THERE IS A RIGHT ANSWER

Ethics and Health Policy

Jeffrey P. Brosco M.D., Ph.D.
Director, Population Health Ethics
Institute for Bioethics & Health Policy

UNIVERSITY OF MIAMI
MILLER SCHOOL OF MEDICINE
INSTITUTE FOR BIOETHICS

Health
Pediatrics
UNIVERSITY OF MIAMI HEALTH SYSTEM

UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

Disclosures

- Employment and Positions
  - Pediatrician, University of Miami/Jackson Health System
  - Director, Population Health Ethics, UM Institute for Bioethics & Health Policy
  - Director, Division of Services for Children with Special Health Needs, Maternal Child Health Bureau (U.S. Department of Health and Human Services)
  - Previously, Deputy Secretary, Children's Medical Services, Florida Department of Health (FDOH)
- No conflicts of interest (no commercial interests)
  - The views expressed in this presentation are mine and do not necessarily reflect the official policies of the US Department of Health and Human Services (HHS) or the Health Resources and Services Administration (HRSA), nor does mention of HHS or HRSA imply endorsement by the US government.

Learning Objectives

At the end of this session, you will be able to

1. Explain some of the strengths and weaknesses of the basis for modern scientific medicine
2. Recognize that values, beliefs, and preferences underlie all health policy
3. Choose a process for making decisions based on scientific information and the values, beliefs, and preferences of the affected population

Ethical Foundation ("Basic Sciences")

- Clinical Medicine
  - Anatomy
  - Physiology
  - Biochemistry
  - Statistics
  - Physics
  - Pathology
  - Histology
  - Etc.
- Ethics
  - Philosophy
  - Psychology
  - Sociology
  - Behavioral economics
  - History
  - Religious studies
  - Anthropology
  - Etc.

Ethics is More Than Just "Principlism"

- "Four core principles"
  - Respect for autonomy
  - Non-maleficence
  - Beneficence
  - Justice
- Other principles
  - 10 Commandments
  - Convention on the Rights of the Child
- Aristotle
  - "Golden Mean"
- Immanuel Kant
  - Categorical imperative
- John Rawls
  - Veil of ignorance
- Utilitarianism
- **Pragmatism**

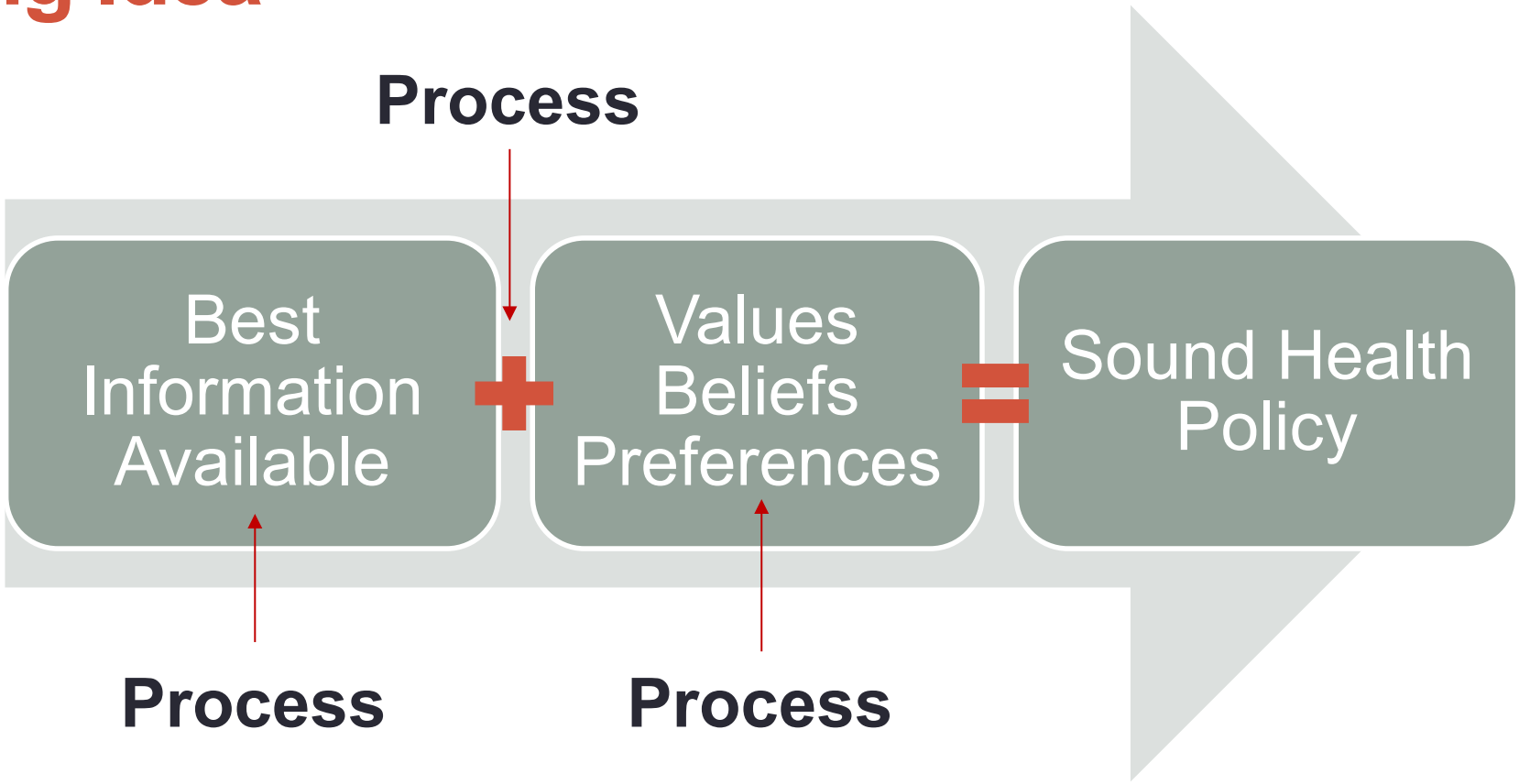
Ethics is NOT just about asking questions

- Ethics is about answers
  - Ethics question are solved because we have to act
    - Better and worse solutions
  - Ethics is embedded in everything we do
    - More obvious in clinical medicine
    - Consent, confidentiality, caring, competence, etc.
- Bioethics is also about epistemology
  - "special epistemological status of science"

Big Ideas

1. Scientific medicine has strengths and weaknesses
   - Experts can provide "best information available"
2. Values, beliefs, & preferences underlie policy
   - Science doesn't tell us what to do
3. Good decisions in health policy come from **processes** that combine best information available with respect for a society's values, beliefs, & preferences

Big Idea


Process
Best Information Available
Values Beliefs Preferences
Sound Health Policy
Process
Process

Examples of Processes in Bioethics

- "Futility" and end of life decisions
  - Substantial disagreement on definition of futility
  - Hospital policies follow a process
    - Mediation, ethics committee consultation, transfer, etc.
- Role of a hospital ethics committee
  - Members have some expertise in bioethics
  - Clinical case consultation follows a process
  - Informed opinions of a diverse group of people help define the range of ethically acceptable actions

Today: Approach to Public Health Ethics

- Case scenarios
  1. Antibiotics for a child with an ear infection
  2. One-year-old child due for measles vaccine
  3. School district policy re measles vaccine
- "Thinking, Fast and Slow"
  - First impulse is "thinking fast"
  - Second thought: what led you to your answer?

