Welcome to the Ohio AAP Spring Education Meeting

<table>
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<tr>
<th>Time</th>
<th>Topic/Speaker</th>
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<tr>
<td>12:00-1:00 pm</td>
<td><strong>HPV Clinical Update, Hesitancy and “On the Horizon” for Immunizations</strong></td>
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<td><em>David Karas, MD, FAAP, Akron Children's Hospital</em></td>
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<td>1:00-1:15 pm</td>
<td><strong>Break</strong></td>
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<td>1:15-2:15 pm</td>
<td><strong>HPV Best Practice Panel from the HPV QI Program</strong></td>
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<td><strong>Moderator:</strong> David Karas, MD, FAAP, Akron Children's Hospital</td>
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<td><strong>Panelists:</strong> Nazhat Taj-Schaal, MD, OSU Outpatient Care, Lewis Center; Tricia Lucin, MD, FAAP, Hillyard Pediatrics; and Natalie Alexander, RN, Nationwide Children's Pediatric &amp; Adolescent Gynecology</td>
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<td>2:15-3:15 pm</td>
<td><strong>School Health &amp; Adolescent Vaccines</strong></td>
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<td><strong>Moderator:</strong> Robert Frenc, MD, FAAP, Cincinnati Children's Hospital Medical Center</td>
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<td><strong>Panelists:</strong> Sara Bode, MD, FAAP, Nationwide Children's Hospital; Lisa Crosby, DNP, APRN, CNP, Cincinnati Children's Hospital Medical Center; and Christina Randolph, DO, MPH, MetroHealth</td>
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<tr>
<td>3:15 pm</td>
<td><strong>Wrap-up and Next Steps</strong></td>
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Ohio AAP Program Overview
Ohio AAP Goofy Golf-July 28, 2023

9 Holes of Golf Fun
Guests will enjoy an evening of networking, golfing and fun activities on each hole in this non-traditional 9-hole outing. Not the greatest golfer?? Perfect, grab a few friends and join us! Singles are welcome too! Come, have fun and help us support Ohio AAP’s Put A Lid On It Bike Helmet Safety Program! SPOTS ARE LIMITED, SO REGISTER NOW!

NEW! Join Us for Trivia
Not a fan of golf, but still interested in supporting the event? New this year; a non-golf option with games and trivia is now available!

Friday, July 28, 2023
5:00 PM Happy Hour • 5:30 PM Tee-Off
Royal American Links, 3500 Miller Pkwy Rd, Galena, OH 43021

REGISTER TODAY by visiting: https://ohioaap.org/goofygolf

Sponsor Options

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<th>$300 per foursome</th>
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Presenting Sponsor
$3,000
- Logo or name recognition on all promotional materials
- Social Media recognition
- 2 foursomes of golfers and 2 drink tickets per player
- 1 hole sponsor
- Full page ad in publication Ohio Pediatrics
- 2 banner ads in newsletter, Ohio AAP Today

Tee-Off Food Sponsor
$1,500
- Logo or name recognition on signage at dining area
- Social Media recognition
- 1 foursome of golfers and 2 drink tickets per player
- 1 hole sponsor

Trivia Sponsor
$1,500
- Logo or name recognition on signage
- Social Media recognition
- 1 foursome of trivia attendees (or golfers) and 2 drink tickets per player
- 1 hole sponsor

Beverage Sponsor
$1,000
- Logo or name recognition on signage at bar area
- Social Media recognition
- 1 foursome of golfers and 2 drink tickets per player
- 1 hole sponsor

Hole Sponsor
$500
- 1 hole sponsor
- 1 foursome of golfers and 2 drink tickets per player
- Social Media recognition

Since it was introduced in 2011, the Ohio AAP’s Put A Lid On It Bike Helmet Program has grown to be one of the Chapter’s finest, reaching community programs. In 13 years, the program has distributed 82,000 helmets across the state!
Ohio AAP Project First Line

ohioaap.org/project-firstline

PROJECT FIRSTLINE PRINTED MATERIALS

PROJECT FIRSTLINE PODCASTS

Reducing Transmission in Clinics (May 26, 2021)
Host: Nick Newman, DO, MS, FAAP Guest: Emily Groho, MPH and Gladys Martinez, MPH

Reducing Transmission in School (May 26, 2021)
Host: Nick Newman, DO, MS, FAAP Guest: Susan Buchanan, MD, MPH

Ventilation and Air Quality (May 26, 2021)
Host: Nick Newman, DO, MS, FAAP Guest: Sergey Grinshpun, PhD

Coming soon...the next set of podcasts from Ohio AAP and CDC’s Project Firstline
Ohio AAP’s own Dr. Sarah Adams (of Growing Up With Dr. Sarah podcast fame) will be speaking with Dr. Deepa Mukundan, University of Toledo College of Medicine and Dr. Eva Johnson, Rainbow Babies and Children’s Hospital about hot topics in infection and disease control. Topics include measles, vaccines and antibiotics stewardship. Stay tuned!

