



Healthcare Worker Exposure  
Response & Outcomes

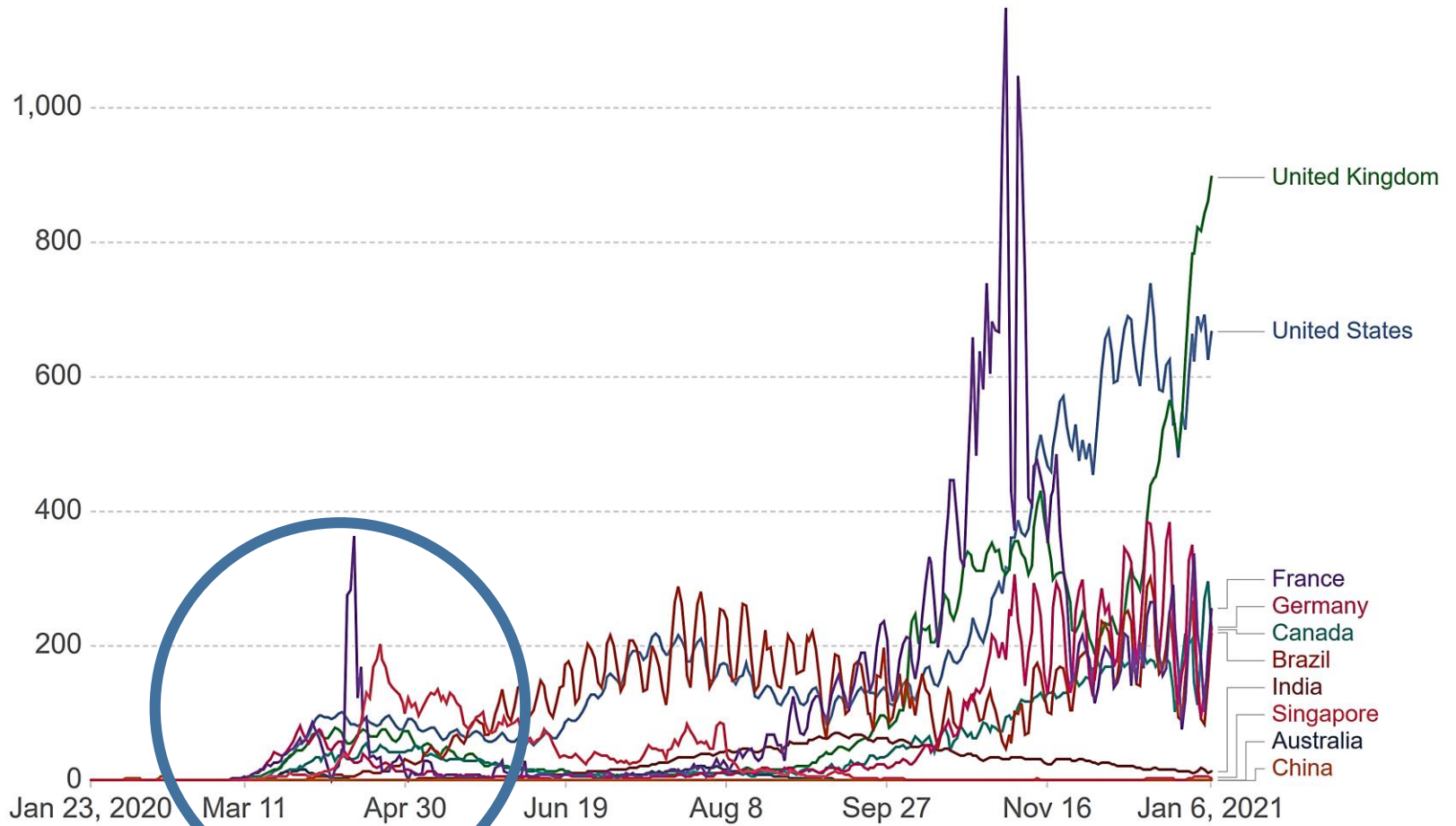
# **HERO-Together: Building vaccine confidence with long-term outcomes data**

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Duke University School of Medicine

**January 7, 2021**

# Daily new confirmed COVID-19 cases per million people

Shown is the rolling 3-day average. The number of confirmed cases is lower than the number of actual cases; the main reason for that is limited testing.



Source: Johns Hopkins University CSSE COVID-19 Data – Last updated 7 January, 06:07 (London time)

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# In April 2020...

“Some have wondered if the force of [the pandemic] will solve the problem of vaccine refusal that has vexed and preoccupied the global public health community for the last several decades.”

Emily Harrison  
*Eur J Epidemiol*  
April 22, 2020

“Given the severity of the current crisis, taking countless lives and sending our socioeconomic systems to the brink of collapse, it seems unimaginable that anyone would reject a Coronavirus vaccine.”

