Vaccine refusal in the time of COVID-19: opportunities for community engagement & research

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With Crisis (can) Come Opportunity

- COVID-19 has caused global morbidity, mortality, and social & economic disruptions
- Seemingly very effective and very safe vaccines
- Demonstrate the value of science, vaccines and public health
Operation Warp Speed (OWS)
Primary Purpose

Ensuring that every American who wants to receive a COVID-19 vaccine can receive one, by delivering safe and effective vaccine doses to the American people beginning January 2021.
COVID-19 Vaccines Available Feb. 2021

- Pfizer-BioNTech and Moderna available through Emergency Use Authorization
  - Large RCTs (40,000+ persons)
  - 2 doses
  - >90% efficacious
  - Very good safety profile
- AstraZeneca, Janssen and Novavax in Phase 3 trials
  - Janssen will be discussed at VRBPAC on 2/26/2021
What Will Vaccine Success Look Like with COVID-19

• Estimated 70+% of population requires immunity to effectively control disease
  • Assumes homogenous uptake
    • Geographical and social clustering undermines community immunity
  • Without children (<16 years of age), translates into @90% coverage with 95% effective vaccines
  • Emerging stains may be problematic
    • Transmitted more easily
    • Vaccine not as effective
COVID Vaccine Challenges

• If we build it, they may not come
  – Variable perceptions of disease burden
  – New vaccine technology
  – Distrust of pharma-industrial complex
  – Perception vaccines rushed

• Politics impacting science and response

• Real or coincidental adverse events derailing the program
COVID-19 Vaccination Intentions Varied by Survey Month

*Positive vaccine intentions includes persons reporting definitely, probably, or somewhat likely to get vaccinated.

Sara Oliver, ACIP 12/12/2020, with permission
Understanding Diverse Communities and Supporting Equitable and Informed Vaccination Decision-Making

NACCHO
National Association of County & City Health Officials

National Indian Health Board

Institute for Vaccine Safety
Johns Hopkins Bloomberg School of Public Health

astho

RWJF & Horizon Foundation Funded

ASSOCIATION OF IMMUNIZATION MANAGERS
Contributors

- **Implementation Partners** -- NACCHO, NIHB, AIM, ASTHO
- **Senior Survey and Engagement Teams** -- Matt Dudley, Jen Gerber, Haley Budigan, Tina Proveaux, Mary Davis Hamlin, Robin Roberts, Mike Hughes, Nadine Tafoya, and Lucy Moore
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- **Local Facilitators of and from the community** -- Brian Turner (NOLA), Terris King (MD), Maria Montes (TX), Liz Velasco (CO), Billie Jo Kipp (MT), Shantel Dubois (ND), Rene Najera (VA)
- **Senior Leadership** -- Dan Salmon, Lilly Kan, Ben Schwartz, Roger Bernier, and Janesse Brewer
Project Goal

Generate information that will be used by state, tribal, local, and territorial health departments, in collaboration with community stakeholders, to most effectively meet their populations’ need, leading to informed decision-making and equitable uptake of safe and effective SARS-CoV-2 vaccines.
Project Methods and Timeline

Wave 1
- Nov 1 - Dec 21, 2020
- 2525 person Panel Survey
- 25 online Community Conversations (approximately 400 people)
- Preliminary findings - 12/15/20
- Webinars, roundtables, ETC
- Peer-reviewed journal article

Wave 2
- Jan 26-Feb 13, 2021
- 25 online Community Conversations (90% retention from Wave 1)
- Preliminary findings - 2/15/21
- Webinars, roundtables anticipated
- Manuscript anticipated

Wave 3
- Survey #2 and Community
- 25 online Community Conversations – TBD (April-June time period)
Rapidly Changing Environment

November 20: Pfizer-BioNTech submits EUA application
November 25: Ipsos survey begins
November 30: Moderna submits EUA application
December 1: Wave 1 meetings begin
December 7: Ipsos survey ends
December 11: Pfizer-BioNTech vaccine approved for EUA
December 14: First person vaccinated against COVID-19 in the US
December 15: Wave 1 meetings end
December 18: Modern vaccine approved for EUA
December 22: First report disseminated to local, state, territorial and tribal public health
December 23: 1 million doses of COVID-19 vaccines given in the US