Resources
- CDC: Increasing Threat of Spread of Antimicrobial-resistant Fungus in Healthcare Facilities
- Project Firstline (American Academy of Pediatrics)
Ohio AAP HPV QI Program

Benefits to Participating in HPV QI Project:

- Find tips & materials to optimize parents’ vaccine confidence.
- Help establish clear vaccine roles in your office.
- Learn collaboratively on how to educate staff on importance of HPV vaccine.

From October 2023 - June 2024, participating practices will receive:

- $1,000 stipend to support office staff time
- 25 Points of MOC Part IV Credit
- Education and materials to combat vaccine hesitancy
- Assistance to maximize your vaccine reimbursement
- QI Coach and team support
- Data reports to measure your changes

Contact Lory Sheeran Winland at lwinland@ohioaap.org
Ohio AAP MOBI and TIES Programs

FREE Immunization EDUCATION WITH CME

- One hour, in-office or virtual training by public health nurse educators focused on childhood (MOBI) and adolescent immunizations (TIES)
- Scheduled at your convenience
- The latest vaccine information and resources including updates to the 2023 Immunization Schedule
- Best practice strategies to improve immunization rates

Provided through a partnership with the Ohio Department of Health’s Immunization Program.

www.ohioaap.org • 614-846-5258
@OHPediatrician • AAPOhio • @OhioAAP Show 2003 Oldani

Ohio Chapter
INCORPORATED IN OHIO

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN
Thank You!
Ohio AAP Lead Prevention Board Book

Contact Alex Miller at amiller@ohioaap.org
Welcome Virtual Attendees
OHIO AAP
SPRING EDUCATION MEETING

QR code for
CHECK IN,
agenda, slides
evaluations &
MOC II questions
https://ohioaap.org/springmeeting/

Information
about our
HPV QI
project
https://ohioaap.org/qi-programs-moc-
iv/hpv-q1-project/

Link to
MOBI/TIES
for more information, to schedule a
training and to get additional
educational rack cards
https://ohioaap.org/projects/mobi/

www.ohioaap.org · @OHPediatricians · AAPOhio · OhioAAP · @OhioAAP · ohioaap
Human Papillomavirus, Vaccine Hesitancy, and “On the Horizon”
David Karas, MD, FAAP
David Karas, MD

- General Pediatrician – Akron Children’s Hospital
- Medical Director, Quality and Informatics – Primary Care Service Line
- Medical Director, Clinical Decision Support and Analytics
- Medical Director, School Health
Commercial Interest Disclosure
David Karas, MD, FAAP

I have a relevant financial relationship with the manufacturer of commercial products (Merck) and/or provider of commercial services discussed in this CME activity.

• I do not intend to discuss an unapproved/investigative use of a commercial product/device in my presentation.

All financial relationships have been mitigated.
Objectives

• Describe the burden of HPV disease
• Discuss reasons for vaccine hesitancy with families
• Anticipate additions to the immunization schedule
What is Human Papillomavirus (HPV)?

- DNA virus
- Over 180 types
- Only affects humans
- Almost everyone gets HPV
- Most common STI
HPV Disease

• Warts
  – Common
  – Plantar
  – Flat
  – Anogenital
Cervical Cancer

Number Needed to Treat to Prevent CIN2/CIN3 = 39
HPV Disease

- Cancer
  - Cervix
  - Oropharynx
  - Vulva
  - Anus
  - Penis
HPV-Associated Oropharyngeal Cancer Rates in Males Surpassed Cervical Cancer Rates in Females¹

During 1999-2015, oropharyngeal SCC rates increased 2.7% per year among men
HPV-Attributed Cancer Occurs in Males and Females in the United States

Model of the CDC’s estimated 2012-2016 United States incidence of cancer cases attributed to 7 HPV Types (16, 18, 31, 33, 45, 52, and 58)\(^1\)

- **Vaginal**: \(~2\) women per day
- **Vulvar**: \(~7\) women per day
- **Anal**: \(~11\) women and \(~5\) men per day
- **Cervical**: \(~27\) women per day
- **Oropharyngeal**: \(~6\) women and \(~29\) men per day

\(~31,400\) **TOTAL CASES EACH YEAR, EQUIVALENT TO**

For most people, HPV clears on its own. But, for those who don’t clear the virus, it could cause certain cancers and diseases.\(^2\,^4\)

There is no way to predict which patients who have HPV will develop cancer.\(^5\)

- The CDC analyzed data from the United States Cancer Statistics (USCS) to assess the incidence of HPV-associated cancers and to estimate the annual number of cancers caused by HPV, overall and by state, during 2012-2016.
- The estimated number of cancers attributable to HPV was calculated by multiplying the average number of HPV-associated cancers by the percentage of cancers diagnosed from 1993-2005 that were attributable to HPV.\(^1\,^6\)
- Not all cervical, vulvar, vaginal, anal, and oropharyngeal cancers are caused by HPV.\(^1\)
- Detection of HPV DNA in an HPV study is insufficient to indicate a causal relation with the tumor.\(^6\)

Estimated cases per day were calculated by dividing annual average by 365 days. This assumes equal distribution by day, which is an estimate and not an exact calculation.

