St. Jude Children's Research Hospital | HPV Cancer Prevention Program

2025 HPV AWARENESS DAY SEMINAR SERIES

Vaccines in the U.S.: A Journey Through History

March 3, 2025

stjude.org/hpv • #EndHPVCancers

Organizer

Akeria Taylor, MPH
Program Coordinator
St. Jude HPV Cancer Prevention Program

Welcome to the HPV Awareness Day Seminar Series

- Today's meeting will be recorded. The link to view the recording and PDF of materials will be shared with all who have registered. In addition, the recording link will be posted publicly in the future.

- If you have any issues during today's meeting, please use the chat or email PreventHPV@stjude.org.

- We will use the Q&A feature for questions. You can post questions at any time to engage with the presenters and organizers.

Learning Objectives

By the end of the seminar, participants will be able to:

- Discuss a brief timeline and history of vaccinations in the U.S.
- Discuss the impact of vaccinations in the U.S.
- Discuss ongoing efforts to promote recommended vaccines in the U.S.

Robert H. Hopkins, Jr., MD

MODERATOR

Medical Director

National Foundation for Infectious Diseases (NFID)

Presenters

Iyabode (Yabo) Beysolow, MD
Public Health Consultant
Owner YB Consultants, LLC

Daniel Salmon, PhD
Professor & Director
Institute for Vaccine Safety
Johns Hopkins Bloomberg School
of Public Health

Amy Pisani, MS
Chief Executive Officer
Vaccinate Your Family

Iyabode (Yabo) Beysolow, MD

SPEAKER

Owner YB Consultants, LLC

Public Health Consultant

March 3, 2025

YB CONSULTANTS, LLC
MEDICAL CONSULTING

Vaccines

A current landscape

Today's topics

- Why do we vaccinate?
- History of vaccine success in the US
- Current landscape
- History of vaccine hesitancy and where we are currently

Faculty Disclosure Information

In accordance with ACCME and ANCC-COA Standards, all faculty members are required to disclose to the program audience any real or apparent conflict of interest to the content of their presentation.

Detailed information regarding all ACIP Vaccine Recommendations is available at www.cdc.gov/vaccines/acip/recs/index.html

Why do we vaccinate?

- To prevent diseases
  - Some of which are life-threatening or can lead to disability
- To strengthen the immune system (babies and older adults)
- To keep us healthy, just as important as nutrition and exercise
- Vaccine-preventable diseases are still around
  - It is always better to prevent a disease than to treat one after it occurs

NFID: https://www.nfid.org/immunization/10-reasons-to-get-vaccinated/ and CDC: https://www.cdc.gov/vaccines-children/reasons/index.html

Vaccines Work!

CDC statistics demonstrate dramatic declines in vaccine-preventable diseases when compared with the pre-vaccine era

DISEASE	PRE-VACCINE ERA ESTIMATED ANNUAL MORBIDITY[1]	MOST RECENT REPORTS OR ESTIMATES OF U.S. CASES	PERCENT DECREASE
Diphtheria	21,053	2[2]	>99%
H. influenzae serotype B (invasive, <5 years of age)	20,000	18[2]	>99%
Hepatitis A	117,333	(est) 37,700[3]	68%
Hepatitis B (acute)	66,232	(est) 20,700[3]	69%
Measles	530,217	1,275[2]	>99%
Meningococcal disease (all serotypes)	2,886[4]	371[2]	87%
Mumps	162,344	3,780[2]	98%
Pertussis	200,752	18,617[2]	91%
Pneumococcal disease (invasive, <5 years of age)	16,069	1,700[5]	89%
Polio (paralytic)	16,316	0[2]	100%
Rotavirus (hospitalizations, <3 years of age)	62,500[6]	30,625[7]	51%
Rubella	47,745	6[2]	>99%
Congenital Rubella Syndrome	152	1[2]	>99%
Smallpox	29,005	0[2]	100%
Tetanus	580	26[2]	96%
Varicella	4,085,120	8,297[8]	>99%

1. CDC. *JAMA* November 14, 2007; 298(18): 2155–63.
2. CDC. National Notifiable Infectious Diseases and Conditions, United States: Annual Tables 2019. Accessed August 2, 2022.
3. CDC. Viral Hepatitis Surveillance – United States, 2019. Published May 2021. Estimated total cases account for under-reporting.
4. CDC. *MMWR* October 6, 1995; 43(53):1–98.
5. CDC. Active Bacterial Core Surveillance (ABCs) Report; Emerging Infections Program Network *Streptococcus pneumoniae*, 2019.
6. CDC. *MMWR*, February 6, 2009; 58(RR-2): 1–25.
7. CDC. New Vaccine Surveillance Network, 2017 data (unpublished); U.S. rotavirus disease now has a biennial pattern.
8. CDC. Varicella Program, 2017 data (unpublished)

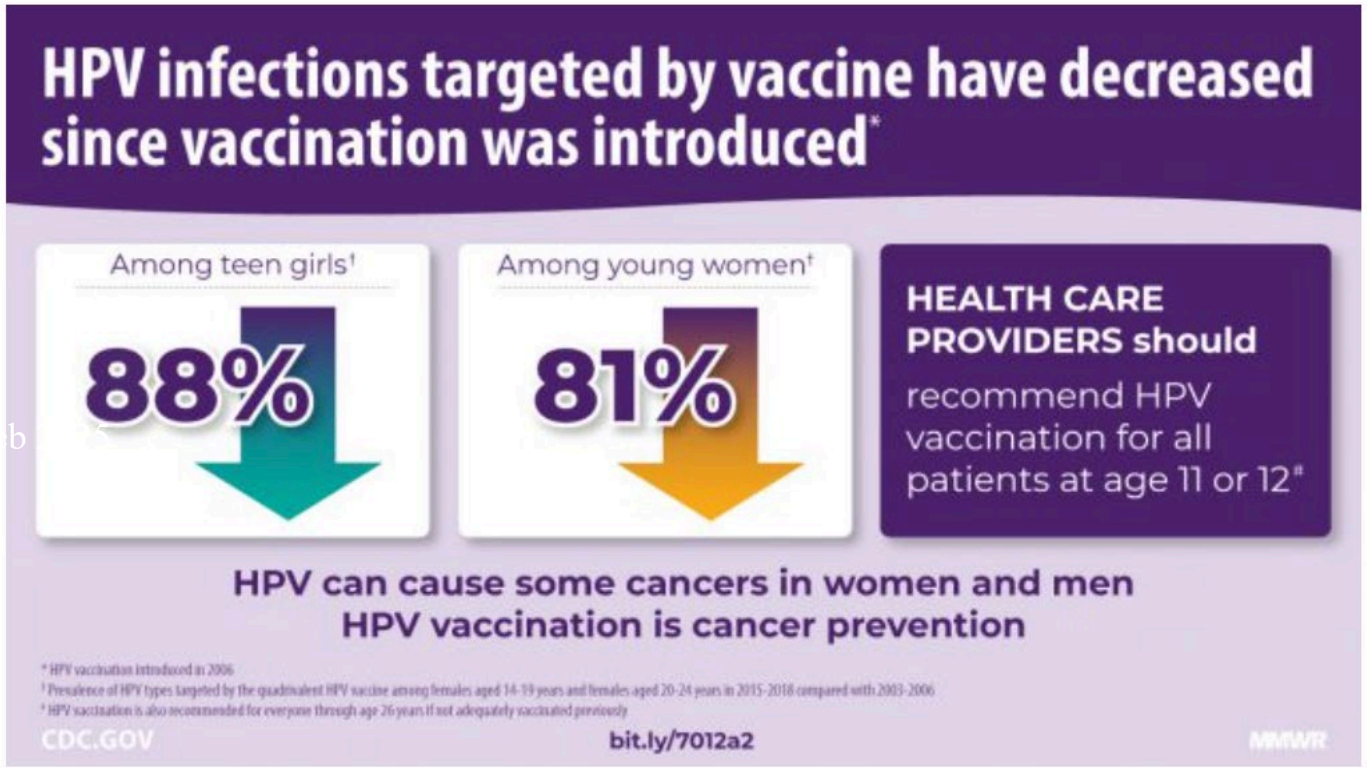
Immunize.org FOR PROFESSIONALS www.immunize.org / FOR THE PUBLIC www.vaccineinformation.org
www.immunize.org/catg.d/p4037.pdf • Item #P4037 (8/22)

Immunize.Org:
www.immunize.org/catg.d/p4037.pdf

Evidence of Reduction in HPV Prevalence

HPV Vaccine introduced in the U.S. in 2006. HPV Vaccination works!!

Within 12 years of vaccine introduction,
infections with the four HPV types (6,11,16 and 18) prevented by Gardasil decreased by 88% among 14–19-year-old females and 81% among 20–24-year-old females in the United States.



Rosenblum, H, Unger ER, Markowitz LE. Declines in prevalence of human papillomavirus vaccine-type infection among females after introduction of vaccine — United States, 2003–2018. MMWR. 2021;70(12):415-420.

Current Childhood Vaccine Coverage levels

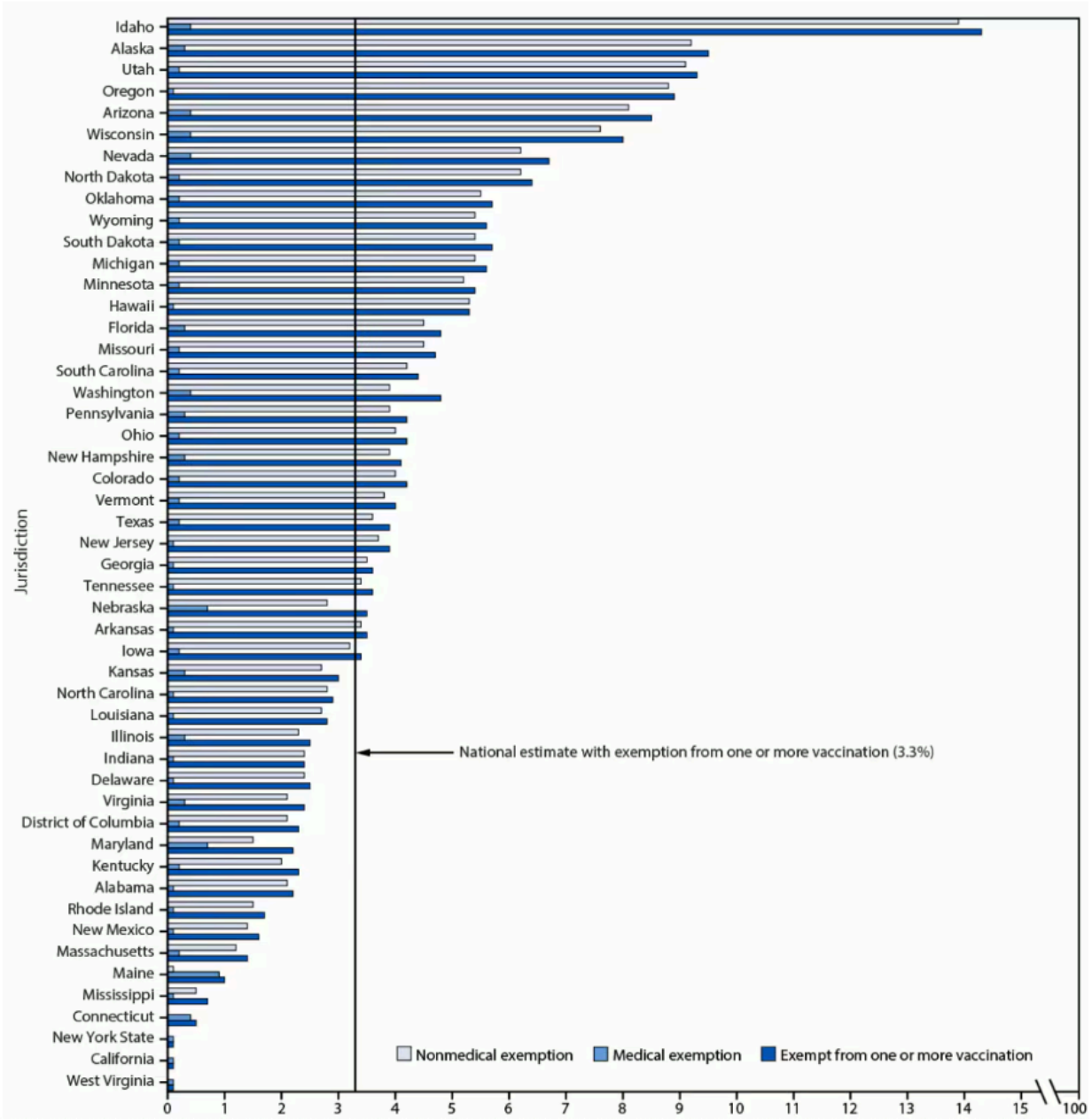
- Nationwide, vaccination coverage with state-required vaccines among children in kindergarten
  - decreased to <93% during the 2023–24 school year
  - remaining below the Healthy People 2030 MMR target of 95% for the fourth consecutive year.

- As recently as the 2019–20 school year, coverage with each measured vaccine was 95%.

Seither R, Yusuf OB, Dramann D, et al. Coverage with Selected Vaccines and Exemption Rates Among Children in Kindergarten — United States, 2023–24 School Year. MMWR Morb Mortal Wkly Rep 2024;73:925–932. DOI: http://dx.doi.org/10.15585/mmwr.mm7341a3

Latest CDC Vaccination Exemptions – Kindergartners, CDC

FIGURE 1. Estimated percentage*,† of kindergartners with medical or nonmedical exemptions from one or more vaccination, jurisdiction§ — United States, 2023–24 school year



CDC MMWR, Oct 2024, 2023-24 school year

The percentage of U.S. Kindergartners with an exemption from 1 or more vaccine:

- Increased to 3.3% (the highest percentage ever reported)
- Increased in 41 jurisdictions
- Exceeded 5% in 14 jurisdictions

Exemptions >5% limit the level of achievable vaccination coverage, which increases the risk for outbreaks of vaccine-preventable diseases.

Seither R, Yusuf OB, Dramann D, et al. Coverage with Selected Vaccines and Exemption Rates Among Children in Kindergarten — United States, 2023–24 School Year. MMWR Morb Mortal Wkly Rep 2024;73:925–932.

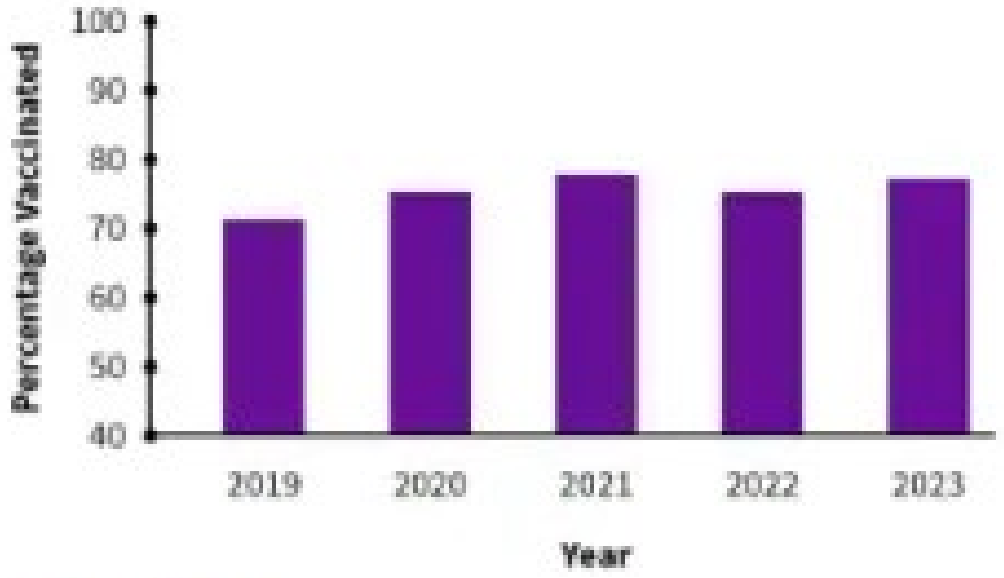
Implications

- In the 2023-24 school year, approximately 280,000 (7.3%) kindergartners in the U.S. did not have documentation of 2 MMR doses and were potentially at risk for measles infection.

- Decreasing vaccination coverage and increasing exemptions increase the risk for vaccine-preventable disease outbreaks.

Seither R, Yusuf OB, Dramann D, et al. Coverage with Selected Vaccines and Exemption Rates Among Children in Kindergarten — United States, 2023–24 School Year. MMWR Morb Mortal Wkly Rep 2024;73:925–932. DOI: http://dx.doi.org/10.15585/mmwr.mm7341a3

HPV vaccination coverage has not improved since the pandemic*



CDC

*≥1 Dose HPV vaccine coverage, 2019-2023 National Immunization Survey-Teen data

bit.ly/m[illegible]

August 22, 2024

Clinicians:

- Review vaccination records
- Recommend routine HPV vaccination at age 11 or 12 years to prevent HPV-attributable cancers†
- Talk about no-cost vaccination through VFC‡

†HPV vaccination can be started at age 9.