December 29: First case of UK variant COVID-19 in US
Jan 13: 10 million COVID-19 vaccines
Jan 20: Inauguration of President Joseph R Biden
Jan 25: First case of Brazil variant COVID-19 identified in the US
Jan 26: Wave 2 meetings begin, first articles on “vaccine tourism” in the US are posted
Feb 4: J&J submits EUA
Feb 13: Wave 2 ends, 50 million doses of COVID-19 vaccine given in the US
Wave 1 Survey Goal & Methods

- **Goal:** Conduct a national survey to better understand interests, preferences, and factors that influence vaccine decision-making across the nation

- **Methods**
  - Ipsos KnowledgePanel
  - November 25 – December 7
  - English and Spanish
  - Accounted for households without internet access
  - 2,525 respondents, including 610 Black, non-Hispanic & 801 Hispanic
Wave 1 Survey Topics

- COVID-19 vaccine intent
- Personal impact of COVID-19
- Confidence in ability to avoid COVID-19
- Confidence in vaccine safety
- Support for communitarian world view vs. individualism
- Support for egalitarianism vs. hierarchy
- Trust in state/local public health & CDC
- Other attitudes RE: COVID-19 (e.g., severity, mask-wearing, value of therapeutics
- Other attitudes RE: COVID-19 vaccines (e.g., effectiveness, safety, importance for outbreak control, providing personal information to get vaccinated)
- Demographics (e.g., gender, age, education, region, income, political affiliation)
**Wave 1 Public Engagement Goal & Method**

**Goal:** Foster community conversations about COVID-19 and vaccine perspectives to better understand *why* people see things as they do and what factors are important to their decision-making

**Methods:**
- 25 online conversations (regional and local)
- Nearly 400 participants (Native American, African American, Latinx and vaccine hesitant)
- December 2 – 14
- 90-180 minutes each
- 4 senior facilitators teamed with 7 local facilitators of and from their local communities (Native American, African American, Latinx)
- Standard meeting approach that was customizable, based on local community needs
- English and Spanish
Wave 1 Public Engagement Core Questions

- **What information would be most helpful** as you and our community consider wanting to take the vaccine?
- What are some **practical barriers** that you/others in our community might face if wanting to get vaccinated?
- What **advice would you give our local health department** about what they can do to make it easier for you or people in our community to get vaccinated?
- There is likely to be **confusing and conflicting information** as vaccination rolls-out, similar to the various opinions about wearing a mask; do you think COVID vaccination will have the same range of opinions and **how do you make decisions about vaccination in this context**?
- There are a lot of **reasons people may choose to get vaccinated**, including: to protect yourself, to protect your loved ones, and/or to protect your community at large. We want to especially talk about the last part...
Wave 1 Survey Findings

Three groups, categorized by intent to be vaccinated:

- **Intenders** (50% of the population)
  - Those definitely or probably getting vaccinated as soon as possible
- **Wait and learn** (40% of the population)
  - Those probably getting vaccinated but not right away + those who will probably not get vaccinated
- **Unlikelys** (10% of the population)
  - Those definitely not getting vaccinated
Intender

- 61% of over >60 years of age
- 32% of Black, non-Hispanics
- 63% of Bachelor’s degree or more education
- Democrats (63%); Republicans (46%); Independents (48%)
- More likely to:
  - Support for communitarian world view vs. individualism
  - Support for egalitarianism vs. hierarchy
  - Trust health departments and CDC
- Much more likely to be confident in vaccine safety
Intenders

- Compared to the **rest of the population**, **more** likely to:
  - Be in a metro than non-metro statistical area (odds ratio [OR]: 1.43)
  - Have a high income than low income (OR: 1.6)
  - Be diagnosed with a high-risk condition for COVID-19 (OR: 1.48)
  - Have received a flu shot in the past 12 months (OR: 3.87)
  - Discuss COVID-19 with their healthcare provider (OR: 6.07)
  - Perceive COVID-19 as severe (OR: 2.08)
  - Consider a COVID-19 vaccine important to stop the spread of infection (OR: 44.37)
  - Wear a mask usually or almost always (OR: 3.20)
Wait and Learn

- 33% of Elderly
- 52% of Black, non-Hispanics
  - Compared to **intenders**, about twice as likely to be Black, non-Hispanic (OR: 2.51)
- More likely to:
  - Be in good (OR: 1.72) or fair (OR: 1.64) health (compared to excellent health)
  - Have known someone with a previous serious vaccine reaction (OR: 2.74)
  - Be worried about the government requiring personal information to get a COVID-19 vaccine (OR: 1.86)
  - Be concerned about the government and drug companies experimenting on people like them (OR: 3.74)
Wait and Learn

