CENTRALIZED HPV VACCINATION RECALL AMONG MICHIGAN ADOLESCENTS

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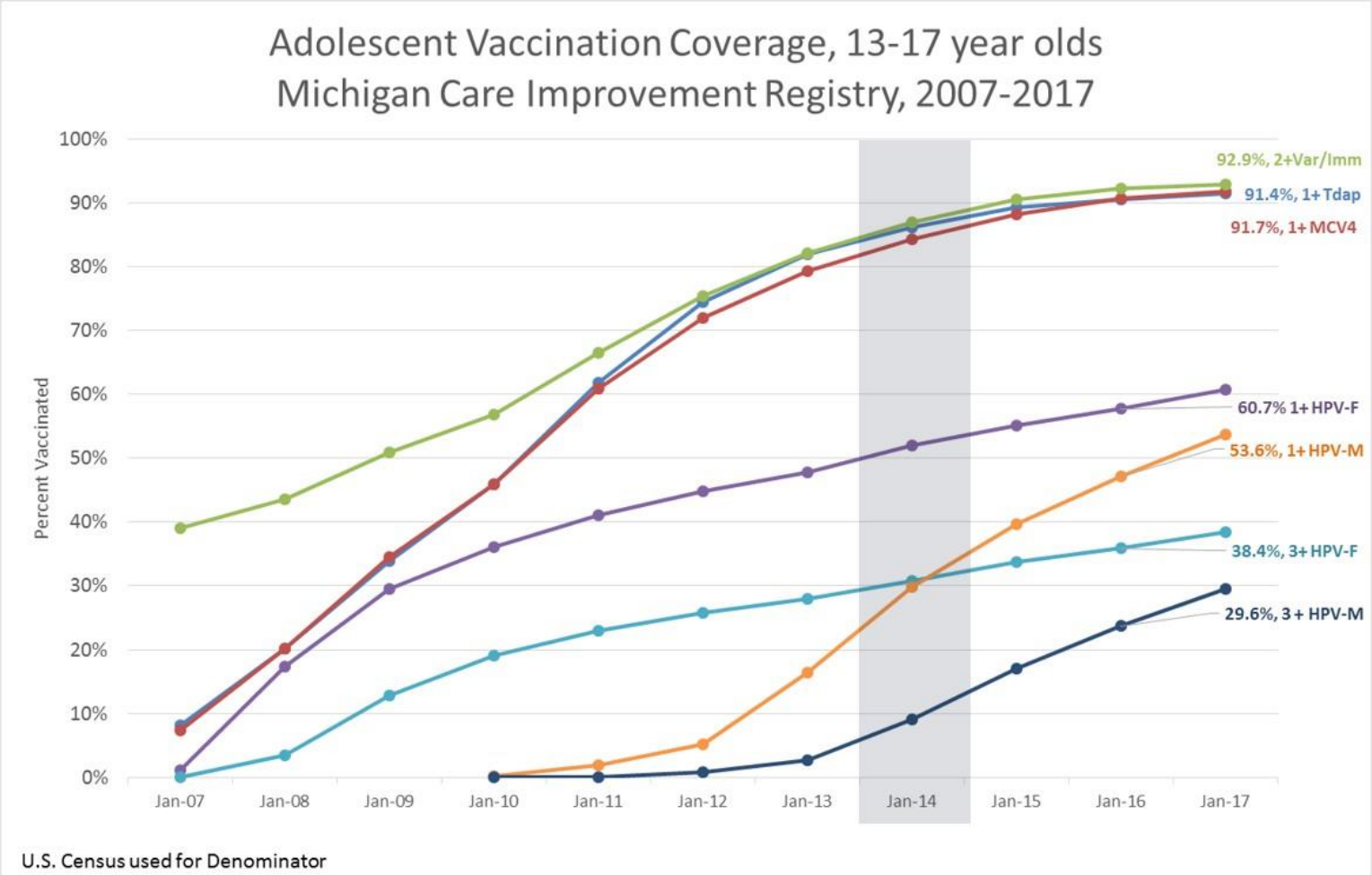
BACKGROUND

FUNDING

- 2013 Prevention and Public Health Fund Grant: Increasing Human Papillomavirus Vaccination Coverage Rates among Adolescents
  - To improve HPV vaccination rates of children aged 11 through18 years by:
    - Dissemination of centralized, statewide recall notices using MCIR
    - Classic style and follow-up AFIX meetings
    - An extensive communication campaign
    - Health care provider education and training
    - Joint stakeholder initiative

