Pediatric Immunization Update
Carole Moloney, APRN
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SESSION OBJECTIVES

• Summarize the current ACIP recommendations of immunizations of children and adolescents.
• Discuss recent changes in recommendations and rationale.
• Summarize the proper use of the combination vaccines- Which ones at what age.
• Discuss the special groups of patients requiring additional vaccines/variation in vaccine schedules such as high risk infants, previously under immunized children and children traveling abroad.
Pediatric and Adolescent Immunization Update

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### Children age 0 months through 18 years

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Minimum Age for Dose 1</th>
<th>Dose 1 to Dose 2</th>
<th>Minimum Interval Between Doses</th>
<th>Dose 2 to Dose 3</th>
<th>Dose 3 to Dose 4</th>
<th>Dose 4 to Dose 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B§</td>
<td>Birth</td>
<td>6 weeks</td>
<td>8 weeks</td>
<td>8 weeks</td>
<td>6 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Hepatitis A§</td>
<td>Birth</td>
<td>6 weeks</td>
<td>4 weeks</td>
<td>6 months</td>
<td>6 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Inactivated poliovirus§</td>
<td>Birth</td>
<td>6 weeks</td>
<td>4 weeks</td>
<td>4 weeks</td>
<td>4 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Meningooccal†</td>
<td>Birth</td>
<td>6 weeks</td>
<td>4 weeks</td>
<td>6 months</td>
<td>6 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Measles, mumps, rubella§</td>
<td>12 months</td>
<td>6 weeks</td>
<td>6 weeks</td>
<td>6 months</td>
<td>6 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Pertussis§</td>
<td>Birth</td>
<td>6 weeks</td>
<td>6 weeks</td>
<td>6 months</td>
<td>6 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Pneumococcal</td>
<td>6 weeks</td>
<td>6 weeks</td>
<td>6 weeks (as final dose for healthy children)</td>
<td>6 months</td>
<td>6 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Varicella§</td>
<td>12 months</td>
<td>6 weeks</td>
<td>6 weeks</td>
<td>6 months</td>
<td>6 months</td>
<td>6 months</td>
</tr>
</tbody>
</table>

**Children and adolescents age 7 through 18 years**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Minimum Age for Dose 1</th>
<th>Dose 1 to Dose 2</th>
<th>Minimum Interval Between Doses</th>
<th>Dose 2 to Dose 3</th>
<th>Dose 3 to Dose 4</th>
<th>Dose 4 to Dose 5</th>
</tr>
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<tbody>
<tr>
<td>Diphtheria, tetanus, and acellular pertussis</td>
<td>7 years</td>
<td>6 weeks</td>
<td>6 weeks</td>
<td>6 months</td>
<td>6 months</td>
<td>6 months</td>
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<tr>
<td>Human papillomavirus‡</td>
<td>9 years</td>
<td>Routine dosing intervals are recommended</td>
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<td></td>
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<tr>
<td>Hepatitis B§</td>
<td>N/A</td>
<td>6 weeks</td>
<td>8 weeks and at least 16 weeks after first dose.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Inactivated poliovirus§</td>
<td>N/A</td>
<td>6 weeks</td>
<td>4 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meningooccal†</td>
<td>N/A</td>
<td>6 weeks</td>
<td>4 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measles, mumps, rubella§</td>
<td>N/A</td>
<td>6 weeks</td>
<td>4 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varicella§</td>
<td>N/A</td>
<td>6 weeks</td>
<td>4 weeks</td>
<td></td>
<td></td>
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</tbody>
</table>

**NOTE:** The above recommendations must be read along with the footnotes of this schedule.
Combination Vaccines

Can reduce the number of injections: Reduce anxiety and procedural pain
Can improve the coverage rates
Can improve the timeliness of vaccination
Can improve parent, patient and provider satisfaction
Improved vaccine compliance

Potential to reduce costs and improve office efficiency

1 Marshall, G.S. et al Use of Combination Vaccines is Associated with Improved Coverage Rates. The Pediatric Infectious Journal Vol 26 No 6 June 2007 496-500


