Energy and Commerce Subcommittee on Oversight and Investigations
Hearing on "Confronting a Growing Public Health Threat: Measles Outbreak in the U.S."
February 27, 2019

Questions for the Record

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Pallone (D-NJ):

Q1. This year marks the 25th anniversary of the Vaccines for Children (VFC) program, which ensures all children are guaranteed life-saving vaccines regardless of their parent or guardian's ability to pay. According to National Immunization Survey data from CDC, however, there are growing disparities in childhood vaccination rates based on socioeconomic status, whether a child is privately or publically insured and whether a child lives in a rural area. What can we do to resolve access issues and ensure we do not lose any of the amazing progress we've made through VFC?

A1. Most U.S. children receive recommended vaccines on schedule. However, the proportion of children who have received no vaccines has increased in recent years. Communities where children are under-immunized remain, meaning these children have not received all recommended vaccines or are behind the recommended vaccine schedule. There are opportunities to improve vaccination coverage among these groups and strengthen the protective effects of immunization.

The Vaccine for Children's program has been a cornerstone to ensure easy access to vaccines by providing vaccine at no-cost for eligible children, including uninsured, Medicaid-eligible, and American Indian and Alaska Native children. Removing the financial barriers to immunizations has resulted in overall high vaccine coverage rates and the near elimination of disparities. However, CDC data indicates that there are some emerging disparities in child and adolescent coverage rates.

A higher proportion of uninsured children are more likely to have received no vaccinations by age two than insured children, and vaccination rates for HPV are more than 11 percentage points lower for children in rural communities compared to urban areas. The lower rates in these groups suggest it is harder for some children to get access to vaccine providers. With VFC, access to a provider and a vaccine should never be a barrier to vaccination. Concentrated efforts are required to address any potential obstacles to vaccination, including minimizing costs, connecting parents with providers, ensuring adequate supply, identifying new opportunities for vaccination, reducing missed or skipped provider visits, and educating providers.

Q2. Planning for Healthy People 2030, the national health promotion and disease prevention objectives for the next decade, is now underway. How can immunization play a role in long-term planning for public health goals?

A2. Healthy People provides science-based, national goals and objectives with 10-year targets designed to guide national health promotion and disease prevention efforts to improve the health of all people in the United States. The Immunization and Infectious Disease (IID) work

group is responsible for 17 core objectives moving forward in Healthy People 2030, and seven of those objectives are related to immunization. The proposed Healthy People 2030 objectives represent key metrics for immunization compliance especially related to childhood and adolescence. Among the proposed objectives, two pertain to measles, mumps, and rubella (MMR) vaccination coverage—at age 2 years and at kindergarten—as well as an objective for HPV for adolescents, and one for seasonal influenza for persons 6 months of age and older. Immunization coverage indicators for these vaccine/age group help to identify areas of concern.

Q3. While national vaccination rates remain high, according to CDC data from 2017, the estimated MMR vaccination coverage among 13 to 17 year-old young people ranged from 77.8% to 97% across states and local counties in the country. Does CDC assess these data and develop an annual map of the vaccination rates in the United States by county in order to identify areas requiring further public health engagement, or for forecasting purposed to identify potential geographic areas where outbreaks of vaccine preventable disease could be most likely?

A3. CDC monitors vaccination coverage through the National Immunization Survey and through the collection of state-reported data. Although MMR vaccine coverage among teens varied from 84.7% (Texas) to 97.7% (Georgia), 40 states had MMR coverage of 90% or higher in 2017. State and/or local health departments may assess vaccination coverage at the county level. Many states use their immunization information systems (IIS) for county-level vaccination coverage assessment,[1] and some make county-level estimates available online. CDC provides funding and technical support for development and use of IIS to 50 states, local area awardees, and U.S.-affiliated jurisdictions.