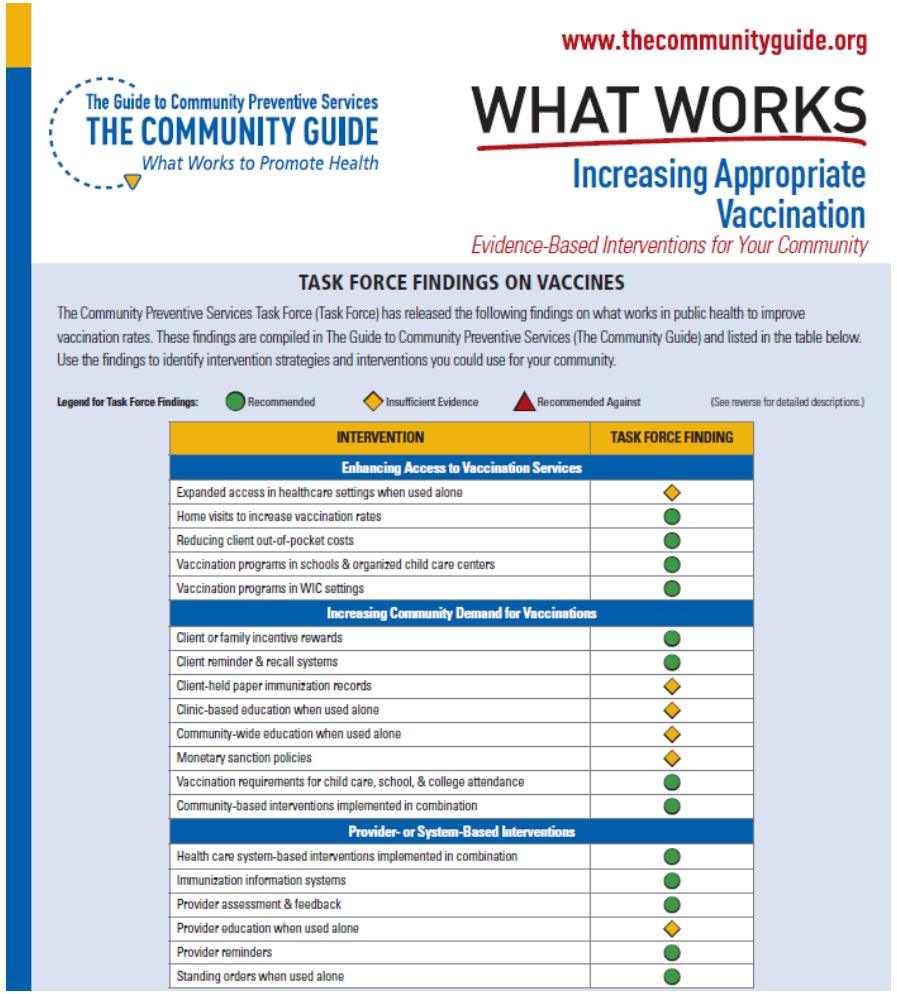
HPV VACCINE COVERAGE



- Recall was planned in 2014
- 1+ Tdap and 1+ MCV coverage ~ 85%
- HPV coverage
  - Females
    - 1+ ~ 50%
    - 3+ ~ 30%
  - Males
    - 1+ ~ 30%
    - 3 + ~ 10%

VACCINE REMINDER / RECALL

- The Community Preventive Services Task Force indicates that the one of the most effective mechanisms to improve vaccination rates are through interventions that alert those who are:
  - Eligible for vaccinations (reminders) or
  - Are overdue (recalls)
- Reminders and recalls are often conducted in tandem and can be delivered through a variety of modalities, including telephone, postal mail, email, SMS text message, or secure patient portals.



www.thecommunityguide.org

The Guide to Community Preventive Services
THE COMMUNITY GUIDE
What Works to Promote Health

WHAT WORKS
Increasing Appropriate Vaccination
Evidence-Based Interventions for Your Community

TASK FORCE FINDINGS ON VACCINES

The Community Preventive Services Task Force (Task Force) has released the following findings on what works in public health to improve vaccination rates. These findings are compiled in The Guide to Community Preventive Services (The Community Guide) and listed in the table below. Use the findings to identify intervention strategies and interventions you could use for your community.

Legend for Task Force Findings: ● Recommended ◆ Insufficient Evidence ▲ Recommended Against (See reverse for detailed descriptions.)

INTERVENTION	TASK FORCE FINDING
Enhancing Access to Vaccination Services	
Expanded access in healthcare settings when used alone	◆
Home visits to increase vaccination rates	●
Reducing client out-of-pocket costs	●
Vaccination programs in schools & organized child care centers	●
Vaccination programs in WIC settings	●
Increasing Community Demand for Vaccinations	
Client or family incentive rewards	●
Client reminder & recall systems	●
Client-held paper immunization records	◆
Clinic-based education when used alone	◆
Community-wide education when used alone	◆
Monetary sanction policies	◆
Vaccination requirements for child care, school, & college attendance	●
Community-based interventions implemented in combination	●
Provider- or System-Based Interventions	
Health care system-based interventions implemented in combination	●
Immunization information systems	●
Provider assessment & feedback	●
Provider education when used alone	◆
Provider reminders	●
Standing orders when used alone	●

RECALL SOURCE

- One factor that may contribute to the success of a recall is whether the source of these notifications is the patients' individual primary care practice, or a more centralized health system or public health organization.
- Barriers to the success of provider-based recalls have been documented:
  - Limitations of staff time
  - Cost
  - National data suggest few providers conduct any type of reminder
- Centralized recalls which typically originate from a health department or health system have been demonstrated as being more effective than practice-based reminders.