Combination Vaccines: So Many Choices

- DTaP-IPV-HepB (Pediarix, GlaxoSmithKline)
- DTaP-IPV/Hib (Pentacel, Sanofi Pasteur)
- DTaP-IPV (Kinrix, GlaxoSmithKline)
- Hep A-HepB (Twinrix, GlaxoSmithKline)
- Hib-HepB (Comvax, Merck)
- MMRV (ProQuad, Merck)
- Hib-MenCY (MenHibrix, GlaxoSmithKline)
DTaP-IPV-HepB: Pediarix, GSK

- Primary series is 3 doses (0.5ml) given IM at 2, 4, and 6 months of age.
- It is licensed for only the first 3 doses of the DTaP series.
- Do not give to infants younger than 6 weeks of age.
- Do not give to children 7 years or older.
- May be used for those infants and children who have fallen behind.
- Must observe spacing intervals such that the minimum interval between doses is equal to the greatest interval of any of the individual antigens.
DTaP-IPV/Hib: Pentacel, Sanofi Pasteur

- 4-dose series in infants and children at ages 2, 4, 6 and 15-18 months.
- Should not be used for any dose in the primary series for children age 5 years and older.
- Should not be used for the booster dose for children ages 4-6 years.
- The DTaP-IPV component is supplied as a sterile liquid which is used to reconstitute the freeze-dried ActHib vaccine.
- Store them together in the carton to reduce the chance of giving one component of the vaccine without the other.
- Yes, you still need to give the IPV booster dose at 4-6 years, even though by using Pentacel they will have already had 4 IPV doses.
DTaP-IPV: Kinrix, GSK

- It is approved for use as the fifth dose of DTaP and the fourth dose of IPV in children 4-6 years of age who received DTaP (Infanrix) and/or DTaP-HepB-IPV (Pediarix) as the first three doses and DTaP as the fourth dose.

- Not for use for children younger than 4 years of age.
HepA-HepB: Twinrix, GSK

- Inactivated combination containing both Hep A virus (HAV) and HBV antigens.
- Vaccine contains 720 EL.U of hepatitis A antigen (half the Havrix adult dose).
- Vaccine contains 20ug of hepatitis B antigen (the full Engerix-B adult dose).
- 3 dose series given IM on a 0,1 and 6 month schedule for those 18 years and older.
- Minimum intervals are 4 weeks between dose 1 and 2 and 5 months between dose 2 and 3.
- Accelerated schedule (eg. Imminent foreign travel): give as a 4 dose schedule at intervals of 0,7 and 21-30 days followed by a fourth dose at 12 months.
Hib-HepB: Comvax, Merck

- March 2014 Merck announced its intention to discontinue the production of Comvax.
- Comvax will not be available for purchase directly from Merck after 12/31/14.
- Wholesalers and distributors may have limited inventory after that date.
MMRV: ProQuad, Merck

- Combination of the MMR and Varicella vaccines.
- For use in children 12 months -12 years of age.
- In 2010, the CDC issued new recommendations for the use of this vaccine.

ACIP reviewed results of post-licensure studies that suggest that, during the 5-12 day post vaccination period, approximately one additional febrile seizure occurred among every 2,600 children ages 12- through 23 months vaccinated with a first dose of MMRV vaccine compared with children in the same age group vaccinated with separate first doses of MMR and varicella vaccine administered during a single office visit.
The recommended ages for the MMR and varicella vaccines remain the same: 12-15 months for the initial dose and 4 through 6 years for the second dose.

Providers who are considering administering the MMRV for the first dose should discuss the benefits and risks of both vaccination options with parents/caregivers.

CDC recommends that providers administer the MMR and varicella vaccines as separate vaccines for the first dose in this age group, 12-47 months.

For the second dose of MMR and varicella vaccines at any age 15months -12 years and for the first dose at age 48 months the use of the MMRV vaccine is generally preferred.