Alex Hartlage  
*JHU Global Health Now*  
April 28, 2020

# A vaccine at pandemic speed

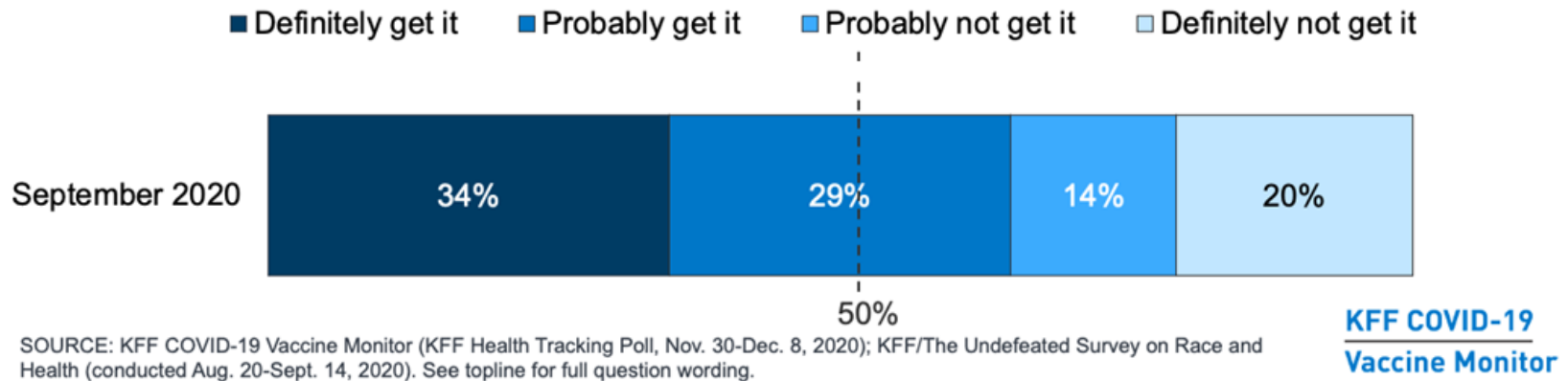
## Vaccine development



## Accelerating factors

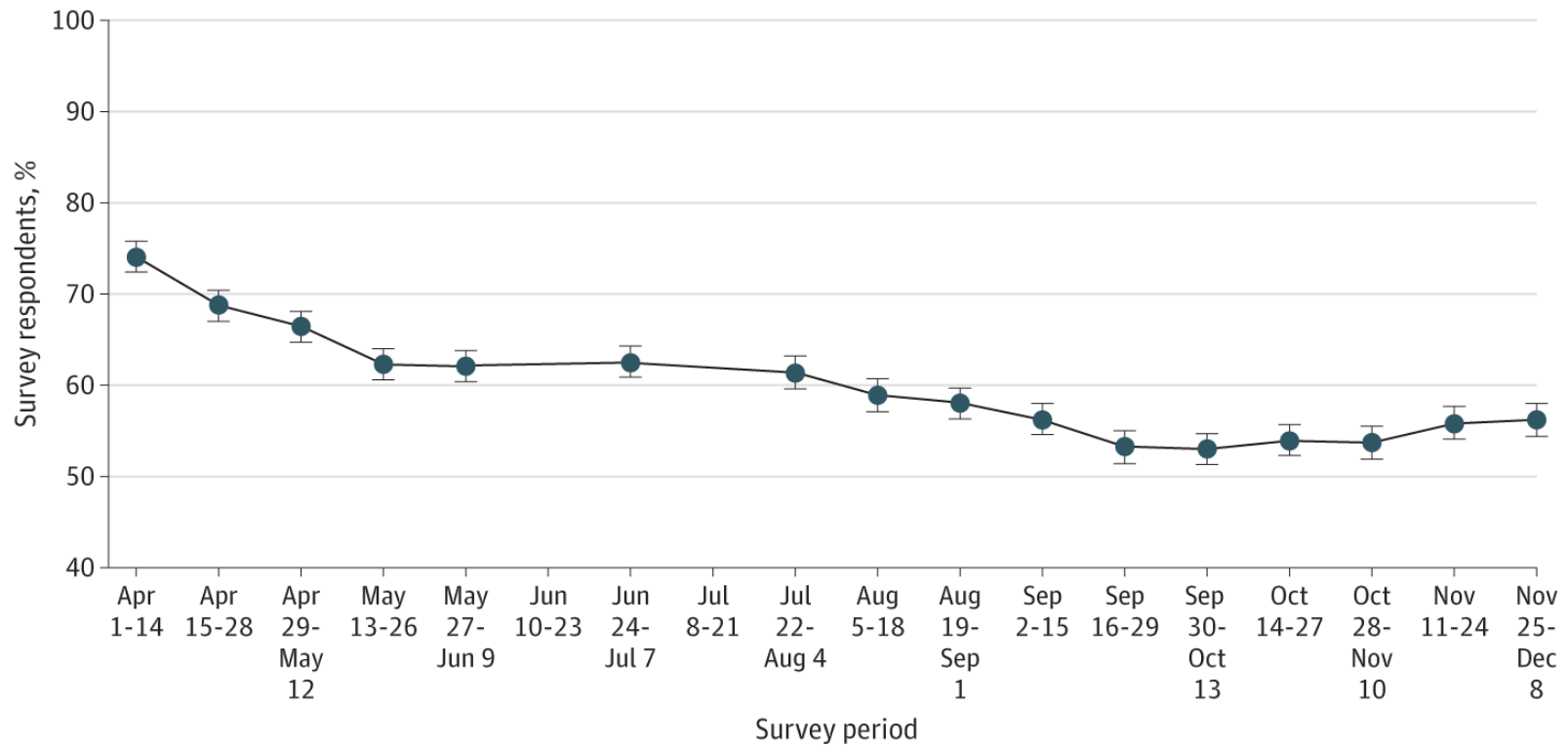
- Prior advances in mRNA technology
- Financial resources to accelerate trial conduct
- Availability of willing volunteers
- Concurrent manufacturing

# If a COVID-19 vaccine was determined to be safe by scientists and available for free to everyone who wanted it, would you....?



Source: KFF COVID-19 Vaccine Monitor

# % of adults who say they would be vaccinated has steadily declined since April



Szilagyi PG, et al. JAMA. Published online December 29, 2020. doi:10.1001/jama.2020.26419

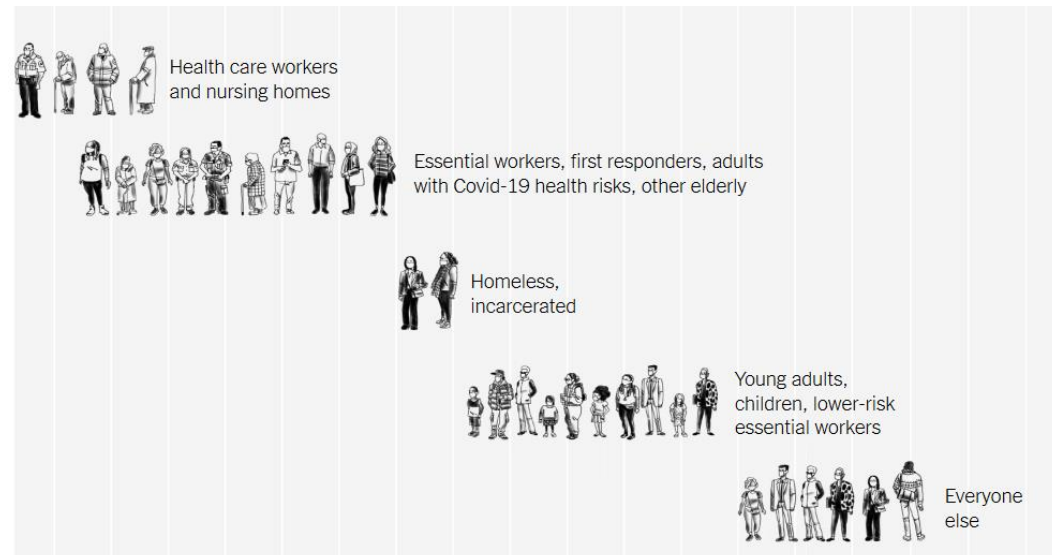
# What is vaccine hesitancy?

Vaccine hesitancy refers to ***delay in acceptance or refusal of vaccines despite availability of vaccination services***. Vaccine hesitancy is complex and context specific, varying across time, place and vaccines. It is influenced by factors such as complacency, convenience and confidence.



# What about healthcare workers?

- May be more open to medical innovation than general population
- Often trusted figures in their communities
- “As health care workers go, so will the rest of the population”



Source: Advisory Committee on Immunization Practices; the National Academies of Sciences, Engineering and Medicine

