

# **HPV VACCINE, TB MASKS AND CHILD CAR SEATS**

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*This is to acknowledge that Anne M. Brancaccio, MD has not disclosed any financial interests or other relationships with commercial concerns related directly or indirectly to this program. Dr. Brancaccio will not be discussing off-label uses in her presentation.*

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INTERESTS:

ANNE MARIE BRANCACCIO, MD IS AN ASSOCIATE PROFESSOR OF GENERAL MEDICINE. SHE JOINED UTSW IN 2004. SHE SPENDS MOST HER DAY IN ASTON CLINIC. SHE ALSO IS ACTIVE IN PCIM CLINIC, AND A MENTOR IN THE COLLEGES PROGRAM. OUTSIDE OF MEDICINE, SHE ENJOYS SWIMMING WITH HER TWO BOYS AND COACHING THEIR SOCCER TEAM.

PURPOSE AND OVERVIEW:

HPV VACCINE HAS BEEN APPROVED BY THE FDA FOR SEVERAL YEARS BUT IS NOT IN WIDESPREAD USE. THIS TALK WILL EXAMINE WHY BOTH THE PUBLIC AND PHYSICIANS ARE NOT ACCEPTING OF THIS VACCINE. TWO OTHER HEALTH INITIATIVES WIDELY ACCEPTED BY THE PUBLIC, CAR SAFETY SEATS AND FIT TESTING, WILL BE DISCUSSED.

EDUCATIONAL OBJECTIVES:

- DISCUSS BASIC FACTS ABOUT HPV VACCINE
- DISCUSS REASONS WHY HPV VACCINE IS NOT REQUIRED FOR SCHOOL ADMISSION
- COMPARE AND CONTRAST TWO OTHER PUBLIC HEALTH INITIATIVES (CAR BOOSTER SEATS AND FIT TESTING FOR TB MASKS) WITH HPV VACCINE

## Objectives

- Discuss basic facts about HPV vaccine
- Discuss reasons why HPV vaccine is not required for school admission
- Compare and contrast two other public health initiatives (car booster seats and FIT testing for TB masks) with HPV vaccine

## HPV Infection Rate—All types

- USA: 1 in 4 women aged 14-59
- Equivalent to 25 million American women
  - 25% of women 14 - 19
  - 45% of women 20 - 24
  - 27% of women 25 – 29
  - 28% of women 30 – 39
  - 25% of women 40 – 49
  - 20% of women 50-59

Most common sexually transmitted disease in US

Half of all sexually active women estimated to become infected at some point in their lives; most clear it

Source: CDC

## Cervical Cancer

- Kills about 4000 women yearly in the US
- About 10,000 -13,000 new cases yearly
- 8<sup>th</sup> most common cancer in women
- Median age at diagnosis is 48
- Mortality from cervical cancer in US half the worldwide rate
- Worldwide: second most common and fifth most deadly cancer in the world in women
- 16/100,000 affected; 9/100,000 die worldwide yearly
- 470,000 new cases and 233,000 deaths yearly
- Source CDC and WHO

## Men and HPV

- 50-75% of sexually active men become infected at some point
- About 5000 cases of anal cancer yearly in US
- About 700 men die yearly from anal cancer
- SOURCE: CDC and American Cancer Society



## Gardasil

- Vaccine against HPV types 6, 11 (Warts), 16 and 18 (cancer) ( Merck)
- Targets viruses that accounts for 50-70% of cervical cancer worldwide and 90% of warts
- 3 dose series over 6 months
- Cervix (Glaxo) approved later for just 16 and 18

## Gardasil

- Approved in 2006 for use on females aged 9-26
- Recommend beginning at age 10-11
- In 2006, approved in six months under FDA's priority review process
- Later approved for use in older women

## Men

- In 2009 CDC gave “Permissive Guidance”
  - Start vaccine at age 11
  - Start to vaccinate routinely ages 13-21 who have not completed 3 doses
  - Any man up to age 26 can be vaccinated
  - Men who are immunocompromised or have sex with men should be vaccinated up to age 26
  - Changed in 2011 by Advisory Council on immunization Practices changed to a recommendation

## CDC Recommendations: Men

- Clinical trials have shown prevention of anal precancers and genital warts, but no studies show prevention of cancer
- Indirect protection of females