CDC=Centers for Disease Control and Prevention. HPV=human papillomavirus.

Burden of HPV Disease

- 1 out of 435 American women dies of cervical cancer
- Over 6100 HPV cancer deaths in the US annually
- Over 295,000 HPV cancer deaths worldwide
Prevent HPV

• Abstinence – Very effective
Prevent HPV

- Abstinence – Very effective
- Condoms – Not great
Prevent HPV

• Abstinence – Very effective
• Condoms – Not great
• Vaccine – Very effective
HPV Cancer Vaccine – Let’s Make Some!

- Viral DNA
- Brewer’s yeast (Saccharomyces cerevisiae)
- L1 proteins self-assemble into little shells with no DNA
- Break open the yeast and purify the VLPs
- Inject into muscle
- Make antibodies
Indication for GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant)

INDICATED FOR THE PREVENTION OF:
- Cervical, vulvar, vaginal, anal, oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58
- Cervical, vulvar, vaginal, and anal precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58
- Genital warts caused by HPV Types 6 and 11

INDICATED FOR THE PREVENTION OF:
- Anal, oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58
- Anal precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58
- Genital warts caused by HPV Types 6 and 11

The oropharyngeal and head and neck cancer indication is approved under accelerated approval based on effectiveness in preventing HPV-related anogenital disease. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
Does it Work?

Impact of HPV vaccination in the first 9 years after its introduction

- HPV 16 and HPV 18 infections: -83%
  Among girls aged 13 to 19 years

- Anogenital warts: -67%
  Among girls aged 15 to 19 years

- Cervical lesions: -51%
  Among girls aged 15 to 19 years

HPV Vaccine Efficacy Against Cancer and Diseases Caused by HPV Types 6, 11, 16, and 18 in Females and Males Ages 16–26 Years

5 AAHS-CONTROLLED CLINICAL STUDIES

Vulvar cancer
HPV 16- or 18-related VIN 2/3 100%
  n=7772

Vaginal cancer
HPV 16- or 18-related ValN 2/3 100%
  n=7772

Cervical cancer
HPV 16- or 18-related CIN 2/3 or AIS ~98%
  n=8493

Genital warts
HPV 6-, 11-, 16-, or 18-related genital warts 99%
  IN FEMALES
  n=7900
  IN MALES
  n=1394

Anal cancer in males
HPV 6-, 11-, 16-, or 18-related AIN 2/3 ~89%
  n=194

~75%

16–26 years old

20,541 FEMALES
4055 MALES

Efficacy of GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] was assessed in 5 AAHS-controlled, double-blind, randomized clinical studies evaluating 24,596 individuals (20,541 girls and women 16–26 years of age and 4055 boys and men 16–26 years of age). The per-protocol efficacy population received all 3 vaccinations within 1 year of enrollment, had no major deviations from the study protocol, were naïve to the relevant HPV type(s) (Types 6, 11, 16, and 18) prior to dose 1, and remained PCR-negative to the relevant HPV type(s) through 1 month post-dose 3 (month 7).
Who Gets Two Doses?

- A 2-dose schedule is recommended for **people who get the first dose before their 15th birthday**. In a 2-dose series, the second dose should be given 6–12 months after the first dose (0, 6-12-month schedule).

- The minimum interval is 5 months between the first and second dose. If the second dose is administered after a shorter interval, a third dose should be administered a minimum of 5 months after the first dose and a minimum of 12 weeks after the second dose.

- If the vaccination schedule is interrupted, vaccine doses do not need to be repeated (no maximum interval).

- Immunogenicity studies have shown that two doses of HPV vaccine given to 9–14-year-olds at least 6 months apart provided as good or better protection than three doses given to older adolescents or young adults.
Dosing

Who Gets Three Doses?

A 3-dose schedule is recommended for people who get the first dose on or after their 15th birthday, and for people with certain immunocompromising conditions.

- In a 3-dose series, the second dose should be given 1–2 months after the first dose, and the third dose should be given 6 months after the first dose (0, 1–2, 6-month schedule).

- The minimum intervals are 4 weeks between the first and second dose, 12 weeks between the second and third doses, and 5 months between the first and third doses. If a vaccine dose is administered after a shorter interval, it should be re-administered after another minimum interval has elapsed since the most recent dose.