CDC monitors vaccination coverage in children 19-35 months with the National Immunization Survey – Child (NIS-Child). In addition to providing national and state-level estimates, estimates are available routinely for the two counties (Bexar County, Texas, and Philadelphia County, Pennsylvania) and three cities (Chicago, Houston, New York City) which receive immunization grant funds directly from CDC. CDC has used small area statistical methods to estimate county-level coverage.[2] The most recent estimates are based on data from 2014-2015 combined and available for 181 counties.

CDC collects state-reported state-level data on vaccination coverage among children in kindergarten[3]). CDC encourages states to post school or community-level estimates online, and maintains a list of state websites with this information[4]. There are currently 29 states listed.

Q4. According to the Pew Research Center, 7 in 10 adults in the United States look online for health information. Has CDC previously engaged with or plan to directly engage with internet, digital, or social media stakeholders, such as Amazon, Facebook, Instagram, Pinterest, Reddit, Twitter, Yahoo, or others on the issue of immunization and their respective policies regarding the promotion or proliferation of anti-vaccine media?

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[1] https://repository.immregistries.org/resource/identifying-immunization-pockets-of-need-small-area-analysis-of-iis-data-to-detect-undervaccinated-p/from/type:documents

[2] County-Level Trends in Vaccination Coverage Among Children Aged 19--35 Months --- United States, 1995--2008: https://www.cdc.gov/mmwr/preview/mmwrhtml/ss6004a1.htm

[3] Mellerson JL, Maxwell CB, Knighton CL, Kriss JL, Seither R, Black CL. Vaccination Coverage for Selected Vaccines and Exemption Rates Among Children in Kindergarten — United States, 2017–18 School Year. MMWR Morb Mortal Wkly Rep 2018;67:1115–1122.https://www.cdc.gov/mmwr/volumes/67/wr/mm6740a3.htm

[4] SchoolVaxView: https://www.cdc.gov/vaccines/imz-managers/coverage/schoolvaxview/pubs-resources.html

A4. It is critical for parents and anyone seeking information on vaccines to become informed health consumers. Unfortunately, some of the information about vaccines online may be inaccurate. CDC advocates tirelessly to protect the American public from disease and other health threats, including vaccine preventable diseases. We are a critical source for credible health information and committed to providing up-to-date, science-based recommendations that anyone, including parents, kids, health departments, businesses, and healthcare providers, can use to make informed health decisions. Additionally, CDC's online information is in the public domain and free for anyone to access, use or repurpose. This includes internet, digital and social media stakeholders like Facebook and others.

When CDC engages in social media, we aim to consistently provide science-based and timely information in plain language to help educate audiences so that they can make informed decisions. We customize our outreach efforts based on the best channels to use for certain audiences, if we have visual elements, what messages resonate with a specific audience, what information is new or newsworthy, and what additional information or links they might need.

Parents and anyone who has questions about vaccines should make sure to talk to their health care provider.

Jan Schakowsky (D-IL):

Q1. When outbreaks occur, our most pressing concern is often and immediate response. However, I believe that we also must reflect on our nation's progress in prevention of vaccine preventable diseases. The Department of Health and Human Services (HHS) Healthy People objectives from immunization and infectious disease are a cornerstone for federal, state, and local efforts to protect against vaccine presentable conditions across the lifespan.

I was surprise to learn that the draft Healthy People 2030 objectives include very few immunization objectives in total. At a time when we are seeing increased outbreaks of diseases that were already virtually eliminated in this country, could you explain the rationale behind the reduction in immunization objectives in the draft Health People 2030 framework? Do you plan to restore these objectives moving forward?

A1. Healthy People provides science-based, national goals and objectives with 10-year targets designed to guide national health promotion and disease prevention efforts to improve the health of all people in the United States. Healthy People 2020 tracks 1,200 objectives, organized into 42 topic areas. A priority of Healthy People 2030 was to reduce this number to 375 objectives. The number of objectives for the Immunization and Infectious disease work group was reduced from 83 to 17, with a significant portion still focused on immunization. The reduction in number of objectives is a reflection of the change to the Healthy People framework, not a reduced prioritization of immunization. We anticipate that fewer objectives overall will result in a higher impact for each of those that remain.