A personal or family (ie sibling or parent) history of seizures of any etiology is a precaution for the use of the MMRV vaccination and these children should receive separate vaccines.
Hib-MenCY: MenHibrix, GSK

- Immunization to prevent invasive disease caused by Neisseria meningitidis serogroups C and Y and Haemophilus influenzae type b.
- It does NOT protect against meningococcal serogroups A, B or W.
- In October 2012, ACIP voted to recommend that infants at risk for meningococcal disease be vaccinated with 4 doses of Hib-MenCY at age 2, 4, 6 and 12 -15 months.
- Includes infants with recognized persistent complement pathway deficiencies, and infants with anatomic or functional asplenia, including sickle cell disease.
- It is not for use in infants who will live or travel abroad as it does not contain meningococcal serogroups A or W which are common outside the US.
The Infant’s Immune System: What we know

- The immune system has the capacity to respond to extremely large number of antigens
- Although children now receive more vaccines than in the past, the young infant is fully capable of generating humoral and cellular immune responses to multiple vaccines simultaneously
- Actual number of antigens they receive has declined over time
- Vaccines do not weaken the immune system, they do not put the vaccinated child at greater risk for subsequent infections.

Offit, P. et al, Pediatrics Vol 109 No 1, January 2202 124-129
The Ability of Neonates and Young Infants to respond to Vaccines

Many parents are concerned about:

- The number of vaccines that infants receive.
- If their immune system is inadequate to handle them.
- If multiple vaccines would overwhelm their immune system.

Premature Infants and Immunizations

- Most premature infants, including those with low birth weights, can be immunized at the usual chronological age. In other words, a child born two months early should still receive his or her first immunizations at 2 months of age (not at 4 months of age).

- An exception to this rule is the hepatitis B vaccine. Premature infants (children born within 36 weeks of conception with a birth weight of less than 4.4 pounds) whose mothers are not infected with hepatitis B virus should receive the hepatitis B vaccine at 1 month of age or at hospital discharge, whichever comes first. However, premature infants whose mothers are infected with hepatitis B virus should receive the vaccine at birth, independent of birth weight.

- If an infant is at least 6 weeks old and has been hospitalized since birth, the first dose of rotavirus vaccine should be delayed until the infant is discharged from the hospital unless discharge occurs after 15 weeks of age. Due to a lack of safety data, the rotavirus vaccine cannot be started after an infant is more than 15 weeks old.
“Dr. Bob’s Selective or Alternative Vaccine Schedule”

In October 2007, Dr. Robert Sears published: “The Vaccine Book: Making the Right Decision for Your Child”, which includes his alternative schedule, an outline of how parents can delay, withhold, separate, or space out vaccines.

Bottom Line: If parents follow these schedules then fewer children will be protected against vaccine-preventable diseases, thereby increasing the likelihood of outbreaks, and increased harm to those children he thinks he is protecting.

Measles in the News

- California Outbreak at 2 Disney Theme Parks began in December 2014.
- Affected more than 130 people.
- 131 people were infected with the B3 strain, 5 had a different genotype.
- Of those 131 cases, 81 (70%) were unvaccinated.
- CDC has stated that 19 different strains have been discovered since 1990.
- California allows exemptions from vaccinations for medical reasons and “personal beliefs”
- During 2013-2014 school year there were 1,000 medical exemptions and more than 17,000 philosophical exemptions
Proposed Legislation in California

- State Sens. Dr. Richard Pan and Ben Allen have proposed eliminating the personal belief exemption altogether in California.

- If their law passes, all of those children would be required to get fully vaccinated in order to go to school. Pan says the most parents in the state would support that.

- "While a small number of children cannot be vaccinated due to an underlying medical condition, we believe there should be no such thing as a philosophical or personal belief exemption, since everyone uses public spaces," Senators Boxer and Feinstein wrote. "As we have learned in the past month, parents who refuse to vaccinate their children not only put their own family at risk, but they also endanger other families who choose to vaccinate."
April 13, 2015: Australia plans on cutting welfare benefits for parents who refuse to vaccinate

This policy will come into effect in January 2016.

The Australian government estimates more than 39,000 children have not been vaccinated under the age of 7 because of their parents objections.

Parents can lose up to $11,000 of welfare benefits per year.

