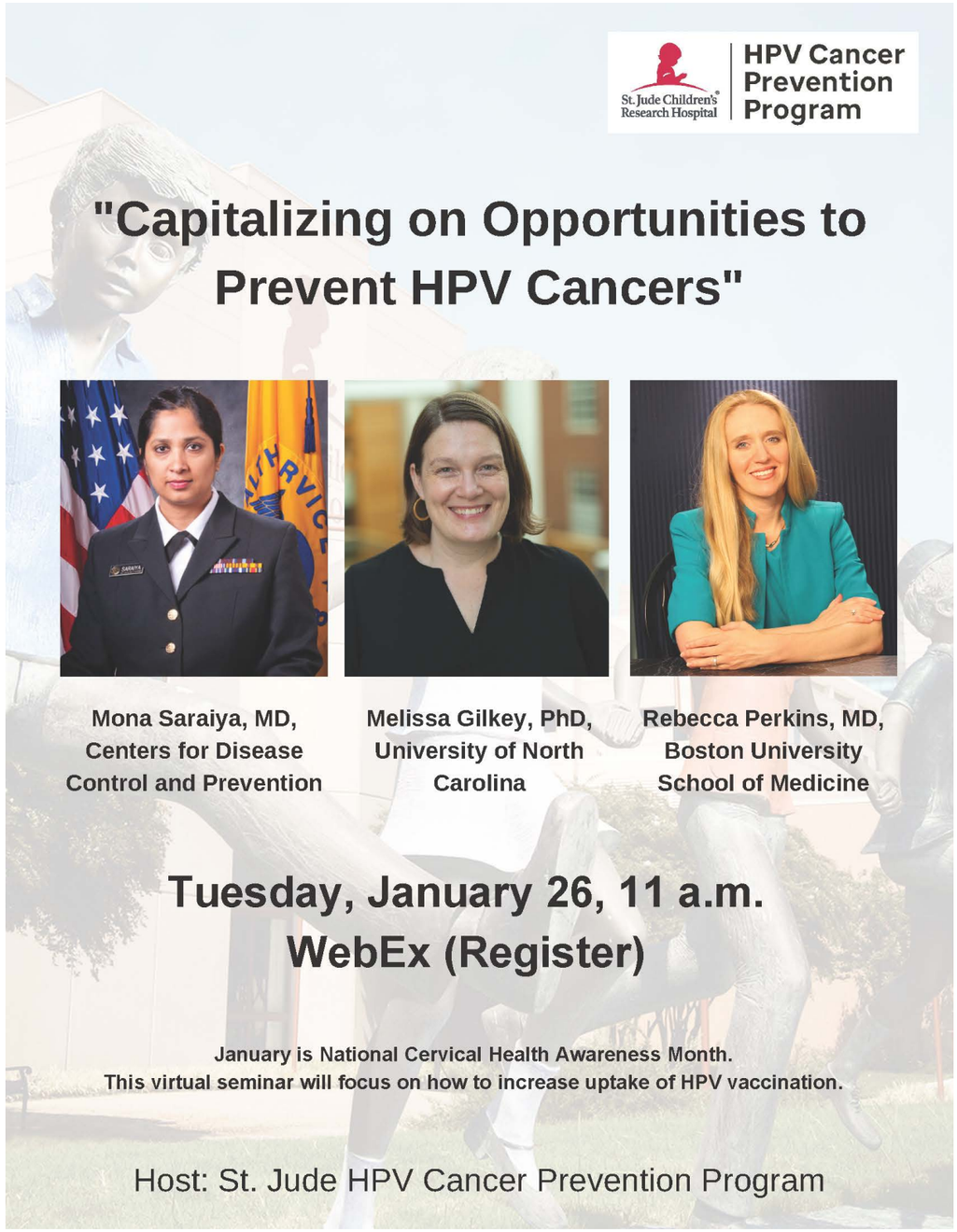
St. Jude Children's Research Hospital®

HPV Cancer Prevention Program

Capitalizing on Opportunities to Prevent HPV Cancers

A Virtual Seminar
Hosted by the St. Jude HPV Cancer Prevention Program
January 26, 2021



Capitalizing on Opportunities to Prevent HPV Cancers

The goal of today's virtual seminar is to share the latest information on how to increase uptake of HPV vaccination to prevent HPV cancers.

St. Jude HPV Cancer Prevention Program

Blue-Sky Projects Accelerate Progress

Promise Magazine, Autumn 2019

What if … we could accelerate efforts to prevent adult cancers by vaccinating children?

Accelerate Progress

[Promise Magazine](), Autumn 2019

Building the HPV Program

- Structure the program team
- Develop and finalize a five-year plan for the program's growth and development
  - Aligned with institutional strategic plan and part of the Community Health Needs Assessment implementation plan
- Build, strengthen, and sustain partnerships – internal and external
- Prepare for implementation – and implementing and evaluating now

HPV Cancer Prevention Program

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Priorities

Community engagement

Partnerships

Health care providers and systems

Public policy and advocacy

HPV Cancer Prevention Program

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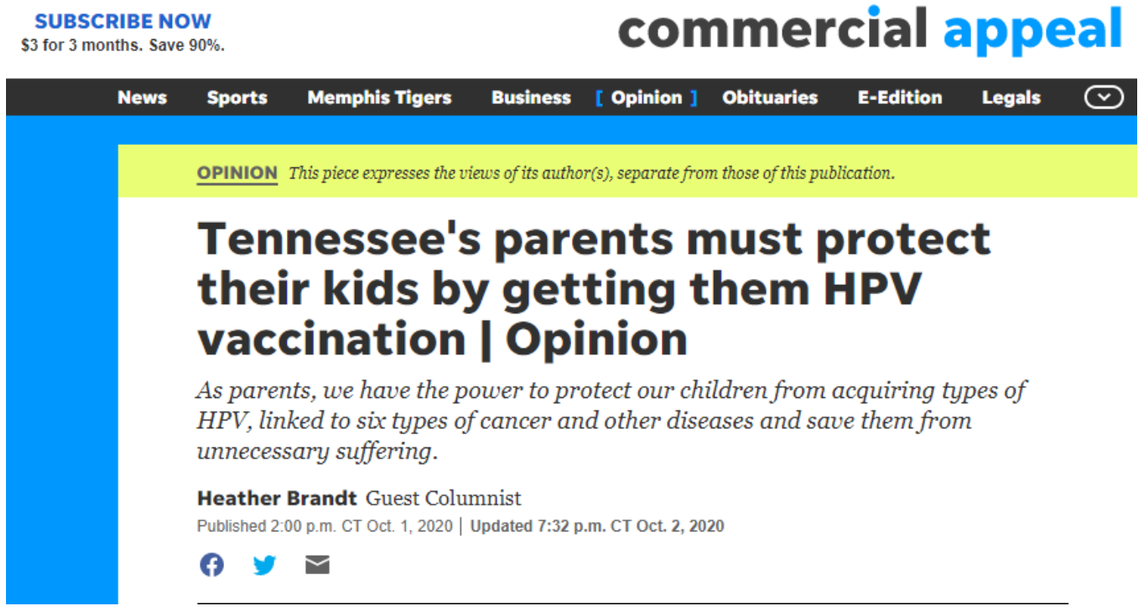
Awareness Activities



Newsweek: Don't Delay Your Child's Vaccinations, Especially Now (August 13, 2020):
https://www.newsweek.com/dont-delay-your-childs-vaccinations-especially-now-opinion-1524992

Commercial Appeal: Tennessee's parents must protect their kids by getting them HPV vaccination (October 1, 2020):
https://www.commercialappeal.com/story/opinion/2020/10/01/protect-tennessees-children-getting-them-hpv-vaccination/5882337002/

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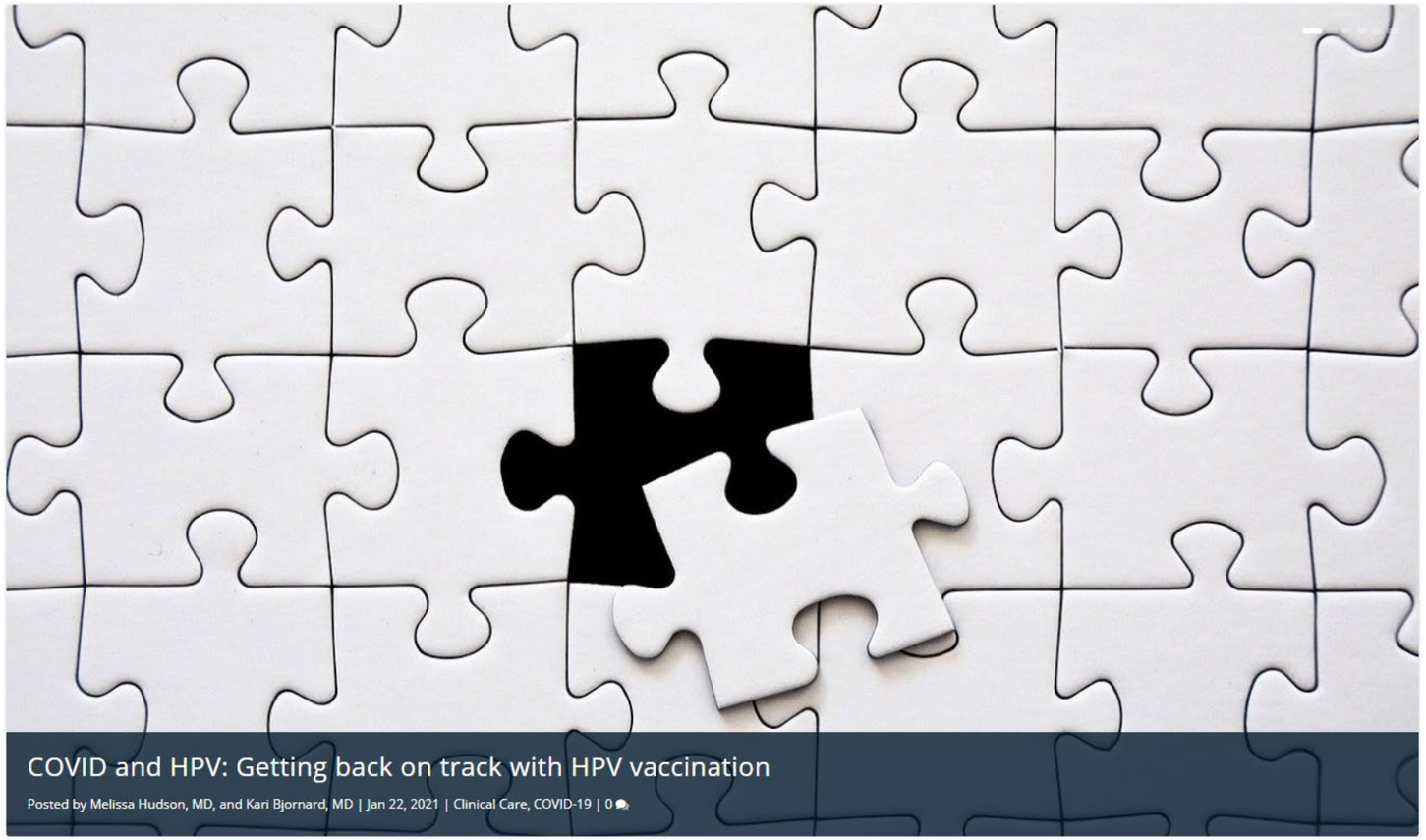
Awareness Activities

ST.JUDE PROGRESS



St. Jude Progress Blogs: COVID and HPV: Getting back on track with HPV vaccination (1/22/2021): https://blogs.stjude.org/progress/hpv-vaccination-collaboration-to-reach-adolescents/

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St. Jude HPV Cancer Prevention Program

Contact us to learn more!

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[HPV Cancer Prevention Program](https://www.stjude.org/research/comprehensive-cancer-center/hpv-cancer-prevention-program.html)
https://www.stjude.org/research/comprehensive-cancer-center/hpv-cancer-prevention-program.html

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CAPT Mona Saraiya, MD, MPH, FACPM

Medical Officer and Team Lead, Epidemiology and Applied Research Branch, Centers for Disease Control and Prevention

Cervical Cancer Moonshot, Division of Cancer Epidemiology and Genetics, National Cancer Institute

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Boston University School of Medicine/ Boston Medical Center

HPV-Cancer Burden and HPV Vaccine Updates

Mona Saraiya, MD, MPH

Division of Cancer Prevention and Control, Centers for Disease Control and Prevention

Cervical Cancer Moonshot, National Cancer Institute

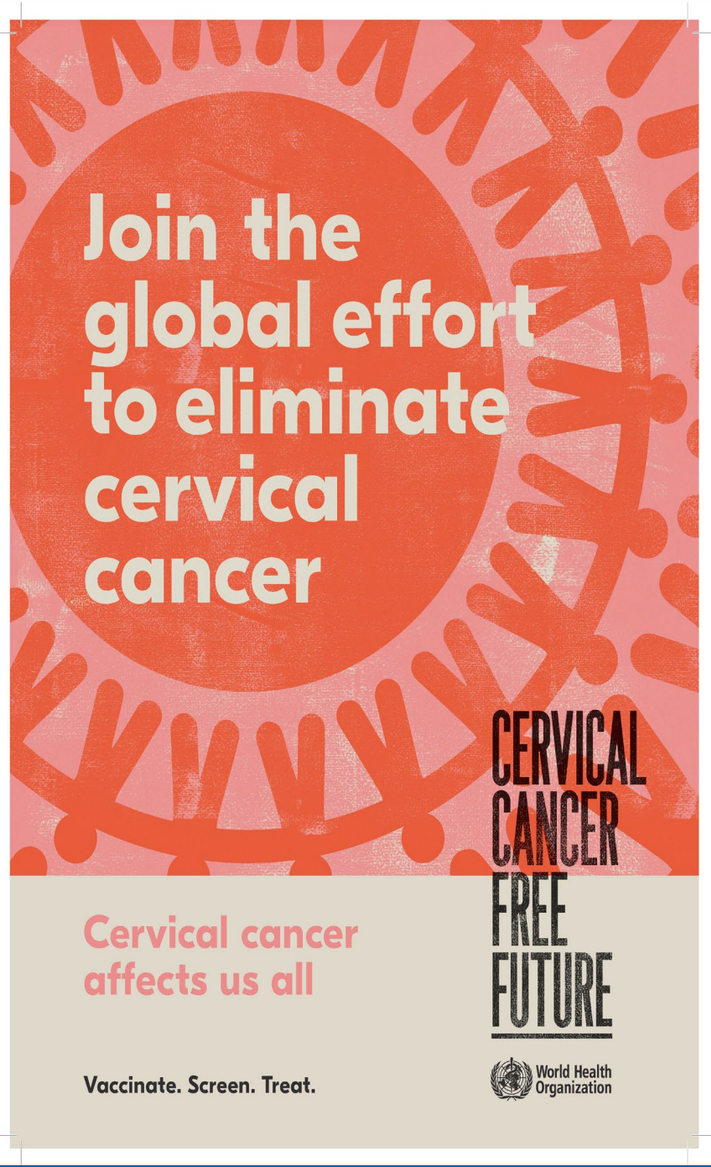
Capitalizing on Opportunities to Prevent HPV Cancers, St Jude's HPV Cancer Prevention Program, Virtual

January 26, 2021

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

- I have not received any funding from sponsors
- I have no conflicts of interest to disclose

WHO Global Initiative



- May 2018: WHO Director General calls for a global initiative for cervical cancer prevention and control, spanning HPV vaccination, screening, diagnosis, treatment of precancer, treatment of cancer, symptom management, and palliative care
- July 2020: World Health Assembly approved resolution
- November 2020: WHO initiative launched!