- Compared to **Intenders**, less likely to:
  - Be in a metro than non-metro statistical area (OR: 0.71)
  - Report a high income versus low income (OR: 0.68)
  - Be a Democrat versus Republican (OR: 0.58)
  - Be diagnosed with a high-risk condition for COVID-19 (OR: 0.68)
  - Have received a flu shot in the past 12 months (OR: 0.32)
  - Discuss COVID-19 with their healthcare provider (OR: 0.23)
  - Perceive COVID-19 as severe (OR: 0.54)
  - Consider a COVID-19 vaccine important to stop the spread of infection (OR: 0.04)
  - Wear a mask usually or almost always (OR: 0.39)
Wait and Learn

- Compared to **Intenders**, about *less* likely to:
  - Support for communitarian world view vs. individualism and egalitarianism vs. hierarchy
  - Have trust in health departments and CDC

- Much less likely to be confident in vaccine safety (OR: 0.12)
Unlikelys

- 15% of Black, non-Hispanics
- 14% of high school education or less
- Compared to **Intenders**, less likely to:
  - Be elderly (OR: 0.38)
  - Have a bachelor’s degree or more compared to less than high school education (OR: 0.24)
  - Have a high income than low income (OR: 0.46)
  - Be a Democrat versus Republican (OR: 0.33)
  - Think they will be infected with COVID-19 (OR: 0.59)
  - Discuss COVID-19 vaccine with their healthcare provider (OR: 0.04)
Unlikely

- Compared to **Intenders**, less likely to:
  - Perceive COVID-19 as severe (OR: 0.29)
  - Consider a COVID-19 vaccine important to stop the spread of infection (OR < 0.01)
  - Have received a flu shot in the past 12 months (OR: 0.10)
  - Discuss COVID-19 with their healthcare provider (OR: 0.04)
  - Wear a mask usually or almost always (OR: 0.16)

- Far less likely to:
  - Support communitarianism (vs. individualism - OR: 0.12) and egalitarianism (vs. hierarchy - OR: 0.37)
  - Trust health departments (OR: 0.20) or CDC (OR: 0.22)
  - Be confident in vaccine safety (OR: 0.02)
Key Issues Emerging from Community Conversations

1. The vast majority of participants are still forming their views and desire more information.
2. While concern about vulnerable family members was often identified as a reason for vaccination, in some minority groups, protecting the community generally also appeared to be a strong motivator.
3. Concerns about vaccine safety.
5. Lack of trust in government and pharma.
6. Trusted sources for information about vaccines.
7. Changing or conflicting information.
Key Issues Emerging from Community Conversations (cont’d)

8. Perceived COVID-19 risk
9. Individualism versus communitarianism
10. Getting “back to normal”
11. Cost of vaccination is perceived as a barrier for some
12. Concerns that COVID-19 vaccine would be mandatory
13. Safe community forums to listen and deliberate
## Retention - Wave 1 to Wave 2

<table>
<thead>
<tr>
<th>Population</th>
<th>Number of Meetings/Location</th>
<th>Wave 1</th>
<th>Wave 2</th>
<th>Retention (%)</th>
</tr>
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<tbody>
<tr>
<td>Regional</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Northeast</td>
<td>39</td>
<td>38</td>
<td></td>
<td>97%</td>
</tr>
<tr>
<td>2 South</td>
<td>33</td>
<td>33</td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>2 West</td>
<td>36</td>
<td>31</td>
<td></td>
<td>86%</td>
</tr>
<tr>
<td>2 Midwest</td>
<td>38</td>
<td>31</td>
<td></td>
<td>82%</td>
</tr>
<tr>
<td>African American</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Baltimore City, MD</td>
<td>24</td>
<td>24</td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>2 New Orleans, LA</td>
<td>24</td>
<td>24</td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>1 Howard County, MD</td>
<td>23</td>
<td>21</td>
<td></td>
<td>91%</td>
</tr>
<tr>
<td>Latinx</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Garfield Co/Glenwood Springs, CO</td>
<td>34</td>
<td>27</td>
<td></td>
<td>79%</td>
</tr>
<tr>
<td>2 Harris County, TX</td>
<td>25</td>
<td>25</td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>2 Fairfax, VA</td>
<td>31</td>
<td>24</td>
<td></td>
<td>77%</td>
</tr>
<tr>
<td>1 Howard County, MD</td>
<td>23</td>
<td>21</td>
<td></td>
<td>91%</td>
</tr>
<tr>
<td>Native American</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Blackfeet, MT</td>
<td>26</td>
<td>22</td>
<td></td>
<td>85%</td>
</tr>
<tr>
<td>2 Spirit Lake, ND</td>
<td>22</td>
<td>18</td>
<td></td>
<td>82%</td>
</tr>
<tr>
<td>Asian American</td>
<td>1 Howard County, MD</td>
<td>16</td>
<td>16</td>
<td>100%</td>
</tr>
<tr>
<td>TOTALS</td>
<td>25 Meetings</td>
<td>394</td>
<td>356</td>
<td>90%</td>
</tr>
</tbody>
</table>
Wave 2 Community Meetings Preliminary Findings