Thinking, Fast and Slow (Daniel Kahneman, 2011)

- **Two kinds of thinking**
  - **1:** Fast, automatic, frequent, emotional, unconscious
    - display disgust when seeing a gruesome image
    - solve 2 + 2 = ?
  - **2:** Slow, effortful, logical, calculating, conscious
    - determine the price/quality ratio of two washing machines
    - solve 17 × 24 = ?
- Cognitive bias
  - Many different factors influence our decisions
  - Significant bias is more common in **fast** thinking

Case # 1: Child with an Ear Infection

- Healthy 2-year-old with signs/symptoms of infection
  - Low fever, moderate right ear pain, and runny nose/congestion
  - Physical exam reveal red, bulging tympanic membrane and no signs of pneumonia
  - No previous ear infections
- Do you prescribe an antibiotic?
  - Yes/No/Maybe (answer in the chat, if you like)
  - What led you to your answer?

Do Antibiotics Work for Ear Infections?

- Randomized Controlled Trial (**RCT**)
  - One way that clinical research is done
    - "Does a treatment work?"
  - Considered a "gold standard" – reducing bias
    - "Control" reduces bias related to placebo effect
      - e.g. treatment of viral infection with an antibiotic
    - "Randomization" reduces confounding factors
      - e.g. breast-feeding and child IQ

Krishnaswami et al. A systematic review of secretin for children with autism. Pediatrics. 2011 May;127(5):e1322-5.

Do Antibiotics Work for Ear Infections?

- 2011 RCT in New England Journal of Medicine
  - 319 children randomized to antibiotic or placebo
  - Measured outcome: improvement by day 8
    - 86.3% of children improved with antibiotic
    - 74.7% of children improved with placebo
  - Side effects (diarrhea)
    - 47.8% with antibiotic
    - 26.6% with placebo

Tähtinen et al. A placebo-controlled trial of antimicrobial treatment for AOM. N Engl J Med. 2011;364(2):116-26.

Clinical Guidelines (best information available)

- Necessary because doctors do not have the time or expertise to review all of the research on every topic
  - Evidence is often complex and conflicting
- Rules/procedures for issuing clinical guidelines
  - Strict disclosure regarding any conflict of interest
  - Standard procedures for reviewing research
  - Predetermined approach to recommendations
    - Magnitude of risk-benefit ratio
    - Certainty of results

Case # 1: Child with an Ear Infection

- Healthy 2-year-old with right ear infection
- Do you prescribe augmentin (antibiotic)?
  - Yes/No/Maybe
    - What do you think? (OK to answer in the chat)
    - But first: what led you to your answer?

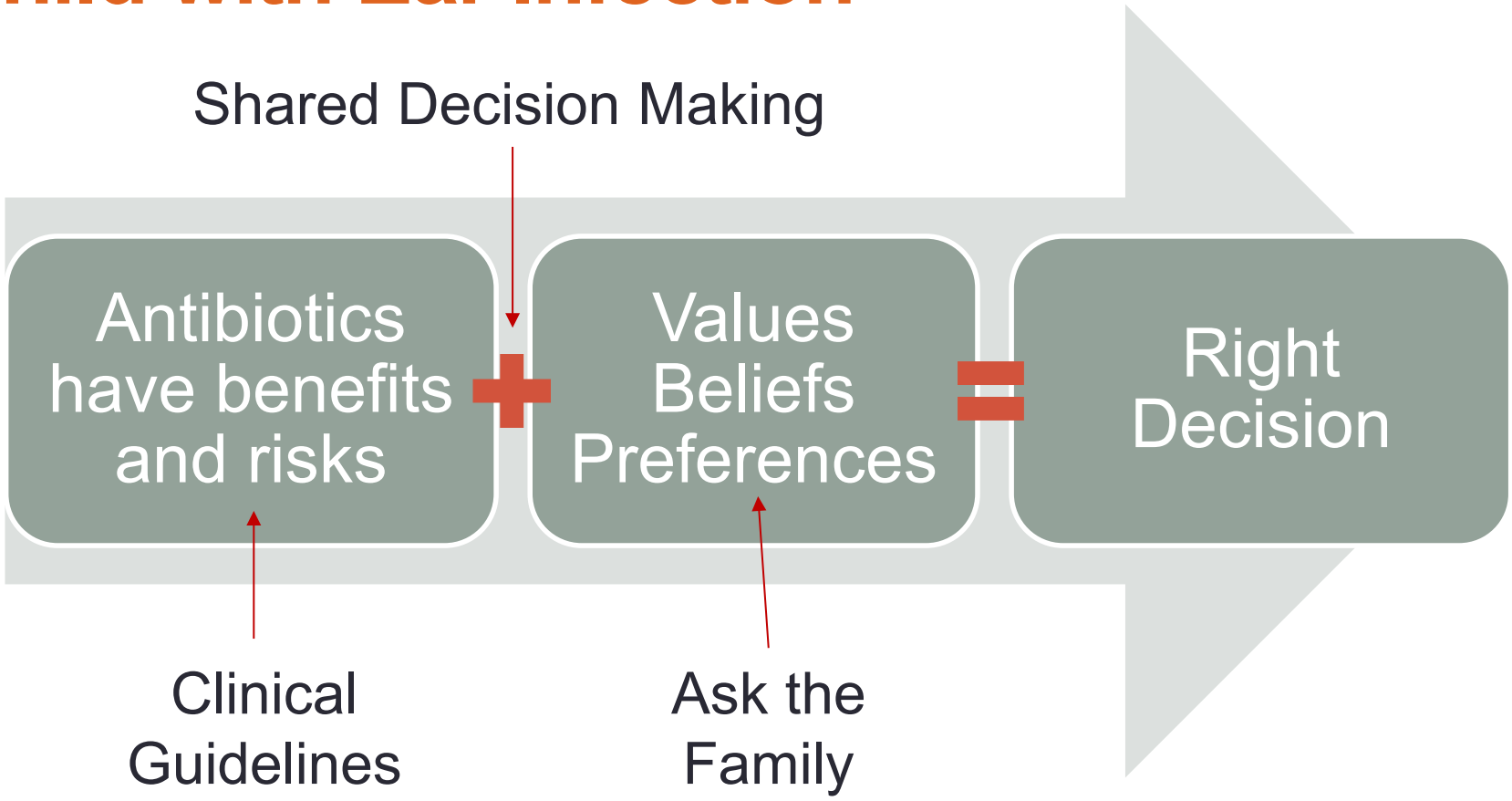
Shared Decision Making

- "Maybe" is the right answer, in this case
  - Best information available (scientific medicine)
  - Values/preferences/beliefs (individual person)
- Clinician guides a person through a decision
- Autonomy – basis for modern bioethics
  - Individuals with capacity and sufficient information make voluntary decisions
  - "Science" rarely tells you what to do . . .

