Screening and contraindications and precautions:

Q: When screening for contraindications and precautions is asking about specific food or medication allergies more useful than asking in general about them?

A: It may be more efficient to inquire about allergies in a generic way (i.e., any food or medication) rather than to inquire about specific vaccine components. Most parents will not be familiar with minor components of vaccine, but they should know if the child has had an allergic reaction to a food or medication that was severe enough to require medical attention.

Q: What are the differences between contraindication and precaution? Could you please elaborate more?

A: From the Pink Book (see <https://www.cdc.gov/vaccines/pubs/pinkbook/genrec.html#contraindications> for more information):

“A contraindication is a condition that increases the likelihood of a serious adverse reaction to a vaccine for a patient with that condition. If the vaccine were given in the presence of that condition, the resulting adverse reaction could seriously harm the recipient. For instance, administering MMR vaccine to a person with a true anaphylactic allergy to gelatin could cause serious illness or death in the recipient. In general, vaccines should not be administered when a contraindication condition is present.

A precaution is a condition in a recipient that ***might*** increase the chance or severity of a serious adverse reaction, or that might compromise the ability of the vaccine to produce immunity (such as administering measles vaccine to a person with passive immunity to measles from a blood transfusion). Injury could result, but the chance of this happening is less than with a contraindication. In general, vaccines are deferred when a precaution condition is present. However, situations may arise when the benefit of protection from the vaccine outweighs the risk of an adverse reaction, and a provider may decide to give the vaccine.”

Q: Is there a schedule available to assist in scheduling vaccine doses for patients receiving monthly IGIV infusions?

A: Such patients may receive any inactivated vaccine recommended for them. They cannot receive live attenuated vaccines for 8 through 11 months after last receipt of IGIV infusion. One should note the patient likely receives enough antibodies from such infusions to prevent measles, mumps, rubella, and varicella infections.

Q: Is Factor 5 Leiden disease a contraindication for any vaccines?

A: Factor 5 Leiden thrombophilia is a genetic disorder that makes it more likely for the person to develop a blood clot sometime during their life (see <https://rarediseases.info.nih.gov/diseases/6403/factor-v-leiden-thrombophilia>). Still, it is estimated that 95% of people with factor V Leiden never develop a clot. While this condition is not listed as a precaution or contraindication to vaccination, if the patient is receiving anticoagulants following a blood clot, one should proceed with vaccination as one would do with any patient with a clotting disorder; see <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/special-situations.html#bleeding>.

Q: Can you address the relationship between Guillain Barre Syndrome (GBS) and vaccines, and which vaccines would be contraindicated if the patient has a history of GBS within 6 weeks of a previous vaccine?

A: Guillain-Barré syndrome (GBS) has been associated rarely with influenza and tetanus-containing vaccines within 6 weeks of vaccination. Prior GBS within 6 weeks of either vaccine is a precaution for future administration of influenza vaccines and/or tetanus-toxoid containing vaccines, respectively.

Catchup vaccination:

Q: We have to do a lot of start over [immunization] for children who have lost their records. Some of our nurses think 8 - 9 vaccines is too many injections and have started giving only school required vaccines. Please share your thoughts.

A: We respect the nurses’ concern. However, the ACIP has stated one can administer more than two vaccines in one muscle if indicated (see <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html>). Fortunately, it should be rare for children to require more than two injections in one limb, or more than eight at one time. Your note also reminds one to have the family look everywhere possible for the child’s records, and checking with neighboring state(s)’ immunization information systems as well. More information about locating vaccination records is at <https://www.cdc.gov/vaccines/parents/records-requirements.html>.

Q: If you have a 18 year old client whose parents did not believe in vaccines and have received none, where would you begin and what time, space, and order would you use?

A: Reviewing the child and adolescent catchup schedule at <https://www.cdc.gov/vaccines/schedules/hcp/imz/catchup.html>, this person is recommended to receive eight vaccine series: HPV, hep A, hep B, IPV, MMR, varicella, meningococcal ACWY, and Tdap/Td. Meningococcal B vaccine may be offered. As discussed above, one can administer two doses of vaccine in each limb, in older children and adults, and thus begin all the recommended vaccine series. Also, MMR, varicella, and IPV can be administered subcutaneously, sparing muscle area for the other vaccines.

Vaccine safety:

Q: Would you classify a rash, after receiving the MMR vaccine, something that we should report to VAERS?

A: You should report any adverse event that concerns you, or the patient. If the event is common, and is not causing the patient significant discomfort, you can choose to not report it.

Q: Is there more risk administering combination vaccines (for example: Pediarix, Quadracel) versus separate vaccines?