Currently parents can choose to opt out of vaccinations for medical or religious reasons or by stating they are “conscientious objectors”, and still receive benefits.

Under the new policy, the exemption as a conscientious objector will be removed starting January 2016.
In joint statement, the Prime Minister and the Social Services Minister stated:

““The choice made by families not to immunize their children is not supported by public policy or medical research nor should such action be supported by taxpayers in the form of child care payments”

Existing medical exemptions will continue.

Guidelines on religious exemptions will be tightened.

A petition in opposition to the reforms has garnered 7,000 signatures to date.
Elmo, Vaccines and a new PSA

- April 19, 2015: In a new video by the Daily Dot, the U.S. Surgeon General, Dr. Vivek Murthy teaches the infamous Elmo of Sesame Street about the importance of getting vaccinations.
- After explaining the health benefits of being vaccinated, Murthy suggests that Elmo sing a song to take his mind of any discomfort he might experience.
- Cue: “Shake It Off” by Taylor Swift!! Enter: Nurse Jane.
- After the successful administration of the vaccine, Elmo comments on how easy that was and asks; “why doesn’t everyone get vaccinated?”
- Dr. Murthy replies: That’s a good question Elmo, that’s a good question”
Recent Meningococcal Serogroup B Cases
Meningococcal Outbreak in Oregon

- In early January 2015, a U of O undergraduate student who lived off campus developed fever, hemorrhagic conjunctivitis, and a non-blanching rash, but no symptoms of meningitis. Blood cultures yielded Neisseria meningitidis, serogroup B.

- 6 University of Oregon students have contracted type B meningococcal disease since mid-January 2015.

- CDC recommends that broader community vaccination be considered when there have been ≥3 cases of infection by a single meningococcal serogroup within a 3-month period, without direct epidemiological links between the cases, and yielding an attack rate of >10 cases per 100,000 in the community at risk. The lack of direct links between cases implies that the infection has escaped the ring of antimicrobial prophylaxis and signals risk to the broader group: the cat has gotten out of the bag.

- One case resulted in the death of a student from Meningococcemia on February 17

- Vaccination efforts continue, and as of 18 March, 9,193 students had been immunized — 42% of the 22,000 target group.
Public Health Benefits of Targeting Adolescents and Young Adults for Vaccination

Approximately 1 in 4 adolescents may be an asymptomatic carrier of *N. meningitidis* and represent the greatest potential as a target to promote herd immunity.

Serogroup B Meningococcal Vaccines

- On October 29, 2014 the FDA licensed the first serogroup B meningococcal vaccine: Trumenba. (Pfizer), 3-dose series (0, 2, 6 months)

- FDA approved this vaccine for use in people 10-25 years of age as a 3-dose series. Bexesero. (Novartis), 2-dose series (0, 1–6 months)

- On January 23, 2015 FDA licensed a second serogroup B meningococcal vaccine: Bexsero. FDA approved this vaccine for use in people 10-25 years of age as a 2-dose series.

- There is no routine recommendation for these vaccines at this time, providers can use these vaccines for 10-25 year olds consistent with the labeled indication.

- Based on the CDC interim guidance these vaccines can be an important tool for controlling outbreaks of serogroup B meningococcal disease.
Policy Options for use of MenB Vaccines

- Persons at increased risk including:
  - persons with persistent complement component deficiencies.
  - Persons with anatomic or functional asplenia.
  - Microbiologists who are routinely exposed to isolates of Neisseria meningitidis
  - Person identified to be at increased risk because of a serogroup B meningococcal disease outbreak.

