CONTRA COSTA
HEALTH SERVICES

Contra Costa Health Plan

COMMUNITY PROVIDER NETWORK MEETING

1350 Arnold Drive, Conference Room #103, Martinez

Tuesday, April 24, 2012 7:30 AM to 9:00 AM

Continental Breakfast will be served

I.	**Call to order**	**J. Tysell, MD**
II.	**Approval of Minutes**	**J. Tysell, MD**
III.	**Medical Director's Report**	**J. Tysell, MD**
IV.	**Pending Legislation** • **Changes for CCHP**	**Patricia Tanquary, MSSW, MPH, PhD** **CEO**
V.	**Provider Concerns**	**J. Tysell, MD**
VI.	**Adjourn**	**J. Tysell, MD**

Next Meeting – July 24, 2012

Please RSVP–(check one) yes__ I will attend/no__
Fax back to: (925) 646-9907 Ph#: 925-313-9500

CPN Quarterly Meeting Dates for 2012

January 24, April 24, July 24, October 23

CONTRA COSTA HEALTH PLAN
Community Provider Network – West County
Meeting Minutes – April 24, 2012

Attending:
J. Tysell, MD; M. Berkery, RN; B. Jacobs, FNP ; C. S. Ming, MD; G. Graves, MD; E. Risgalla, MD; S. Sachdeva, MD; G. J. Zimmerman, MD; L. Yang, MD; J. Quan, MD; S. Huerta, RN, CPNP; T. Mostaghasi, MD
Guests: Patricia Tanquary, CCHP CEO; P. Hackett, RN

Discussion		Action	Accountable
	Meeting called to order @ 7:35 am.		J. Tysell, MD
I.	Agenda approved with no change.		J. Tysell, MD
II.	**Approval of Minutes:** Minutes approved as read.		J. Tysell, MD
III.	**Report of current legislation affecting CCHP presented by CEO.** **SPD Report:** CCHP has been receiving this population on monthly allocations since June 2011. 91% of referrals have selected CCHP from a two plan choice. The last group will be received by transfer on May 1st. For those patients who request a continuing relationship with their previous provider, CCHP is developing Letters of Agreements (LOA) with those providers who wish to continue seeing these patients. This LOA is developed and is in effect for one year. **Dual Eligible:** A plan to transfer all dually eligible Medicare and Medi-Cal eligible SPD and low income persons is in effect in fiscal year 2012-13. A demonstration model for four counties will start in July 2012 with an additional six counties joining in January 2013. Contra Costa is being considered for the January implementation. Continuation of this plan for dual eligible will continue in this demonstration phase during the next six months. A tentative raise in PCP reimbursement to Medicare rates continues to be included in the Federal Budget scheduled for implementation in FY 2012-13. This issue continues to be reviewed through the revision process.		P. Tanquary,CEO
IV.	**Medical Director's Report:** • New RMC Clinic building to be completed in San Pablo near DMC is scheduled to open in Sept 2012. • Referral Dept is increasing to avoid long wait for appointments for both PCP and RMC • Review of Provider's Bulletin		J. Tysell, MD

	Other information: **Immunizations** • Reminder of 7th grade Tdap requirement. School Districts firm about not accepting non-immunized teens. Important to record in chart and in CAIR. • Many parents postpone immunizations • Suggestions for talking with parents shared also document on risks of not immunizing your child • Poster on need for measles vaccine for providers to share with parents (copy ready) **Changes in Medical Care Consent for Minors introduced.** • New changes/additions discussed • Confidentiality concerns addressed • Suggestions for talking with parents about health issues		B. Jacobs, FNP B. Jacobs, FNP
VI.	**Adjourn:** Meeting adjourned @ 8:55 am.		J. Tysell, MD

Next meeting – July 24, 2012

CONTRA COSTA HEALTH PLAN
Community Provider Network – West County
Meeting Minutes – January 24, 2012

Attending:
J. Tysell, MD; B. Jacobs, FNP; M. Berkery, RN; P. Hackett, RN; S. M. Chang, MD; G. Graves, MD; M. Nguyen, MD; J. O'Meany, PA; H. E. Risgalla, MD; I. Salceda, PA; J. G. Zimmerman, MD; Sara Huerta, NP
Guests: Barbara Sheehy, MS California Children's Services

Discussion		Action	Accountable
I.	Meeting called to order @ 7:45 am.		J. Tysell, MD
II.	Agenda approved with no change.		J. Tysell, MD
III.	**Approval of Minutes:** Minutes approved as read.		J. Tysell, MD
IV.	**Medical Director's Report:**		J. Tysell, MD
V.	**HEDIS:** • CPN patients and patients who deliver at community hospitals are less likely to get Post Partum visits • CCHP is exploring whether a collaboration with Public Health Department can help facilitate postpartum visits in the desired 3 to 8 week timeframe after delivery. • Though many prenatal patients in the CCRMC network begin care with labs, etc., they must see a **provider** in the first trimester to meet HEDIS standards **Dual Eligible:** • Could be next group mandated into managed care. • Medi-Cal Health Plans would be responsible for benefits not covered by Medicare, e.g. some DME, some medications. **County Health Services Staffing:** • Several groups of employees will experience cuts in pay. • Several PCPs have moved to Kaiser • CCRMC has developed an incentive program to encourage PCPs to stay. **EPIC (Electronic Health Record):** • Expected to go live July, 2012. • Will allow CPN providers to see member health info from CCRMC system. **QIPs (Quality Improvement Projects):** • Two being studied by CCHP: Pediatric Obesity and new statewide collaboration to reduce hospital readmissions **SPDs:** • Over 6000 new SPD members to date • Dr. Cammisa now employed part time by CCHP to assist with QM and UM activities related to SPDs, e.g. Hep C protocols. Working closely with Dr. Tysell.		J. Tysell, MD
VI.	**CCS (California Children's Services)**: • CCS working closely with CCHP • Conditions covered by CCS may be changed/restricted with review by CCS physician. • Speaker Barbara Sheehy, MS, Administrator of program • Long term medical program for kids with serious and chronic medical problems, since 1920's • CCS-eligible conditions are almost any chronic serious condition, and include cancers, heart problems, hearing aids, and wheelchairs.		B. Sheehy, MS

	• PCPs can refer directly or through CCHP. Children will be screened by CCS to see if they qualify.		
VII.	**Adjourn:** Meeting adjourned @ 9:00 am.		J. Tysell, MD