‡Vaccines for Children program

MMWR

Exemption Types

Medical

Must be reviewed and re-issued annually by provider if medical contraindication persists

Religious

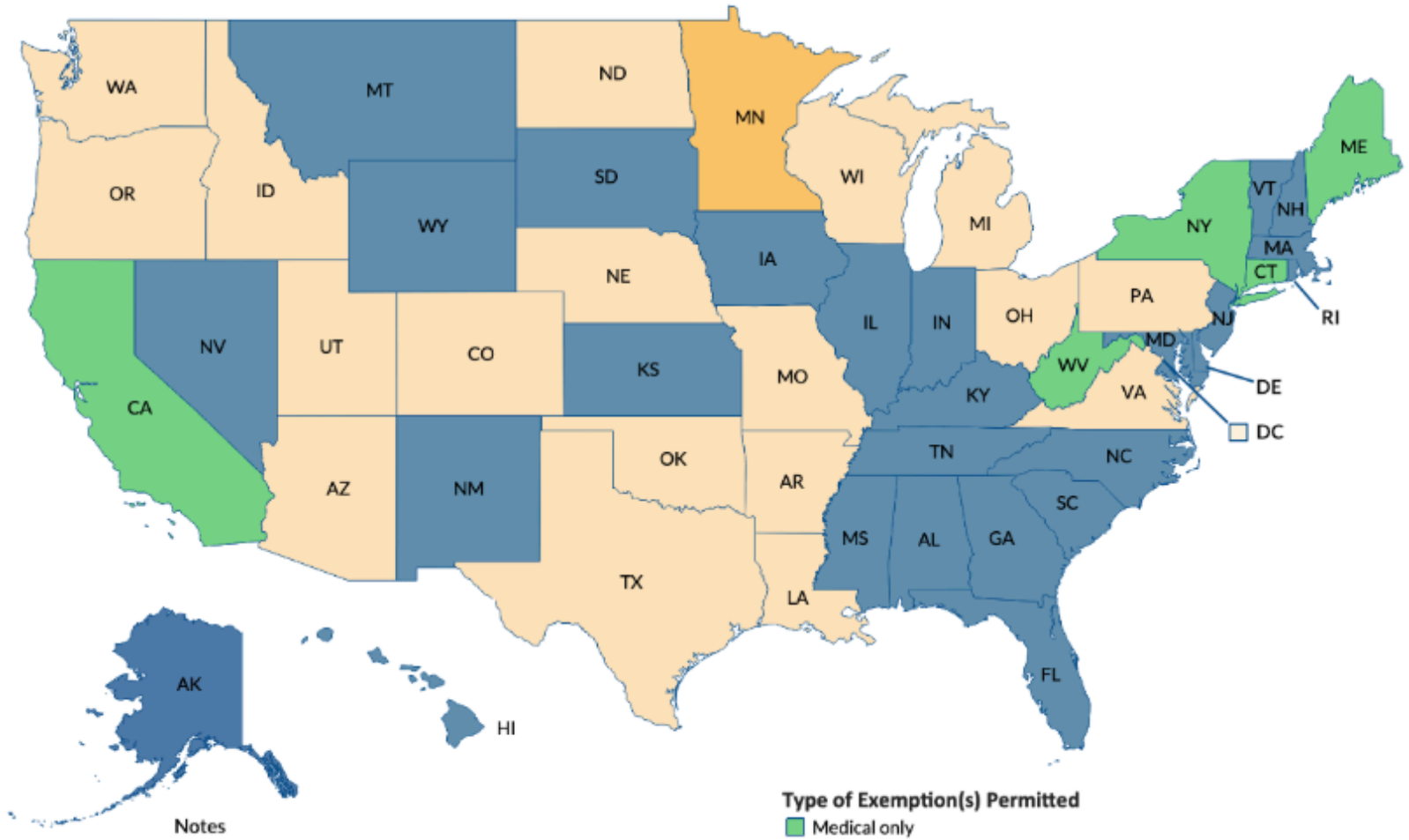
May be seen at higher rates in states without philosophical/personal belief exemptions

Philosophical/Personal Belief

May be seen at higher rates in private schools and/or geographically clustered

Exemptions Permitted for State Childcare and School (K–12) Immunization Requirements

May 2024



Notes

AZ: Religious exemption for childcare only, personal belief exemption for school (K-12) only

CO: Religious and personal belief exemptions combined under category of "nonmedical exemption"

DC and VA: Personal belief exemption for HPV only

MO and NE: Personal belief exemption for childcare only

WA: Personal belief exemption not allowed for MMR

Type of Exemption(s) Permitted

- Medical only
- Medical, religious
- Medical, personal belief
- Medical, religious, personal belief

Immunize.org

Source: state immunization programs
For details, see data table: www.immunize.org/official-guidance/state-policies/vaccine-requirements/exemptions-child-school-2024

https://www.immunize.org/offi
guidance/state-policies/vaccine
requirements/exemptions-child
school-2024/

AAP News™ Latest News Collections

SHARE

Measles outbreak in Texas grows to 24 cases; pediatricians urge vaccination

February 14, 2025

Steve Schering, Staff Writer

https://www.dshs.texas.gov/news-alerts/measles-outbreak-feb-18-2025
https://publications.aap.org/aapnews/news/31289?utm_source=MagnetMail&utm_medium=email&utm_term=PA_OnCall&utm_campaign=OnCall_Weds_Feb12_2025?autologincheck=redirected

According to the Texas Dept of State Health Services, as of 2/18/2025: 58 cases

"Most of the patients are younger than 18.

Majority of cases UNVACCINATED or vaccine status unknown. 4 cases vaccinated.

13 patients have been hospitalized.

15 of the cases are children younger than 4 years,
33 cases are children 5-17 years
6 cases among adults.

..Residents of Gaines Cty, which had a nearly 18% vaccine exemption rate among kindergartners in the 2023-24 school year. "

3 cases reported in New Mexico (2/14/25).

AAP News™ Latest News Collections

SHARE

Unvaccinated child dies of measles amid outbreak in Texas

February 26, 2025

Steve Schering, Staff Writer

Download PDF

Article type: News

Topics: Infectious Diseases, Vaccine/Immunization

An unvaccinated school-aged child has died after testing positive for measles amid an outbreak in west Texas, health officials confirmed Wednesday.

The Texas Department of State Health Services (DSHS) said the child was hospitalized last week in Lubbock and is the

As of Feb. 28, 146 cases of measles have been confirmed in Texas since the outbreak began in late January. Most of the cases are unvaccinated or status unknown, majority children, and 20 people have been hospitalized. Texas DSHS

New Mexico reports 9 cases in Lea County (2/25).

AAP News

Latest News Collections

SHARE

CDC: Flu likely has peaked this season, but 12 more pediatric patients have died

February 28, 2025
Sean Stangland, Associate Editor

https://publications.aap.org/aapnews/news/31506/CDC-Flu-likely-has-peaked-this-season-but-12-more.

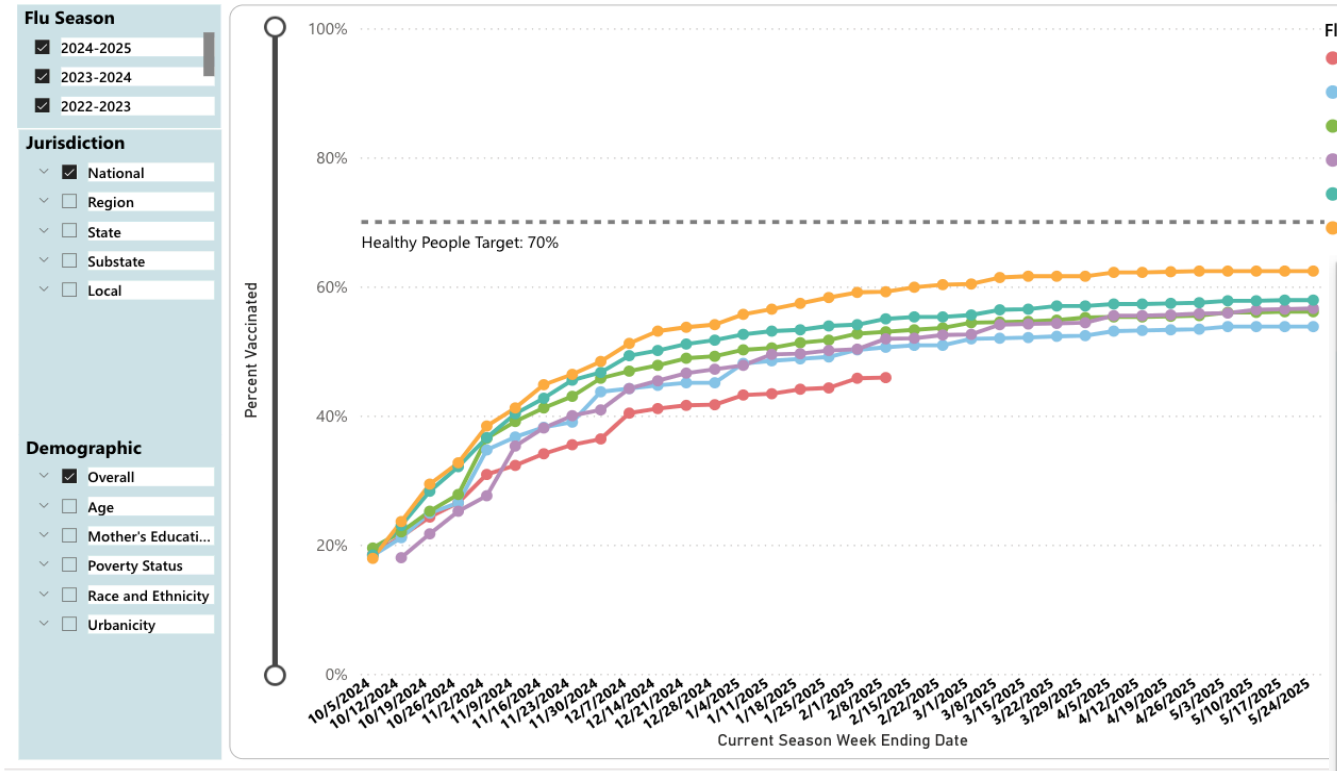
Unfortunately, there have been 98 pediatric flu deaths reported in the U.S. thus far for the 2024-25 season. (as of 2/28/25).

Seasonal flu activity remains elevated (2/21/25) and continues to increase across the country.

AAP and CDC recommend everyone 6 months and older get vaccinated against the flu and COVID-19. Eligible infants, high-risk toddlers, pregnant people, and older people should get immunized against RSV.

Fig. 2A: Child Line Graph	Fig. 2B: Child Bar Graph	Fig. 2C: Child Coverage and Vaccination Intent	Fig. 2D: Child Maps	Fig. 2E: Child Comparison Tables

Figure 2A. Weekly Cumulative Influenza Vaccination Coverage*,†,‡, by Flu Season and Selected Demographics, Children 6 Months–17 Years, United States
Data Source: National Immunization Survey-Flu



Flu Season	Demographics	Jurisdiction	Influenza Season Data Collection Interview Ending Date	Percentage Vaccinated	95% CI (%)
2024-2025	Overall	National	2/15/2025	45.8%	44.5 - 47.1
2023-2024	Overall	National	2/17/2024	50.9%	50.2 - 51.6
2022-2023	Overall	National	2/18/2023	53.3%	52.6 - 54.0
2021-2022	Overall	National	2/12/2022	52.0%	51.4 - 52.6
2020-2021	Overall	National	2/13/2021	55.3%	54.5 - 56.1
2019-2020	Overall	National	2/15/2020	59.9%	59.1 - 60.7

If all data rows are not visible in tooltip, reduce the number of dimensions selected.

https://www.cdc.gov/fluvaxview/dashboard/children-vaccination-coverage.html

https://www.cdc.gov/respiratory-viruses/data/vaccination-trends.html

Defining Vaccine Hesistancy

YB Consultants, LLC

News Release

American Academy of Pediatrics Offers Strategies to Improve Communication on Vaccines

ITASCA, IL—The American Academy of Pediatrics (AAP) in a new clinical report offers guidance for pediatricians and others who care for children on the best ways to address vaccine concerns and increase immunization rates. Keeping communities healthy through the use of vaccines also requires improving everyone's access to health care and increasing diversity and representation among scientists and health care professionals.

The AAP clinical report, "Strategies for Improving Vaccine Communication and Uptake" will be published in the March 2024 issue of Pediatrics (online Feb. 26). Clinical reports created by AAP are written by medical experts, reflect the latest evidence in the field, and go through several rounds of peer review before being approved by the AAP Board of Directors and published in Pediatrics.

Vaccines prepare children's and teens' immune systems to detect and respond to viruses and bacteria, helping them stay healthy so they can take part in activities important for their mental and physical health, education, and development. When many people in a community are immunized against diseases like measles, pertussis, and pneumococcal infection, the diseases are less likely to spread. When everyone can access immunizations, it protects our public health.

"We wrote this clinical report with primary care pediatricians in mind, as we know what an important topic this is for all of us who have these conversations with parents," said Sean T. O'Leary, MD, MPH, FAAP, chair of the AAP Committee on Infectious Diseases and a lead author of the report. "Working with parents who have questions about vaccines is an opportunity to build rapport and trust with a family and, ultimately, protect their children and the community."

The AAP advises pediatricians to use evidence-based methods of communication with families, including:

For Release:
2/26/2024

Media Contact:
Lisa Black
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Terminology

- **Vaccine Attitudes:** thoughts and feelings about vaccination>>> Shapes intentions, behavior and actions.

- Vaccine Intentions: shape vaccine behavior, actions one takes with respect to vaccination.

- **Vaccine Confidence**: belief that vaccine are safe, effective, system trustworthy. (attitude)

- **Vaccine Hesitancy**: conflicted about or opposed to getting vaccinated. (intention)

- **Vaccine Uptake**: receipt of a vaccine. (behavior)

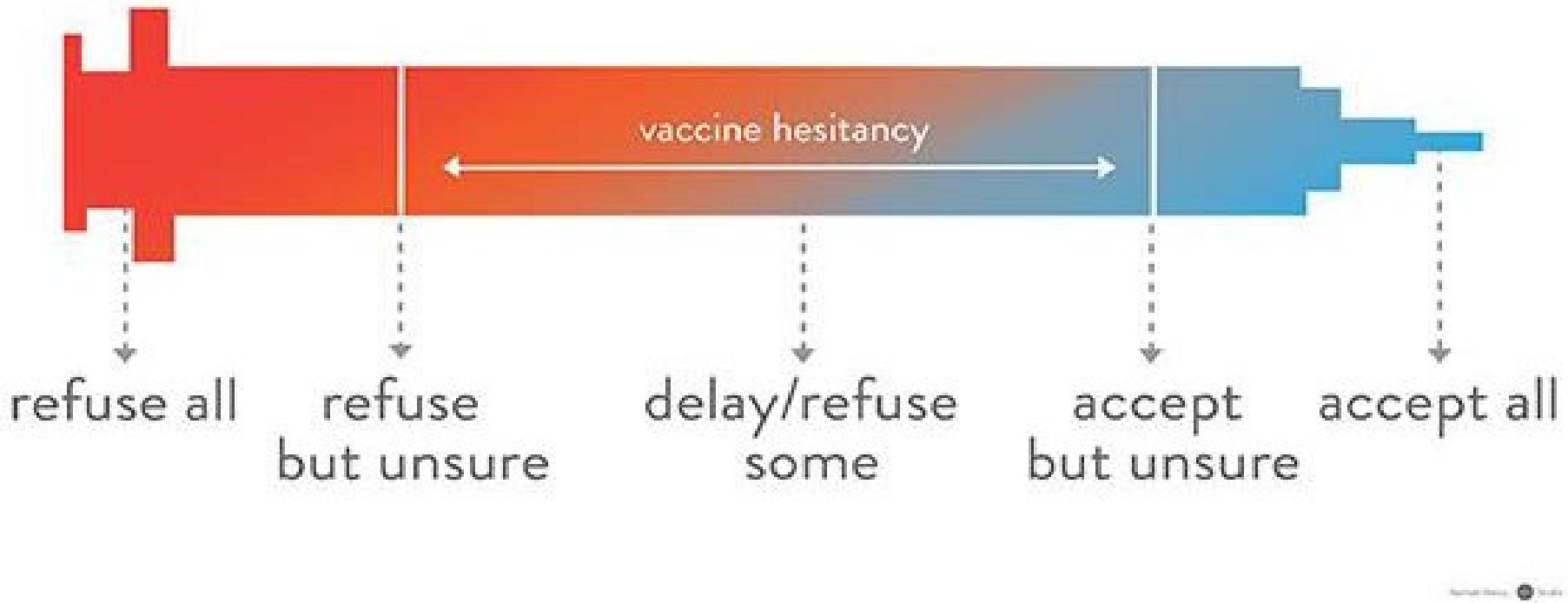
O'Leary et al, Strategies for Improving Vaccine Communication and Uptake: https://doi.org/10.1542/peds.2023-065483

World Health Organization (W.H.O.) Definition of Vaccine Hesitancy

- Refers to a delay in acceptance (reluctance) or refusal of safe vaccines despite the availability of vaccination services
- Complex and context-specific issue
- Variance across time, place, and vaccines
- Influenced by many factors
- Deemed top 10 threat to global health in 2019

O'Leary et al, Strategies for Improving Vaccine Communication and Uptake: https://doi.org/10.1542/peds.2023-065483

Continuum of Vaccine Acceptance



National Immunization Survey found that 20% of US parents reported that they were "hesitant about childhood shots" in 2019.

Graphic by Hannah Henry

Examples of Types of Vaccine Hesitancy

Example Archetypes of Parental Attitudes, Intentions, and Behaviors Toward Vaccines[5,11]

Example Archetypes	
Immunization supporter	Parents recognize the importance of vaccines and vaccinate their children. Parents generally have a strong relationship with their health care provider or have strong trust in health care systems.
Go along to get along	Parents do not question vaccines and generally vaccinate their children but may lack a detailed knowledge of vaccines.
Cautious acceptor	Parents may have minor concerns about vaccines but ultimately vaccinate their children.
Fence-sitter	Parents have significant concerns about vaccines. Parents may be knowledgeable about or have spent time thinking about vaccines. Parents may vaccinate their child with some or all vaccines or may refuse or delay vaccines. Parents may not demonstrate trust in their health care provider regarding vaccine information.
Refuser	Parents refuse all vaccines for their child. Their reasons for refusal may include distrust in the medical system, safety concerns, and religious or other personal beliefs.