The proposed Healthy People 2030 objectives represent key metrics for immunization compliance especially related to childhood and adolescence. Among the proposed objectives, two pertained to measles, mumps, and rubella (MMR) vaccination coverage—at age 2 years and at kindergarten—as well as an objective for HPV for adolescents, and one for seasonal influenza for persons 6 months of age and older. Immunization coverage indicators for these vaccine/age groups help to identify areas of concern.

Monitoring and reporting vaccination coverage rates is a core function of CDC's Immunization program. CDC will continue to monitor and report vaccination coverage for all routinely recommended vaccines through the National Immunization Survey.

Brett Guthrie (R-KY):

Q1. In May 2015, the journal Science published a report in which researchers found that the measles infection can leave a population at an increased risk for mortality from other diseases for two to three years. Besides this report, is there evidence that measles increases susceptibility to other infections?

A1. The report in Science was a modeling study and CDC cannot comment on the utility of the model or how the study was done. There are no other similar studies; however, there are numerous reports of non-specific benefits of measles vaccination. Children that are vaccinated for measles are less likely to die from other infectious diseases.

Measles infection is immunosuppressive and can lead to increased susceptibility to opportunistic infections. Most measles deaths are the result of bacterial secondary infections. The duration of measles immunosuppression is likely variable among individuals infected with measles virus, and depends on a number of host factors, comorbidities, as well as exposures to other pathogens following the primary measles infection. The attached review discusses the immunosuppressive effects of measles.

Q2. What are antigens? How much are used in MMR vaccine? How does that small amount compare to the antigens that are encountered in the environment?

A2. Antigens are proteins or carbohydrates that are recognized by the immune system. Vaccine antigens are typically purified from bacteria or viruses or produced by recombinant technology based on knowledge of protein sequences. They are incorporated into vaccines to trigger specific immune responses, usually the production of antibodies. Antibodies protect the body from disease by binding to antigens found on infecting bacteria or viruses and inactivating or destroying them.

Babies are exposed to numerous bacteria and viruses on a daily basis. Eating food introduces new bacteria into the body; numerous bacteria live in the mouth and nose; and infants place their hands or other objects in their mouth hundreds of times every hour, exposing the immune system to still more germs. However, when a baby is born, his or her immune system is ready to respond to the many antigens in the environment and the selected antigens in vaccines.

When a child has a cold, he or she is exposed to up to 10 antigens, and exposure to strep throat involves about 25 to 50 antigens. Each vaccine in the childhood vaccination schedule has between 1-69 antigens that are weakened or dead and therefore cannot cause infection the way other antigens can. A child who receives all the recommended vaccines in the 2018 childhood immunization schedule may be exposed to up to 320 vaccine antigens by the age of 2. The MMR vaccine contains three different weakened live viruses: measles, mumps, and rubella, and 24 antigens.

Q3. Is ensuring high vaccination rates a federal responsibility at all or does ensuring adequate vaccination coverage just a state issue?

A3. CDC works closely with public health agencies and private partners to improve and sustain immunization coverage by developing, disseminating and supporting the implementation of evidence-based strategies to improve access to and use of immunization services. One tool states have used to maintain low rates of vaccine-preventable disease is vaccination law. State vaccination laws include vaccination requirements for children in public and private schools and day care settings, college/university students, and healthcare workers and patients in certain facilities. State laws also affect access to vaccination services by determining whether providing

vaccinations to patients is within the scope of practice of certain healthcare professionals, such as pharmacists.

All states, the District of Columbia, and territories have vaccination requirements for children attending childcare facilities and schools. These vaccination requirements are important tools for maintaining high vaccination coverage and low rates of vaccine-preventable diseases. Exemptions from vaccination requirements may apply for some children.

CDC works with state and local health departments to collect and report data on school vaccination coverage, exemption rates, and grace period and provisional enrollment each year. Immunization programs can use these data to understand and address undervaccination among kindergartners and to identify schools and communities where focused interventions could improve coverage with required vaccines.

