

# **COVID Vaccine Update**

## **2 Dec. 2020**

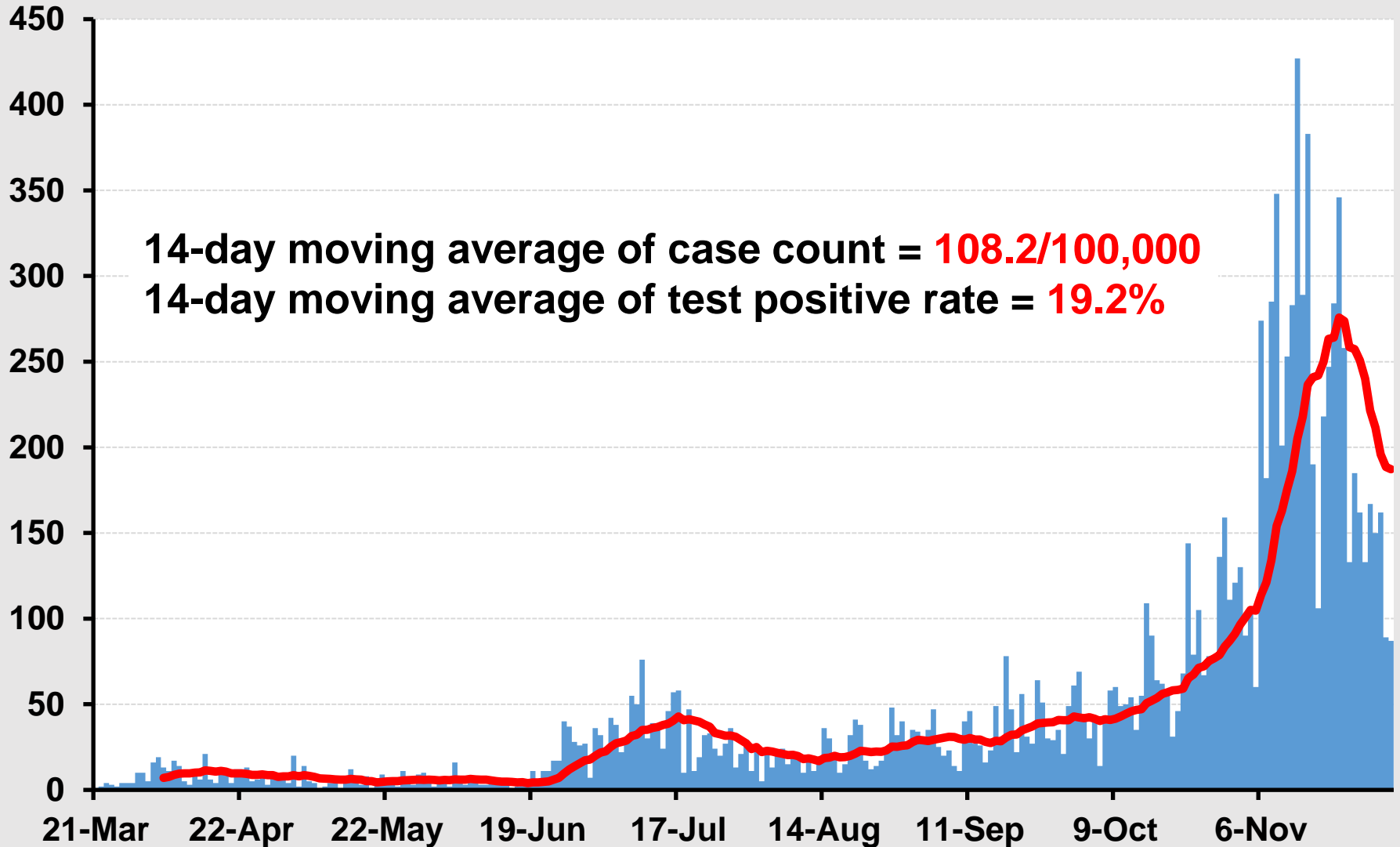
**Louis M. Katz MD**

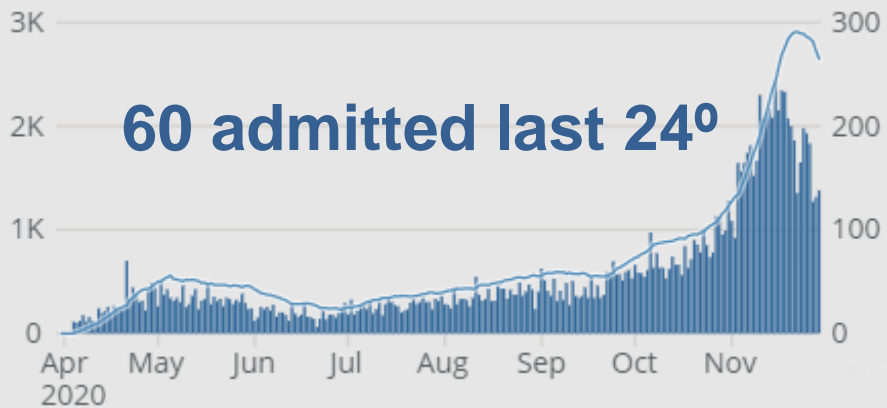
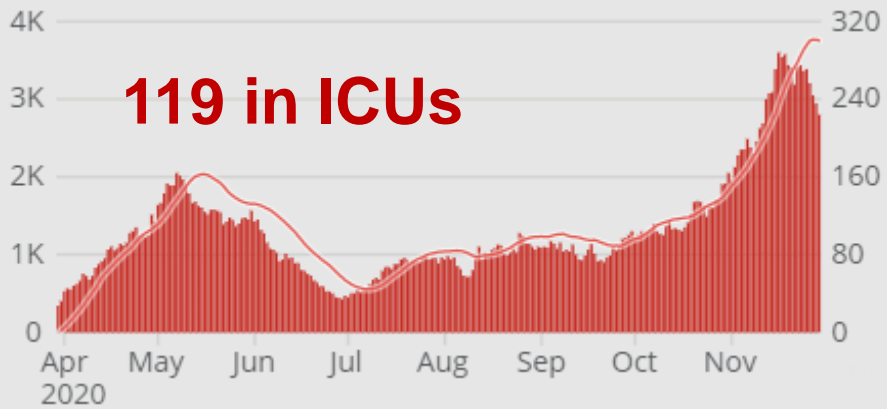
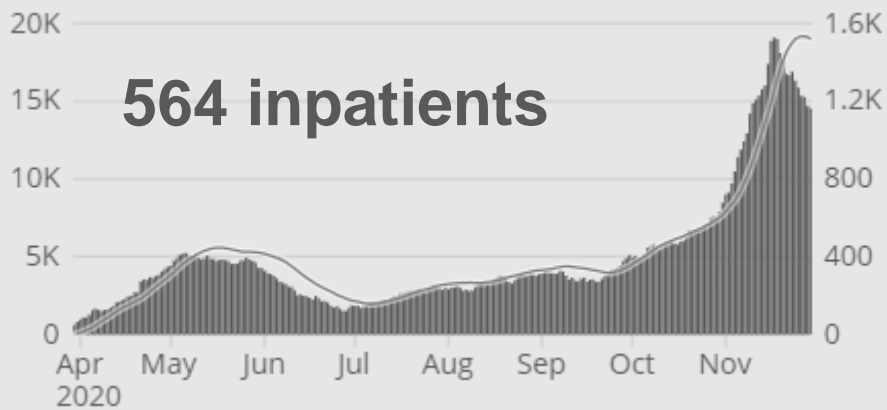
**Medical Director, Scott County Health Dept.**

**Adjunct Clinical Professor Infectious Diseases,  
University of Iowa**

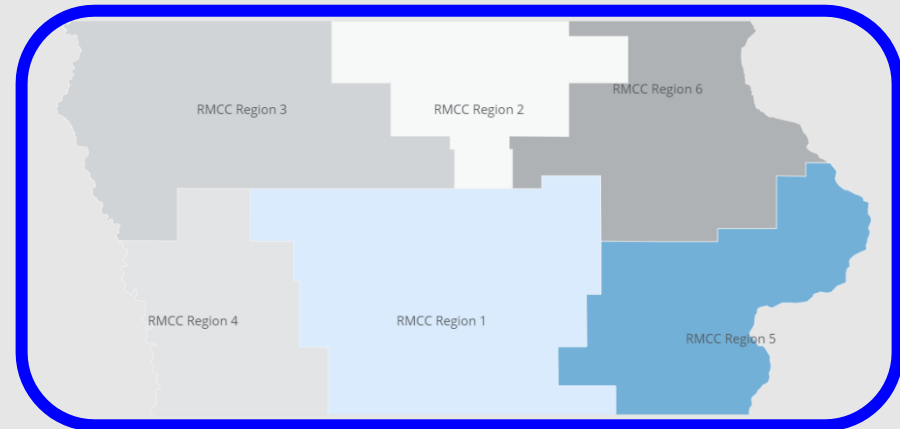
# Confirmed and epi-linked infections and 14-day moving average

SCHD 2 Dec. 2020 n=12,049





# Key resource capacity metrics RMCC Region 5



- **76 patients on ventilators**
- **184 ICU beds available**
- **524 ventilators available**

# Vaccine candidates of interest

<b>Platform</b>	<b>Company</b>	<b>Phase 1-2</b>	<b>Phase 2-3</b>
<b>mRNA</b>	<b>Moderna</b>	<b>Enrolled</b>	<b>Enrolled</b>
	<b>BioNTech &amp; Pfizer</b>	<b>Enrolled</b>	<b>Enrolled</b>
<b>Viral vectored</b>	<b>AstraZeneca &amp; U of Oxford</b>	<b>Enrolled</b>	<b>Enrolled</b>
	<b>Janssen (J &amp; J)</b>	<b>Enrolled</b>	<b>Ongoing</b>
	<b>Merck</b>	<b>Ongoing</b>	<b>--</b>
<b>Protein subunit</b>	<b>Novavax</b>	<b>Ongoing</b>	<b>Ongoing</b>
	<b>GDK and Sanofi</b>	<b>Ongoing</b>	<b>--</b>