Process: “Shared Decision Making”

- What you do as a clinician in this case? Ask!
- “Your child has an ear infection, and 8 out of 10 get better on their own (vs. 9 out of 10 who take antibiotics)
- “Antibiotics can help but they have side effects.
- “Some parents would say: ‘I prefer to let nature take its course. Let’s avoid antibiotics.’
- “Others would say: I want to try anything that might help my child, even a little bit.”
- “Some parents prefer for me to make the decision.
- “What do you think?”

Child with Ear Infection



Case # 2: One-year-old Child for Check-up

- Well child
  - Healthy, growing well, developing normally
  - Routine vaccines include MMR
    - MMR = Measles, Mumps, Rubella
- Do you recommend the MMR vaccine?
  - Yes/No/Maybe (answer in the chat, if you like)
  - What led you to your answer? “fast/slow thinking”

Do Vaccines Work? COVID example

- December 2020 RCT in New England Journal of Medicine
  - 43,448 people randomized to vaccine or placebo
    - 21,720 received vaccine
    - 21,728 received placebo
  - Measured outcome: COVID infection
    - Vaccine: 8 cases of COVID
    - Placebo: 162 cases of COVID
  - Side effects: fatigue and headache
    - 59% & 52% with vaccine; 23% & 24% with placebo

Polack et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020 Dec 31;383(27):2603-2615.

Do Vaccines Work?

- What is your measured outcome ("endpoint")?
  - Infections
  - Admission to hospital or critical care
  - Deaths
  - Long-term outcome
    - Example of "long COVID" in children
      - 2024 study of hospital records of 1,037,936 patients
      - Vaccine 35.4% effective

Razzaghi et al. Vaccine Effectiveness Against Long COVID in Children. Pediatrics. 2024 Apr 1;153(4):e202306444

Are Vaccines Safe?

- **Vaccine Adverse Event Reporting System (VAERS)** - FDA/CDC
  - "Nation's early warning system"
  - Online reporting system; clinicians & manufacturers required by law to report events
  - 85% to 90% of reports are not serious; serious reports are followed up
- **Vaccine Safety Datalink (VSD)** - CDC
  - Electronic health record data from 13 large health care organizations (12.5 million)
  - Can "test" whether specific problems are indeed associated with vaccines
- **Biologics Effectiveness and Safety System (BEST)** - FDA
  - Claims data, electronic health records, and linked claims-EHR databases (100 million)
  - Rapid studies, look at sub-populations (e.g. pregnant women)
- **Clinical Immunization Safety Assessment (CISA)** CDC, medical centers
  - Medical and scientific vaccine expertise to look in depth at specific cases

Evidence re Vaccines and Autism (JAMA 2003)

Table. Rate Ratio of Autism and Other Autistic-Spectrum Disorders Comparing Children Vaccinated With a Thimerosal-Containing Vaccine to Children Vaccinated With a Thimerosal-Free Formulation of the Same Vaccine

		Autism			Other Autistic-Spectrum Disorders		
	Person-Years at Risk	No. of Cases	RR (95% CI)*	RR (95% CI)†	No. of Cases	RR (95% CI)*	RR (95% CI)†
Vaccinations							
All thimerosal-free	1 660 159	303	1.00	1.00	430	1.00	1.00
Any containing thimerosal	1 220 006	104	0.85 (0.60-1.20)	0.85 (0.60-1.20)	321	1.12 (0.88-1.43)	1.12 (0.88-1.43)
Doses of thimerosal-containing vaccine							
None	1 660 159	303	1.00	1.00	430	1.00	1.00
1 dose (25 µg eHg)	169 920	18	0.99 (0.59-1.68)	1.01 (0.60-1.71)	40	0.96 (0.67-1.39)	0.95 (0.66-1.37)
2 doses (75 µg eHg)	447 973	33	0.71 (0.46-1.09)	0.70 (0.46-1.09)	130	1.20 (0.92-1.56)	1.20 (0.92-1.56)
3 doses (125 µg eHg)	602 113	53	0.96 (0.63-1.46)	0.96 (0.63-1.47)	151	1.11 (0.83-1.48)	1.13 (0.84-1.51)
Trend (increase in RR per 25 µg eHg)			0.98 (0.90-1.06)	0.98 (0.90-1.06)		1.03 (0.97-1.09)	1.03 (0.98-1.09)

Abbreviations: CI, confidence interval; eHg, ethylmercury; RR, rate ratio.
*Adjusted for confounders: age and calendar period.
†Fully adjusted: age, calendar period, child's sex, child's place of birth, birth weight, 5-minute Apgar score, gestational age, mother's age at birth of child, and mother's country of birth.

Hviid A et al. Association between thimerosal-containing vaccine and autism. JAMA. 2003 Oct 1;290(13):1763-6.