OBJECTIVES

- Increase HPV vaccination coverage by conducting a centralized, statewide HPV recall
- Evaluate the impact of the centralized, statewide recall on initiation and completion of the HPV vaccine series
- Determine if centralized recall letters using the existing recall functions in MCIR should be an ongoing strategy to improve HPV initiation and completion rates

METHODS

THE MICHIGAN CARE IMPROVEMENT REGISTRY (MCIR)

- MCIR is populated through a linkage with Vital Records birth data
- State law requires that all vaccination doses administered in Michigan to children aged ≤ 19 years be reported to MCIR
  - Parents or guardians may opt their child out of MCIR by written notice
- MCIR has been a Centers for Disease Control and Prevention Sentinel Site since 2001
  - Requires minimum standards of provider and patient participation, data quality, and timeliness
- A key function of MCIR is the ability to assess a child's status for each vaccine series and determine whether they are up-to-date, eligible, or overdue for the next recommended dose within a series
  - MCIR has been programmed to make series assessments based on the schedule recommended by the Advisory Committee on Immunization Practices (ACIP)
  - An exemption is for the first dose of HPV vaccine; for this dose, MCIR considers an adolescent overdue for the first dose of HPV vaccine at age 12 years, rather than 13 years

MCIR SERIES ASSESSMENT EXAMPLE

	Immunizations						Other
Series	Dose 1	Dose 2	Dose 3	Dose 4	Dose 5	Dose 6+	Status
DTP/DTaP/ DT/Td/Tdap	08/17/2004 DTaP	10/21/2004 DTaP	12/17/2004 DTaP	08/17/2005 DTaP	09/04/2009 DTaP-Daptacel	07/20/2016 Tdap	Up-To-Date Next Due 07/20/2026
Polio	08/17/2004 IPV	10/21/2004 IPV	05/17/2005 IPV	09/04/2009 IPV			Series Complete
MMR	08/17/2005 MMR	09/04/2009 MMR					Series Complete
Hepatitis B	10/21/2004 Hib-HepB	05/17/2005 Hib-HepB	08/17/2005 Hib-HepB				Series Complete
Varicella	05/17/2005 Varicella	09/04/2009 Varicella					Series Complete
HPV							HPV DUE NOW
Hepatitis A							Hepatitis A DUE NOW
Seasonal Influenza							Seasonal Influenza DUE NOW
Meningococcal Conjugate	07/20/2016 Meningococcal Conj, MCV4						Up-To-Date Next Due 05/06/2020

→ Not currently due, but needs more doses

→ No more doses are needed

→ Overdue

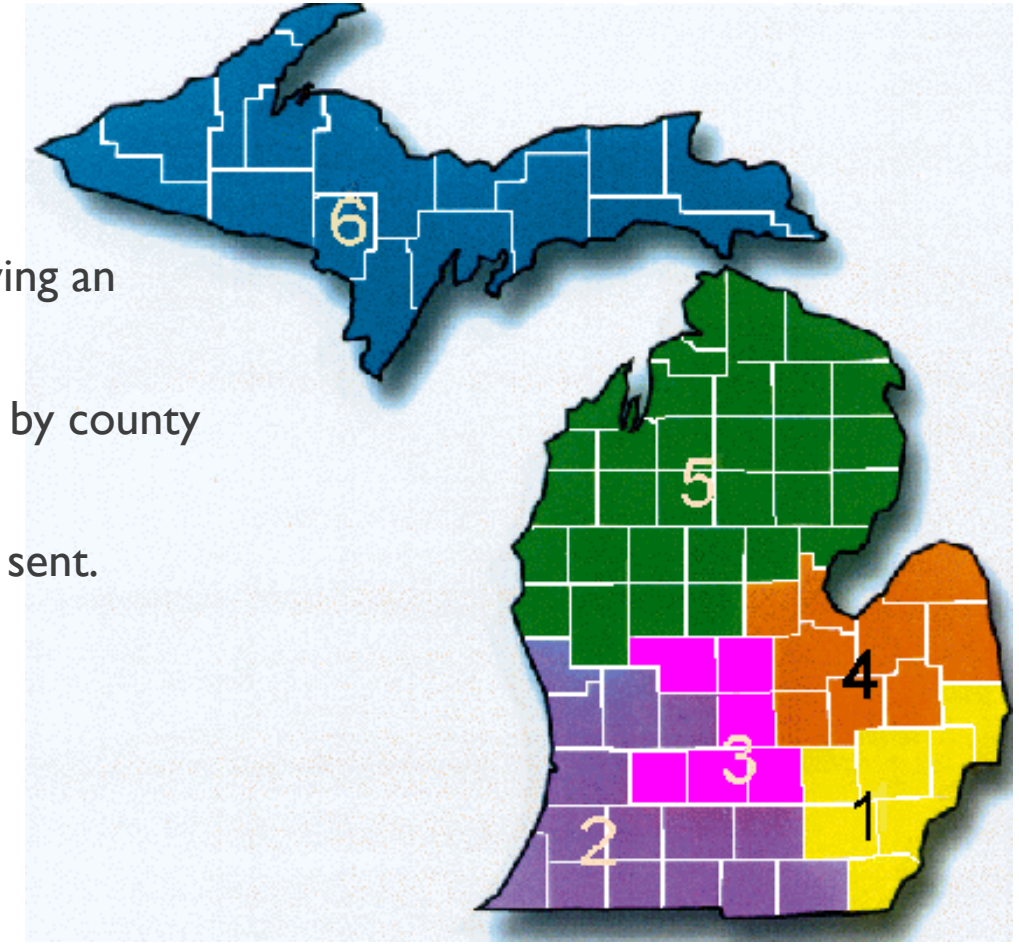
→ Not currently due, but needs more doses