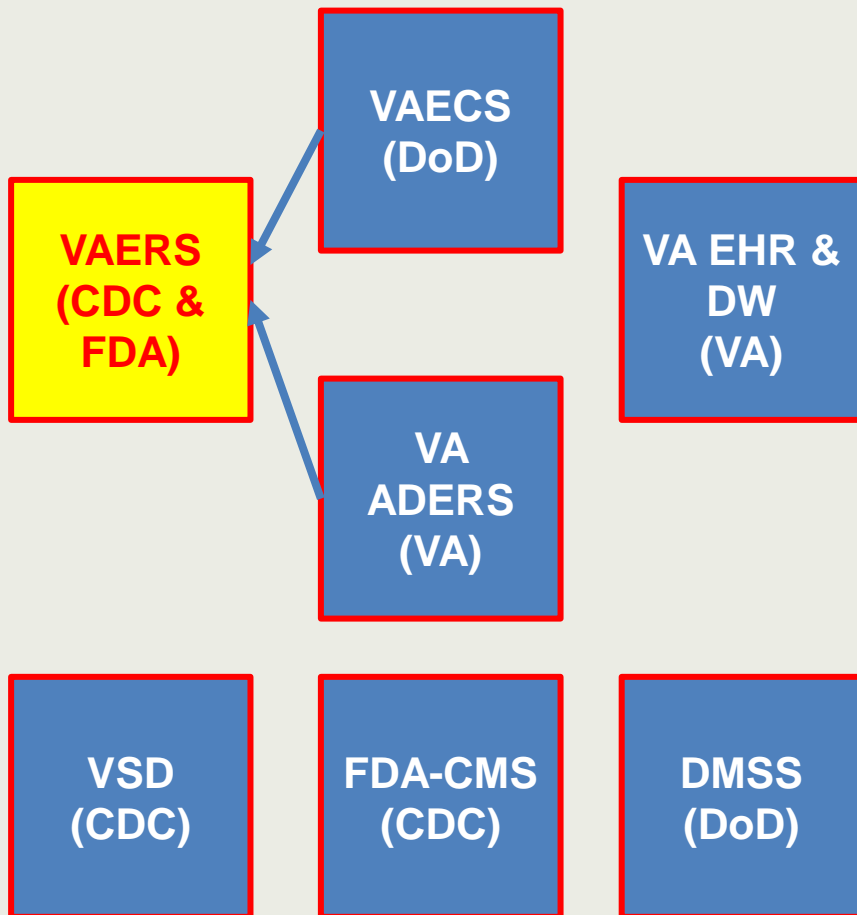
# How many press releases does it take to make data?

	Efficacy for "infection"	Comments
mRNA	94.5%	Effective for severe
	95%	Effective for severe
Viral vectored	62-90%	Dependent on regimen

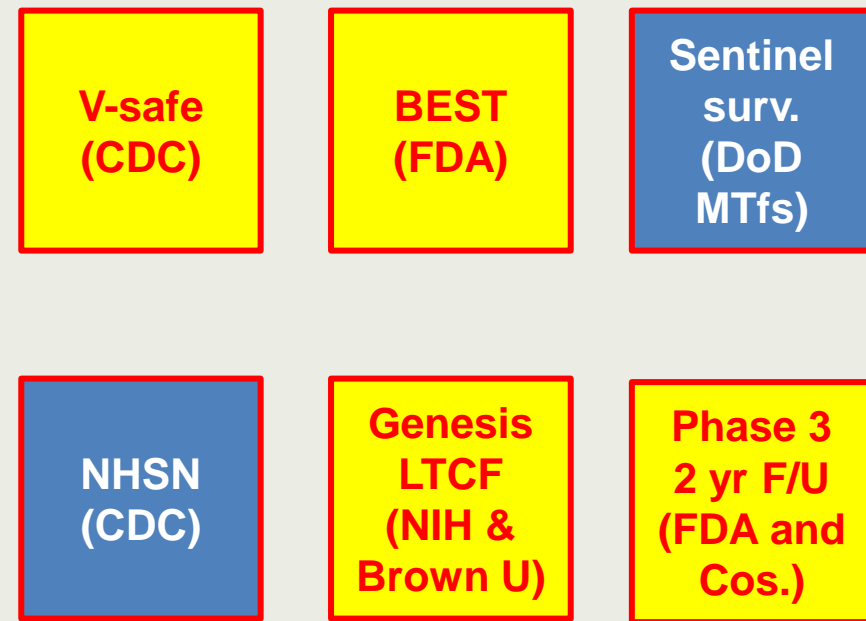
Data on impact on infection vs. illness and on transmission not yet available.

# Safety signal detection systems

## Existing



## New



# Public needs to prep for vaccine side effects

“Take Tylenol and suck it up,” says one researcher. Fever, aches show vaccine works

By Meredith Wadman

This summer, computational biologist Luke Hutchison volunteered for a trial of Moderna's COVID-19 vaccine. But after the second injection, his arm swelled up to the size of a “goose egg,” Hutchison says. He can't be sure he got the vaccine and not a placebo, but within a few hours, Hutchison, who was healthy and 43, was beset by bone and muscle aches and a 38.9°C fever. “I started shaking, I had cold and hot rushes,” he says. “I was sitting by the phone all night long thinking: ‘Should I call 911?’”

Hutchison's symptoms resolved after 12 hours. But, he says, “Nobody prepared me for the severity of this.”