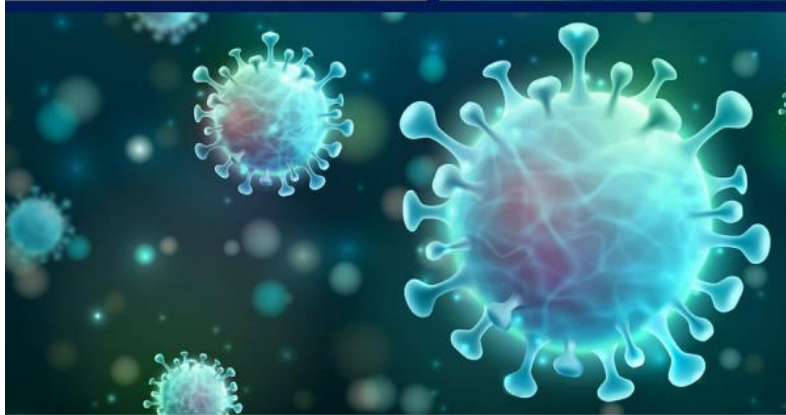


# HERO Registry

**HERO**



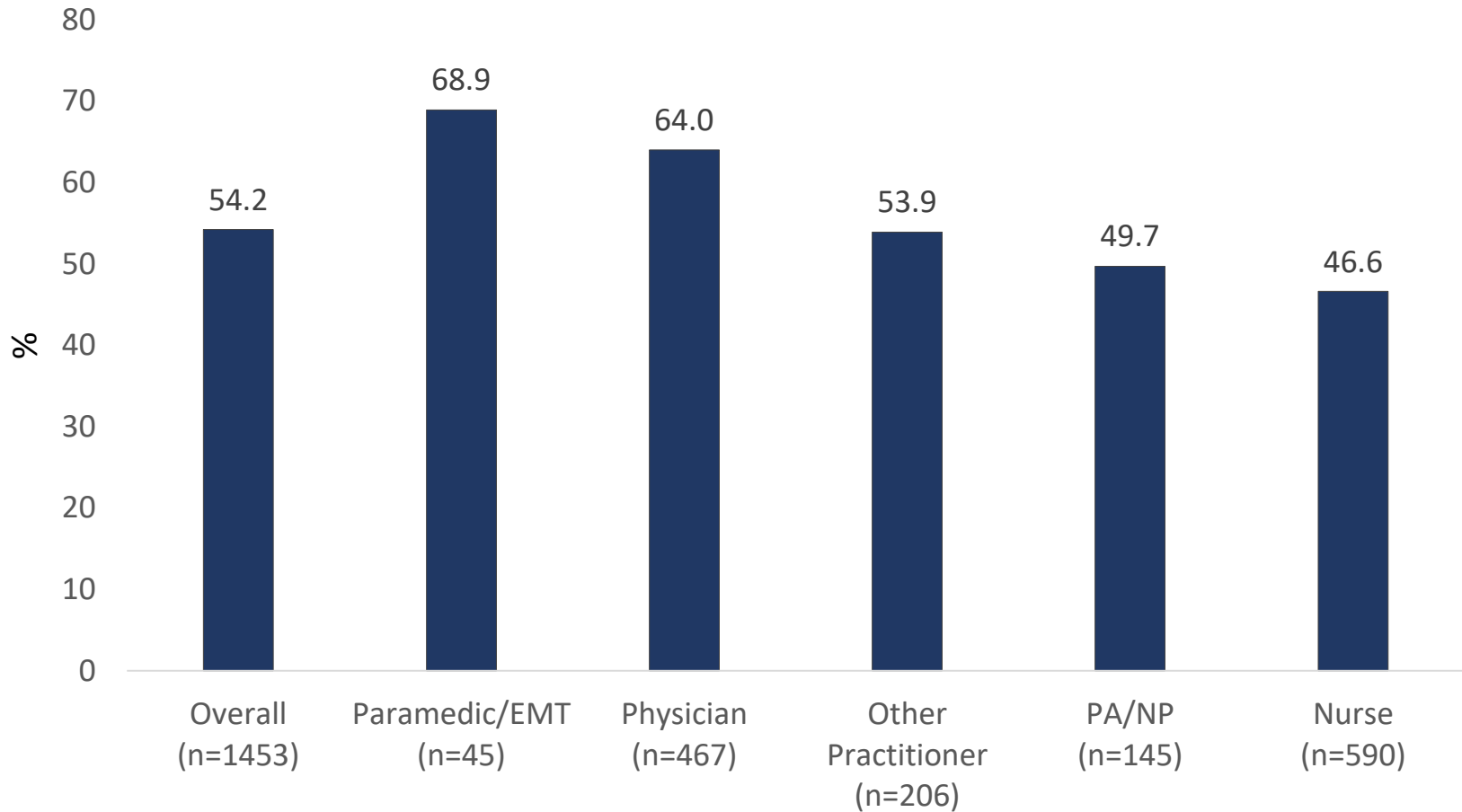
Healthcare Worker Exposure  
Response & Outcomes



- PCORI-funded national community of HCWs
- Launched in April 2020
- Participants answer periodic surveys about risk factors, COVID-19 testing and infection, and well-being
- Hot Topics polling for rapid feedback on high-priority issues in the HCW community



“If an *FDA emergency use-approved* vaccine to prevent coronavirus/COVID-19 was available right now at no cost, would you agree to be vaccinated?” (n=1453)