1. Increased comfort for many
2. Perspective varies by community
3. Safety concerns persist
4. Information needs are evolving
Vaccine Intent by Study Wave

[Diagram showing percentage of participants selecting various vaccine intent options by study wave, with specific data points for Native American Wave 1 (N=40), Native American Wave 2 (N=37), African American Wave 1 (N=68), African American Wave 2 (N=11), Latina/Latino Wave 1 (N=93), Latina/Latino Wave 2 (N=82), and Regional Wave 1 (N=141).]
5. Concern about speed of vaccine development has diminished
6. Experience with vaccine rollout has been uneven
7. There is still a Wait and Learn perspective for many
8. Support for decision-making needs to be customized for each community
9. For those who do not want a vaccine now (or maybe ever), there is an interest in how else (short of vaccination) they can support the end of the pandemic
10. “Meeting this Moment”
Take Home Messages

● Currently demand is greater than supply
  ○ Make vaccine easily available for those who want it
  ○ Ensure access for those experiencing health disparities

● Substantial proportion of the public still haven’t made up their minds
  ○ This is reasonable
  ○ Opportunity to support their informed-decision making
  ○ Public health needs to build trust now by being a partner
Where are we vulnerable?

- Perception that Politics is Driving Science
- Vaccine safety scare undermining public confidence
Politics Driving Science

- Former President Trump downplaying pandemic
  - “It’s going to disappear. It is disappearing.” (Oct 2020) as major surge starting
  - Acknowledged approach was intentional
- FDA scrutinized that politics impacted their decision to grant an EUA for hydroxychloroquine and later convalescent plasma
- The CDC, which normally would lead efforts around pandemic response and related communications, has largely been sidelined in the response to COVID-19 with widespread accounts of political officials interfering with CDC COVID-19 reports
New Administrations Affords Opportunity

- CDC can assert their expertise and demonstrate to the country their value
  - President Biden has strongly stated that he will follow the science
  - Requires resources for feds, states and localities
  - Starting to see CDC rather than politicians providing information

- Political polarization of the country remains a challenge
Risks for Vaccine Safety Scare to Derail Program

- Real safety problem that would change risk/benefit calculation always possible, but unlikely
- Coincidental relationship with vaccination much higher risk
  - Bad things happen to people every day (background rates of disease)
  - If vaccinate a lot of people quickly (mass vaccination program), coincidental relationships can derail the program
Vaccine Safety Science: Rigor

- Approval process ensures benefits > risks for populations & outcomes studied
- Observational studies after approval to examine uncommon events, excluded populations, subpopulations, and delayed onset adverse events
- Infrastructure (large healthcare databases) very helpful for rigor and timeliness
Clinical Trial Limitations: Sample Sizes Needed to Detect Rare Adverse Events and Impact

<table>
<thead>
<tr>
<th>Rates (%)</th>
<th>Sample Size *</th>
<th>Number Potentially Affected**</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 vs. 0.2</td>
<td>50,000</td>
<td>328,000</td>
</tr>
<tr>
<td>0.1 vs. 0.3</td>
<td>17,500</td>
<td>656,000</td>
</tr>
<tr>
<td>0.05 vs. 0.1</td>
<td>100,000</td>
<td>164,000</td>
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<tr>
<td>0.01 vs. 0.02</td>
<td>500,000</td>
<td>32,800</td>
</tr>
<tr>
<td>0.01 vs. 0.03</td>
<td>175,000</td>
<td>65,600</td>
</tr>
</tbody>
</table>

*Two-arm trial, power 80%, alpha (2 sided) = 5%
** 100% vaccine coverage for the US

Source: Adapted from Ellenberg 2001
“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
## Estimates of Coincident, Temporally-Associated Events