He says the public should be better prepared than he was, because a subset of people may face intense, if transient, side effects, called reactogenicity, from Moderna's vaccine. Some health experts agree.

“Somebody needs to address the elephant: What about vaccine reactogenicity? While it's ... not going to cause any long-term issues ... how is that perception going to go with the public once they start receiving it?” asks Deborah Fuller,

Some researchers suspect the immune system's response to that delivery vehicle is causing the short-term side effects.

Those transient reactions should not dissuade people from getting vaccinated in the face of a pandemic virus that kills at least one in 200 of those it infects, says Florian Kramer, a vaccinologist at the Icahn School of Medicine at Mount Sinai, who participated in Pfizer's trial. Sore arms, fevers, and fatigue are “unpleasant but not dangerous,” he says. “I'm not concerned about [reactogenicity] at all.”

Most people will escape “severe” side effects, defined as those that prevent daily activity. Fewer than 2% of recipients of the Pfizer and Moderna vaccines developed se-

epidemiologist at the University of Michigan School of Public Health.

So front-line public health workers will need “to have a story that gets out in front of [stories like Hutchison's]—that responds to the way that people are going to try to make that a story about vaccine injury,” says Bernice Hausman, an expert on vaccine controversy at the Pennsylvania State University College of Medicine.

“Transparency is key, Hausman emphasizes. Rather than minimizing the chance of fever, for instance, vaccine administrators could alert people that they may experience a fever that can feel severe but is temporary. “That would go a significant way toward people feeling like they are being told the truth.”

Adis Drew Weissman, an immunologist at the University of Pennsylvania whose research contributed to both vaccines: “The companies just have to warn people: ‘This is what you need to expect. Take Tylenol and suck it up for a day.’”

Hausman also sees a need to support people who have serious reactions. For example, people may need “a hotline with a nurse triaging ... figuring out if you need to go to the hospital or not. Will your medical expenses be covered if you have serious reactions.”

### Special delivery

Two apparently successful coronavirus vaccines use fat bubbles called lipid nanoparticles to deliver messenger RNA (mRNA) to cells. Once there, the mRNA directs cells to produce the virus' spike protein, provoking an immune response to that foreign protein.



