

ALLEGHENY COUNTY BOARD OF HEALTH

MINUTES

July 13, 2016

Present: Lee Harrison, MD, Chair
William Youngblood, Vice Chair
Karen Hacker, MD, Secretary
Edith Shapira, MD
Anthony Ferraro (via telephone)
Joylette Portlock, PhD
Caroline Mitchell
Ellen Stewart, MD
Donald Burke, MD
Kotayya Kondaveeti, MD

Absent:

1. **Call to Order**

The meeting was held in the Gold Room of the Allegheny County Courthouse. Dr. Harrison called the meeting to order. Dr. Harrison announced that an executive session was held to discuss personnel matters.

2. **Approval of Minutes from May 4, 2016**

Dr. Harrison asked if there were any questions about the minutes. There were none.

Action: Dr. Burke moved to approve the minutes, Dr. Stewart seconded the motion.

Motion passed unanimously.

Dr. Harrison announced that the agenda format had been tweaked, in order to offer clarity as to which items the Board intended to vote on. Dr. Hacker reminded the audience to please turn off their cell phones.

3. **Public Comments on Agenda Items**

A. Dr. Jonas Johnson re: HPV vaccination

Dr. Johnson, a physician, stated that he endorsed mandating HPV vaccination. He stated that the HPV vaccine is safe and highly effective and that it should be used.

B. Alison Fujito re: HPV vaccination

Ms. Fujito opposed the mandate and stated all three of her children have had adverse reactions to vaccines. She stated that patients should have the liberty to decline this vaccination. Ms. Fujito submitted written comments to the Board.

C. Kristi Wees re: HPV vaccination

Ms. Wees stated that she opposes the mandate, and said there is no way to know if a person is genetically susceptible to vaccine injury. She stated that if you know that a vaccine may cause harm to some, and you mandate that vaccine, you are violating a fundamental precept of bioethics, and that is to first do no harm. Ms. Wees submitted written comments to the Board.

D. George Fechter re: HPV vaccination

Mr. Fechter was not present at this time.

E. Janet Cook re: HPV vaccination

Ms. Cook stated that she is a representative for the Pennsylvania Coalition for Informed Consent and opposes the mandate. She stated that she has concerns with the format that the Board is using for hearings on the proposal to mandate HPV vaccines. Ms. Cook submitted written comments to the Board.

F. Dr. Alan Finkelstein re: HPV vaccination

Dr. Finkelstein, a family physician, endorsed an HPV mandate and stated that science does not point to adverse outcomes. He stated that he hopes daughters won't have to face the fear of abnormal pap smears. He noted the pain of having one of his patients die at age 26 from cervical cancer.

G. Dr. Eugene Myers re: HPV vaccination

Dr. Myers, a Distinguished Professor at Pitt and a Department Chairman, endorsed the HPV mandate. He stated that anyone is vulnerable to HPV, and that many are unaware of it due to HPV's few signs and symptoms. He stated that there is now a unique situation, of a vaccine being able to prevent cancer. He stated that all five of his grandchildren are vaccinated against HPV.

H. Amy Rafferty re: HPV vaccination

Ms. Rafferty opposed the mandate and stated that she has no vested interest in the vaccine. She stated that the HPV 9 vaccine is new to the market and expressed concern about the lack of research into the vaccine. She stated that parents need to have influence over these decisions.

I. James Lyons-Weiler re: HPV vaccination

Mr. Lyons-Weiler opposed the mandate and stated that he was a lifelong biomedical researcher, and that he has no conflict of interests with this issue. He noted that the Vaccine Court has found in favor of parents and made vaccine manufacturers pay compensation to them.

J. Dr. Ana Radovic re: HPV vaccination

Dr. Radovic, an adolescent medicine physician, stated that the fact that the HPV vaccine is not mandated puts pediatricians at a disadvantage. She said that even if the vaccine were mandated, parents could still opt out. However, mandating the vaccine would help pediatricians.

K. Jessica Fitzgerald re: HPV vaccination

Ms. Fitzgerald stated that she opposes the mandate and believes that parents have the right to make healthcare choices for their children. She stated that HPV is not communicable in a school setting.

L. Michelle Sprague re: HPV vaccination

Ms. Sprague, opposed the mandate and stated that her son was damaged by vaccines. She says that a mandate would strip away parents' rights. She stated that vaccine makers are protected better than children are.

M. Erin Rogers re: HPV vaccination

Ms. Rogers opposed the mandate and stated that Gardasil is unnecessary and has never been fully tested, but that it has caused serious adverse reactions and deaths. She stated this decision must stay with parents. Ms. Rogers submitted written comments to the Board.

At this time, Dr. Harrison asked if George Fechter was currently present to give his comments. Mr. Fechter was.

M. George Fechter: HPV vaccination

Mr. Fechter endorse the mandate and stated that he is the chairman of the Eye and Ear Foundation. He stated that there are approximately thirty thousand traffic fatalities annually, which is the same number of HPV cancers annually. He stated that if traffic fatalities could be prevented, it would be met with huge applause.

N. Ashley Stevens, Adagio Health, re: E-Cigarettes

Ms. Stevens supported the regulations and stated that she is an external affairs manager at Adagio Health. She stated that it is debatable if e-cigarettes are a healthy alternative to traditional cigarettes. She stated that nicotine is very addictive for minors, and that e-cigarette manufacturers are using candy flavors. She stated that nicotine has neurotoxic effects on adolescents and leads to an addiction for life.

O. Bill Godshall, Smokefree Pennsylvania, re: E-Cigarettes

Mr. Godshall stated that he was previously a public health educator for ACHD, and opposes the regulation. He noted that he supports banning sales of e-cigarettes to minors. He stated that banning vaping in workplaces will cause harm. He stated that the proposed workplace vaping ban is likely preempted by the PA Clean Indoor Air Act. He requested a public hearing and comment period if the Board moves it forward. Mr. Godshall submitted written comments to the Board.

P. Cassandra Wood, American Lung Association, re: E-Cigarettes

Ms. Wood supported the regulation and thanked the Board for the steps they are taking to protect citizens. She stated that e-cigarettes are a tobacco product, and that they are the most common tobacco product used by youth.

At this time, Dr. Harrison announced that Mr. Ferraro had called in to the meeting.

Q. Richard Marino re: E-cigarettes

Mr. Marino stated that he is the owner of Cool Vapes and opposed the regulation. He stated that e-cigarettes are not tobacco products, and that there is no evidence of harm from e-cigarettes. Mr. Marino submitted written comments to the Board.

R. Marc Conn re: E-Cigarettes

Mr. Conn stated that he is the owner of Steel City Vapors and opposed the regulation. He stated that he supports the ban on sale to minors. He also stated that business owners should be able to make their own decision on whether to allow vaping. Mr. Conn submitted written comments to the Board.

S. Ray Firth re: Lead

Mr. Firth supported the Board in making lead a priority. He stated that there is no safe level of lead, and that its effects are irreversible. He supported the ability to order the removal or containment of lead hazards. Mr. Firth submitted written comments to the Board.

T. Amy Nevin re: Lead

Dr. Nevin stated that she has been a pediatrician in Beltzhoover for twelve years, and that she supports universal lead screening. She stated that lead remains a risk to kids in Allegheny County. She stated that the damage from lead is permanent, and that there is no safe level of lead for children.

At this time, Dr. Harrison thanked all of the speakers for their comments to the Board.

4. Old Business

A. Update on Live Well Allegheny

Dr. Hacker stated that the Live Well campaign continues to move forward. She stated that twenty-five municipalities, of which Green Tree was the most recent, six school districts,

and twenty-six restaurants were current members of the campaign. She stated that work was in progress regarding Live Well Allegheny Workplaces. She stated that grants for Live Well were received from both the Richard King Mellon and Hillman Foundations.