Q4. At what point would exemptions from vaccination become a federal issue?

A4. In considering state vaccine requirements and exemptions, the federal government's role is to provide the evidence base and recommendations for the use of vaccines to protect Americans from diseases that are preventable. State legislatures have access to their State Public Health Officials and the evidence base and vaccine recommendations when determining their state requirements.

Q5. What is your professional judgement of the likely public-health impact of state vaccination exemptions based on personal or professional beliefs?

A5. State and local school vaccination requirements exist to ensure that students are protected from vaccine-preventable diseases. Every state requires children enrolled in public school to be vaccinated against a series of diseases, including measles. Most states also require children in private schools to be vaccinated. All states establish vaccination requirements for children as a condition for day care attendance.

All states allow an exemption to the required vaccines when it is medically necessary, and all but three states (California, Mississippi, and West Virginia) also allow non-medical exemptions based on religious or personal beliefs. Many states have laws expressly allowing state and local health officials or school administrators to temporarily exclude children from school during an outbreak. Children who are not vaccinated are often required to stay home from school and school-related functions until the outbreak ends or they get vaccinated.

During the 2017-2018 school year, the median rate of school exemptions from one or more vaccines was 2.2%, ranging from 0.1% in Mississippi to 7.5% in Oregon. Median vaccination coverage was 94.3% for 2 doses of measles, mumps, and rubella vaccine. Although the overall percentage of children with an exemption was low, this was the third consecutive school year that a slight increase was observed. Reasons for the increase cannot be determined from the data reported to CDC but could include the ease of the procedure for obtaining exemptions or parental vaccine hesitancy. Reported exemptions do not distinguish between exemptions for one vaccine versus all vaccines. Previous studies indicate that most children with exemptions have received at least some vaccines.[5]

[5] Mellerson JL, Maxwell CB, Knighton CL, Kriss JL, Seither R, Black CL. Vaccination Coverage for Selected Vaccines and Exemption Rates Among Children in Kindergarten — United States, 2017–18 School Year. MMWR Morb Mortal Wkly Rep 2018;67:1115–1122. https://www.cdc.gov/mmwr/volumes/67/wr/mm6740a3.htm

Q6. What is the definition of an outbreak?

A6. An outbreak of measles is defined as three or more cases in a cluster. Prompt recognition, reporting, and investigation of measles is important because the spread of the disease can be limited with early case identification and public health response including vaccination and quarantine of susceptible contacts without presumptive evidence of immunity. Laboratory confirmation is essential for all measles outbreaks. State and local health departments have the lead in investigating measles cases and outbreaks.

Q7. When measles spreads in a locality that is under-vaccinated, does the spread only stay in that pocket of under-vaccination?

A7. Measles is a highly contagious virus that lives in the nose and throat mucus of an infected person. It can spread to others through coughing and sneezing. Also, measles virus can live for up to two hours in an airspace where the infected person coughed or sneezed. If other people breathe the contaminated air or touch the infected surface, then touch their eyes, noses, or mouths, they can become infected. Measles is so contagious that if one person has it, up to 90% of the people close to that person who are not immune will also become infected. When measles gets into communities with pockets of unvaccinated people, outbreaks are more likely to occur. These communities make it difficult to control the spread of the disease, endangering people that are unable to be vaccinated including infants younger than 12 months of age.

Q8. How does the CDC determine the rates of non-vaccination and the reasons for non-vaccination?

A8. CDC monitors vaccination coverage through the National Immunization Survey and through the collection of state-reported data. The National Immunization Survey (NIS) is a family of surveys that determines rates of vaccination in two-year-old children (NIS-Child), in adolescents ages 13-17 years (NIS-Teen), and influenza vaccination in children 6 months through 17 years. CDC collects data from randomly selected parents during a telephone interview, and then collects detailed vaccination histories for their children from medical providers. These data are used to track vaccination coverage over time, and identify states and sociodemographic groups with lower vaccination coverage. CDC determines rates of vaccination among children entering kindergarten by requiring reporting of summary data from state and selected local areas and territories. States collect this information to determine compliance with their school entry immunization laws and regulations. Together, these data sources assess receipt of recommended vaccines throughout childhood.