## Typical FDA Approvals

- A *Priority Review* designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A *Priority Review* means that the time it takes FDA to review a new drug application is reduced. The goal for completing a *Priority Review* is six months

## Vaccinations Mandatory in Texas

### 2012-2013 Texas Minimum State Vaccine Requirements for Students Grades K-12

This chart summarizes the vaccine requirements incorporated in the Texas Administrative Code (TAC), Title 25 Health Services, Subchapter 67.41 to 67.72. This chart is not intended as a substitute for consulting the TAC, which has other provisions and details. [Click here for more on the TAC language.](#)  
The Department of State Health Services (DHS) is granted authority to set immunization requirements by the Texas Administrative Code, Chapter 25, Health & Safety, Subchapter A, General Provisions.



#### IMMUNIZATION REQUIREMENTS

A student shall show acceptable evidence of vaccination prior to entry, attendance, or transfer in a child-care facility or public or private elementary or secondary school in Texas.

Vaccine Required (Antidote to toxin and antibodies)	Minimum Number of Doses Required by Grade Level					NOTES
	K - 3rd	4th - 5th	7th	8th - 10th	11th - 12th	
Diphtheria/Tetanus/Pertussis (DTaP/DT/DTaP)	5 doses or 4 doses	5 doses or 4 doses	3 dose (DTaP) series and 1 Tdap/DT booster within last 10 years	2 dose primary series and 1 Tdap/DT booster within last 10 years	3 doses	3 doses at distinct intervals; primary series, one dose must have been received on or after the 4th birthday; booster, 4 doses in total; requirement if the 4th dose was not received on or after the 4th birthday: For students aged 7 years and older, 1 dose must meet the requirements; one dose must be received on or after the 11th birthday. For students aged 11 years and older, 1 dose of Tdap is required if at least 10 years have passed since the last dose of tetanus/diphtheria/tetanus toxoid (Td/TdP) vaccine. For 11-12 grade, 1 dose of Tdap is required when 10 years have passed since the last dose of tetanus/diphtheria/tetanus toxoid (Td/TdP) vaccine. It is acceptable to place a Tdap if an initial dose has been received in another state.
Polio <sup>1</sup>	4 doses or 3 doses	4 doses or 3 doses	4 doses or 3 doses	4 doses or 3 doses	4 doses or 3 doses	4 doses of polio vaccine must be received on or after the 4th birthday. However, 3 doses and 1 booster dose of the 1st dose is acceptable for older than 4th birthday.
Mumps, Measles, and Rubella <sup>2,3</sup> (MMR)	2 doses	2 doses	2 doses	2 doses	2 doses	The first dose of MMR must be received on or after the 1st birthday. For K-12 grade, 2 doses of MMR are required. The 1st dose of MMR is required for all students entering school, and one dose each of mumps and measles is required.
Hepatitis B <sup>2</sup>	3 doses	3 doses	2 doses	2 doses	2 doses	For students aged 11-12 years, 2 doses are of the hepatitis B vaccine: Hepatitis B vaccine (HBV) and HBV booster. (HBV and HBV booster are not required for students aged 11-12 years and older.)
Varicella <sup>2,3</sup>	2 doses	1 dose	2 doses	1 dose	1 dose	The first dose of varicella must be received on or after the 1st birthday. For students K-12 and 11-12 grade, 2 doses are required. 1 dose is required for all other grade levels. For any student who receives the 2nd dose on or after 11 years of age, 2 doses are required.
Meningococcal			1 dose			
Hepatitis A <sup>2,3</sup>	2 doses					The first dose of Hepatitis A must be received on or after the 1st birthday.

<sup>1</sup> Examples of the doses include: 1 dose of polio vaccine, 1 dose of polio vaccine, 1 dose of polio vaccine, 1 dose of polio vaccine, 1 dose of polio vaccine.

<sup>2</sup> Examples of the doses include: 1 dose of mumps vaccine, 1 dose of measles vaccine, 1 dose of rubella vaccine, 1 dose of mumps vaccine, 1 dose of measles vaccine, 1 dose of rubella vaccine.

<sup>3</sup> Examples of the doses include: 1 dose of hepatitis B vaccine, 1 dose of hepatitis B vaccine, 1 dose of hepatitis B vaccine, 1 dose of hepatitis B vaccine, 1 dose of hepatitis B vaccine.