B. Update on Grants

Dr. Hacker stated that ACHD has received a new grant for violence prevention efforts.

C. HPV Vaccination

Abby Wilson, ACHD Deputy Director, thanked everyone for sharing their views on this topic and stated that the Board would not be voting this day on implementing a mandate. Ms. Wilson stated that the Jewish Healthcare Foundation made a presentation during the Board's May 2016 meeting regarding HPV vaccination data. Ms. Wilson shared HPV policies from other municipalities and reminded everyone that the Board discussed, at the May meeting, requiring school nurses to report HPV vaccination rates. She stated that on June 22, 2016, a public forum was held to hear comments on HPV vaccination. A transcript of the forum was made available. Additionally, over 1,100 letters, e-mails and phone calls were received sharing opinions about this topic. Ms. Wilson stated that she read every comment.

Ms. Wilson gave examples of why commenters opposed a mandate of the HPV vaccine: that vaccination should be a parental choice, concerns about government over-reach regarding individual liberty, concerns about the safety of the vaccine, the fact that HPV is not transmitted in school, allegations regarding conflicts of interests, cost concerns, questions about the general effectiveness of vaccines, the belief that sexual behavior is a private decision, and concerns this mandate could lead to unwanted pregnancies. Ms. Wilson thanked those who shared their personal stories while submitting their comments.

Ms. Wilson then gave examples of why other commenters supported a mandate of the HPV vaccine: the fact that HPV can cause cancer, the belief that the vaccine is safe, the vaccine's affordability, a support for cost-effectiveness as vaccinations save money down the road, references to Australia seeing a significant decrease of genital warts, concerns about cancers of the head and neck, the belief that mandates can make a difference – using the Polio vaccine as an example, and the fact that vaccination children at age 11-12 will protect them before they are exposed to it.

Dr. Hacker stated that the comments will be posted online.

Dr. Harrison thanked Ms. Wilson. Dr. Harrison gave the Board a presentation titled “Human Papilloma Virus Vaccines”. (*The presentation is attached to the end of the Minutes*). Dr. Harrison ended his presentation by stating that increasing HPV vaccine rates will lead to a reduction in cancer deaths. He stated that he is looking for direction from the Board, as to whether the Board would wish to pursue a mandate and/or enhance HPV vaccination rates through other means.

Mr. Ferraro stated that he liked the presentation, and thanked those who shared their comments on the topic. Mr. Youngblood asked if this vaccine was offered in ACHD clinics. Dr. Hacker stated that it was. Mr. Youngblood stated that ACHD needed to provide more information to non-medical folks, and suggested a PR campaign. Dr. Harrison stated that was a good point, and that it needs to be taken seriously with identifiable end points. Dr. Hacker asked what strategies were used in communities that have higher HPV vaccination rates. Ms. Wilson stated that the communities with the highest rates were DC, Rhode Island, Chicago, and Philadelphia; three of which received a CDC grant for community outreach. She stated that a mandated immunization registry helps target clusters of low vaccination rates. Dr. Harrison asked about vaccine registry data for Allegheny County. Dr. Hacker stated that the Pennsylvania Statewide Immunization Information System (PA-SIIS) is underutilized, and that there are efforts to get electronic health records to connect with PA-SIIS. Dr. Kristen Mertz, ACHD Epidemiologist, noted that this system has been improving.

Dr. Kondaveeti stated that he believes this decision should be between pediatricians and parents. He stated that he supports immunization registries, but does not support mandating the HPV vaccine. Dr. Burke stated that the Board heard several heart-wrenching stories regarding vaccination concerns, and asked if there is a way to engage that group. Dr. Harrison stated that he too is a parent, and that he is open to suggestions. He stated that there are four thousand cervical cancer deaths in the United States that can be vaccine preventable.

Ms. Mitchell stated that she has concerns regarding due process in the Board's public hearings. Her concerns specifically regarded the three minute limit for comments and the fact that data presented was not subject to cross-examination. She stated that the Board needs to be careful to ensure the public process complies with the laws of Pennsylvania. At this time, Dr. Harrison asked if the other members of the Board would disclose if they had any conflicts of interest.

Ms. Mitchell stated that she had no conflicts of interest, and is a constitutional lawyer.

Dr. Burke stated that he is an infectious disease physician who has worked on vaccine development for his whole life. He stated that he served in the US military for 23 years, and developed vaccines while in the Army. He stated that he was the sixth person in the world to receive the hepatitis A vaccine. While in the Army, he received only standard officers' pay. He stated that he works on HIV, and has worked with Merck and Sanofi. Since leaving the Army and entering academia, he has never taken direct payment for vaccine-related work, but has had travel expenses paid. Dr. Burke stated that he is the Jonas Salk Professor of Global Health at the University of Pittsburgh Medical Center.

Mr. Youngblood stated that he does not have any conflicts of interest.

Dr. Hacker stated that she does not have any conflicts of interest.

Dr. Kondaveeti stated that he does not have any conflicts of interest. He stated that he is pro-vaccine, but is not in favor of mandating the HPV vaccine.

Dr. Stewart stated she is an OB/GYN who received a community service award with \$25 in 1982.

Dr. Shapira stated that she is a psychiatrist, and has a family association with a supermarket chain that does have pharmacies.

Mr. Ferraro stated that he does not have any conflicts of interest.

Dr. Portlock stated that she completed internships at DuPont and Merck decades ago.

Dr. Harrison stated that the Board must make sure it fulfills all legal requirements, and must be mindful of these requirements every step of the way. Dr. Hacker stated that requirements including presenting the regulations to the Board for approval, and then entering into a comment period lasting a minimum of thirty days. ACHD is then required to respond to the comments received and post this information publicly.

Dr. Burke pointed out that Board members are not paid for their service on the Board.

Dr. Portlock stated that it was essential to do more to present information, while being mindful of what the best science was. She stated that this was an issue of trust. Mr. Youngblood stated that many individuals talked to him about this subject, most of whom didn't believe this vaccine should be mandated. He stated that it was the obligation of the Board to inform the County about the pros and cons of this subject. Ms. Mitchell suggested that ACHD undertake public hearings to better understand HPV vaccination issues. Dr. Harrison replied that we're already clear on the issues. Dr. Kondaveeti suggested that Dr. Hacker come up with bullet points, without mandating vaccination. Dr. Burke supported providing education. Dr. Hacker stated that concerned individuals can invite her to their organizations.

Action: Mr. Ferraro moved that ACHD shall enhance efforts to improve HPV vaccination coverage rates with the understanding that ACHD staff will present to the Board a plan for review to accomplish this goal. Dr. Shapira seconded the motion.

The motion passed 8-1. Ms. Mitchell voted against the motion.

Dr. Stewart stated that she appreciated the diversity of opinions that were offered. She spoke of the need to commit to a robust education program. Dr. Harrison stated that would require a concrete plan. Ms. Wilson made it clear that she was not delivering a legal opinion, but offered to conduct a briefing on Sunshine Act requirements and stated that she felt ACHD was already surpassing its legal obligations. Dr. Hacker pointed out that ACHS is already the host organization for the Immunization Coalition, and that the Department can increase those efforts.