- Broader use of MenB vaccines in adolescent and college students.
Policy Options: Age-Groups to be Included for Persons at Increased Risk

- **Persons aged 10–25 years only**
  - Licensed age indication

- **Persons aged ≥2 months**
  - Bexsero® licensed for persons aged ≥2 months in other countries
  - Data not currently available for Trumenba® for children <10 years
  - Potential for expanded age indication in US in the future
    - Work Group will review data for persons aged 2 months–10 years and may propose expanded policy options for persons at increased risk in the future

- **Persons aged ≥10 years**
  - Goes beyond licensed indication but no theoretical differences in safety for those >25 years as compared to those 10–25 years
Vote

- A serogroup B meningococcal (MenB) vaccine series should be administered to persons aged ≥10 years at increased risk for meningococcal disease. (Category A) This includes:
  - Persons with persistent complement component deficiencies\(^1\)
  - Persons with anatomic or functional asplenia\(^2\)
  - Microbiologists routinely exposed to isolates of *Neisseria meningitidis*
  - Persons identified to be at increased risk because of a serogroup B meningococcal disease outbreak

\(^1\)Including inherited or chronic deficiencies in C3, C5-9, properdin, factor D, factor H, or taking eculizumab (Soliris®)
\(^2\)Including sickle cell disease
HPV Vaccine: What is currently recommended?

- The Advisory Committee on Immunization Practices (ACIP) recommends routine HPV vaccination at age 11 or 12 years.
- The vaccination series can be started beginning at age 9 years.
- Vaccination is also recommended for females aged 13 through 26 years and 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.
- ACIP recommends vaccination of men who have sex with men and immunocompromised persons through age 26 years if not vaccinated previously.
New HPV 9 Vaccine

- On December 10, 2014, the FDA approved Gardasil 9 (Merck).
- This vaccine has the potential to prevent approximately 90% of cervical, vulvar, vaginal and anal cancers.
- Seven HPV types in GARDASIL 9 (HPV 16, 18, 31, 33, 45, 52 and 58) cause approximately 90 percent of cervical cancer cases and approximately 80 percent of high-grade cervical lesions (cervical precancers, defined as CIN 2, CIN 3 and AIS) worldwide. These seven HPV types also cause 85-90 percent of HPV-related vulvar cancers, 80-85 percent of HPV-related vaginal cancers, and 90-95 percent of HPV-related anal cancers.
- HPV types 6 and 11 cause approximately 90 percent of genital warts cases.
- In addition, approximately 50 percent of cases of low-grade cervical lesions (CIN 1) are caused by the nine HPV types included in the vaccine.
What are the new recommendations?

- 9vHPV, 4vHPV or 2vHPV can be used for routine vaccination of females aged 11 or 12 years and females through age 26 years who have not been vaccinated previously or who have not completed the 3-dose series.

- 9vHPV or 4vHPV can be used for routine vaccination of males aged 11 or 12 years and males through age 21 years who have not been vaccinated previously or who have not completed the 3-dose series.

- ACIP recommends either 9vHPV or 4vHPV vaccination for men who have sex with men and immunocompromised persons (including those with HIV infection) through age 26 years if not vaccinated previously.
Why are the recommendations being updated now?

- 9-valent HPV vaccine (9vHPV) was approved by the Food and Drug Administration on December 10, 2014. This vaccine targets HPV types 6, 11, 16, and 18, the types targeted by the quadrivalent HPV vaccine (4vHPV), as well as five additional types, HPV types 31, 33, 45, 52, and 58.

- ACIP reviewed results of a randomized trial among approximately 14,000 females aged 16 through 26 years that showed noninferior immunogenicity for the types shared by 4vHPV and 9vHPV and high efficacy for the five additional types.

- Other trials in the 9vHPV clinical development program included studies that compared antibody responses across age groups and females and males and concomitant vaccination studies.

- The recommendation was designated as a Category A recommendation (recommendation for all persons in an age- or risk-factor–based group).
Current HPV vaccine coverage rates in the United States

- The Advisory Committee on Immunization Practices recommends human papillomavirus (HPV) vaccination for girls and boys at ages 11 or 12 years. The 2012 National Immunization Survey-Teen indicated only 53.8% of girls and 20.8% of boys aged 13–17 years had received ≥1 dose of HPV vaccine.

- Vaccination coverage significantly increased in 2013; 57.3% of girls and 34.6% of boys received ≥1 dose of HPV vaccine. The percentage of parents reporting that they received a clinician recommendation for the HPV vaccine was significantly higher in 2013 compared with 2012 for both parents of girls (64.4% versus 61.0%) and parents of boys (41.6% versus 28.0%).