Next meeting – April 24, 2012

MANDATED SPD DISTRIBUTION - 2012

	TOTAL SPDs	NEW TO CCHP	PERCENT
June 2011	**1036**	**1017**	**98%**
July (1051)		(460)	
July & August	**2166**	**1746**	**81%**
August (1115)		(1286)	
September	**1029**	**990**	**96%**
October	**1097**	**949**	**87%**
November	**1024**	**936**	**91%**
December	**1107**	**829**	**75%**
January 2012	**1022**	**993**	**97%**
February	**940**	**794**	**85%**
March	**799**	**742**	**93%**
April	**992**	**924**	**93%**
TOTALS	**11212**	**9920**	

AVERAGE: JUNE – APRIL = 90%

DHCS California Department of HealthCareServices

News Release

NUMBER: 12-05
FOR IMMEDIATE RELEASE
April 4, 2012

CONTACT: Norman Williams
(916) 440-7660
www.dhcs.ca.gov

DHCS ANNOUNCES INITIAL COUNTIES SELECTED FOR PROJECT TO IMPROVE CARE FOR CALIFORNIANS ELIGIBLE FOR BOTH MEDICARE AND MEDI-CAL

SACRAMENTO – The California Department of Health Care Services (DHCS) today announced that Los Angeles, Orange, San Diego and San Mateo counties would be the initial participants in a proposed three-year demonstration project aimed at improving the coordination of care for low-income seniors and persons with disabilities who are dually eligible for Medicare and Medi-Cal. These are the first of up to 10 counties that could take part in the project in 2013.

"Currently, most dual eligible beneficiaries access services through a complex system of disconnected programs that often leads to beneficiary confusion, delayed care, poor care coordination, inappropriate utilization and unnecessary costs, issues we are addressing with this proposal," said DHCS Director Toby Douglas. "The goal is to design a seamless system that helps dual eligible beneficiaries get the health care services they need and improve health outcomes in a more fiscally efficient manner."

California has approximately 1.1 million people enrolled in both Medicare and Medi-Cal. They are among the state's highest-need and highest-cost users of health care services, accounting for nearly 25 percent of Medi-Cal spending. The proposed three-year project would enroll a portion of California's dual eligible beneficiaries into integrated care delivery models. An estimated $678.8 million in General Fund savings is expected in fiscal year (FY) 2012-13, increasing to $1 billion in 2013-14.

As part of the announcement, the state released a comprehensive draft proposal for public comment that outlines the demonstration project. It is funded by the Affordable Care Act and requires the approval of the federal Centers for Medicare & Medicaid Services (CMS).

The demonstration project is a key part of the Governor's Coordinated Care Initiative, which is aimed at improving beneficiary health outcomes and care quality, while achieving substantial savings from the rebalancing of care delivery away from institutional settings and into people's homes and communities.

Today's announcement follows an extensive public stakeholder process and rigorous site selection process. A team involving departments across the California Health and Human Services Agency reviewed 22 proposals from health plans operating in ten counties. The review team determined that the selected health plans would, upon implementation, improve dual eligible beneficiaries' care experiences and health outcomes.

-more-

Current state law permits implementation in 2013 in the four named counties. Pending further state and federal authority, readiness reviews and preparations, the state believes it will be possible to conduct the demonstration in up to six additional counties in 2013: San Bernardino, Riverside, Santa Clara, Contra Costa, Alameda and Sacramento.

"We will build upon California's existing structure of managed care health plans, county mental health programs and home- and community-based social services to achieve the financial and service integration necessary to accomplish this goal," added Douglas.

Under the demonstration, the selected health plans would receive a blended monthly payment from Medicare and Medi-Cal to provide their enrollees all needed services. Beneficiaries will have a single health plan membership card and a care team to help coordinate their services.

Moreover, all medical and long-term services and supports would be integrated as managed care benefits, and strong coordination of mental health and substance use services will be required. A key component for helping people avoid unnecessary hospitalizations and nursing home admissions will be the In-Home Supportive Services (IHSS) program, the nation's largest personal care provider program.

"In-Home Supportive Services is an important service that assists more than 440,000 people with services they need to live independently at home," said Will Lightbourne, director of the California Department of Social Services, which oversees the IHSS program. "IHSS will remain an entitlement program and the consumers' current rights, including the right to self-direct their care by hiring, firing and directing their IHSS workers, will not change."

Pending approval from CMS, the state would begin notifying beneficiaries of upcoming changes due to the proposed demonstration in the fall of 2012. Enrollment would begin in January 2013. Beneficiaries can choose to keep their Medicare benefits separate from this integration, but those who do not opt out of the demonstration will be enrolled on a phased-in basis throughout 2013.

Further details on how the demonstration would be implemented are described in a comprehensive proposal released today in draft version for public comment. Following a 30-day period for stakeholder input, California will submit this proposal to CMS for approval.

For more information about the demonstration, please visit www.CalDuals.org. All the health plan applications may be viewed online at http://www.dhcs.ca.gov/provgovpart/Pages/RFSApplications.aspx.

###

Shots For School

Information for Providers

What can I do to help my patients meet the 7th Grade Tdap Requirement?

As soon as possible:

- **Issue recalls and reminders to your patients who have not yet received Tdap.**
  - Remember Td does NOT meet the new requirement! Tdap can be given at any time after the last dose of Td.
- **Immunize your patients who have not yet received Tdap yet to protect them against the ongoing risk of pertussis and also meet the new requirement**
  - Immunize at every opportunity, including appointments for mild illness or injury.
- **Document your Tdap immunization clearly in the paper or electronic records that your patients will share with school staff.**
  - The California Immunization Registry (CAIR) provides rapid, clear and simple documentation of Tdap immunization, saving time and effort for the many California providers and schools who use CAIR. Providers and health plans who wish to begin using CAIR may contact the CAIR Help Desk at 800-578-7889 or www.cairweb.org.
- **Combine Tdap immunization with other recommended care.**
  - CDC, AAP and the Society for Adolescent Medicine recommend that all 11- to 12-year olds get a preteen check-up to provide all recommended immunizations, other preventive care and anticipatory guidance.

