



The Long Road to a Universal Influenza Immunization Recommendation: What Took So Long?

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Disclaimer

- Thanks to Tony Fiore (CDC) for sharing slides
- I know that it is difficult to change long-standing beliefs.
- For many the “status quo” is good enough – safe and comfortable, and the opinion of many.
- I apologize, but I don’t hold those same beliefs and won’t be able to accommodate those needs today.

My Career Goals Regarding Influenza

1. Universal recommendation for influenza immunization (accomplished!)
2. Requirement that ALL HCWs are immunized (more work to do)
3. Get the world to recognize we need a personalized approach to vaccines (we have started down the path on this one)
 - TIV infants
 - LAIV children, young adults
 - TIV middle age adults
 - High dose TIV elderly

Stages of Policy Formulation:

1990-2010

1. Not old enough to know better. (1990)
2. Old enough to know better. (1995)
3. Not old enough to know. (1997)
4. Old enough to know. (1999)
5. Not old enough. (2000)
6. Old enough. (2005)
7. Not old. (current)
8. Old. (future!)
9. Not. (way in the future!!)

Reality

- There is a complex, and oft ignored, interplay between vaccine use, cognitive linguistics, human behavior and perceptions, and policy
- The connection between human behavior and frames (beliefs, perceptions) in regards to risk is particularly fascinating and *profoundly* influences vaccine policy and use among *both* patients and providers

Influenza Reality

- Epidemics occur *every* year – generally taking approx. 40,000 lives
- 1 out of every 8,000 Americans dies each year due to this disease
- Predominantly, though not exclusively, deaths occur among elderly who don't respond well to available vaccines
- Herd immunity works
- Unpredictable periodic pandemics occur
- For 2009–2010, 2 million years of life were lost, primarily among persons not covered by current recommendations
- Cost (direct and indirect) is estimated at \$87 billion/year
- Influenza vaccines are safe and effective
- This should be a “no brainer” ...why wasn't it?

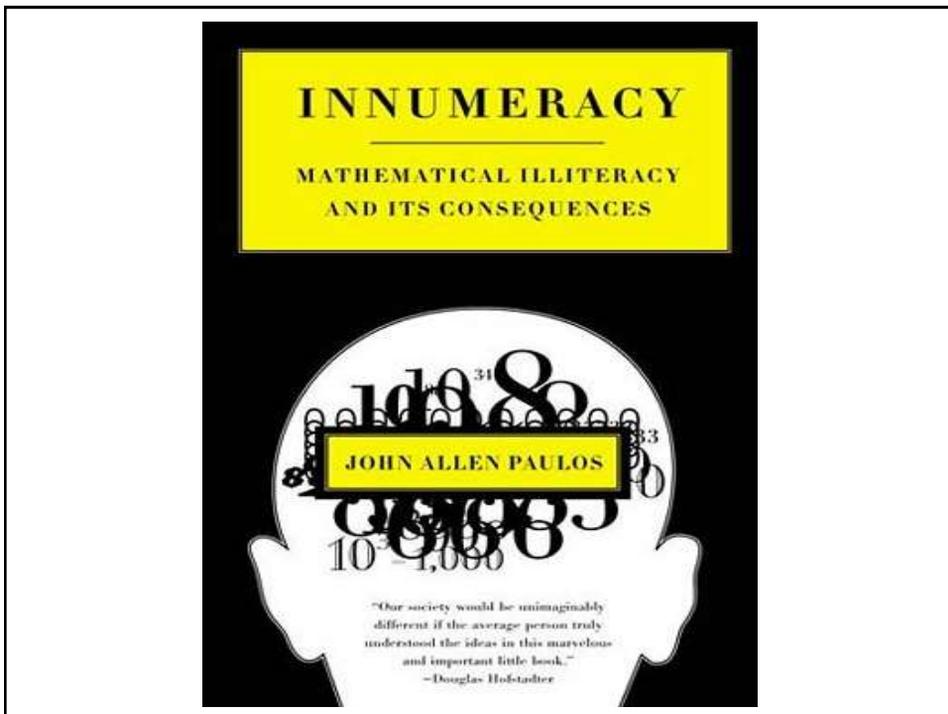
The Nature of Beliefs, Narratives, Cultural Frames, and Policy Decisions

Cultural Frames

- Vaccinology and the public health are about moral values.
- Moral values are articulated as words – and words are defined relative to at least one frame (belief).
- We think (and make decisions) in terms of systems of frames (assembled into concepts and beliefs), that we believe to be moral and make sense.
- Cognitive unconscious: the system of concepts (“frames”) that structure our brains and thinking, and which can mislead us.