A: ACIP’s General Best Practice Guidelines state one of the possible disadvantages of combination vaccines includes: “… adverse events that might occur more frequently after administration of a combination vaccine compared with administration of separate antigens at the same visit, such as fever that occurs with the combination MMRV vaccine and combination DTaP-HepB-IPV vaccine.” One should note such vaccines “… can reduce the number of injections patients receive and alleviate concern associated with the number of injections…” as well as possibly reduce cost and improved vaccination coverage. More information is at <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html> under Combination Vaccines.

Q: Does [the National Vaccine Injury] compensation program cover VAPP?

A: By VAPP, you mean vaccine associated paralytic polio, which has been associated with oral polio vaccines. It is included in the compensation program’s Vaccine Injury Table at <https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/vaccine-injury-table.pdf>. Therefore, if demonstrated to have occurred within the time allowed after oral polio vaccination, compensation is recommended.

Q: Is the Vaccine Injury Compensation Program (VICP) applicable only for childhood vaccines? Can it be used for vaccines required by employers (e.g. hospital employees)?

A: The VICP website states “For a vaccine to be covered, the Centers for Disease Control and Prevention (CDC) must recommend the category of vaccine for routine administration to children or pregnant women, and it must be subject to an excise tax by federal law.” Therefore, such vaccines including most influenza vaccines, MMR, and varicella vaccines recommended for health care personnel, regardless of their age, are included in the program, as are any injuries identified in persons, regardless of age.

Q: We had a case of an 8 year old healthy boy, who, after receiving JE vaccine in the afternoon, at night, he got seizures and became unconscious. Then, his parent took him to hospital, everything seems to be fine. One year after, he got seizures again like last time. His parent believe that he might get some adverse effect from the vaccination. Is it possible to call that it is the adverse of the vaccine? How could we find out that effects are due to the JE vaccination?

A: While seizures following JE vaccination have been reported, studies have not included persons with adverse events occurring more than 60 days after vaccination. If the patient has not been examined by a neurologist, recommending such an examination would seem appropriate.

Q: Can the vaccine data safety link provide any cross validation, specifically an estimate of the degree of possible under-ascertainment [of vaccine adverse events] in VAERS?

A: We recognize that there is underreporting to VAERS, although the reporting efficiency appears higher for clinically serious events than for non-serious events (refer to the Rosenthal and Chen study cited below). Healthcare providers generally use clinical judgment when deciding to report a suspected vaccine adverse event to VAERS. It is important to understand that VAERS is primarily a signal detection and hypothesis generating system. When unusual or unexpected patterns are detected in VAERS that might be indicative of a vaccine safety problem they can be further assessed in more robust data systems, like the Vaccine Safety Datalink. Although complete ascertainment would be ideal, VAERS is capable of performing its safety monitoring function in the absence of complete ascertainment of possible vaccine adverse events.

Using the Vaccine Safety Datalink for cross validation of possible under-ascertainment of adverse events reported to VAERS could be complicated by fact that these two systems are fundamentally different and serve different purposes. VAERS is a spontaneous reporting (or passive surveillance) system (i.e., people choose to report suspected adverse events to CDC and FDA), while VSD is an electronic health record database used for active surveillance and research and there is no decision by a patient, healthcare provider, or other third party to report an event (i.e., information is captured in the course of routine clinical care). Because of these differences, the data in VAERS and VSD are not directly comparable, making it challenging to conduct an analysis of under-ascertainment using these two systems.

CDC has used methods to check the efficiency of VAERS reporting. See Rosenthal S, Chen R. Am J Public Health. 1995 Dec;85(12):1706-9. The reporting sensitivities of two passive surveillance systems for vaccine adverse events (available at <https://www.ncbi.nlm.nih.gov/pubmed/7503351>) and Verstraeten T, Baughman AL, Cadwell B, Zanardi L, Haber P, Chen RT; Enhancing vaccine safety surveillance: a capture-recapture analysis of intussusception after rotavirus vaccination. Am J Epidemiol. 2001 Dec 1;154(11):1006-12 (available at <https://www.ncbi.nlm.nih.gov/pubmed/11724716>).

Additionally, VAERS has been shown to be an effective tool for signal detection.