## Vaccine Exemptions in Texas

- Medical reason
- Conscientious/religion objection
- Member of Armed services
- 13,000 opt out in 2011
- Only Arkansas, Mississippi and West Virginia will **not allow exemption for religious belief**
- AMA is opposed to vaccine exemptions for religious beliefs

## States with mandatory HPV vaccination

- None
- Several have required insurance companies to cover, or to provide materials in schools
- Since 2006, NH has provided free to all girls under age of 18 ( Live Free or Die); 14,000 doses given the first year
- South Dakota has similar program

## What happened in Texas?

- April 2007, Governor Perry issued an executive order mandating vaccine for all girls entering sixth grade
- Texas legislature overruled
- Governor Perry withheld his veto

## Merck contributes to Governor Perry's Campaign

Perry received \$6000 from Merck

Perry's former chief of Staff is now a lobbyist for Merck

Perry's current chief of Staff's mother in law is Texas State Director of Women in Government

Executive from Merck's vaccine division sits on the board of Women in Government

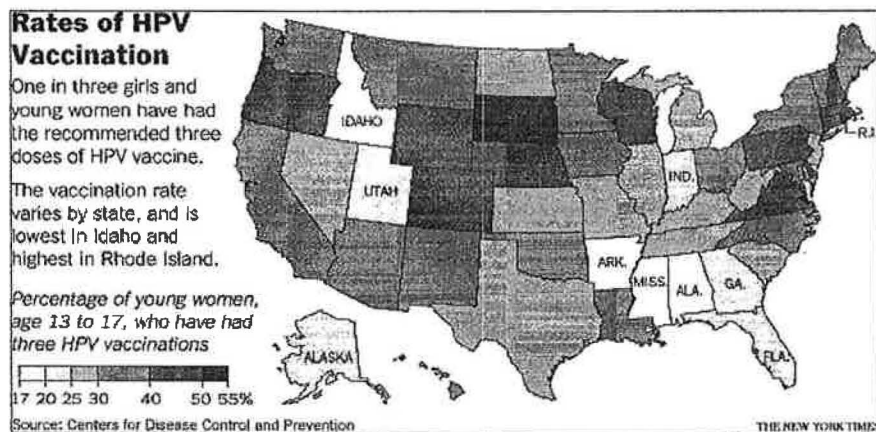
## Website for Women in Government

[www.womeningovernment.org](http://www.womeningovernment.org)

## Vaccination Rates

- In 2011 only 32% of all girls in the US 13- 18 years of age
- Average age for first intercourse about 17 for both boys and girls
- Source: CDC

## Chart from New York Times



## TMA did not support Governor Perry

- “Mandating a vaccine for a disease not spread by casual and/or occupational contact—and currently only available to one gender—represents a considerable departure from past practice concerning school immunization requirements. School immunizations requirements came into existence to protect schoolchildren from outbreaks of contagious disease in the school setting, not to compel vaccination”

## Hepatitis B Vaccine

- In 1991 national strategy adopted to eliminate HBV:
  - vaccination of Infants at birth
  - all children under 19 years of age not yet vaccinated
  - Sex partners and household contacts of HBV positive persons
  - Men who have sex with men
  - Sexually active persons with more than one partner in the last 6 months
  - Persons seeking evaluation of any sexually transmitted disease
  - IV drug Users
  - Healthcare workers
  - ERSD –dialysis and headed towards dialysis
  - Anyone with chronic liver disease
  - HIV positive
  - Travelers to high HBV areas
  - All DM patients 19-59—greater than 60 at doctors discretion
  - Or anyone that asks for one

## Hepatitis B (continued)

- In 2009, 3, 374 reported new HBV cases; estimated actual about 38,000
- Estimated total number of US infected with HBV is 800, 000- 1.4 million
- 620,000 estimated die worldwide from HBV



## TMA survey

- January 2008 TMA conducted an online survey of Texas PCP
- Only 27 % knew lifetime risk of HPV; only 45% knew what percentage of cervical cancer caused by HPV
- 20% not convinced it was safe; 12% not convinced effective

## TMA survey

- Biggest barriers cited were
  - insurance coverage (97%)
  - lack of parental understanding of HPV (94%)
  - Difficulty getting children into office for 3 vaccinations (82%)
  - Parental concerns about riskier behavior (70%)

## Morality Argument

- Cervix (Glaxo) provides protection against only two HPV strains, 16 and 18
- No protection against warts
- Merck mentions no protection in its ads from warts



## HPV Vaccine Side Effects Do Not Include Sluttiness

The HPV vaccine is pretty scary stuff. For starters, you probably heard from your aunt that this lady told Michele Bachman that it totally made her daughter "mentally retarded." And even if those who get the shots don't end up like that poor girl no one was ever able to locate, the vaccine is rumored to transform girls into little harlots...