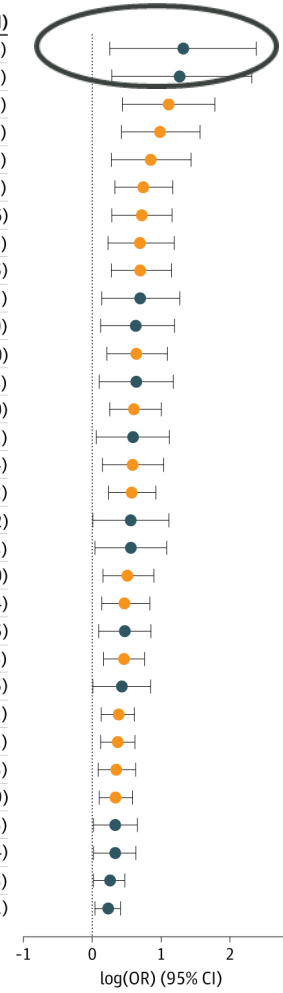
JAMA Network™

From: **Maternal Inflammatory Proteins in Pregnancy and Neurodevelopmental Disorders at Age 10 Years**

JAMA Psychiatry. Published online March 12, 2025. doi:10.1001/jamapsychiatry.2025.0122

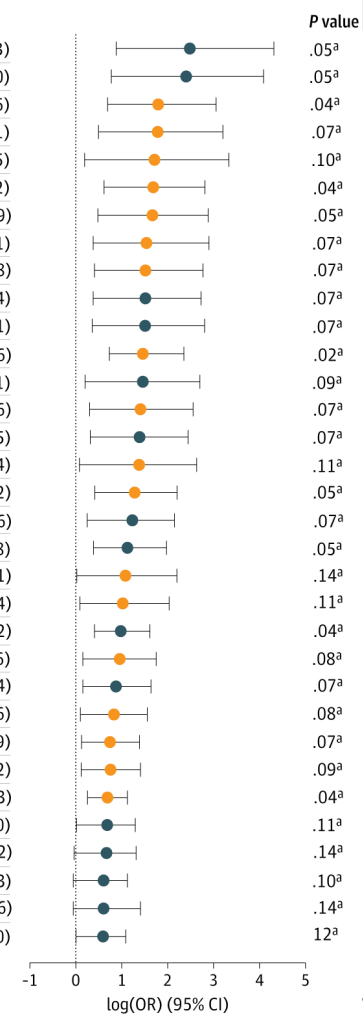
A Maternal plasma proteins associated with any NDDs

Source	log (OR) (95% CI)	*P* value
IL-15RA	1.31 (0.25-2.39)	.06[a]
CSF-1	1.28 (0.29-2.32)	.06[a]
VEGFA	1.10 (0.44-1.79)	.02[a]
CD5	0.99 (0.43-1.57)	.02[a]
SLAMF1	0.85 (0.28-1.44)	.03[a]
IL-12B	0.74 (0.33-1.17)	.02[a]
CCL3	0.72 (0.29-1.16)	.02[a]
LAP-TGF-beta-1	0.71 (0.23-1.19)	.03[a]
FGF-23	0.71 (0.28-1.15)	.02[a]
CD244	0.70 (0.14-1.27)	.06[a]
IL-18R1	0.65 (0.12-1.20)	.07[a]
MCP-1	0.65 (0.22-1.10)	.03[a]
TNFRSF9	0.64 (0.10-1.18)	.07[a]
MCP-2	0.62 (0.25-1.00)	.02[a]
uPA	0.59 (0.06-1.12)	.11[a]
CCL23	0.59 (0.15-1.04)	.05[a]
IL6	0.58 (0.24-0.92)	.02[a]
TNFB	0.55 (0.01-1.12)	.14[a]
CD40	0.55 (0.04-1.08)	.12[a]
MMP-10	0.52 (0.16-0.90)	.03[a]
IL8	0.48 (0.14-0.84)	.04[a]
TNF	0.48 (0.10-0.85)	.06[a]
CCL19	0.46 (0.17-0.76)	.03[a]
TRANCE	0.43 (0.01-0.85)	.13[a]
MMP-1	0.37 (0.13-0.62)	.03[a]
FGF-19	0.37 (0.12-0.62)	.03[a]
CXCL10	0.36 (0.09-0.63)	.05[a]
CXCL9	0.34 (0.10-0.59)	.03[a]
CD8A	0.34 (0.02-0.66)	.12[a]
CCL28	0.32 (0.02-0.64)	.12[a]
CXCL1	0.25 (0.02-0.48)	.12[a]
IFN-gamma	0.23 (0.04-0.41)	.06[a]



B Plasma proteins associated with autism

Source	log (OR) (95% CI)	*P* value
DNER	2.47 (0.87 to 4.33)	.05[a]
VEGFA	2.36 (0.78 to 4.10)	.05[a]
CCL11	1.82 (0.70 to 3.06)	.04[a]
CD244	1.80 (0.50 to 3.21)	.07[a]
TRAIL	1.73 (0.20 to 3.35)	.10[a]
GDNF	1.69 (0.62 to 2.82)	.04[a]
uPA	1.68 (0.49 to 2.89)	.05[a]
TWEAK	1.60 (0.39 to 2.91)	.07[a]
FLT3L	1.54 (0.41 to 2.78)	.07[a]
SLAMF1	1.53 (0.39 to 2.74)	.07[a]
SCF	1.52 (0.36 to 2.81)	.07[a]
FGF-23	1.50 (0.74 to 2.36)	.02[a]
CD40	1.42 (0.21 to 2.71)	.09[a]
LAP-TGF-beta-1	1.41 (0.31 to 2.56)	.07[a]
CCL23	1.36 (0.32 to 2.45)	.07[a]
CD5	1.35 (0.09 to 2.64)	.11[a]
TRANCE	1.31 (0.42 to 2.22)	.05[a]
CCL3	1.22 (0.25 to 2.16)	.07[a]
CCL28	1.13 (0.39 to 1.98)	.05[a]
PD-L1	1.09 (0.03 to 2.21)	.14[a]
IL-12B	1.05 (0.10 to 2.04)	.11[a]
FGF-19	0.99 (0.41 to 1.62)	.04[a]
MMP-10	0.96 (0.16 to 1.76)	.08[a]
MCP-2	0.90 (0.16 to 1.64)	.07[a]
CCL4	0.83 (0.10 to 1.56)	.08[a]
IL10	0.76 (0.13 to 1.39)	.07[a]
CXCL6	0.75 (0.12 to 1.42)	.09[a]
CXCL9	0.69 (0.26 to 1.13)	.04[a]
CCL19	0.68 (0.02 to 1.30)	.11[a]
TNF	0.67 (-0.03 to 1.32)	.14[a]
IL-2RB	0.59 (-0.05 to 1.13)	.10[a]
IL-22 RA1	0.58 (-0.05 to 1.16)	.14[a]
CXCL10	0.57 (0.01 to 1.10)	12[a]



Date of download: 3/17/2025

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Advisory Committee on Immunization Practices (ACIP)