Illustration

- People make decisions (including about vaccines) in a variety of ways
 - Heuristics
 - Emotion
 - Data
 - Other
- How you make decisions (esp. policy) has major ramifications for outcomes
- Examples

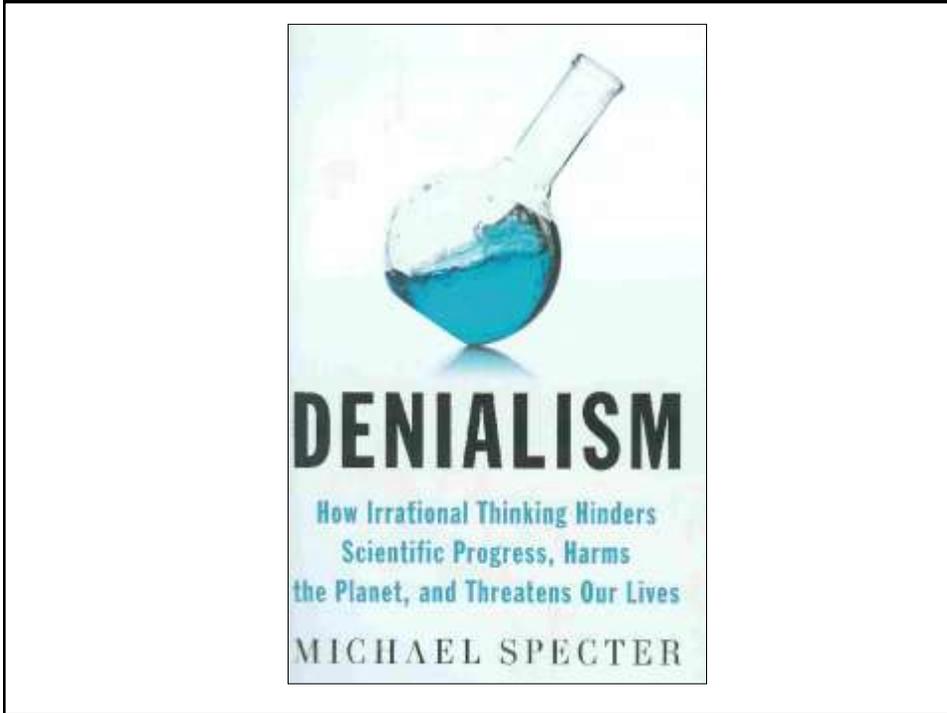


How To Spot An Innumerate

- No known genotype differences to date...
- Phenotype – Verbal
 - “I don’t care what the data say I believe...”
 - “I’m just afraid that...”
 - “It’s too risky, what if happens?”
 - “What if too many people want the vaccine?”
 - “How do we know it’s safe to get the flu vaccine every year?”

A Primer for the Innumerate

- Temporality \neq Causality
- Correlation \neq Causality
- Innumerates:
 - Have a strong tendency to personalize
 - Dramatically underestimate the frequency of coincidences
 - Believe that the plural of “anecdote” is “data”
 - Value anecdote or emotion over facts
 - Cannot understand or manipulate concepts of probability/risk



Always, Always...

- Without exception since the late 20th century, vaccines have *a/ways* been met with skepticism, fear, and denialism – this seems to be coded into our cultural DNA
- This may relate to several factors
 - Poor communication style and content for the intended audience
 - Distrust of the government, pharma, others
 - Innumeracy among the public and providers

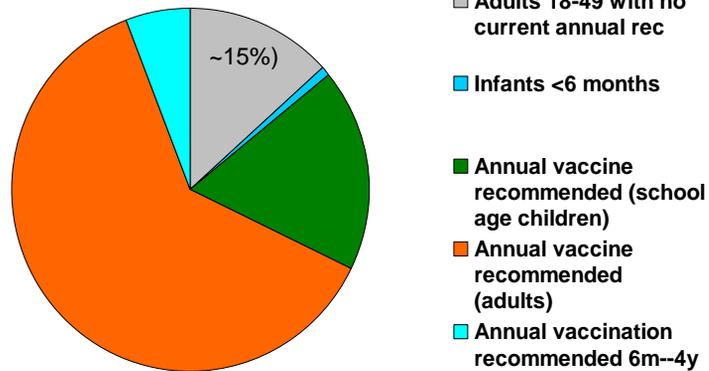
“We Have Met the Enemy...”