What immunizations are required for my patients to attend school?
To protect the public's health, many, but not all, *recommended* childhood vaccines are also *required* by California law and regulations in order to attend school. The immunizations currently required for pupils in California **for the 2012-13 School Year** include:

Immunization required for 7th grade:

- Tdap (pertussis booster)

Immunizations required to enter Kindergarten:

- Polio
- DTaP
- MMR
- Hepatitis B
- Varicella (Chickenpox)

Updated October 2010

Talking with Parents about Vaccines for Infants

Strategies for Health Care Professionals

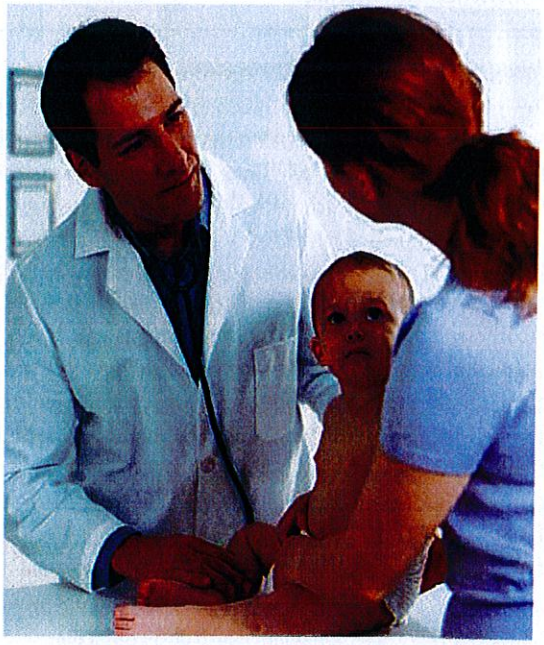
Immunization professionals and parents agree: times have changed.

Because of questions or concerns about vaccines, well-child visits can be stressful for parents. As their infant's health care provider, you remain parents' most trusted source of information about vaccines. This is true even for parents with the most questions and concerns. Your personal relationship uniquely qualifies you to help support parents in understanding and choosing vaccinations.

However, time for infant health evaluation at each well visit is at a premium, as you check physical, cognitive, and other milestones and advise parents on what to expect in the coming months. Therefore, making time to talk about vaccines may be stressful for *you*. But when an infant is due to receive vaccines, nothing is more important than making the time to assess the parents' information needs as well as the role they desire to play in making decisions for their child's health, and then following up with communication that meets their needs.

When it comes to communication, you may find that similar information—be it science or anecdote or some mix of the two—works for most parents you see. But keep a watchful eye to be sure that you are connecting with each parent to maintain trust and keep lines of communication open.

We hope that these brief reminders—and the materials that you, your staff, and parents can find on our website— will help ensure your continued success in immunizing infants and children. Success may mean that all vaccines are accepted when you recommend them, or that some vaccines are scheduled for another day. If a parent refuses to vaccinate, success may simply mean keeping the door open for future discussions about choosing vaccination.



THIS RESOURCE COVERS:

- What you may hear from parents about their vaccine safety questions and how to effectively address them
- Proven communication strategies and tips for having a successful vaccine conversation with parents
- This brochure is part of a comprehensive set of educational materials for health care professionals and parents available at *http://www.cdc.gov/vaccines/conversations*

Nurses, physician assistants, and other office staff play a key role in establishing and maintaining a practice-wide commitment to communicating effectively about vaccines and maintaining high vaccination rates: from providing parents with educational materials, to being available to answer their questions, to making sure that families who may opt for extra visits for vaccines make and keep vaccine appointments.

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

CDC Centers for Disease Control and Prevention

AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

What You May Hear From Parents

As you plan for responding to parents' concerns, it may be useful to think of parental questions in the following categories.

Questions about whether vaccines cause autism

Parents may encounter poorly designed and conducted studies, misleading summaries of well-conducted studies, or anecdotes made to look like science—claiming that vaccines cause autism. Many rigorous studies show that there is no link between MMR vaccine or thimerosal and autism. Visit *http://www.cdc.gov/vaccines/conversations* for more information to help you answer parents' questions on these two issues. If parents raise other possible hypotheses linking vaccines to autism, four items are key: (1) patient and empathetic reassurance that you understand that their infant's health is their top priority, and it also is your top priority, so putting children at risk of vaccine-preventable diseases without scientific evidence of a link between vaccines and autism is a risk you are not willing to take; (2) your knowledge that the onset of regressive autism symptoms often coincides with the timing of vaccines but is not caused by vaccines; (3) your personal and professional opinion that vaccines are very safe; and (4) your reminder that vaccine-preventable diseases, which may cause serious complications and even death, remain a threat.

"All those people who say that the MMR vaccine causes autism must be on to something."

"Autism is a burden for many families and people want answers—including me. But well designed and conducted studies that I can share with you show that MMR vaccine is not a cause of autism."

Questions about whether vaccines are more dangerous for infants than the diseases they prevent

Today, parents may not have seen a case of a vaccine-preventable disease firsthand. Therefore, they may wonder if vaccines are really necessary, and they may believe that the risks of vaccinating infants outweigh the benefits of protecting them from infection with vaccine-preventable diseases. Visit *http://www.cdc.gov/vaccines/conversations* for up-to-date information on diseases and the vaccines that prevent them that you can share with parents. You may be able to provide information from your own experience about the seriousness of the diseases, the fact that cases and outbreaks of vaccine-preventable diseases are occurring now in the U.S., and that even when diseases are eliminated in the U.S., they can make a rapid return in children and adults who are not immunized if travelers bring the diseases into the U.S. You also can remind parents about ongoing efforts to ensure the safety of vaccines, including the large-scale reporting system, Vaccine Adverse Event Reporting System (*http://www.vaers.hhs.gov*), used to alert FDA and CDC to any possible problems with a vaccine so that they can be studied in more detail.

"What are all these vaccines for? Are they really necessary?"

"I know you didn't get all these vaccines when you were a baby. Neither did I. But we were both at risk of serious diseases like Hib and pneumococcal meningitis. Today, we're lucky to be able to protect our babies from 14 serious diseases with vaccines."