Action: Dr. Burke moved that ACHD staff will present a plan for how to address the public concerns of the safety and efficacy of vaccines. Mr. Ferraro seconded the motion. **The motion passed unanimously.**

D. E-Cigarette Regulation Draft

Ms. Wilson stated that the proposed regulation changes haven't been published yet. She stated that in May, Megan Tulikangas, of the University of Pittsburgh, presented information to the Board regarding e-cigarettes. The Board asked staff to develop proposals related to minor access to e-cigarettes, food safety, and use in indoor public places. Research was conducted, with the assistance of the University of Pittsburgh's Health Policy Institute, and regulations have been drafted. During this period, ACHD received over 400 letters from the users of e-cigarettes. Ms. Wilson reported that she also personally visited vape shops. She stated that concerns about regulating e-cigarettes included the impact on the use of e-cigarettes for smoking cessation, tax implications with the state budget, and questions about the harmfulness, or lack thereof, of the products.

Ms. Mitchell expressed concerns if Article XXII has been made available to the public. Dr. Portlock and Dr. Hacker replied that the Board would have the option to vote on whether to send this proposed regulation to public comment. Ms. Mitchell stated that commenters should be afforded the full-opportunity for cross-examination. Dr. Hacker stated that a public comment period for these regulations would follow the regular procedures. She stated that ACHD regularly holds public comment periods, particularly related to air quality issues. She stated that comments can be submitted via mail, e-mail, or telephone over a 30 day period. ACHD will then issue a response document to the comments that were received. She stated that a public comment period could include a public forum. Ms. Wilson stated that anyone can comment during a public comment period, and that a public forum is not required. Dr. Hacker stated that details of a public comment period would be published in a newspaper.

Ms. Wilson shared the Board's e-mail address to send comments to. She reported that she met with experts to include Bill Godshall, and the American Cancer Association. She also spoke with Tom Farley, the Health Commissioner of the City of Philadelphia. She stated that the evidence and resources that ACHD used were available in a bibliography posted on ACHD's website.

Ms. Wilson read a letter from Dr. Farley stating that, in 2014, Philadelphia banned the sale of e-cigarettes to minors and prohibited their use indoors. He stated these were taken as precautionary measures, as the e-cigarette flavoring does appeal to youths. His letter stated that implementation of these regulations has gone smoothly in Philadelphia.

Ms. Tulikangas read a letter from Dr. Brian Primack. Dr. Primack is the Director of the University of Pittsburgh's Center for Research on Media, Technology, and Health. He was unable to personally attend the Board meeting due to hospitalization. Dr. Primack's letter stated that he

has been studying tobacco alternatives for a decade. It stated that he supports ACHD's regulations, as he believes they will reduce morbidity and mortality. Though he recognizes the need to do as much as possible to help smokers quit, he has concerns if e-cigarettes are valuable for smoking cessation. His letter stated that e-cigarette use among youth is increasing, and that the youth are not using the e-cigarettes for cessation purposes. Rather, the youth are at a high risk to transition to smoking traditional cigarettes.

Ms. Wilson thanked the vaping industry for their input into the proposed regulations. She stated that ACHD took seriously the request for an exception for vape shops. She stated that there is a hygiene concern regarding vaping and food safety. She said the proposed regulations would ban the use of e-cigarettes in indoor public places where cigarettes are already currently banned. She introduced Jeff Bailey, an ACHD attorney.

Mr. Bailey stated that the changes to Article III, regarding food safety, were because a vaper's hands would be near their mouths while vaping. In a food establishment, this would be a hygiene concern of having workers touching food after their hands were near their mouths. Article XXII was a new regulation that Mr. Bailey drafted. He stated that it mirrors the Current Clean Indoor Air Act, which bans smoking indoors. He said a number of exceptions were included, giving smoking bars as an example. Mr. Bailey pointed out that the Clean Indoor Air Act does not presently include e-cigarettes. He also stated that the definition of a vaping shop was mirrored from the definition of a cigar shop, and pointed out that the shops can not allow minors to be present inside if they wish to qualify for an exception to the regulation. He also stated that to discourage a lounge environment, no food would be allowed for on-establishment consumption in excepted establishments. He stated that enforcement provisions mirror housing and food safety regulations, and that penalties for violation can be civil or criminal in nature. He stated that municipal police forces could enforce the regulation.

Dr. Harrison asked if there were any questions.

Dr. Portlock expressed concern that some of the penalties, up to imprisonment, seemed severe. Mr. Bailey stated that those penalties were typical for ACHD regulations. Dr. Harrison asked how often those penalties were invoked and if they were reserved for extreme cases. Dr. Hacker reiterated that these penalties mirrored ACHD's current penalties. Jim Thompson, ACHD Deputy Director, also stated that these penalties mirror ACHD Environmental Health penalties, with the exception of air quality penalties. He stated that multiple factors are considered and that enforcement discretion is used. He stated that during his tenure, imprisonment has never come up.

Mr. Youngblood asked about the applicability of these regulations to parks. Mr. Bailey replied that these regulations were only for indoor places. Dr. Hacker stated that some outdoor places, such as PNC Park, have already banned outdoor use.

Action: Dr. Stewart moved to put the proposed regulations to public comment. Dr. Shapira seconded the motion.

The motion passed unanimously.

E. Discussion of Lead Activities

Dr. Hacker stated that a lot has occurred since the Board's last meeting. She stated that the numbers of children being tested for lead in Pennsylvania are lower than ACHD would like. Dr. Harrison asked what the target number would be. Dr. Hacker replied that as far as she's concerned, 100% should be the target. She stated that the present rate in Allegheny County is 20%.

Dr. Hacker stated that Flint brought the issue of lead back to the surface. She pointed out though that most lead exposure is from homes, not from water. She noted that 70% of homes in Pennsylvania, and 89% in Allegheny County, were built prior to 1978 which was when lead was banned in paint. She stated that there is a connection between lead exposure and areas of poverty. She also stated that lead interventions do work and provided the Board with evidence of a decrease in lead blood levels following risk assessments conducted by ACHD staff.

She informed the Board that Allegheny County had recently received a lead-abatement grant, allowing 200 homes to become lead-free. ACHD has also applied for a grant from the state to address lead issues. There are also several bills related to lead being considered by the Pennsylvania General Assembly, HB 1917, HB 1918, SB 18, and SB 20.

Dr. Hacker stated that ACHD would consider mandatory lead screening for children at 9-12 months, and again at 24 months. ACHD will also continue to educate the public about lead, monitor state legislation, seek additional funds to work with landlords, and seek additional funds to support expanded testing by the pediatrics community. Dr. Harrison asked what the feedback from the pediatric community was. Dr. Hacker said that it was generally positive, but that pediatricians would need an expensive piece of equipment to conduct the testing. Mr. Youngblood expressed concerns about the enforceability of a mandate, and also pointed out that there is no registry of rental properties.

Dr. Harrison stated that there is a question of what the Board wishes to do, and what does the Board wish to defer to the state. Dr. Harrison asked when will things occur at the state level. Dr. Hacker stated that she can't answer for the state.

Dr. Kondaveeti expressed cost concerns, asking how much the testing will cost and who will pay for it. Dr. Hacker stated that insurance companies will pay. Dr. Burke expressed concerns that holding homeowners responsible for lead-abatement could lead to huge expenses for them. Dave Namey, ACHD Housing & Community Environment Program Manager, stated that his program does not do enforcement on owner-occupied homes, but that owners do have to

disclose the presence of lead. Dr. Hacker pointed out that homeowners can do lead-abatement that is not costly.

Dr. Burke expressed concerns that a child could be labeled as a “lead-baby”, and that such labeling could change expectations for them. Dr. Shapira stated that the alternative was that the child could be a “lead-baby” and they don't know it. Dr. Hacker assured the Board that all information that ACHD would receive about this would be Protected Health Information.