O'Leary et al, Strategies for Improving Vaccine Communication and Uptake: https://doi.org/10.1542/peds.2023-065483

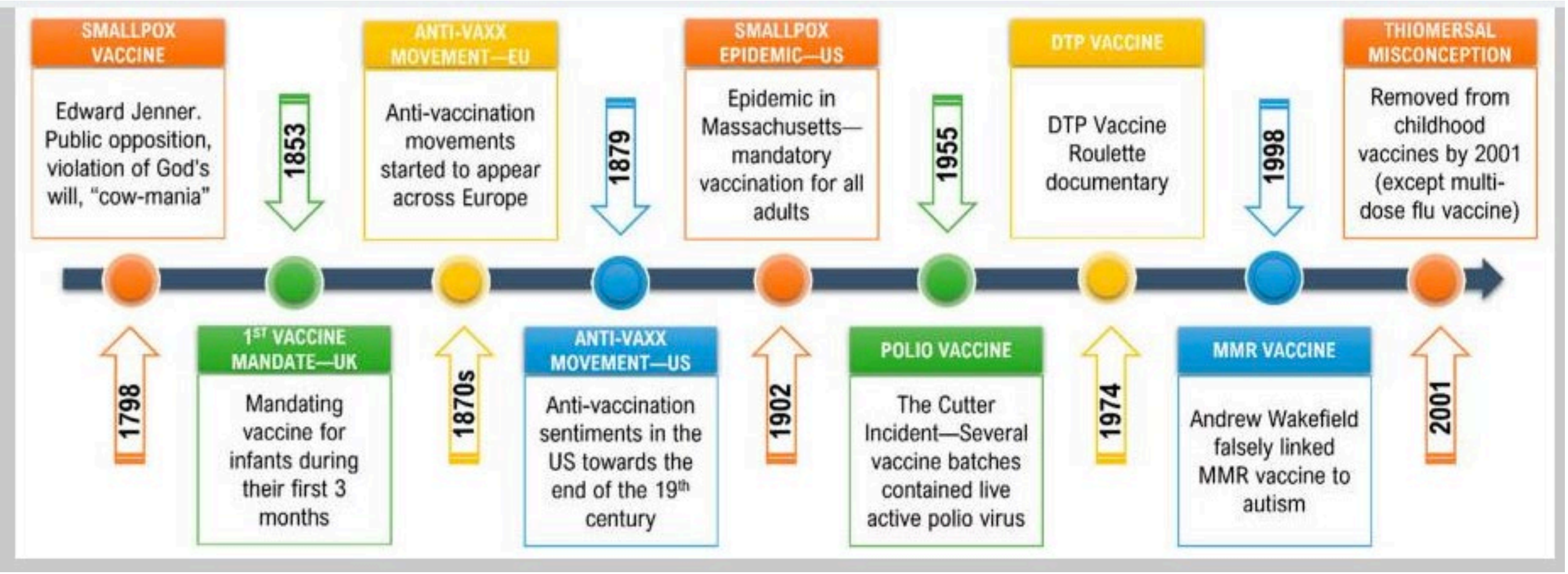
History- Vaccine Hesitancy

Vaccine hesitancy is not new

- 1790's Edward Jenner
  - Public opposition to Smallpox Vaccine
  - "Cow Mania"

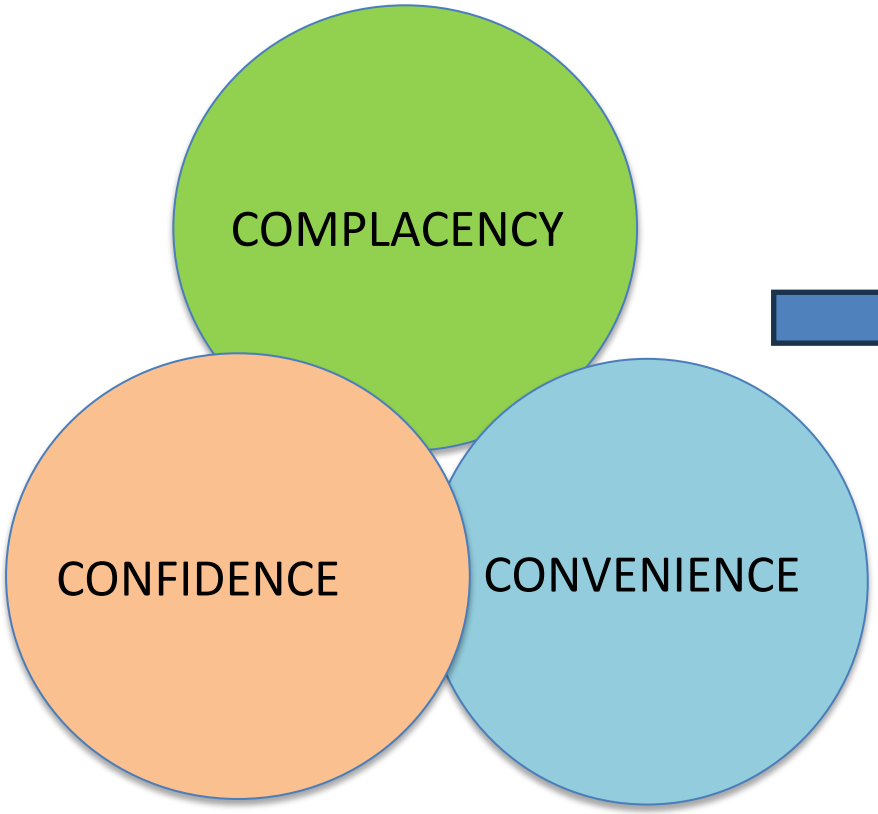
An 1802 engraving, *The Cow Pock—or—the Wonderful Effects of the New Inoculation* plays on the fears of a crowd of vaccinees. ©The Trustees of the British Museum

Vaccine Hesitancy: Contemporary Issues and Historical Background, Oct 2022, Vaccines, Nuwarda et al:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9612044/
https://www.who.int/news/item/18-08-2015-vaccine-hesitancy-a-growing-challenge-for-immunization-programmes
https://www.smithsonianmag.com/smithsonian-institution/history-shows-americans-have-always-been-wary-vaccines-180976828/



Vaccine Hesitancy: Contemporary Issues and Historical Background, Oct 2022, Vaccines, Nuwarda et al: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9612044/
Vaccine hesitancy timeline: early hesitancy and modern controversies. Vaccination resistance existed since the discovery of vaccines, and public trust in their efficacy and overall safety has been challenged by various controversies up until the modern era.

3 Cs Model of Hesitancy (2011-14)



5 As Model (2016)

ACCESS

AFFORDABILITY

AWARENESS

ACCEPTANCE

ACTIVATION

5Cs MODEL (2018)

COMPLACENCY

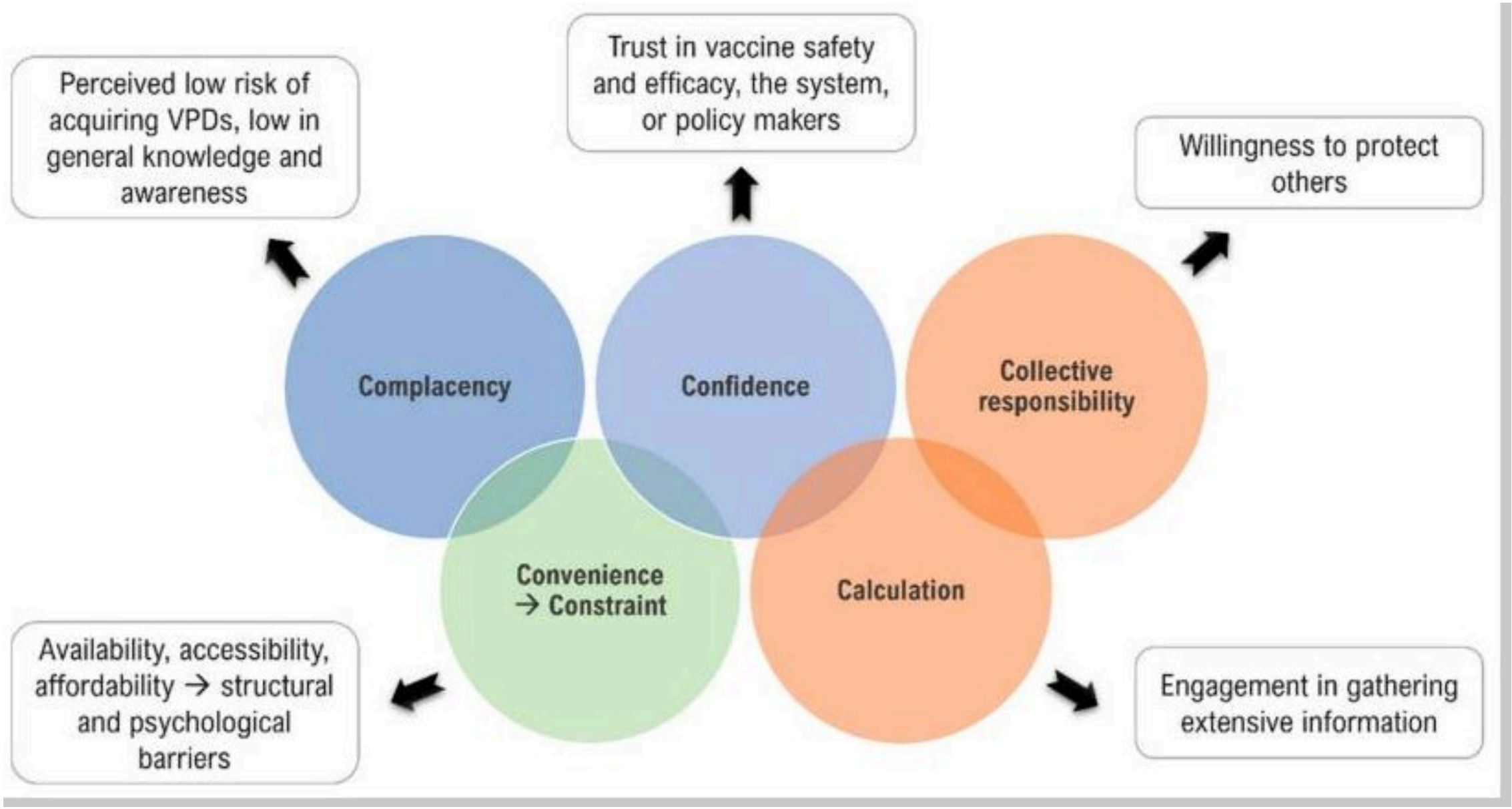
CONFIDENCE

CONVENIENCE>CONSTRAINT

COLLECTIVE RESPONSIBILITY

CALCULATION

Welch et al 2023: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10385302/, How Scientists View Vaccine Hesitancy
Nuwarda et al, 2022: Vaccine Hesitancy: Contemporary Issues and Historical Background, Vaccines. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9612044/#B7-vaccines-10-01595



Nuwarda et al, 2022: Vaccine Hesitancy: Contemporary Issues and Historical Background, Vaccines. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9612044/#B7-vaccines-10-01595

What leading hesitancy factors have you seen/heard in your setting?

- Needle phobia or fear of pain?
- Misperceptions about vaccine-preventable disease or vaccines (or vaccine-specific myths)?
- Preference for natural infection?
- Desire for family autonomy?
- Myths about relationship of vaccine to sexual activity (for HPV)?
- Provider didn't specifically recommend the vaccine?
- Provider-level hesitancy?
- COVID-19 vaccine hesitancy? (safety, effectiveness, politics, trust, historical mistrust, social media)

Consequences of Vaccine Hesitancy

SOCIETAL COSTS

INDIVIDUAL COSTS

PAYER COSTS

PEDIATRIC PRACTICE COSTS

O'Leary ST,et al; American Academy of Pediatrics, Committee on Infectious Diseases, Committee on Practice and Ambulatory Medicine, Committee on Bioethics. Strategies for Improving Vaccine Communication and Uptake. Pediatrics. 2024;153(3

Resources

Increasing HPV Vaccination

- 24 primary care pediatric practice
- Bundled, practice-based intervention with three components over a 6-month period
  - Online clinician training on HPV vaccine communication
  - Performance feedback on missed HPV vaccination opportunities
  - Clinician prompts for HPV vaccination
- Outcome measures:
  - Missed opportunities

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Volume 155, Issue 2
February 2025

ARTICLES | JANUARY 06 2025

A Bundled, Practice-Based Intervention to Increase HPV Vaccination

Peter G. Szilagyi, MD, MPH ✉; Alexander G. Fiks, MD, MSCE; Cynthia M. Rand, MD, MPH; Mary Kate Kelly, MPH; A. Russell Localio, PhD; Christina S. Albertin, MPH; Sharon G. Humiston, MD, MPH; Robert W. Grundmeier, MD; Jennifer Steffes, MSW; Kristin Davis, PhD; Laura P. Shone, DrPH, MSW; Greta McFarland, MD; Dianna E. Abney, MD; Alisa J. Stephens-Shields, PhD

a Contributed equally as co–first authors.

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https://doi.org/10.1542/peds.2024-068145 **Article history**

Szilagy et al https://publications.aap.org/pediatrics/article/155/2/e2024068145/200551/A-Bundled-Practice-Based-Intervention-to-Increase?searchresult=1

Thank You

YB Consultants, LLC

Daniel Salmon, PhD

SPEAKER

Professor & Director

Institute for Vaccine Safety

Johns Hopkins Bloomberg School of Public Health

stjude.org/hpv • #EndHPVCancers

Vaccine Safety Systems and Improving Vaccine Decision-Making

Daniel Salmon, PhD, MPH

Director, Institute for Vaccine Safety

Professor, International Health and Health, Behavior and Society

Johns Hopkins Bloomberg School of Public Health

Why Safety Monitoring Matters

- Ensure that benefits of vaccines outweigh the risks for individuals and populations
  - High standards as often for healthy children and prevention
- Optimize the use of limited resources
- Improve and maintain public confidence in vaccines – high vaccine coverage

Post hoc ergo propter hoc

"after this, therefore because of this", is a logical fallacy …since that event *followed* this one, that event must have been *caused* by this one."

The fallacy lies in coming to a conclusion based *solely* on the order of events, rather than taking into account other factors that might rule out the connection.

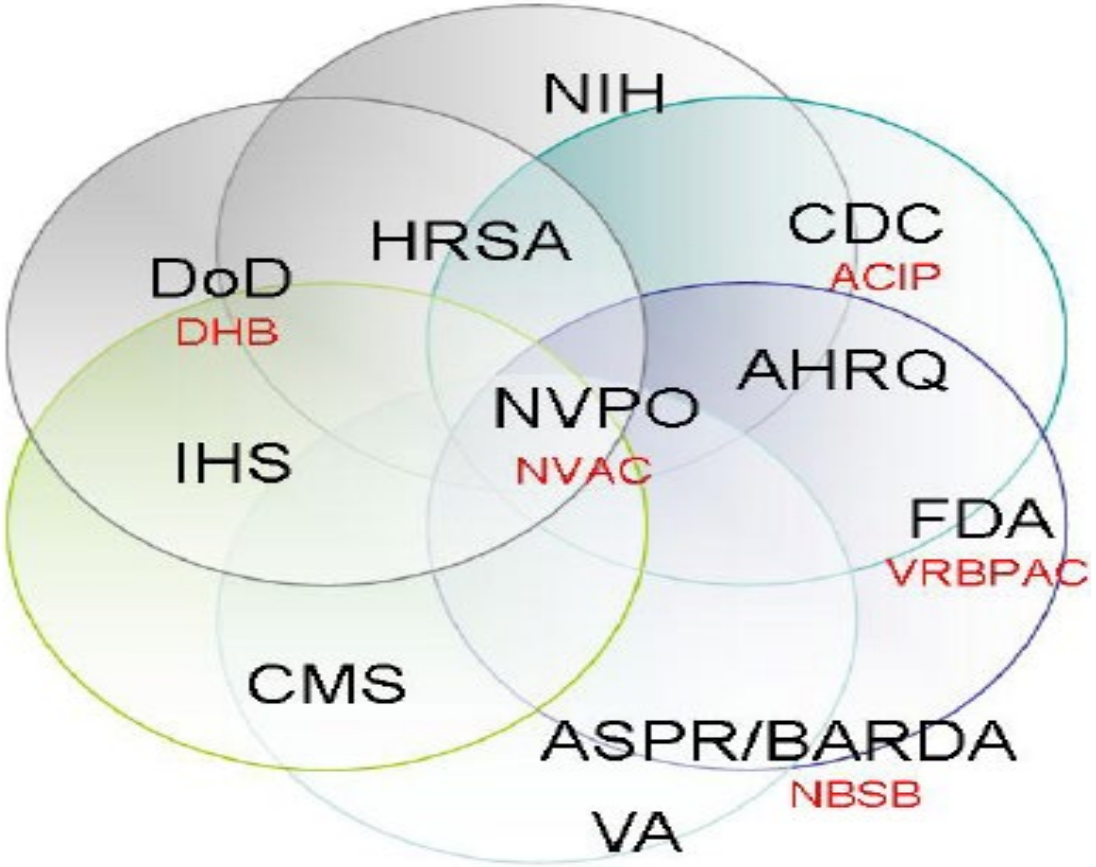
http://dictionary.sensagent.com/post+hoc+ergo+propter+hoc/en-en/

Adverse Events Following Immunization (AEFI) will occur

- Important to differentiate between coincidental events and events causally related to vaccination
  - 2,500 miscarriages and 3,000 heart attacks each day in US
- Important to rapidly identify and follow-up vaccine safety signals
- Robust scientific follow up takes time

US Federal Vaccine System

- NIH – basic research, vaccine development & evaluation incl. clinical trials
- FDA – licensure, inspection, post-licensure surveillance
- CDC – post-licensure surveillance, clinical assessment, communication
- HRSA - compensation
- NVPO – coordination



Advisory Committees in Red

Phase I Clinical Trials - Safety

- No Gross Toxicity
- Gather safety data on dose-related immune response

20-100 Healthy Subjects

Phase II Clinical Trials - Safety

- Assess common, short-term side effects
- Explore reactions between investigational drug and already licensed drug

100-100 (up to 1,000) Healthy Subject

Phase III Clinical Trials - Safety

- Confirm safety
- Define risk/benefit relationship
- Gather information for licensure application and package insert

1,000-20,000+ Persons

“Pro”s of Clinical Trials

- The Gold Standard - Double blind, randomized trials
  - Reduce Confounding
  - Reduce Bias
- Strict inclusion and exclusion criteria
  - Reduces risk to participants
  - Reduces Confounding
- Incremental phases to minimize risk and optimize information obtained

Limitations of Clinical Trials

- Inclusion/Exclusion criteria
  - Can not evaluate AEs in persons excluded from studies (medicated, concurrent medical conditions)
  - Can not evaluate delayed AEs
- Small sample size
  - Can not evaluate rare AEs
  - Can not evaluate AEs in sub-populations