## Data on Promiscuity

- 2012 study looked at 1200 women aged 15-24
- Those with vaccine more likely to use condom
- No difference in number of sex partners between those who had vaccine and those who did not
- Source: CDC

## Republicans Primary Michelle Bachman comment

- Mrs. Bachmann, of Minnesota, raised that concern by suggesting that Mr. Perry had put young girls at risk by forcing **“an injection of what could potentially be a very dangerous drug.”** Appearing on NBC’s “Today” show, she recounted that after the debate in Tampa, Fla., a tearful mother approached and said her daughter had suffered “mental retardation” after being vaccinated against HPV. **“It can have very dangerous side effects,”** Mrs. Bachmann said.

### Back to other problems: TMA Also cited the cost

- \$300-\$500 for the series in 2007
- Aetna, Unicare, and Blue Cross covered the vaccine fully in 2007
- Now most insurers pay for it

### Vaccines for Children program (VFC)

- CDC negotiated decreased price of about \$200/ series (!)
- Children can get free vaccine if eligible for Medicaid, Native Americans, Alaskans, or have insurance that does not cover the vaccine
- Obtained at Federally Qualified Health Center

## Would this be cost effective?

- **Census stats:**
  - Texas has about 6.9 million under age of 18
  - \$300 pop– \$2.1 billion
  - About 1.5 million babies yearly in Texas
  - \$450 million yearly
  - US 32 million babies born every year

Source: US census data

## Cost effective Studies

- Limited because unknown length of protection
- Most recent data shows efficacy at 8 years
- Source: CDC

### NEJM 2008

- Assuming lifelong immunity
- Cost effective ratio of vaccination of 12 year girls is \$43,000 per quality adjusted life year gained (QALY)
- If you need a booster at ten years, up \$140,000 per quality adjusted life year

### Vaccine 2008

- Looked at eight articles
- Determined QALY is \$16,000 - \$27,000

## CDC Study 2003

Projected cost effectiveness of an HPV vaccine

75% effective : \$22,755 QALY

35% effective: \$52,398 QALY

Source: CDC

## Canadian Study

Number needed to treat to prevent an episode  
of genital warts is 8

Number needed to treat to prevent a case of  
cervical cancer is 324

Source: CMAJ 2007 Aug 28

## Disease of the poor

- 92 percent of cervical cancer deaths occur in low and middle income countries; 90 percent of revenue market for cervical cancer treatment comes from high income countries
- Most women with cervical cancer diagnosis have never had a pap , or have not had one in at least five years

Source: Food and Drug Law Journal, 2007

## TB FIT Testing

In 1980's, marked increase in TB cases in healthcare workers associated with AIDS

- In between 1980-1990; 20 health care workers in US in ICU with multidrug resistant TB; 10 died
- Source: Emerging Infectious Disease, March-April 2001



## FIT Testing

- US PPD conversion rate among health care workers less than 1% per year
- UTSW: 6,000 employees about 30 yearly are PPD positive with negative CXR
- UTSW: of new hires, 1/30 are PPD positive with negative CXR
- UTSW: Until January 2012, PPD used for post exposure; no post exposure conversion since 2003.
- UTSW: in 2011, one case of active TB (not a clinician)
- Source: CDC and Employee health Departments, UTSW

## OSHA rules

- OSHA adopted the N95 mask in 1995 as the standard protective mask
- FIT testing recommended to ensure no gaps between face and mask—evolved recommendation over the 1990s to 2001 using portacount type FIT testing
- Cost of this estimated to be about \$250 million yearly
- Source: Emerging Infectious Disease, March-April 2001

## FIT testing with the Portacount



## FIT Testing ensures a better fit

- Australian study
  - 82.9% of tested had proper fit with first mask
  - 12.3% on second try
  - 4.8% took a third test
- Doctors has highest failure rate on first try (81 of 604)—highest proportion of Asian Females