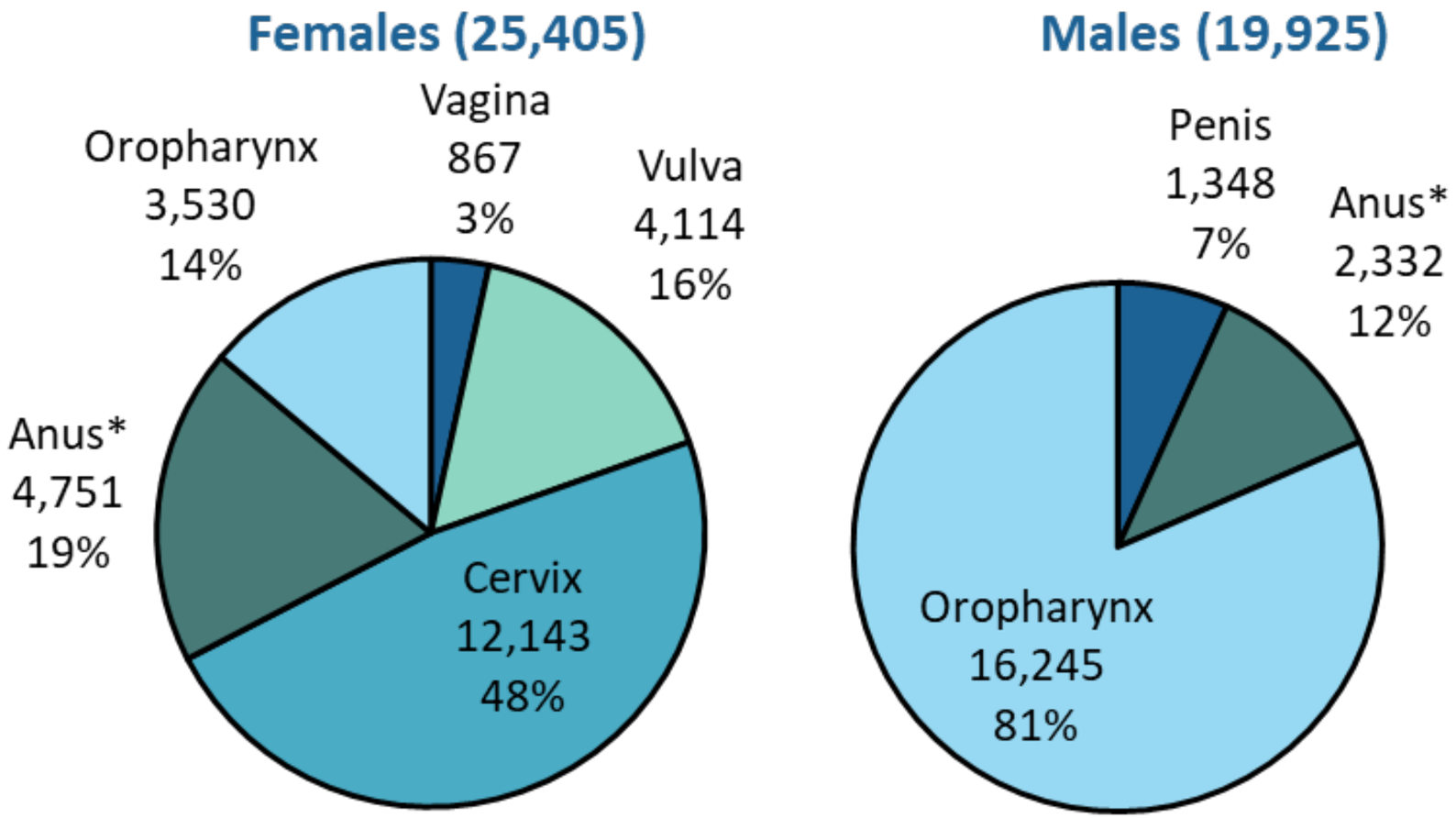
WHO 2030 Goals: 90-70-90

- 90% of girls receive HPV vaccination
- 70% of women screened with a high-quality test
- 90% of women found to have an abnormal test undergo timely and appropriate follow-up
- 90% of women diagnosed with invasive cervical cancer undergo timely and high-quality cancer treatment with effective symptom control
- (30% reduction in cervical cancer mortality, consistent with UN Sustainable Development Goals for 30% reduction in NCD mortality)

Discussion Topics Today

- Burden of HPV Disease
- Practice Guidelines of HPV Vaccine
- Safety and Effectiveness of HPV Vaccine
- Coverage
- Monitoring Impact of HPV Vaccination

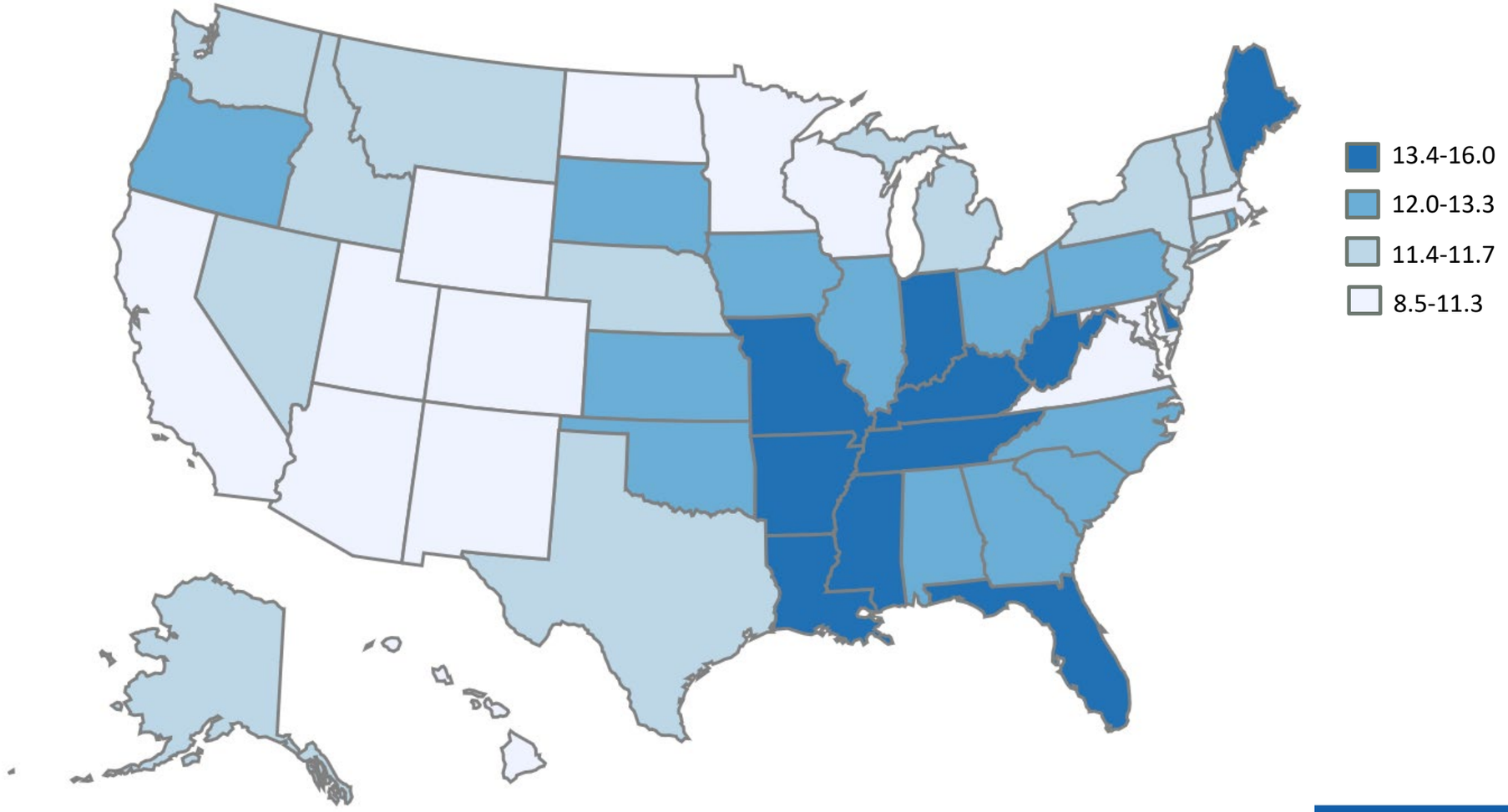
Annual Number of New HPV-Associated Cancer Cases, United States, 2013-2017



*Includes anal and rectal squamous cell carcinomas.

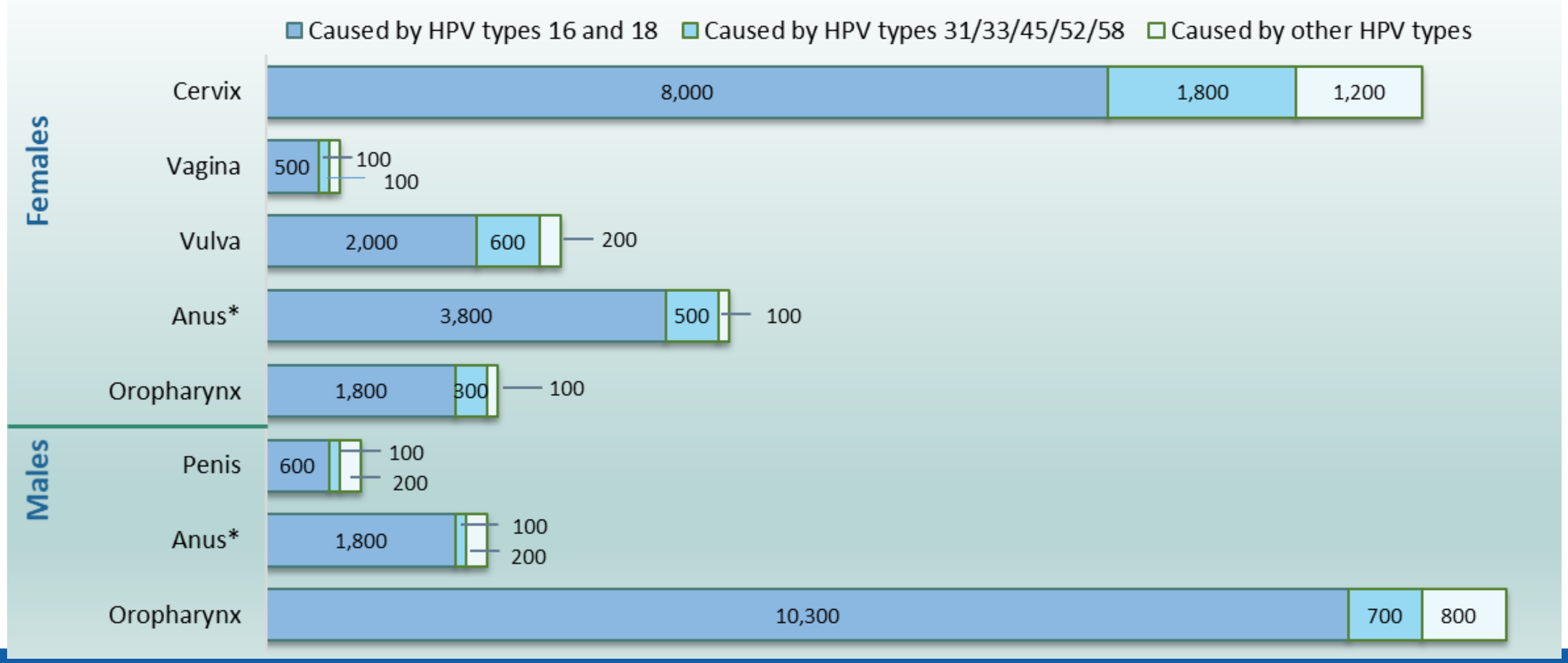
www.cdc.gov/cancer/hpv

HPV-Associated Cancer Rates by State, United States, 2013-2017



Rates per 100,000 population
https://www.cdc.gov/cancer/hpv/statistics/state/

Estimated Number of Cancer Cases Attributable to HPV by Sex, Cancer Type, and HPV Type, United States, 2013-2017



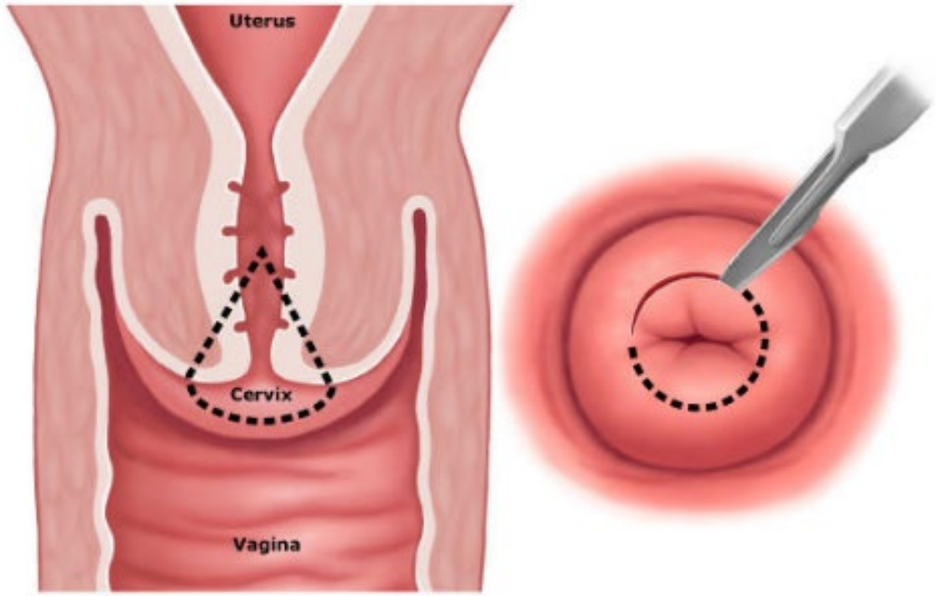
*Includes anal and rectal squamous cell carcinomas.

www.cdc.gov/cancer/hpv


Cervical cancer
is a disease of
inequality

Cervical Pre-Cancer in U.S. Females

- ~196,000 high grade cervical lesions every year



McClung NM, et.al. MMWR Morb Mortal Wkly Rep. 2019 Apr 19;68(15):337-343.

HPV vaccine recommendations

3 doses
Age 11-12
Catch-up through 26

3 doses
Age 11-12
Catch-up through 21

GARDASIL 9
Human Papillomavirus 9-valent Vaccine
(Recombinant, adsorbed)

2 doses if start before age 15

Catch-up through 26

Age 27-45 based on shared clinical decision making

2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019

Monitoring HPV Vaccine Safety

CDC Support for HPV Vaccination in the United States

United States Vaccine Safety System

System	Collaborators	Description
Vaccine Adverse Event Reporting System (VAERS)	CDC and FDA	Frontline, spontaneous reporting system to detect potential vaccine safety issues
Vaccine Safety Datalink (VSD)	CDC and 8 integrated health care systems	Large-linked database system used for active surveillance and research ~12.1 million members (~3.7% of US pop)
Clinical Immunization Safety Assessment (CISA) Project	CDC and 7 academic centers	Expert collaboration that conducts individual clinical vaccine safety assessments and clinical research
Post-Licensure Rapid Immunization Safety Monitoring Program (PRISM)	FDA and 6 partner organizations	Large distributed database system used for active surveillance and research ~170 million individuals (~53% of US pop)

Over 12 Years of HPV Vaccine Safety Data

- HPV vaccines are safe
- Reactions after vaccination may include:
  - Injection site reactions: pain, redness, and/or swelling in the arm where the shot was given
  - Systemic: fever, headaches
- HPV vaccines should not be given to anyone who has had a previous allergic reaction to the HPV vaccine or who has an allergy to yeast
- Brief fainting spells (syncope) and related symptoms (such as jerking movements) can happen soon after any injection, including HPV vaccine
- Patients should be seated (or lying down) during vaccination and remain in that position for 15 minutes

Gee, et al. *Hum Vaccine Immunother.* 2016.

Evaluating and Monitoring 9-Valent HPV Vaccine Safety in the United States

- Monitoring of VAERS reports
  - Clinical review of serious reports including deaths and other prespecified adverse events
  - Data mining to identify disproportional reporting
- Vaccine Safety Datalink
  - Near real-time monitoring of 10 prespecified outcomes
  - Evaluation of spontaneous abortion
- PRISM
  - Active surveillance and surveillance of serious, unexpected events
- Manufacturer postmarketing commitments
  - Two 10-year studies to assess long-term safety
  - Observational study to further characterize the safety profile in 10,000 persons
  - Pregnancy registry

HPV Vaccination Is Safe

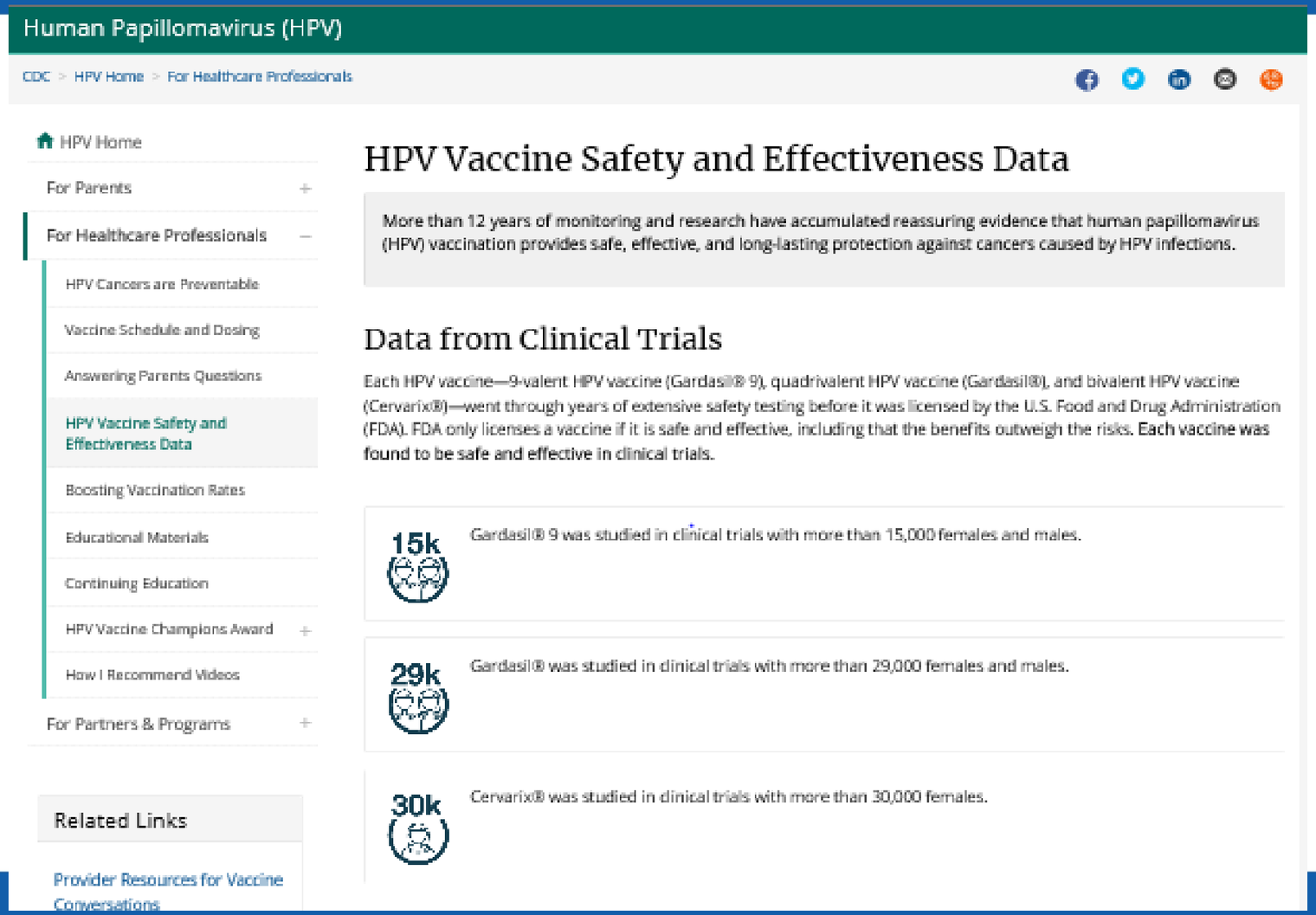
HPV vaccine safety studies have been very reassuring: HPV vaccine has a good safety profile.