Downloaded from <https://science.sciencemag.org/> on December 2, 2020

# “No serious safety concerns”

- Media releases
- Severe ADEs = those interrupting ADLs

## Moderna

## Pfizer/BioNTech

**Fever 39-40°C**

**<2%**

**Fatigue**

**9.7%**

**3.8%**

**Myalgia**

**8.9%**

**Arthralgia**

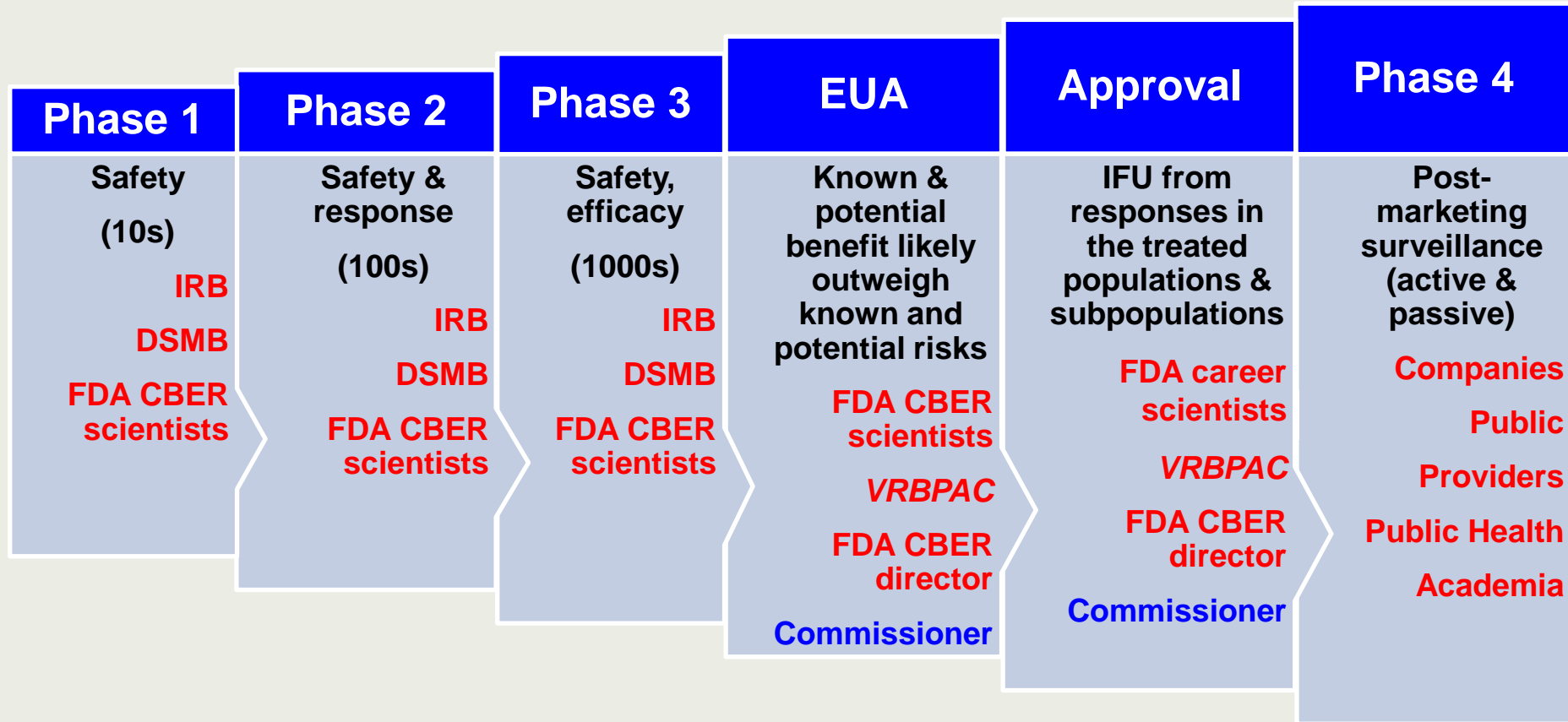
**5.2%**

**HA**

**4.5%**

**2%**

# COVID-19 vaccine approval



- Vaccine DSMB for Warp Speed is independent of HHS
- Only the FDA Commissioner is a political appointee
- VRBPAC is an independent, unpaid panel of SMEs



# Criteria for priority (ACIP)

- **Science**
- **Implementation**
- **Ethics**
  - **Maximize benefits, minimize harms**
  - **Promote justice**
  - **Mitigate health inequities**

# NASEM vaccine priority framework

## Phase 1

### Phase 1a

- High-risk HCW
- First responders

### Phase 1b

- High-risk comorbidity
- Older adults in congregate and crowded residences

## Phase 2

- K-12 school staff & child care workers
- Critical risk workers
- Moderate-risk comorbidity
- Homeless shelters and group homes
- Jails and prisons
- Other older adults

## Phase 3

- Young adults
- Children
- Workers of high importance not included in phase 1 or 2

## Phase 4

- All others

# Proposed interim phase 1 sequence

**Phase 1a: HCW  
and LTCF residents  
(approved 13-1 by  
ACIP 1 Dec. 2020)**

**Phase 1b: Essential workers  
(e.g. education, food and ag,  
utilities, police and fire,  
transportation)**

**Phase 1c: Adults with high-risk  
medical conditions and adults  
≥65 years**



**Time from EUA**

# Phase 1a groups:

**13-1 “aye” 1 Dec. 2020 ACIP vote**

## Health care personnel

**≈21 million individuals**  
(no priority ratings)

- Hospitals
- LTC
- Outpatient venues
- Home health care
- Pharmacies
- EMS/1<sup>st</sup> responders
- Public health

## LTC residents

**≈3 million individuals**  
(priority based on availability)

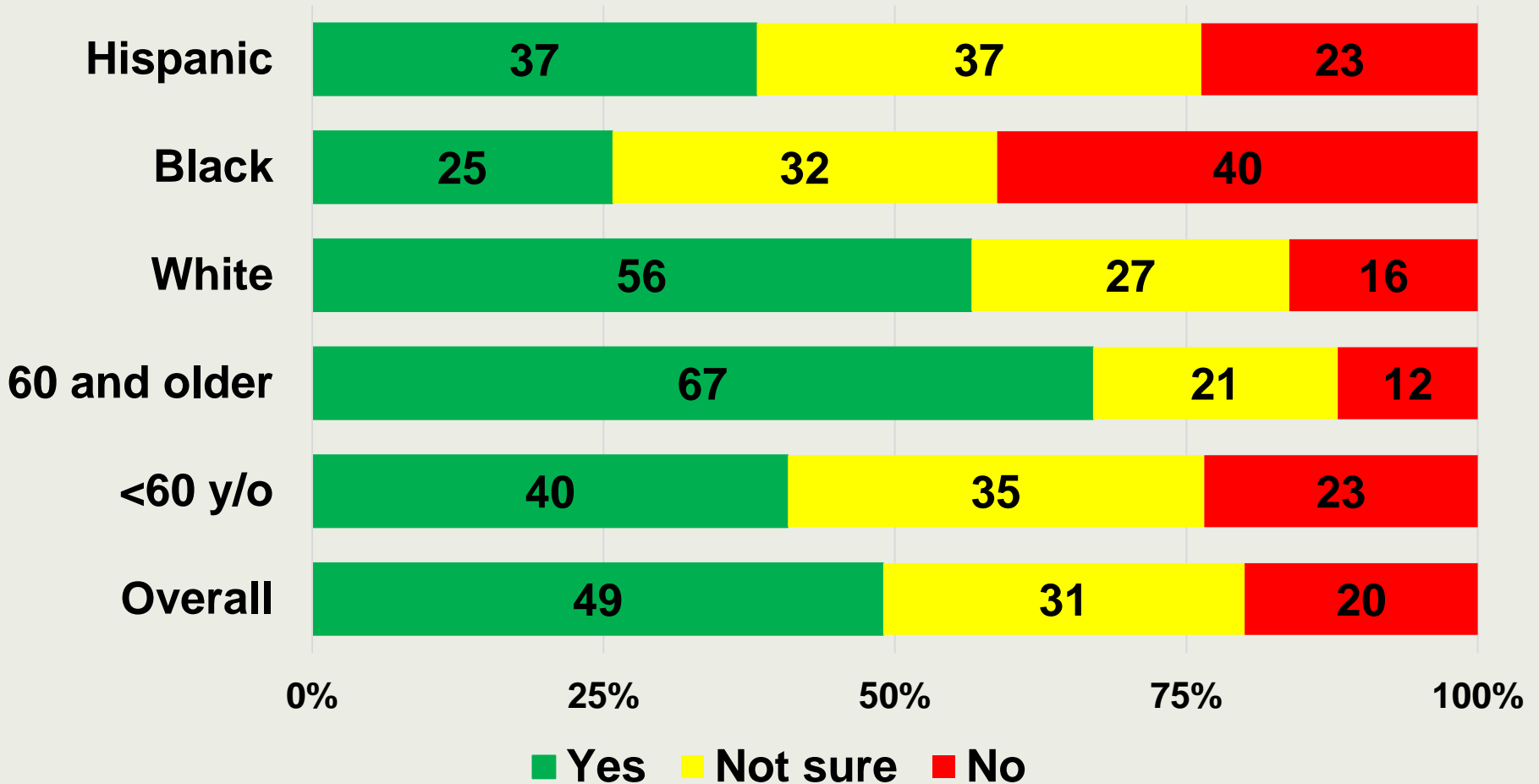
- Skilled nursing facilities  
(≈1.3 million beds)
- Assisted living facilities  
(≈0.8 million beds)
- Other residential care  
(≈0.9 million beds)