More information is available at:

* Niu MT, Erwin DE, Braun MM. Vaccine. 2001 Sep 14;19(32):4627-34. Data mining in the US Vaccine Adverse Event Reporting System (VAERS): early detection of intussusception and other events after rotavirus vaccination. Available at <https://www.ncbi.nlm.nih.gov/pubmed/11535310>
* Leroy Z, Broder K, Menschik D, Shimabukuro T, Martin D. Vaccine. 2012 Mar 2;30(11):2020-3. Febrile seizures after 2010-2011 influenza vaccine in young children, United States: a vaccine safety signal from the vaccine adverse event reporting system. Available at <https://www.ncbi.nlm.nih.gov/pubmed/?term=leroy%2C+VAERS%2C+seizure>
* CDC. Safety of influenza A (H1N1) 2009 monovalent vaccines - United States, October 1-November 24, 2009. MMWR Morb Mortal Wkly Rep. 2009 Dec 11;58(48):1351-6. Available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5848a4.htm>

Q: In the Danish autism/MMR study described by Madsen et al [see <https://www.nejm.org/doi/full/10.1056/NEJMoa021134>], there was no true "no vaccine group" -- all those in the no vaccine group had received other vaccines, though not MMR vaccine. How does this study prove no association of autism with other vaccines?

A: The Madsen et al study was only designed to evaluate the risk of MMR vaccination related to autism, given the many concerns at that time about a possible association. Therefore, the study limited itself to assessing that possible association.

Q: How do you define "unvaccinated" participants in vaccine studies?

A: It depends on the study. Generally, if only one vaccine is studied, the comparisons are between people who have received that vaccine, and those who have not.

Q: Have there been any autism spectrum disorder (ASD) studies done on possible associations with vaccines other than MMR vaccine?

A: Some studies, and reviews by the Institute of Medicine on this topic are listed here: <https://www.cdc.gov/vaccinesafety/concerns/autism.html>. There have been studies evaluating other vaccines which contained thimerosal and ASD, such as DTaP vaccines. No association with ASD was identified, or the data were not robust enough to determine if an association existed.

Additional studies include:

* Uno Y, Uchiyama T, Kurosawa M, Aleksic B, Ozaki N. The combined measles, mumps, and rubella vaccines and the total number of vaccines are not associated with development of autism spectrum disorder: the first case-control study in Asia. Vaccine. 2012 Jun 13;30(28):4292-8.
* DeStefano F, Price CS, Weintraub ES. Increasing exposure to antibody-stimulating proteins and polysaccharides in vaccines is not associated with risk of autism. J Pediatr. 2013;163(2):561-567.
* Price CS, Thompson WW, Goodson B, Weintraub ES, Croen LA, Hinrichsen VL, et al. Prenatal and infant exposure to thimerosal from vaccines and immunoglobulins and risk of autism . Pediatrics. 2010;126(4):656-664.
* Verstraeten T, Davis RL, DeStefano F, Lieu TA, Rhodes PH, Black SB, et al. Safety of thimerosal-containing vaccines: A two-phased study of computerized health maintenance organization databases Pediatrics. 2003;112(5):1039-1048.

Q: Why are there are no fully non-vaccinated vs vaccinated studies of vaccine safety?

A: Comparisons of fully vaccinated children to those having received no vaccines do not meet current standards for ethical study design in a clinical trial. Intentionally depriving children of vaccines for purposes of scientific study is unethical by modern standards of care: the known benefits of vaccines drastically outweigh the risks.

It is also not feasible to do an observational study on vaccinated vs. unvaccinated children because there are differences in the two groups that would bias the study results. In spite of these concerns, there is at least one observational study that was done on vaccinated vs. fully non-vaccinated children. Schmitz R, Poethko-Müller C, Reiter S, Schlaud M. Dtsch Arztebl Int. 2011 Feb;108(7):99-104. Vaccination status and health in children and adolescents: findings of the German Health Interview and Examination Survey for Children and Adolescents (KiGGS). See <https://www.ncbi.nlm.nih.gov/pubmed/21412506>

More detailed information about the study of vaccinated vs. unvaccinated children and the safety of the recommended immunization schedule are available at:

* The Institute of Medicine publication: The Childhood Immunization Schedule and Safety at <http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2013/Childhood-Immunization-Schedule/ChildhoodImmunizationScheduleandSafety_RB.pdf>
* Glanz JM, Newcomer SR, Jackson ML, Omer SB, Bednarczyk RA, Shoup JA, DeStefano F, Daley MF. White Paper on studying the safety of the childhood immunization schedule in the Vaccine Safety Datalink. Vaccine. 2016 Feb 15;34 Suppl 1:A1-A29. Available at <https://www.ncbi.nlm.nih.gov/pubmed/26830300>

Q: Can you cite studies that show long term impact of injecting a child with proteins they are already allergic toG?

A: The Advisory Committee on Immunization Practices (ACIP) recommends that all persons be screened for allergies prior to being vaccinated. If a child has an allergy to any component of a vaccine, a healthcare provider may advise against vaccination or take additional precautions. Allergic reactions are acute events with a fairly rapid onset following an exposure and relatively quick resolution when compared to chronic diseases.