Source: HERO Registry Hot Topics Polling, October 2020

# November 2020



• LIVE TV  

**Pfizer and BioNTech say final analysis shows coronavirus vaccine is 95% effective with no safety concerns**

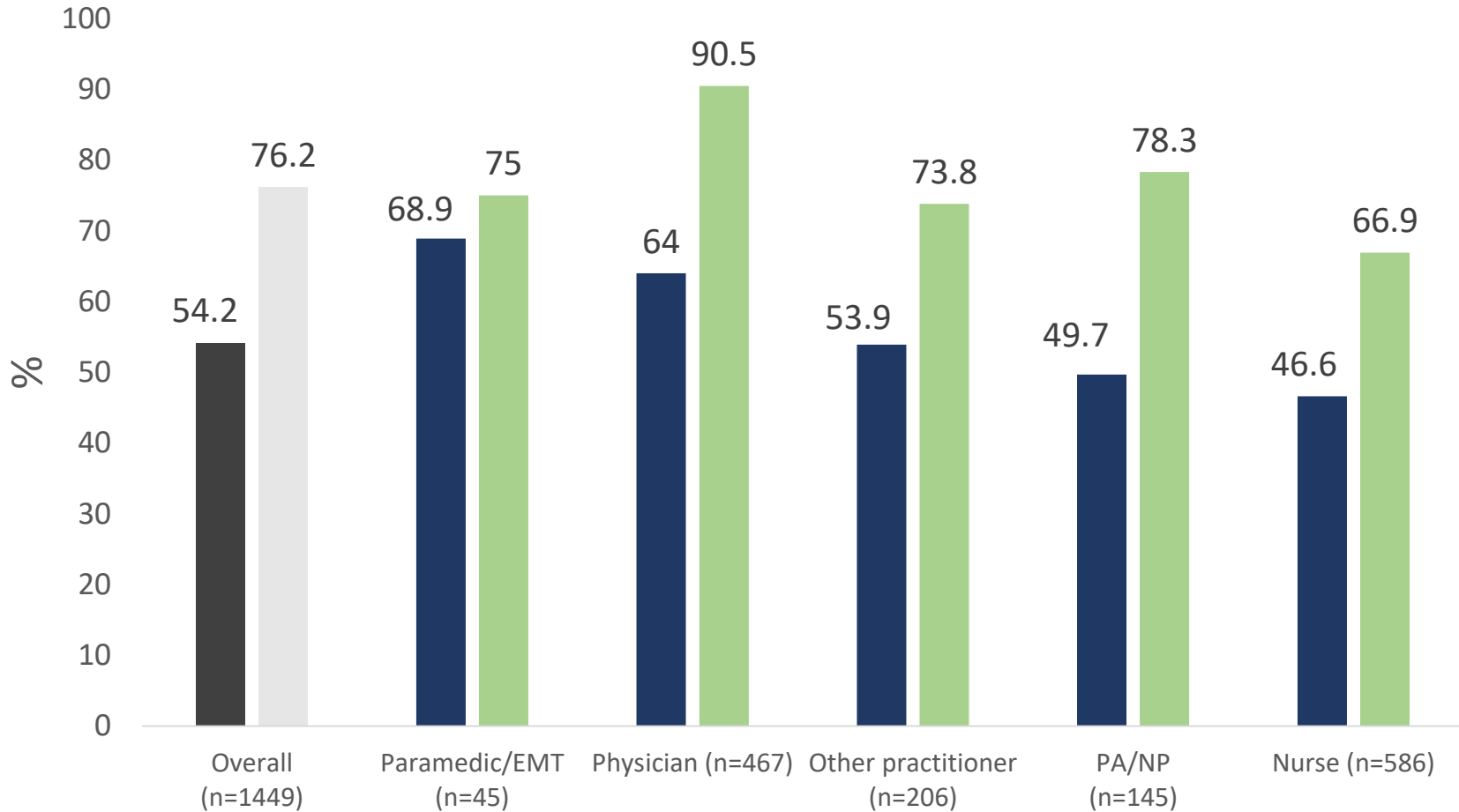


• LIVE TV

**Moderna's coronavirus vaccine is 94.5% effective, according to company data**



# % reporting they would take an EUA-approved vaccine

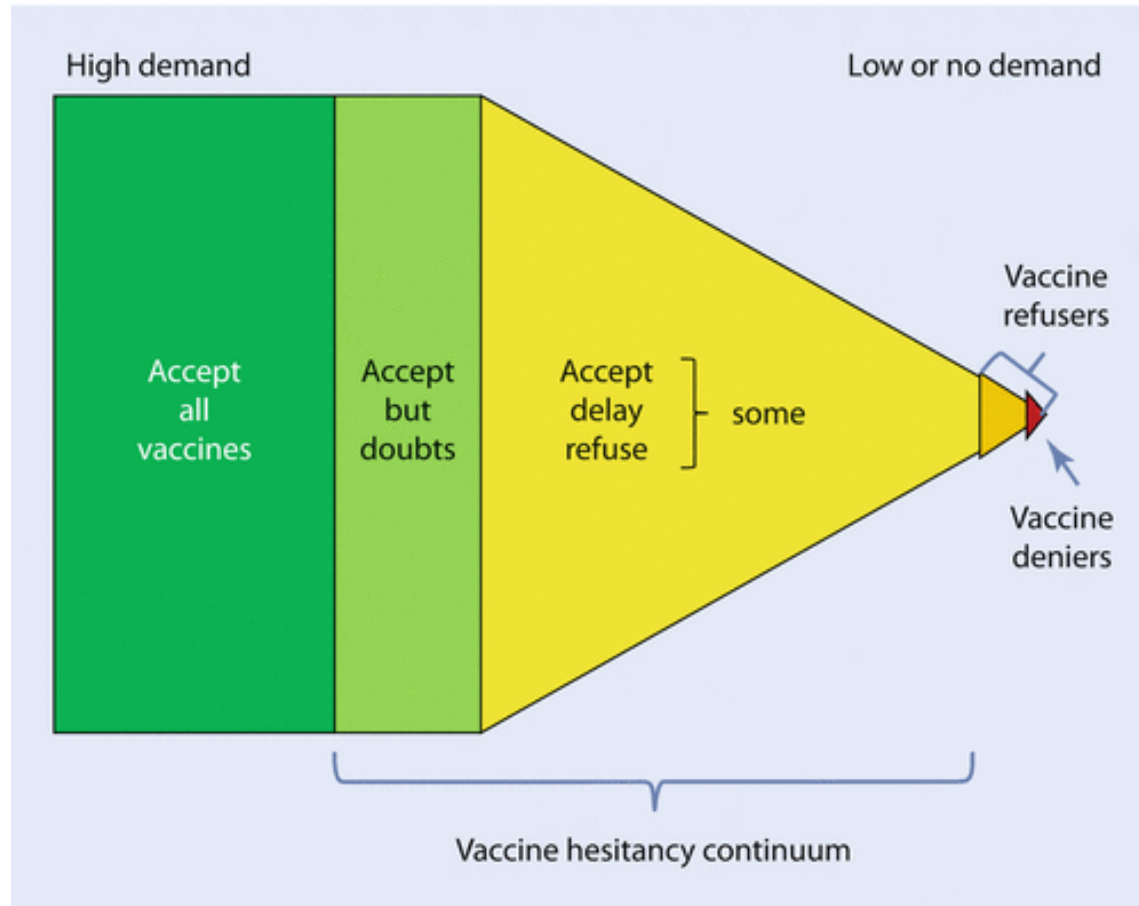


**Absolute overall increase=22%**

# Similarity of October and December populations

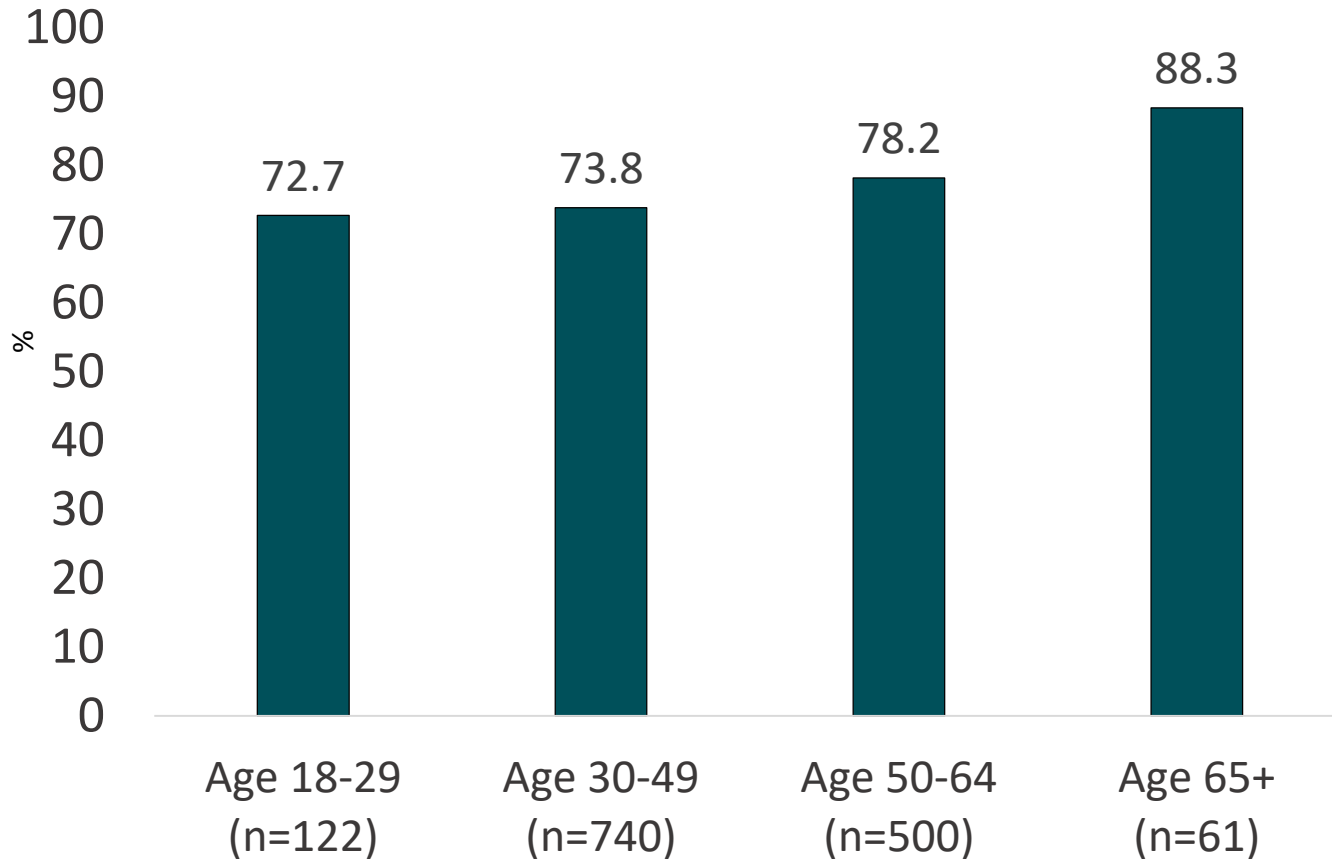
- October: n=2070 participants
- December: n=1541 participants
- No differences in age, race, gender, medical history, or professional role
- N=998 participants overlapped
  - 69%: Yes at both timepoints
  - 15%: No at both timepoints
  - 13%: No → Yes
  - 2.9% Yes → No

# Vaccine hesitancy is a continuum



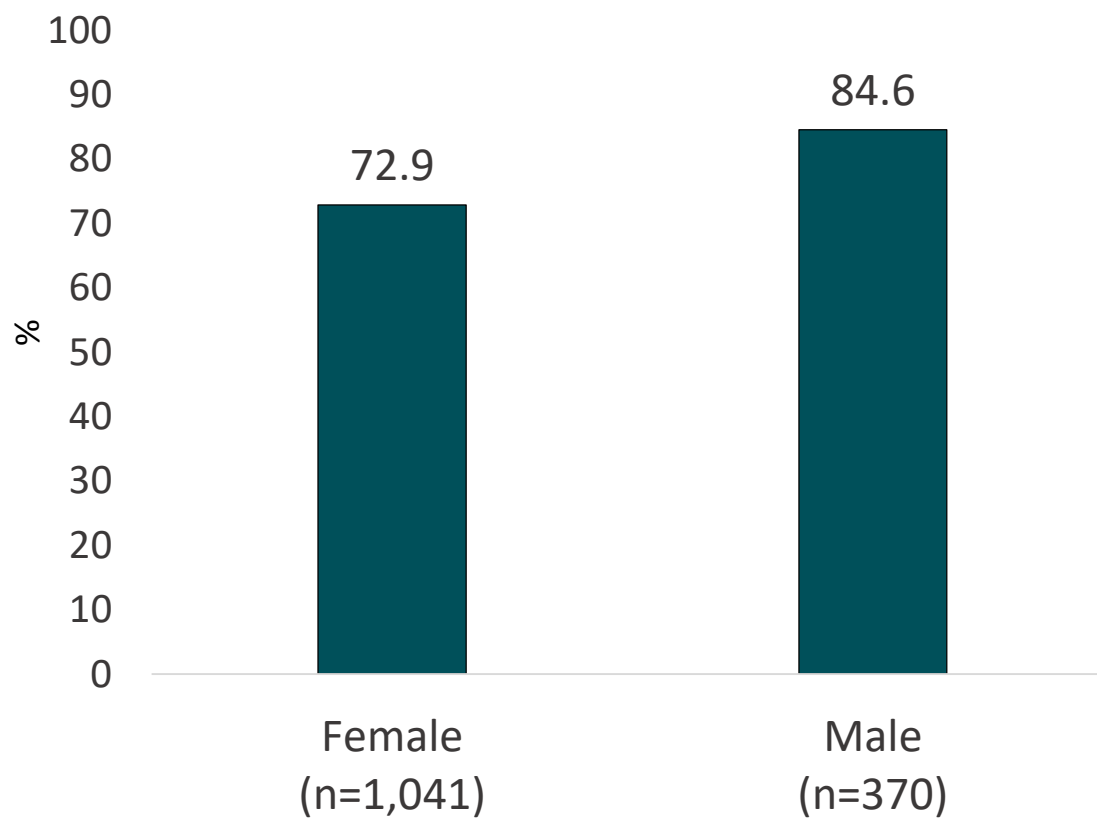
Butler R. (2017) Vaccine Hesitancy, Acceptance, and Demand. In: Vesikari T., Van Damme P. (eds) Pediatric Vaccines and Vaccinations. Springer, Cham. [https://doi.org/10.1007/978-3-319-59952-6\\_4](https://doi.org/10.1007/978-3-319-59952-6_4)