MCIR RECALL FUNCTIONS

- Based on its assessments, MCIR has the capability to recall adolescents overdue for any dose within any series
- Adolescents are eligible for a recall in the MCIR system if they have not:
  - Been opted-out by a parent or guardian
  - Been flagged as deceased
  - Been flagged as migrant
  - Been recalled within the previous 60 days
  - Received two or fewer immunizations
  - Been flagged by a provider to not receive recall notifications
  - Had patient status set to Inactive at either the provider or jurisdictional level
  - Been flagged with an invalid address

RANDOMIZATION

- Adolescents were grouped by household, as determined by having an identical address in MCIR
- Households were randomized into two groups (recall, control) by county and age and gender of the oldest child within the household
- MCIR region determined the wave in which recall letters were sent.

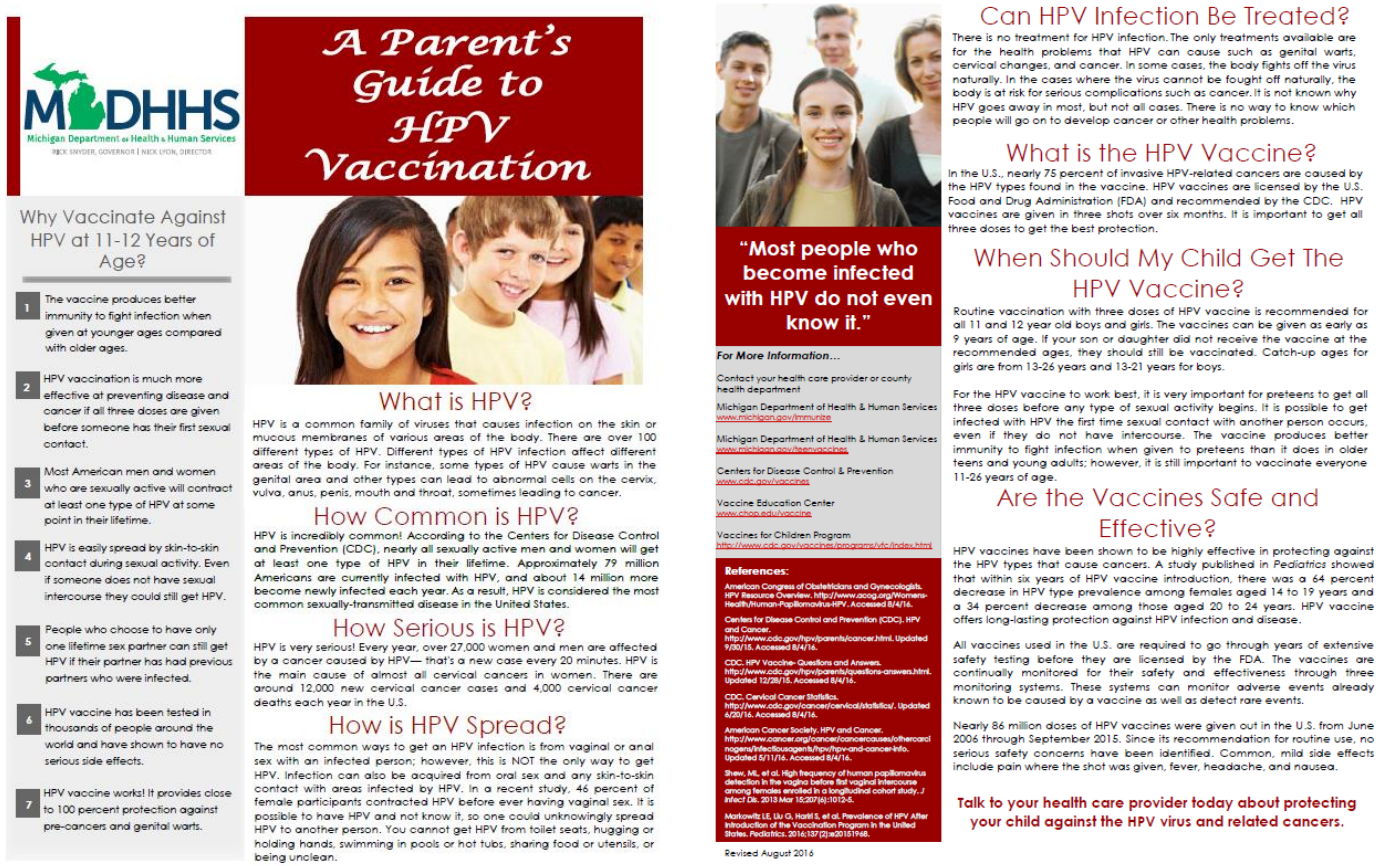


RECALL NOTIFICATION

- The initial recall waves were aimed at adolescents who had already initiated, but not completed, the HPV series
  - At the time of the intervention (which commenced in December, 2014), ACIP recommendations indicated that adolescents should complete a 3 dose HPV series. Consequently, we recalled adolescents who had received two doses of HPV vaccine and were determined by MCIR to be overdue for their final (third) dose of HPV vaccine.
- We began our recall notification with MCIR regions 2 and 3; the same process was subsequently implemented for regions 4 and 5, followed by regions 1 and 6
- The same procedure was subsequently employed for our recall aimed at adolescents 12 through 18 years who were overdue for their first dose of HPV vaccine

NOTIFICATION LETTER

- Each eligible adolescent in the recall group was sent a standard, MCIR-generated letter and Q&A document by postal mail
- The control group received the same mailing, lagged by at least 60 days following the notifications sent to the recall group in order to allow sufficient time for outcomes to be observed



MDHHS
Michigan Department of Health & Human Services

A Parent's Guide to HPV Vaccination

Why Vaccinate Against HPV at 11-12 Years of Age?

1. The vaccine produces better immunity to fight infection when given at younger ages compared with older ages.
2. HPV vaccination is much more effective at preventing disease and cancer if all three doses are given before someone has their first sexual contact.
3. Most American men and women who are sexually active will contract at least one type of HPV at some point in their lifetime.
4. HPV is easily spread by skin-to-skin contact during sexual activity. Even if someone does not have sexual intercourse they could still get HPV.
5. People who choose to have only one lifetime sex partner can still get HPV if their partner has had previous partners who were infected.
6. HPV vaccine has been tested in thousands of people around the world and have shown to have no serious side effects.