- If the vaccination schedule is interrupted, vaccine doses do not need to be repeated (no maximum interval).
Risks and Side Effects

• More than 135 million doses of HPV vaccines have been given

Vaccines, like any medicine, can have side effects. Common side effects from HPV shots are mild and get better within a day or two. These include:

• Pain, redness, or swelling in the arm where the shot was given
• Fever
• Dizziness or fainting (fainting after any vaccine, including HPV vaccine, is more common among adolescents than others)
• Nausea
• Headache or feeling tired
• Muscle or joint pain
Vaccine Hesitancy

“Be curious, not judgmental”
- Ted Lasso  Walt Whitman
Vaccine History

• Vaccines are not new...
Smallpox

- “Smallpox” is not the “great pox” (syphilis)
- Fever, vomiting, mouth ulcers, rash
- 30% fatality
- Has been found in Egyptian mummies
- Killed 300 million people in the 20th century
Smallpox Vaccine

- Airborne transmission resulted in very severe disease
- Skin infections were milder
- Inoculation may have been performed in China as early as the 10th century
- Powdered scabs or pus placed in nose or small cut
Smallpox Vaccine – Edward Jenner

- Milkmaids did not get smallpox
- Cowpox seemed to induce immunity to smallpox
- Numerous physicians tested cowpox vaccines
- Scraped pus was injected into patient’s arms and then they were later exposed to smallpox without developing disease
- Jenner published in 1798
Modern Vaccine Hesitancy

• 1998 – Andrew Wakefield published in *Lancet*
  • MMR increased risk of autism
  • 12 patients, no controls
  • Serious scientific misrepresentation and ethical violations
  • Wakefield was funded by lawyers suing vaccine manufacturers
Common Myths

- Autism
- Mercury, aluminum, formaldehyde
- Too many vaccines at once
- Natural immunity is better
- Infertility
- Promiscuity
- Induced-magnetism
- 5G
Wisconsin Girl Dies as a Result of Receiving Gardasil HPV Vaccine

An online article claiming that a 12-year-old girl in Waukesha, Wisconsin, died as a result of receiving the Gardasil HPV vaccine is based on misinformation.

By David Emery
Published 5 August 2016
Wisconsin Girl Dies as a Result of Receiving Gardasil HPV Vaccine

An online article claiming that a 12-year-old girl in Waukesha, Wisconsin, died as a result of receiving the Gardasil HPV vaccine is based on misinformation.

By David Emery
Published 5 August 2016

Actual Cause of Death: Diphenhydramine Intoxication
NHS Trust suspends cervical cancer vaccinations after girl, 14, dies within hours of jab

By DANIEL MARTIN FOR THE DAILY MAIL
UPDATED: 08:43 EDT, 2 October 2009

Natalie Morton: The schoolgirl died hours after having the cervical cancer jab
NHS Trust suspends cervical cancer vaccinations after girl, 14, dies within hours of jab

By DANIEL MARTIN FOR THE DAILY MAIL
UPDATED: 08:43 EDT, 2 October 2009

Actual Cause of Death: Chest Tumor

Natalie Morton: The schoolgirl died hours after having the cervical cancer jab
Tens of thousands of teenage girls believed to have fallen ill with debilitating illnesses after routine HPV cervical cancer jab

- Medicines and Healthcare Products Regulatory Agency had 8,228 adverse reaction reports in 10 years - only estimated 10 per cent of real tally
- Side effects including chest and abdominal pains, exhaustion, breathing difficulties, fibromyalgia and postural orthostatic tachycardia syndrome
- Some have been left wheelchair-bound by apparent effects of vaccine
- Despite this MHRA said it had no concerns on numbers of HPV complaints

By FIONA MACRAE SCIENCE CORRESPONDENT FOR THE DAILY MAIL

- Report deaths prior to autopsy
- Sensational stories get more clicks
- Feel the need to present “both sides” equally
- This is a false equivalence since only one side has evidence
The COVID-19 Era

• Events of the past decade have led to increased polarization, decreased pluralism, and heightened group identity
• Search algorithms, social media, and traditional media polarize and sensationalize to increase revenue
• The more people identify with their group, the more they accept that group’s beliefs
The COVID-19 Era

• Anti-vaccination spans political parties
• Far left:
  – Distrust of Big Pharma
  – All “natural”
• Far right:
  – Distrust of government
  – Suspicion of the science establishment
  – Cherishing personal freedoms (no mandates)
The COVID-19 Era

• Ideology does have a strong effect on trust in government experts...
The COVID-19 Era

• Ideology does have a strong effect on trust in government experts...

• Political worldview *does not* seem to influence how much people trust their primary health care provider

  • The influence of political ideology and trust on willingness to vaccinate (nih.gov)
The COVID-19 Era

- Ideology does have a strong effect on trust in government experts...
- Political worldview *does not* seem to influence how much people trust their primary health care provider

Families trust us!

