

Vaccine Safety Concerns and Values: A Sampling of Three Communities

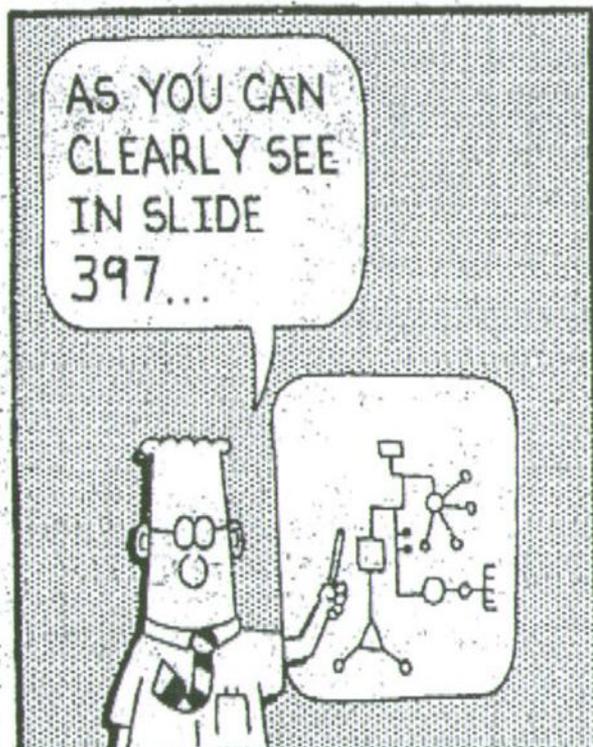
The Keystone Center

Outline of Presentation

- Background
- Keystone's Role
- Objectives of Public Meetings
- Methods (choosing communities, participants, an agenda)
- Results (discussions, scenarios, polling, surveys)
- Implications for ISO Research Agenda
- Considerations for Task 2
- Next Steps

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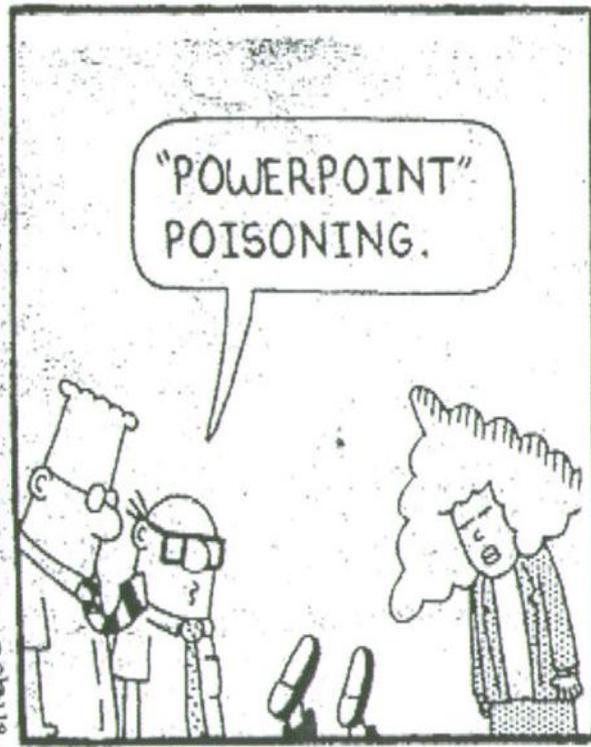
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Background

- April 11, 2008 – A call for increased public and stakeholder input.
- Fall 2008 – Keystone began work with the Steering Committee (representatives include NVAC Working Group, HHS, CDC, ISO, ASTHO, and NACCHO) to plan public engagement activities.
 - Community Engagement
 - Stakeholder Engagement

Methods

Criteria for Selecting Community Meeting Locations

- Indianapolis, IN and Birmingham, AL
 - Cities
 - Active state and local health departments
 - Average rates of vaccination
 - Different geographic parts of the country
- Ashland, OR
 - Active state and local health department
 - About 25% exemption rate



Community Meetings: Approach to the Day

- Project Overview (Keystone)
- Background
 - Vaccine Safety Overview (Non-Federal Government Expert)
 - Scientific Agenda Overview (Immunization Safety Office)
- Discussion: Community Perspectives
 - Small Group Discussions (Facilitated by Keystone, ASTHO, ISO, HHS)
 - Identify General Concerns
 - Discuss Issues through 5 Scenarios
 - Allocate Research Funds to Studies (in Ashland, Indianapolis only)
- Discussion and Polling (Plenary)
- Summary, Next Steps, and Wrap-Up

Community Meetings

What They Are Not; What They Are

What they are not:

- A statistically verifiable random sample of views in the U.S.
- Designed with intention to persuade communities to any particular viewpoint



What they are:

- A sampling of what 3 communities in different parts of the U.S. think about vaccines and vaccine safety
- Intended to encourage dialogue and increase understanding about where community members have comfort or concerns regarding vaccines and vaccine safety
- Designed to illuminate values that underpin community views regarding vaccines and vaccine safety

Pre-Meeting Survey Results: About the Community Participants

	Birmingham	Ashland	Indianapolis
Total # of Participants	70	46	52
Have Children	80%	81%	69%
Women	83%	70%	66%
18-34	23%	14%	15%
35-54	28%	41%	54%
55+	49%	45%	31%
Hispanic & Non-Hispanic White	8%	89%	53%
Hispanic & Non-Hispanic Black	83%	0%	36%
Attended/completed high school	35%	9%	38%
Attended/completed college	56%	43%	38%
Attended/completed grad school	9%	48%	23%

Pre-Meeting Survey Results: Community Views on Vaccines

	Birmingham	Ashland	Indianapolis
Very confident or confident in vaccines	61%	35%	63%
Not at all confident in Vaccines	1%	37%	2%
Would expect serious side effects	36%	57%	37%
Would not expect serious side effects	26%	15%	54%
Very confident or confident in CDC research	53%	36%	52%
Not at all confident in CDC research	6%	32%	6%
Self, family, or friend had a serious reaction	17%	46%	19%

SMALL GROUP DISCUSSION RESULTS

Specific Concerns

- Diseases

- Autism
- Autoimmune disease
- Diabetes
- Arthritis
- Asthma

- Specific Vaccines

- MMR
- Gardasil
- Flu

- Specific Ingredients

- Mercury/Thimerosal
- Additives
- Aborted fetal cells
- Preservatives
- Eggs
- Aluminum
- Anti-freeze

- Mandatory Vaccinations

Safety: Concerns about vaccines as currently given

- Ingredients
- Number of vaccines given
- Schedule
- Combinations (of vaccines, of ingredients)
- Side effects (short-term, long-term)
- Interactions with meds, allergies, cosmetics, personal care products, environmental factors
- Do vaccines cause the disease they target?
- Manufacturing security, safety of supply

Safety: Concerns about data, studies, and the vaccination system

- Why hasn't there been a study of vaccinated and unvaccinated populations?
- Do studies ask the right questions?
- Are reporting data accurate? Are people reporting the right things?
- Have alternative perspectives have been excluded from the dialogue about vaccine safety?
- Does the vaccination system work right? Does it track the right information? Does it have the right approach to safety?

Effectiveness: Do vaccines work?

- In the long term? In the short term?
- Do we get enough to be truly immunized?
- Do we have enough supply?

Special Populations: Are the risks and benefits the same for everyone?

- Genetically pre-disposed
- Different demographic groups (race, gender)
- Elderly
- Immune compromised
- Premature babies
- Pregnant

Trust: Who can we trust to tell us the truth?

- Secrecy of decision making, studies, reporting, etc.
- Who's on NVAC? Who's in charge?
- Conflict of interest; pharmaceutical companies and government
- Scientists – are they independent?

Access: Not everyone who wants to be vaccinated can get vaccinated.

- Cost of vaccinations
- Insurance coverage
- Access to health care

Education: Access to information about risks and benefits is lacking but very important.

- Do doctors know about the risks and benefits?
- Parents can't learn about risks and benefits because doctors won't spend the time because insurance companies won't pay.
- People should have access to study data—they want to know who is doing the studies, what the results are, and what it means. “It's safe” isn't enough.
- Where can people go to get complete and accurate information?

Scenario Results

Scenarios

- 5 stories that provide people with trade-offs
 - Based on real vaccines and real adverse events
- Intended to elucidate values
- Increasingly more difficult questions and trade-offs

Polling

- Quantitative measure of values
- Allows others to see results in real time
- Validate what we heard in small groups

Scenario and Polling Results - Priorities

- **Rare, severe AEs > Common, mild AEs**
- **Children \geq Adults**
- **Public and Scientific Concern**
- **Vulnerable Populations**
- **Susceptible Populations**
 - **Especially autism**

Results: Allocation Exercise

Category of Research	Ashland	Indianapolis
New vaccine for infants and children; required for daycare and school; scientific concern about severe injury	24%	25%
For infants and children; required for daycare and school; severe but uncommon injury	24%	22%
Vaccine for infants and children; scientists find no link with autism but public and some scientists are concerned about a risk of autism in some children (~1000 children/yr)	16%	18%
For adults; required for some jobs; severe but uncommon injury	6%	10%
For infants and children; not required for daycare or school; causes severe but uncommon injury	4%	8%
For infants and children; required for daycare and school; frequent but not severe injury	5%	7%
New vaccine for infants and children; required for daycare and school; public concern about severe injury	12%	10%
Other (see next slide)	10%	1%

“Other”: Some participants wrote in additional research studies they support:

- Studies of:
 - Vaccinated and unvaccinated populations
 - How vaccines are combined and scheduled
 - Treatments for AEs
 - Alternatives to disease prevention
- Reporting of AEs

Limitations

- Representativeness of the meetings.
- Could have been a fuller list of “what we don’t know” in the vaccine overview presentation.
- Facilitator reporting on small group discussion was not consistent in terms of level of detail provided.
- Improvements could have been made in terms of scenarios and polling questions.
- Allocation exercise – would have been nice to have done the exercise at all 3 communities.