CDC and FDA continue to monitor and evaluate the safety of HPV vaccines, along with all vaccines.

Clinicians can reassure parents who may have concerns that HPV vaccination is safe.

https://www.cdc.gov/vaccinesafety/vaccines/hpv/hpv-safety-faqs.html

HPV Vaccine Safety and Effectiveness Data

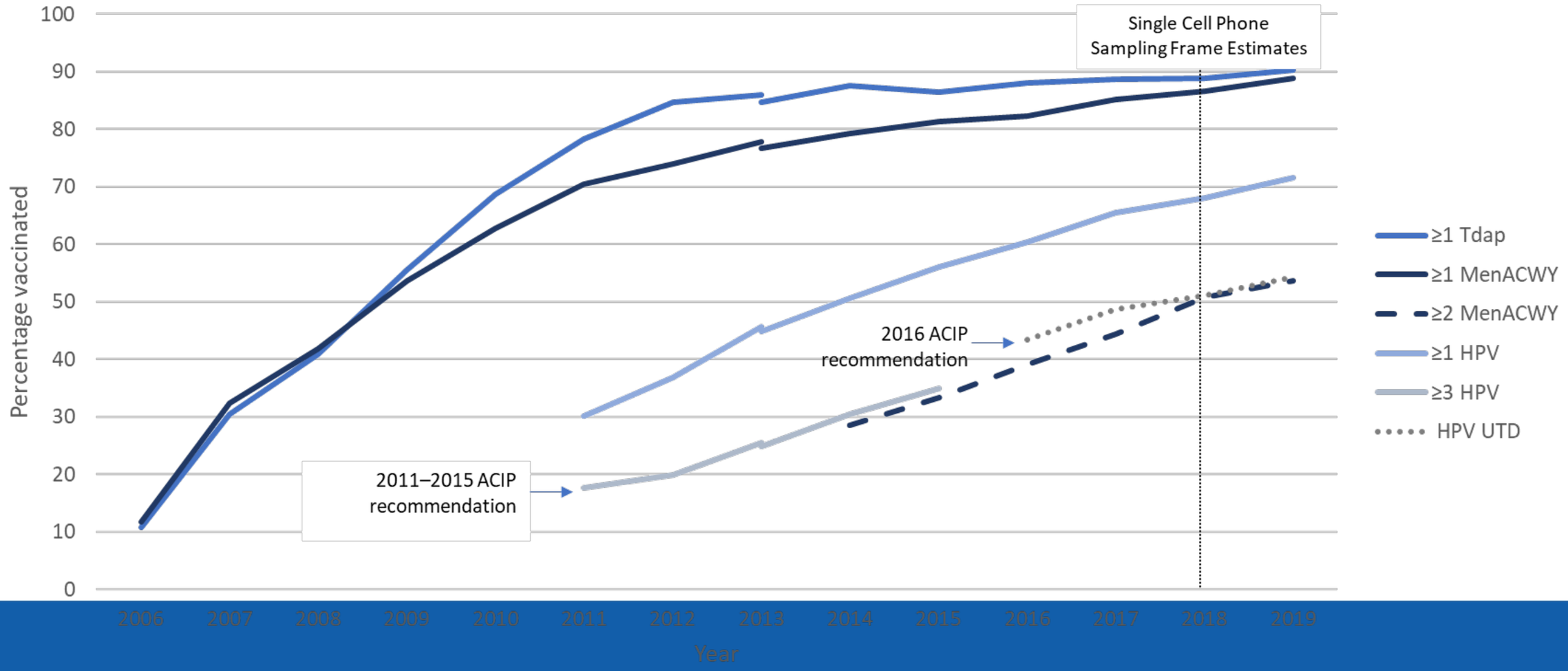


https://www.cdc.gov/hpv/hcp/vaccine-safety-data.html

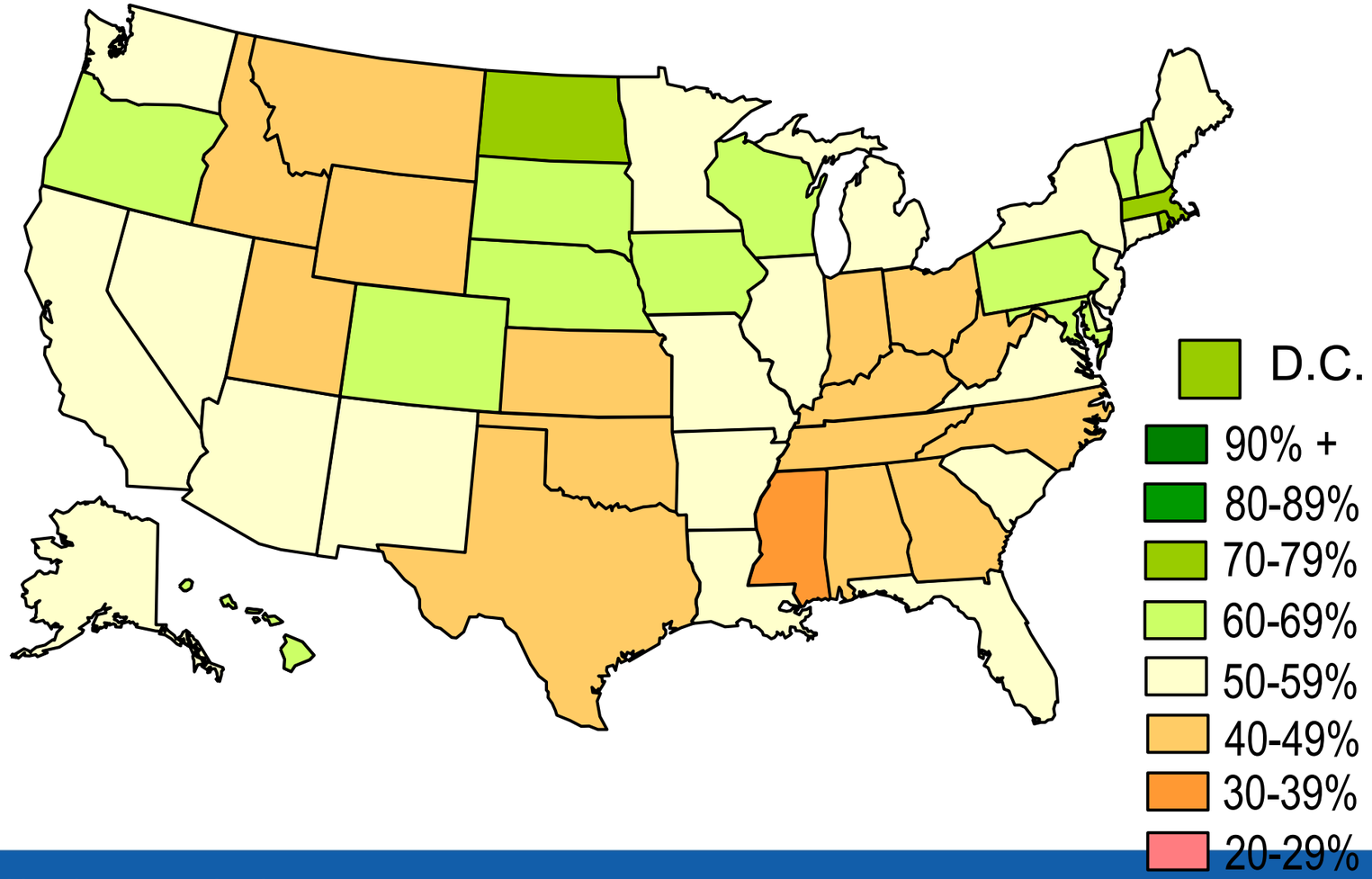
Monitoring HPV Vaccine Coverage

CDC Support for HPV Vaccination in the United States

Estimated vaccination coverage among adolescents aged 13-17 years by year – National Immunization Survey-Teen, United States, 2006-2019

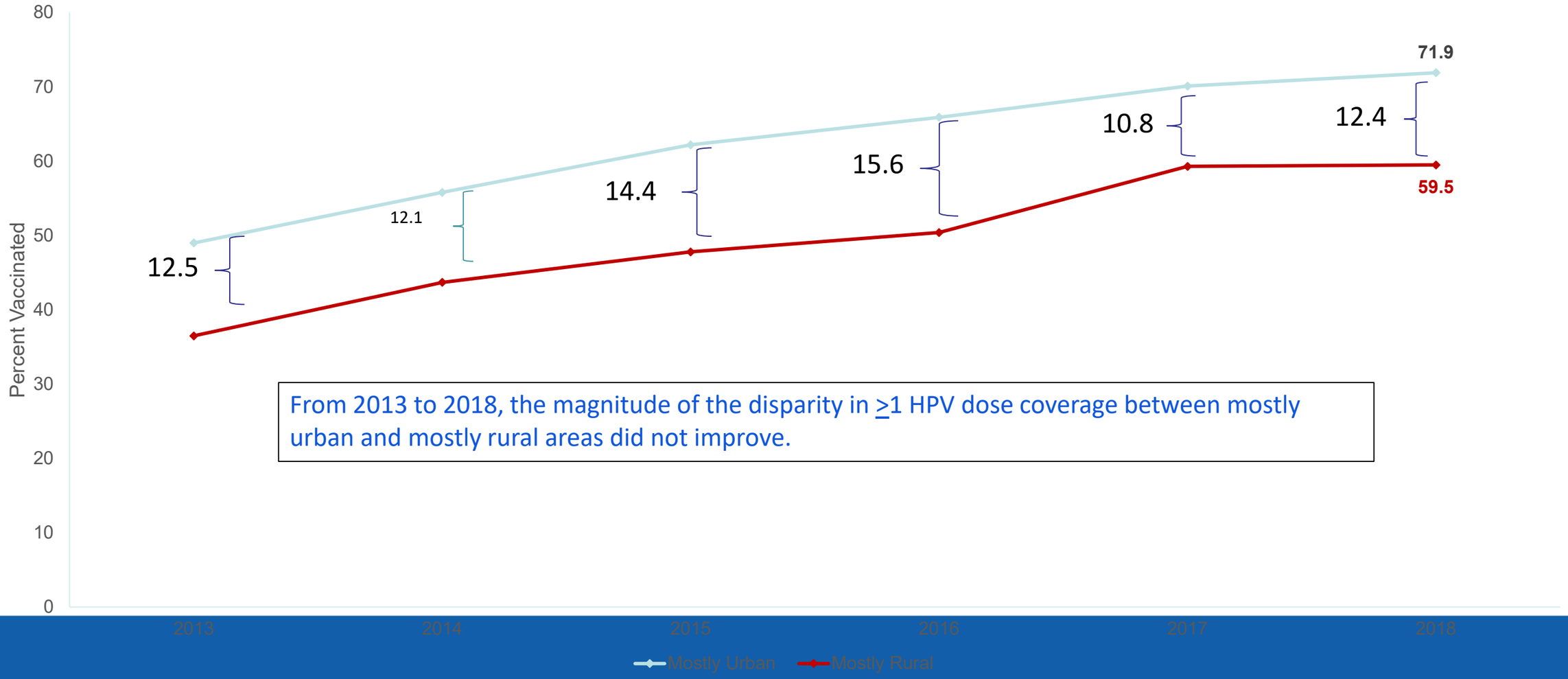


Estimated Up-to-Date HPV Vaccination Coverage among Adolescents, 2019
National Coverage = 54%



Source: CDC. National, state, and local area vaccination coverage among adolescents aged 13-17 years---United States, 2019

≥1 HPV vaccination coverage in rural areas is consistently lower



From 2013 to 2018, the magnitude of the disparity in ≥1 HPV dose coverage between mostly urban and mostly rural areas did not improve.

Walker et al. 2019 Human Vaccines and Immunotherapeutics.