7. HPV vaccine works! It provides close to 100 percent protection against pre-cancers and genital warts.

What is HPV?

HPV is a common family of viruses that causes infection on the skin or mucous membranes of various areas of the body. There are over 100 different types of HPV. Different types of HPV infection affect different areas of the body. For instance, some types of HPV cause warts in the genital area and other types can lead to abnormal cells on the cervix, vulva, anus, penis, mouth and throat, sometimes leading to cancer.

How Common is HPV?

HPV is incredibly common! According to the Centers for Disease Control and Prevention (CDC), nearly all sexually active men and women will get at least one type of HPV in their lifetime. Approximately 79 million Americans are currently infected with HPV, and about 14 million more become newly infected each year. As a result, HPV is considered the most common sexually-transmitted disease in the United States.

How Serious is HPV?

HPV is very serious! Every year, over 27,000 women and men are affected by a cancer caused by HPV— that's a new case every 20 minutes. HPV is the main cause of almost all cervical cancers in women. There are around 12,000 new cervical cancer cases and 4,000 cervical cancer deaths each year in the U.S.

How is HPV Spread?

The most common ways to get an HPV infection is from vaginal or anal sex with an infected person; however, this is NOT the only way to get HPV. Infection can also be acquired from oral sex and any skin-to-skin contact with areas infected by HPV. In a recent study, 46 percent of female participants contracted HPV before ever having vaginal sex. It is possible to have HPV and not know it, so one could unknowingly spread HPV to another person. You cannot get HPV from toilet seats, hugging or holding hands, swimming in pools or hot tubs, sharing food or utensils, or being unclean.

"Most people who become infected with HPV do not even know it."

For More Information…

Contact your health care provider or county health department

Michigan Department of Health & Human Services
www.michigan.gov/immunize

Michigan Department of Health & Human Services
www.michigan.gov/teenvaccines

Centers for Disease Control & Prevention
www.cdc.gov/vaccines

Vaccine Education Center
www.chop.edu/vaccine

Vaccines for Children Program
http://www.cdc.gov/vaccines/programs/vfc/index.html

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CDC. Cervical Cancer Statistics. http://www.cdc.gov/cancer/cervical/statistics/. Updated 6/20/16. Accessed 8/4/16.

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Shew, ML, et al. High frequency of human papillomavirus detection in the vagina before first vaginal intercourse among females enrolled in a longitudinal cohort study. J Infect Dis. 2013 Mar 15;207(6):1012-5.

Markowitz LE, Liu G, Hariri S, et al. Prevalence of HPV After Introduction of the Vaccination Program in the United States. Pediatrics. 2016;137(2):e20151968.

Revised August 2016

Can HPV Infection Be Treated?