Q: [The Immunization Action Coalition at] www.immunize.org is funded by vaccine manufacturers -- why do you keep sending viewers to a website with deep conflict of interest?

A: CDC collaborates with multiple organizations and groups, including vaccine manufacturers. We realize many groups may have certain biases, and seek to identify those, while working with these partners. The materials cited in today’s presentation from the Immunization Action Coalition had to do with no particular vaccine, but how to screen persons for contraindications to vaccination.

Q: Why do you recommend not having a patient leave a practice for refusal of vaccines? Isn't it considered unsafe to other patients such as infants?

A: The American Academy of Pediatrics (AAP) has written extensively on the issue of dismissing patients from a practice because they are not accepting vaccination (see <https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunizations/Pages/refusal-to-vaccinate.aspx>). While CDC does not have an official position on dismissing such patients from a practice, the AAP position reviews the issues in detail, and concludes:

“AAP Policy

The current AAP Clinical Report, Countering Vaccine Hesitancy, provides information about addressing parental concerns about vaccination. It can assist pediatricians with understanding vaccine development and safety monitoring processes, and it reviews the current state of vaccine exemptions, discusses communication strategies for responding to parental concerns and considers the option of dismissal from a practice of families which refuse vaccinations.

The current AAP Policy, Responding to Parental Refusals of Immunization of Children, can assist pediatricians in understanding the reasons parents may have for refusing to immunize their children, review the limited circumstances under which parental refusals should be referred to child protective services agencies or public health authorities, and provide practical guidance to assist the pediatrician faced with a parent who is reluctant to allow immunization of his or her child.”

Q: Why do you state the Institute of Medicine (IOM) findings about safety of the childhood immunization schedule as they found no evidence -- meaning - they found no studies? I believe the term they used was "paucity" -- a paucity of evidence "scientific or otherwise" saying the current schedule was safe.

A: The IOM report about the childhood schedule concluded:

“The charge to the Committee on the Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule was to (1) review scientific findings and stakeholder concerns related to the safety of the recommended childhood immunization schedule and (2) identify potential research approaches, methodologies, and study designs that could inform this question, considering strengths, weaknesses, as well as the ethical and financial feasibility of each approach. As reviewed by prior Institute of Medicine studies, a substantial literature exists on adverse effects of individual vaccines, but few studies have focused on elements of or the recommended childhood immunization schedule as a whole. The lack of conclusive evidence linking adverse events to multiple immunizations or other “schedule” exposures suggests that the recommended schedule is safe. There are concerns from some stakeholders that merit exploration through research if epidemiological signals are detected and an indication of biological plausibility is available. However, the committee concludes that it is not ethical to implement any study requiring that some children receive fewer vaccines than recommended as part of the childhood immunization schedule because this would needlessly endanger children’s lives. The committee concludes that data from existing surveillance systems, such as the Vaccine Safety Datalink, could be used and offer the best means for ongoing research efforts regarding the safety of the schedule. In recognition of this, future federal research approaches should

•collect and assess evidence regarding public confidence in and concerns about the entire childhood immunization schedule, with the goal to improve communication with health care professionals, and between health care professionals and the public regarding safety;

•standardize definitions of key elements of the schedule, and relevant health outcomes;

•establish research priorities on the basis of epidemiological evidence, biological plausibility, and feasibility; and

•continue to fund and support the Vaccine Safety Datalink project to study the safety of the recommended immunization schedule.”

Q: There were 135 vaccine injuries for which IOM [in its 2011 report Adverse Effects of Vaccines: Evidence and Causality] could not find ANY studies to examine in the 2011 report, and did not prove vaccines are not related to many different types of illnesses.

A: This particular IOM report concluded:

“The committee finds that evidence convincingly supports a causal relationship between some vaccines and some adverse events—such as MMR, varicella zoster, influenza, hepatitis B, meningococcal, and tetanus-containing vaccines linked to anaphylaxis. Additionally, evidence favors rejection of five vaccine-adverse event relationships, including MMR vaccine and autism and inactivated influenza vaccine and asthma episodes. However, for the majority of cases (135 vaccine-adverse event pairs), the evidence was inadequate to accept or reject a causal relationship. Overall, the committee concludes that few health problems are caused by or clearly associated with vaccines.”

The complete report is at <http://nationalacademies.org/HMD/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx>.

Q: It's NOT so much the antigens as the OTHER ingredients in the vaccine -- aluminum -- that impact the immune system. What data does CDC have to demonstrate these other ingredients are safe?

A: Vaccines containing adjuvants are tested for safety and efficacy in clinical trials before they are licensed for use in the United States. Once licensed, all vaccines are continuously monitored for safety by CDC and FDA in the post-licensure period. For more information please see: <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/common-ingredients-us-licensed-vaccines>.