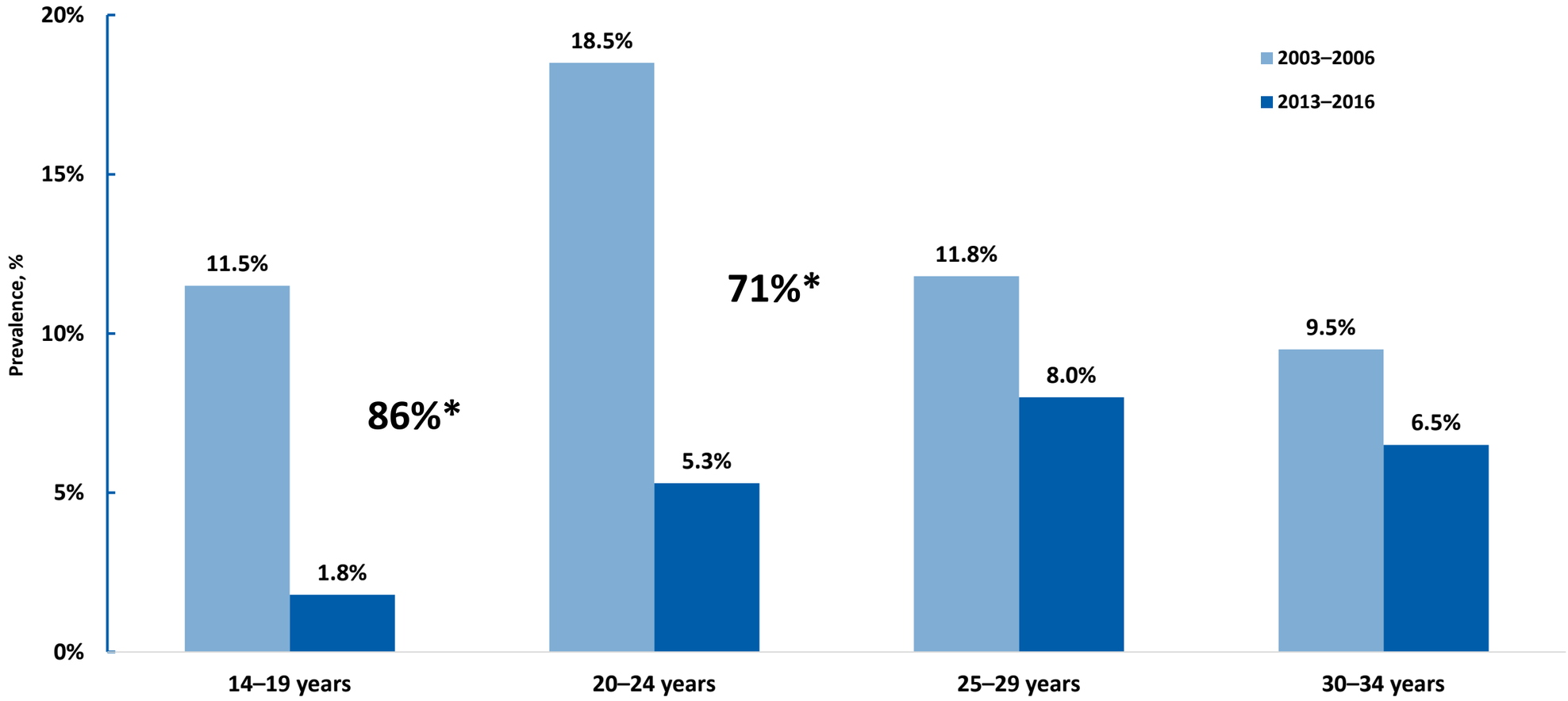
Monitoring Impact of HPV Vaccination

Evaluating impact of HPV vaccine in the United States/Globally

- HPV infection
- Genital Warts
- Cervical precancers

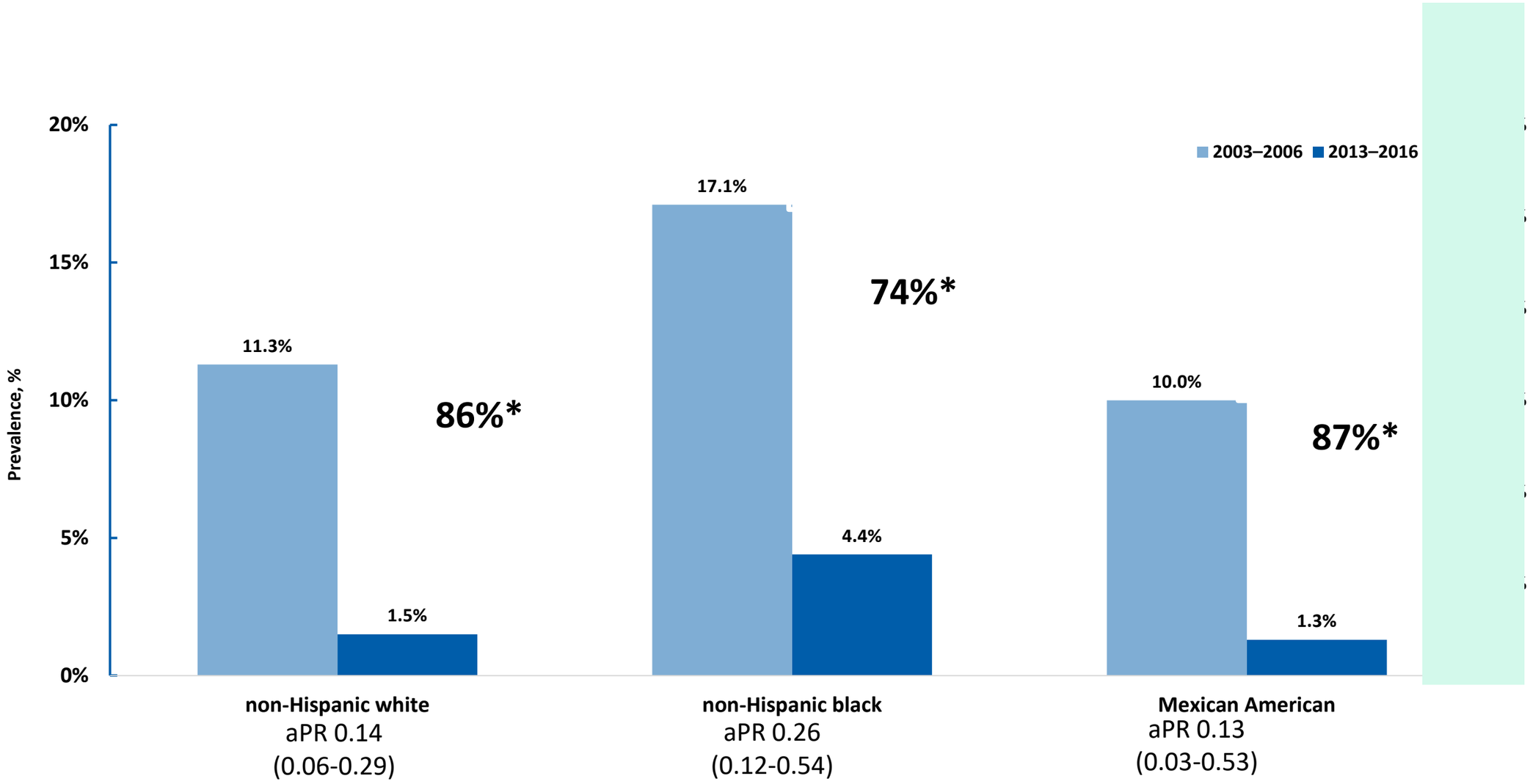
- Other precancers?
- Invasive cervical cancer?

Prevalence of Vaccine-type HPV (HPV 6,11,16,18) in Females, 2013-2016 Compared to Pre-vaccine Era



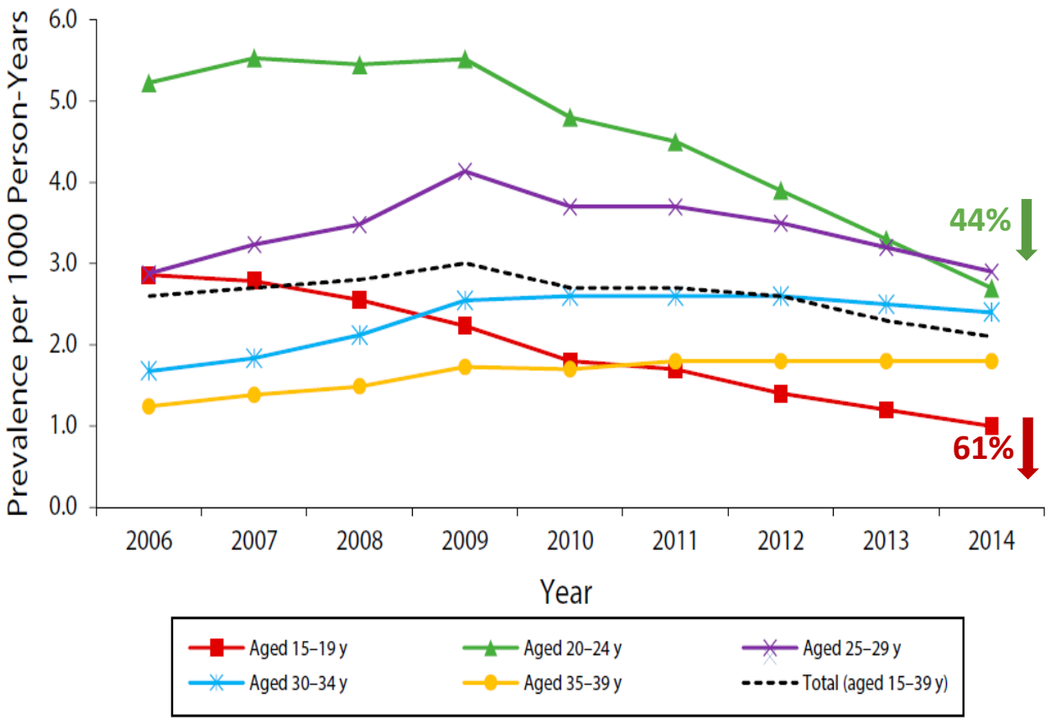
McClung et al. JAH 2019 65(6):715-722 *statistically significant declines

Prevalence of Vaccine-type HPV (HPV 6,11,16,18) in 14-19 Year-old Females, 2013-2016 Compared to Pre-vaccine Era, by Race/Ethnicity

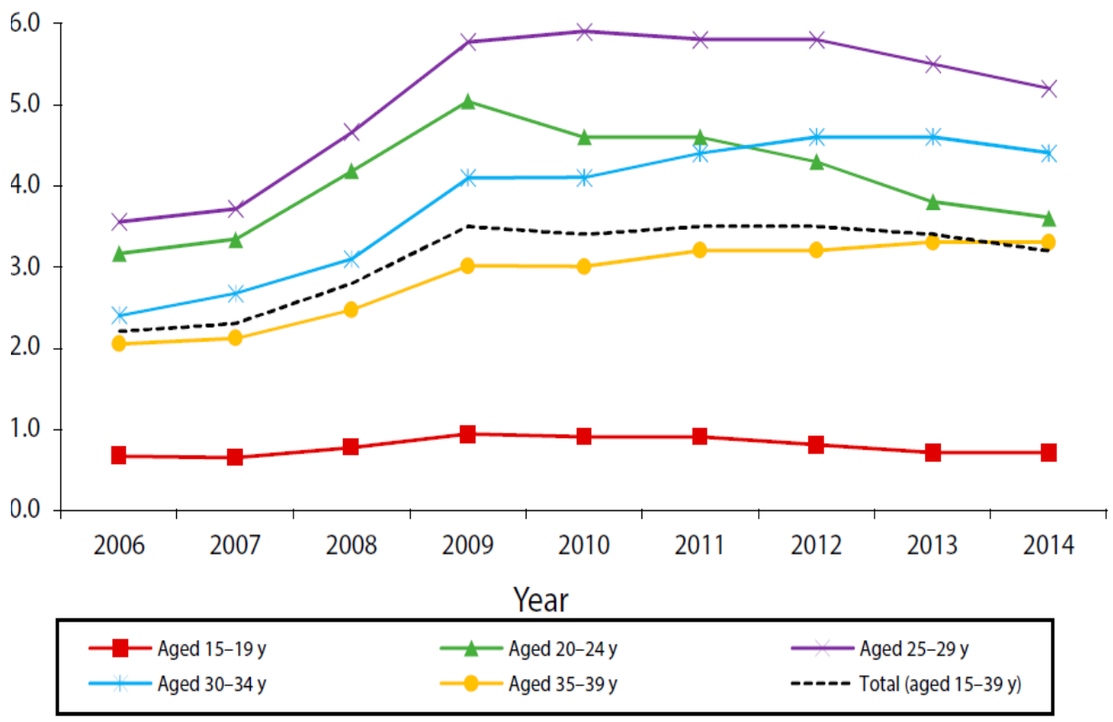


McClung et al. JAH 2019 65(6):715-722 *statistically significant declines

Anogenital Wart Prevalence among 15–39 Year-Olds with Private Insurance, United States, 2006–2014



Females

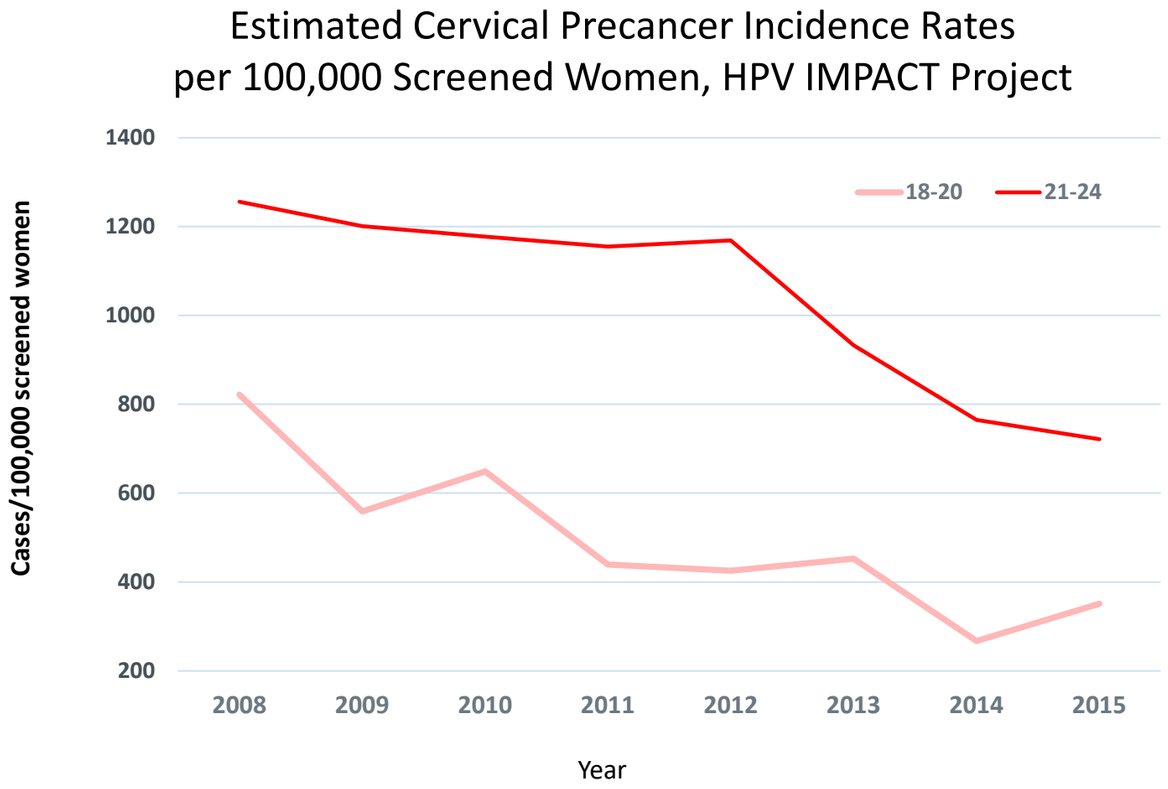


Males

Flagg et al. Am J Public Health 2017

Cervical Precancer Incidence Rates among Screened Women, HPV IMPACT Project, 2008-2015

- **Rates decreased significantly in estimated screened women aged 18–20 and 21–24 years**



Gargano et al. *Clin Infect Dis.* 2019.

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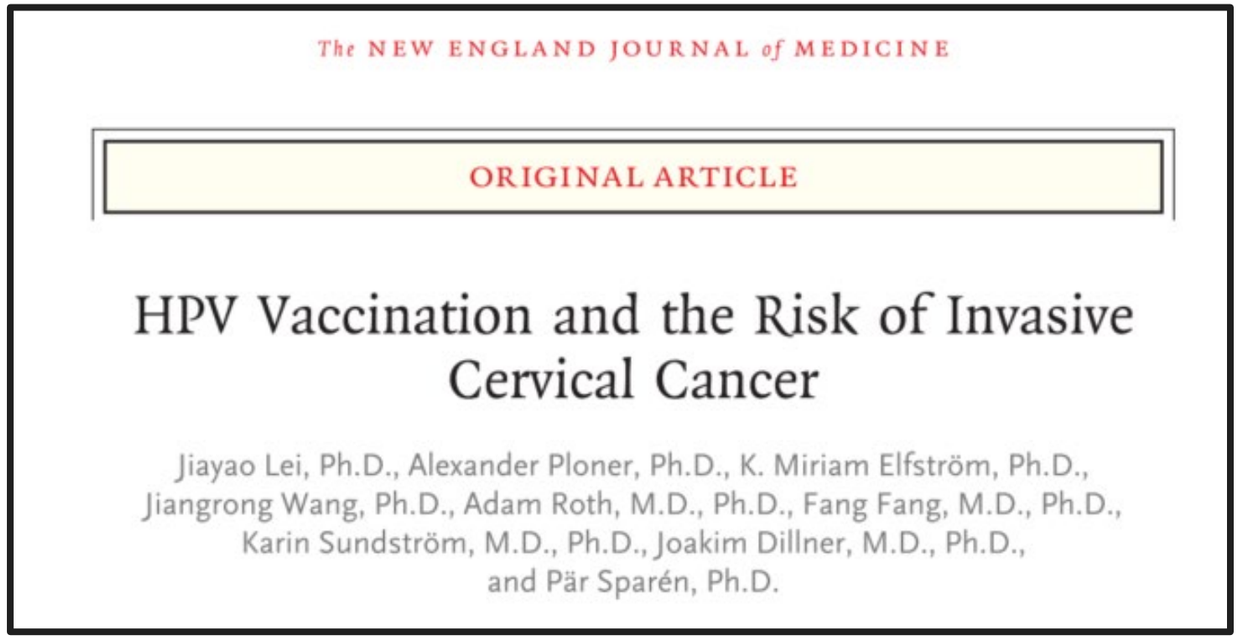
HPV impact on invasive cervical cancer



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

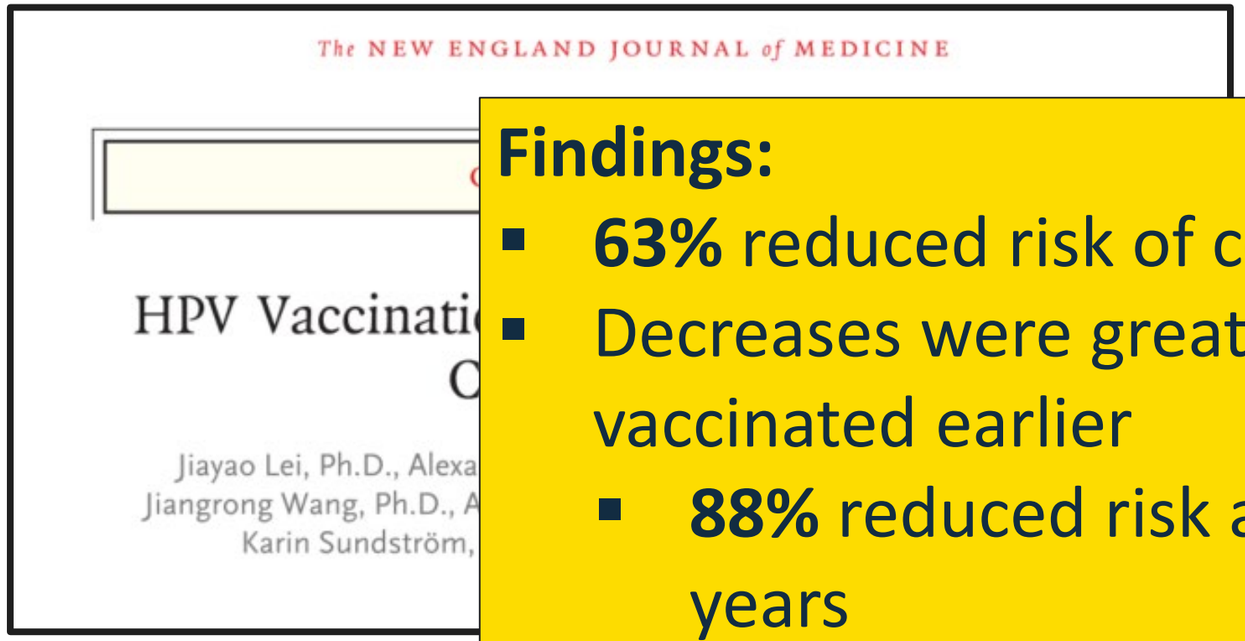
HPV Vaccination and the Risk of Invasive Cervical Cancer

Jiayao Lei, Ph.D., Alexander Ploner, Ph.D., K. Miriam Elfström, Ph.D., Jiangrong Wang, Ph.D., Adam Roth, M.D., Ph.D., Fang Fang, M.D., Ph.D., Karin Sundström, M.D., Ph.D., Joakim Dillner, M.D., Ph.D., and Pär Sparén, Ph.D.