- Physicians and nurses are *not* exempt from innumeracy, and have generally *not* had a significantly positive influence on recent vaccine communication and coverage rates – despite the importance of their views to patient decisions
 - To some degree pediatricians have individually and corporately done the best of all specialty groups
 - We seem unable to change this state of affairs

**“I’m all for progress –
It’s change I can’t
stand.”**

Mark Twain

U.S. Population Groups by Vaccination Recommendation Status



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Current Vaccination Recommendations for Adults Ages 19-49

- **Approximately 50% already have an indication for annual vaccination**
 - Women who will be pregnant during influenza season and their contacts
 - Persons who are contacts of
 - Children younger than 5 years old
 - Elderly adults
 - Those with chronic medical conditions
 - Healthcare workers
- **Permissive recommendation for all: "Anyone who wants to be vaccinated"**

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First ACIP Discussion

- 2003–2006: Chair, Adult Immunization Workgroup, ACIP
- Discussion of universal influenza immunization recommendations during this time
- Moderate interest, but not enough to bring forth a recommendation to full ACIP

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Dr. Gregory A. Poland of the Mayo Clinic endorsed the concept of recommending flu vaccination for the entire U.S. population.

Universal Influenza Recommendation

- **February 2006 ACIP Meeting**
 - First motion made and vote called for: “ACIP signals its intent to move toward a universal recommendation”
- **Concerns**
 - Vaccine supply
 - Cost
 - Safety of repeated vaccinations

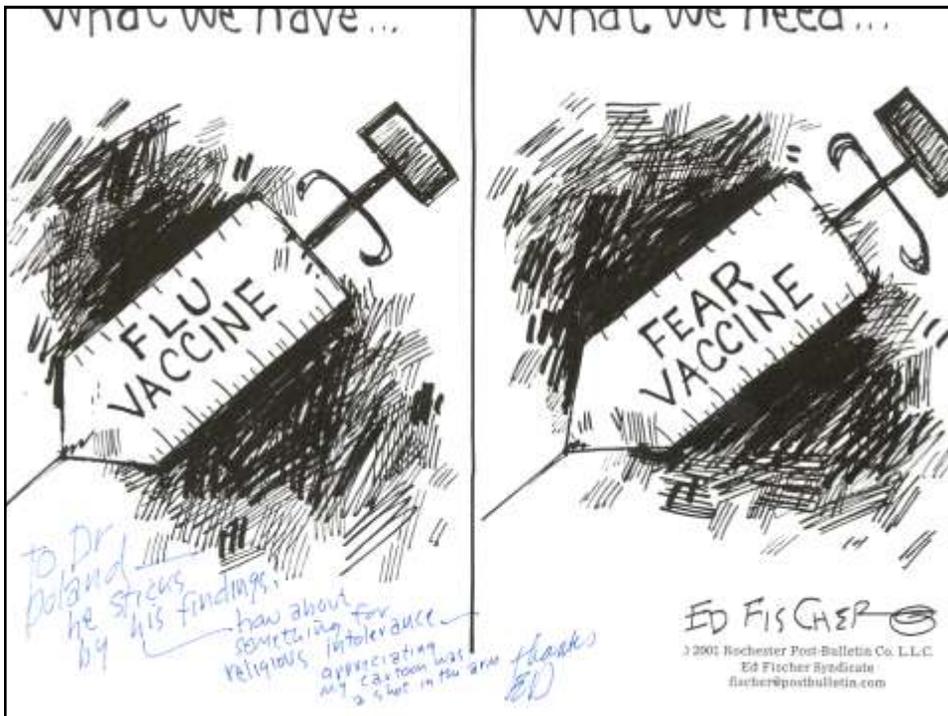
ACIP Meeting – February 2006

Dr. Poland confessed to being bothered by “creeping incrementalism.” Bicycle helmets are recommended, knowing there are not enough, as are annual mammograms without enough facilities to do them. Already, 40,000 people die annually of a vaccine-preventable disease. Health care workers are frustrated with the additional groups added every year and the “ticking clock” of pandemic influenza. Dr. Poland declared that now is the time for ACIP to be bold and to recommend influenza vaccination for all Americans. No other strategy would so well galvanize all involved, from the manufacturers to governments.