<table>
<thead>
<tr>
<th>Coincident events</th>
<th>Number of coincident events since a vaccine dose:</th>
<th>Baseline incidence rate used for estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Within 1 day</td>
<td>Within 7 days</td>
</tr>
<tr>
<td><strong>Guillain-Barré Syndrome</strong> (per 10 million vaccinated people)</td>
<td>0.51</td>
<td>3.58</td>
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<tr>
<td><strong>Optic Neuritis</strong> (per 10 million female vaccinees)</td>
<td>2.05</td>
<td>14.40</td>
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<tr>
<td><strong>Spontaneous abortions</strong> (per 10 million vaccinated pregnant women)</td>
<td>3,970</td>
<td>27,800</td>
</tr>
<tr>
<td><strong>Sudden death</strong> within 1 hour of onset of any symptoms (per 10 million vaccinated people)</td>
<td>0.14</td>
<td>0.98</td>
</tr>
</tbody>
</table>

Black et al. Importance of background rates of disease in assessment of vaccine safety during mass immunisation with pandemic H1N1 influenza vaccines; Table 6. Lancet 2009; 374; Oct. 30 [Epub].
Monitoring COVID Vaccine Safety
What is Needed?

• Identify adverse events following immunization and evaluate if caused by vaccine
  – GBS in 1976

• Address spurious associations
  – Bad things happen every day & will happen after vaccination

• Ability to distinguish between the two with rigor, speed and credibility
Examples of What Works #1
The Cutter Incident

• Launch of the polio vaccine program was accompanied with reports of paralysis following vaccination
• Langmuir had recently formed the Epidemic Intelligence Service (EIS) at CDC to rapidly investigate outbreaks
• Investigation identified some vaccine (primarily manufactured by Cutter Laboratories) was not fully inactivated and had caused wild disease
• Vaccine program was halted for a very short time
• Because of this rapid investigation, robust and rigorous science, objectivity of risk assessment and transparency the program quickly resumed
Example of What Works #2
2009-10 H1N1 Safety Monitoring and Communication

• Mass vaccination program
  – In midst of vaccine crisis in confidence
  – 1976 Swine Flu Fiasco

• Most comprehensive vaccine safety and communication program ever, anywhere

• Vaccine safety crisis around H1N1 never occurred in US
What Hasn’t Worked?

• Autism
• Simultaneous Vaccines
• Vaccine Ingredients
16 methodologically sound, controlled epidemiological studies exploring an association between Autism Spectrum Disorder (ASD) and receipt of MMR vaccine, thimerosal in vaccines, and simultaneous vaccination with multiple vaccines **by 2019**

<table>
<thead>
<tr>
<th>First author</th>
<th>Journal</th>
<th>Pub Year - month</th>
<th>Country</th>
<th>Exposure</th>
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<td>Taylor B</td>
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<td>DeStefano F</td>
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<td>US</td>
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<td>Jain A</td>
<td>JAMA</td>
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<td>US</td>
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<td>2015-05</td>
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<td>MMR/Thimerosal</td>
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<td>Hviid A</td>
<td>Ann Intern Med</td>
<td>2019-03</td>
<td>Denmark</td>
<td>MMR</td>
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*Dudley at al, Lancet ID, 2020*
Vaccine Autism Controversies and Studies Over Time

1977/8
1997/8

MMR Wakefield 1998 - Feb

Thimerosal PHS/AAP 1999 - July

Multi-Vac 1999 – July ???

Finland MMR Makela 2002-Nov
UK MMR Taylor 2002-Feb

Denmark MMR Madsen 2002-Dec

UK MMR Farrington 2001-Jun

Denmark Thimerosal Hvid 2003-Oct

US Thimerosal Verstraeten 2003-Nov

US Thimerosal Andrews 2004-Sep

UK MMR Smeeth 2004-Sep

US Thimerosal Croen 2008-Sep

US Thimerosal Price 2010-Oct

Japan Multi-vacc Uno 2012-Jun

Japan Thimerosal Uno 2015-May

US Multi-vacc Destefano 2013-Aug

Denmark MMR Hviid 2019-Mar
Vaccine Safety Science & Communication

• Good science takes time whereas anecdote, sensationalism and bad science travels quickly
• Very difficult to changes someone’s mind (cognitive dissonance and affirmation bias)
• Need to inform views as being formed
The Moment is Now

• We have the opportunity for vaccines and public health to turn the tide on the pandemic
• Tremendous impact on COVID-19
• Demonstrate the value of vaccines, public health, and the science and institutions that can make a difference
Vaccine refusal in the time of COVID-19: opportunities for community engagement & research

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Johns Hopkins Bloomberg School of Public Health