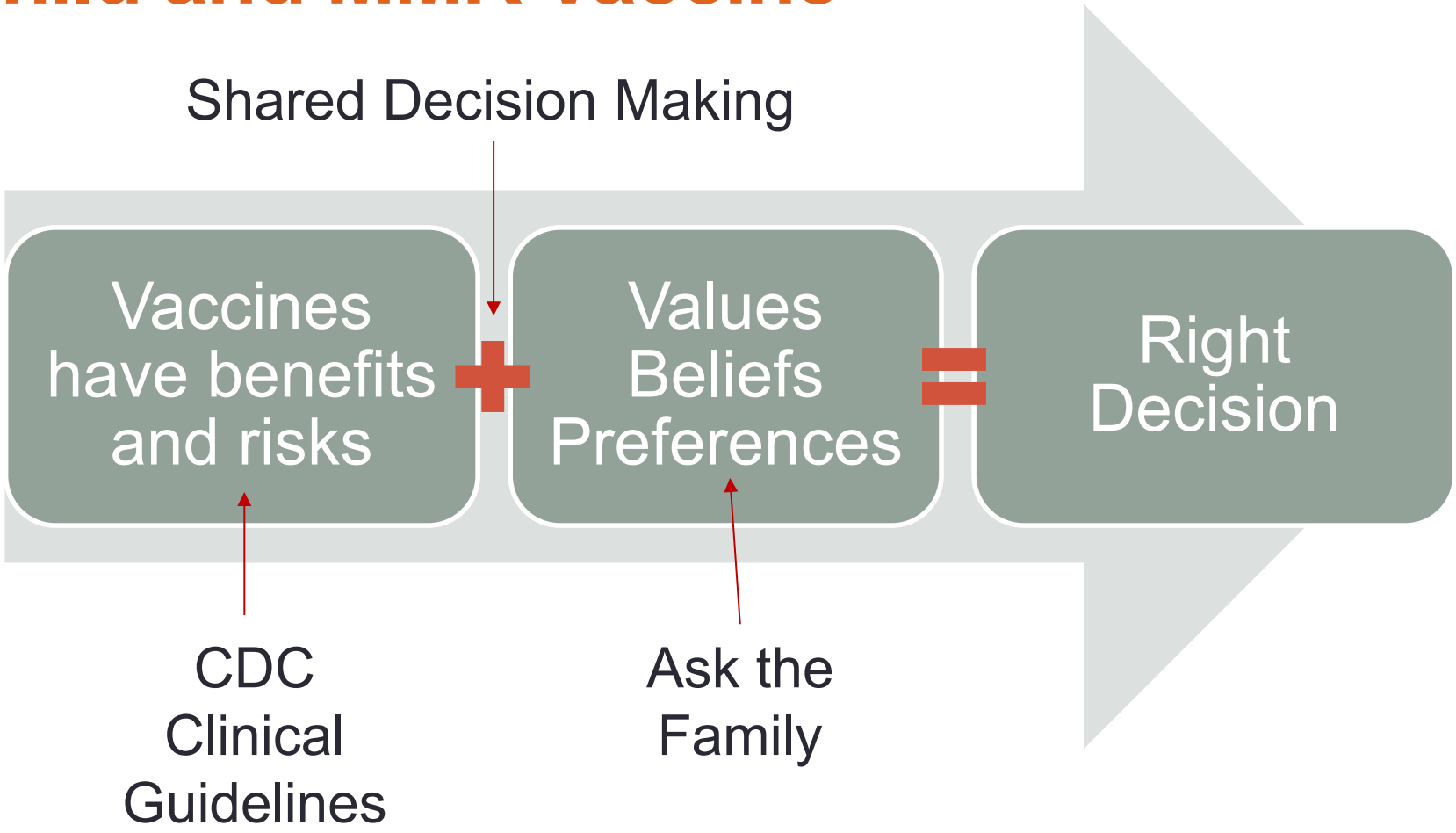
- Federal advisory committee
  - Recommendations for vaccine policy
- CDC sets the immunization schedules based ACIP
  - Clinical Guideline for doctors and patients to follow
  - Health insurers cover all costs for vaccines on schedule
- Based on balance of benefits/harms
  - MMR recommended at 12-15 months of age
  - Booster at 4-6 years of age

https://www.cdc.gov/acip/about/index.html

Case # 2: One-year-old Child Check-up

- Do you recommend an MMR vaccine?
  - Yes/No/Maybe (answer in the chat?)
  - What led you to your answer?

Child and MMR Vaccine



Different from Ear Infection Case?

- Do you recommend an MMR vaccine?
  - Your answer has public health implications
- Decision affects other people
  - Threat to people who can't get the vaccine
    - Infants; people with cancer, transplants, etc.
  - "Herd immunity" protects the entire community
  - Resources required to respond to an outbreak

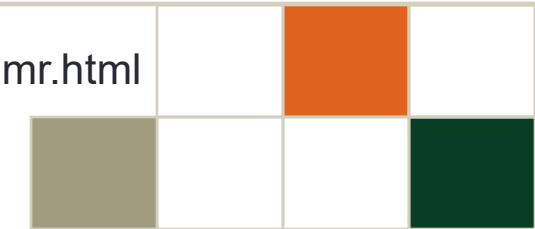
Case # 3: MMR Requirements

- Should MMR vaccine be routinely required for school entry?
  - Yes/No/Maybe (do NOT answer in the chat)
  - Kahneman's *Thinking, Fast and Slow*
    - Group identity
    - Information sources

Best Available Information

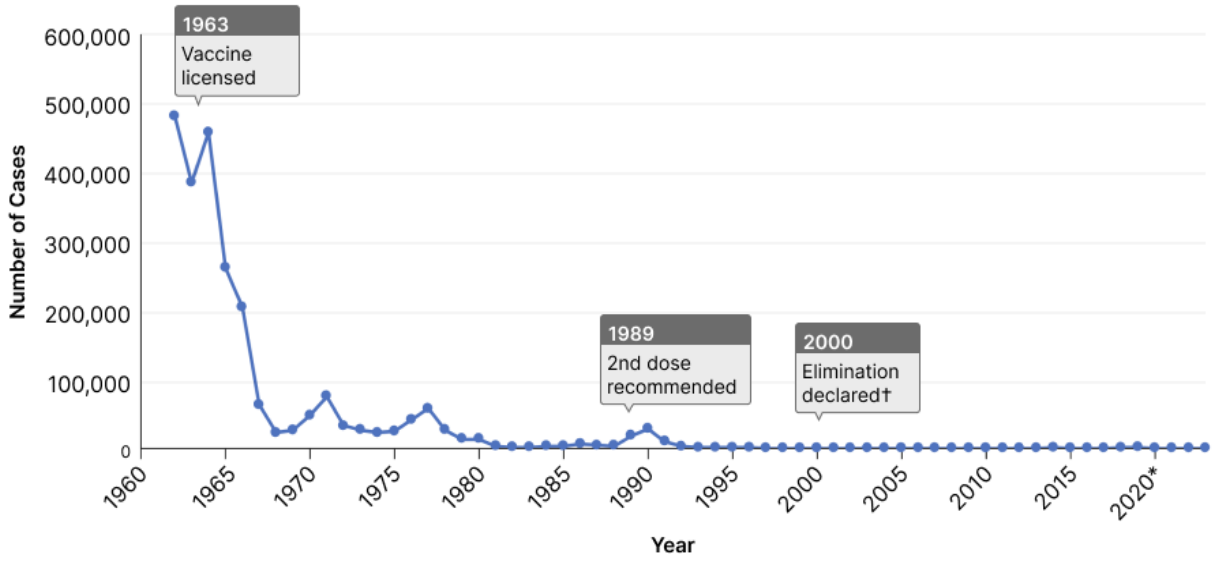
- Herd immunity
  - >95% of a population vaccinated
  - Varies according to specific disease
- Measles
  - Infection: >1/1000 mortality, encephalitis
  - Vaccine side effects
    - 1/3000 febrile seizure
    - 1/40,000 immune thrombocytopenic purpura (ITP)