CDC helps to identify local pockets of lower vaccination coverage with data collected from schools on their compliance with state immunization requirements. Once identified, CDC supports state health departments to develop targeted strategies in addressing hesitancy issues relevant to these specific communities. CDC also encourages immunization programs to report school or community level vaccination coverage and exemption rates among kindergartners.

CDC works to identify the causes of vaccine hesitancy through an ongoing research to practice approach. We use principles of behavioral theory, risk communication approaches, and original research to develop and implement best practices for addressing vaccine hesitancy. Analysis of these data is used to identify areas for further investigation to better understand reasons for non-vaccination. Periodically, additional questions have been added to the National Immunization Survey on parental attitudes toward vaccination. Those data will be used to

determine how much of non-vaccination may be due to vaccine hesitancy as compared to issues related to access or other sociodemographic-related barriers to vaccination.

Q9. How does the CDC support state and local health departments to contain measles outbreaks?

A9. Through its Immunization Program, CDC provides vaccines and funding to 64 awardees to support immunization workforce and systems at the state and local levels. This immunization infrastructure is critical in responding to measles outbreaks. When requested, CDC provides states with rapid, on-site assistance during outbreak investigations and supports states with risk communication during emergency responses, including measles. CDC helps states quickly detect measles cases by testing laboratory specimens from both routine and complex suspected measles cases and helps interpret laboratory results. In addition, CDC's Public Health Emergency Preparedness (PHEP) cooperative agreement supports critical public health infrastructure, training staff to effectively respond to outbreaks and other emergency responses.

CDC provides important updates including information on outbreaks, vaccine policy, and clinical guidance to the public, parents, healthcare providers, and other stakeholders through a variety of media, including the CDC website, e-mails, and webinars, and through professional associations. CDC develops and disseminates travel notices regarding countries with measles outbreaks so that travelers are aware of vaccination recommendations.

Q10. What is involved with contact tracing in a measles outbreak?

A10. Prompt recognition, reporting, and investigation of measles cases are important because of how quickly measles can spread. Outbreaks can be contained with early case identification and vaccination of susceptible contacts. State and local health departments conduct case investigations for every confirmed measles case to assure timely reporting of suspected cases and to mitigate the risk of exposure.

As part of a measles case investigation, state and local health departments assess the potential for further transmission based on exposed contacts of the case-patient. The investigation also examines the presumptive evidence of immunity of contacts during the infectious period, which is between four days before to four days after onset of rash. Contact tracing consists of a thorough review of all places a case-patient may have stayed or visited during the infectious period, identification of contacts exposed in these settings, interviews of contacts to assess presumptive immunity to measles, and administration of appropriate post-exposure prophylaxis when indicated.

Based on the findings of individual case investigations, state and local health departments:

- identify the population at risk of infection (unvaccinated preschool-age children, high school students who have only received one dose of measles vaccine, persons who visited the emergency room of a hospital on a certain day, etc.);
- determine where transmission is occurring or likely to occur, such as in households, daycare, schools, health care settings, and in congregate settings like churches, colleges and prisons; and
- identify persons who are at highest risk of infection or transmission including other unvaccinated children, students attending other schools, immunocompromised persons, pregnant women, health care personnel, infants under 12 months of age.

Exposed persons who cannot readily document presumptive evidence of measles immunity are offered postexposure prophylaxis (vaccine or immunoglobulin) or excluded from settings where they can infect others such as school, day care, or hospitals. Except in health care settings, unvaccinated persons who receive their first dose of MMR vaccine within 72 hours postexposure may return to childcare, school, or work. Individuals who are at risk for severe disease and complications from measles (e.g., infants under 12 months of age, pregnant women without evidence of measles immunity, and severely immunocompromised persons regardless of vaccination status) should receive immunoglobulin within 6 days.