Sample Sizes Needed to Detect Rare Adverse Events

Rates (%)	Sample Size *	No. Potentially Affected
0.1 vs. 0.2	50,000	4,000
0.1 vs. 0.3	17,500	8,000
0.05 vs. 0.1	100,000	2,000
0.01 vs. 0.02	500,000	400
0.01 vs. 0.03	175,000	800

* Two-arm trial, power 80%, alpha (2 sided) = 5%
Source: Ellenberg 2001

Post-Licensure Studies (Phase IV)

- Expand safety profile to include:
  - Intermediate or rare AEs
  - Subpopulations
- Address emerging safety issues issues

Passive Surveillance

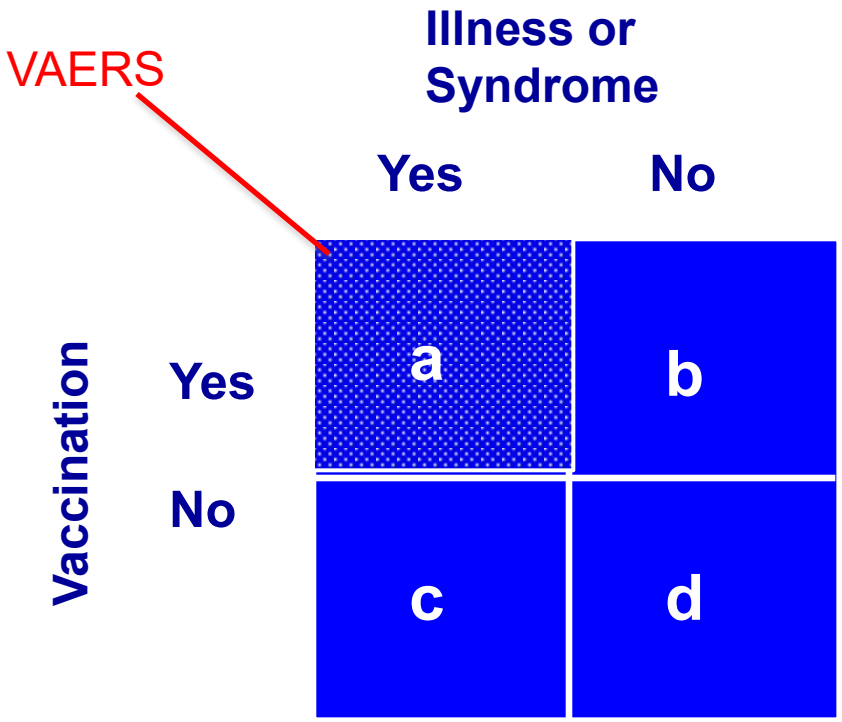
- Purpose: to detect signals of unanticipated events that may deserve further follow-up

- Primary Limitation: Usually can not determine if event is caused by vaccine or coincidental
  - Lack of good denominator and comparison (unvaccinated) group
  - Potential Bias (under-reporting, incomplete reporting, over-reporting, etc).

Vaccine Adverse Event Reporting System (VAERS)

- Co-administered by CDC and FDA
- Accepts reports from anyone
- Limitations
  - Under reporting
  - Incomplete data
- Designed for detecting signals or generating hypothesis
  - Can not assess causality

Establishing Causal Link: Adverse Event and Vaccine



Rate in vaccinated a/a+b
Rate in unvaccinated c/c+d

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Source: R T Chen

Assessing Associations between Vaccines & Adverse Events: Active Surveillance

- Vaccine Safety Datalink (VSD)
- FDA BEST
- Centers for Medicare & Medicaid Services (CMS)
- Department of Defense (DoD)
- Department of Veterans Affairs (VA)
- Indian Health Service (IHS)

Assessing Associations between Vaccines & Adverse Events: Active Surveillance

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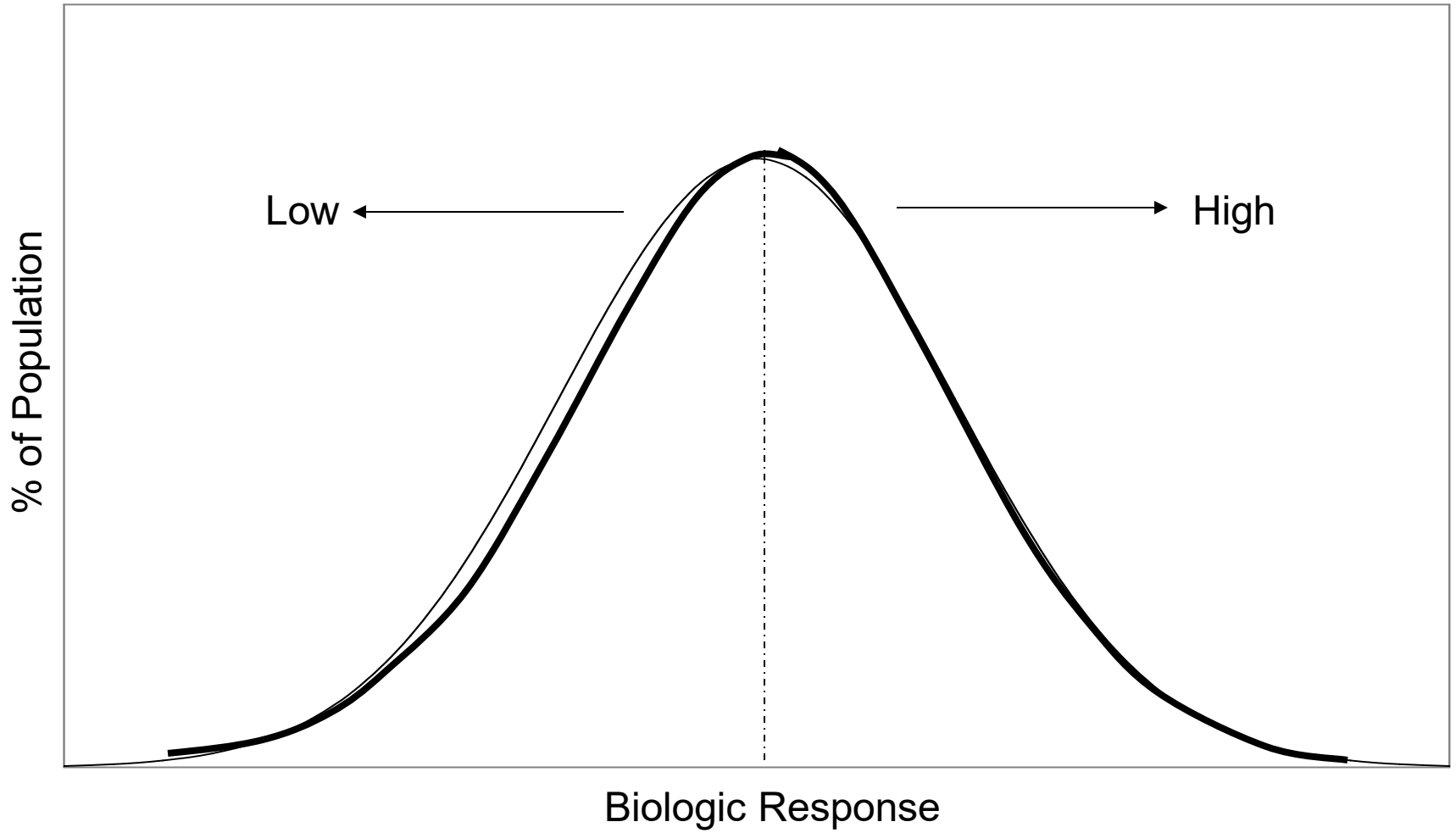
Vaccine Safety Datalink (VSD)

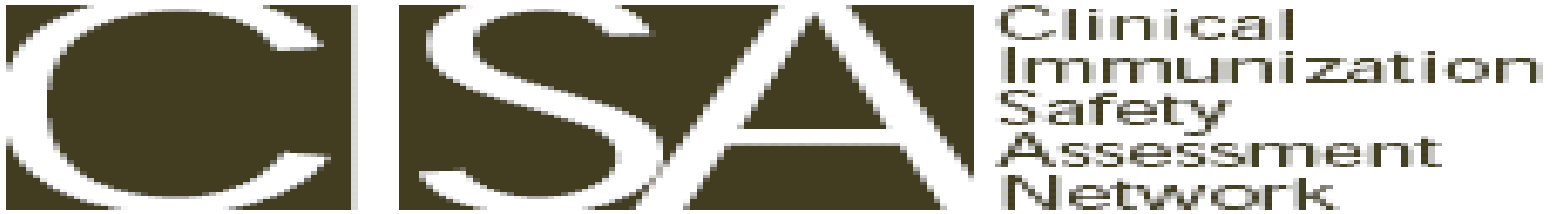
- Developed by CDC –about 35 years ago
- ~11 million people in 13 linked MCOs
- Includes vaccination, hospital, outpatient, and laboratory data

Distribution of Biologic Response* to Immunizations in the Population



* e.g., Immunogenicity, Reactogenicity

Source: R T Chen

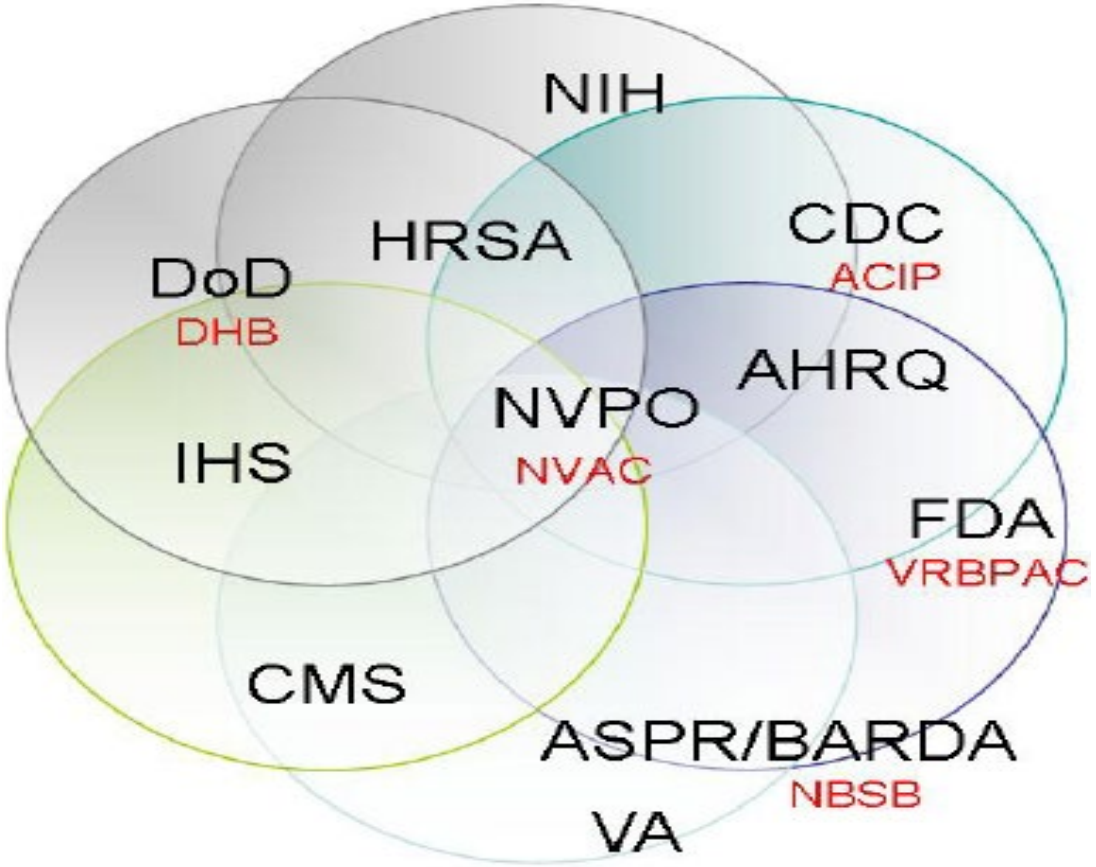


- The Need:
  - Vaccine adverse events occur rarely for each clinician
  - Medical “outliers” difficult to advance science on, like orphan disease (leukemia)
- The Solution:
  - Academic centers of excellence
  - Vaccine safety clinicians
  - Clinical subspecialty for referrals
  - Laboratory research capabilities

Source: R T Chen

US Federal Vaccine System

- NIH – basic research, vaccine development & evaluation incl. clinical trials
- FDA – licensure, inspection, post-licensure surveillance
- CDC – post-licensure surveillance, clinical assessment, communication
- HRSA - compensation
- NVPO – coordination



Advisory Committees in Red

Problem:

How do you widely disseminate
the right message
from the right messenger
to the right person?

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Immunization Groups or Profiles

- Immunization Advocates
  - actively seek vaccination
- Go Along to Get Along
  - follow the advice of their doctors and perceived social norms to vaccinate
- Cautious Acceptors
  - vaccinate, but with some caution
- Fence-Sitters
  - very uncertain in their vaccine decisions
- Refusers
  - actively reject some or all vaccines

Interventions need to be careful not to raise concerns that do not already exist

Edwards KM. Pediatrics 2016
Keane. Vaccine 2005
Leask J. BMC Pediatr 2012
Gust D. Am J Health Behav 2005
Gust DA. Pediatrics 2008
Smith PJ. Pub Health Repo 2011

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Most important to target; Overcome concerns and accept timely vaccines

Edwards KM. Pediatrics 2016
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Leask J. BMC Pediatr 2012
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Most challenging to reach; Possibility to accept at least some vaccines

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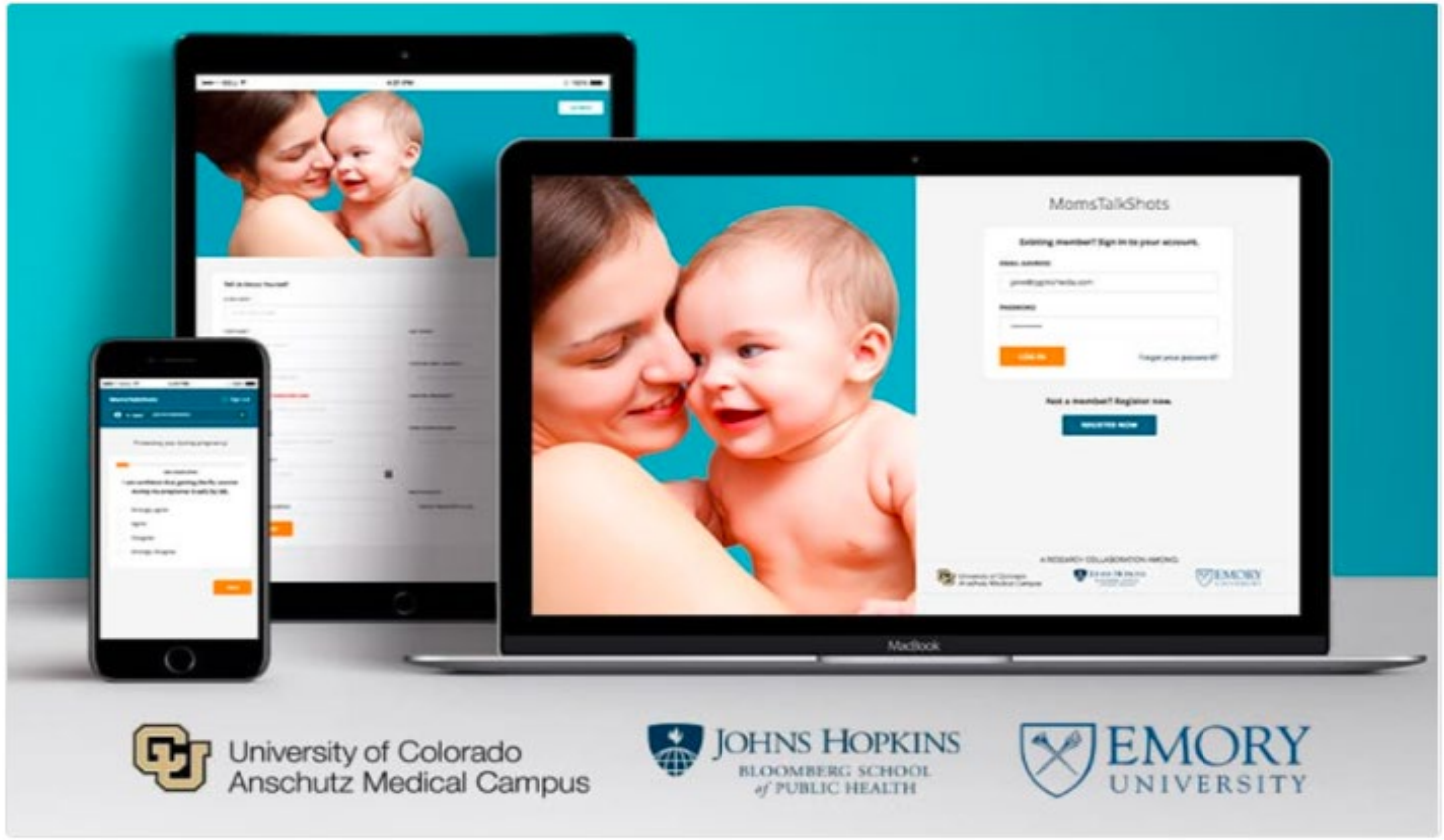
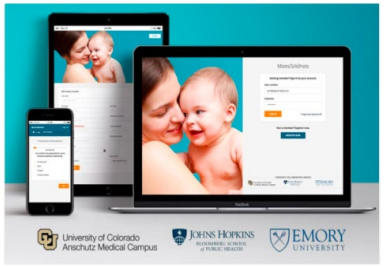


MomsTalkShots

An Individually-Tailored Vaccine Educational Application

Daniel A. Salmon, Rupali J. Limaye, Matthew Z. Dudley, Oladeji K. Oloko, Cathy Church-Balin, Mallory Ellingson, Christine Spina, Sara E. Brewer, Walter Orenstein, Neal A. Halsey, Allison Chamberlain, Robert A. Bednarczyk, Fauzia Malik, Paula Frew, Sean T. O'Leary, Saad B. Omer

Supported in part by the National Institutes of Health, Grant number R01AI110482; mPI Salmon and Omer



MomsTalkShots

- Individually-tailored educational Website for smartphones, tablets and computers

Salmon D et al. Vaccine. 2019 Oct 8;37(43):6478-6485.