- [The influence of political ideology and trust on willingness to vaccinate](nih.gov)
Presumptive Delivery Strategy

• Today your child will get their diphtheria, tetanus, and pertussis booster, their HPV cancer vaccine, and their meningitis vaccine...
What if they say “no”?

• Respond with genuine *curiosity* and *empathy*
• Parents only refuse vaccines because they believe that it is in the best interest of their children
• We actually have the same goal!
• An argument or attack only makes people defensive
What if they say “no”?

- For many, vaccine hesitancy is not due to a knowledge deficit
- It is due to cultural beliefs and perceived risk
- It is rare for evidence to overcome belief
- We can identify barriers by asking...
What if they say “no”?

• “What are your concerns about the vaccine?”
Many Reasons for Hesitancy

- Medical
- Religious
- Cultural
- Political
- Personal
Do Vaccines Work? - Yes

• Smallpox – eradicated by 1980
• Polio – only endemic in Pakistan and Afghanistan
• Measles
Are Vaccines Safe? - Yes

- All vaccines are vigorously tested for safety and efficacy
- Serious side effects are rare (1-2 severe allergic reactions per million doses)
- Vaccine Adverse Event Reporting System
Case Study - RotaShield

• Rotavirus vaccine approved in August 1998
• Intussusception was identified in early trials, but was not statistically significant
• Normal rate is 1 in 3000
• Increased risk was 1-2 in 10,000
• Vaccine was withdrawn from use
• How long did it take?
Case Study - RotaShield

- Rotavirus vaccine approved in August 1998
- Intussusception was identified in early trials, but was not statistically significant
- Normal rate is 1 in 3000
- Increased risk was 1-2 in 10,000
- Vaccine was withdrawn from use
- How long did it take? – 9 months!

*Vaccines: VPD-VAC/Rotavirus/RotaShield and Intussusception Historical info (cdc.gov)*
Will Too Many Vaccines Overload the Immune System? - Yes

• Administering 10,000 vaccines at once would likely deplete B-cell capacity
• The immunization schedule recommended by the ACIP has been tested and is safe
• There are no data on alternative schedules

• Addressing Parents’ Concerns: Do Multiple Vaccines Overwhelm or Weaken the Infant’s Immune System? | American Academy of Pediatrics (aappublications.org)
Do Vaccines Cause Autism? - No

• Many large-scale studies have found no link between vaccines and autism
• Thimerosal was removed from all single dose vaccines due to theoretical risk. There has been no decrease in the rates of autism.

• Autism and Vaccines | Vaccine Safety | CDC
Are Vaccines Made From Aborted Fetuses? – Kind of...
• Varicella, Rubella, Hepatitis A, and J&J COVID-19 vaccines are grown in human cell cultures obtained from fetuses decades ago
• There is no human tissue in the vaccines

• Vatican Statement on Vaccines Derived From Aborted Human Fetuses (immunize.org)
Is My Child At Risk of Getting that Disease? - Depends

- Polio – No
- Strep pneumo – Yes
- Chickenpox – Probably. And it will be yucky.
- Cervical cancer:
  - 1 in 45 unvaccinated and unscreened women
  - 1 in 532 with regular screening
  - Risk of severe reaction to vaccine = 1 in 1,000,000

- Age at last screening and remaining lifetime risk of cervical cancer in older, unvaccinated women: a modelling study - The Lancet Oncology
COVID-19 Vaccine

• Pfizer-BioNTech and Moderna: mRNA for spike protein
• Johnson & Johnson: adenovirus vector with spike protein DNA
COVID-19 Vaccine Side Effects

- Pain, redness, swelling
- Tiredness, headache, muscle pain, chills, fever
- Anaphylaxis 2-11 per 1 million doses
- J&J: Blood clots in women 18-49y (7 per million)
- mRNA: Myocarditis in young males (35 per million – COVID disease has much higher risk)
COVID-19 Vaccine Schedule – Pfizer-BioNTech

- 6m-4y: Three doses and at least 1 bivalent
- 5y+: One bivalent dose
- Immunocompromised 5y+: Two bivalent doses

As of 4/18/23...
COVID-19 Vaccine Schedule – Moderna

• 6m-5y: Two doses and at least 1 bivalent
• 6y+: One bivalent dose
• Immunocompromised 6m-5y: Three doses and at least 1 bivalent
• Immunocompromised 6y+: Two bivalent doses

As of 4/18/23...
COVID-19 Vaccine Facts

• Can I get COVID from the shot? – No
• Will it make me infertile? – No
• Will it change my DNA? – No
• Will it make me magnetic? – Doubt it
• Does it contain microchips that track me with 5G? – I don’t think that is a thing...
• 99% of COVID deaths are unvaccinated
So What Do I Do?

• Paternalism will not work
• Arguing will not work
• Build an empathetic relationship
• Not a doctor and patient, but two people trying to figure out what is best for a child they both care about
So What Do I Do?