Questions about the number of vaccines and vaccine ingredients

Some parents may have a general concern that there are too many vaccines. With respect to timing and spacing of vaccines, the childhood vaccine schedule is designed to provide protection at the earliest possible time against serious diseases that may affect infants early in life. *The Childhood Immunization Schedule* fact sheet (*http://www.cdc.gov/vaccines/conversations*) may be useful for those parents, as well as for parents who have specific questions. Some parents may be able to specify their concerns: whether each vaccine is needed, whether giving several vaccines at one time can cause harm, whether vaccine ingredients are harmful, or how well each vaccine works. For these parents, you can specifically reinforce the seriousness of the diseases prevented by vaccines, and share your knowledge that no evidence suggests that a healthy child's immune system will be damaged or overwhelmed by receiving several vaccines at one time. *Understanding Vaccine Ingredients* (*http://www.cdc.gov/vaccines/conversations*) can help you counter myths that have circulated about vaccine ingredients. You may need to share with some parents that not only should each vaccine series be started on time to protect infants and children as soon as possible, but each multi-dose series must be completed to provide the best protection.

"I'm really not comfortable with my 2-month-old getting so many vaccines at once."

"There's no proven danger in getting all the recommended 2-month vaccines today. Any time you delay a vaccine you leave your baby vulnerable to disease. It's really best to stay on schedule. But if you're very uncomfortable, we can give some vaccines today and schedule you to come back in two weeks for the rest, but this is not recommended.

Questions about known side effects

It is reasonable for parents to be concerned about the possible reactions or side effects listed on the Vaccine Information Statements, especially fever, redness where a shot was given, or fussiness that their child may experience following vaccination. Remind parents to watch for the possible side effects and provide information on how they should treat them and how they can contact you if they observe something they are concerned about. To reinforce how rare serious side effects really are, share your own experience, if any, with seeing a serious side effect from a vaccine.

"I'm worried about the side effects of vaccines. I don't want my child to get any vaccines today."

"I'll worry if your child *doesn't* get vaccines today, because the diseases can be very dangerous—most, including Hib, pertussis, and measles, are still infecting children in the U.S. We can look at the Vaccine Information Statements together and talk about how rare serious vaccine side effects are."

Questions about unknown serious adverse events

Parents who look for information about vaccine safety will likely encounter suggestions about as-yet-unknown serious adverse events from vaccines. It is not unreasonable that parents find this alarming. You can share what the world was like for children before there were vaccines. And you can share that increases in health problems such as autism, asthma, or diabetes don't have a biologic connection to vaccination. We have no evidence to suggest that vaccines threaten a long, healthy life. We know lack of vaccination threatens a long and healthy life.

"You really don't know if vaccines cause any long-term effects."

"We have years of experience with vaccines and no reason to believe that vaccines cause long-term harm. I understand your concern, but I truly believe that the risk of diseases is greater than any risks posed by vaccines. Vaccines will get your baby off to a great start for a long, healthy life."

Communication Strategies—How to Have a Successful Dialogue

A successful discussion about vaccines involves a two-way conversation, with both parties sharing information and asking questions. These communication principles can help you connect with parents by encouraging open, honest, and productive dialogue.

Take advantage of early opportunities such as the prenatal, newborn, 1-week, and 1-month visits to initiate a dialogue about vaccines. These also are good opportunities to provide take-home materials or direct parents to immunization websites that you trust. This gives parents time to read and digest reputable vaccine information before the first and all future immunizations. And when parents have questions, you can build on the reputable information that they already have reviewed. With parents who have many questions, consider an extended visit to discuss vaccinating their child.

Take time to listen.

If parents need to talk about vaccines, give them your full attention. Despite a full schedule, resist the urge to multi-task while a parent talks. Maintain eye contact with parents, restate their concerns to be sure you understand their viewpoint, and pause to thoughtfully prepare your reply. Your willingness to listen will likely play a major role in helping parents with their decisions to choose vaccination.

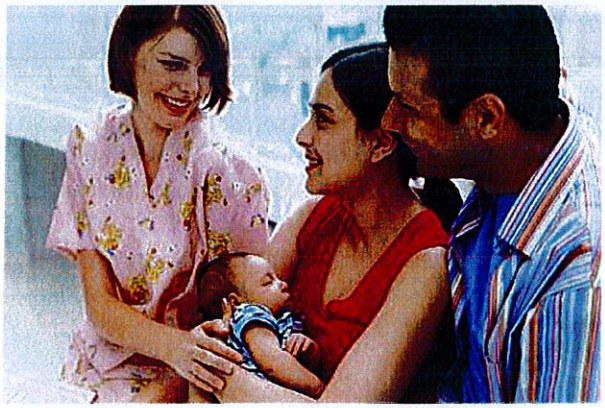
Solicit and welcome questions.

If parents seem concerned about vaccines but are reluctant to talk, ask them open-ended questions and let them know that you want to hear their questions and concerns.

Put yourself in parents' shoes and acknowledge parents' feelings and emotions, including their fear and desire to protect their children. Remind parents that you know why they are concerned—their infant's health is their top priority. Remind them that it is yours, too.

Keep the conversation going.

If parents come to you with a long list of questions or information from the Web or other sources, don't interpret this as a lack of respect for you. Instead, acknowledge that spending time to research vaccines means that this is an important topic for the parents. If you appear offended by questions, or if you imply that a parent's questions are uncalled for, dialogue may shut down and trust may be eroded.



Science versus anecdote?

Too much science will frustrate some parents. Too little science will frustrate others. For some parents, too much anecdotal information won't hit the mark. For others, a story from your experience about an unprotected child who became ill, or knowing that children in your family have received all of their vaccines, will be exactly on target. Which approach to use will depend on your knowledge of the family. Watch and listen. Be prepared to use the mix of science and personal stories that will be most effective in addressing parents' questions.

Acknowledge benefits and risks.

Always discuss honestly the known side effects caused by vaccines. But don't forget to remind parents of the overwhelming benefit of preventing potentially serious diseases with vaccines. It's honest to say that not vaccinating is a risk that will worry you.

Respect parents' authority.

Many parents today want to work in partnership with their child's physician. Of course, you work in partnership with parents every day, for example, by eliciting reports from them about how their infants are progressing. By talking respectfully with parents about their immunization concerns, you can build on this partnership, build trust, and support parents in the decision to choose vaccination.

Reduce the stress of shots.