There is no treatment for HPV infection. The only treatments available are for the health problems that HPV can cause such as genital warts, cervical changes, and cancer. In some cases, the body fights off the virus naturally. In the cases where the virus cannot be fought off naturally, the body is at risk for serious complications such as cancer. It is not known why HPV goes away in most, but not all cases. There is no way to know which people will go on to develop cancer or other health problems.

What is the HPV Vaccine?

In the U.S., nearly 75 percent of invasive HPV-related cancers are caused by the HPV types found in the vaccine. HPV vaccines are licensed by the U.S. Food and Drug Administration (FDA) and recommended by the CDC. HPV vaccines are given in three shots over six months. It is important to get all three doses to get the best protection.

When Should My Child Get The HPV Vaccine?

Routine vaccination with three doses of HPV vaccine is recommended for all 11 and 12 year old boys and girls. The vaccines can be given as early as 9 years of age. If your son or daughter did not receive the vaccine at the recommended ages, they should still be vaccinated. Catch-up ages for girls are from 13-26 years and 13-21 years for boys.

For the HPV vaccine to work best, it is very important for preteens to get all three doses before any type of sexual activity begins. It is possible to get infected with HPV the first time sexual contact with another person occurs, even if they do not have intercourse. The vaccine produces better immunity to fight infection when given to preteens than it does in older teens and young adults; however, it is still important to vaccinate everyone 11-26 years of age.

Are the Vaccines Safe and Effective?

HPV vaccines have been shown to be highly effective in protecting against the HPV types that cause cancers. A study published in *Pediatrics* showed that within six years of HPV vaccine introduction, there was a 64 percent decrease in HPV type prevalence among females aged 14 to 19 years and a 34 percent decrease among those aged 20 to 24 years. HPV vaccine offers long-lasting protection against HPV infection and disease.

All vaccines used in the U.S. are required to go through years of extensive safety testing before they are licensed by the FDA. The vaccines are continually monitored for their safety and effectiveness through three monitoring systems. These systems can monitor adverse events already known to be caused by a vaccine as well as detect rare events.

Nearly 86 million doses of HPV vaccines were given out in the U.S. from June 2006 through September 2015. Since its recommendation for routine use, no serious safety concerns have been identified. Common, mild side effects include pain where the shot was given, fever, headache, and nausea.

Talk to your health care provider today about protecting your child against the HPV virus and related cancers.

OUTCOMES

- Primary outcome
  - Administration and report to MCIR of an HPV vaccine dose within 60 days of mailing
- Additional outcome
  - Report of previously administered HPV vaccine doses to MCIR within 60 days of mailing

RESULTS


If there were a vaccine against cancer, wouldn't you get it for your kids?
against HPV.
www.cdc.gov/vaccines/teens


If there were a vaccine against cancer, wouldn't you get it for your kids?
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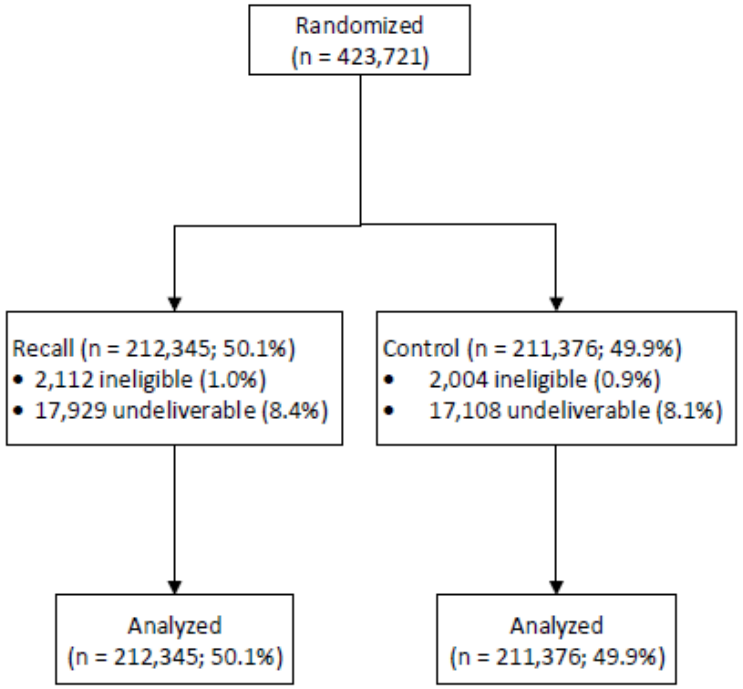
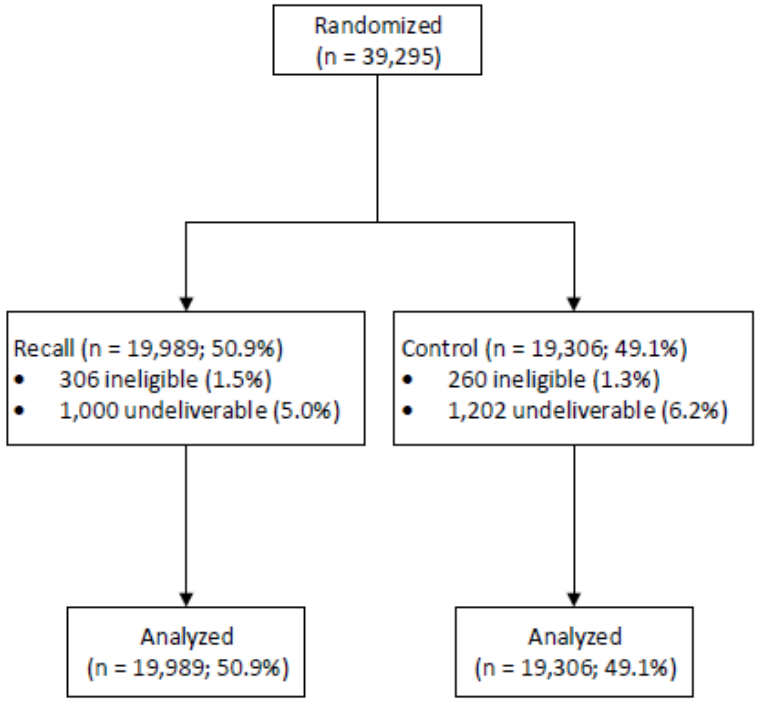
RANDOMIZATION