• Emotions and stories are often more persuasive than facts
• Do you have stories of people who have been impacted by vaccine-preventable disease?
• Did you do research prior to vaccinating your own children?
Ohio AAP Resources

- Maximizing Office Based Immunization (MOBI) and Teen Immunization Education Sessions (TIES) | Ohio AAP

Maximizing Office Based Immunization (MOBI) and Teen Immunization Education Sessions (TIES)

According to the National Immunization Survey, only 66.4% of Ohio babies have received all of the immunizations recommended to keep them safe from many dangerous diseases. For teens, while 85.1% have received the Tdap vaccine and 87.3% have received the meningococcal serogroup ACWY vaccine, the rates for HPV are still very low for both boys and girls. The Ohio Chapter, American Academy of Pediatrics' immunization programs, Maximizing Office Based Immunization (MOBI) and Teen Immunization Education Sessions (TIES), combines more than 20 years of evidence-based science to educate physician offices on the best practices on immunizing their patients.

The programs are one-hour, in-office peer-to-peer education presentations that provide continuing medical education (CME) credits to physicians. Nurses and medical assistants can claim the hour of continuing education.

The MOBI and TIES programs have impacted many lives since it began in 1996:

- 700 practices reached per year
- Approximately 350,000 patients
- 77% of practices successfully implemented immunization best practices
Ohio AAP Resources

- Ohio Champions for Vaccines (OC4V) | Ohio AAP
Ohio AAP Resources

• Immunization Resources | Ohio AAP
Ohio AAP Resources

- It’s Okay to Ask – FastVaxFacts (ohioaap.org)
• COVID-19 Resources | Ohio AAP
In Summary

• Vaccine hesitancy is as old as vaccines
• Be curious, not judgmental
• Build a personal, respectful, empathetic bond
• A relationship built in an exam room can be very powerful
On the Horizon - Pneumococcal

- Streptococcus pneumoniae
- >100 serotypes
- Acute otitis media, acute bacterial sinusitis, community-acquired pneumonia, meningitis
- 4 million illnesses, 445K hospitalizations, 22K deaths
On the Horizon - Pneumococcal

- Prevnar (PCV7) – 1999
- Prevnar 13 (PCV13) – 2010
- Vaxneuvance (PCV15) – 2022
- Prevnar 20 (PCV20) – 2023 (probably)

- However, max benefit around 4 years before serotype replacement
On the Horizon - Pneumococcal

- PCV15 Vaxneuvance (Merck)
- Serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F
On the Horizon - Pneumococcal

• PCV20 Prevnar 20 (Pfizer)
• Serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F
• Approved for 18y+
• Likely pediatric indication in 2023
On the Horizon - Pneumococcal

- Same schedule as Prevnar 13
- Approval has been based on immunogenicity data
- Increased serotypes, but decreased immune response
- Good enough for invasive disease, but maybe not for AOM and ABS

S. pneumo in ears (yellow = in PCV20)  Potential coverage

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<th>Serotype</th>
<th>Coverage</th>
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<td>35B (22%)</td>
<td>9% PCV13</td>
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<tr>
<td>15B/C (18%)</td>
<td>17% PCV15</td>
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<tr>
<td>23B (11%)</td>
<td>32% PCV20</td>
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<tr>
<td>21 (8%)</td>
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<td>15A (6%)</td>
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</tr>
<tr>
<td>33 F, 23A (5%)</td>
<td></td>
</tr>
<tr>
<td>3, 19 F, 19A, 22 F, 10, 16 F, 11C (3%)</td>
<td></td>
</tr>
<tr>
<td>11A (2%)</td>
<td></td>
</tr>
</tbody>
</table>
On the (Longer) Horizon - Pneumococcal

- GSK
- 24-valent in phase II
- 30-plus in development

**MAPS vaccines** are designed for robust B-cell and T-cell immune response.

<table>
<thead>
<tr>
<th>Protein Antigens</th>
<th>Polysaccharide Antigens</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD8+ Cytotoxic T-Cells</td>
<td>B-Cell</td>
</tr>
<tr>
<td>CD4+ Helper T-Cells Th1/Th17</td>
<td>B-Cell</td>
</tr>
<tr>
<td>CD4+ Helper T-Cells Th2</td>
<td>B-Cell</td>
</tr>
</tbody>
</table>

MAPS technology uniquely enables
- Unparalleled CD8+ response
- Broad CD4+ T-Cell responses
- Pathogen-specific B-Cell response

rhizavidin-protein fusion antigen
polysaccharide antigen
On the Horizon – Pentavalent Meningococcal Vaccine

ACWY finally meets B...

