Avoiding Missed Opportunities – Separating Real from Perceived Contraindications to Vaccination

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Why is it important to understand true vaccine contraindications?

- Contraindications are conditions under which vaccines should not be administered.
- A precaution is a condition in a recipient that might increase the risk for a serious adverse reaction, might cause diagnostic confusion, or might compromise the ability of the vaccine to produce immunity. Many are temporary.
- Misperceptions that certain conditions are valid contraindications or precautions result in missed opportunities for vaccination.





 Michael is here for his 6 month visit. Mom reports he has congestion, cough and loose stools for the past 2 days. PE c/w URI.

Q: Do you give Michael vaccines today?





Vignette #1- poll

Q: Do you vaccinate Michael at the current visit? Yes

No





- Mom is a bit sleep-deprived, and now remembers that in addition to his other symptoms Michael has had fever of 99-101.5.
- Q: Do you vaccinate Michael at the current visit?





Q: Do you vaccinate Michael at current visit? Yes

No





 Dad now reminds Mom that he had taken Michael to urgent care several days ago, and he was diagnosed with OM. He is currently on a course of amoxicillin.





Q: Do you vaccinate Michael at current visit? Yes

No



- The presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines.
- This precaution avoids causing diagnostic confusion between manifestations of the underlying illness and possible adverse effects of vaccination or superimposing adverse effects of the vaccine on the underlying illness.
- The safety and efficacy of vaccinating persons who have mild illnesses have been documented. Studies indicate that failure to vaccinate children with minor illnesses can impede vaccination efforts
- Hospitalization should be used as an opportunity to provide recommended vaccinations





Preventing Influenza in the Pediatric Patient at Hospital Discharge: Give it a Shot!

Rebecca Barros, M.D.

April 4, 2017





- Describe the importance of vaccinating high-risk, hospitalized pediatric patients with the influenza vaccine
- Implement strategies to vaccinate high-risk pediatric patients with the influenza vaccine at hospital discharge
- Discuss next-steps in targeting hospitalized pediatric patients for the influenza vaccine





A 12-month-old male presents to the emergency room with nasal congestion, cough, fever to 104 degrees Fahrenheit and increased work of breathing. His mother states that he was hospitalized approximately 6 weeks ago for RSV bronchiolitis. Antigen testing reveals that the patient has influenza A. He is admitted for 3 days due to an oxygen requirement.

Review of his records indicates that he did not receive the influenza vaccine this year, despite multiple opportunities, including the recent hospitalization.





Children's Hospital Orange County: Influenza Vaccines Administered By Year at Hospital Discharge





- Offering Influenza and Tdap vaccination to parents of hospitalized children
- Visual reminders on computers used for order entry on the oncology floor
- Interface of the California Immunization Registry (CAIR) System with our electronic medical record
- Provider education



High-Risk Hospitalized Population

- Approximately 1,500 Heme/Onc patients hospitalized annually
- In 2016- 154 or 10% of Heme/Onc patients immunized with influenza vaccine at hospital discharge





 Jenny is 12 months old and is here for vaccines including MMR and Varicella. Mom notes that her 4 yo brother has been dx'd with ALL and receiving induction chemoRx. The oncologist had mentioned he needs to stay away from live virus vaccines.

Q: True or false - Jenny should not be vaccinated with live virus vaccines while her sib is immune suppressed.





Vignette #2 - poll

Q: True or false - Jenny should not be vaccinated with live virus vaccines while her sib is immune suppressed.

True

False





- Household contacts and other close contacts of persons with altered immunocompetence should receive all ageand exposure-appropriate vaccines.
- MMR vaccine viruses are not transmitted to contacts, and transmission of varicella-zoster virus vaccine strain is rare.





 Sam, 24 months, is due for his Hep A vaccine. During his last visit, he received a DTaP, and had 6 cm of redness/swelling/ pain at the vaccination site with low grade fever for 24h.

Q: Is it safe to give his Hep A vaccine today?





Vignette #3 - poll

Q: Is it safe to give his Hep A vaccine today? Yes

No





 ACIP recommends that a history of extensive swelling after the fourth dose of DTaP should not be considered a contraindication to receipt of a fifth dose at school entry. Parents should be informed of the increase in reactogenicity that has been reported following the fourth and fifth doses of DTaP.





 Maddy, 15 months, appears to have developed multiple environmental and antibiotic allergies. There is a strong family history of atopy as well. Her mother is concerned about an allergic reaction to vaccines.

Q: Is it safe for Maddy to receive her vaccines today?





Vignette #4 - poll

Q: Is it safe for Maddy to receive her vaccines today?YesNo





 Mom now tells you that Maddy has had hives when she eats eggs. She askes if it is ok for her to receive MMR today.