Dr. Harrison asked the Board to focus on what policy they may want to pursue. He asked the Board if they want to consider a mandate. Dr. Hacker stated that she believes in our County, with our older housing stock, that we should be screening all children. She noted the need to consult with ACHD's legal team.

At this time, Dr. Shapira noted that she was in favor of mandating lead screening as she excused herself from the meeting.

Ms. Mitchell stated that she would be uncomfortable voting without knowing the implications. Dr. Stewart stated that if the problem is that a testing device costs \$4,700, that is a low barrier to protecting children. She stated that the money for devices could be raised from foundations. Mr. Youngblood stated that he believed in testing and education. However, he noted that his area of the County has newer housing stock, and that a mandate will get a lot of pushback. He felt that as a regulatory body, ACHD should be perceived as part of the solution. He asked if ACHD could offer through its clinics. Dr. Portlock asked if testing could be mandated under certain screening stipulations. Dr. Hacker replied that this would require further research.

Ms. Mitchell stated that she would like additional information before voting, and suggested tabling any proposal until the next meeting. Dr. Harrison asked if it would be reasonable to come back with more information at the next meeting. Dr. Hacker stated that we can come back with more information and look at costs to us as a Department to get involved in testing.

At this time, Dr. Portlock stated that she would be ok with deferring the Air Toxics agenda item to the next meeting. Dr. Portlock and Ms. Mitchell both excused themselves and left the meeting. A quorum was maintained as Mr. Ferraro (via phone), Dr. Stewart, Dr. Kondaveeti, Dr. Harrison, Mr. Youngblood, and Dr. Burke remained at the meeting.

Dr. Burke stated that he would like to see more information regarding lead and water.

F. Restaurant Inspection Stickers

This item was deferred.

5. New Business

A. Air Toxics Risk in the County

This item was deferred.

B. Clean Air Fund Request – Support for Carnegie Science Center Future Cities Competition

Jayne Graham, ACHD Air Quality Program Manager, stated that this is a renewal request for \$4,000 for school years 2016-2017 and 2017-2018. She stated that students design a modern city, and then research and write an essay addressing that year's theme (in 2017, this is public spaces that serve diverse populations). Ms. Graham stated that this is a good project that the Air Quality program is very pleased with, and that this is money well-spent.

Action: Mr. Youngblood moved to approve funding of \$4,000 from the Clean Air Fund for the Future Cities Competition. Dr. Kondaveeti seconded the motion.

Motion passed unanimously.

6. **Director's Report**

Dr. Hacker had nothing additional to report for the Director's Report.

7. **Announcements**

There were no announcements.

9. **Public Comments on Non-Agenda Items**

A. Thaddeus Popovich re: Air Pollution

Mr. Popovich was not present at this time to offer his comment.

B. Angelo Taranto re: Air Quality Issues (Clairton petition, Controller Wagner's audit report, and Shenango)

Mr. Taranto was not present at this time to offer his comment.

9. **Adjournment**

Dr. Harrison suggested an adjournment. All Board members present voted in favor of adjourning.

Human Papilloma Virus Vaccines

Lee H. Harrison, MD

Professor of Medicine and Epidemiology

University of Pittsburgh

Chairman, Allegheny County Board of Health

Allegheny County Board of Health Meeting

Allegheny County Courthouse

July 13, 2016

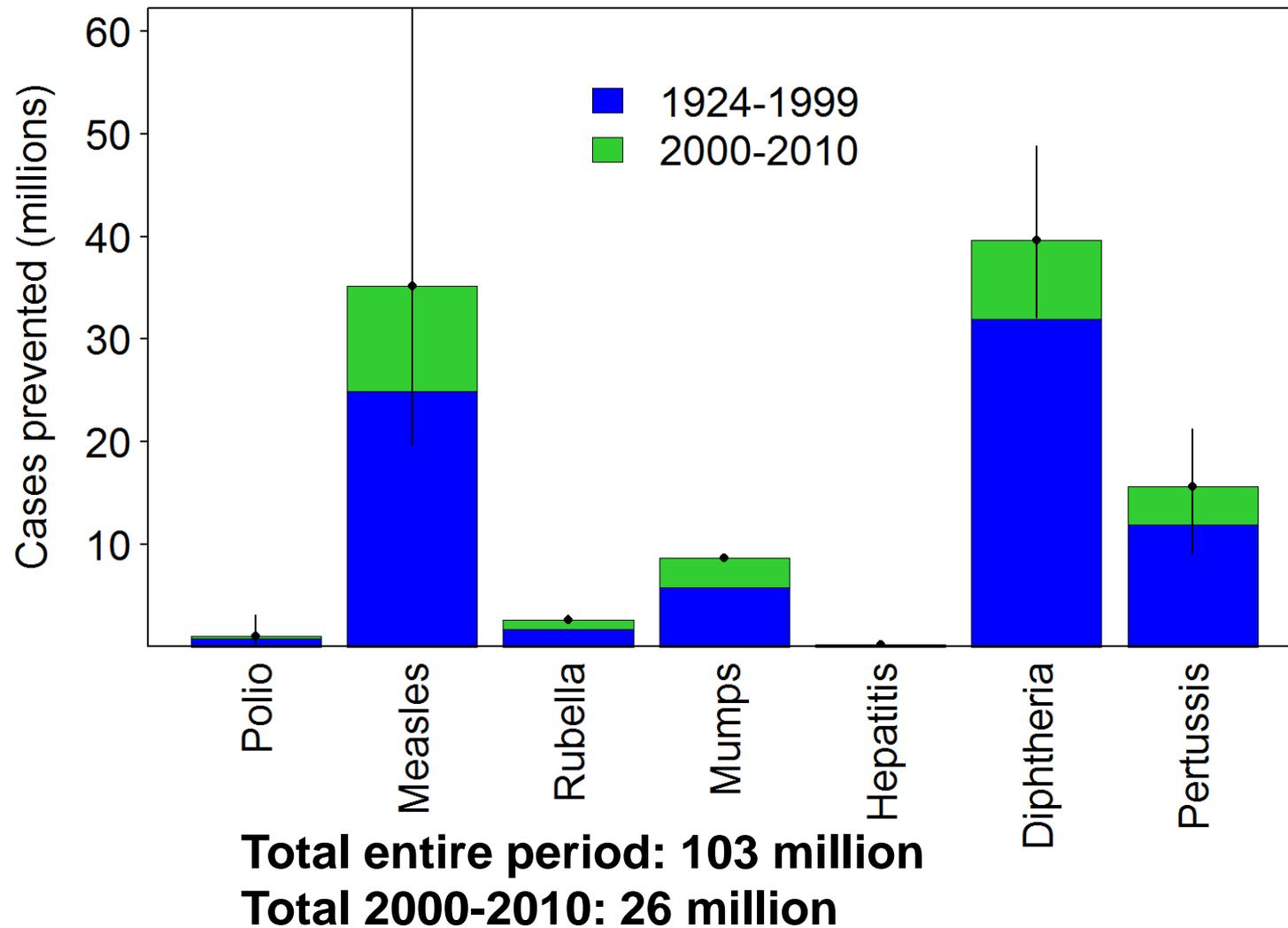
Disclosures

- July 1, 2012-present: Voting member of CDC's Advisory Committee on Immunization Practices (ACIP)
 - Before July 1, 2012: Consulting with vaccine industry on epidemiology and vaccine prevention of meningococcal and pneumococcal infections
 - No relationship with industry on HPV vaccines
 - My son and daughter both received 3 doses of HPV vaccine according to ACIP recommendations
-