**GSK MenABCWY Vaccine**
- Comprised of Menceve 1 Vial (serogroups ACWY) and Bexsero (serogroup B)
  - Both currently licensed in US

**Pfizer MenABCWY Vaccine**
- Comprised of Nimenrix (serogroups ACWY) and Trumenba (serogroup B)
  - Trumenba currently licensed and available in US
  - Nimenrix not licensed in US but used extensively in Europe and elsewhere
On the Horizon – Pentavalent Meningococcal Vaccine

### Enhanced Meningococcal Disease Surveillance Report, 2020

#### Meningococcal Disease Cases and Incidence by Serogroup and Age

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>B</th>
<th>C</th>
<th>W</th>
<th>Y</th>
<th>Nongroupable</th>
<th>Other‡/Unknown</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1</td>
<td>7 (0.19)</td>
<td>3 (0.08)</td>
<td>0 (0.00)</td>
<td>3 (0.08)</td>
<td>1 (0.03)</td>
<td>2 (0.05)</td>
<td>16 (0.43)</td>
</tr>
<tr>
<td>1–4</td>
<td>6 (0.04)</td>
<td>5 (0.03)</td>
<td>0 (0.00)</td>
<td>2 (0.01)</td>
<td>2 (0.01)</td>
<td>4 (0.03)</td>
<td>19 (0.12)</td>
</tr>
<tr>
<td>5–10</td>
<td>2 (0.01)</td>
<td>2 (0.01)</td>
<td>1 (0.00)</td>
<td>4 (0.02)</td>
<td>0 (0.00)</td>
<td>3 (0.01)</td>
<td>12 (0.05)</td>
</tr>
<tr>
<td>11–15</td>
<td>1 (0.00)</td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
<td>1 (0.00)</td>
<td>1 (0.00)</td>
<td>2 (0.01)</td>
<td>5 (0.02)</td>
</tr>
<tr>
<td>16–23</td>
<td>9 (0.03)</td>
<td>4 (0.01)</td>
<td>1 (0.00)</td>
<td>3 (0.01)</td>
<td>7 (0.02)</td>
<td>6 (0.02)</td>
<td>30 (0.09)</td>
</tr>
<tr>
<td>24–44</td>
<td>11 (0.01)</td>
<td>11 (0.01)</td>
<td>2 (0.00)</td>
<td>9 (0.01)</td>
<td>8 (0.01)</td>
<td>7 (0.01)</td>
<td>48 (0.05)</td>
</tr>
<tr>
<td>45–64</td>
<td>13 (0.02)</td>
<td>19 (0.02)</td>
<td>5 (0.01)</td>
<td>17 (0.02)</td>
<td>3 (0.00)</td>
<td>8 (0.01)</td>
<td>65 (0.08)</td>
</tr>
<tr>
<td>≥65</td>
<td>6 (0.01)</td>
<td>10 (0.02)</td>
<td>6 (0.01)</td>
<td>11 (0.02)</td>
<td>4 (0.01)</td>
<td>3 (0.01)</td>
<td>40 (0.07)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>55 (0.02)</strong></td>
<td><strong>54 (0.02)</strong></td>
<td><strong>15 (0.00)</strong></td>
<td><strong>50 (0.02)</strong></td>
<td><strong>26 (0.01)</strong></td>
<td><strong>35 (0.01)</strong></td>
<td><strong>235 (0.07)</strong></td>
</tr>
</tbody>
</table>
On the Horizon – Meningitis B

• Not cost effective
• $9.6 million to $12.7 million per quality adjusted life year
• Number needed to vaccinate to prevent 1 death = 1.6 – 2.8 million
• However…
Neisseria meningitis vs Neisseria gonorrhea

• Greater than 90% homology between membrane proteins
• Bexsero has group B OMVs
• Studies show up to 40% efficacy against gonorrhea
• 55 cases of meningitis B vs 700,000 cases of gonorrhea
• This can really change the math...
RSV

• 1967: Formalin-inactivated vaccine for RSV (FIRSV)
• RSV-naïve infants developed enhanced RSV disease
  – 80% hospitalized, 2 deaths
  – Did not develop protective antibody
  – Did develop helper T cells, but no cytotoxic T cells
  – Just caused eosinophil and immune complex deposition in lungs
On the Horizon - RSV

- Pfizer – RSVpreF (ABRYSV0)
- Bivalent (A and B)
- Targets viral fusion protein that it uses to enter cells
- Administered to pregnant women
- Efficacy against “severe medically attended lower respiratory tract illness”
  - First 90 days: 81.8%
  - First 6 months: 69.4%
On the Horizon - RSV

- Nirsevimab – Monoclonal antibody
- Collaboration between AztroZeneca and Sanofi
- IgG has a 21-day half-life
- Several mutations can extend that
- YTE mutation decreases clearance by 80% and increases half-life by 4
- ONE TIME DOSE!
- Reduced medically attended RSV by 70-80%
- Approved in EU