# The black hole: limited supplies of vaccine & data

<b>What</b>	<ul style="list-style-type: none"><li>• <b>Barriers:</b><ul style="list-style-type: none"><li>• Pfizer (ultracold)</li><li>• Moderna (frozen)</li><li>• 2-dose primary series at this point</li></ul></li><li>• <b>No data:</b> duration of immunity, booster need, coadministration, pregnancy/breastfeeding <i>etc.</i></li><li>• <b>Few data in LTC on efficacy or safety</b></li></ul>
<b>When</b>	<ul style="list-style-type: none"><li>• <b>(Right) after VRBPAC on 10 Dec. 2020</b></li></ul>
<b>Who</b>	<ul style="list-style-type: none"><li>• <b>1a: frontline HCWs, LTC residents</b></li><li>• <b>Who will take vaccine as availability expands?</b></li></ul>

# Do you plan to get vaccinated when available?



# When will Dr. Katz take a COVID-19 vaccine?

## The first day it is available to him

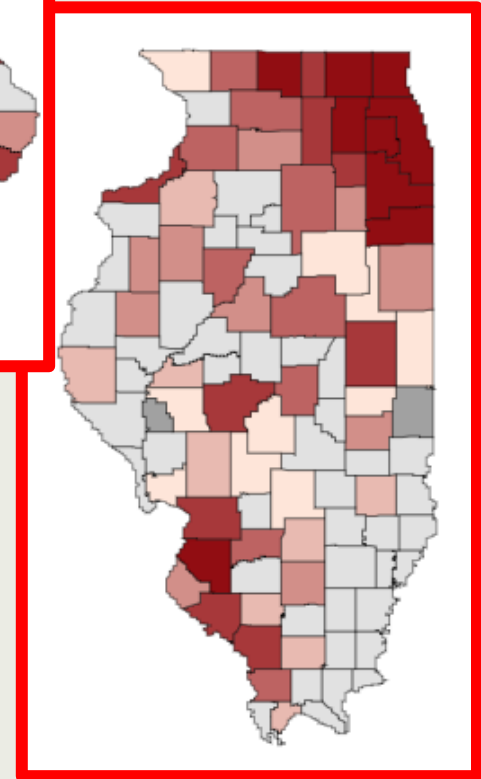
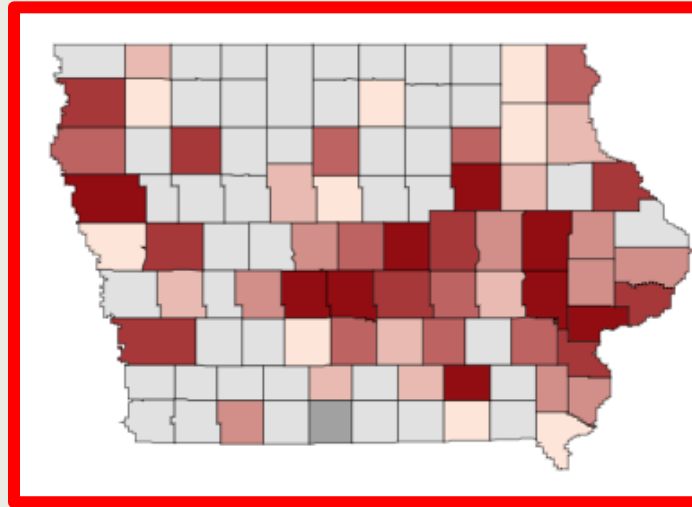
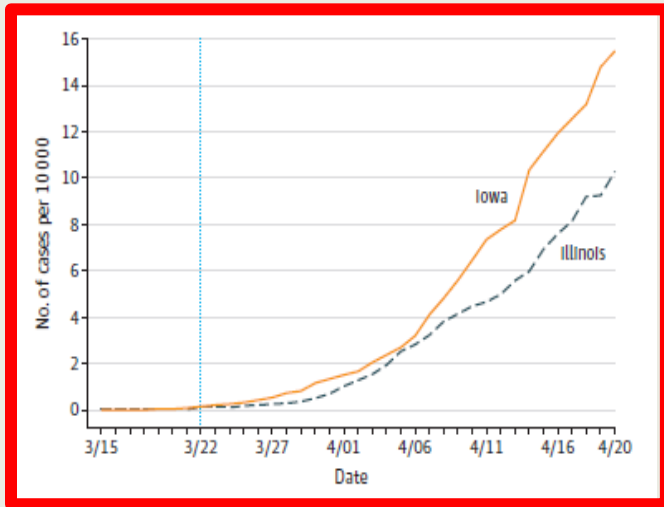
- Based on the data
  - Assuming the efficacy data are confirmed at VRBAC meeting Dec. 10
  - Assuming no new safety concerns
- Based on his trust of the career scientists at FDA/CBER and the integrity of the FDA advisory committee process