# HCW vaccine willingness by age



Source: HERO Registry Hot Topics Poll – 12/20 (n=1541)

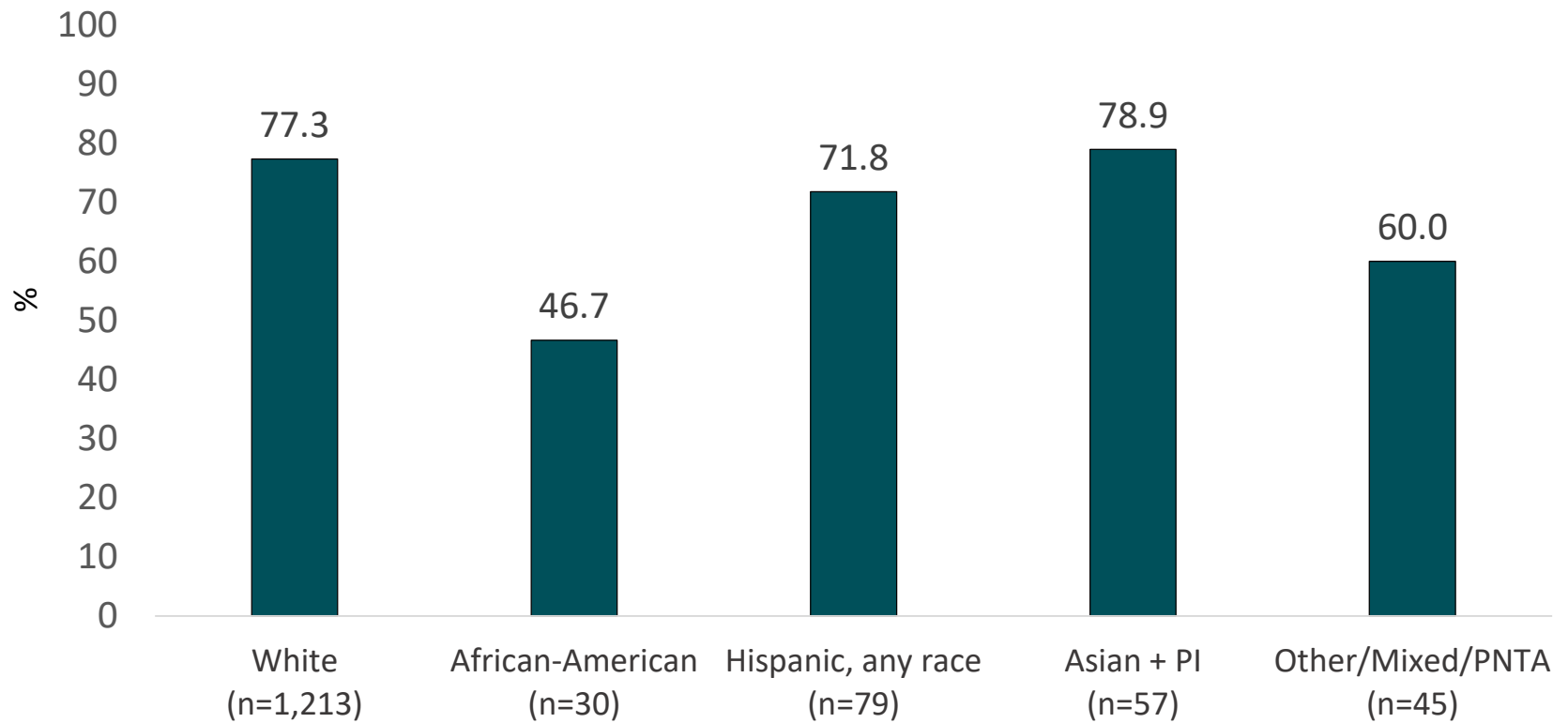
# HCW vaccine willingness by gender



Source: HERO Registry Hot Topics Poll – 12/20 (n=1541)



# HCW vaccine willingness by race



Source: HERO Registry Hot Topics Poll – 12/20 (n=1541)

# Prioritizing Equity



**“[Mistrust stems from] well-documented harms both in stories that have been passed down across generations and in the present lived experience. ”**

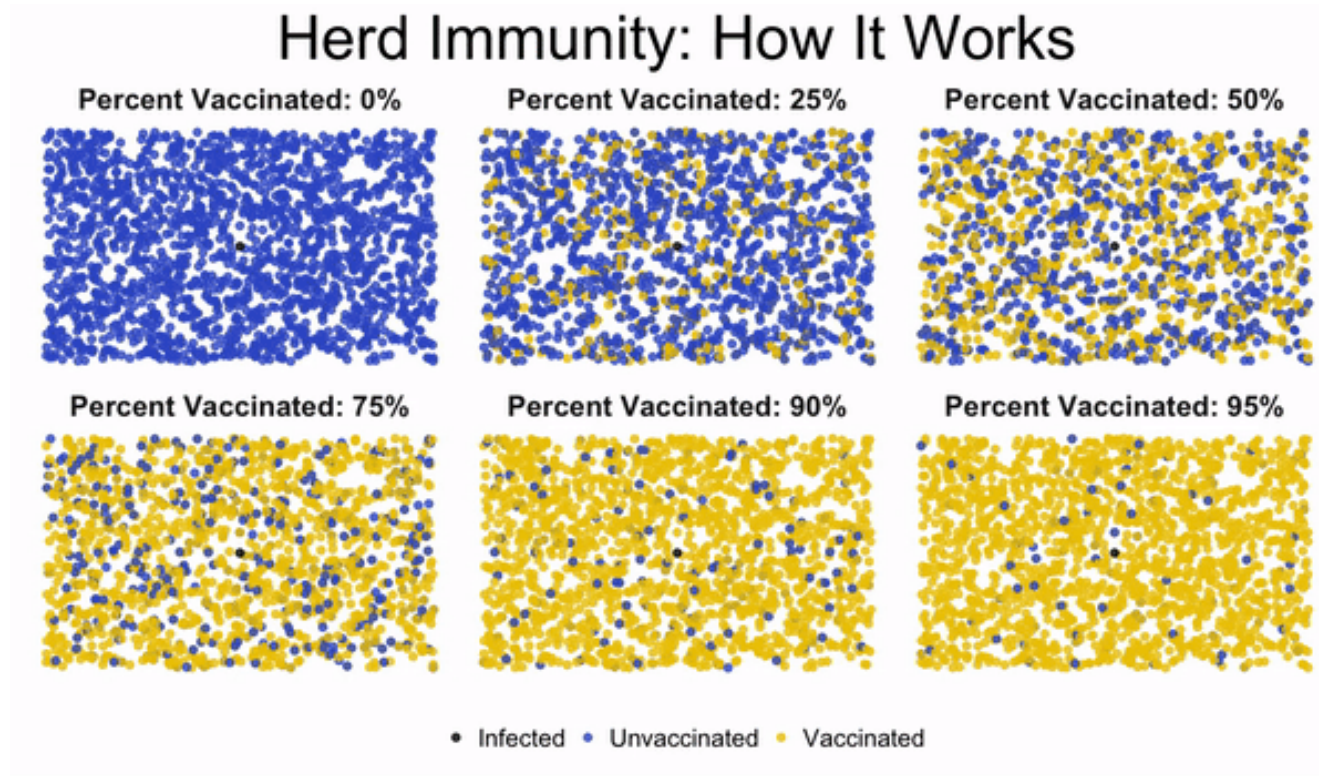
-Aletha Maybank, MD, MPH  
AMA Chief Health Equity Officer