He suggested a universal recommendation could be phrased as follows: “Annual influenza vaccination is encouraged for all Americans to reduce morbidity and mortality, work and school place disruption, and infection. It also aids pandemic preparedness. There also are specific age and condition recommendations for groups who should receive priority for vaccine.”

ACIP Meeting – February 2006

Dr. Ben Schwartz, of the National Vaccine Program Office, reported on the October 2005 meeting on readiness for a universal influenza vaccination recommendation. The attendees agreed that there is a large burden of illness associated with influenza. Workshop participants acknowledged information gaps remain on the indirect effects of vaccinating some populations (e.g., incomplete data on the benefit of school children to reduce disease among family members and the elderly), and on the effectiveness and safety of repeated annual vaccinations. Ultimately, the meeting participants reached consensus to move toward a universal recommendation, but recommended that implementation occur in stages over time to avoid unintended consequences.



ACIP Meeting – February 2006

Dr. Poland moved to state that a strategy of universal influenza immunization is being evaluated by the ACIP. The motion was seconded by Dr. Lieu.

Vote

In favor: Allos, Beck, Campbell, Finger, Gilsdorf, Lieu, Morse, Morita, Poland, Stinchfield, Treanor, Womeodu

Opposed: None

Abstained: None

The motion passed.

Dr. Abramson summarized that the next statement would acknowledge that ACIP is working toward the goal of annual universal influenza vaccination in the U.S.

Universal Influenza Recommendation

- February 2006 ACIP Meeting
 - First motion made and vote called for: “ACIP signals its intent to move toward a universal recommendation”
- June 2006 ACIP Meeting
 - Second motion made and vote called for: “Plan is to implement by 2013” !?!

Potential Time-Frame for Modifying the Annual Influenza Vaccination Recommendations

- 2006–2008: Assess and address critical issues
- 2008–2009: Consider expanding recommendation to include all school-aged children (5–18 years)
- 2010–2011: Expand recommendations to include household contacts and caregivers of school-aged children.
- 2012–2013: Recommend universal vaccination, if necessary (extend recommendations to persons 18–49 years).

ACIP Meeting – June 2006

Dr. Poland's position was that the proposed timeline would not decrease confusion among providers and the public about influenza vaccination. He also found the interval to the 2013 target date to be unacceptably lengthy, because a large segment of the U.S. population will continue to become infected with and die from influenza before that time. Dr. Poland expressed concern that the influenza morbidity and mortality would result in billions of dollars in direct and indirect costs prior to 2013. Moreover, the workgroup's proposed timeline is risk-based and no evidence has been produced to support these types of programs. A faster timeline to a universal policy would actually contribute to an expansion in vaccine supply.

Dr. Poland urged the ACIP to minimize the focus on vaccine safety because this approach decreases confidence in and unnecessarily raises concerns about the influenza vaccine. He noted that a five-year pilot study of a universal policy in Ontario, Canada resulted in a doubling of vaccination levels in high-risk groups and the development of vaccine distribution and administration programs to increase pandemic preparedness. Dr. Poland supported a universal policy at this time with an incremental approach to emphasize special risk groups.

What Was Said

- “It’s the right thing – but are we ready?”
- “How do we know there will be enough vaccine? Don’t want to create a demand we can’t meet!”
- “How do we know it’s safe to get a flu vaccine every year?” (this was from a CDC staffer!)
- “Let’s implement this slowly...”
- “Let’s be moderate...”

Two More Years of Workgroup Discussions (2008-2010)

Expanding Recommendations to Adults 9–49 y/o: Issues and Concerns

- Vaccine supply
- Vaccine safety
- Vaccine effectiveness
- Disease burden
- Cost–effectiveness
- Feasibility
- Acceptability
- Implementation

Workgroup Discussions: Expanding Annual Vaccination to Healthy Adults Age 19–49

- **Vaccine supply:** Excess vaccine in every season
- **Vaccine safety:** Safe. Serious adverse events are extremely rare
- **Vaccine effectiveness:** 50–90%, depending on match, season
- **Disease burden:** Similar to adolescents. Scant population–based data on outpatient visits or work loss. From trials, 0.5–2.5 days work lost per illness. Issues of presenteeism.
- **Cost–effectiveness:**
 - In range with costs for older adolescents

Workgroup Recommendation Oct 2008: Vaccination for Healthy Adults 19–49

- **Continued support for routine vaccination of contacts of persons at risk for influenza complications:**
 - Persons 50 years old or older
 - Persons younger than 5 years old
 - Pregnant women
 - Persons with chronic medical conditions
- **Continued support for permissive recommendation (any healthy adult who wants to be vaccinated should be vaccinated)**

What Changed?