# Pre- and asymptomatic transmission: the *most important stuff* we have learned

- Syndromic surveillance ineffective (c.f. flu, SARS-1, MERS)
- Need for universal source control
  - Masks on all
  - Physical and Social distancing
  - Reasonable environmental controls
- Need for universal testing of exposed individuals
- Need for interval testing of “high risk” populations?
  - HCW
  - LTCF staff
  - 1<sup>st</sup> responders
  - Students??



# Stay at home?

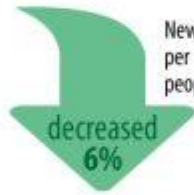


**Iowa is 1 of 5 states in the US that have not issued a stay-at-home order during the coronavirus disease 2019 (COVID-19) pandemic.**

**The estimates indicate excess cases in the border Iowa counties by as many as 217 cases after 1 month without a stay-at-home order. This estimate of excess cases represents 30.4% of the 716 total cases in those Iowa counties by that date.**

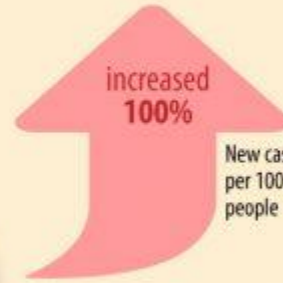
## Kansas implemented a mask mandate on July 3; some counties opted out\*

Counties with a mask mandate†



New cases  
per 100,000  
people

Counties without a mask mandate†



New cases  
per 100,000  
people

CDC recommends everyone age 2 years and older wear masks in public

\* Change in rate of infections July 3–9 vs. August 17–23

† Mandated counties (n=24); nonmandated counties (n=81)

CDC.GOV

bit.ly/MMWR112020b

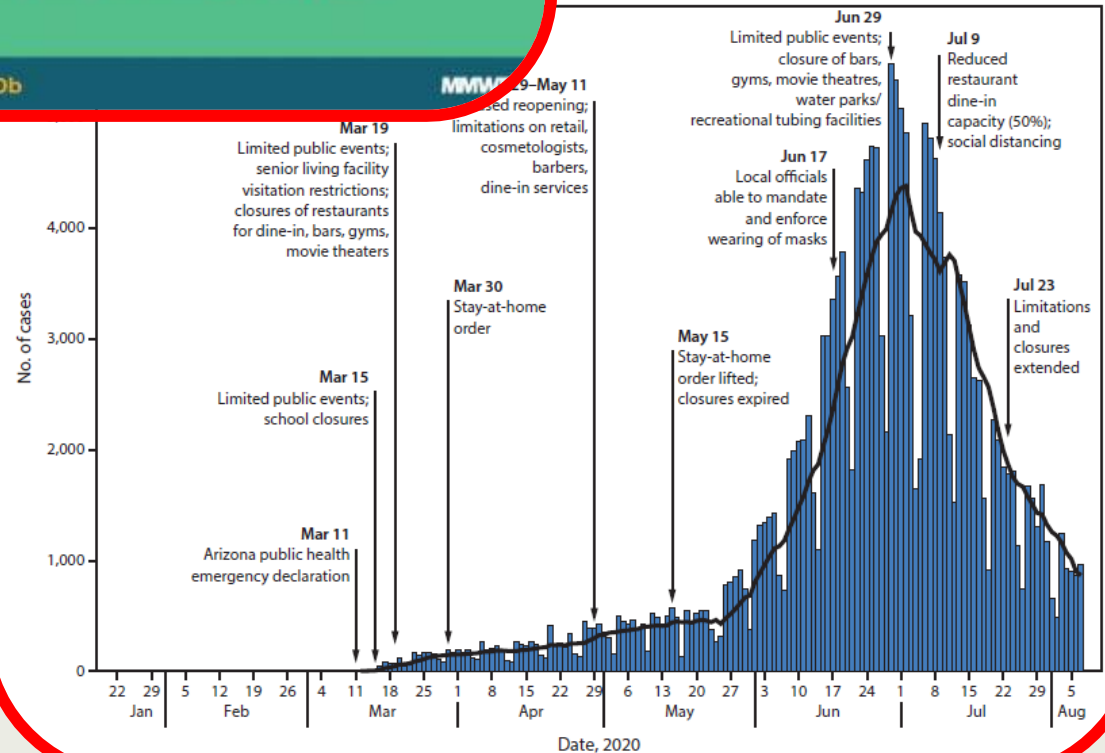
# Impacts of NPIs

case counts† and 7-day moving averages§ — Arizona, January

***“...state mandated... mitigation efforts and routine public health interventions can reduce the occurrence of new COVID-19 cases, hospitalizations and deaths”. 82%, 88% and 100% respectively***

Kanu FA. *MMWR*. 6 Nov. 2020.