**“This is the most central conversation... [we need to] double down on the important role of health care providers as trusted messengers.”**

-Marcella Nunez-Smith, MD, MHS  
Chair, President-elect Biden’s COVID-19  
Equity Task Force

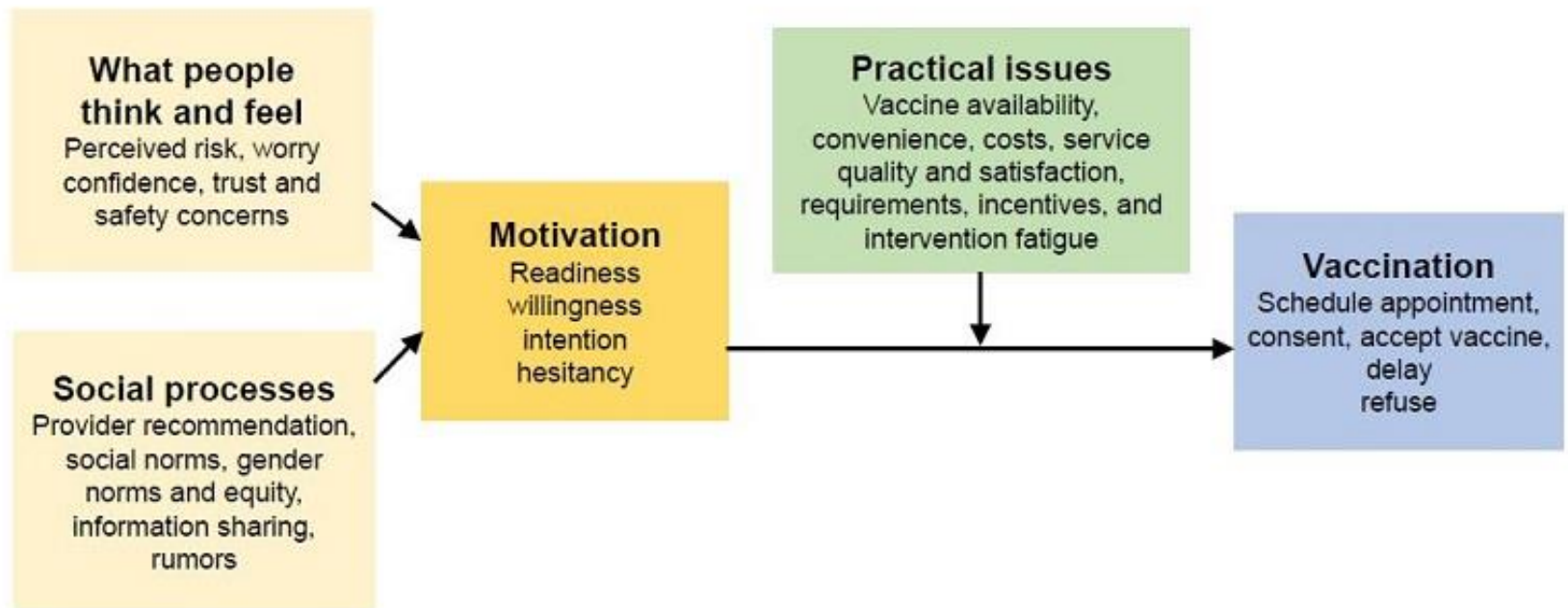
American Medical Association. Prioritizing Equity video series: “Trustworthiness & Vaccines”. December 11, 2020.

# Back to “normal”



# How do we address vaccine hesitancy?

## Increasing Vaccination Model



Source: The BeSD expert working group. Based on: Brewer NT, Chapman GB, Rothman AJ, Leask J, and Kempe A (2017). Increasing vaccination: Putting psychological science into action. *Psychological Science for the Public Interest*. 18(3): 149-207

# State of the research

- Vaccine hesitancy is a complex behavioral phenomenon
- Relatively young field
- No universal best practice intervention to address hesitancy in all its contexts
- Locally tailored and multi-component approaches needed

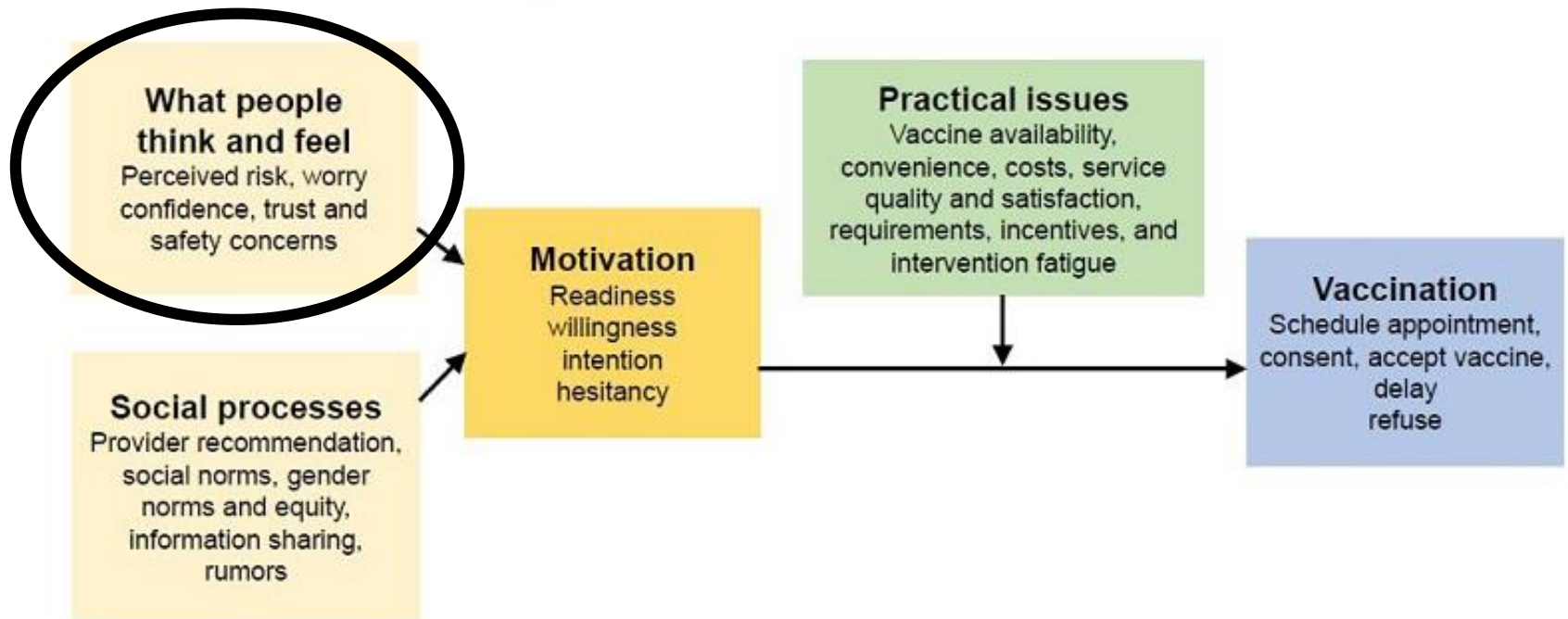
# Future research needs to...