Persons who do not receive appropriate postexposure prophylaxis within the appropriate time should be excluded from affected institutions in the outbreak area until 21 days after the onset of rash in the last case of measles.

Q11. What resource burdens are imposed on state and local health departments to contain a measles outbreak?

A11. State and local health departments have the lead in investigating measles cases and outbreaks. When a suspected measles case is identified the local health department is responsible for an exhaustive investigation process. This is a significant burden on local public health in that they must expend resources in obtaining clinical specimens so that the diagnosis of measles can be confirmed by state or other public health laboratories; identify other individuals and communities that may have been exposed to the disease; provide immunizations or immune globulin as appropriate to exposed individuals and advise individuals if they need to avoid public places; and when warranted local or state health departments may hold special immunization clinics for impacted communities or facilities. Local or state health workers are responsible for monitoring large numbers of individuals who may have been exposed to measles. Additional investigations occur for any new cases to prevent the illness from spreading further.

State health department responsibilities include coordination of activities between jurisdictions within the state, providing or coordinating financial or other resources as needed, providing laboratory support, and coordinating with CDC.

For additional information, please see the following:

- Marx GE, Chase J, Jasperse J, et al. Public Health Economic Burden Associated with Two Single Measles Case Investigations — Colorado, 2016–2017. MMWR Morb Mortal Wkly Rep 2017;66:1272–1275. DOI: http://dx.doi.org/10.15585/mmwr.mm6646a3

- Wendorf KA, Kay M, Ortega-Sánchez IR, Munn M, Duchin J. Cost of measles containment in an ambulatory pediatric clinic. Pediatr Infect Dis J 2015;34:589–93. https://doi.org/10.1097/INF.0000000000000682

- Ortega-Sanchez IR, Vijayaraghavan M, Barskey AE, Wallace GS. The economic burden of sixteen measles outbreaks on United States public health departments in 2011. Vaccine 2014;32:1311–7. https://www.sciencedirect.com/science/article/pii/S0264410X13013649?via%3Dihub.

Q12. Are more federal resources needed to help support the state and local response?

A12. CDC is using available resources to address current outbreaks in states and local areas. CDC provides funding to support state and territorial immunization programs to 64 awardees, including all 50 states. These funds help support public health immunization workforce and systems at the state and local levels, including to respond to vaccine preventable disease outbreaks. CDC also provides critical epidemiology and laboratory capacity to respond to outbreaks, providing technical assistance to state and local areas. We expect outbreak responses to be an ongoing issue, and resource needs will be considered as new issues emerge.

Q13. As you may know, the Washington Poison Center was activated by the Washington State Department of Health (DOH) in mid-January to take calls on behalf of Clark County Public Health from both the public and healthcare facilities related to the measles outbreak. The Clark County Public Health Measles Hotline number is forwarded to the Washington Poison Center, and thus far, its personnel have taken a total of 1,162 calls on this matter. The measles hotline is staffed 24/7/365, and these calls are in addition to the average 175 toxicology calls received on a daily basis.

To adequately address the significant volume of incoming measles calls, the Washington Poison Center leadership developed an innovative process to recruit healthcare and medical students to serve as on-call contractors to assist with measles-related calls. Within 36-hours of project conception, 50 students from the fields of pharmacy, nursing and naturopaths were recruited, contracted and trained be the center's toxicology processionals. This approach has received accolades from the state Secretary of Health, the state Office of Emergency Preparedness and Response and numerous state legislators.

The University of Washington School of Pharmacy, Nursing and Public Health, as well as Bastyr University, played an integral role in addressing this public health outbreak. Do you believe it is important to have an established CDC training program for these types of students so that there will be a team pf people ready to be activated quickly in times of crisis? Are there resources that could be activated to provide this curriculum?

A13. CDC supports the education and training of state and local public health officials through a variety of resources. CDC's Public Health Emergency Preparedness (PHEP) cooperative agreement supports critical public health infrastructure, training staff to effectively respond to outbreaks and other emergency responses. States may use this funding and other support from CDC to develop training programs for surge capacity in the event of a public health emergency.