Show parents ways they can make the vaccination visit less stressful for the child. It can begin by reinforcing that crying is a normal response for the child and suggesting that they stay calm so that the child does not become aware of their stress. For infants, you can suggest that parents use a favorite blanket or toy to distract the baby from the pain of the shots, and that they touch and soothe the baby, talk softly, and smile and make eye contact during the shots. After shots for infants, mothers may wish to cuddle or breastfeed. For toddlers, there are many more options to distract from the pain of the shot, including telling a favorite story, singing, or taking deep breaths and blowing out the pain. After the shots, toddlers can be praised for getting through the shots and reassured that everything is OK.

After the Office Visit

Document parents' questions and concerns.

A thorough record of your discussion will be an invaluable reference during the child's future visits.

Follow up.

If parents express extreme worry or doubt, contact them a few days after the visit. A caring call or e-mail will provide comfort and reinforce trust.

What If Parents Refuse to Vaccinate?

Excluding children from your practice when their parents decline immunizations is not recommended. It can put the child at risk of many different health problems—not just vaccine-preventable diseases. Remember, unvaccinated infants did not decide for themselves to remain unvaccinated. They need your care. Make sure that parents are fully informed about clinical presentations of vaccine-preventable diseases, including early symptoms. Diseases like pertussis and measles are highly contagious and may present early as a non-specific respiratory illness. Parents who refuse vaccines should be reminded at every visit to call before bringing the child into the office, clinic, or emergency department when the child is ill so appropriate measures can be taken to protect others. When scheduling an office visit for an ill child who has not received vaccines, take all possible precautions to prevent contact with other patients, especially those too young to be fully vaccinated and those who have weakened immune systems.

If a parent refuses to vaccinate, you can share the fact sheet *If You Choose Not to Vaccinate Your Child, Understand the Risks and Responsibilities (http://www.cdc.gov/vaccines/conversations)*, which explains the risks involved with this decision including risks to other members of their community, and the additional responsibilities for parents, including the fact that, when their child is ill, they should always alert health care personnel to their child's vaccination status to prevent the possible spread of vaccine-preventable diseases. You also can tell the parent that you would like to continue the dialogue about vaccines during the next visit, and then make sure to do so. You may wish to have them sign AAP's *Refusal to Vaccinate* form *(http://www.aap.org/immunization/pediatricians/pdf/refusaltovaccinate.pdf)* each time a vaccine is refused so that you have a record of their refusal in their child's medical file.

Remember, not all parents want the same level of medical or scientific information about vaccines. By assessing the level of information that a particular parent wants, you can communicate more effectively and build trust.

For the information resources mentioned in this sheet, and others, look for *Provider Resources for Vaccine Conversations with Parents* at ***http://ww.cdc.gov/vaccines/conversations*** or call **800-CDC-INFO** (800-232-4636). These resources are free to download and ready for color or black and white printing and reproduction.

If You Choose Not to Vaccinate Your Child, **Understand the Risks and Responsibilities.**

Last updated October 2009

If you choose to delay some vaccines or reject some vaccines entirely, there can be risks. Please follow these steps to protect your child, your family, and others.

With the decision to delay or reject vaccines comes an important responsibility that could save your child's life, or the life of someone else.

Any time that your child is ill and you:

- call 911;
- ride in an ambulance;
- visit a hospital emergency room; or
- visit your child's doctor or any clinic

you must tell the medical staff that your child has not received all the vaccines recommended for his or her age.

Keep a vaccination record easily accessible so that you can report exactly which vaccines your child has received, even when you are under stress.

Telling healthcare professionals your child's vaccination status is essential for two reasons:

- When your child is being evaluated, the doctor will need to consider the possibility that your child has a vaccine-preventable disease. Many of these diseases are now uncommon, but they still occur, and the doctor will need to consider that your child may have a vaccine-preventable disease.
- The people who help your child can take precautions, such as isolating your child, so that the disease does not spread to others. One group at high risk for contracting disease is infants who are too young to be fully vaccinated. For example, the measles vaccine is not usually recommended for babies younger than 12 months. Very young babies who get measles are likely to be seriously ill, often requiring hospitalization. Other people at high risk for contracting disease are those with weaker immune systems, such as some people with cancer and transplant recipients.

Before an outbreak of a vaccine-preventable disease occurs in your community:

- Talk to your child's doctor or nurse to be sure your child's medical record is up to date regarding vaccination status. Ask for a copy of the updated record.
- Inform your child's school, childcare facility, and other caregivers about your child's vaccination status.
- Be aware that your child can catch diseases from people who don't have any symptoms. For example, Hib meningitis can be spread from people who have the bacteria in their body but are not ill. You can't tell who is contagious.

CDC
AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA
American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

When there is vaccine-preventable disease in your community:

- It may not be too late to get protection by getting vaccinated. Ask your child's doctor.
- If there are cases (or, in some circumstances, a single case) of a vaccine-preventable disease in your community, you may be asked to take your child out of school, childcare, or organized activities (for example, playgroups or sports).
- Your school, childcare facility, or other institution will tell you when it is safe for an unvaccinated child to return. Be prepared to keep your child home for several days up to several weeks.
- Learn about the disease and how it is spread. It may not be possible to avoid exposure. For example, measles is so contagious that hours after an infected person has left the room, an unvaccinated person can get measles just by entering that room.
- Each disease is different, and the time between when your child might have been exposed to a disease and when he or she may get sick will vary. Talk with your child's doctor or the health department to get their guidelines for determining when your child is no longer at risk of coming down with the disease.

Be aware.

- Any vaccine-preventable disease can strike at any time in the U.S. because all of these diseases still circulate either in the U.S. or elsewhere in the world.
- Sometimes vaccine-preventable diseases cause outbreaks, that is, clusters of cases in a given area.
- Some of the vaccine-preventable diseases that still circulate in the U.S. include whooping cough, chickenpox, Hib (a cause of meningitis), and influenza. These diseases, as well as the other vaccine-preventable diseases, can range from mild to severe and life-threatening. In most cases, there is no way to know beforehand if a child will get a mild or serious case.
- For some diseases, one case is enough to cause concern in a community. An example is measles, which is one of the most contagious diseases known. This disease spreads quickly among people who are not immune.

If you know your child is exposed to a vaccine-preventable disease for which he or she has not been vaccinated:

- Learn the early signs and symptoms of the disease.
- Seek immediate medical help if your child or any family members develop early signs or symptoms of the disease.