**(hint: reality challenged
denialism)**

What Changed?

- **2009–2010 pandemic**
 - ~90% of hospitalizations and deaths among those <65, and many among adults 19–49 y/o
 - Unprecedented demand for seasonal vaccine
 - New immunization programs that vaccinated adults
- **2009 H1N1–like viruses likely to continue circulation in 2010–11**

Estimates – US Influenza A/H1N1 Mortality

- **Deaths: 7,500 – 44,100**
- **Mean age of deaths: 37 years (>85% of deaths occurred in persons < 60 y/o)**
 - Seasonal influenza mean age of death = 76 y/o
- **Years of Life Lost: 334,000 – 1,973,000**

Best Comparative Estimates – US

	Deaths	Mean age of deaths	YLL
2009 pandemic	7,500 – 44,100	37.4	334,000 – 1,973,000
1968 pandemic	86,000	62.2	1,693,000
1957 pandemic	150,600	64.6	2,698,000
1918 pandemic	1,272,300	27.2	63,718,000
Average A/H3N2 (1979–2001)	47,800	75.7	594,000

PLoS Currents: Influenza, 2010

New Risk Factor for Influenza Complications

- Obesity: 28% of adults are obese; 5% morbidly obese in the US
- Disproportionate number of obese, particularly morbidly obese, among severely ill during 2009 H1N1 pandemic
 - Independent risk factor for severe illness in one unpublished analysis
 - Most (60–80%) obese or morbidly obese with influenza complications (hospitalization or death) had concomitant chronic medical condition(s)

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Race As A Risk Factor

- African-Americans have 2 fold higher rates of hospitalization in some influenza seasons
- Differences in hospitalization rates by race/ethnicity noted during 2009 H1N1 pandemic
 - African-Americans, Hispanics with higher hospitalization rates, Native peoples
- AI/AN had 4-fold increased mortality rate during 2009 pandemic in 1 small study*

*MMWR Dec 2009

New Workgroup Options: 2009–2010

1. No change
2. Add new possible risk factor indications
 - a) Obesity?
 - b) Race/ethnicity?
 - c) Provisional new risk factor indication(s) for 2010–11 season; re-evaluate later
3. Provisional universal recommendation for 2010–11 season; re-evaluate later
4. Universal recommendation: Two sub-options
 - a) Full implementation immediately in 2010–11, or
 - b) Phase-in: 2 stage as was done for universal childhood recommendation
 - 1) Begin vaccinating all adults in 2010–11 season where feasible, with special efforts to reach adults with newly recognized risk factors
 - 2) Full implementation 2011–12 season

Option: No Change

- **Pro**
 - Consistent with 2008 decision to wait for more information and see how child recommendation plays out
 - Keeps focus on those at higher risk in this age group
 - No additional demands on supply, programs
- **Con**
 - Younger adults not infected or vaccinated during 2009–10 still at higher risk for infection c/w with other risk groups
 - Young adults with risk factors, and their care providers, often do not recognize current vaccine indication and coverage remains low
 - Does not take into account new information on risk factors
 - Does not take advantage of interest in vaccine and program momentum associated with pandemic response

Option: Add New Indications

- **Pro**
 - Acts on new information
 - Targets higher risk group
- **Con**
 - Some uncertainty regarding true risk vs. proxy or previously known risk
 - Another small incremental change – who is left?
 - Past experience indicates that persons with risk factors don't recognize need for vaccination

Option: Universal Recommendation: Pros

- **Seasonal vaccine will include 2009 H1N1 –like virus; many adults <65 will remain susceptible in Fall 2010**
- **Addresses issue of adults with risk factors not being aware of vaccination recommendations**
- **Long term goal to advance to universal adult recommendations had been signaled for several years**
- **Potential to take advantage of new interest in influenza vaccination**
 - Universal recommendations might address low coverage among adults with risk factors
 - Don't self identify as being at risk
 - Financing/reimbursement might follow
 - Potential for another pandemic real
- **Newly recognized risk factors among 18–49 year olds for 2009 H1N1 – obesity and race/ethnicity?**
 - Incremental expansion to 90+% (from current 85%) difficult to justify