Institute for Vaccine Safety

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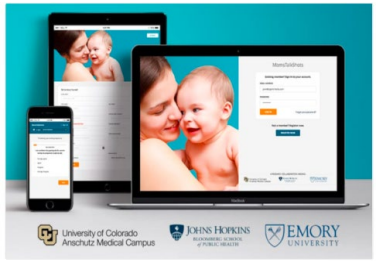
of PUBLIC HEALTH



MomsTalkShots

- Individually-tailored educational Website for smartphones, tablets and computers
- Collects survey data on demographics, vaccine intentions, knowledge, attitudes, beliefs, norms, and trust in information sources

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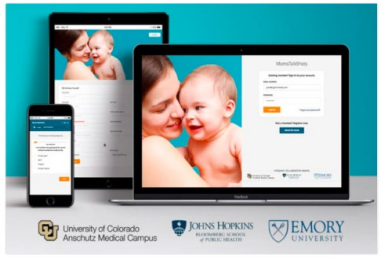

MomsTalkShots

- Individually-tailored Website for smartphones, tablets and computers
- Collects survey data on demographics, vaccine intentions, knowledge, attitudes, beliefs, norms, and trust in information sources
- Delivers tailored informational videos to improve vaccine informed decision-making, uptake and sustained changes in vaccine attitudes and beliefs

Salmon D et al. Vaccine. 2019 Oct 8;37(43):6478-6485.

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Impact of *MomsTalkShots?*

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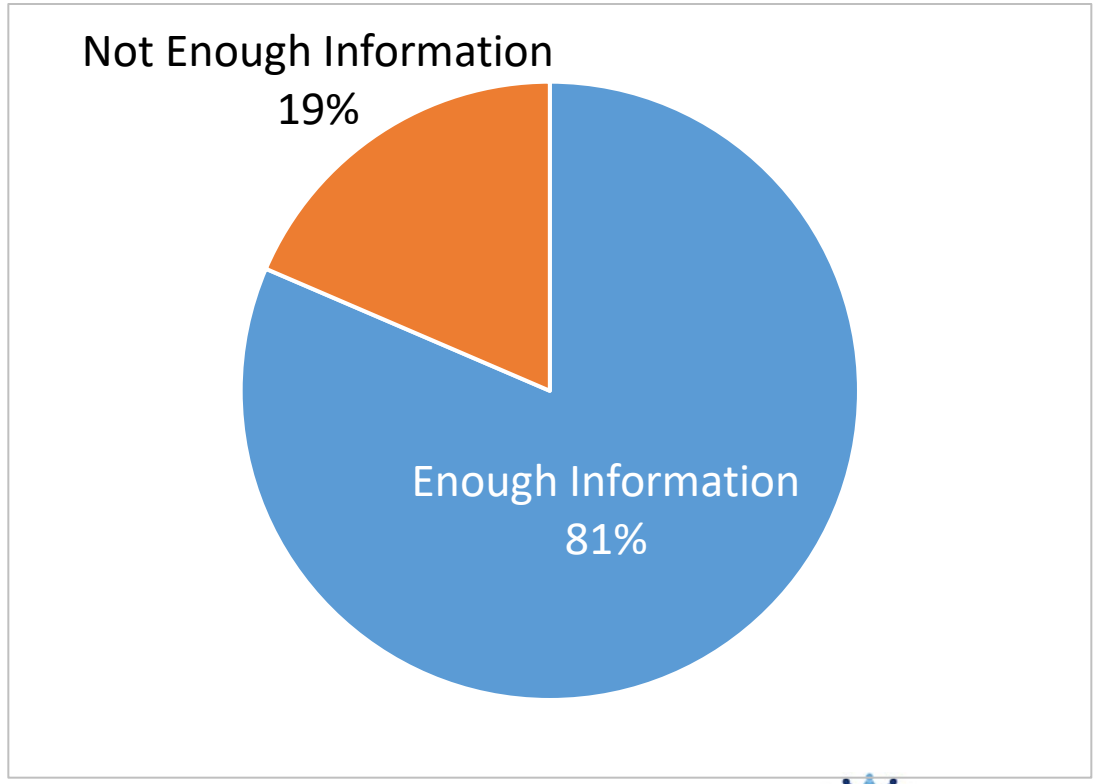
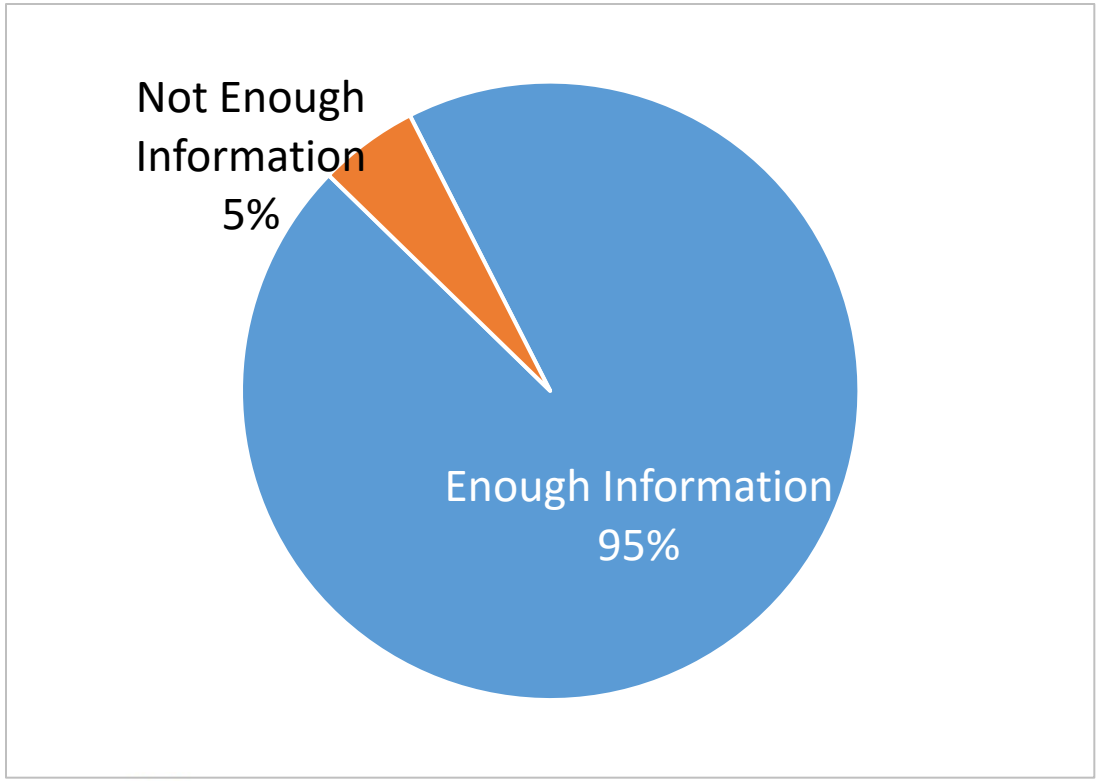
- Vaccine knowledge, attitudes and beliefs
- Maternal vaccine uptake

Changes in Self-Assessment of Knowledge of Maternal Vaccines Pre and Post Videos

Pre Video



Post Video



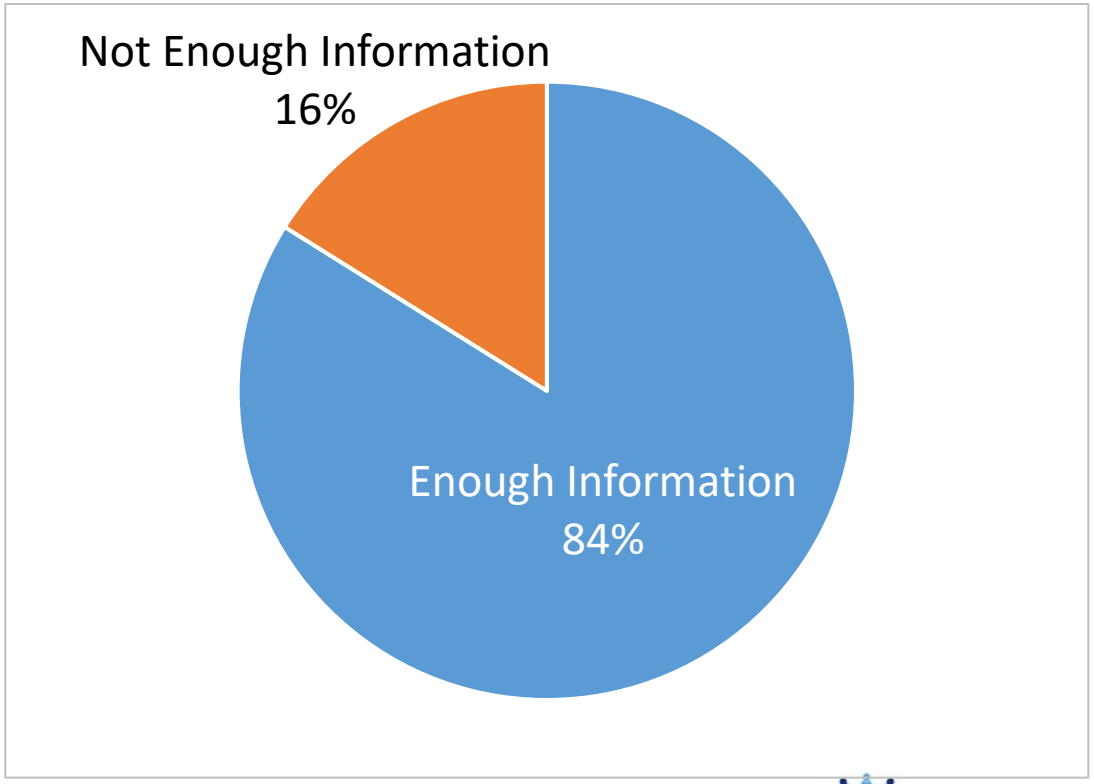
Dudley MZ, et al.BMC Public Health. 2022 Nov 21;22(1):2134.

Institute for Vaccine Safety

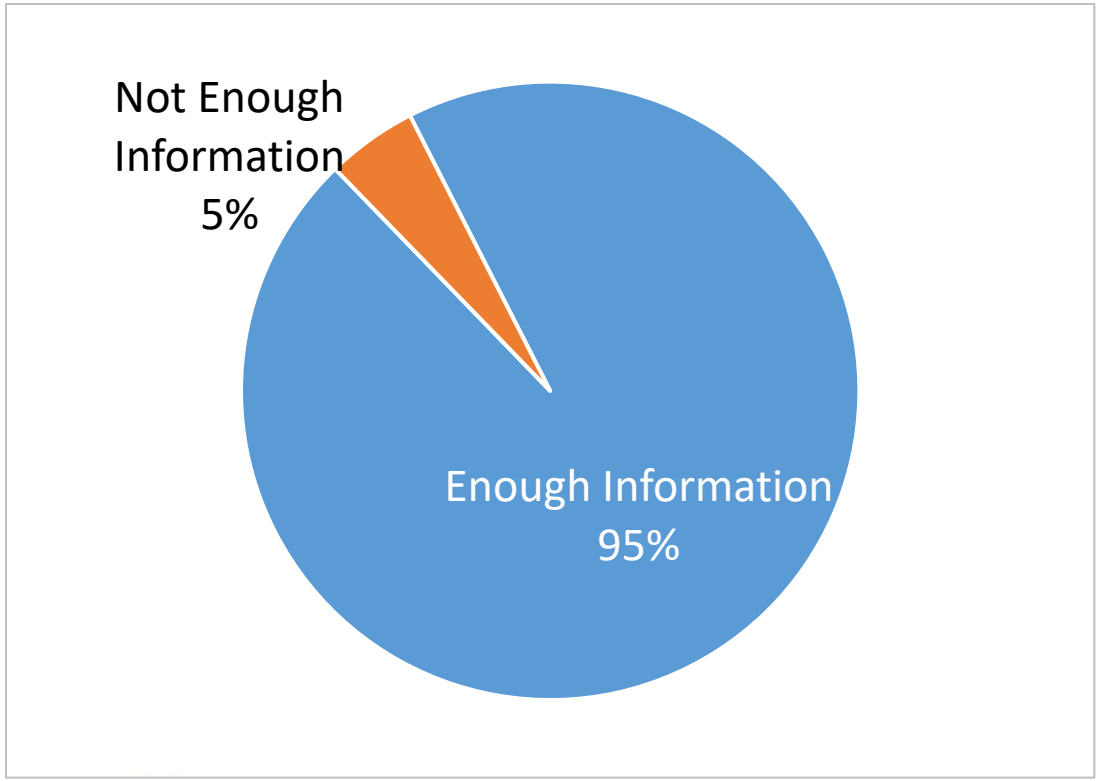
Johns Hopkins Bloomberg School of Public Health

Changes in Self-Assessment of Knowledge of Infant Vaccines Pre and Post Videos

Pre Video



Post Video



Dudley MZ, et al.BMC Public Health. 2022 Nov 21;22(1):2134.

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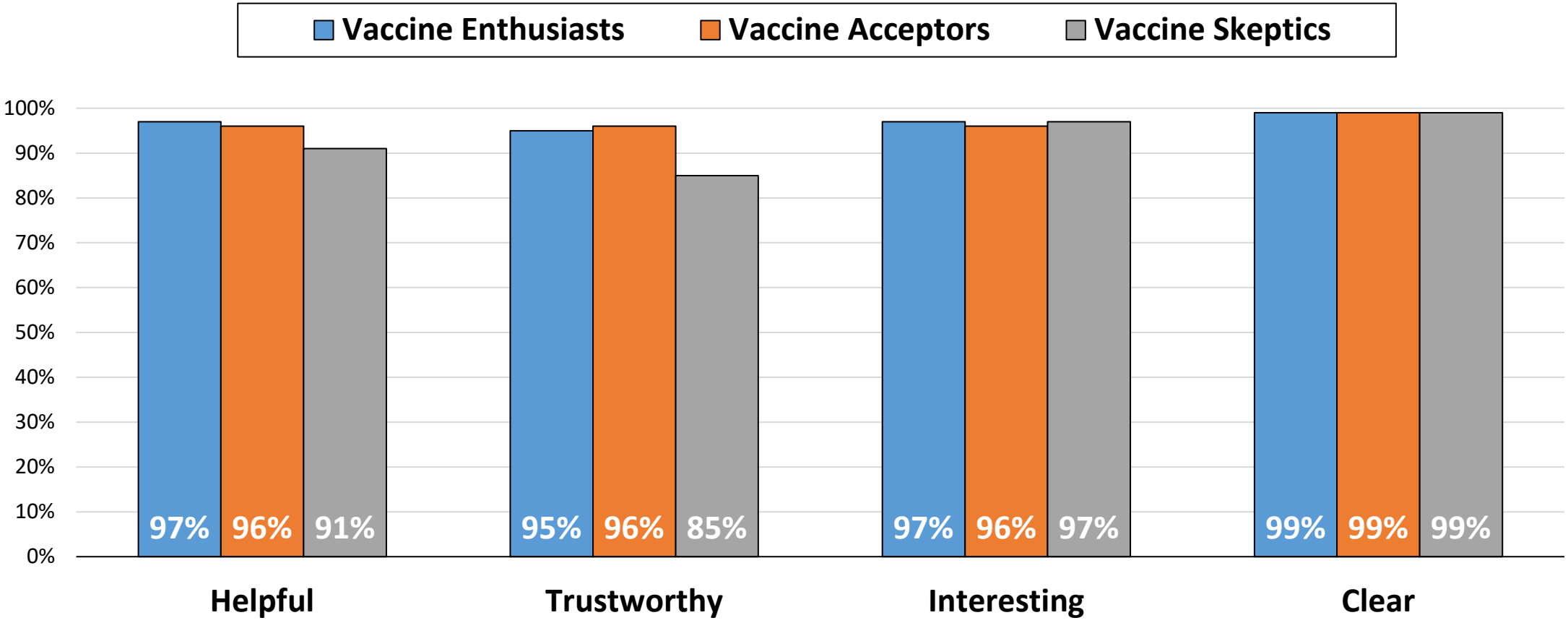
Usability by audience segmented groups



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Moms uncertain about or not planning to vaccinate for influenza who received *MomsTalkShots* (*vs* did not)

- **61%** more likely to vaccinate for influenza (chart confirmed)

  Relative Risk: 1.61; 95%CI: 1.18-2.21

Omer SB et al. Vaccine. 2022 Aug 12;40(34):4955-4963.

Institute for Vaccine Safety | Johns Hopkins Bloomberg School of Public Health

Omer, SB, *et al.* Submitted.

Moms who received *MomsTalkShots* (*vs* did not) on year after birth

- **5 times** more likely to be confident about infant vaccine safety
- **75%** less likely to have concerns about infant vaccine safety

Dudley MZ et al. BMC Public Health. 2022 Nov 21;22(1):2134.

Institute for Vaccine Safety | Johns Hopkins Bloomberg School of Public Health

Dudley, MZ, *et al.* Submitted.

Mom's close contacts who received *MomsTalkShots* (cocooning)

- RCT imbedded in RCT

Dudley MZ et al. Vaccine. 2021 Feb 5;39(6):961-967.

Institute for Vaccine Safety | Johns Hopkins Bloomberg School of Public Health

Dudley, MZ, *et al.* Vaccine 2021.

Mom's close contacts who received *MomsTalkShots* (cocooning)

- RCT imbedded in RCT
- Found it usable
  - 97% helpful
  - 99% trusted it
  - 96% interesting
  - 100% clear to understand

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  - 100% clear to understand
- Increased knowledge of influenza and Tdap vaccines
- Had **7 times** higher odds of receiving influenza vaccine
  - Odds Ratio: 6.97; 95% Confidence Interval: 2.25–21.64

Dudley MZ et al. Vaccine. 2021 Feb 5;39(6):961-967.

Institute for Vaccine Safety | Johns Hopkins Bloomberg School of Public Health

Dudley, MZ, *et al.* Vaccine 2021.

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Let's Talk Shots

Welcome to Let's Talk Shots!