  IMPORTANT: Notify the doctor's office, urgent care facility, ambulance personnel, or emergency room staff that your child has not been fully vaccinated before medical staff have contact with your child or your family members. They need to know that your child may have a vaccine-preventable disease so that they can treat your child correctly as quickly as possible. Medical staff also can take simple precautions to prevent diseases from spreading to others if they know ahead of time that their patient may have a contagious disease.

- Follow recommendations to isolate your child from others, including family members, and especially infants and people with weakened immune systems. Most vaccine-preventable diseases can be very dangerous to infants who are too young to be fully vaccinated, or children who are not vaccinated due to certain medical conditions.
- Be aware that for some vaccine-preventable diseases, there are medicines to treat infected people and medicines to keep people they come in contact with from getting the disease.
- Ask your healthcare provider about other ways to protect your family members and anyone else who may come into contact with your child.
- Your family may be contacted by the state or local health department who track infectious disease outbreaks in the community.

If you travel with your child:

- Review the CDC travelers' information website (www.cdc.gov/travel) before traveling to learn about possible disease risks and vaccines that will protect your family. Diseases that vaccines prevent remain common throughout the world, including Europe.
- Don't spread disease to others. If an unimmunized person develops a vaccine-preventable disease while traveling, to prevent transmission to others, he or she should not travel by a plane, train, or bus until a doctor determines the person is no longer contagious.

For more information on vaccines, ask your child's healthcare provider, visit **www.cdc.gov/vaccines/parents**, or call **800-CDC-INFO** (800-232-4636)

VISITING ANOTHER COUNTRY? PROTECT YOUR FAMILY.

THINK MEASLES.

Measles is widespread in places like Europe, Africa, Asia, India, and the Philippines.

BEFORE YOU TRAVEL

Tell your doctor where you are traveling. Babies and children may need measles protection at a younger age than usual.

AFTER YOU TRAVEL

Call your doctor if anyone gets a fever and rash within 3 weeks of returning from your trip. Describe where you traveled.

Talk with your doctor if you are planning an international trip.

For more information go to **www.cdc.gov/travel**.

Minors, Medical Care Consent (Chapter 652) Summary of the Law

What's in the New Law?

Beginning on January 1, 2012, a new California law (known as AB 499 or Chapter 652, Statutes of 2011) expands the legal authority of minors 12 years and older to consent to confidential medical services for the ***prevention*** of sexually transmitted diseases (STDs) without their parents' consent.

Little in the law is actually new. For the past 50 years, California Family Code Section 6926 has allowed minors 12 years and older to consent to *diagnosis and treatment* of STD services, such as the treatment of gonorrhea or syphilis. Because of advances in STD prevention, the law has been updated.

STD prevention strategies include, but aren't limited to:

- Hepatitis B vaccination
- Human papillomavirus (HPV) vaccination
- Medications to prevent HIV infection, before or after exposure
- Additional STD prevention services that may become available in the future

What's Not in the New Law?

The law does not

- Require minors to seek or receive HPV vaccination, hepatitis B vaccination, or any other preventive services
- Provide additional funding or resources for the vaccinations and other STD prevention services. Moreover, the law explicitly states that the parents or guardians of the minor are not liable for the costs of such services.

Confidentiality Concerns

In many cases, health care providers are not permitted to share information or records regarding a minor's STD prevention services with a parent or legal guardian without the minor's written authorization. Health care providers should be aware that

- There is no law that requires providers to record a vaccination in the California Immunization Registry (CAIR).
- Insurance companies may share claims information about STD prevention services with primary policy holders, such as parents.
- Immunization data about minors in CAIR and other record systems may be accessible to parents.

Help for Those in Need

CDPH encourages parents to talk with their preteens and teens about how to grow up healthy, including how to prevent STDs. Most parents are involved in their children's health care decisions. However, some teenagers live in unstable or abusive homes and cannot safely discuss health issues with their parents.

California's new law is designed to help protect the health of these teenagers, just as current laws allow youth to receive confidential care for reproductive health care, mental health care, and substance abuse treatment. In addition to protecting an adolescent from disease, this law will reduce the risk of spreading infections to others.

Recommendations on the Use of Quadrivalent Human Papillomavirus Vaccine in Males — Advisory Committee on Immunization Practices (ACIP), 2011

On October 25, 2011, the Advisory Committee on Immunization Practices (ACIP) recommended routine use of quadrivalent human papillomavirus (HPV) vaccine (HPV4; Gardasil, Merck & Co. Inc.) in males aged 11 or 12 years. ACIP also recommended vaccination with HPV4 for males aged 13 through 21 years who have not been vaccinated previously or who have not completed the 3-dose series; males aged 22 through 26 years may be vaccinated. These recommendations replace the October 2009 ACIP guidance that HPV4 may be given to males aged 9 through 26 years (*1*). For these recommendations, ACIP considered information on vaccine efficacy (including data available since October 2009, on prevention of grade 2 or 3 anal intraepithelial neoplasia [AIN2/3], a precursor of anal cancer), vaccine safety, estimates of disease and cancer resulting from HPV, cost-effectiveness, and programmatic considerations. The evidence for HPV4 vaccination of males was evaluated using Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methods (*2*).

Background of HPV Vaccination Program in the United States

HPV4 is directed against HPV types 6, 11, 16, and 18, and was licensed by the Food and Drug Administration (FDA) for use in females in June 2006. Bivalent HPV vaccine (HPV2; Cervarix, GlaxoSmithKline) is directed against HPV 16 and 18, and was licensed for use in females in October 2009. ACIP recommends either vaccine for routine use in females aged 11 or 12 years (*3*). In 2009, HPV4 was licensed for use in males for prevention of genital warts; in December 2010, FDA added prevention of anal cancer in males and females as an indication for use (*4*). Since 2006, HPV vaccine coverage in females has increased but remains low. In 2010, coverage with at least 1 dose among females aged 13 through 17 years was 48.7%, and 3-dose coverage was 32.0% (*5*). Coverage with at least 1 dose among males aged 13 through 17 years was <2%.