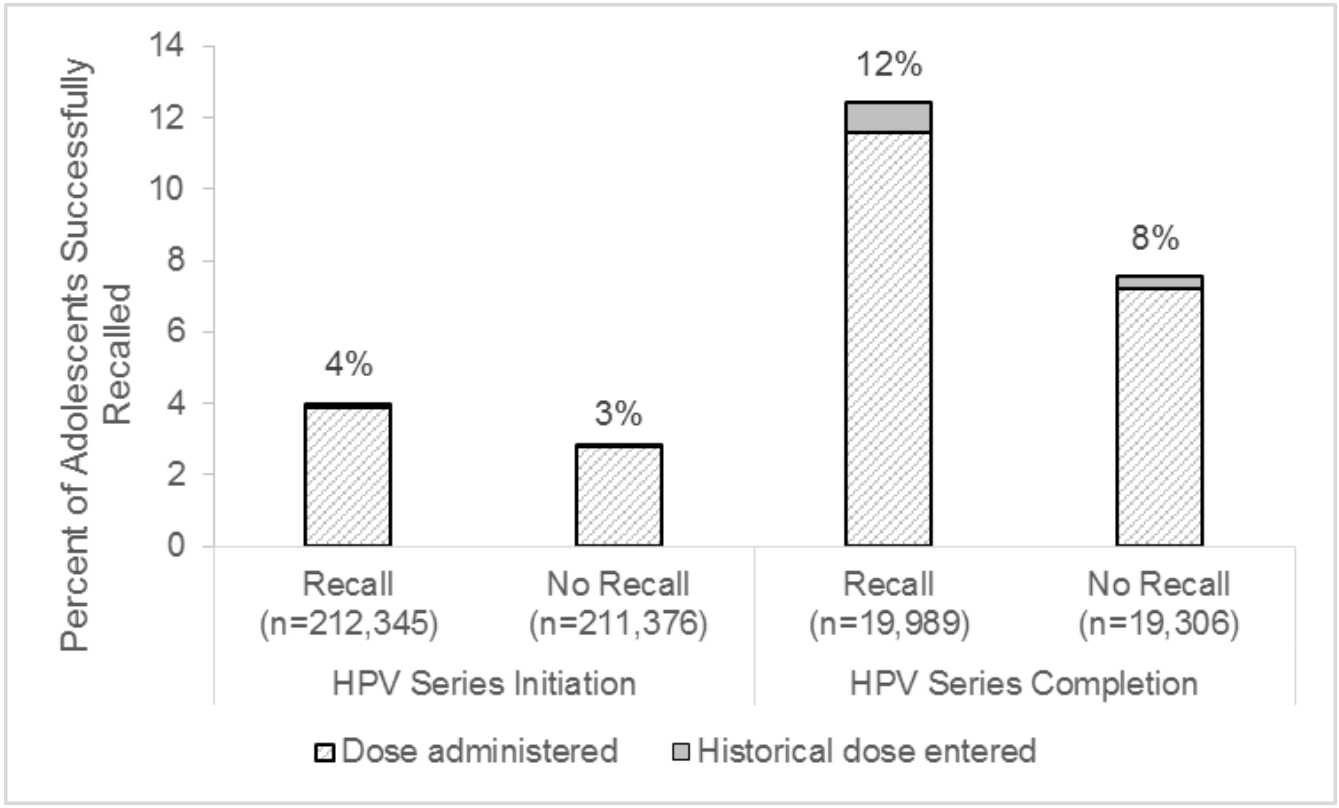
HPV Series Initiation



HPV Series Completion



OVERALL RESULTS



CUMULATIVE INCIDENCE (CI) AND RISK DIFFERENCE (RD) BY GROUP, HPV SERIES INITIATION

	HPV Series Initiation								
	Recall (n=212,345)			No Recall (n=211,376)					
	n	CI per 100	95% CL	n	CI per 100	95% CL	p-value	RD per 100	95% CL
Total	8619	4.06	3.98, 4.14	6114	2.89	2.82, 2.96	<0.001	1.17	1.06, 1.28
Age Group									
12 years	2737	7.90	7.62, 8.19	2263	6.54	6.28, 6.80	<0.001	1.36	0.98, 1.75
13-15 years	3651	4.04	3.91, 4.17	2452	2.73	2.63, 2.84	<0.001	1.31	1.14, 1.48
16-18 years	2231	2.55	2.45, 2.66	1399	1.61	1.52, 1.69	<0.001	0.95	0.81, 1.08
Gender									
Female	3758	4.08	3.95, 4.21	2836	3.09	2.98, 3.20	<0.001	0.99	0.82, 1.16
Male	4860	4.05	3.93, 4.16	3278	2.74	2.65, 2.83	<0.001	1.31	1.16, 1.45
N/A	78	--	--	41	--	--	--	--	--
Region									
1 and 6	4237	3.57	3.47, 3.68	2945	2.49	2.40, 2.58	<0.001	1.08	0.94, 1.22
2 and 3	2887	5.27	5.08, 5.45	2100	3.84	3.68, 4.00	<0.001	1.43	1.18, 1.67
4 and 5	1495	3.84	3.65, 4.03	1069	2.78	2.62, 2.95	<0.001	1.06	0.80, 1.31

CUMULATIVE INCIDENCE (CI) AND RISK DIFFERENCE (RD) BY GROUP, HPV SERIES COMPLETION

	HPV Series Completion								
	Recall (n=19,989)			No Recall (n=19,306)			p-value	RD per 100	95% CL
Total	2482	12.42	11.96, 12.87	1460	7.56	7.19, 7.94	<0.001	4.85	4.26, 5.44
Age Group									
11-12 years	431	16.90	15.45, 18.36	273	11.38	10.11, 12.65	<0.001	5.52	3.59, 7.45
13-15 years	1201	14.03	13.30, 14.79	678	8.14	7.55, 8.73	<0.001	5.89	4.95, 6.84
16-18 years	850	9.57	8.96, 10.18	509	5.94	5.44, 6.44	<0.001	3.64	2.85, 4.43
Gender									
Female	1237	11.66	11.05, 12.27	738	7.20	6.70, 7.70	<0.001	4.45	3.66, 5.24
Male	1244	13.28	12.59, 13.96	722	7.97	7.41, 8.53	<0.001	5.31	4.42, 6.19
N/A	7	--	--	2	--	--	--	--	--
Region									
1 and 6	1350	12.57	11.95, 13.20	812	7.73	7.22, 8.24	<0.001	4.85	4.04, 5.66
2 and 3	727	12.44	11.59, 13.28	426	7.51	6.82, 8.19	<0.001	4.93	3.84, 6.02
4 and 5	405	11.88	10.80, 12.97	222	7.12	6.21, 8.02	<0.001	4.77	3.36, 6.18

DISCUSSION

OVERALL EFFECT

- Using MCIR for a centralized, statewide recall mailing was effective for prompting the completion of the HPV vaccine series