Michael C. Burgess, M.D. (R-TX)

Q1. What safety monitoring systems are in place to ensure that the vaccines on the Advisory Committee on Immunization Practices (ACIP) recommended schedule are not causing a lot of side effects?

A1. The United States' long-standing vaccine safety program closely and constantly monitors the safety of vaccines to make sure that vaccines used in the United States are safe. Vaccines are rigorously tested, and a vaccine sponsor must demonstrate that the vaccine is safe and effective before it can be licensed by the U.S. Food and Drug Administration (FDA). The FDA ensures that vaccines undergo a rigorous and extensive development program and assesses the safety and effectiveness of drugs and biological products, such as vaccines, for their intended uses. FDA conducts a thorough evaluation of this information to make a determination whether to license a vaccine for use in the United States. CDC's Division of Healthcare Quality Promotion - Immunization Safety Office (ISO) conducts post-licensure vaccine safety monitoring on vaccines licensed and recommended for routine use in the public by the U.S. Advisory Committee on Immunization Practices (ACIP).

It is important to have robust vaccine safety monitoring, including multiple systems that work in different ways to complement each other and allow CDC to rapidly detect and assess possible safety problems. CDC and FDA use a number of systems to monitor vaccine safety:

- **Vaccine Adverse Event Reporting System (VAERS)**
  - Collaboration between CDC and FDA
  - U.S. national frontline spontaneous (passive) reporting system to rapidly detect potential vaccine safety problems
  - The system is not designed to determine whether a reported adverse event was caused by vaccination, but it serves as an early warning system and helps CDC and FDA identify areas for further study
  - Potential safety problems identified in VAERS are further studied and/or investigated through CDC's Vaccine Safety Datalink or CDC's Clinical Immunization Safety Assessment Project

- **Vaccine Safety Datalink (VSD)**
  - Collaboration between CDC and integrated managed health plans
  - Considered the gold standard system for monitoring vaccine safety in the world
  - Large linked database system used for active surveillance to look for rare, serious adverse events and to conduct studies to address gaps in vaccine safety knowledge

- **Clinical Immunization Safety Assessment (CISA) Project**
  - Collaboration between CDC, medical research centers, and other vaccine safety experts
  - Conducts individual clinical vaccine safety assessments and clinical research studies on adverse events following vaccination
  - Improves understanding of potential vaccine adverse events at the individual patient-level and in special populations (e.g., pregnant women and elderly) and develop prevention strategies to address those concerns

- **FDA Sentinel Postlicensure Rapid Immunization Safety Monitoring System (PRISM)**
  - Collaboration and Contract with Harvard Pilgrim HealthCare
  - Engages more than 20 insurers and academic partners
  - Active surveillance, claims-based data system that covers more than 170 million patients in the US

- PRISM is used to addressed regulatory questions concerning vaccine safety and effectiveness

- **FDA-CMS and use of Medicare Claims data for vaccine safety surveillance**
  - Collaboration between FDA and Center for Medicare & Medicaid Services to conduct vaccine surveillance, safety and effectiveness studies
  - Covers persons 65 years of age and older plus younger disabled persons.
  - Covers more than 50 million US beneficiaries

- **FDA Biologics Effectiveness and Safety (BEST) System**
  - Includes approximately 75 million patient electronic health records (EHR) and more than 50 million patient claims data.
  - Provides rapid access to medical chart information
  - BEST can also be used to addressed regulatory questions concerning vaccine safety and effectiveness

More information is available at:
https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/index.html

Q2. Why is it important that vaccines are administered on schedule according to CDC/ACIP guidelines?