We provide accurate and updated information about vaccines in short, engaging videos. Videos are personalized based on how you answer a few anonymous questions, so you get only the information you want.

Let's Talk Shots

Learn about routine vaccines and get personalized answers to your vaccine questions. Let's get started.

Let's Talk Covid Vaccines

Learn about Covid vaccines and get personalized answers to your vaccine questions. Let's get

Daniel Salmon, PhD – Vaccinology & Vaccine Safety
Janesse Brewer, MPA – Community Engagement
Matthew Dudley, PhD – Vaccine Communication & Epidemiology
Tina Proveaux – Vaccine Safety & Communication
Angie Gust, PhD, MPH – Vaccine Acceptance
Peter Orton, PhD, Instructional Media Design

Amelia Jamison, MAA, MPH – Project Coordination
Rajiv Rimal, PhD - Behavioral Science
Holly Schuh, PhD – Vaccine Epidemiology
Steve Harvey, PhD, Behavioral Sciences

Robert Breiman, MD – Infectious Diseases
Walter Orenstein, MD – Vaccine Policy
James Lavery, PhD – Qualitative Research & Stakeholder Engagement

Robina Josiah Willock, PhD – Health Equity & Research Methodology

Lucie Marisa Bucci, MA – Vaccine Advocacy

Jana Shaw, MD, MPH, MS – Pediatric Infectious Disease & Immunology

Lee-Sien Kao - Behavioral Science
Ric LaGrange, PhD – Behavioral Science

Shaelyn Laurie – Survey Development
Rikki Sargent, PhD – Social Psychology

Michelle Cantu - Dissemination
Lilly Kan - Dissemination
Tori Decea - Dissemination

Kathleen McNamara – Resource Coordination
Wanda Montecalvo – Qualitative Insights
Sarah Price – Qualitative Insights

Katelyn Wells – Dissemination

Animation and Media Design Team
Bonnemaison Inc.

Veronica Womack, PhD – Qualitative Research

Leo Weakland – Project Management

Jeongwon (Jeong) Yang, MA, Msc – Social Media Strategy

Application of Behavioral Theory in LetsTalkShots – part 1

Behavioral Theory	Application
Tailoring	• Get the right message to the right person from the right messenger • Specific concerns only asked of people who indicate not confident getting vaccinated • Tailoring to specific concerns also helps avoid *mere exposure*/familiarity effects (inadvertently spreading misinformation/normalizing specific concerns).
Timing Inoculation Theory	• Provide a small dose of arguments "from the other side" the audience is likely to encounter, so that they are more able to resist the message when they are subsequently exposed
Health Belief Model	• Animation including disease susceptibility and severity, vaccine effectiveness and safety, and cue to action • Using football and soccer stadiums to visualize risk of vaccines and diseases and benefits of vaccination • Use of metaphors for concepts such as variable vaccine effectiveness as an umbrella providing partial protection during a heavy rain

Salmon D et al. Front Public Health. 2023 Jun 30;11:1195751.

Institute for Vaccine Safety | Johns Hopkins Bloomberg School of Public Health

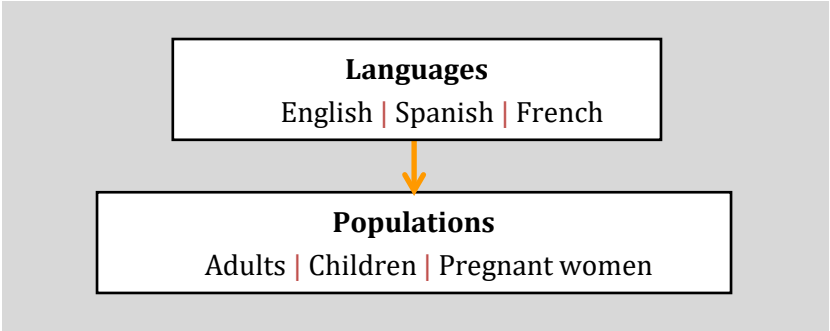
Application of Behavioral Theory in LetsTalkShots – part 2

Behavioral Theory	Application
Transtheoretical Model for behavioral change	• Tailoring call to action to where the person is on the hesitancy spectrum.
Bandura's Social Cognitive Theory	• Emphasizes role of self-efficacy or individuals' belief in their capability to perform a behavior by emphasizing choice
Salience	• Visualization and metaphors to make the science clearer/more salient • Congruency in personal stories and credible sources
Psychological reactance	• Animation and overall messages framed as information to help people make their own decisions (rather than pressure to get a vaccine).
Theory of normative conduct	• Benefit animation, which all people receive, emphasizes community benefits and impact of most people getting vaccinated.

Salmon D et al. Front Public Health. 2023 Jun 30;11:1195751.

Institute for Vaccine Safety | Johns Hopkins Bloomberg School of Public Health

Let’sTalkCovidVaccines



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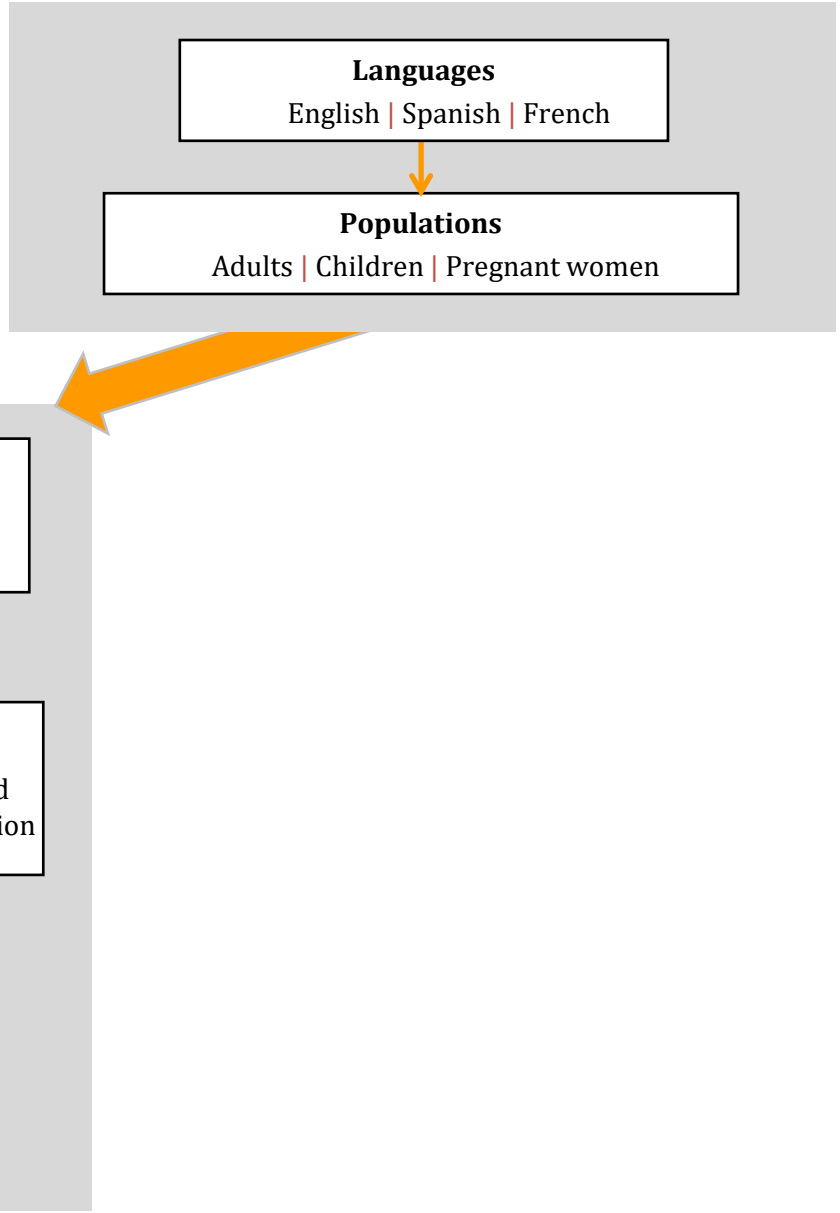
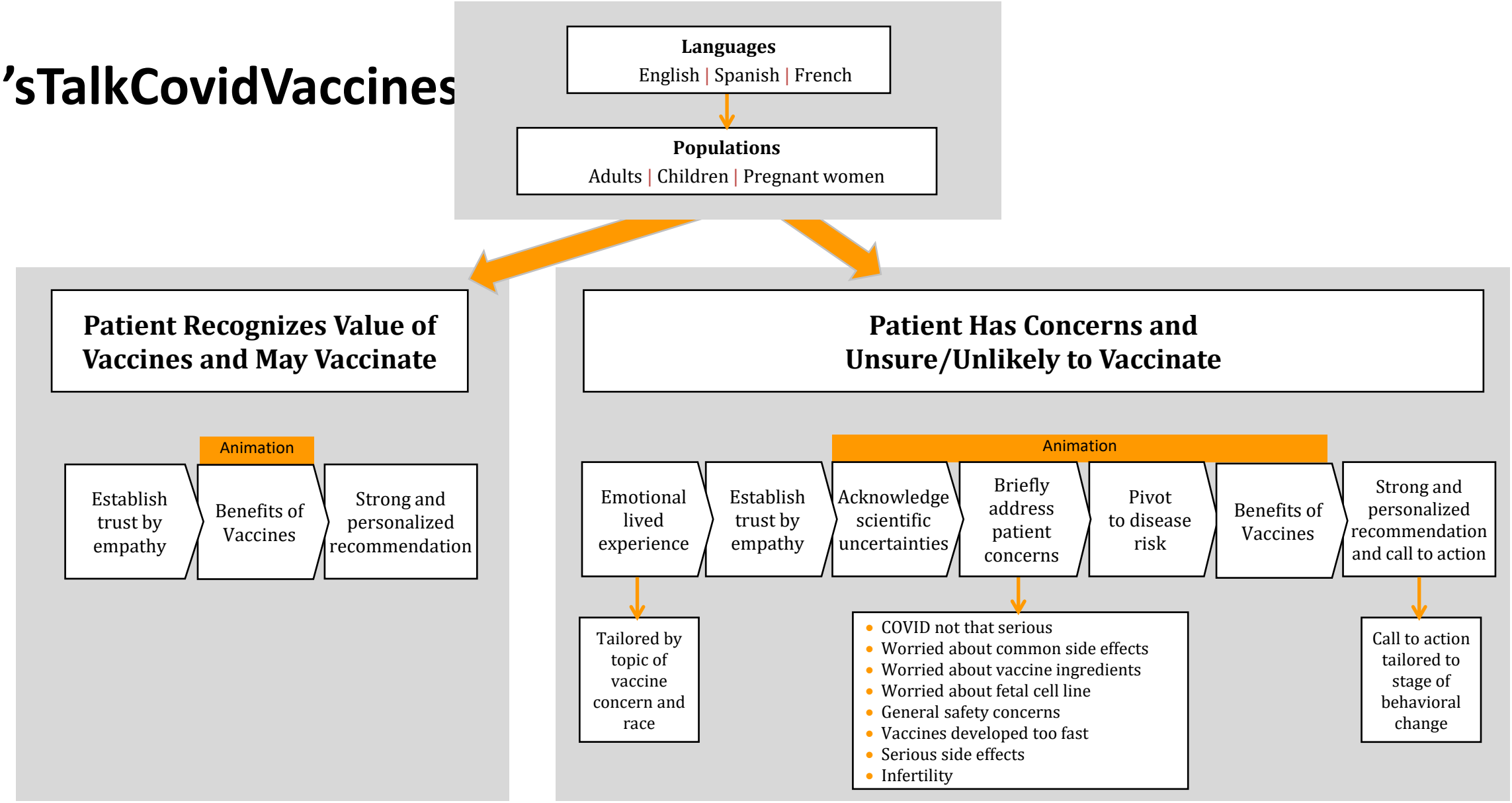


Let'sTalkCovidVaccines



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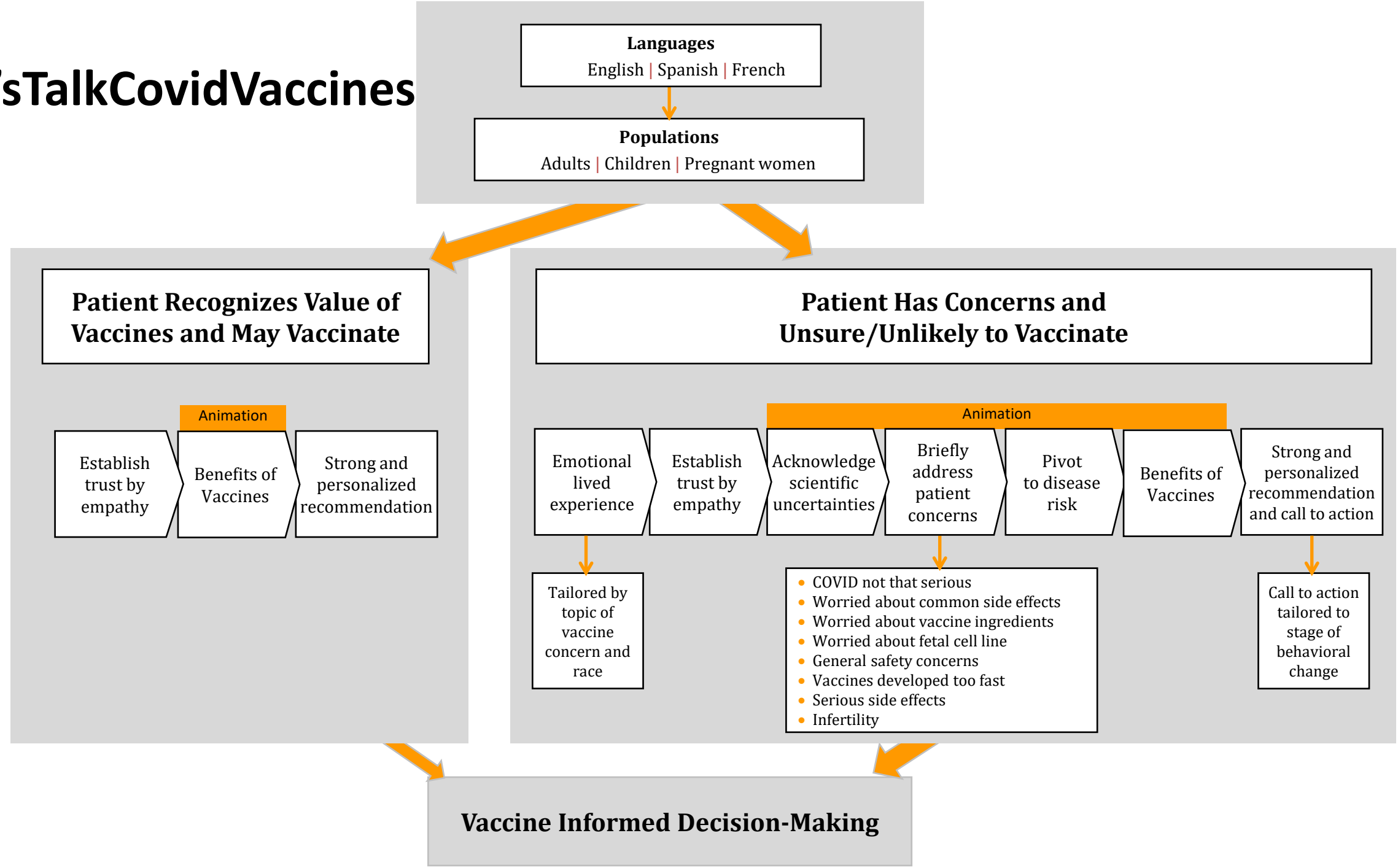

Testing Content

- Focus Groups
  - 27 African-American, Hispanic, and White focus groups
  - 6 groups of pregnant women
  - 12 groups of parents and adults
  - Intent to learn what they liked and what they didn’t like, and why

Salmon D et al. Front Public Health. 2023 Jun 30;11:1195751.

Testing Content

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  - Intent to learn what they liked and what they didn't like, and why
- Large RIWI Survey
  - Usability
  - Impact of Personal Narrative
  - Impact of Credible Source Racial Congruency

Salmon D et al. Front Public Health. 2023 Jun 30;11:1195751.

Expanded to include all vaccine across the lifespan

- ~70 more pieces of animation (total time: >3 hours)
- 40 focus groups & Ipsos survey for testing

Salmon D et al. Front Public Health. 2023 Jun 30;11:1195751.