Post-Meeting Survey Results: Perceptions of the Meeting

	Birmingham	Ashland	Indianapolis
Better understand risks and benefits	93%	47%	94%
More confidence in vaccine safety	71%	26%	55%
More confidence in CDC research	83%	38%	61%
Discussion was fair to all	98%	91%	98%
Process was effective at identifying values	94%	68%	87%
Important points were left out of discussion	42%	49%	30%

DISCUSSION

Implications for the draft ISO Scientific Agenda and Task 2.

Specific Issues

Implications for Task 2 of Your Charge

REPORTING

- Are reporting data accurate? Are people reporting the right things?

INCREASING DIALOGUE AND TRANSPARENCY

- Are there important perspectives excluded from the dialogue?
- Is there a way to increase transparency through oversight, etc?

CREDIBLE SCIENCE

- Who is credible? To whom?

Specific Issues

Implications for Task 2 of Your Charge

EDUCATION/COMMUNICATION

- To what extent can this be improved? Where can consumers find good, credible information about the benefits and risks of vaccines?

ACCESS

- Does everyone have equal access to good information and medical care as it relates to vaccines? Do there need to be changes in how healthcare approaches vaccination?

OVERALL APPROACH

- Does the vaccination system work right? Does it track the right information? Does it have the right approach to safety?

Values: To inform prioritization and the safety system more broadly

- **Children** as special—precious, vulnerable, “the future,” so much to live for
- **Choice** as a predominant principle in healthcare; freedom to choose how to approach health and healthcare for oneself and one’s family
- **Informed consent** as the foundation of decision making based on learning and understanding the risks and benefits of vaccines
- **Social responsibility** as a key reason for getting vaccinated; making community health an individual priority

Values: To inform prioritization and the safety system more broadly -- continued

- **Transparency** as a requirement in government and government-sponsored activities, particularly as they relate to the science and policies associated with vaccines and vaccine safety
- **Independent and trusted science** as an important cornerstone for vaccine safety research
- **Parental instinct and knowledge** as critical and credible components in family healthcare; although parents don't all have formal medical training, they know their children in ways that medical professionals cannot
- **All lives** as important and deserving of care and attention; shared stewardship of those more vulnerable populations such as the sick, pregnant women, infants, etc.

A Stakeholder Approach

The Keystone Center

Themes from Stakeholder Conversations

- Broad agreement
 - Everyone wants a robust ISO scientific agenda
- Desire for:
 - Meaningful, deliberative discussion
 - Inclusive and transparent process
 - Some depth on the draft ISO Scientific Agenda
 - Time to talk about other issues related to the vaccine system more broadly
 - Time to do this right

Other Feedback

- Mixed views about who should be included in conversations about a scientific agenda
 - Role of scientists
- Skepticism by some about whether HHS/CDC/ISO are genuine in asking for feedback
- Skepticism about whether it will result in anything meaningful
- Hopeful that this is an opportunity to do something important with those that have traditionally seen things differently

Stakeholder Meeting

- March 16
- Stakeholders will identify themselves and register for the meeting
- Proposed objectives:
 - 1) Identify gaps in the ISO scientific research agenda;
 - 2) Develop some prioritization criteria for further consideration;
 - 3) Weight criteria; and
 - 4) Identify any other issues stakeholders think are important and worthy of further dialogue regarding vaccines and vaccine safety.

Ideal Participants

- Interested in and knowledgeable about vaccines and vaccine safety issues
- Comfortable in discussions about science as well as values
- Demonstrated ability to work with people who have very different views
- Capable and willing to focus on the task at hand

Preparation for March Stakeholder Meeting

- Writing group to work in advance of March Stakeholder Meeting
 - Objective: Prepare draft materials for March Stakeholder Meeting
 - Diversity of representatives from different sectors
 - NVAC
 - CDC/ISO and HHS
 - Industry/vaccine manufacturers
 - Medical associations
 - Bioethics
 - Groups that work on vaccine-related issues
 - Legislative
 - State and local health
 - Alternative medicine
 - Unaffiliated groups
 - Parents
 - Observers from the community meetings
 - Others

Thank You.