Approach:

- Swedish nationwide registries were used to identify nearly 2 million girls and women aged 10-30 years during 2006-2017
- Evaluated association between HPV vaccination and risk of invasive cervical cancer

HPV impact on invasive cervical cancer


The NEW ENGLAND JOURNAL of MEDICINE

HPV Vaccinati
C

Jiayao Lei, Ph.D., Alexa
Jiangrong Wang, Ph.D., A
Karin Sundström,

Findings:

- **63%** reduced risk of cervical cancer
- Decreases were greater among those vaccinated earlier
  - **88%** reduced risk among ages <17 years
  - **53%** reduced risk among ages 17-30 years

Approach:

- Swedish nat 2 million girls and women aged 10-30 years during 2006-2017
- Evaluated association between HPV vaccination and risk of invasive cervical cancer

HPV impact on invasive cervical cancer

CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION | RESEARCH ARTICLE

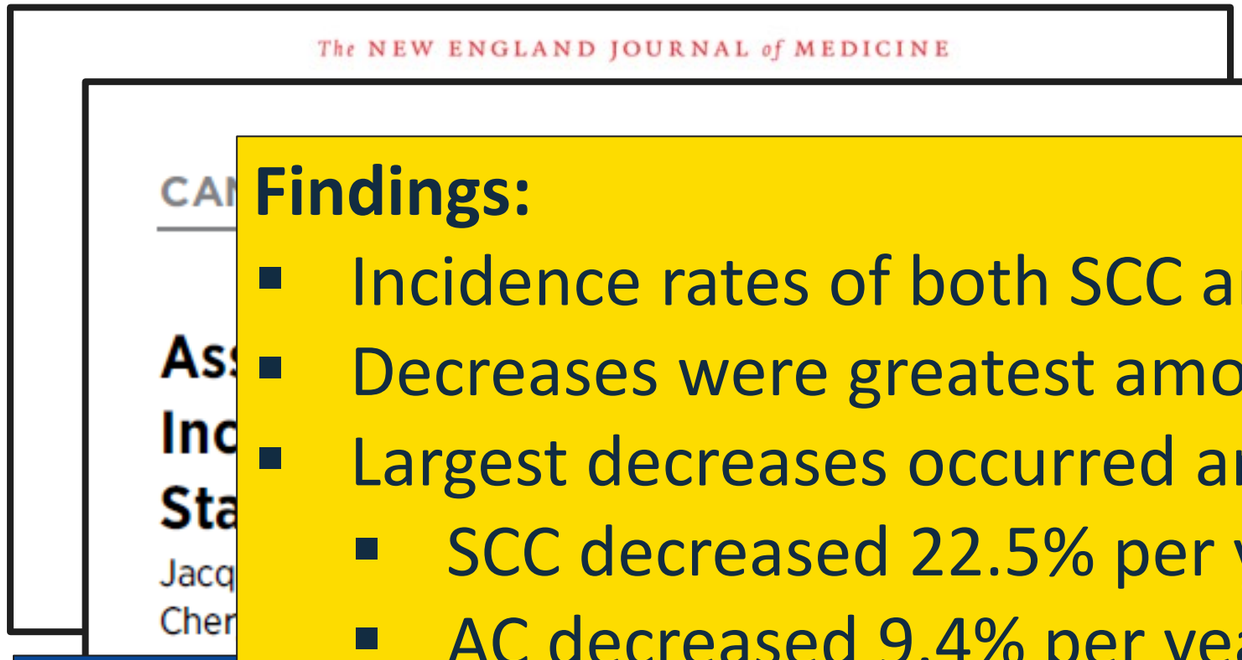
Assessing Impact of HPV Vaccination on Cervical Cancer Incidence among Women Aged 15–29 Years in the United States, 1999–2017: An Ecologic Study

Jacqueline M. Mix[1,2], Elizabeth A. Van Dyne[1,3], Mona Saraiya[1], Benjamin D. Hallowell[1], and Cheryll C. Thomas[1]

Approach:

- USCS database during used to examine trends in incidence rates of invasive cervical cancer by histology and age
- Limited to women aged 15-29 years, where vaccine may have the greatest impact

HPV impact on invasive cervical cancer



Findings:

- Incidence rates of both SCC and AC decreased
- Decreases were greatest among women aged 15-20 years
- Largest decreases occurred among women aged 15-20 years
  - SCC decreased 22.5% per year during 2010-2017
  - AC decreased 9.4% per year during 2006-2017

Approach:

- USCS database used to examine trends in incidence rates of invasive cervical cancer by histology and age
- Limited to women aged 15-29 years, where vaccine may have the greatest impact

Condoms

Primary prevention

HPV vaccines

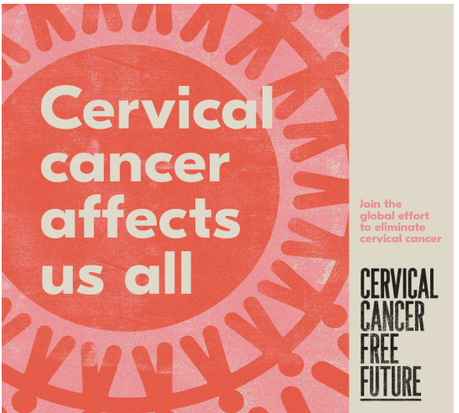
Secondary prevention

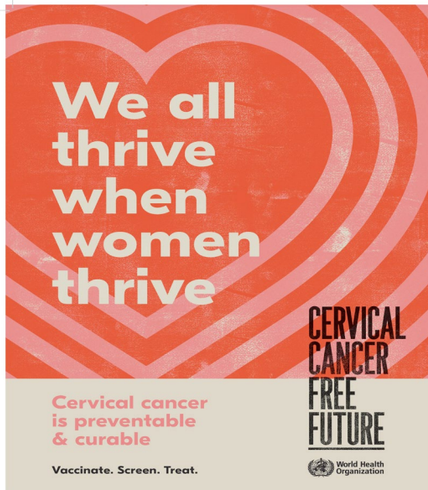
Treatment

Health education

Screening and diagnosis

Palliative care





Thank you
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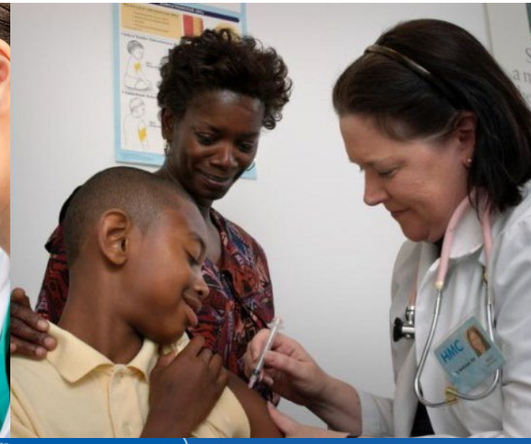
Acknowledgements: Lauri Markowitz, Virginia Senkomago, Jacqueline Mix, Shannon Stokely CDC



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Improving HPV Vaccine Delivery in the COVID-19 Era

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Disclosures

No financial disclosures

Overview

Key barriers to HPV vaccination

- Provider communication
- Parental hesitancy
- COVID-19 pandemic

Interventions to get HPV vaccination back on track

- Provider training
- Reminder recall
- Vaccine only visits

Barriers to HPV Vaccination




Key barriers to HPV vaccination

Provider recommendations

Parental hesitancy

COVID-19 pandemic

Provider recommendations are powerful

Adolescents who receive a provider recommendation have ~9x higher odds of receiving HPV vaccine

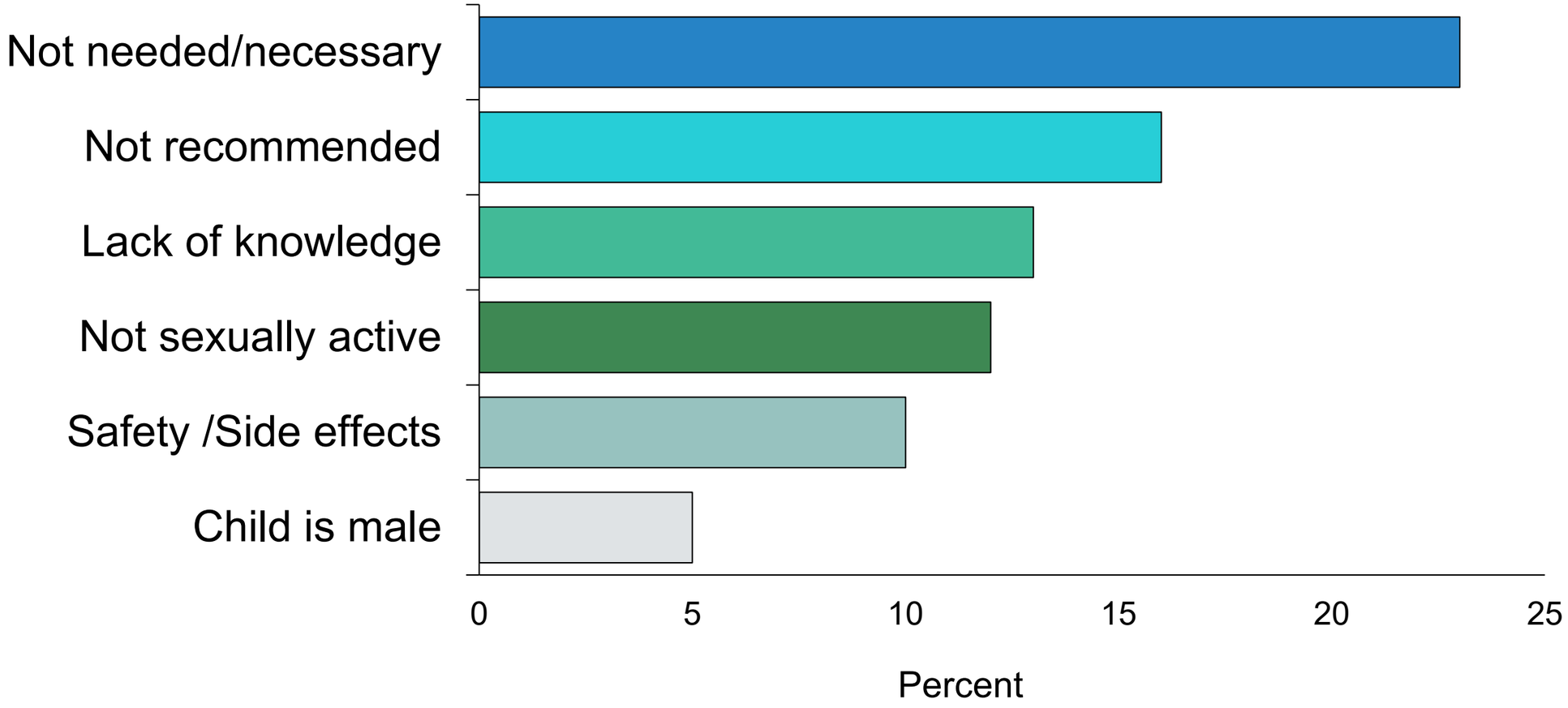
Provider recommendations need improvement

About half of physicians (51%) report using ≥2 lower-quality recommendation practices:

- Late recommendations for boys or girls
- Moderate or lower endorsement
- Risk-based recommendations
- Not recommending same-day vaccination

Gilkey et al., 2015, *Cancer Epidemiol Biomarkers Prev*

Parents' reasons for HPV vaccine hesitancy are diverse



Hanson KE et al., 2018, *Clinical Infect Diseases*

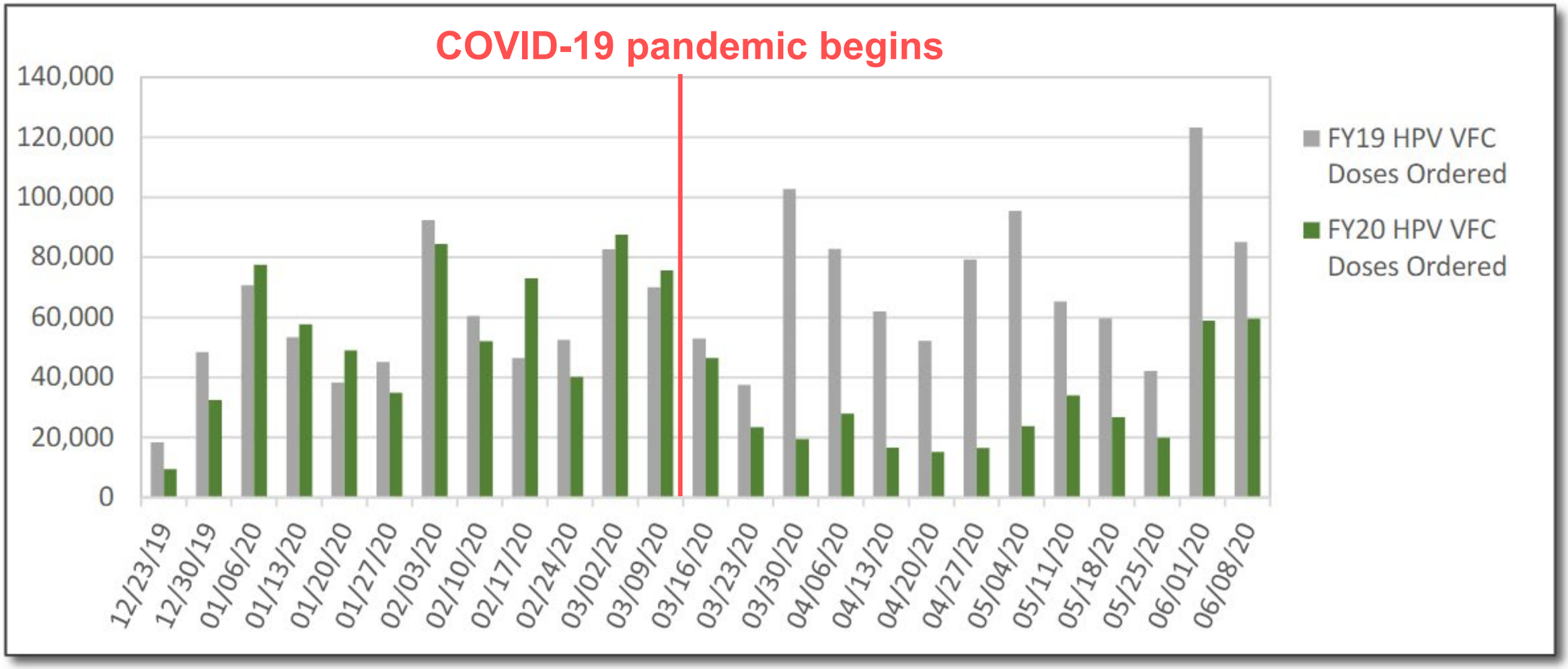
COVID-19 is challenging HPV vaccine delivery