Burden of Disease and Cancer in Males

HPV-associated cancers in males include some anal, penile, and oropharyngeal cancers caused primarily by HPV 16 (*6–9*). An estimated 22,000 HPV 16- and 18-associated cancers occur annually in the United States, including an estimated 7,000 HPV 16- and 18-associated cancers in males (*9*). Data from U.S. cancer registries have shown increases in the incidence of oropharyngeal and anal cancers in men (*8,9*); an evaluation of data from 1973–2007 found increases of 1% per year for oropharyngeal cancers and 3% per year for anal cancers (*9*). Nononcogenic HPV types, primarily 6 and 11, cause >90% of genital warts (condylomata) and most cases of recurrent respiratory papillomatosis. Approximately 250,000 cases of genital warts occur each year in the United States among sexually active males (*10,11*).

Efficacy

In a phase III efficacy trial, HPV4 had high efficacy for prevention of genital warts among 4,055 males aged 16 through 26 years. Exclusion criteria included history of genital warts, history of genital lesions possibly HPV-related, and less than one or more than five lifetime sex partners. Among those who received all 3 vaccine doses and were seronegative at day 1 and DNA-negative day 1 through month 7 to the respective HPV type (per protocol population), efficacy for prevention of HPV 6-, 11-, 16-, and 18-related genital warts was 89.3% (95% confidence interval [CI] = 65.3%–97.9%); efficacy for HPV 6- and 11-related genital warts was similar. Efficacy for prevention of HPV 6-, 11-, 16- and 18-related genital warts among males who received at least 1 vaccine dose, regardless of baseline infection or serology (intent to treat population), was 68.1% (CI = 48.8%–80.7%) (*4*). No efficacy was observed among males who were infected with the respective HPV type at baseline. Although grade 1, 2, and 3 penile/perineal/perianal intraepithelial neoplasias were evaluated, too few were observed, and efficacy was not demonstrated (*4*).

A substudy of the phase III efficacy trial included 598 men who have sex with men (MSM), aged 16 through 26 years; outcomes were genital warts; AIN grades 1, 2, or 3 (AIN1/2/3); and AIN2/3. Per protocol efficacy for prevention of HPV 6-, 11-, 16-, and 18-related genital warts was 88.1% (CI = 13.9%–99.7%) (Carlos Sattler, MD, Merck, personal communication, August 2011). Per protocol efficacy for prevention of HPV 6-, 11-, 16-, 18- related AIN1/2/3 was 77.5% (CI = 39.6%–93.3%), and against AIN2/3 was 74.9% (CI = 8.8%–95.4%) (Table) (*4*). In the intent to treat population, efficacy for prevention of HPV 6-, 11-, 16-, and 18-related AIN1/2/3 was 50.3% (CI = 25.7%–67.2%), and prevention of HPV 6-, 11-, 16-, and 18-related AIN2/3 was 54.2% (CI = 18.0%–75.3%) (*4*). In the intent to treat population, efficacy for prevention of any HPV type-related AIN2/3 was 24.3% (CI = -13.8%–50.0%) (*4*). No studies have evaluated the efficacy of HPV4 for prevention of recurrent respiratory papillomatosis or oropharyngeal cancer.

The efficacy of HPV4 for prevention of HPV-related precancerous lesions and disease is supported further by studies

TABLE. Efficacy of quadrivalent HPV vaccine for prevention of HPV 6-, 11-, 16-, and 18-related genital warts, AIN1/2/3, or AIN 2/3, per protocol,* in males aged 16 through 26 years†

	Control		Vaccine		Vaccine efficacy	
Condition	No.	Cases	No.	Cases	%	(95% CI)
Genital warts	1,404	28	1,394	3	89.3	(65.3–97.9)
AIN1/2/3§	208	24	194	5	77.5	(39.6–93.3)
AIN2/3§	208	13	194	3	74.9	(8.8–95.4)

Abbreviations: HPV = human papillomavirus; AIN = anal intraepithelial neoplasia; CI = confidence interval.
Source: Food and Drug Administration. Highlights of prescribing information. Gardasil (human papillomavirus quadrivalent [types 6, 11, 16 and 18]). Available at http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm111263.pdf.
* Per protocol population included males who received all 3 vaccine doses, were seronegative at day 1 and DNA negative at day 1 through month 7 to the respective HPV type, with case counting beginning after month 7.
† Participants were enrolled from North America, South America, Europe, Australia, and Asia; median duration of follow-up was 2.3 years for the study in all males and 2.6 years for the study in men who have sex with men (MSM).
§ Efficacy for AIN studied in MSM.

among females. In three trials, HPV4 had high efficacy (>98%) for prevention of HPV 6-, 11-, 16-, and 18-related grade 2 or 3 cervical intraepithelial neoplasia (CIN2/3) or adenocarcinoma in situ (AIS), grade 2 or 3 vulvar intraepithelial neoplasia (VIN2/3), and grade 2 or 3 vaginal intraepithelial neoplasia (VaIN2/3) (*12*).

Immunogenicity

Data on immunogenicity in males are available from the phase III trial conducted among males aged 16 through 26 years and from bridging immunogenicity studies conducted among males aged 9 through 15 years (*4*). Seroconversion was high for all four HPV vaccine types and postvaccination antibody titers were significantly higher in males aged 9 through 15 years compared with males aged 16 through 26 years (*4*). Data from a follow-up study of 500 boys who were in an immunogenicity study showed no cases of persistent infection or disease related to any of the four HPV vaccine types during 6 years of follow-up (*13*). The high efficacy found in the clinical trials in females and males to date has not allowed identification of a minimum protective antibody titer.

Safety

Clinical trial data in approximately 5,300 males found that the most common adverse events were mild or moderate, and were most commonly injection-site reactions (*4*). Headache and fever were the most commonly reported systemic adverse events in vaccine recipients and controls (*4*). Since licensure, at least 40 million doses of HPV4 have been distributed in the United States through September 2011. National postlicensure safety data indicate that HPV4 adverse events were similar to those from prelicensure trials (*14*). Postlicensure safety data from the Vaccine Safety Datalink study, including data from >600,000 HPV4 doses administered, showed no statistically significant increased risk for the outcomes studied, including Guillain-Barré syndrome, stroke, venous thromboembolism, appendicitis, seizures, syncope, allergic reactions, and anaphylaxis (*15*). Postlicensure safety data from a manufacturer-sponsored study found no increased risk for outcomes such as anaphylaxis and venous thromboembolism; however, persons who were vaccinated with HPV4 were more likely to faint on the day they were vaccinated than another period in which vaccine was not administered (*16*). ACIP recommends that vaccination providers should consider observing patients for 15 minutes after all vaccinations, including HPV vaccination.