The right message from the right messenger to the right person

- A full-length movie (> 3 hours) worth of animation with vaccines in pregnancy, infants, children, adolescents, adults and elderly, including common concerns by vaccine and population

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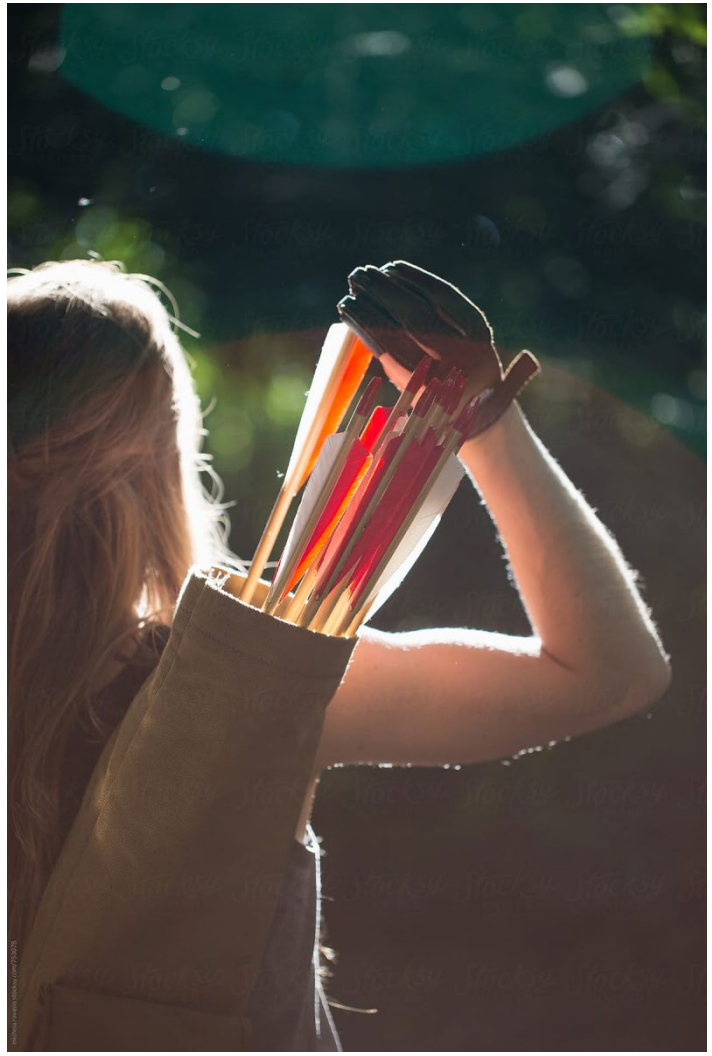
- A large and diverse range of credible sources

LetsTalkShots.Org

- Evaluate in other populations through RCTs
- Disseminate through partners
- Integration into clinical practice with training & information for clinicians

One More Arrow in Our Quiver



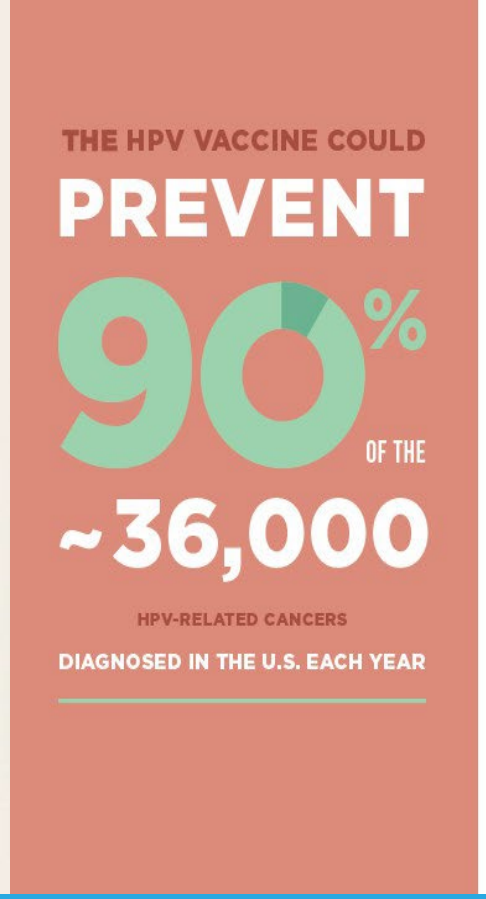
Amy Pisani, MS

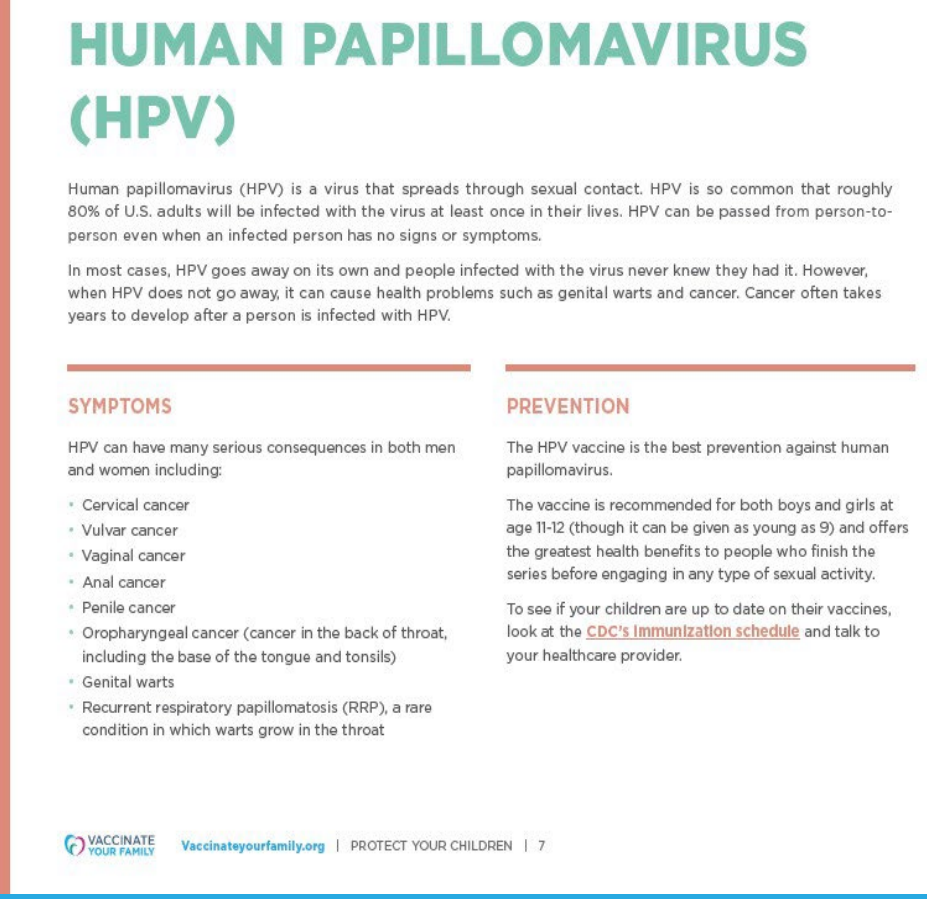
SPEAKER

Chief Executive Officer
Vaccinate Your Family

stjude.org/hpv • #EndHPVCancers

VACCINATE YOUR FAMILY





HUMAN PAPILLOMAVIRUS (HPV)

Human papillomavirus (HPV) is a virus that spreads through sexual contact. HPV is so common that roughly 80% of U.S. adults will be infected with the virus at least once in their lives. HPV can be passed from person-to-person even when an infected person has no signs or symptoms.

In most cases, HPV goes away on its own and people infected with the virus never knew they had it. However, when HPV does not go away, it can cause health problems such as genital warts and cancer. Cancer often takes years to develop after a person is infected with HPV.

SYMPTOMS

HPV can have many serious consequences in both men and women including:

- Cervical cancer
- Vulvar cancer
- Vaginal cancer
- Anal cancer
- Penile cancer
- Oropharyngeal cancer (cancer in the back of throat, including the base of the tongue and tonsils)
- Genital warts
- Recurrent respiratory papillomatosis (RRP), a rare condition in which warts grow in the throat

PREVENTION

The HPV vaccine is the best prevention against human papillomavirus.

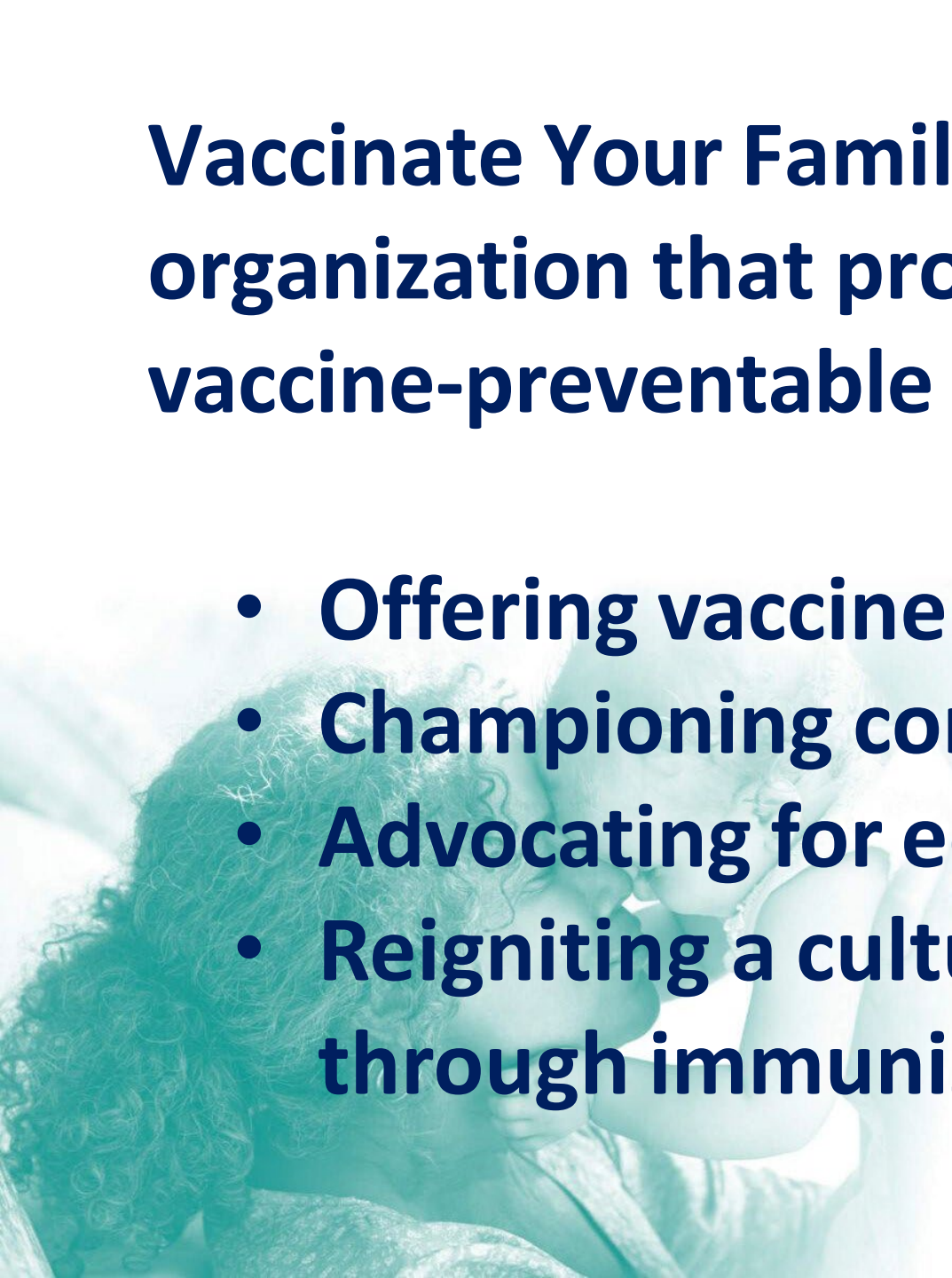
The vaccine is recommended for both boys and girls at age 11-12 (though it can be given as young as 9) and offers the greatest health benefits to people who finish the series before engaging in any type of sexual activity.

To see if your children are up to date on their vaccines, look at the CDC's Immunization schedule and talk to your healthcare provider.

Vaccines in the U.S.: A Journey Through History

Amy Pisani, MS, CEO, Vaccinate Your Family

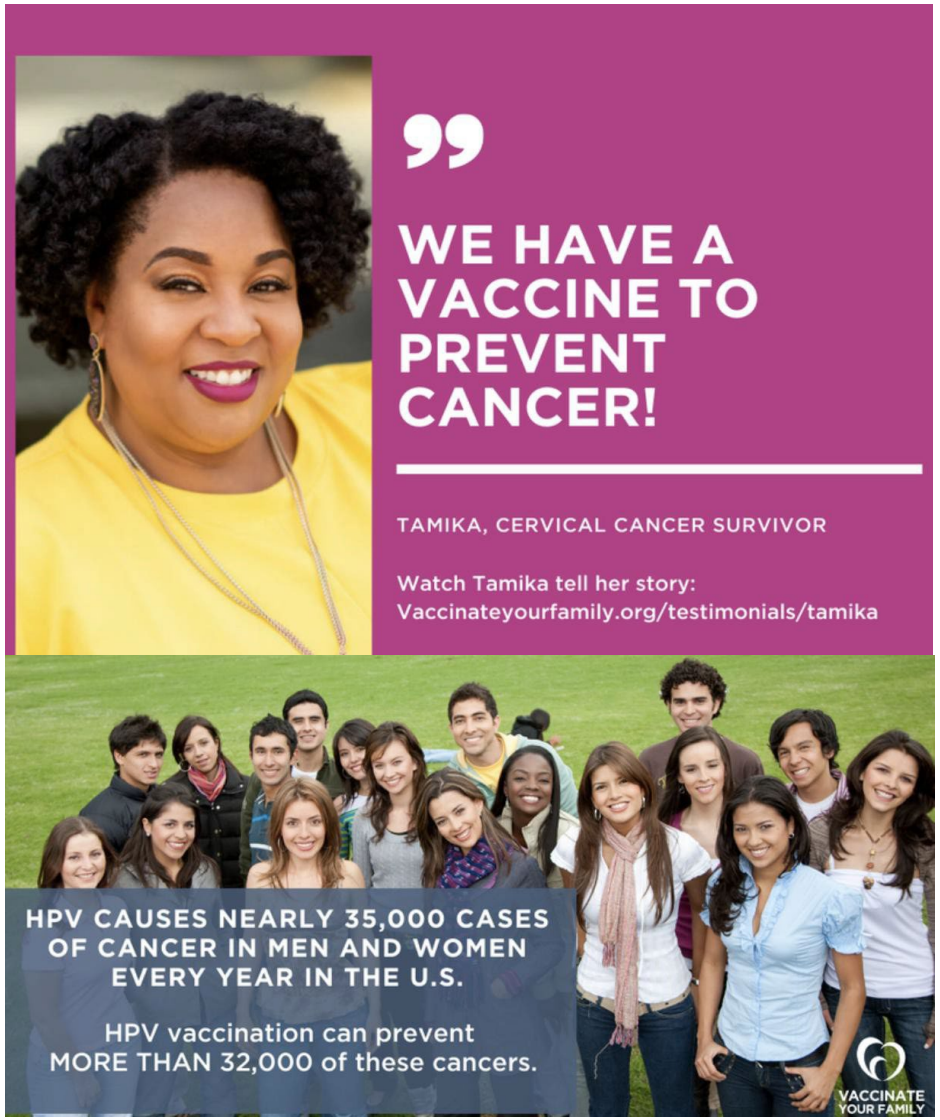
Presenting on Vaccine Advocacy

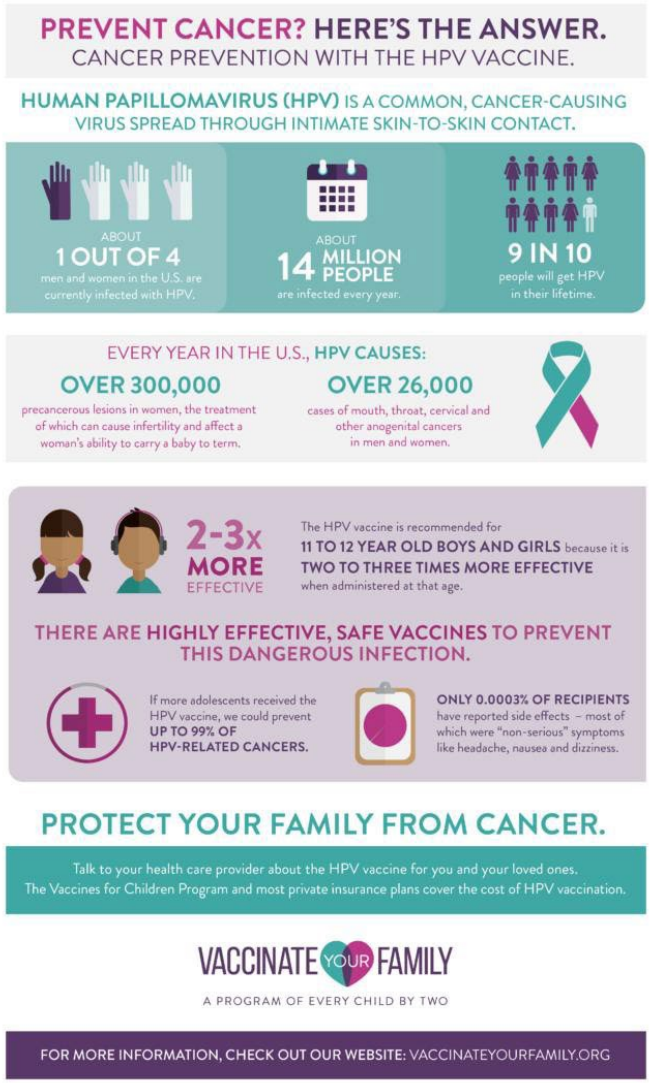


Vaccinate Your Family is a non-partisan organization that protects people of all ages from vaccine-preventable diseases by:

- **Offering vaccine education**
- **Championing community partners**
- **Advocating for equitable vaccine access**
- **Reigniting a culture of disease prevention through immunization.**

VYF is committed to Raising HPV Awareness





https://vaccinateyourfamily.org/vaccines-diseases/#human-papillomavirus-hpv

Don't Skip Campaign with Gabrielle Union Wade

https://www.youtube.com/watch?v=DPosVHEIoH4

Policy and Public Health

Policy plays a huge role in public health, especially around equity, access, and infrastructure.