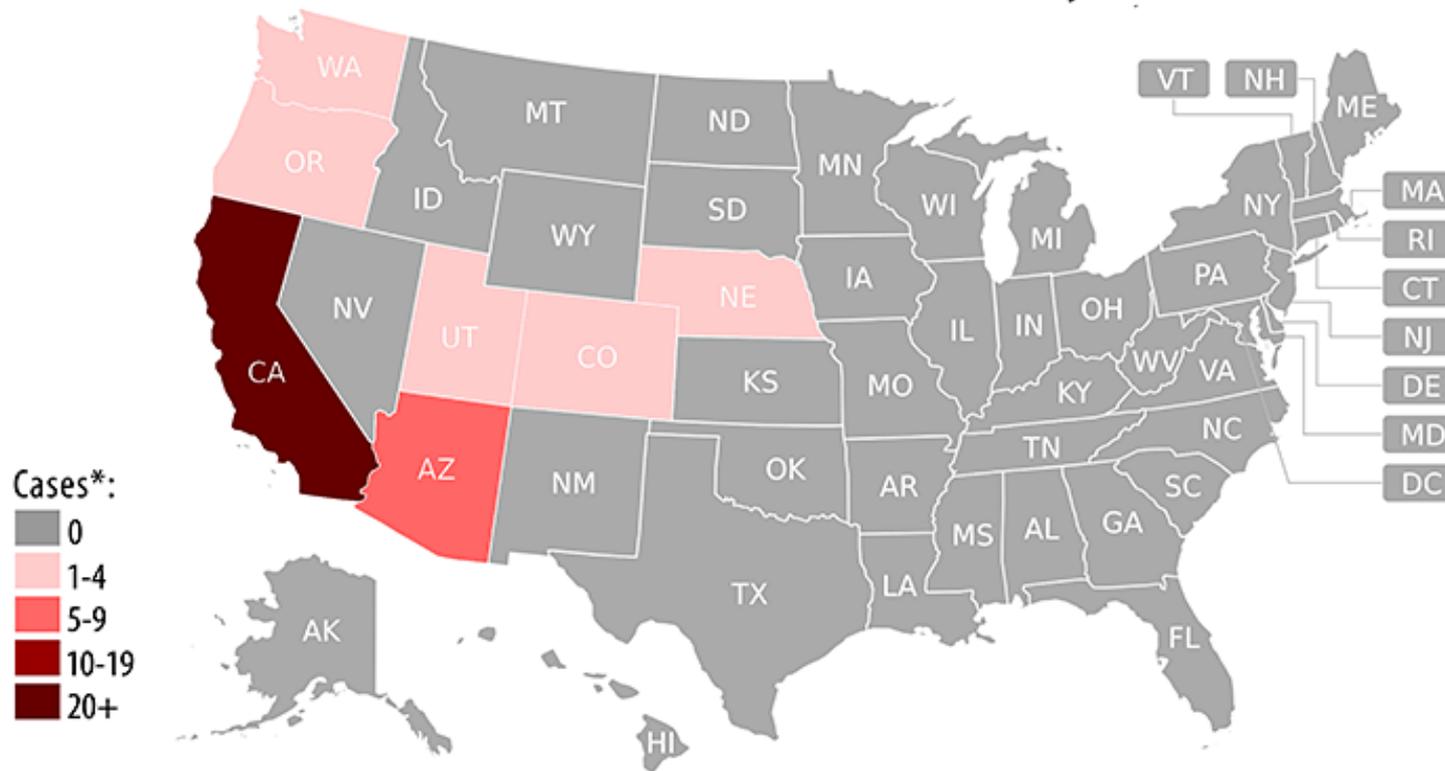
Why are we having this discussion?

To improve HPV vaccination rates in Allegheny County, which will lead to fewer HPV-related cancers and deaths

Disease cases prevented by vaccination, United States, 1924-1999 and 2000-2010



Multi-state measles outbreak associated with Disneyland, Dec 28, 2014- Feb 27, 2015



From December 28, 2014 to February 27, 2015, 140 people from 7 states in the U.S. [AZ (7), CA (124), CO (1), NE (2), OR (1), UT (3), WA (2)] were reported to have measles and are considered to be part of a large, ongoing outbreak linked to an amusement park in California.

*Provisional data reported to CDC's National Center for Immunization and Respiratory Diseases



Six cases of *Haemophilus influenzae* type b (Hib) disease in children <5, Pennsylvania 2009

At least **six unvaccinated children** in Southeastern Pennsylvania have been infected and **two have died** in the nation's biggest recent outbreak of Hib, a once-devastating disease that was virtually eradicated 20 years ago.. . . .

Five cases of *Haemophilus influenzae* type b (Hib) disease in children <5, Minnesota, 2008

Patient	Month	Age	Clinical syndrome	Outcome	Hib vaccine
1	January	15 mos	Meningitis	Survived	2 doses: 2, 5 months
2	February	3 yrs	Pneumonia	Survived	0 doses*
3	November	7 mos	Meningitis	Died	0 doses*
4	November	5 mos	Meningitis	Survived	2 doses: 2, 4 months
5	December	20 mos	Epiglottitis	Survived	0 doses*

*Parent or guardian deferral or refusal

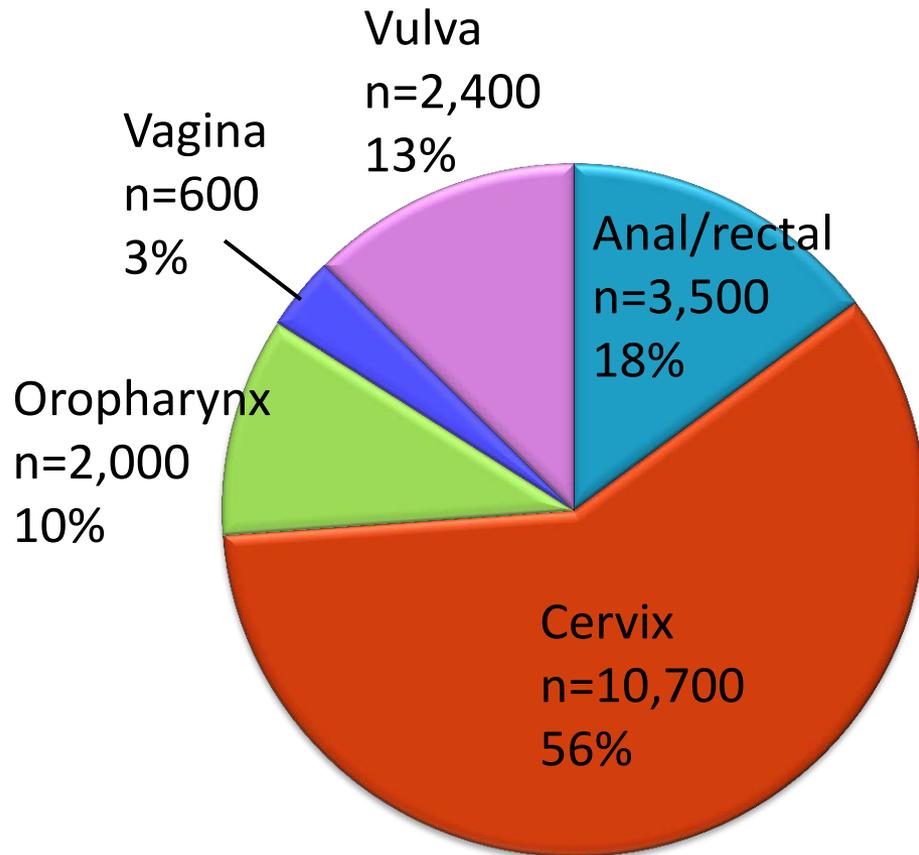
Human papilloma virus (HPV) infection

- Most females and males infected with HPV during lifetime
- Estimated 79 million Americans currently infected
 - 54% of women 20-24 have cervical HPV; anogenital infection high in men
 - Acquisition rapid: 39% of university women positive by 2 yrs after 1st intercourse
 - 14 million new infections/year in the US
 - Half of new infections occur at 15-24 years of age
 - Many do not know that they have been infected
- 90% clear naturally within 2 years; persistent infections are the concern
- Time from infection to cancer can take decades
- Over 150 HPV types