- Target subgroups who are hesitant
- Use multicomponent interventions
- Focus on meaningful engagement (dialogue-based)
- **Match intervention to the cause of hesitancy**
- Evaluate outcomes of hesitancy, acceptance, and lessons learned

# Why Data?

# Perceived risk & safety concerns can impact downstream behavior

## Increasing Vaccination Model



Source: The BeSD expert working group. Based on: Brewer NT, Chapman GB, Rothman AJ, Leask J, and Kempe A (2017). Increasing vaccination: Putting psychological science into action. *Psychological Science for the Public Interest*. 18(3): 149-207



# Reasons for vaccine hesitancy

If no, why not? (check all that apply)

- I am concerned about safety of vaccines in general
- I am concerned about safety of the COVID-19 vaccine specifically
- I have had an adverse reaction to a vaccine in the past
- I do not believe the vaccine will be effective in preventing COVID-19
- I am using other methods to prevent COVID-19
- I am not worried about getting COVID-19
- Other (specify): \_\_\_\_\_

# Reasons for EUA Vaccine Hesitancy by Healthcare Worker Role (%)

	October (n=942)	December (N=366)
<b>Concerned about safety of COVID-19 vaccine specifically</b>	<b>84.0</b>	<b>82.4</b>
Do not believe the vaccine will be effective	9.7	7.4
Using other methods to prevent COVID-19	8.2	12.4
Concerned about safety of vaccines in general	4.7	9.3
Not worried about getting COVID-19	4.0	8.5
Have had an adverse reaction to vaccines in the past	3.0	5.5

# Data in Context

U.K.

## Two in U.K. Suffer Allergic Reaction to Pfizer's Covid-19 Vaccine

Regulator says people with history of significant allergic reactions shouldn't get the shot



**CDC: With nearly 5 million Americans vaccinated, just 29 have had confirmed allergic reactions**

Hilary Brueck 22 hours ago



# HERO-Together Rationale

Healthcare workers will be early SARS-CoV-2 vaccine recipients



Emergency use-authorization will be based on limited follow-up data



There is a need for long-term safety data in broad populations



# HERO-Together Design

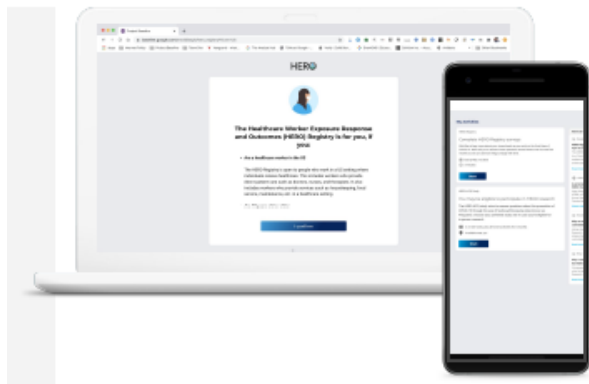
- A prospective, observational, multicenter cohort study of 20,000 adult U.S. healthcare workers who received a COVID-19 vaccine within the past 60 days.
- Healthcare workers may self-enroll in-person at the vaccination site or may self-enroll remotely.
- Following enrollment and consent, all participants will enter data into a secure participant facing web-portal at baseline, 1 week, 2 weeks, 4 weeks, 8 weeks, 12 weeks, and at 6-, 9-, 12- 18-, and 24-months.
- Decentralized, site-less follow-up through online portal
- Rescue event and medical record capture through call center

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**TOGETHER**  
KEEPING COMMUNITIES  
HEALTHY WITH VACCINATION

# Study Navigators

Partner with participating health systems to

- Promote the study
- Support participant sign-up
- Improve quality of vaccine data entry
- Build community & solidarity around research mission



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# Data Elements of Interest



Vaccine info



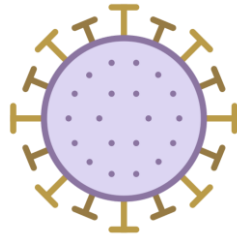
Medical history



Unexpected  
medical care



Safety events



COVID-19 Info



Quality of life

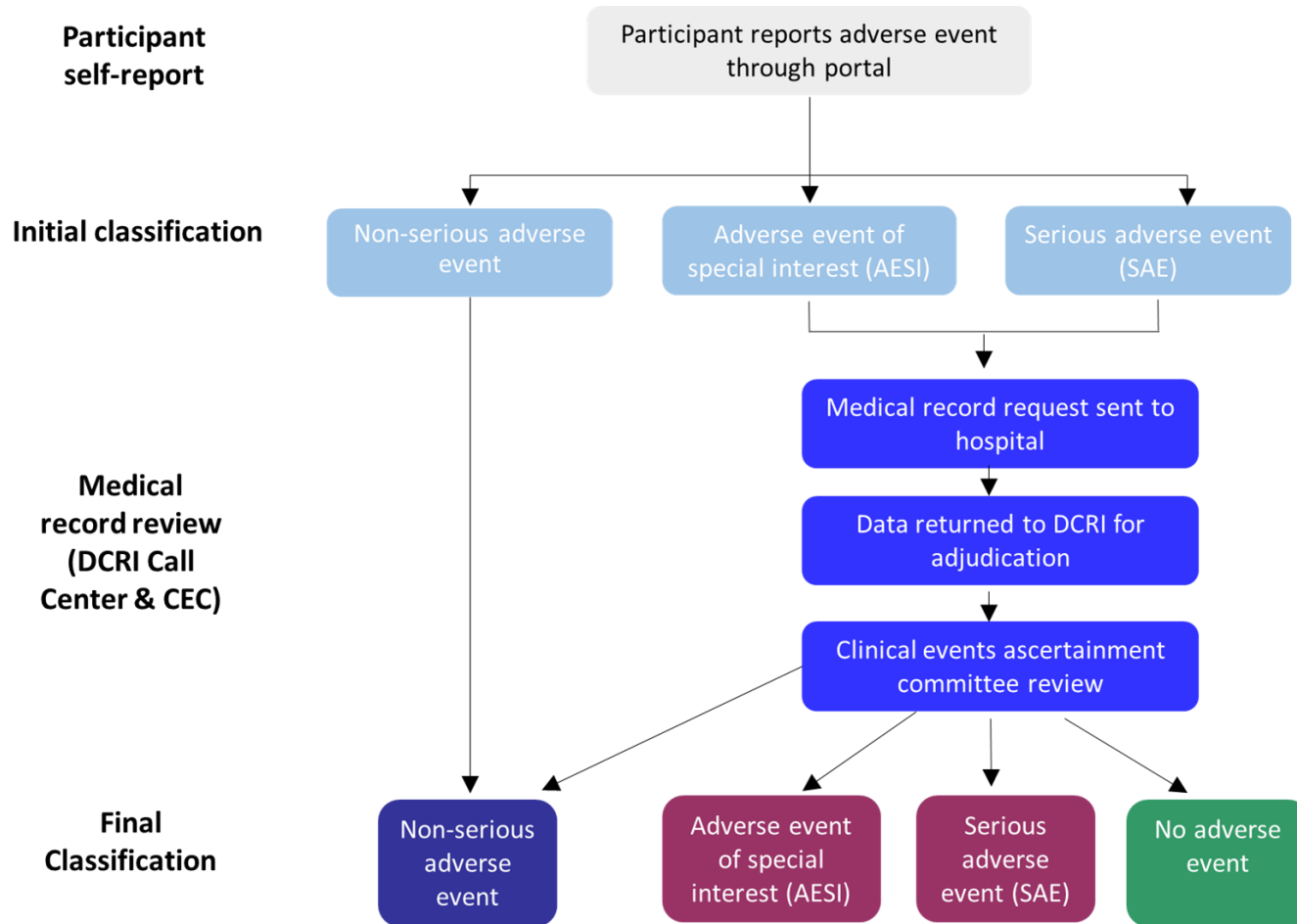
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HEALTHY WITH VACCINATION

# Assessment Schedule

Data Element	Baseline	1 week	2 weeks	4 weeks	8 weeks	3-, 6-, 9- 12-, 18-, 24- mo.
E-consent	X					
Medical release	X					
Vaccine information	X					
Demographics	X					
Medical history	X					
PROs	X	X				X
COVID-19 infection	X					X
Safety outcomes		X	X	X	X	X



# Decentralized Event Capture



# What does HERO-Together add (e.g., Phase 3 trial follow-up, V-SAFE, Sentinel)?

- Broad population
  - Phase 3 trials excluded pregnant/breastfeeding, immunocompromised
- Verified events
- Extensive list of adjustment variables
- Return of results