Vignette #4-poll

Q: Is it safe for Maddy to receive her MMR today? Yes

No





 Mom has heard that flu vaccine contains eggs, and that egg allergy is a contraindication to influenza vaccination, and does not want her to receive flu vaccine today.





Vignette #4-poll

Q: Is it safe for Maddy to receive influenza vaccine today?YesNo



- Although allergic reactions are a common concern for vaccine providers, these reactions are uncommon and anaphylaxis following vaccines is rare, occurring at a rate of approximately one per million doses for many vaccines. Epinephrine and equipment for managing an airway should be available for immediate use.
- The best practice to prevent allergic reactions is to identify individuals at increased risk by obtaining a history of allergy to previous vaccinations and vaccine components that might indicate an underlying hypersensitivity.
- Acute allergic reactions following vaccinations might be caused by the vaccine antigen, residual animal protein, antimicrobial agents, preservatives, stabilizers, or other vaccine components. Lists are available from CDC.



- Current measles and mumps vaccines are derived from chicken embryo fibroblast tissue cultures and do not contain significant amounts of egg proteins. Studies indicate that children with egg allergy, even children with severe hypersensitivity, are at low risk of anaphylactic reactions to these vaccines
- Skin testing with the vaccine may not be predictive of an allergic reaction to immunization.
- Most immediate hypersensitivity reactions after measles or mumps immunization appear to be reactions to other vaccine components, such as gelatin.
- Therefore, children with egg allergy may be given MMR or MMRV vaccines without special precautions.
 CHOC Children's

- Although most IIV and LAIV vaccines are produced in eggs and contain measurable amounts of egg protein, recent data have shown that IIV administered in a single, age-appropriate dose is well tolerated by most recipients with a history of egg allergy.
- More conservative approaches in children with a history of egg allergy, such as skin testing or a 2-step graded challenge, no longer are recommended.
- No data have been published on the safety of administering LAIV to egg-allergic recipients.



Recommendations regarding influenza vaccination of persons who report allergy to eggs: Advisory Committee on Immunization Practices, United States, 2016-17 Influenza season.

NOTE: Regardless of a recipient's allergy history, all vaccination providers should be familiar with the office emergency plan and be currently certified in cardiopulmonary resuscitation. Epinephrine and equipment for maintaining an airway should be available for immediate use. (CDC. General recommendations on immunization—recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2011;60(No. RR-2)



IIV=Inactivated Influenza Vaccine; RIV=Recombinant Influenza Vaccine.



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What Are Contraindications?

- Contraindications to vaccines are conditions that, when present, do not allow for the safe or effective administration of a vaccine.
- Screening for contraindications and precautions is important to prevent potential serious adverse reactions following vaccination. Everyone should be screened before every vaccine dose.
- <u>https://www.cdc.gov/vaccines/hcp/acip-</u> <u>recs/general-recs/contraindications.html</u>



CONTRAINDICATIONS VS PRECAUTIONS

- A contraindication to vaccination is a condition in a patient that increases the risk of a serious adverse reaction and for whom this increased risk of an adverse reaction outweighs the benefit of the vaccine. A vaccine should **not** be administered when a contraindication is present
- Most precautions result from temporary conditions (eg, moderate or severe illness), and a vaccine can be administered when the illness abates. However, vaccination may be recommended in the presence of a precaution if the benefit of protection from the vaccine outweighs the risk.





False Contraindications

- Some clinicians misperceive certain conditions as valid contraindications or precautions
- These misperceptions result in missed opportunities to administer recommended vaccines.



Conditions that are not contraindications

- Mild acute illness with or without fever
- Mild-to-moderate local reaction (i.e., swelling, redness, soreness); low-grade or moderate fever after previous dose
- Lack of previous physical examination in well-appearing person
- Current antimicrobial therapy
- Convalescent phase of illness
- Preterm birth (hepatitis B vaccine is an exception in certain circumstances)
- Recent exposure to an infectious disease
- History of penicillin allergy, other nonvaccine allergies, relatives with allergies, or receiving allergen extract immunotherapy hildren's.



Take-Away

- Consider how all clinicians in your office address contraindications
- Does everyone follow the same protocol?
- Take this information back to your practice and discuss





Resources – Contraindications

- IAC Clinic Resources: Screening Questionnaires
- IAC Ask the Experts: Precautions and Contraindications

Source: Immunization Action Coalition



CDC General IZ Best Practices – 4/17

- Available on ACIP web page (<u>https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html</u>)
- The General Best Practice Guidelines for Immunization replace the General Recommendations on Immunization, last published in the Morbidity and Mortality Weekly Report (MMWR) in 2011.
- The General Best Practice Guidelines for Immunization goes beyond vaccination recommendations to give providers guidelines on vaccination practice. The document will help vaccination providers to assess vaccine benefits and risks, use recommended administration practices, understand the most effective strategies for ensuring that vaccination coverage in the population remains high, and communicate the importance of vaccination to reduce the effects of vaccine-preventable disease.



