antiterrorism laws.[161]

In an era of increasingly limited state funds, there is a danger that legislatures will turn to laws that restrict personal liberty as a substitute for providing the resources necessary for positive public health programs that actually prevent disease and improve health. Such symbolic "grandstanding" may be especially tempting for representatives whose reelection depends more on those who finance their campaigns than on the voters.[162] But it shifts responsibility for protecting the public health from the government to individuals and punishes those who are least able to protect themselves. The Bill of Rights was designed to protect individuals against abuses by the state, even when the abuses have the support of the majority. This is why constitutional protection of liberty remains so important.

One practical reason for protecting constitutional rights is that it encourages social solidarity. People are more likely to trust officials who protect their personal liberty. Without trust, public officials will not be able to persuade the public to take even the most reasonable precautions during an emergency, which will make a bad situation even worse. The public will support reasonable public health interventions if they trust public health officials to make sensible recommendations that are based on science and where the public is treated as part of the solution instead of the problem. Public health programs that are based on force are a relic of the 19th century; 21st-century public health depends on good science, good communication, and trust in public health officials to tell the truth. In each of these spheres, constitutional rights are the ally rather than the enemy of public health. Preserving the public's health in the 21st century requires preserving respect for personal liberty.

Notes

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