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Option: Universal Recommendation: Cons

- **Questions remaining unanswered**
 - Why don't recommended adults get vaccinated?
 - What strategies might work?
 - What is uptake among children after universal rec?
 - Little evidence that age based recommendation for 50–64 year olds increased coverage
 - Vaccine shortages and delays in 2000–05 likely contributed to slow uptake in 50–64 yo
 - Potential to lose focus on those clearly at higher risk (medical risk factors, pregnant)
 - Likely to be ahead of other countries/WHO – disproportionate use of vaccine resources in U.S.?

Workgroup Opinions

- **No one favored the following options:**
 - Status quo
 - Incremental addition of new risk factors
 - Provisional universal recommendations
- **All favored advancing to universal recommendation**
 - Split regarding immediate implementation vs phased in implementation over 2 years

Universal Recommendation for Adults: Two Options

- **Those who favored phased in approach:**
 - Concerned that immediate implementation creates demand on programs with insufficient notice
 - Concerned that vaccine pre-booking already occurred and might lead to demand exceeding supply for some providers
- **Those who favored immediate implementation:**
 - 2009 H1N1-like viruses will circulate in 2010-11, will continue to cause increased morbidity among young adults, including those who do not currently have a vaccine indication
 - Does not fully address current problem – that persons at risk don't self identify – until 2011-12
 - Does not take immediate advantage of current interest in vaccination among younger adults and their providers

ACIP Meeting – February 2010

- ACIP unanimously passed a resolution endorsing a universal influenza recommendation for all Americans!
- 7 years after I first formally proposed it ...
- Conclusion: Policy changes are slow and difficult to achieve absent an undeniable external threat that illuminates the futility of denialism

FEBRUARY 26, 2010...7:35 PM

Universal Influenza Immunization: Now Is the Right Time

 [Jump to Comments](#)

On February 24th, the CDC's [Advisory Committee on Immunization Practices \(ACIP\)](#) filled in the final piece of its piecemeal influenza immunization recommendations by [advising](#) that healthy adults aged 19-49 receive the vaccine along with all the [previously targeted groups](#) aged 6 months and older. Thanks to the 2009 pandemic H1N1, now everyone is considered “high risk” for the flu.



Dr. Greg Poland

But some experts had been urging the move long before last year. [Dr. Gregory Poland](#) of the Mayo Clinic had been particularly outspoken, often delivering impassioned pleas to his fellow ACIP members to end the “creeping incrementalism” of adding new risk groups to the list one by one. He urged the committee instead to simply recommend flu vaccine for all. In a 2006 [point/counterpoint](#) in our primary care publications with current ACIP chair [Dr. Carol Baker](#) of Baylor College of Medicine, Dr. Poland said

he believed the time was right; she didn't.

At that time, many experts agreed with Dr. Baker. They supported the universal immunization concept in principle, but said more evidence was needed to justify it and better infrastructure was required to make it feasible.

At the February ACIP meeting, I asked Dr. Baker what had changed. Her answer: “What we've learned is that infrastructure is built *after* ACIP makes a recommendation. Otherwise, there's a year to say, ‘Well,



Lessons Learned

- Framing must come before policy.
- One such frame: The provision of vaccines (and vaccine policy) is a moral issue and requires acting responsibly, powerfully, and courageously.
- Incrementalist thinking is the opposite of these virtues, and in the case of vaccine policy, can hurt people.
- We now live in the stage Thomas Kuhn predicted – old and new paradigms coexist with little interaction – this inhibits innovative solutions and common understandings.

Lessons Learned, continued

- Public health policy, like medicine, must always be practiced in an environment where you have less data than you would like
- Policy can be made *before* absolute clarity is achieved
- Recommendations drive infrastructure development – *not* the other way around
- Change is difficult...fear is omnipresent
- Now, lets get a HCW flu vaccine requirement!

**“We learn from
history that men
never learn anything
from history.”**

George Bernard Shaw

For Handouts of Slides or References

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Thanks! Gregory A. Poland, MD

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