Van Dyke ME et al. *MMWR*. 27 Nov. 2020.



# Masking?

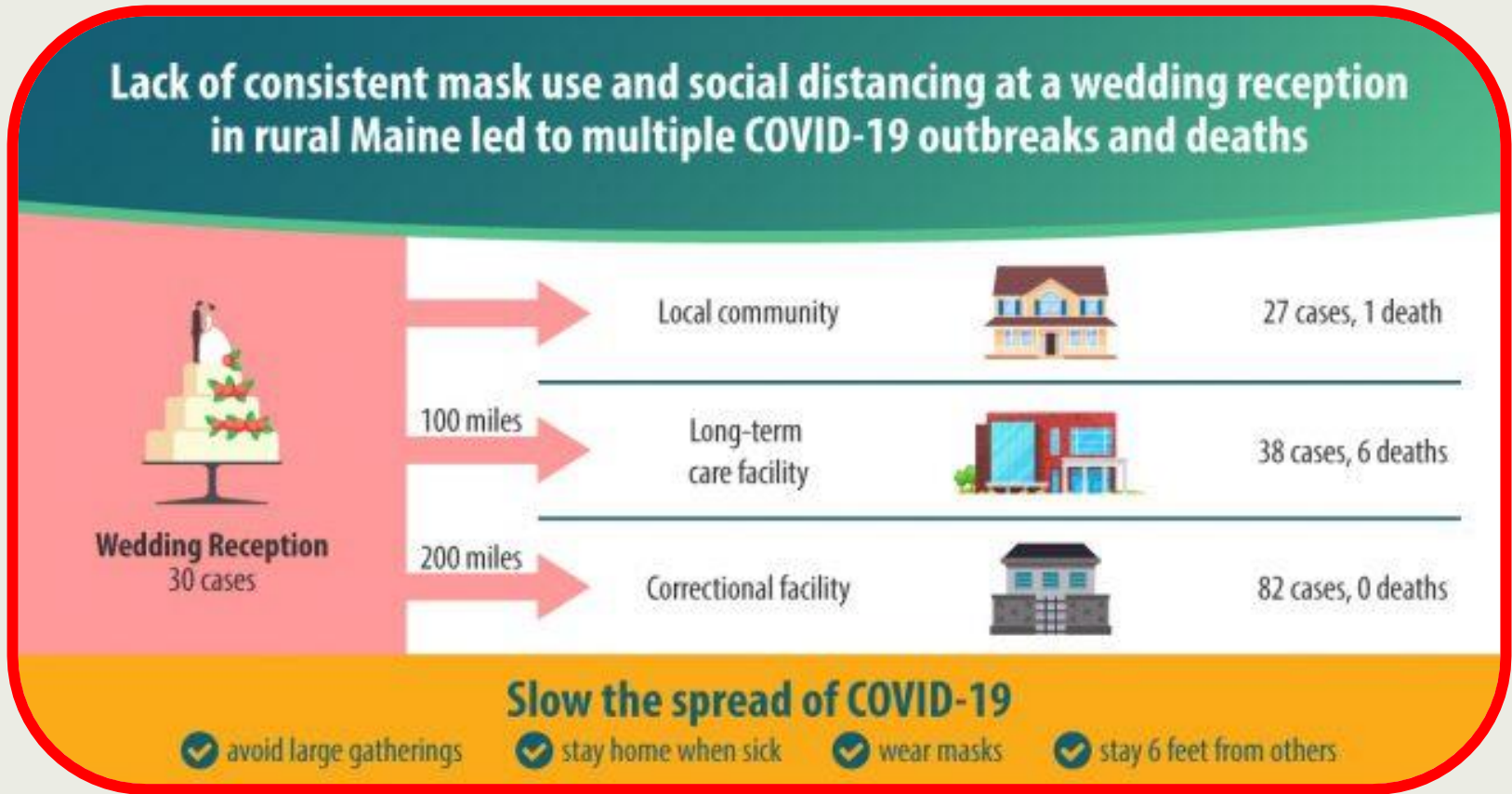
Absence of Apparent Transmission of SARS-CoV-2 from Two Stylists After Exposure at a Hair Salon with a Universal Face Covering Policy — Springfield, Missouri, May 2020



- 2 symptomatic stylists with lab confirmed COVID-19 worked for 2 weeks
- 139 clients exposed
- Both stylists and clients wore masks per company policy
- No symptomatic 2<sup>o</sup> cases
- 0/67 PCR screens positive

Hendrix *et al.* *MMWR.* 17 July 2020

# Common sense ignored = 7 corpses



1. 2/55 guests with symptoms of COVID at reception...
2. ...that exceeded state's maximum capacity guidelines...
3. ...without attendees masking or distancing

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