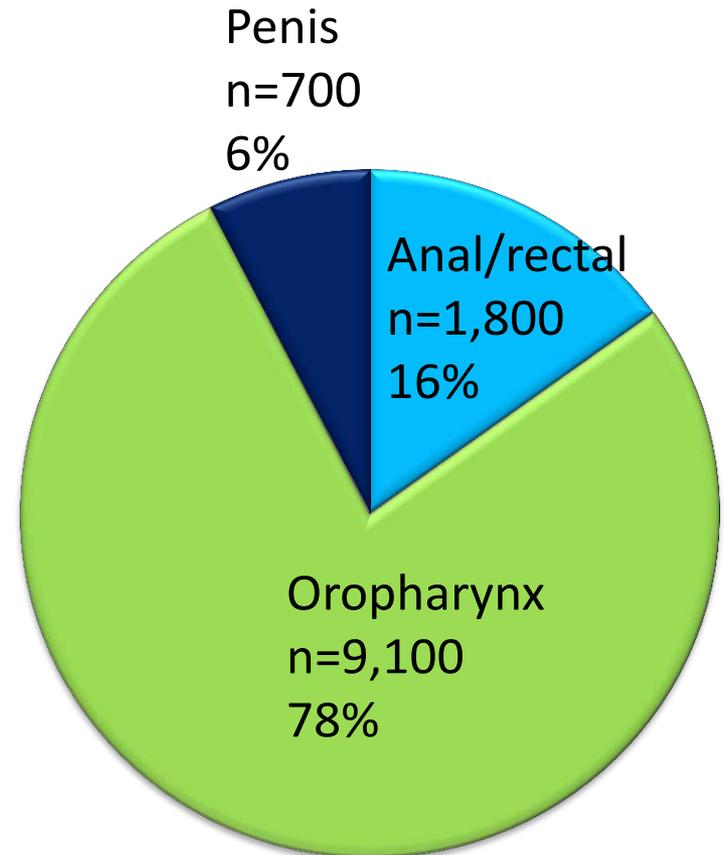
HPV as cause of cancer

- 90% of anal and cervical cancers
- 70% of vaginal/vulvar cancers
- 60% of penile cancers
- 70% of head and neck cancers

Cancers Attributable to HPV per Year, U.S., 2008-2012



Women (n = 19,200)



Men (n = 11,600)



Why does HPV vaccine coverage matter?

- There are 26 million girls <13 years old in U.S.
- If none vaccinated:
 - 168,400 will develop cervical cancer
 - 54,100 will die from cervical cancer
- Comparing 30% versus 80% vaccine coverage, every year:
 - 4,400 future cervical cancer cases will not be prevented
 - 1,400 cervical cancer deaths will not be prevented

Common HPV types and Disease Manifestations

HPV type

Manifestations

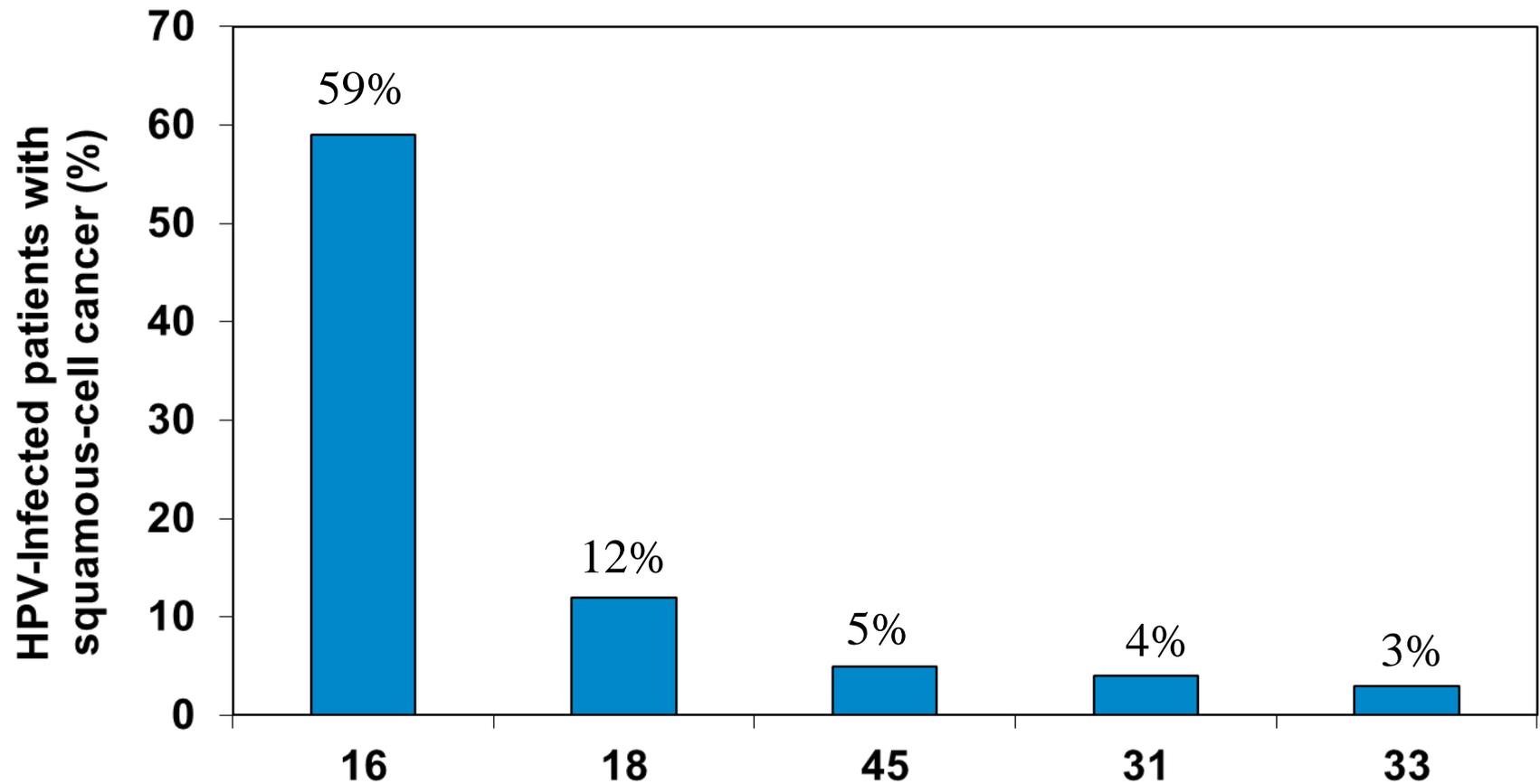
16, 18, 31, 33, 45,
52, 58, others

Cancers of cervix, penis, anus,
oropharynx

6, 11

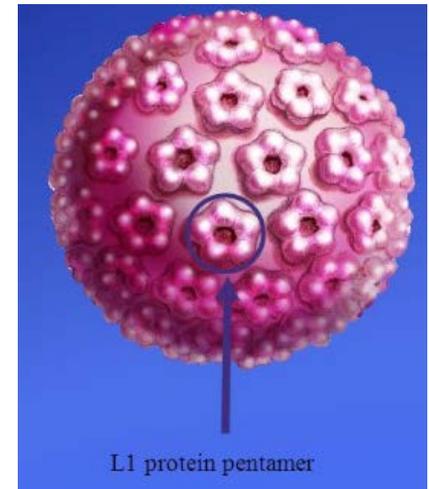
Condyloma acuminata (genital
warts)