- Despite the availability of safe and effective HPV vaccines, many adolescents have not been vaccinated. Vaccination coverage of adolescent girls by age 13 years increased across seven birth cohorts but missed vaccination opportunities persist.

- Improving practice patterns so that clinicians and their staff members use every opportunity to recommend HPV vaccines for boys and girls and address questions from parents is necessary to reduce vaccine-preventable HPV infections and cancers caused by HPV.
Barriers to Compliance with Immunization Recommendations

- Number of Immunizations/Shots
- Healthcare Providers
- Public Policy
- Parental Concerns and Objections
- Financial/Insurance/Reimbursement
- Knowledge
- Pain and Anxiety
Barriers to Compliance: Healthcare Providers

- The ever-changing recommended immunization schedule
- Missed opportunities to vaccinate
- Cost/Reimbursement
- Provider education and recommendation
Barriers to Compliance: Public Policy

- As of March 2006, all states permitted medical exemptions to school and daycare immunization requirements.
- 48 states allowed religious exemptions.
- 19 states had a provision for personal belief exemptions (religious, philosophical and any other unspecified nonmedical exemption).
- Exemptors are at increased risk of acquiring and transmitting disease, especially pertussis.

Omer et al. JAMA, October 11, 2006-Vol 296, No 14
Barriers to Compliance: Parents’ Concerns and Objections

- Parents may lack knowledge about immunizations, and be confused about changing schedules
- They underestimate the risk of vaccine–preventable diseases
- Overestimate the risk of vaccine side effects
- Have doubts and concerns about vaccine safety
- Are concerned about the number, timing and antigen load in vaccines and the possibility of overwhelming the immune system
- Influenced by negative publicity and anti-vaccine movements
Overcoming Barriers to Optimal Immunization: Partnering with Parents

“Vaccines are one of medicine’s greatest achievements. Without vaccines, millions of children and adults would contract serious diseases that are now preventable by vaccines, and many would have long-lasting effects or even die. Vaccinations are one of the most important public health measures for preventing diseases.” (1)

Clinicians are key to addressing parental misconceptions and knowledge gaps that may hinder immunization efforts.

Partnering with parents, clinicians can often overcome these barriers, thereby improving immunization rates.
Improving Immunization Rates

Provider Based Strategies

When providers recommend vaccinations, parents overwhelming comply.¹

Minimize Missed Opportunities

Utilize Information Systems

Patient Based Strategies

Education of parents and patients

Minimize pain and anxiety

Address myths and realities

An estimated 1.9 million American children travel internationally each year and that number is growing.

You have to be familiar with the risks of travel to help them stay safe and healthy. Issues include:

- Diarrhea.
- Malaria and other diseases spread by bugs.
- Rabies
- Accidents
- Routine and Travel Vaccines
World Travel: Watch Level One
December 3, 2014-April 24, 2015

- Measles: Germany, Ethiopia, Vietnam, Philippines, Angola, Kyrgyzstan, Bosnia & Herzegovina
- Chikungunya: Pacific Islands, Mexico, Caribbean, Central America, South America
- Cholera: Haiti, Mexico, Dominican Republic, Cuba, Ghana
- Typhoid: Uganda
- Hand, Foot and Moth Disease (HFMD): Singapore
- H5N1 Bird Flu: Egypt
- Avian Flu H7N9: China
- Malaria: Brazil
- Dengue: Malaysia, Brazil
- Ross River Virus: Australia
Travel Information

Find other travel health information on the CDC Travelers' Health website (http://wwwnc.cdc.gov/travel/), including:

- Destination pages (http://wwwnc.cdc.gov/travel/destinations/list)
- Traveler Information Center (http://wwwnc.cdc.gov/travel/page/traveler-information-center)
- Clinician Information Center (http://wwwnc.cdc.gov/travel/page/clinician-information-center)
- Travel Notices
References


References

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- Lauri E. Markowitz MD, NCHHSTO, CDC 2/26/15 HPV Data