A2. The Advisory Committee on Immunization Practices (ACIP) is a group of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the United States. CDC sets the immunization schedules based on ACIP's recommendations that have been approved by the CDC Director. These recommendations are set to protect infants, children, adolescents, and adults against vaccine-preventable diseases at the earliest age possible

The ACIP carefully examines data about each vaccine-preventable disease to determine at what ages the rates of the disease peak. Protection against vaccine-preventable disease at the earliest time possible is critical, especially for young children or other high risk groups, for whom a disease can be especially serious. For example, pertussis vaccine is recommended in the United States beginning at 2 months of age to protect infants. That timing saves lives that would otherwise be lost to the disease if vaccines were not given at a very young age.

The immunization schedule also is based on balancing the risk of being exposed to the disease against the added protection of vaccinating at the age that a vaccine works best. Before a vaccine is licensed by the FDA, extensive testing is done to determine the best ages to safely and effectively give the vaccine.

Q3. What is the impact of outbreak response on the ability of state and local public health officials to perform routine public health functions?

A3. State and local health departments have the lead in investigating measles cases and outbreaks. When a suspected measles case is identified the local health department is responsible for an exhaustive investigation process. This is a significant burden on local public health in that they must expend resources in obtaining clinical specimens so that the diagnosis of measles can be confirmed by state or other public health laboratories; identify other individuals and communities that may have been exposed to the disease; provide immunizations or immune globulin as

appropriate to exposed individuals and advise individuals if they need to avoid public places; and when warranted local or state health departments may hold special immunization clinics for impacted communities or facilities. Local or state health workers are responsible for monitoring large numbers of individuals who may have been exposed to measles. Additional investigations occur for any new cases to prevent the illness from spreading further.

State health department responsibilities include coordination of activities between jurisdictions within the state, providing or coordinating financial or other resources as needed, providing laboratory support, and coordinating with CDC.

For additional information, please see the following:

- Marx GE, Chase J, Jasperse J, et al. Public Health Economic Burden Associated with Two Single Measles Case Investigations — Colorado, 2016–2017. MMWR Morb Mortal Wkly Rep 2017;66:1272–1275. DOI: http://dx.doi.org/10.15585/mmwr.mm6646a3

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Q4. Why is it important to eradicate infectious diseases like measles? Couldn't we just have low levels of circulating disease?

A4. Before the measles vaccination program started in 1963, about 3 to 4 million people got measles each year in the United States. Of those people, 400 to 500 died, 48,000 were hospitalized, and 4,000 developed encephalitis (brain swelling) from measles.

In 2000, the United States declared that measles was eliminated from this country. The United States eliminated measles because it has a highly effective measles vaccine, a strong vaccination program that achieves high vaccination coverage in children, and a strong public health system for detecting and responding to measles cases and outbreaks. CDC defines measles elimination as the absence of continuous disease transmission for 12 months or more in a specific geographic area. Measles is no longer endemic (constantly present) in the United States.

Maintaining elimination is still a priority for the United States. Since measles is still common in many countries, travelers will continue to bring this disease into the United States. Measles is highly contagious, so anyone who is not protected against measles is at risk of getting the disease. People who are unvaccinated for any reason, including those who refuse vaccination, risk getting infected with measles and spreading it to others. And they may spread measles to people who cannot get vaccinated because they are too young or have specific health conditions.

Q5. The federal government is working to develop objectives for the Healthy People 2030 goals; how can immunization best be positioned within these goals to maximize national and individually protection from infectious diseases?

A5. Healthy People provides science-based, national goals and objectives with 10-year targets designed to guide national health promotion and disease prevention efforts to improve the health of all people in the United States. The Immunization and Infectious Disease (IID) work group is responsible for 17 core objectives moving forward in Healthy People 2030, and seven of those objectives are related to immunization. CDC included Healthy People 2030 objectives that represent key metrics for immunization compliance especially related to childhood and adolescence. Among the proposed objectives, two pertained to measles, mumps, and rubella (MMR) vaccination coverage—at age 2 years and at kindergarten—as well as an objective for HPV for adolescents, and one for seasonal influenza for persons 6 months of age and older. Immunization coverage indicators for these vaccine/age groups help to identify areas of concern.