Most Prevalent HPV Types That Cause Cancer



HPV Vaccine (4vHPV and 9vHPV): Virus-like particles (VLP)

- L1 protein expressed in *Saccharomyces cerevisiae* (baker's yeast)
- Purified L1 protein self assembles into empty shells that resemble HPV
- Look like HPV to immune system but can't cause infection
- Induce type-specific neutralizing antibodies
- Nontoxic and immunogenic
- 2-valent, 4-valent, 9-valent vaccines



Quadrivalent (6,11,16,18) HPV vaccine efficacy in females

- Randomized, double-blind, placebo-controlled phase 3 trial of 12,167 girls/women 16-26 years old
- HPV vaccine (6,11,16,18) or placebo (alum adjuvant) given at 0, 2, 6 months
- Duration: 5 years
- Primary endpoint: Incidence of HPV 16/18-related cervical intraepithelial neoplasia 2/3, adenocarcinoma *in situ*
- Most common side effects: injection site reactions

Quadrivalent (6,11,16,18) HPV vaccine efficacy in females

End point	VE (95% CI)
HPV types 16,18	
Per-protocol, susceptible	98% (86%-100%)
Intention-to-treat*	44% (26%-58%)
Any HPV type	
Intention-to-treat*	17% (1%-13%)

*includes women with prevalent CIN/previous HPV 16 of 18 infection

Recommended childhood immunization schedule, United States, ACIP, 2016

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16–18 yrs
Hepatitis B ¹ (HepB)	1 st dose	←.....2 nd dose.....→			←.....3 rd dose.....→											
Rotavirus ² (RV) RV1 (2-dose series); RV5 (3-dose series)			1 st dose	2 nd dose	See footnote 2											
Diphtheria, tetanus, & acellular pertussis ³ (DTaP: <7 yrs)			1 st dose	2 nd dose	3 rd dose				←.....4 th dose.....→			5 th dose				
<i>Haemophilus influenzae</i> type b ⁴ (Hib)			1 st dose	2 nd dose	See footnote 4			←.....3 rd or 4 th dose..... See footnote 4								
Pneumococcal conjugate ⁵ (PCV13)			1 st dose	2 nd dose	3 rd dose			←.....4 th dose.....→								
Inactivated poliovirus ⁶ (IPV: <18 yrs)			1 st dose	2 nd dose	←.....3 rd dose.....→						4 th dose					
Influenza ⁷ (IIV; LAIV)					Annual vaccination (IIV only) 1 or 2 doses						Annual vaccination (LAIV or IIV) 1 or 2 doses		Annual vaccination (LAIV or IIV) 1 dose only			
Measles, mumps, rubella ⁸ (MMR)					See footnote 8		←.....1 st dose.....→					2 nd dose				
Varicella ⁹ (VAR)							←.....1 st dose.....→					2 nd dose				
Hepatitis A ¹⁰ (HepA)							←.....2-dose series, See footnote 10.....→									
Meningococcal ¹¹ (Hib-MenCY ≥ 6 weeks; MenACWY-D ≥ 9 mos; MenACWY-CRM ≥ 2 mos)			See footnote 11											1 st dose		Booster
Tetanus, diphtheria, & acellular pertussis ¹² (Tdap: ≥ 7 yrs)														(Tdap)		
Human papillomavirus ¹³ (2vHPV: females only; 4vHPV, 9vHPV: males and females)														(3-dose series)		
Meningococcal B ¹¹														See footnote 11		
Pneumococcal polysaccharide ⁵ (PPSV23)												See footnote 5				

Nine-valent HPV vaccine



Common HPV types and Disease Manifestations

HPV type

Manifestations

16, 18, 31, 33, 45,
52, 58, others

Cancers of cervix, penis, anus,
oropharynx

6, 11

Condyloma acuminata (genital
warts)

Common HPV types and Disease Manifestations

HPV type

Manifestations

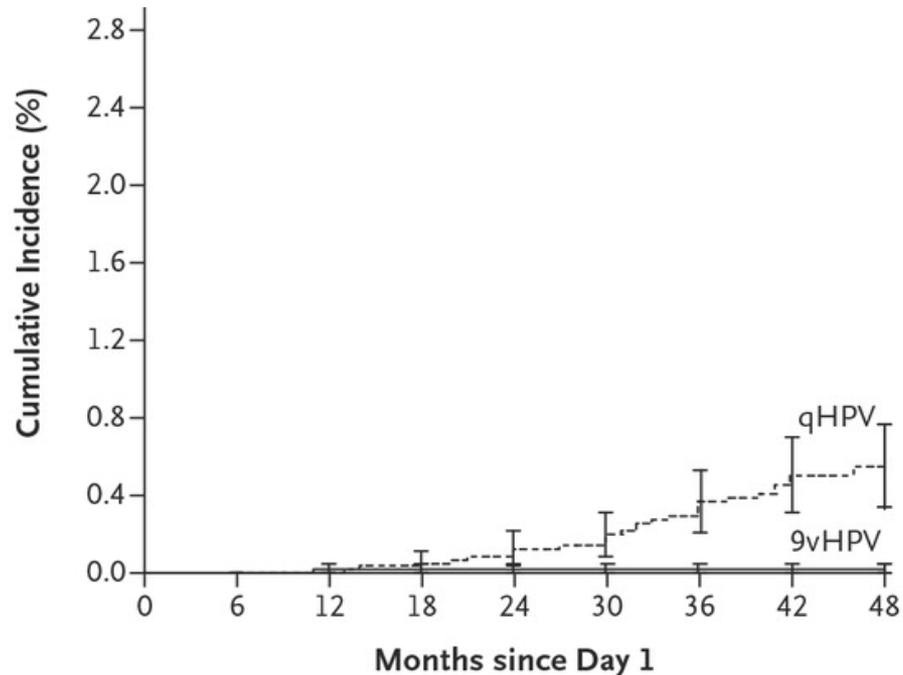
16, 18, 31, 33, 45,
52, 58, others

Cancers of cervix, penis, anus,
oropharynx

6, 11

Condyloma acuminata (genital
warts)

Time to high-grade cervical disease, HPV-31, 33, 45, 52, 58, per-protocol (susceptible) population, randomized, double-blind study of 4vHPV v. 9vHPV



Efficacy 96.7% (95% CI, 80.9%-99.8%)

No. at Risk

9vHPV	5948	5948	5823	5668	5533	5346	5000	3213	949
qHPV	5943	5943	5810	5663	5516	5346	5038	3243	1008

Cumulative Cases

9vHPV	0	0	1	1	1	1	1	1	1
qHPV	0	0	0	3	7	11	20	26	27

Reduction in HPV prevalence, females 14-19 years old, NHANES, 2003-2006 (prevaccine era) and 2009-2012 (vaccine era)

Year	Prevaccine era prevalence (%) (2003-2006)	% Reduction
Any HPV	32.9	7
Non-4vHPV	31.2	4
Non-4vHPV HR	20.7	1
HPV31, 33, 45	4.3	34
HPV31, 33, 45, 52, 58	8.4	18
4vHPV	11.5	64*
HPV16, 18	7.1	63*

4vHPV: 6, 11, 16, 18

9vHPV: 6, 11, 16, 18, 31, 33, 45, 52, and 58.