https://www.cdc.gov/vaccine-safety/vaccines/mmr.html



Measles Outbreak (US), 2025

- 607 confirmed measles cases
- 74 hospitalizations (nearly all children)
- 3 deaths (2 children)
- 97% of cases are unvaccinated (or unknown)
- Gaines County, Texas
  - 82% MMR vaccine rate
  - >95% recommended



CDC data as of April 3, 2025.
https://publications.aap.org/aapnews/news/31764/CDC-provider-letter-offers-guidance-on-measles

American Samoa, 2019

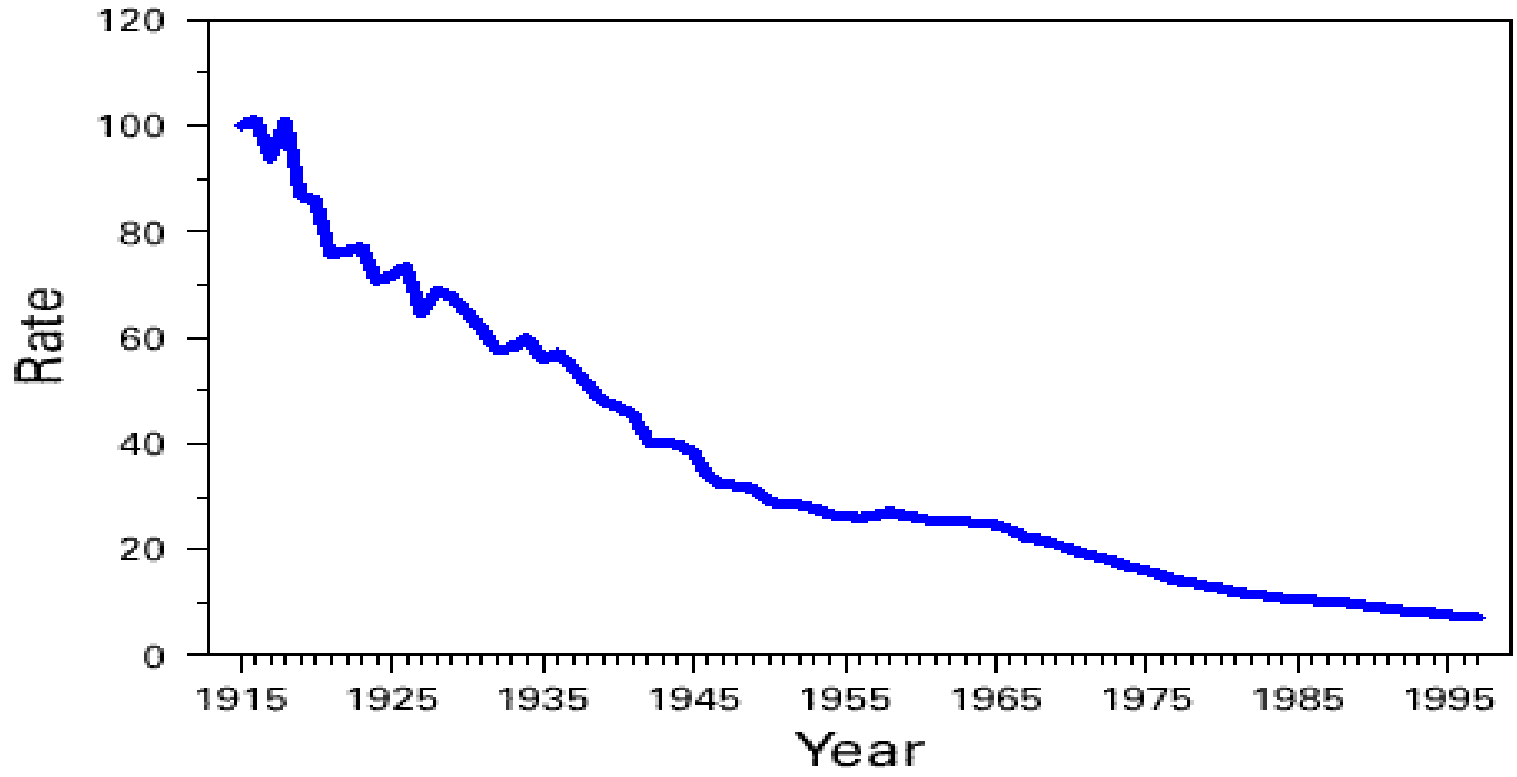
- 2013 antivaccine groups spread concerns over vaccine safety
- By 2018 60% of children did NOT receive the MMR vaccine
- Sep - Dec 28, 2019
  - 5667 reported infections
  - 81 deaths, mostly young children
- Health care system overwhelmed
    - International emergency medical teams
    - 550 clinical, public health and logistics personnel

Champredon et al. Curbing the 2019 Samoa measles outbreak. Lancet Infect Dis. 2020 Mar;20(3):287-288.

Casey et al. The roles of emergency medical teams. Western Pac Surveill Response J. 2024 Apr 26;14(6 Spec edition):1-7.

Infant Mortality (US Bureau of Statistics)

FIGURE 1. Infant mortality rate,* by year — United States, 1915–1997



*Per 1000 live births.

Ethics re Vaccine Requirements

- Obligation to vaccinate
  - “Easy rescue” argument
    - Moral obligation to help others when small burden
  - Social contract
    - Unfair to benefit from herd immunity
- Focus on the individual
  - Right to bodily integrity
  - Well-being of the child (e.g., if excluded from school)

O'Leary ST et al. Strategies for Improving Vaccine Communication and Uptake. Pediatrics. 2024 Mar 1;153(3):e2023065483.

Religious Ideas re Vaccine Requirements

- Major religions support vaccination
  - Importance of compassion, love, & caring for others
  - Vaccines components and manufacturing processes do not violate Jewish, Islamic, Catholic law
- "Philosophical" objections

Grabenstein JD. What the world's religions teach, applied to vaccines and immune globulins. Vaccine. 2013;31(16):2011–2023.