- While MCIR recall notification was also associated with increased HPV vaccine series initiation, the overall effect was modest
  - Despite inclusion of a fact sheet developed to anticipate questions parents may have about the HPV vaccine
    - Consistent with prior studies that have shown no commensurate increase in the acceptability of HPV vaccines, despite increased knowledge obtained through information sheets provided to parents.
    - Rather, HPV series initiation is demonstrably increased when providers take time to discuss the vaccine with parents, make a strong recommendation, and use presumptive language.
  - Included all adolescents aged 12 through 18 years eligible for a recall who had not yet initiated the HPV vaccine series
    - Address may not have been current,
    - May not have discussed the HPV vaccine with their provider, or
    - May have already refused the HPV vaccine were also included in the recall for series initiation.

VARIATION BY GROUPS

- Our findings indicate that the effect of HPV recall notification for both series initiation and completion varied across subgroups by age, gender, and geographic region of the state
  - Greatest among younger adolescents
    - Earlier completion of the HPV vaccine series is beneficial not only because vaccination at a younger age is associated with a stronger immune response, but also because the full benefit of the vaccine is achieved when the series is completed prior to exposure to HPV through sexual activity

POSSIBLE VARIATION BY SEASON

- In both recalls, we noticed the greatest impact in regions 2 and 3
- This effect was small for series completion, but for initiation, we saw a 1.4% difference between the intervention and control groups in regions 2 and 3, compared to about a 1% difference in regions 1 and 6 and regions 4 and 5
- The intervention in regions 2 and 3 may have benefitted from the timing of the recall letter, which was mailed in early September and may have prompted parents to discuss the HPV vaccine at an already-scheduled back-to-school office visit.
  - Most of the vaccines recommended for adolescents aged 11 through 12 years are administered in the fall.
  - Future recall efforts may be timed to take advantage of this effect

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