p <0.01

Systematic review and meta-analysis: Population-level impact and herd effects following HPV vaccination

- Review of 20 studies in 9 high income countries within 4 years of vaccine introduction
- In countries with >50% coverage, among females <20 yrs
 - HPV 16/18 prevalence decreased at least 60%
 - Anogenital warts decreased ~60%
 - Evidence of herd effects with decreases in anogenital warts among older females and in males
 - Some evidence of cross protection against nonvaccine types
- In countries with <50% coverage
 - Smaller decreases in vaccine type prevalence/anogenital warts
- No significant increase in non-vaccine types

HPV vaccine safety

- Most common pre-licensure side effects: pain, swelling, redness at site
- Rates of local side effects higher with 9vHPV than 4vHPV
- Most common adverse events post-licensure in addition to injection site reactions: syncope, dizziness, nausea, headache, fever
- Anaphylaxis has occurred rarely
- Persons with severe allergies to yeast or any vaccine component* should not receive the vaccine
- Across all pre-licensure clinical studies (29,323 participants)
 - 21 deaths (0.1%) in 4vHPV groups and 19 (0.1%) in control/placebo groups; none considered vaccine related
 - 1.5% in both groups developed possible autoimmune disorders

***Virus-like particles, aluminum hydroxyl phosphate sulfate adjuvant, sodium chloride, L-histidine, polysorbate, sodium borate**

Recommended childhood immunization schedule, United States, ACIP, 2016

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16–18 yrs
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Tetanus, diphtheria, & acellular pertussis ¹² (Tdap: ≥ 7 yrs)														(Tdap)		
Human papillomavirus ¹³ (2vHPV: females only; 4vHPV, 9vHPV: males and females)														(3-dose series)		
Meningococcal B ¹¹													See footnote 11			
Pneumococcal polysaccharide ⁵ (PPSV23)											See footnote 5					

Why does ACIP recommend HPV immunization at 11-12 years of age?

- Vaccines safe and immunogenic in this age group
- Antibody response 1.7-2.7x higher for 9-15 year olds than 16-26
- Vaccines most effective before sexual debut
- Data suggesting that protection will be long lasting
- Programmatic issues: MCV4 and Tdap vaccines are recommended for this age group

Estimated vaccination coverage among adolescents 13-17 years of age – National Immunization Survey-Teen, United States and Pennsylvania, 2014

	United States	Pennsylvania
Females		
≥1 HPV	60.0%	66.8%
≥2 HPV	50.3%	57.9%
≥3 HPV	39.7%	48.2%
Males		
≥1 HPV	41.7%	47.4%
≥2 HPV	31.4%	35.9%
≥3 HPV	21.6%	26.0%

Common misconceptions about HPV vaccine

1. Shouldn't immunize because of replacement of vaccine types with "more dangerous" HPV strains
 2. VAERS data show that HPV vaccines are unsafe
 3. Claims paid by the National Vaccine Injury Compensation Program (VCIP) show that HPV vaccines are unsafe
 4. My child isn't sexually active, doesn't need HPV vaccine
 5. Many people cannot afford HPV vaccine because it is too expensive
 6. Infringement on religious rights
-

Misconception #1: Shouldn't immunize because of replacement of vaccine types with "more dangerous" HPV strains (type replacement, TR)

- All cancer-causing HPV types are dangerous
 - TR valid theoretical concern for vaccines that do not cover all types
 - Occurred with 7-valent pneumococcal conjugate vaccine (Pevnar7)
 - Increase from non-vaccine types **much lower** than reduction in vaccine types
 - **Huge public health impact** of vaccine despite type replacement
 - Addressed by adding 6 additional serotypes to vaccine (Pevnar13)
 - Surveillance shows no firm evidence of TR with HPV vaccine
 - Change from 4-valent to 9-valent HPV vaccine should reduce risk
 - If TR occurs with HPV vaccine, additional types could be added to vaccine
 - **Bottom line:** Possibility of TR is not scientifically valid reason to not use HPV vaccine
-

Misconception #2: VAERS data show that HPV vaccines are unsafe

- VAERS = Vaccine Adverse Events Reporting System*
- Anyone can submit a report to VAERS
- Not possible to attribute causality (e.g., person killed by gunshot wound after vaccination can be reported)
- “Hypothesis-generating” surveillance system
- Useful for identifying previously unidentified adverse events
 - Cluster of 9 intussusception cases following RotaShield in 6 months
 - Additional studies confirmed association
 - Vaccine withdrawn from market in 1999
 - Myopericarditis after smallpox vaccine
- No unusual signals about HPV vaccines in VAERS
- **Bottom line:** VAERS does not suggest HPV vaccine safety problem

*<https://vaers.hhs.gov/>

CDC Immunization Safety Office post-licensure vaccine safety monitoring infrastructure

- Vaccine Adverse Events Reporting System (VAERS)
 - Joint effort of CDC and FDA
 - Frontline spontaneous reporting system for potential vaccine safety issues
 - Hypothesis generating
 - Vaccine Safety Datalink (VSD)
 - Collaboration between CDC and 9 integrated healthcare systems
 - 9.4 million members
 - Active surveillance and research
 - Can calculate rates and risk estimates
 - Clinical Immunization Safety Assessment (CISA) Project
 - CDC and 7 academic centers
 - Expert collaboration that conducts individual clinical vaccine safety assessments and clinical research
-

Misconception #3: Claims paid by the National Vaccine Injury Compensation Program (VCIP) show that HPV vaccines are unsafe

- VCIP created in 1980s after lawsuits against manufacturers and healthcare providers raised concerns about vaccine shortages and reductions in vaccination rates, which could have caused a resurgence of vaccine preventable diseases
- **No-fault** alternative to traditional legal system for resolving vaccine injury petitions
- Compensation does not necessarily mean that vaccine caused injury: in 80% of settlements, HHS has not concluded that vaccine caused injury
- **Bottom line:** VCIP payment data cannot be used to make inferences about HPV vaccine safety

Misconception #4: My child isn't sexually active and therefore doesn't need HPV vaccine

- HPV vaccine is highly efficacious in preventing new HPV infection
 - HPV vaccine has no impact on existing HPV infection
 - HPV infection is very common and is acquired in a high proportion of persons soon after sexual debut
 - If wait until sexually active, HPV vaccine less likely to prevent the cancers it was intended to prevent
 - **Bottom line:** HPV vaccine should be given **before** sexual debut
-

Misconception #5: Many people cannot afford HPV vaccine because it is too expensive

- Per-dose cost to CDC: \$141.60; Private sector: \$177.70
- HPV vaccine is on the CDC/ACIP immunization schedule and therefore covered by the Vaccines for Children Program (VFC)
- Child is eligible for VFC if <19 years old and is one of the following:
 - Medicaid-eligible
 - Uninsured
 - Underinsured
 - American Indian or Alaska Native
- **Bottom line:** HPV vaccine is expensive but available to children regardless of insurance coverage

Misconception #6: Infringement on religious rights

- Allegheny County (and all other U.S. jurisdictions) have school regulations for mandated vaccines
 - Grades K-12: tetanus, diphtheria, polio, measles, mumps, rubella, hepatitis B, varicella
 - Grades 7-12: tetanus/diphtheria/pertussis, meningococcal vaccine
- Medical exemption
- Religious exemption: “religious grounds or on the basis of a strong moral or ethical conviction similar to a religious belief”
- **Bottom line:** Adding HPV vaccine to the vaccines required for school would not infringe on religious rights because of the existing exemption

Why are we having this discussion?

To improve HPV vaccination rates in Allegheny County, which will lead to fewer HPV-related cancers and deaths

Discussion