# Creating a community

## Learning Together: What HERO Surveys Say

August 3, 2020

## Understanding the Science: An Update on Vaccine Trials

October 2, 2020

## COVID-19 mRNA Vaccines: How Did They Get Here So Fast?

January 7, 2021



HeroesResearch  
@HeroesResearch

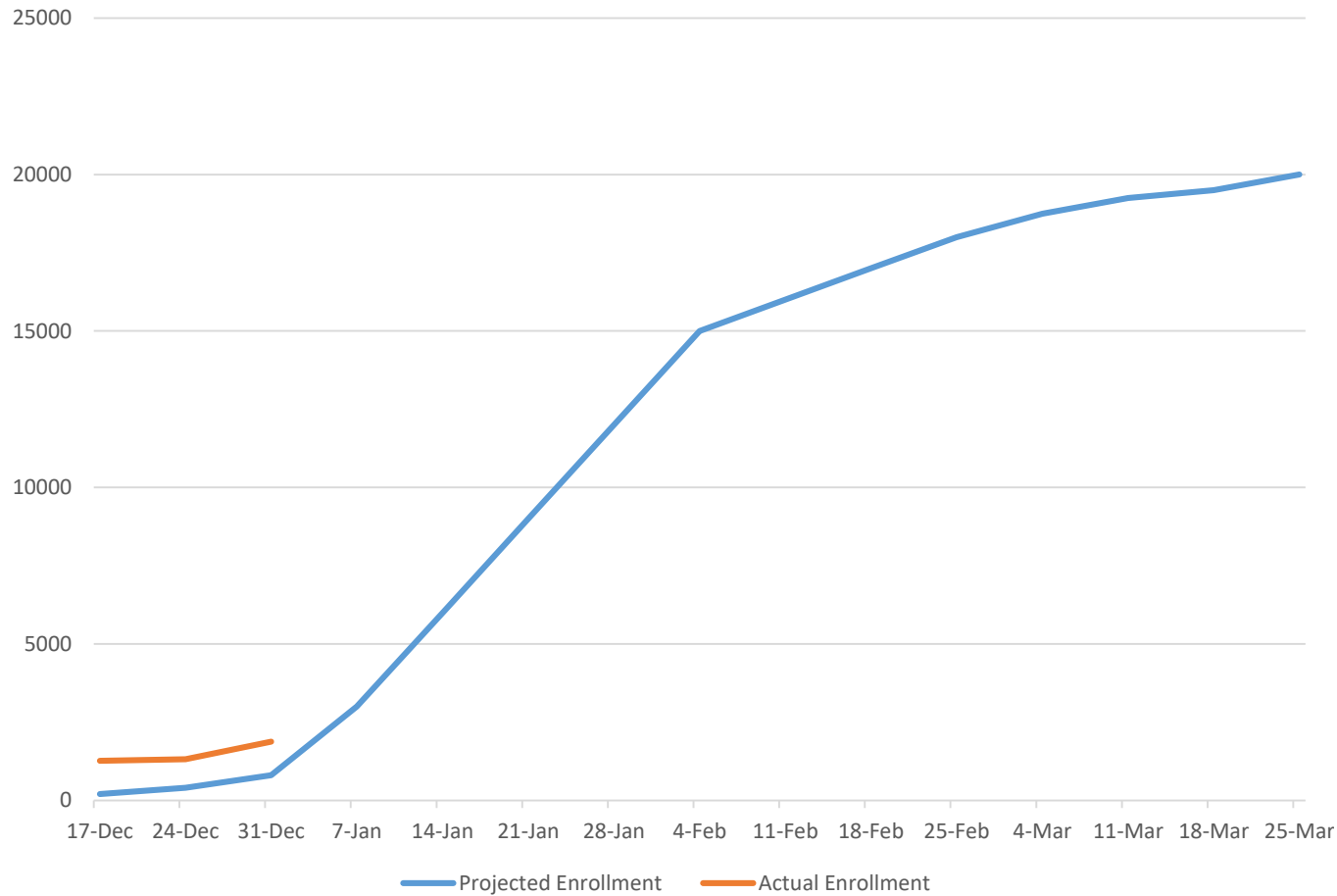


What's next after #COVID19 vaccination?  
#HEROTOGETHER is a new research study for vaccinated #HealthcareWorkers to assess the long-term impact of the #COVID19 #vaccines over time. Learn more and take part at [heroesresearch.org/together](https://heroesresearch.org/together) @PCORnet @PCORI



Jan 4, 2021

# HERO Together n=2,820



- Launched December 17<sup>th</sup>

# Project Team

## Duke

### Project leadership

Lauren Cohen  
Beth Fraulo  
Adrian Hernandez  
Laura Webb  
Susanna Naggie

### Statistics & Data

Peter Merrill  
Haolin Xu  
Laine Thomas  
Kevin Anstrom  
Jun Wen  
Jack Shostak  
Ryan Fraser

### Call Center

Tina Harding  
Khaula Baloch

### Safety/CEA

Stacey Mangum  
Marsha Marquess  
Kimberly Brown

### Communications

Jenny Cook  
Patty McAdams  
Daniel Richardson

### Institutional Outreach

Leanne Stanton

## Verily

Kevin Obana  
Jess Mega  
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Nick Ragan  
Naxin Wang  
Rob Martorano  
Lea Jabbour  
Alex Wormwuth  
Brandon Davis  
Rachel Taylor  
Rob Califf

## Pfizer

Heather Rubino  
Ann Madsen  
Ulka Campbell

# Vaccinated? Join us!

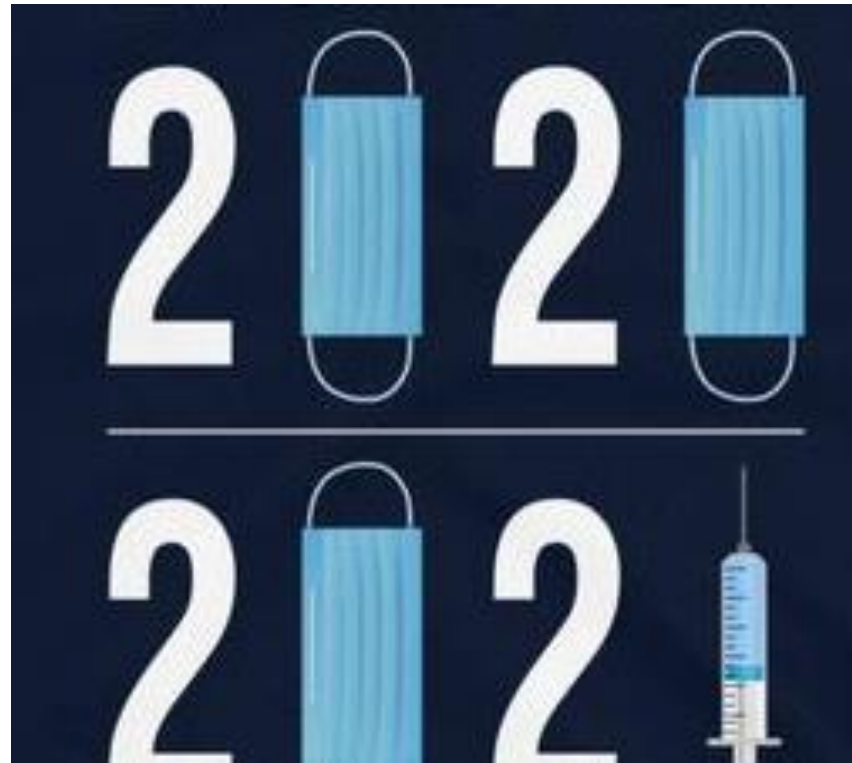
[HeroesResearch.org](https://HeroesResearch.org)

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KEEPING COMMUNITIES  
HEALTHY WITH VACCINATION

# Happy New Year!



# WHO Review of Systematic Reviews

- 11 published reviews/meta-analyses (2006-2014) focused on increasing vaccine uptake
- No strong evidence to recommend any specific intervention to address hesitancy
- Few studies directly targeting vaccine hesitant patients
- Reminders can help improve uptake but no data on hesitancy
- Mixed evidence for HCW training, community-based interventions, mass media interventions
- Pro-immunization messaging can backfire among those with strongly negative vaccine views

World Health Organization. Report of the Strategic Advisory Group of Experts on Vaccine Hesitancy (November 2014).