Source: *Infect Control Hospital Epidemiol*: Sept  
,2010

## Will We Use them?

- N95 respirators were infrequently used, even for high-risk procedures such as endotracheal intubation (25%) and respiratory aspiration (12%), and in high-risk areas such as the respirology ward (69.2%), emergency department (29.5%), intensive care unit (8.8%), and TB room isolation (39.5%)
- Source: *Int J Tuberc Lung Dis.* 2005 May

## COST

- Four urban, one rural hospital
- Median cost per hospital was \$89,000 (1998 data) range (\$ 2,000 -223,000) for masks, and \$17,187 ( \$8,700-26,000) for FIT testing
- UTSW budget for next year: \$60,000

Source: *Infect Control Hosp Epidemiol* Sept, 1998, Occupational Health

## Parkland North



## Car Crashes

- Leading cause of death for ages 4-18
- 24% of all deaths are alcohol related
- Source: American Academy of Pediatrics

## Car crash fatalities

- <http://www-nrd.nhtsa.dot.gov/Pubs/811552.pdf>

## Car crash fatalities (cont'd)

- <http://www-nrd.nhtsa.dot.gov/Pubs/811387.pdf>

## Car seats



## Car seats

- Texas in 2009 required booster seats for all children until 8 years old
- If the child is over 4'9" (57") , regardless of age no seat required
- \$25 first offense; \$250 for second
- Law requires seat to be used in accordance with the manufacturer's instructions
- Source: Texas Dept of Public Safety

## Any data on boosters?

- 72% misuse rate
- Crash dummy data not considered that meaningful
- Source: American Academy of Pediatrics 2011

## Conflicting studies

- One study: risk of any injury for 4-7 years reduced 57% by booster seat compared to lap belt
- Another showed 45%
- Another: no difference between adult belt and booster for ages 4-8 for fatal crashes; slight protection from booster for all injuries
- Source: American Academy of Pediatrics 2011

## Is it cost effective?

- vPediatrics, 2006 Nov;118(5):1994-8. Cost-outcome analysis of booster seats for auto occupants aged 4 to 7 years. Miller TR, Zaloshnja E, Hendrie D. Source Pacific Institute for Research and Evaluation, 11710 Beltsville Dr, Suite 125, Calverton, MD 20705, USA. miller@pire.org Abstract

**OBJECTIVES:** The purpose of this work was to analyze the societal return on investment in booster seats and in laws requiring their use in the United States. Booster seats reduce crash-related injury. Their use is mandatory for vehicle occupants aged 4 to 7 years in most of the United States. This study estimates the injury cost savings attributable to booster seat use. **METHODS:** Seat cost came from pricing on the Web and at retailers. Costs of passing and enforcing a legal mandate were estimated as a percentage of the costs of seat use. Injury risk when belted absent a seat was computed from national probability samples of crashes in the last years before booster seats entered into general use (1993-1999). Published estimates were used of the percentage of reduction in injuries achieved with booster seats, the mix of diagnoses reduced, and injury cost by diagnosis. The computations used a 3% discount rate. We studied the net cost per quality-adjusted life year saved, benefit-cost ratio, and net savings per seat. **RESULTS:** A booster seat costs 30 dollars plus 167 dollars for maintenance and time spent on installation and use. This investment saves 1854 dollars per seat, a return on investment of 9.4 to 1. Even lower bound estimates in sensitivity analysis indicated that society would benefit from the use of booster seats. Seat laws offer a return of 8.6 to 1. **CONCLUSIONS:** Belt-positioning booster seats offer a sound return on investment. Booster seat use laws should be passed, publicized, and enforced nationwide.

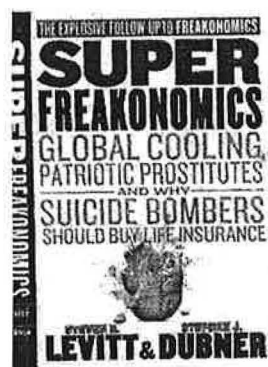
## Real cost of booster seats

- I own eight—two at cost of about \$100; six at about cost of \$30
- Have owned eight others—most expensive was \$300; least was about \$60; 2 given for free by relatives ( who showed me incorrect usage—had to go to Children's hospital to show me how to install)
- One third of all new cars bought in US last year were SUVs
- US News and World Report May 12, 2012





## Freakonomics



## Many thanks

- Frank, my husband
- Jack Boullion
- Tam McNamara
- Pod 2 in Aston clinic
- Sandie Miller

## Let's go fishing



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