Beyfortus is given as a single injection into the thigh muscle. It is given once before the RSV season starts or at birth for infants born during the RSV season. The recommended dose is 50 mg for children weighing less than 5 kg and 100 mg for children weighing 5 kg or more.
On the (Longer) Horizon - EBV

- 125,000 cases of infectious mononucleosis
- 10% have fatigue lasting >6m
- Can cause hepatitis, neurologic problems, Hodgkin and Burkitt lymphoma, SLE, MS
- Phase I at NIH
On the (Longer) Horizon – Group A Strep

• A vaccine from the 70s demonstrated 89% efficacy
• In 1979, FDA banned Group A Strep organisms or derivatives from vaccines
• Rule revoked in 2006
• One vaccine, StreptAnova has gone through Phase I
• May be > 80% effective
On the Horizon – Acne

Sanofi working a vaccine targeting *C. acnes* virulence factors

Still in Phase I
References

- Countering Vaccine Hesitancy | American Academy of Pediatrics (aappublications.org)
- Vaccines: VPD-VAC/Rotavirus/Rotashield and Intussusception Historical info (cdc.gov)
- Addressing Parents’ Concerns: Do Multiple Vaccines Overwhelm or Weaken the Infant’s Immune System? | American Academy of Pediatrics (aappublications.org)
- Autism and Vaccines | Vaccine Safety | CDC
- Vatican Statement on Vaccines Derived From Aborted Human Fetuses (immunize.org)
- The influence of political ideology and trust on willingness to vaccinate (nih.gov)
- Age at last screening and remaining lifetime risk of cervical cancer in older, unvaccinated women: a modelling study - The Lancet Oncology
Resources

• Maximizing Office Based Immunization (MOBI) and Teen Immunization Education Sessions (TIES) | Ohio AAP
• Ohio Champions for Vaccines (OC4V) | Ohio AAP
• Immunization Resources | Ohio AAP
• COVID-19 Resources | Ohio AAP
• Immunizations (aap.org)
• It’s Okay to Ask – FastVaxFacts (ohioaap.org)
• Need Help Responding to Vaccine-Hesitant Parents? (immunize.org)
Time for a break

See you in 15!
HPV Best Practice Panel

**Moderator:** David Karas, MD, FAAP, Akron Children's Hospital

**Panelists:** Nazhat Taj-Schaal, MD, OSU Outpatient Care, Lewis Center; Tricia Lucin, MD, FAAP, Hilliard Pediatrics; and Natalie Alexander, RN, Nationwide Children’s Pediatric & Adolescent Gynecology
Disclosures

David Karas, MD, FAAP has the following relationship to disclose:

• Merck Speakers Bureau

All relevant financial relationships have been mitigated
Our Panelists

Moderator: David Karas, MD, FAAP, Akron Children's Hospital

Nazhat Taj-Schaal, MD
OSU Outpatient Care, Lewis Center

Tricia Lucin, MD, FAAP
Hilliard Pediatrics

Natalie Alexander, RN
Nationwide Children’s Pediatric & Adolescent Gynecology
Ohio AAP HPV QI Program

Benefits to Participating in HPV QI Project:

Find tips & materials to optimize parents’ vaccine confidence.

Help establish clear vaccine roles in your office.

Learn collaboratively on how to educate staff on importance of HPV vaccine.

From October 2023 - June 2024, participating practices will receive:

- $1,000 stipend to support office staff time
- 25 Points of MOC Part IV Credit
- Education and materials to combat vaccine hesitancy
- Assistance to maximize your vaccine reimbursement
- QI Coach and team support
- Data reports to measure your changes

Contact Lory Sheeran Winland at lwinland@ohioaap.org
School Health and Vaccines
Panel Discussion

**Moderator:** Robert Frenck, MD, FAAP, *Cincinnati Children’s Hospital Medical Center*

**Panelists:** Sara Bode, MD, FAAP, *Nationwide Children’s Hospital;*
Lisa Crosby, DNP, APRN, CNP, *Cincinnati Children’s Hospital Medical Center;* and
Christina Randolph, DO, MPH, *MetroHealth*
Disclosures

Robert Frenck, MD, FAAP has the following relationships to disclose:

• Pfizer and Moderna to conduct clinical trials.
• Consultant for Pfizer, Merck, Sanofi, Johnson and Johnson

All relevant financial relationships have been mitigated
Our Panelists

**Moderator:** Robert Frenck, MD, FAAP, *Cincinnati Children’s Hospital Medical Center*

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_Nationwide Children’s Hospital_

Christina Randolph, DO, MPH
_MetroHealth_

Lisa Crosby, DNP, APRN, CNP
*Cincinnati Children’s Hospital Medical Center*
Thank You!

Your follow-up email includes

- Evaluation Form
- CME/MOC Part II Claiming Form
- Links to Enroll in Upcoming QI Programs and Education
- Ohio AAP 2023 Annual Meeting

Save the Date - November 3-4, 2023
Thank You!