Public Opinions re Vaccine Requirements

- Surveys
  - March 2025
    - 57% said children should not be allowed to attend school
      - 35% said they should be allowed to attend
- Participatory Democracy
  - Deliberative Polling
    - Random sample of people gathers to learn about an issue, including small group discussions
    - Results represent an “informed” general public

History of Vaccination

- Smallpox
  - Highly contagious, 30% mortality
  - 1796 Edward Jenner - cowpox
  - 1959 World Health Organization (WHO)
    - Smallpox eradicated in 1977
- Mandatory vaccination in Europe in early 1800s
  - Societies of anti-vaccinationists emerged right away
    - Unequal treatment
    - Undue infringement of individual liberty

https://www.cdc.gov/smallpox/about/history.html

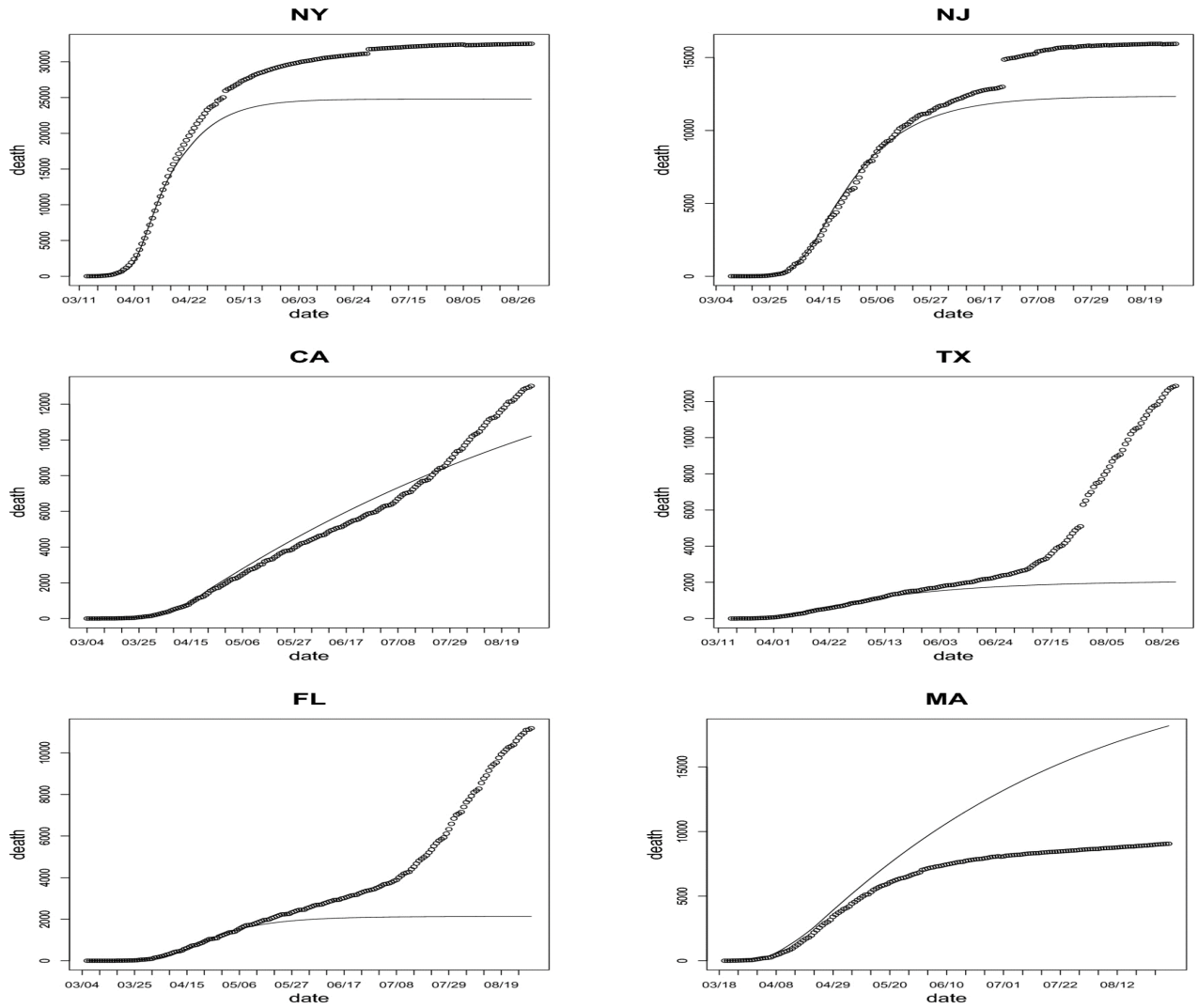
https://www.oah.org/tah/august-2/vaccination-resistance/

Conflict in Values/Beliefs/Preferences

- Benefits to society outweigh individual rights
  - Limits and obligations of “freedom”
  - We are a nation of laws
- Individual freedom worth protecting even if some people die or are harmed
  - Risk tolerance

