Public Health and Clinical Medicine

Joshua M. Sharfstein, M.D.

November 5, 2016
Disclosures

Consultant to Audacious Inquiry and Sachs Policy Group
Two Perspectives on Health

Clinical Medicine: Care of the Patient

Population Health: a Healthy Community
Two Ships Passing in the Night

Clinical Medicine
- Insurance Coverage
- Quality
- Outcomes
- Measurement

Public Health
- Restaurant Inspections
- Lead Poisoning
- Clean Air
- Clean Water
- Injury Prevention
- Emergency Response
Public Health

“What we as a society do collectively to assure the conditions in which people can be healthy.”

-- Institute of Medicine, 1988

Photo: CDC
10 Core Functions of Public Health

Source: CDC
DETERMINANTS OF HEALTH

Policies and Interventions

Physical Environment

Behavior

Individual Biology

Social Environment

Access to Quality Health Care

IOM, Healthy People 2010
A CENTURY OF SAVING LIVES—MILLIONS AT A TIME 1916/2016
CLINICAL VS PUBLIC HEALTH APPROACHES


Fire Department

Police Department

Health Department

A CENTURY OF SAVING LIVES—MILLIONS AT A TIME 1916/2016
Pop Quiz

Can public health authorities…

• Quarantine a city?
• Conscript physicians to provide care?
• Shut down a hospital?
Definitions of Crisis

• “A time of intense difficulty or danger”
• “A time when a difficult or important decision must be made”
• “The turning point of a disease when an important change takes place, indicating either recovery or death.”

--Oxford English Dictionary
Crisis – and Response

- Ebola virus
- Zika virus
- Epidemic of opioid overdose
- Flint, Michigan
- Drug pricing
The Opportunity in Crisis for Engagement Between Health and Healthcare

• “Crisis creates a context in which challenges to existing norms and practices may be made…”
Examples

- Training (opioids)
- Surveillance (influenza)
- Mobilization for treatment (opioids, anthrax)
  - Emergency authority
- Support for Clinicians (Ebola)
- Policy Change (all)
Case 1

14-month-old girl with a 2-week history of a diaper rash that then generalized, associated with body swelling, light hair, and pallid skin.
More History

Breastfed until 8 months
Did not tolerate formula
Switched to rice-based “milk”
Diagnosis: Kwashiorkor

Body requires 1-2 g/kg/day of protein
Rice-based beverages <1 g per 8 oz
At least 12 cases of kwashiorkor in literature from rice-based beverages, including deaths
Marketing of Rice-Based Beverages

Rice Dream: “Complete nutrition – Rice dream is enriched with the same amount of Calcium, Vitamins, A, D & B12 found in milk.”

   – Website: Nutritional profile is “similar to milk.”

WestSoy Rice Beverage:

Exploring alternatives to milk? Don’t skip our delicious WestSoy Rice Beverage or you’ll miss out on a refreshing, nutritious drink you’re sure to love! It tastes so good, and it’s enriched with calcium and vitamins A and D, making it a perfect choice for people who don’t drink dairy milk.\(^2\)
Drink Rice: “a healthy, non-allergic alternative to dairy, soy, or nut beverages. A tasty drink everyone can enjoy.”

RiceMilk by Whole Foods: “a tasty alternative to dairy or soymilk.”
Moving from Case to Policy


**Press**: Philadelphia Inquirer

**Government**: Congressman Henry A. Waxman letter to FDA

RiceDream Package now advises against use by kids under 5 unless advised by MD
Case 2

9 month old boy referred to the ED by primary care doctor for evaluation of persistent crying and fever. A cough with runny nose for 2-3 weeks, intermittent fever. Vital signs on arrival had fever and elevated heart rate, otherwise stable. Mother reports giving $\frac{3}{4}$ dropper of ibuprofen. Stable blood tests, given antibiotics and sent home.
12 hours later, the infant returned to the Emergency Department in full cardiopulmonary arrest, and was pronounced dead after 20 min of advanced life support.
Postmortem blood and hepatic tissue analyses revealed markedly elevated levels of pseudoephedrine, PPA and dextromethorphan.

Cause of death - mixed drug intoxication.

The case is presented to the Health Commissioner at child fatality review.
What to do?

- Medical Examiner has associated four deaths in Baltimore with their use, and others are reported in medical literature.