- Dramatic short-term declines in HPV vaccine ordering/administration

COVID-19 versus HPV

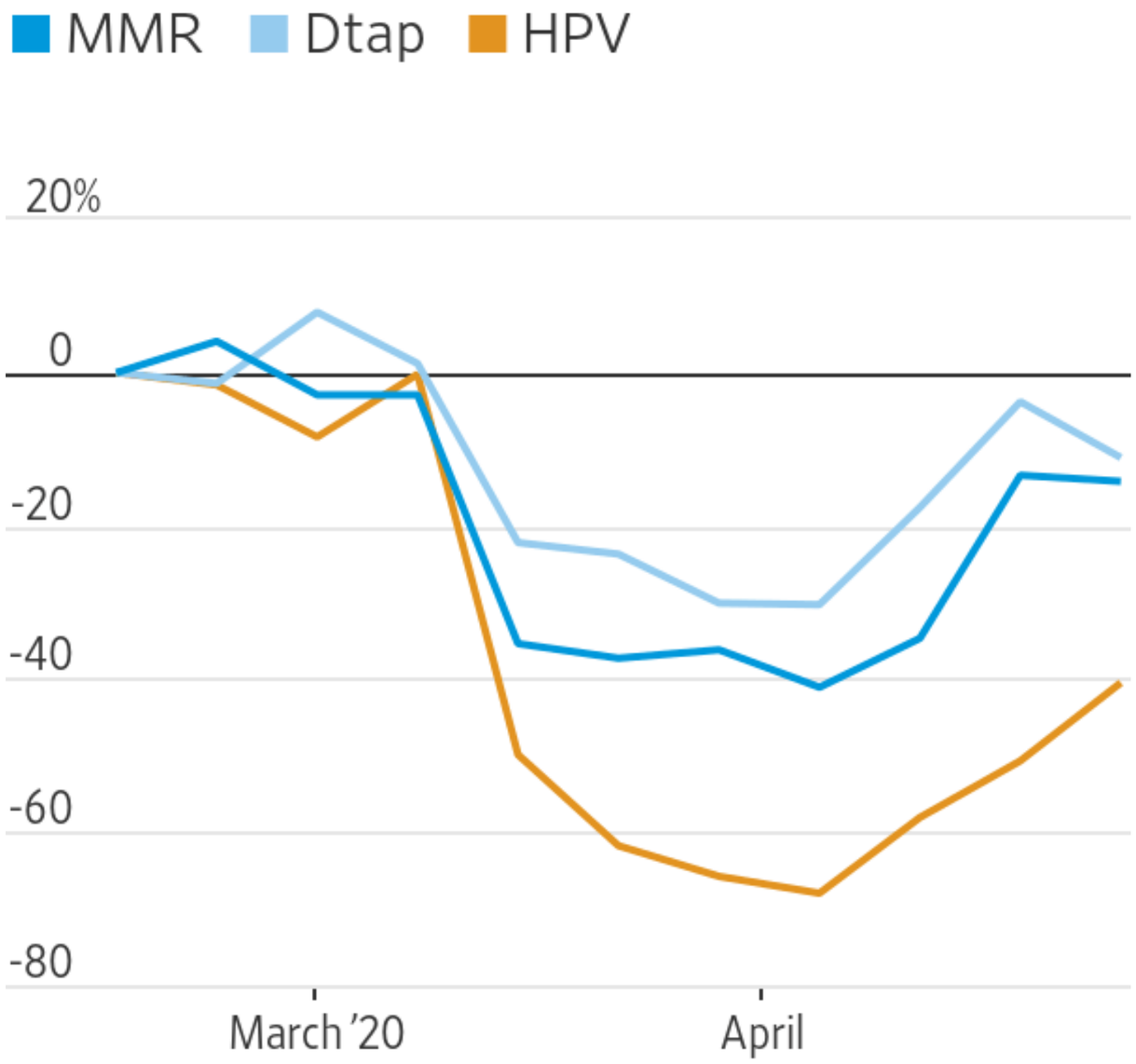
Gilkey et al, 2020, *Journal of Adolescent Health*

HPV vaccine ordering in the U.S.



Elam-Evans et al., 2020, *MMWR*

% change in children receiving vaccines



Data source: Physician's Computer Co, May 2020, *Wall Street Journal*
*Not peer reviewed

COVID-19 is challenging HPV vaccine delivery

- Dramatic short-term declines in HPV vaccine ordering/administration
- Longer-term declines in the volume of preventive care visits
- Reduced focus on HPV vaccine QI

COVID-19 versus HPV

Gilkey et al, 2020, *Journal of Adolescent Health*

COVID-19 is challenging HPV vaccine acceptance

- Fewer prompts for “back-to-school” care
- Parents may have new reasons for HPV vaccine hesitancy, such as fear of COVID-19 exposure during office visits or vaccine cost

Gilkey et al, 2020, *Journal of Adolescent Health*

Getting HPV vaccination back on track




Getting HPV vaccination back on track

1. Improve provider recommendations
2. Use reminder/recall and address parents' concerns
3. Offer vaccine-only visits

Use presumptive recommendations

Note **child's age**.

Announce children this age are **due** for vaccines that prevent several diseases.

Say you will vaccinate **today**.

Now that Sophia is 11, she's due for 3 vaccines to protect against meningitis, HPV cancers, and pertussis. We'll give them at the end of the visit.

3-arm RCT in 30 NC primary care clinics

Announcement approach training

- A **5% point increase** in HPV vaccine initiation by 3 months.

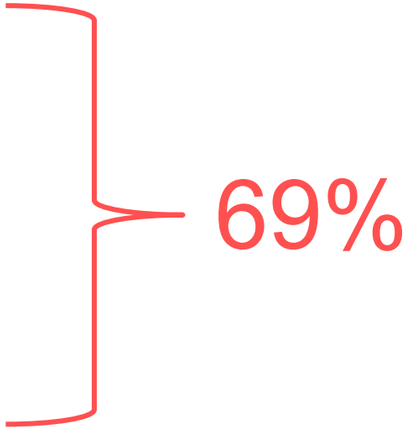
Brewer, et al., 2017, *Pediatrics*

Other ways to improve recommendations

- Start early at ages 9-10
- Emphasize cancer prevention
- Unify the care team
- Keep trying

Parents who initially declined HPV vaccination (*n*=494)

- Almost half (45%) reported getting HPV vaccine at a later visit
- Another 24% planned to in the next year
- Secondary acceptance was more common among parents who got follow-up counseling



Kornides, et al., 2018, *Academic Pediatrics*

Use patient reminder/recall

- Describe how your clinic is preventing COVID-19 exposure
- Note that programs are available to cover HPV vaccine cost

Offer vaccine-only visits

- Drive through clinics
- Concomitant vaccination
- Vaccination and telehealth

Other intervention strategies

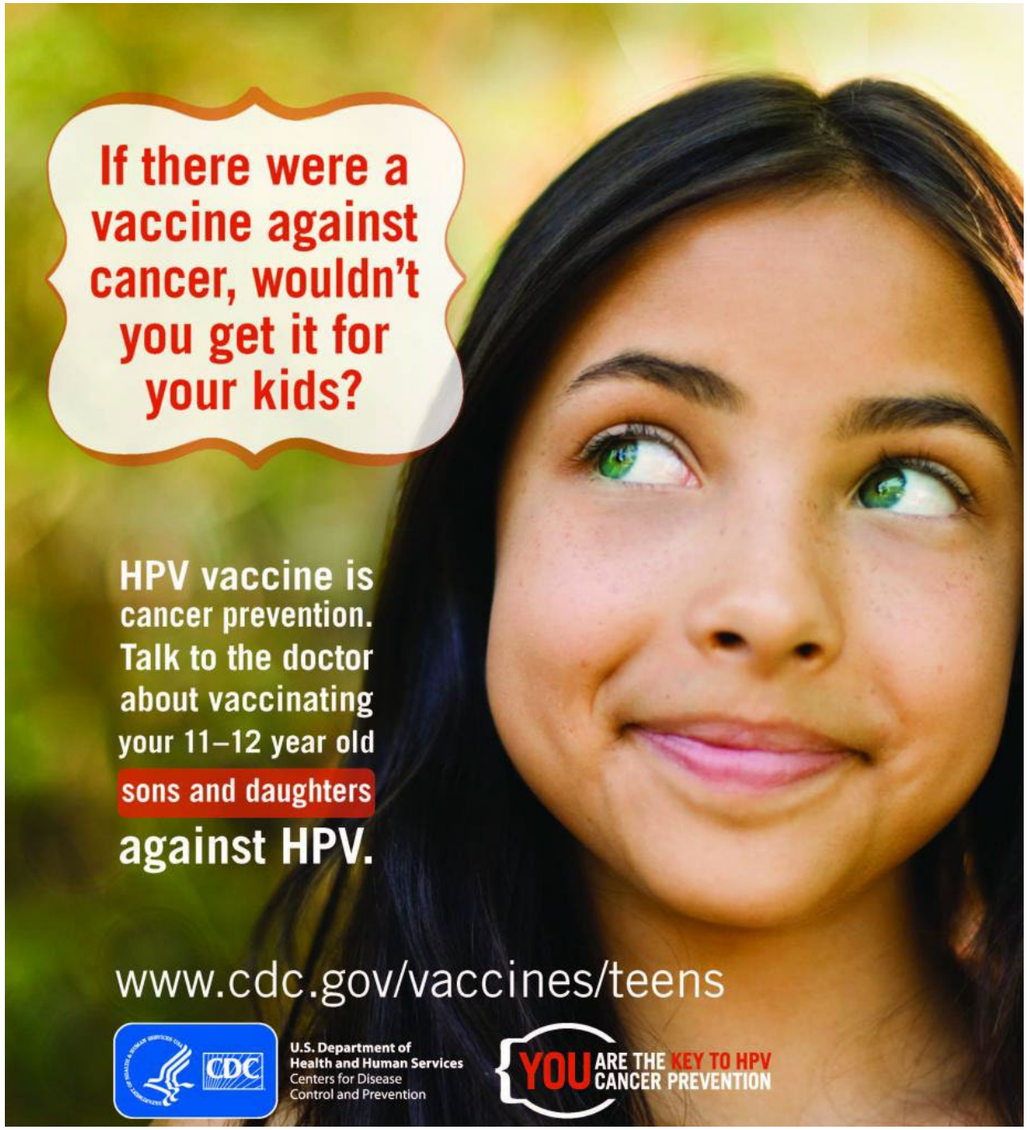
- Quality improvement coaching
- Vaccine delivery in alternative settings

Spencer, et al., 2020, *Pediatrics*

Conclusions

Conclusions

- We've made great strides in increasing HPV vaccine coverage
- COVID-19 threatens to wipe out recent gains
- We must support primary care providers in recommending and administering HPV vaccine to get coverage back on track



Rebecca B. Perkins MD, MSc
Boston University School of Medicine /
Boston Medical Center

Presenter Disclosure Information

- I, Rebecca Perkins, have been asked to disclose any significant relationships with commercial entities that are either providing financial support for this program or whose products or services are mentioned during our presentations.
  - I have no relationships to disclose.

Objectives

- Describe the impact of multilevel interventions
- Rationale for starting recommendations before age 11
- Role of the National HPV Vaccination Roundtable

Multi-level interventions

Provider level + systems level

Patients may be included as well

Vaccination Program: DOSE HPV

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- Evidence-based program to increase HPV vaccination rates
- Core principles: repeated contacts, education, QI support

- Incentives: MOC and CME credits for providers

https://ebccp.cancercontrol.cancer.gov/index.do

Dissemination and Implementation trial of DOSE-HPV

5 practices serving low-income and minority populations

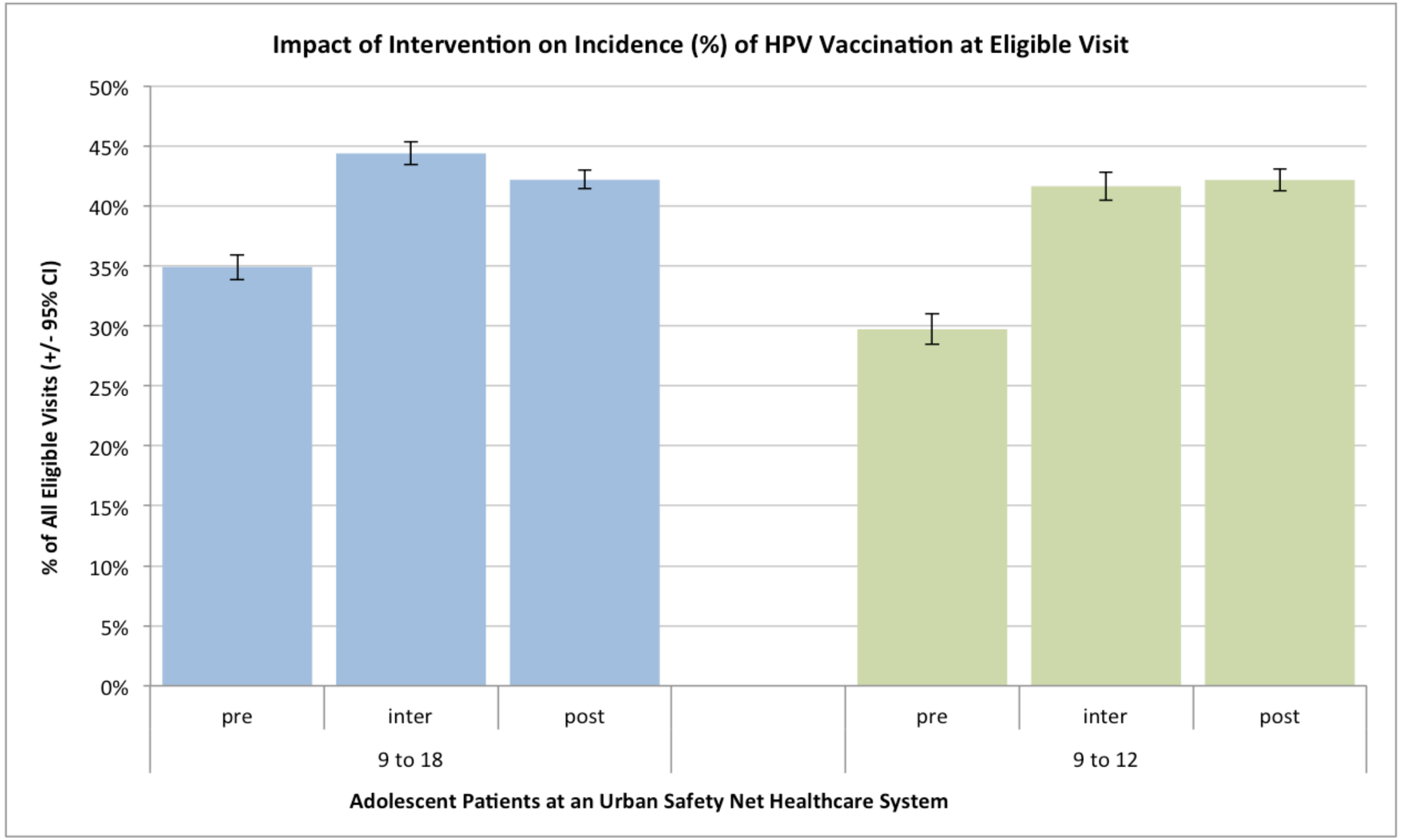
Stepped wedge design implemented 2016-2018

Compared vaccination rates in pre-intervention, intervention, and post-intervention periods using random effects generalized linear regression models with clustering of patients within providers and clinics

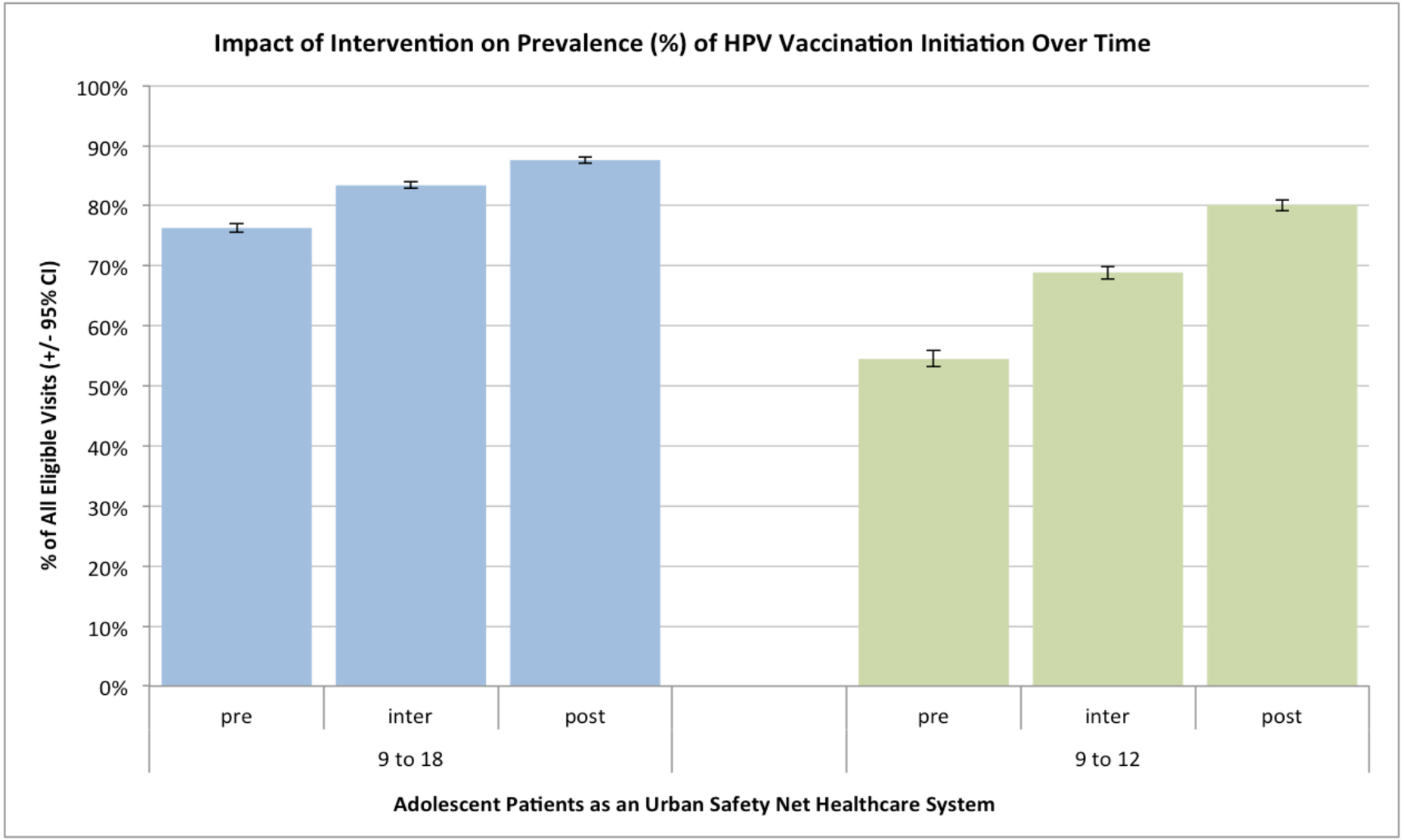
Primary outcomes:

- likelihood that an eligible child visiting the clinic receives vaccination
- cumulative effect on population-level vaccine initiation and completion rates

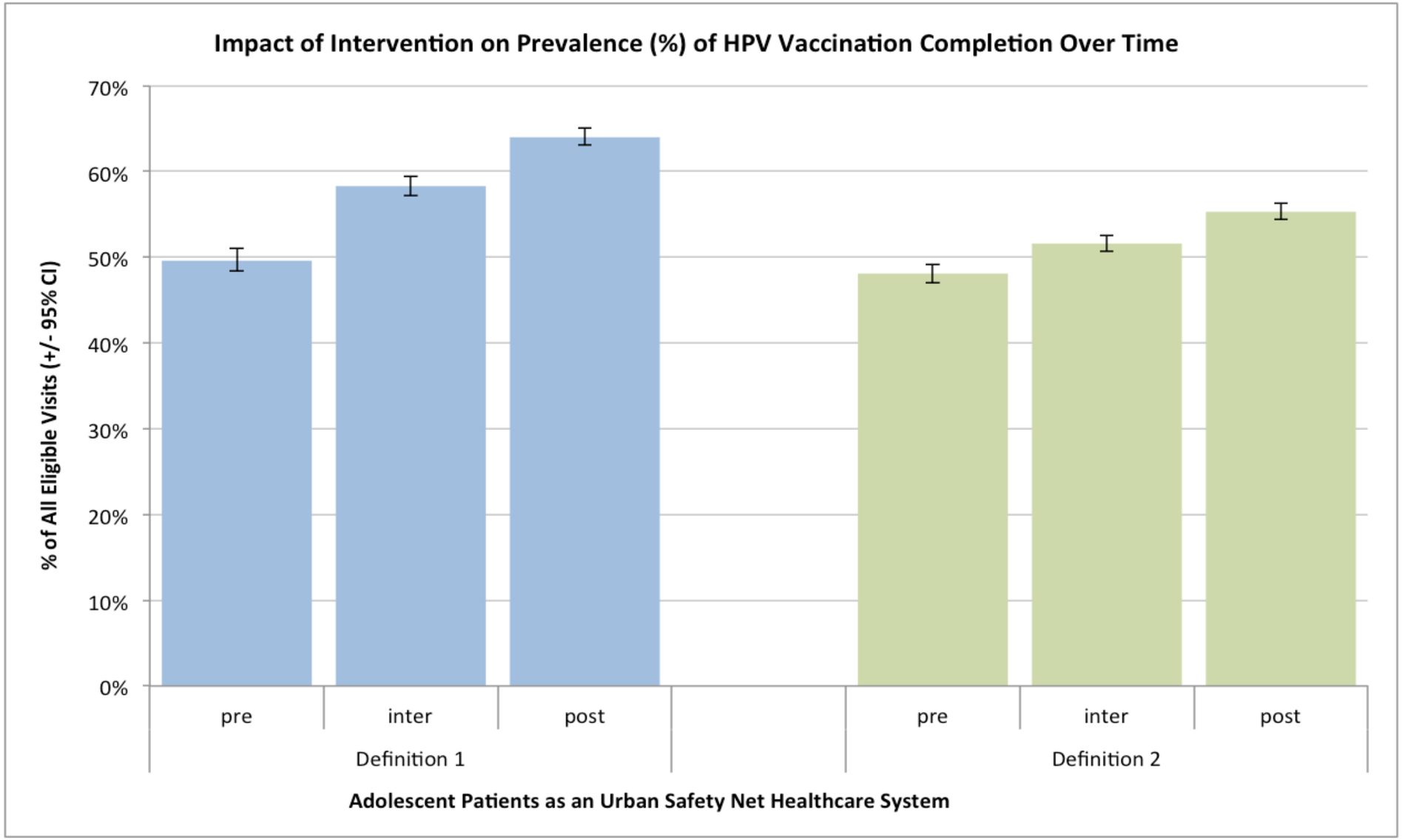
Sustained >10% increased likelihood of vaccination at eligible visit



Continuing increase in population prevalence to >80% vaccine initiation over time



Continuing increase in population prevalence of vaccine completion over time (~10%)



HPV VACs
Vaccinate Adolescents against Cancers

+

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Potential for dissemination and implementation

Collaboration with ACS Vaccinate Adolescents against Cancers (VACs) program:

- Additional work with FQHC networks
- VACs intervention components: provider training, QI methods, systems changes
- DOSE HPV team added MOC credits

HPV VACs
Vaccinate Adolescents against Cancers

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- **12 FQHCs Systems** began Fall 2016-Dec. 2017

  45 clinic intervention sites

  - Focus on preteens turning 13 in measurement year (n=3283)

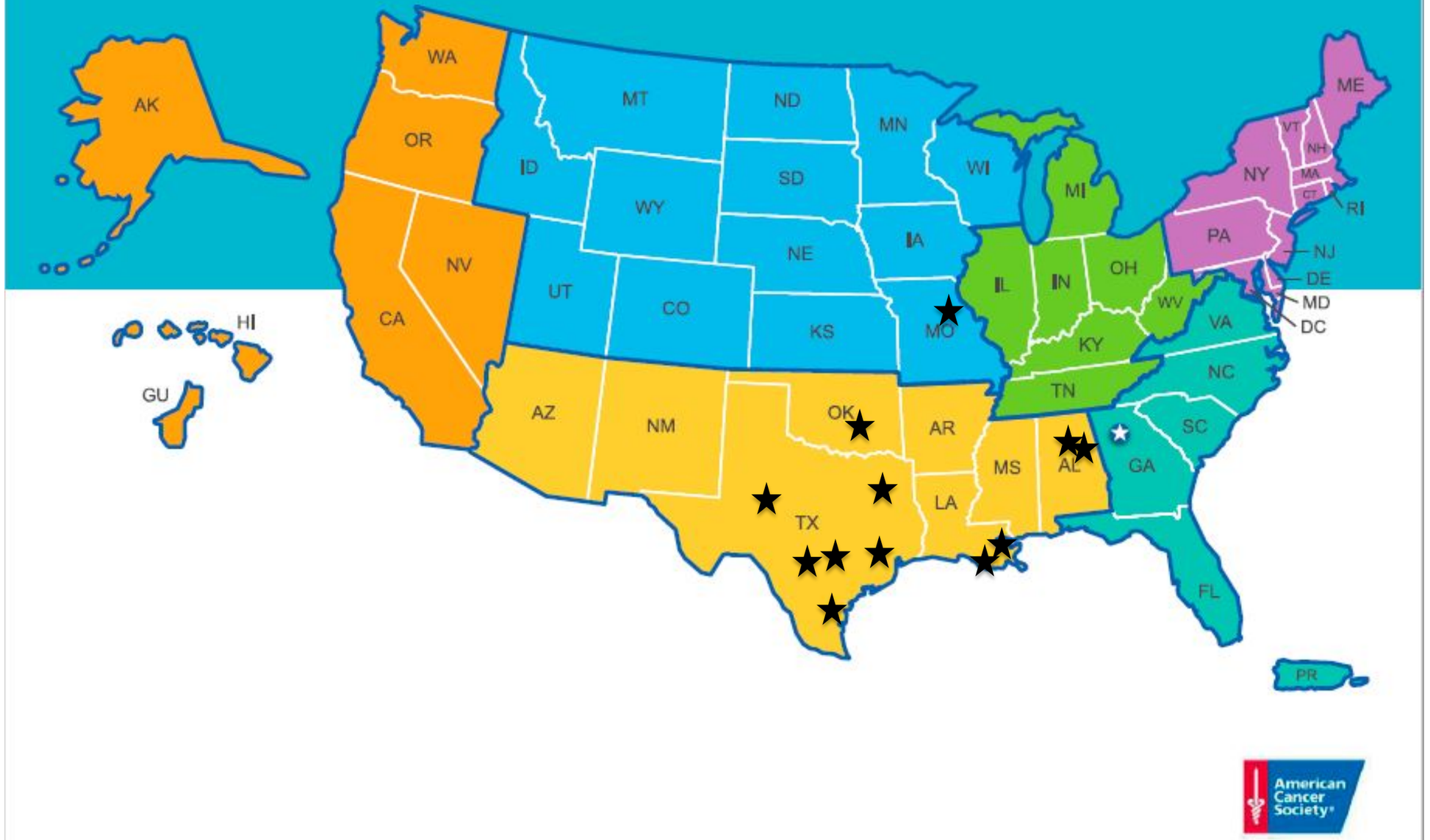
- Pilot **Quality Improvement Interventions**

  - Focus on **structured quality improvement**

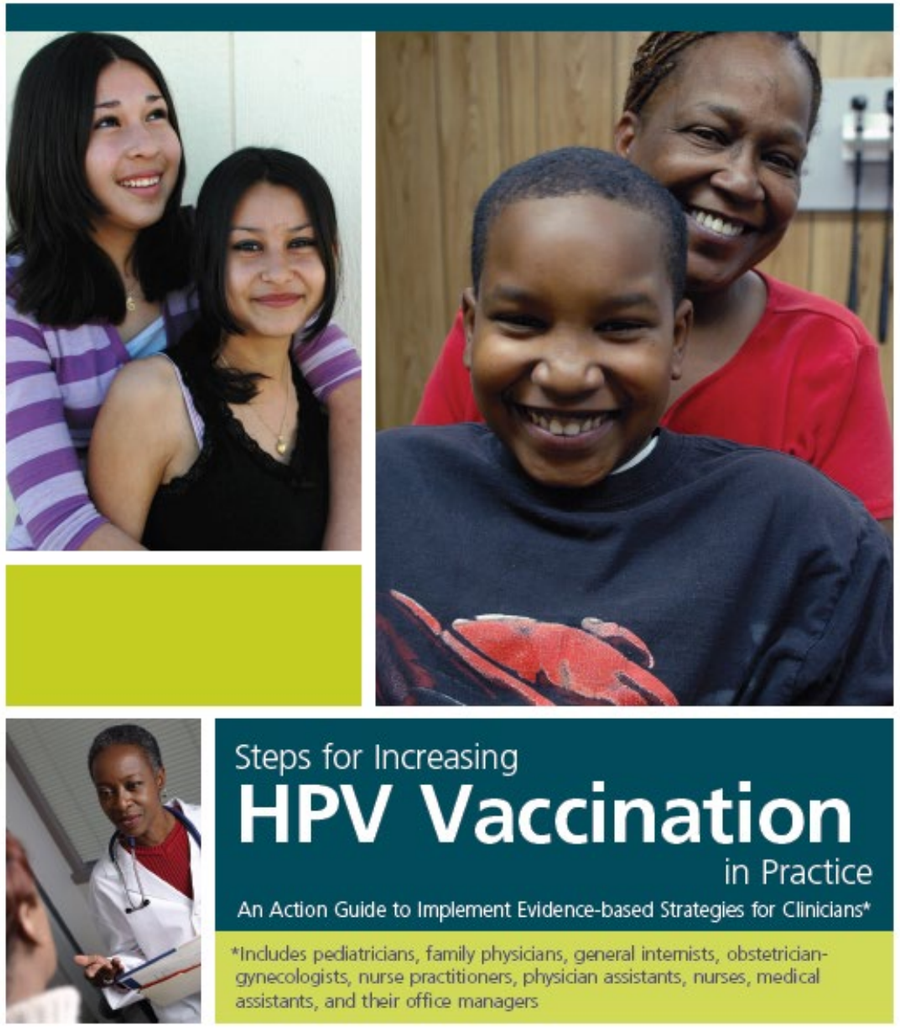
  - Providers receive **Maintenance of Certification Part IV** and 20 Performance Improvement CME Credits

American Cancer Society Region Map

HPV VACs MOC Pilot Sites



American Cancer Society



Steps for Increasing HPV Vaccination in Practice:

An Action Guide to Implement Evidence-based Strategies for Clinicians

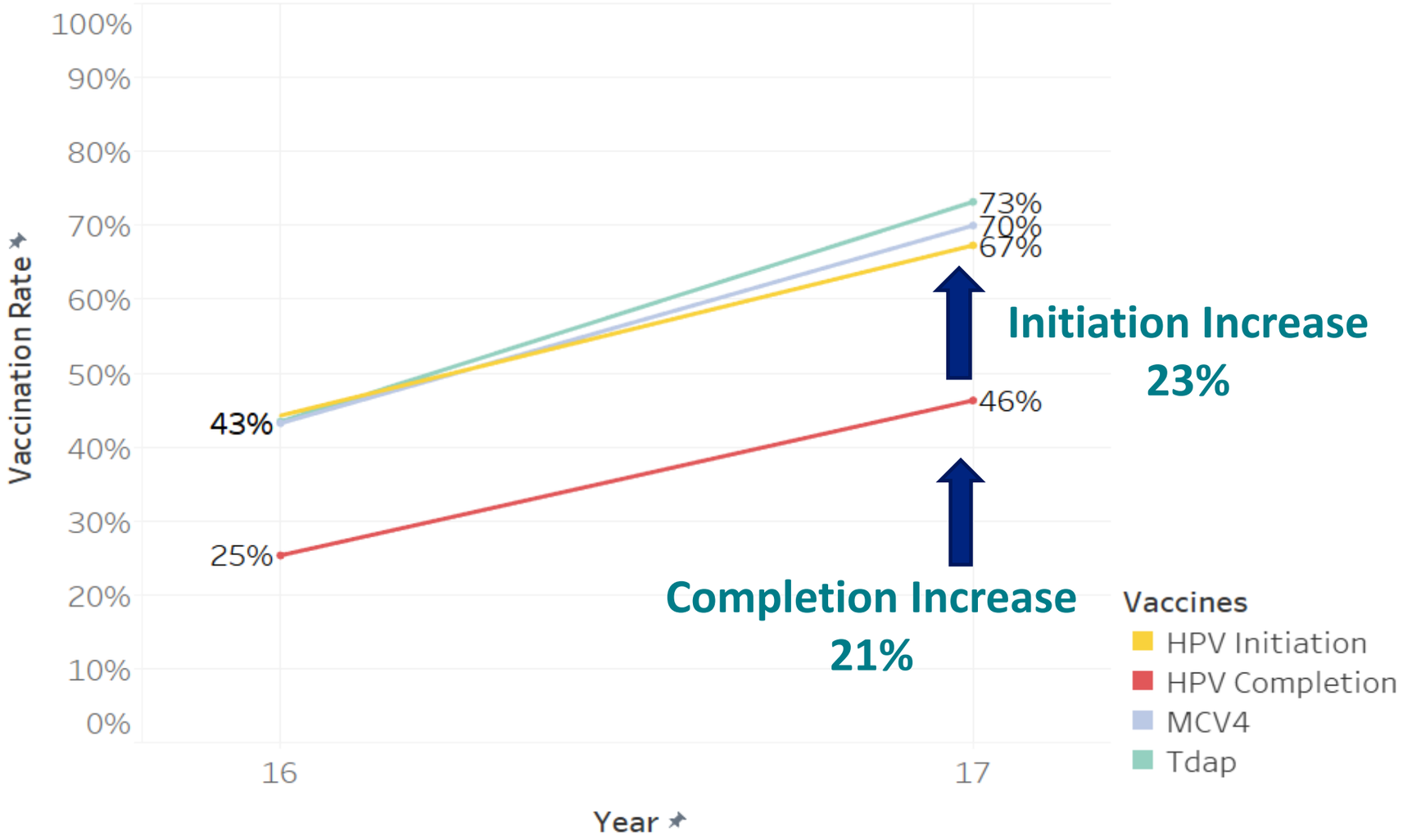
http://bit.ly/HPVStepsActionGuide

- Toolkit+
- Road map
- Portal to resources
- Launched June 2015
- Tested and improved by 30 FQHC Pilots

HPV VACs
Vaccinate Adolescents against Cancers

American Cancer Society

Average Adolescent Vaccination Rates at MOC Pilot Systems, 2016 to 2017



HPV Initiation, Tdap, and MCV4 among all 12 MOC Pilot systems, implementing the intervention in 45 clinic sites.

HPV Completion among 10 MOC Pilot systems with complete data.