Cost-Effectiveness

The cost-effectiveness* of male vaccination is sensitive to a range of assumptions, such as vaccine efficacy, vaccine coverage of females, the range of health outcomes included, and the effect of HPV-associated diseases on quality of life (*17–20*). Adding male vaccination to female-only vaccination becomes more cost-effective when all HPV-associated health outcomes are included in the model and vaccine coverage of females is low (e.g., 3-dose vaccine coverage <50% by age 12 years). Adding male vaccination to female-only vaccination becomes less cost-effective when considering scenarios such as only the health outcomes for which evidence of vaccine efficacy is available, when vaccine coverage of females is high (such as 3-dose vaccine coverage >70% by age 12 years), if vaccinated males have mostly vaccinated sex partners, and when male vaccination is compared with a strategy of increased vaccine coverage of females (*20*). At the current vaccine price, adding male vaccination at age 12 years to a female-only vaccination

* By charter, when considering recommendations for use of a vaccine, ACIP members' deliberations should include consideration of vaccine efficacy, as well as cost-benefit and risk-benefit analyses. No predefined threshold for cost-effectiveness is considered. To ensure that economic data presented to ACIP and its working groups are uniform in presentation, understandable, and of the highest quality, lead economists and the Health Economics Research Group at CDC developed *Guidance for Health Economics Studies Presented to the ACIP*, available at http://www.cdc.gov/vaccines/recs/acip/economic-studies.htm. The guidance specifically mandates technical review of any economic study that is presented to ACIP.

strategy would cost approximately $20,000–$40,000 per quality-adjusted life year (QALY) in the more favorable scenarios and approximately $75,000 to >$250,000 per QALY in less favorable scenarios (*18–20*). Vaccination of adult males becomes less cost-effective as age at vaccination increases, and models suggest the cost per QALY gained by vaccinating males >21 years would be approximately 2–4 times that of vaccinating males aged <18 years (*21*).

Special Populations

MSM are at higher risk for conditions associated with HPV types 6, 11, 16, and 18 than are heterosexual men; diseases and cancers that have a higher incidence among MSM include AIN, anal cancers, and genital warts (*22,23*). HPV4 clinical trial data demonstrated high efficacy for prevention of genital warts, AIN1/2/3, and AIN2/3 (*4*). HPV4 is not licensed for males aged >26 years, and no information is available on the efficacy for prevention of outcomes in MSM aged >26 years. A cost-effectiveness analysis estimated <$50,000 per QALY for vaccination of MSM through age 26 years, using various assumptions (*24*).

Persons infected with the human immunodeficiency virus (HIV) also have a high burden of HPV-associated outcomes. Genital warts are more common and more difficult to treat in HIV-infected persons (*25*). AIN and anal cancer are common in HIV-infected MSM, and data suggest that effective antiretroviral therapy has not reduced the burden of anal cancer (*26*). One small trial in HIV-infected boys and girls found HPV4 to be safe and immunogenic (*27*), as did a study in HIV-infected men (*28*). Antibody titers to vaccine types 6 and 18 were lower in HIV-infected children than those observed in age-matched HIV-uninfected children; the clinical significance of this is not known (*27*). Ongoing studies will evaluate the efficacy and duration of immune response in HIV-infected persons.

GRADE

Data on HPV4 for males were reviewed according to GRADE methods (*2*). Factors considered in determining the recommendation included benefits and harms, evidence type, values and preferences, and health economic analysis.[†]

Rationale

Although the largest number of HPV-associated cancers occur in women (approximately 15,000 HPV 16- and 18-associated cancers each year), an estimated 7,000 HPV 16- and 18-associated cancers occur each year in men in the United States. These include anal, oropharyngeal, and penile cancers. HPV4 has high efficacy for prevention of genital warts, AIN1/2/3, and AIN2/3 in males. HPV4 also has high efficacy for prevention of genital warts, CIN1/2/3 or AIS, CIN2/3, VIN2/3, and VaIN2/3 in females. Although data show HPV4 prevents various outcomes, no data are available on the efficacy for prevention of oropharyngeal or penile cancers. Vaccination of males would provide direct benefits and likely would reduce HPV 6, 11, 16, and 18 transmission, and resulting infection, disease, and cancers in females (through herd immunity). However, no clinical efficacy data demonstrating that HPV4 prevents HPV transmission are available.

Because HPV4 is prophylactic, it would be most effective when given before exposure to HPV through sexual contact. The recommendation for vaccination at ages 11 or 12 years is supported by data from the efficacy trial, demonstrating highest efficacy in males who had no evidence of previous or current HPV vaccine type infection, data on sexual behavior in the United States, and immunogenicity studies showing higher antibody titers after vaccination of males at ages 9 through 15 years compared with those aged 16 through 26 years. Other vaccines are recommended at age 11 or 12 years, including HPV vaccine for females. The population level benefits decrease with increasing age at vaccination, especially after age 21 years.

Recommendations

ACIP recommends routine vaccination of males aged 11 or 12 years with HPV4 administered as a 3-dose series (recommendation category: A, evidence type: 2[§]). The vaccination series can be started beginning at age 9 years. Vaccination with HPV4 is recommended for males aged 13 through 21 years who have not been vaccinated previously or who have not completed the 3-dose series. Males aged 22 through 26 years may be vaccinated. Recommendations for administration and precautions are unchanged from previous recommendations (*1*).

Recommendations for Special Populations

HPV4 is not a live vaccine and can be administered to persons who are immunocompromised as a result of infection (including HIV), disease, or medications. The immune response and vaccine efficacy might be less than that in immunocompetent persons. For immunocompromised males, ACIP recommends routine vaccination with HPV4 as for all males, and vaccination through age 26 years for those who have not been vaccinated previously or who have not completed the 3-dose series.

[†] Additional information is available at http://www.cdc.gov/vaccines/recs/acip/grade/table-refs.htm.

[§] Recommendation category A: recommendation that applies to all persons in an age or risk-based group. Evidence type 2: randomized controlled trials with important limitations or exceptionally strong evidence from observational studies.

MSM are at higher risk for infection with HPV types 6, 11, 16, and 18 and associated conditions, including genital warts and anal cancer. For MSM, ACIP recommends routine vaccination with HPV4 as for all males, and vaccination through age 26 years for those who have not been vaccinated previously or who have not completed the 3-dose series.

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