CDC Best practice Guidance- 4/2017

The updated guidelines include:

- 1. Confirmation that if a patient is not acutely, moderately, or severely ill, vaccination during hospitalization is a best practice;
- 2. New information on simultaneous vaccination and febrile seizures;
- 3. Enhancement of the definition of "precaution" to include any condition that might confuse diagnostic accuracy;
- 4. More descriptive characterization of anaphylactic allergy;
- 5. Incorporation of protocols for management of anaphylactic allergy;
- 6. Allowances for alternate route (subcutaneous instead of intramuscular) for hepatitis A vaccination;
- 7. An age cutoff of 12 years through 17 years for validating a dose of intradermal influenza vaccine;





CDC Best practice Guidance- 4/2017

8. Deletion of much of the storage and handling content, including information on storage units, temperature monitoring, and expiration dates (this content is now contained and continually updated in CDC's Vaccine Storage and Handling Toolkit, available at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html);

9. Incorporation of the Infectious Diseases Society of America guidance on vaccination of persons with altered immunocompetence;

10. Timing of intramuscular administration in patients with bleeding disorders;

- 11. Updated data on vaccination record policy;
- 12. Additional impacts of the Affordable Care Act on adult vaccination; and

13. Updated programmatic contact information on source material for vaccine information.



Contraindication true vs perceived tables

- TABLE 4-1. Contraindications and precautions to commonly used vaccines
- TABLE 4-2. Conditions incorrectly perceived as contraindications to vaccination (i.e., vaccines may be given under these conditions)





VAERS

- The Vaccine Adverse Event Reporting System (VAERS) is a national passive surveillance system that monitors the safety of vaccines licensed in the US, jointly administered by the CDC and the FDA.
- VAERS accepts reports of suspected adverse events after administration of any vaccine.
- The strengths of VAERS are that it is national in scope, can rapidly detect safety signals, and can detect rare and unexpected adverse events.





- Like all passive surveillance systems, VAERS is subject to limitations, including reporting biases such as underreporting, inconsistent data quality and completeness, lack of denominator data, and absence of an unvaccinated comparison group.
- Because of these limitations, determining causal associations between vaccines and adverse events from VAERS reports usually is not possible.
- Health care professionals who suspect that any clinically significant adverse event occurred after any vaccination are strongly encouraged to report the event, regardless of whether or not it is listed on the VAERS Table of Reportable Events Following Vaccination

VAERS

- People other than health care professionals also may submit a report of a suspected adverse event to VAERS.
- Vaccine product problems and vaccine administration errors may also be reported.





VAERS

- Information in VAERS reports is evaluated and analyzed to determine whether there are unusual patterns of adverse events associated with vaccines
- Medical records are obtained for serious reports
- FDA physicians perform postmarketing safety evaluations 18 months after approval of a vaccine or after its use in 10,000 individuals, whichever is later.
- The FDA also presents a safety summary to an independent pediatric advisory committee after the first 12 months of safety data after licensure of a vaccine for use in children.







- Periodically, reviews of surveillance summaries from VAERS data are published. These summary reports may provide reassurance of the safety of a vaccine, or they may describe findings ("signals") of associations that require further evaluation.
- Vaccine safety concerns identified through VAERS nearly always require further studies for confirmation.
- At a minimum, determination of causality requires the demonstration that the incidence of an adverse event following immunization is > expected in an unvaccinated population or that the incidence in a specific time frame following vaccination is > expected in an unvaccinated population within that time frame

New Vaccine Adverse Event Reporting System (VAERS) Website and Ways to Report to VAERS

- VAERS 2.0 includes a new reporting form and a new website that allows you to:
 - Easily submit a VAERS report electronically
 - Access VAERS data
 - Learn more about how CDC and FDA monitor the safety of vaccines
- By the end of 2017, the paper form will be phased out



Resources

- References
 - AAP Red Book
 - CDC <u>Vaccine Contraindications and Precautions:</u> <u>Recommendations and Guidelines</u>
 - CDC <u>Chart of Contraindications and Precautions to Commonly</u> <u>Used Vaccines</u>
 - IAC <u>Guide to Contraindications and Precautions to Commonly</u> <u>Used Vaccines</u>