Provider Feedback (n=45)

- **91% of learners made changes in practice:**
  - Initiating vaccination at younger ages (starting at age 9 or 10)
  - Changing verbal presentation of vaccine (framed in terms of cancer prevention, bundled recommendation, not differentiating the vaccine, i.e. “due for all routine vaccinations”)
  - Strong recommendation at sick and wellness visits
  - Implementing standing orders
  - Implementing reminder/recall systems

Initiating vaccine series early was a key component of these interventions

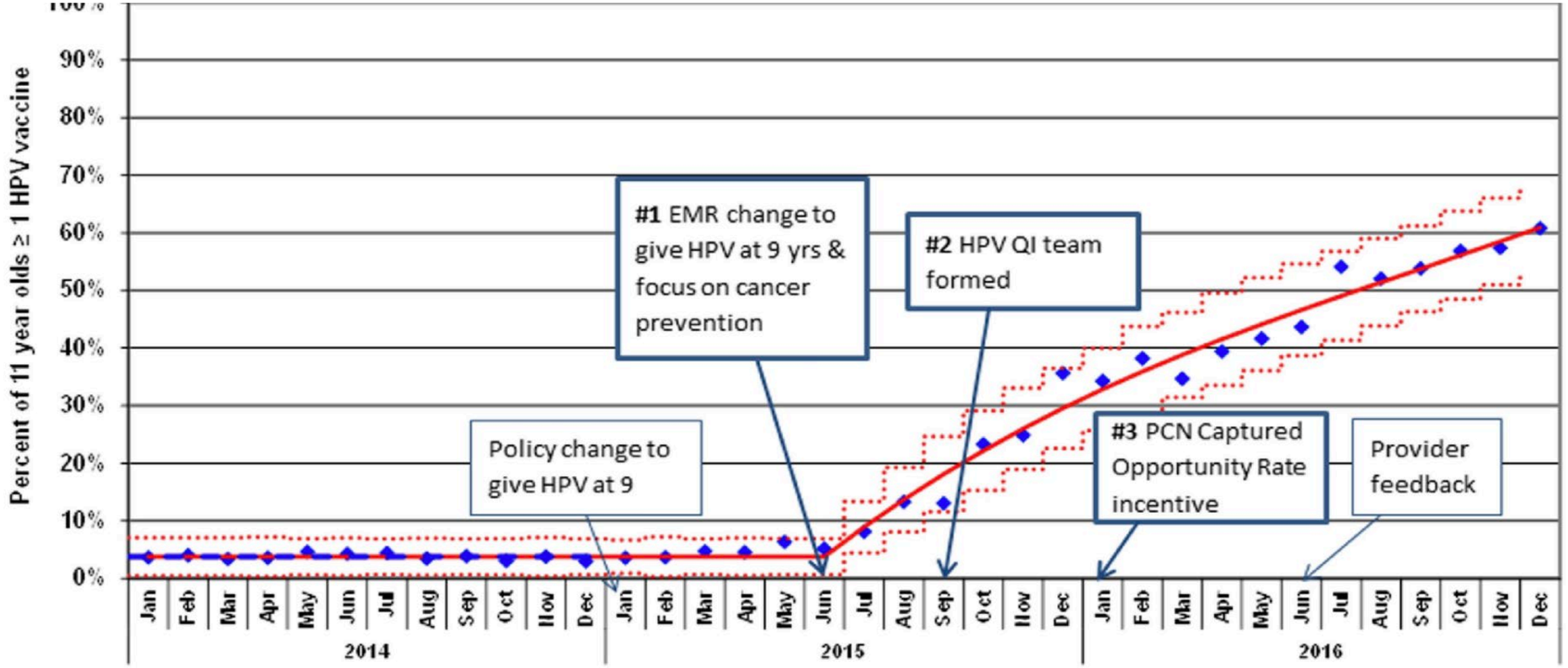
Advantages of starting at age 9

- Fewer missed opportunities
- Higher completion rates
- Fewer potential issues with COVID vaccines
  - CDC recommends that no vaccinations be given within 2 weeks of a COVID vaccine
    - This totals 8 weeks when both doses considered
  - COVID vaccines may be available for ages 12+ in the late spring

Quality Improvement Initiative to Improve Human Papillomavirus Vaccine Initiation at 9 Years of Age ☆

Martha J. Goleman MD [a, b], Millie Dolce PhD [a], Jennifer Morack MS, MSW [a]

QI intervention in clinics serving 75,000 patients in low-income neighborhoods Initiation of series at age 9 led to steady increase in vaccination by age 11



Younger age at initiation of the Human Papillomavirus (HPV) vaccination series is associated with higher rates of on-time completion

Jennifer L. St Sauver, PhD, MPH,[1,2] Lila J. Finney Rutten, PhD, MPH,[1,2] Jon O. Ebbert, MD,[2,4] Debra J. Jacobson, MS,[5] Michaela E. McGree, BS,[5] and Robert M. Jacobson, MD[2,3]

Completion of the vaccine by age 13.5	OR (95% CI)	P
Age at initiation		<0.001
11–12	Reference	
9–10	22.09 (8.96, 54.50)	

- Population-based cohort of 36,000 children in MN

- Likelihood of completion was 22 times higher when series initiated at ages 9-10 compared to 11-12

Disseminating HPV vaccination best practices

This is Us:

The National HPV Vaccination Roundtable

Funding for the HPV Roundtable was made possible (in part) by the Centers for Disease Control and Prevention Cooperative Agreement grant number NH23IP922551-04, CFDA # 93.733. The content does not necessarily reflect the official policies of the Department of Health and Human Services, nor does the mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.

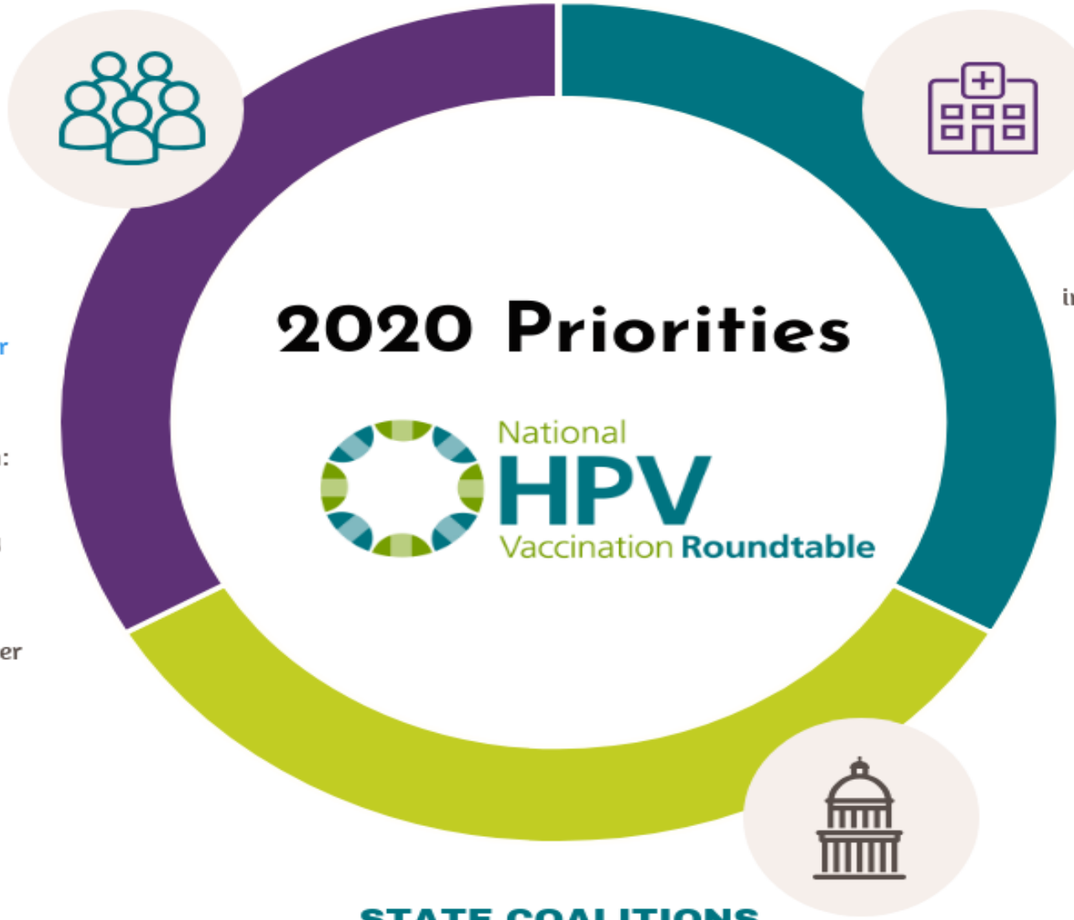
~70 organizations working at the intersection of immunization and cancer prevention

MISSION

The HPV Roundtable's mission is raise HPV vaccination rates and to prevent HPV cancers.

We do this by convening, communicating with, and catalyzing our member organizations, and by extension the public.

OUR 2020 PANDEMIC RESPONSE



MEMBER ENGAGEMENT

Grow content for YouTube, Facebook, LinkedIn and blog

Advance strategy on HPV cancer elimination as a public health problem

Deploy the new HPV Prevention: Nurses Get it Done! Toolkit

Conduct annual member survey and assess members' HPV activities

Expand opportunities for member presentations, publications and participation

INTEGRATED DELIVERY SYSTEMS

Lead national *We're In! 2020* initiative to catalyze health systems

Implement HPV Learning Collaborative with AMGA

Disseminate Health System resources

STATE COALITIONS

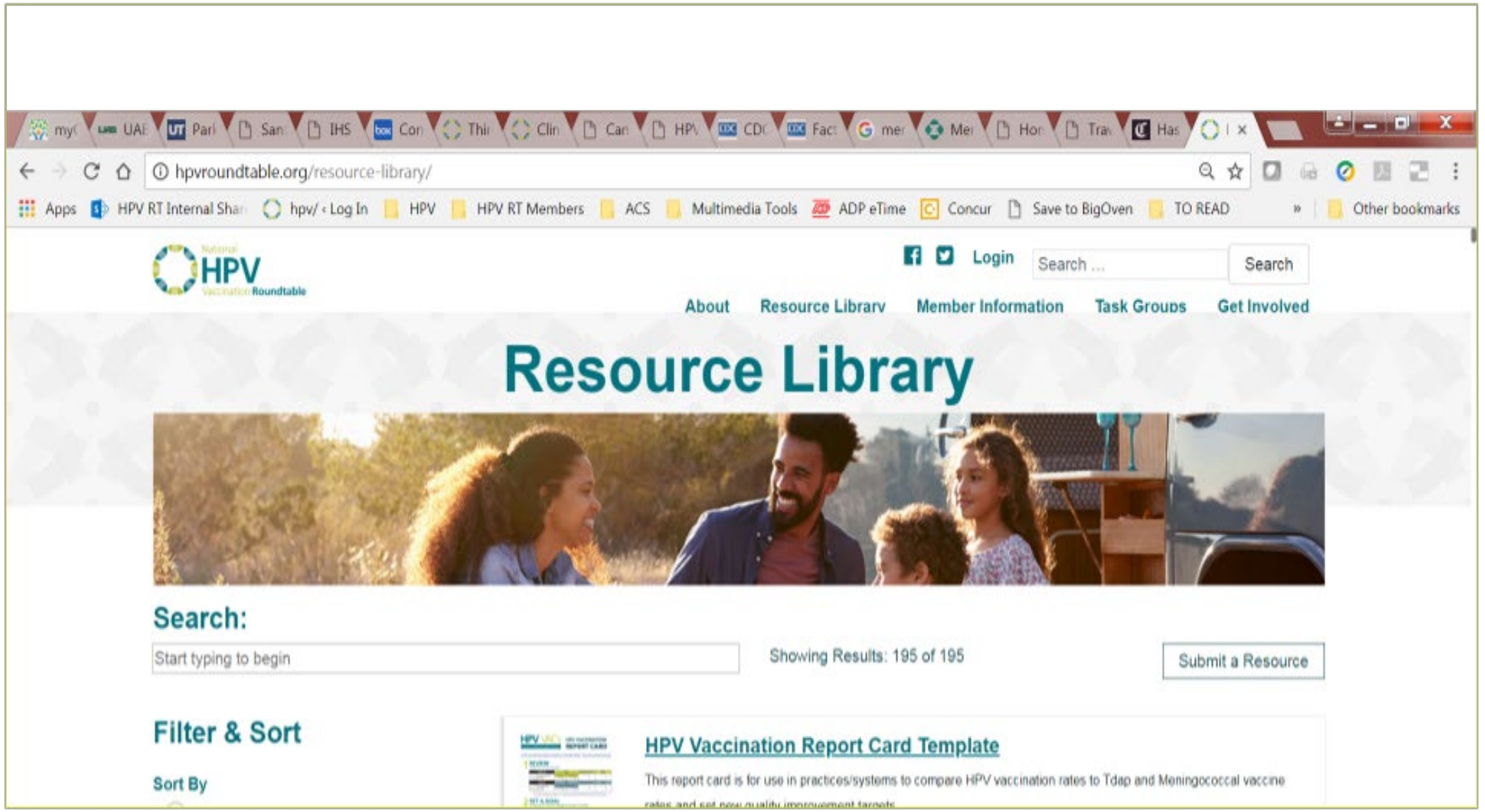
Align state efforts to *We're In! 2020*

Host regional leadership summit for Northern Plains/Northwestern states

Provide ongoing support to Southeastern states

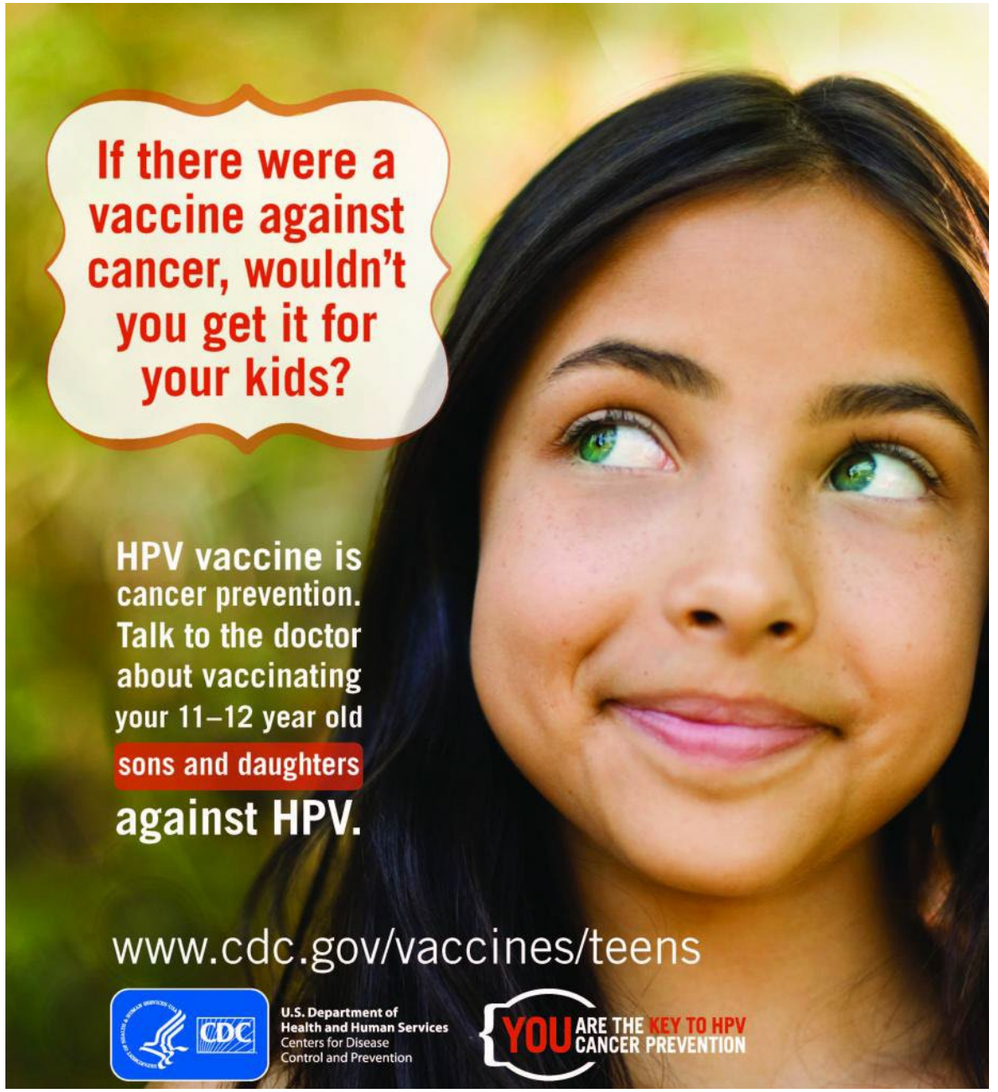
HPV Roundtable Resource Library

www.hpvroundtable.org/resource-library



Conclusions

- HPV vaccination has promise for reducing 6 types of cancers
- COVID-19 threatens vaccination coverage
- We must support primary care providers in recommending and administering HPV vaccine to get coverage back on track
- Starting at age 9 can facilitate catch-up



Questions & Answers

HPV Cancer Prevention Program
https://www.stjude.org/research/comprehensive-cancer-center/hpv-cancer-prevention-program.html

Please take a few moments to complete the evaluation after the virtual seminar ends. Your feedback will help us plan future offerings. Thank you!

St. Jude Children's Research Hospital

HPV Cancer Prevention Program

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