Some examples from VYF's view:

Federal Policy Highlights

- ACA, VFC, IRA, Medicare/Medicaid (and expansion)
- **Key Initiatives:**
  - Section 317 Immunization Program
  - Vaccines for Children & Uninsured Adults Programs
  - PREVENT HPV Cancers Act
  - Vaccine access for all, regardless of immigration status
  - Inflation Reduction Act implementation
  - Vaccine recommendation changes

State Policy

- Protecting school & daycare entry requirements

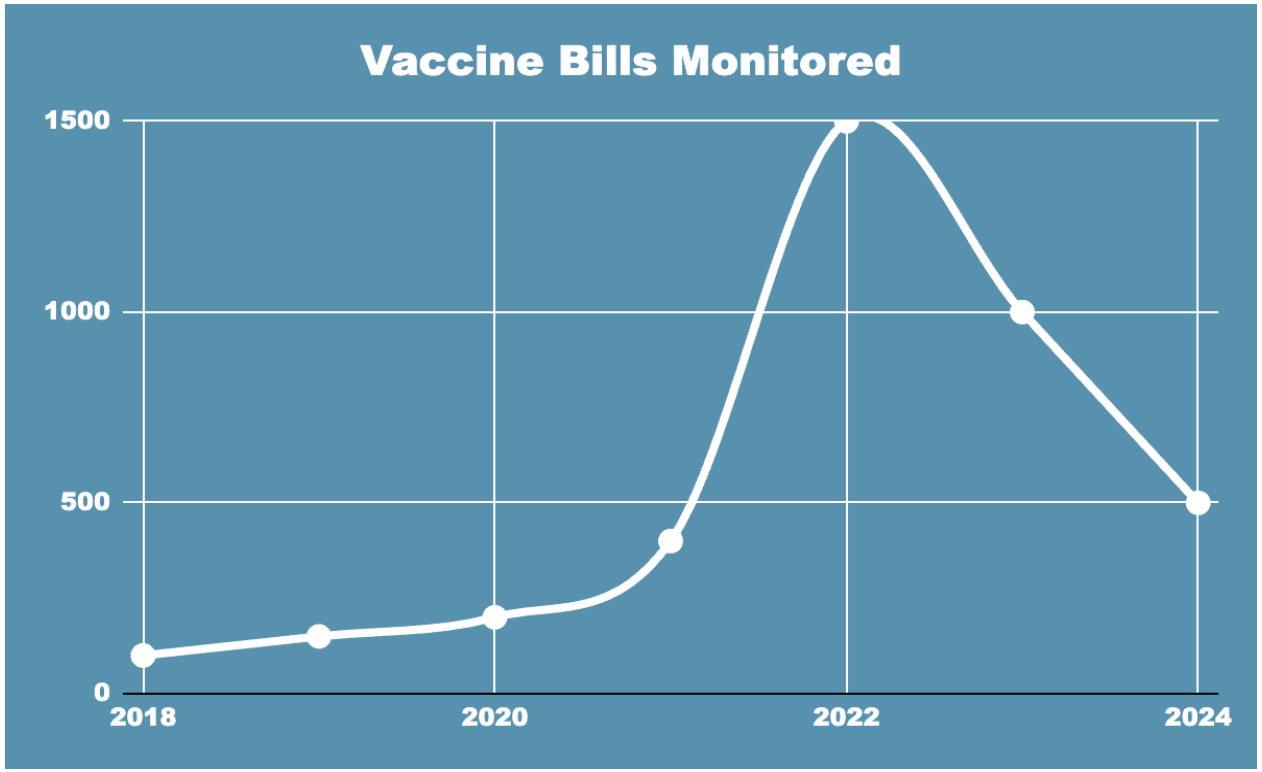
Legal Challenges

- Impact on public health laws and authority

VYF's Advocacy Efforts

- Monthly policy calls & action alerts
- *State of the ImmUnion* report
- Social media engagement
- SQUAD advocate stories
- Revamped partner portal

Grassroots involvement is critical!



Post-Pandemic Surge:

- Vaccine-related bills at the state level have skyrocketed
- More challenges expected at the federal level

The Power of Constituent Voices:

- Personal stories are critical in defeating harmful legislation
- Building champions for good policies through community support

You Are the Expert:

- You understand the issue, the need, and the community better than anyone

Success Stories:

- Connecticut's 2021 elimination of religious exemptions for student immunizations

What's coming in 2025

- **Federal Policy Concerns**:
  - **Anti-Vaccine Advocates in Leadership**: Potential threats to federal funding (e.g., 317 Immunization Program)
  - **Reforms to Key Agencies**: Risks to ACIP, CDC, HHS, FDA, and vaccine recommendations
  - **Vaccine Injury Compensation Program**: Threats to funding and support
- **State Policy Concerns**:
  - **Increased Exemptions**: State legislators may push for more exemptions or remove vaccine requirements
  - **State Law Adjustments**: Some states are strengthening vaccine laws, while others may roll back protections
- **Legal Concerns**:
  - **Challenges to Public Health Laws**: Legal battles against public health authority
- **Public Concerns**:
  - **Distrust & Hesitancy**: Growing skepticism of government and vaccine hesitancy
  - **Confusion**: Mixed messages from changing recommendations

If choosing this path…

Activities may include:

- **Submitting comments to the Advisory Committee on Immunization Practices (ACIP)**
- **Congressional Outreach**
- **State and local outreach**

Let’s go through each…

Submitting Comments to ACIP

How to Submit Public Comments:

- **Written Comments**:
  - Submit via regulations.gov
  - Visit cdc.gov/acip/meetings for details on how to submit
  - Comments are published on regulations.gov

- **Oral Comments**:
  - By lottery during virtual meetings
  - 3-minute time limit per speaker

Tips for Public Comments:

- Be polite and clear
- State what you are requesting (e.g., "I strongly encourage the Committee to...")
- Explain why the issue matters to you
- Example: "This issue is important to me because..."

Meeting Dates:

- Feb. 26-27 (Postponed)
- June 25-26
- Oct. 22-23

Congressional Outreach

Connecting with Policymakers

Ways to Engage

- Letters/Emails
- Phone Calls
- In-District Meetings, Events, & Town Halls

Crafting Your Message

- **Have an Ask**
- Explain the problem, why they should care, and how your solution fixes it.

Key Reminder:

- **You are the expert!**
  - You know the issue, the need, and the community.
  - Policymakers want to hear from you. Be a resource!

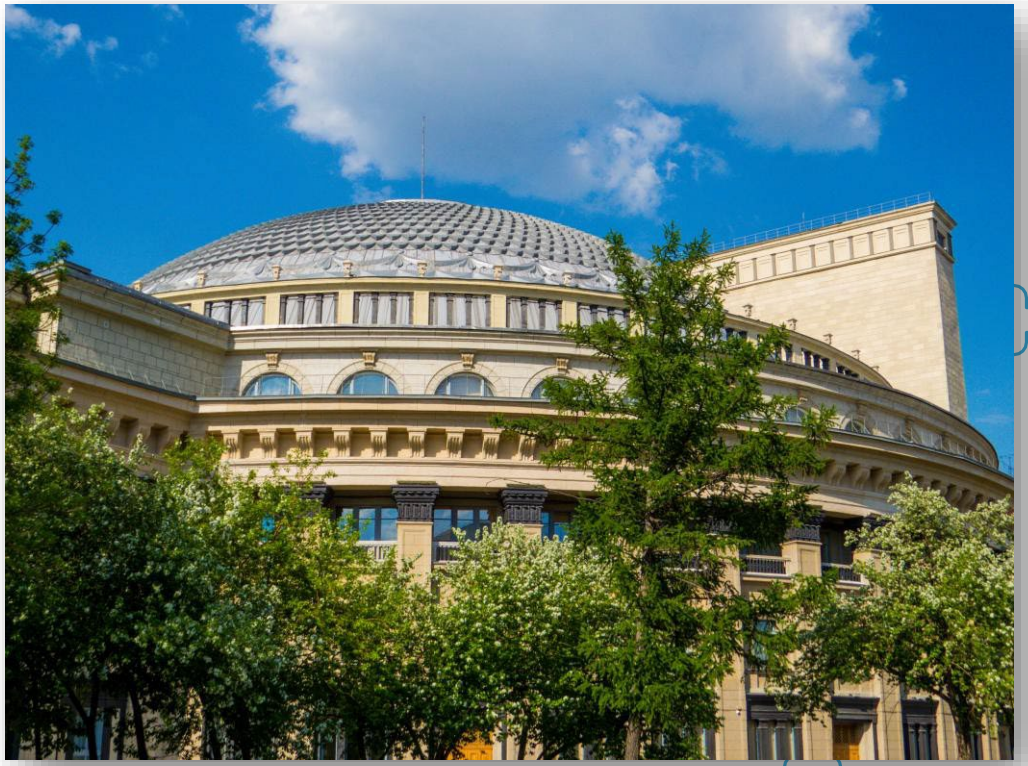
Connecting with State and Local leaders

Key Groups to Engage:

- State Legislators
- School Boards
- Local Health Departments

Tips for Effective Advocacy:

- **Be Prepared**: Know your facts, anticipate questions
- **Be Flexible**: Work with limited time, staff, and space
- **Leave-Behinds**: Bring materials for follow-up
- **Make Your Ask**: Stay focused on the key message
- **Be Polite & Unwavering**: Support science and public health
- **It's OK Not to Know Everything**: Offer to be a resource for HPV and other vaccines
- **Follow Up**: Reinforce your message after the meeting

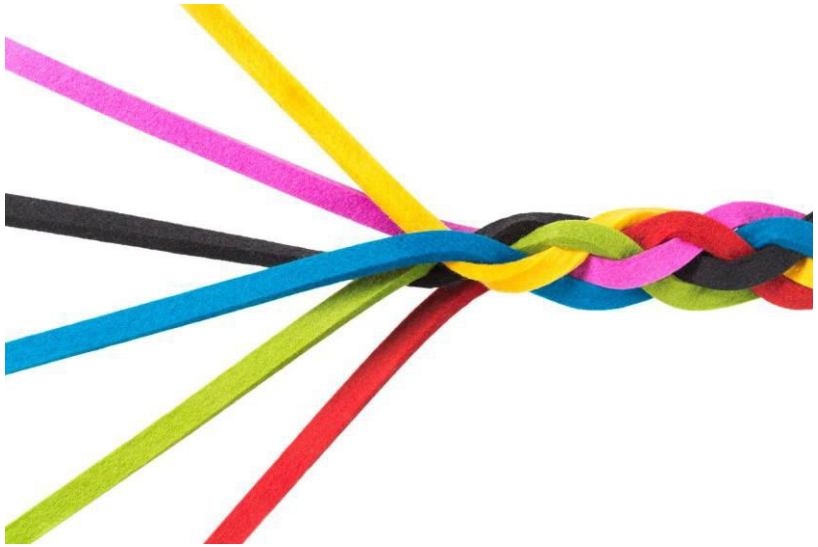


Building Relationships

Building Relationships with Advocates, Legislators, and Staffers

- **Be a Resource**:
  - Build strong relationships even when there's no immediate ask
  - Be available for information, advice, and support

- **Public Sentiment Matters**:
  - In a climate of increased misinformation, **pro-vaccine voices** are essential
  - Community connections and health education are critical to shaping public opinion



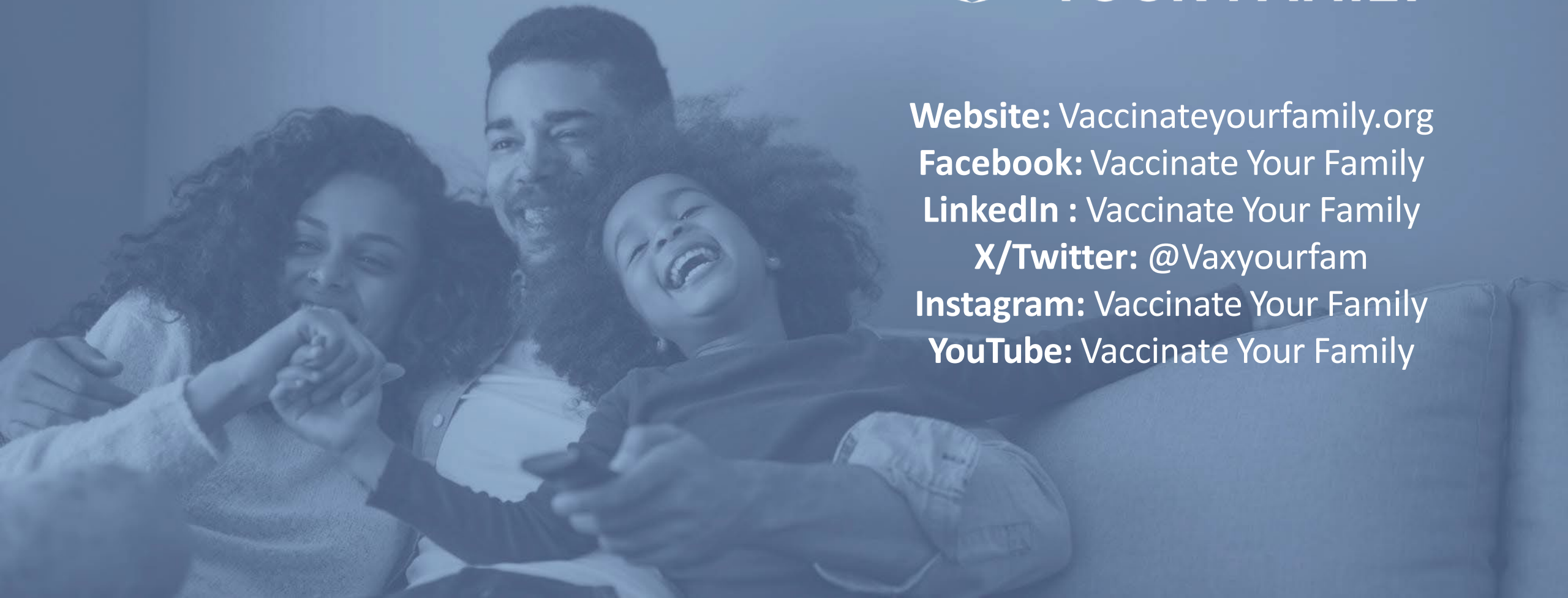
Resources

Find your federal, state, and local legislators: usa.gov

- **Vaccinate Your Family: Are Vaccines Safe? www.vaccinateyourfamily.org**
- **VYF HPV page:** https://vaccinateyourfamily.org/vaccines-diseases/#human-papillomavirus-hpv
- **Legislator Archetype Information on VYF's VaxCollab partner portal: vaxcollab.org**
- **National Conference of State Legislatures 50 State Searchable Bill Tracking Database https://www.ncsl.org/technology-and-communication/ncsl-50-state-searchable-bill-tracking-databases**
- **Immunize.org: State Policies, including Immunization Requirements for Childcare, School, and College by State: https://www.immunize.org/official-guidance/state-policies/state-websites/**
- **Families for Vaccines Chapters in OR, MT, SD, AZ, CO, LA, ME, TN, MA, NH, WV - https://www.safecommunitiescoalition.org/chapters**
- **State Immunization Coalitions: immunizationcoalitions.org/network-members/?listing=1**
- **Directory of local health departments: naccho.org/membership/lhd-directory**

Thank You!

Amy Pisani
amy@vaccinateyourfamily.org



VACCINATE YOUR FAMILY

Website: Vaccinateyourfamily.org
Facebook: Vaccinate Your Family
LinkedIn : Vaccinate Your Family
X/Twitter: @Vaxyourfam
Instagram: Vaccinate Your Family
YouTube: Vaccinate Your Family

Moderated Discussion

Iyabode (Yabo) Beysolow, MD
Public Health Consultant
Owner YB Consultants, LLC

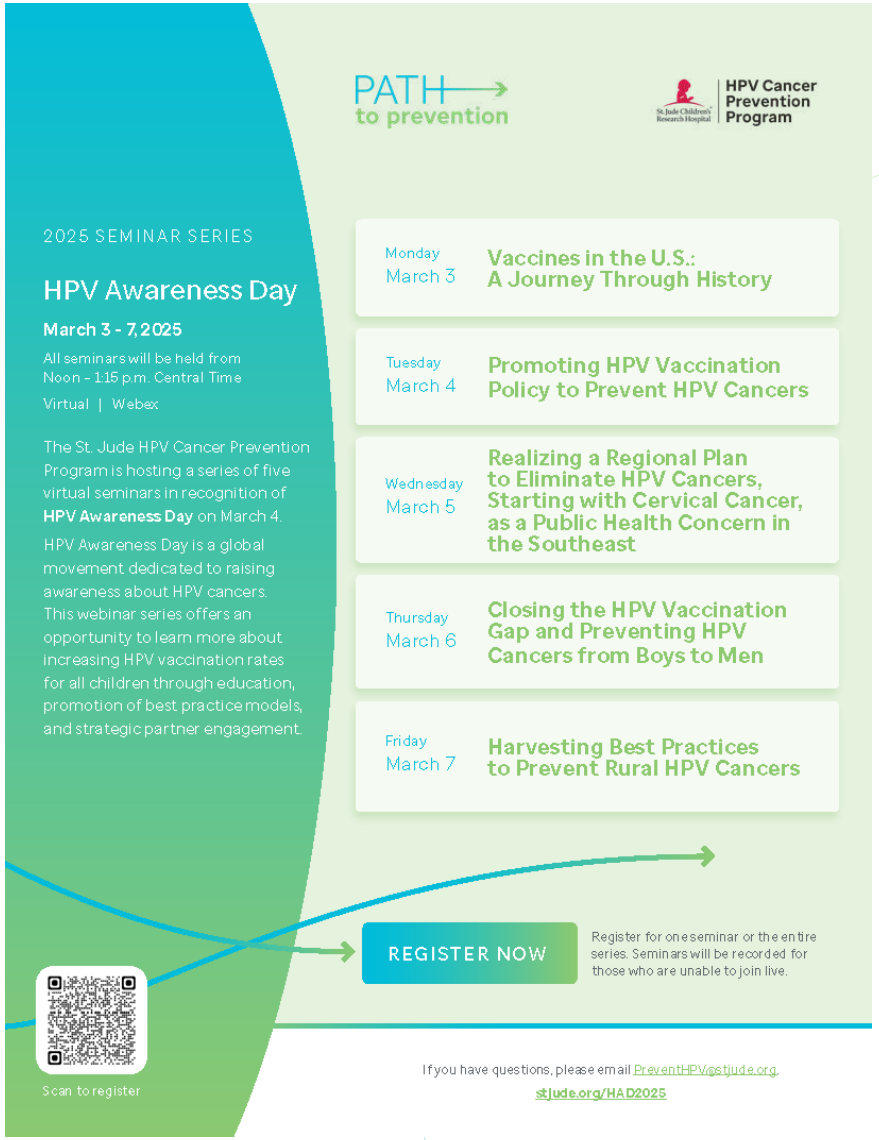
Daniel Salmon, PhD
Professor & Director
Institute for Vaccine Safety
Johns Hopkins Bloomberg School
of Public Health

Amy Pisani, MS
Chief Executive Officer
Vaccinate Your Family

Closing Remarks

Upcoming HPV Awareness Day Seminars

Register at stjude.org/HAD2025



One Less Worry Campaign 2025 is Live!

Seminar Evaluation, March 3

Please take a brief moment to complete an evaluation of today's seminar. Your feedback is important to us and will be used to plan future offerings.

Thank you for joining us today!

Email preventHPV@stjude.org with any questions!