- There is no evidence of efficacy for these medications in children.
The Baltimore Statement

“The evidence shows that these products have no benefit, and the side effects may indeed cause harm”

“Recommend that families be aware of these risks and not use over-the-counter cough and cold medications for children ages five and under.”
Closer Look

• OTC cough and cold meds approved through FDA monograph

• Never evaluated in pediatric population for monograph process

• While technically considered “Generally Recognized As Safe” … not safe, not effective, not generally recognized as such
March 1, 2007

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, Room 1-23
12420 Parklawn Dr., Rockville, MD 20857

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition under 21 CFR Sec. 10.30. This Citizen Petition requests the Commissioner of Food and Drugs to take the following action with respect to 21 CFR 341, the Final Monograph (FM) for Cold, Cough, Allergy, Bronchodilator, Antiasthmatic Drug Products for Over-the-Counter Human Use.

ACTION REQUESTED

The Petitioner requests the Commissioner to:

1. Provide a statement to the public explaining that over-the-counter antitussive, expectorant, nasal decongestant, antihistamine and combination cough and cold products have not been shown to be safe and effective for the treatment of cough and cold in children under six years of age.

2. Notify manufacturers of these products whose labeling 1) uses such terms as “infant” or “baby,” or 2) displays images of children under the age of 6 that:
   a. Such marketing is not supported by scientific evidence; and
   b. Manufacturers will be subject to enforcement action at any time.
U.S. Reviewing Safety of Children’s Cough Drugs

By GARDINER HARRIS  MARCH 2, 2007

The medicine sections of supermarkets and drugstores usually carry products marketed for young children.

Mike Mergen for The New York Times
SILVER SPRING, Md., Oct. 19 — A Food and Drug Administration panel of experts voted today to ban scores of popular over-the-counter cough and cold products intended for children under the age of 6.

If put into practice, the vote could transform pharmacy shelves and change the way many parents cope with the myriad colds caught by young children. The vote comes a week after major manufacturers agreed to withdraw more than a dozen cough and cold products labeled for use in infants and babies.

But there are reasons to suspect that further changes, if they come, will not be immediate.

While the panel voted 21 to 1 to ban these products for use in children younger than 2, its vote to ban them in children aged 2 to 5 was 13 to 9. The F.D.A. usually follows the advice of its independent expert panels, but the closer the vote, the more likely the agency is to ignore the advice.
In 2007, amid mounting concern that infant cough and cold medicines were unsafe and misused, manufacturers voluntarily withdrew products intended for children younger than 2. The makers revised the labels on the rest of the medicines, which now warn parents that they should not be given to children younger than 4.

Government researchers said on Monday that those moves have had a remarkable effect: a significant decrease in emergency hospital visits by toddlers and infants with suspected medical problems after using these medicines.

Dr. Daniel Frattarelli, a former chairman of the committee on drugs at the American Academy of Pediatrics, praised the study, saying it showed that “the label is a very powerful tool for changing parent behavior.”
Case 3: Ebola

9/28: NIH to receive a patient
9/30: Patient identified in Dallas
10/8: Patient dies
10/12: Healthcare worker tests positive
10/13: Judge halts incinerated waste
10/14: Second healthcare worker tests positive
10/15: Disclosed: 2nd healthcare worker was on a plane
10/19: Congressman: “Every outbreak novel or zombie movie you see starts with somebody from the government sitting in front of a panel like this saying there’s nothing to worry about.”
U.S. Ebola (continued)

10/23: Healthcare worker in NYC who worked overseas
10/24: Governor Christie (NJ) and Governor Cuomo (NY) impose quarantines


What is going on?
Gonsalves and Staley, December:

For those of us who lived through the early days of the U.S. AIDS epidemic, the current national panic over Ebola brings back some very bad memories. The toxic mix of scientific ignorance and paranoia on display in the reaction to the return of health care workers from the front lines of the fight against Ebola in West Africa, the amplification of these reactions by politicians and the media, and the fear-driven suspicion and shunning of whole classes of people are all reminiscent of the response to the emergence of AIDS in the 1980s.

--New England Journal of Medicine, 2014
Rumors

- Importance
- Ambiguity
  - Source
  - Content
- Anxiety
- Personal involvement

“People tend to trust information from acquaintances without verifying it…and they do what others are doing.”*


What’s Happening?

- Crisis in perception if not a disaster in reality
- Fear far out of proportion to risk
- Rumors = big problem
- Core of fear = lack of trust
What to do?

• Relationship with medical system vital
  https://www.youtube.com/watch?v=dC5LATS_eXk

• Address fears directly

• Give people something to do instead of just be afraid
Conclusion

• Important to understand broad charge and authority of public health
• Emergencies and crises bring public health and healthcare into contact
• Strong relationships can lead to mutually beneficial engagement during moments of challenge.