Risk Tolerance

State COVID Policy



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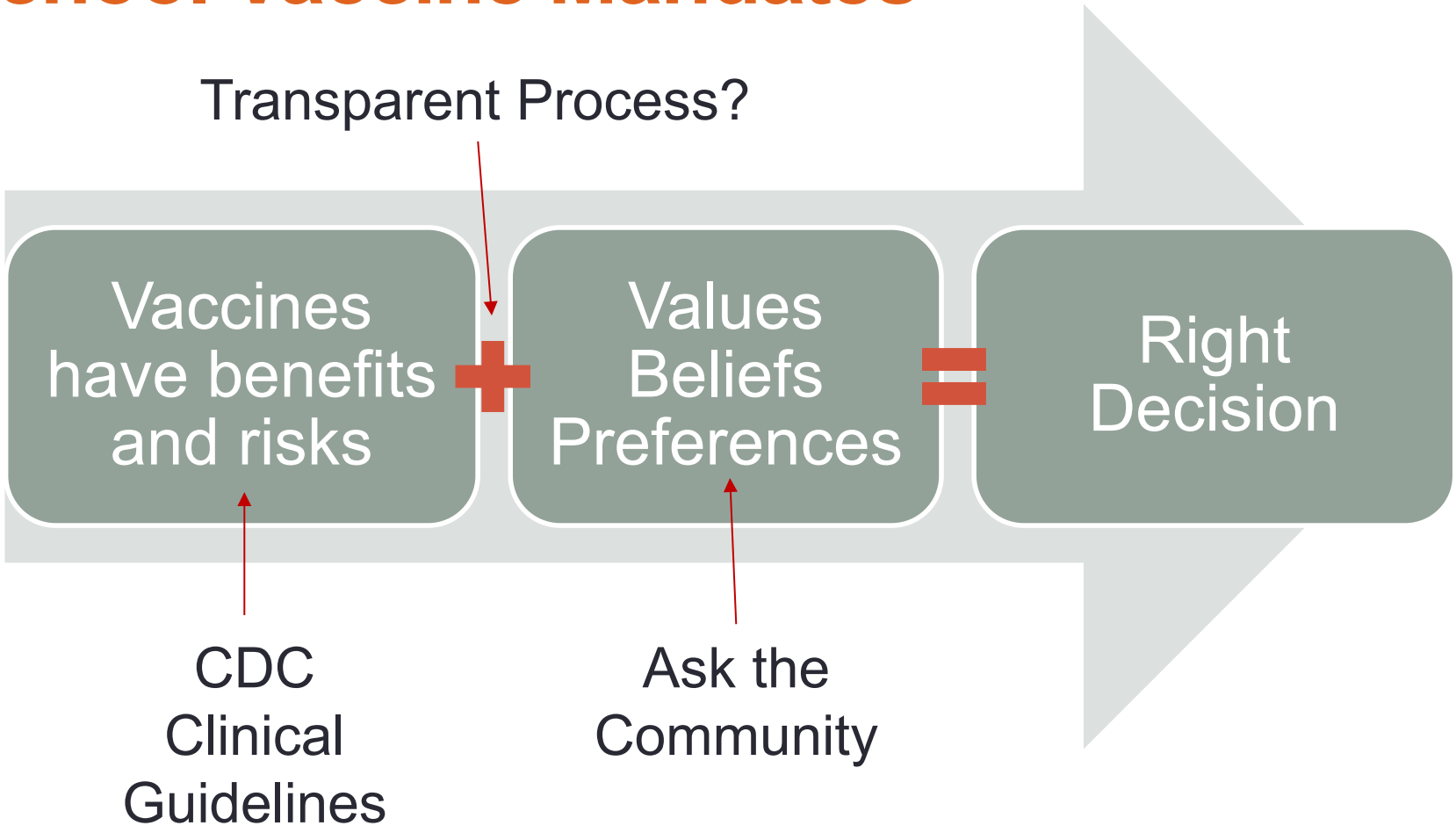
Tam KM et al. Influence of state reopening policies in COVID-19 mortality. Sci Rep. 2022 Jan 31;12(1):1677.

School Vaccine Mandates



One Approach to Vaccine Requirements

- "Libertarian paternalism"
  - People's preferences are often influenced by cognitive biases
    - Appropriate for institutions to steer people's choices in welfare-promoting directions
    - Preserve freedom of choice
- Maximize herd immunity and individual freedom
  - Require vaccines for school attendance (default condition)
  - Allow people to opt out if they really want to, such as
    - Complete a specific form acknowledging risks/benefits
    - Notarization of the form

Real Life

- Ventilator allocation during COVID pandemic
  - Florida Department of Health Ethics Committee
  - Florida Hospital Association
  - Florida Bioethics Network
  - UM/Jackson Policy
    - Committees across the medical campus
    - Co-created by community representatives, including people with disabilities

JAMA Network™

From: **Assessment of Disparities Associated With a Crisis Standards of Care Resource Allocation Algorithm for Patients in 2 US Hospitals During the COVID-19 Pandemic**

JAMA Netw Open. 2021;4(3):e214149. doi:10.1001/jamanetworkopen.2021.4149

Table 2. Adjusted Association of Race and Ethnicity With Maximum and Minimum Priority Scores

Characteristic	Maximum priority score		Minimum priority score	
	IRR (95% CI)	*P* value	IRR (95% CI)	*P* value
Race				
White	1 [Reference]	NA	1 [Reference]	NA
Black	1.00 (0.89-1.12)	.94	1.01 (0.90-1.14)	.83
Asian	0.95 (0.62-1.45)	.81	0.96 (0.62-1.49)	.86
Multiracial	0.93 (0.72-1.19)	.56	0.81 (0.61-1.07)	.14
Ethnicity				
Non-Hispanic	1 [Reference]	NA	1 [Reference]	NA
Hispanic	0.98 (0.88-1.10)	.76	1.00 (0.89-1.13)	.98
Sex				
Male	1 [Reference]	NA	1 [Reference]	NA
Female	0.93 (0.86-1.00)	.05	0.97 (0.89-1.05)	.39
Preferred language				
English	1 [Reference]	NA	1 [Reference]	NA
Spanish	0.95 (0.86-1.06)	.37	0.95 (0.85-1.07)	.41
Other	0.86 (0.69-1.08)	.20	0.87 (0.69-1.11)	.26
Median annual income for zip code, $				
<25 000	1 [Reference]	NA	1 [Reference]	NA
25 000 to <50 000	1.07 (0.97-1.19)	.17	1.10 (0.99-1.22)	.08
50 000 to <75 000	1.01 (0.89-1.14)	.88	1.03 (0.90-1.17)	.69
≥75 000	1.00 (0.84-1.20)	.97	1.10 (0.91-1.33)	.32
Primary insurance				
Medicare/Medicaid	1 [Reference]	NA	1 [Reference]	NA
Commercial	0.84 (0.77-0.91)	<.001	0.83 (0.76-0.91)	<.001
None	0.66 (0.57-0.76)	<.001	0.66 (0.56-0.77)	<.001
Age[a]	1.01 (1.00-1.01)	<.001	1.01 (1.00-1.01)	<.001
Receiving care in COVID-19 unit	0.70 (0.63-0.78)	<.001	0.69 (0.62-0.77)	<.001
Quaternary hospital	0.97 (0.87-1.09)	.62	0.97 (0.86-1.09)	.64

Abbreviations: IRR, incident rate ratio; NA, not applicable.

[a] Age on June 1, 2020; modeled as a continuous variable.

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Conclusion

- Ethics is embedded in everything we do
- Ethics questions have answers
- Best answers come from a process
  - Scientific medicine can provide the best information available at the time of a decision
  - The values, beliefs, & preferences of the community matter, even if hard to determine

Contact Information

Jeffrey P. Brosco M.D., Ph.D.
Director, Population Health Ethics
Institute for Bioethics & Health Policy
jbrosco@miami.edu

UNIVERSITY OF MIAMI
MILLER SCHOOL OF MEDICINE
INSTITUTE FOR BIOETHICS

U Health Pediatrics
UNIVERSITY OF MIAMI HEALTH SYSTEM

UNIVERSITY OF MIAMI
MILLER SCHOOL of MEDICINE