

Hearing title: “Vaccines Save Lives: What is Driving Preventable Disease Outbreaks”

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Saad B. Omer, MBBS MPH PhD

William H. Foege Professor of Global Health

Professor of Epidemiology & Pediatrics

Emory University

I am Saad B. Omer, the William H. Foege Professor of Global Health and Professor of Epidemiology & Pediatrics at Emory University, Schools of Public Health and Medicine. I have served on several scientific and public health advisory committees including the National Vaccine Advisory Committee and the Public Health Committee of the Infectious Diseases Society of America. My research has focused on vaccines –including clinical/field trials, vaccine safety studies, and studies of interventions to increase vaccine acceptance.

I want to thank the Committee for the opportunity to share my perspective on vaccine preventable diseases, the current epidemiology of measles, and the importance of vaccines. In my testimony, I will attempt to answer a few salient questions on this topic. My statement substantially draws from my previous writings and research.

Should we be concerned about the recent measles outbreaks?

The elimination of endemic transmission of measles from the United States in 2000 is considered a significant public health success. Since then, measles has mostly occurred as outbreaks — either because of imported cases (mostly from U.S. travelers returning home with the infection) or among those who come in contact with these cases.

Are the recent cases and outbreaks sporadic, or are we on the verge of the return of widespread measles? While recent measles outbreaks have been contained, the frequency and size of these outbreaks is alarming. For example, according to a CDC study, the annual median number of cases and outbreaks more than doubled during 2009–2014 compared to the earlier post-elimination years (*Fiebelkorn et. al.; J Pediatric Infect Dis Soc.; 2017*). This trend has continued since the publication of the CDC study. A return of widespread measles is not inevitable, but to ensure we prevent it, we need to seriously address causes of non-vaccination including vaccine refusal.

Notably, each year there are children not vaccinated against measles. These nonimmunized children join the ranks of all other susceptible children from years past, increasing the population of susceptible people. With the slow and steady accumulation of people who haven't been immunized, we may only be delaying a large measles outbreak. In fact, in an epidemiological study my research collaborators and I published in 2016, we estimated that 1 in 8 children younger than 18 are susceptible to measles (*Bednarczyk, Orenstein, & Omer; American J. Epi, 2016*).

Importantly, we found that the rate of protection against measles is hovering dangerously close to the “herd immunity threshold” — computed as the proportion of people who need to be immune to prevent outbreaks. Similar findings have been subsequently reported by other researchers, highlighting the need for interventions to improve measles vaccination rates. If vaccine refusal is left unchecked, more people will be susceptible to this disease, leading to larger outbreaks and possibly resumption of sustained transmission.

Why haven't we seen a national level measles outbreak in recent years?

A national outbreak, or an outright national-level measles resurgence, would not be out of the ordinary for a Western country. In recent years, there have been several large sustained outbreaks in Europe. In Italy, for example, approximately 5,000 measles cases were reported from February 2017 to January 2018. Similarly, large national-level outbreaks have occurred in Britain, Germany, and France. In 2008, the World Health Organization reported approximately 60,000 measles cases from countries included in its European region. While most European countries, including Britain, have been certified as having eliminated measles, the disease is still considered endemic in Italy, Germany, and France.

It's not just luck that the United States hasn't seen a similar resurgence. There are many things the United States does right in vaccine policy, compared to Europe. For example, the United States has a tapestry of school-entry vaccine requirements that work. These requirements, based in state laws, have contributed to maintaining high immunization rates and keeping rates of vaccine noncompliance low. In the U.S., the Centers for Disease Control and Prevention (CDC) aggressively monitors and responds to emerging outbreaks — an epidemiological firefighting function it performs with state and local health departments. In Europe, on the other hand, the effectiveness of public health agencies is uneven. The European Centre for Disease Prevention Control, a much smaller and newer agency compared to the American CDC, lacks the resources and mandate to perform a similar function. U.S. professional medical societies such as the American Academy of Pediatrics and the Infectious Diseases Society of America have been at the forefront of vaccine advocacy — leveraging the fact that physicians are the most trusted source of vaccine information.

But while a national measles resurgence in the United States has been so far kept at bay, we cannot be complacent. With the steady accumulation of susceptible individuals in our communities, efforts are required at the national, state, and local level to ensure that this dangerous disease does not return in full force.

What is the role of vaccine refusal in measles outbreaks?

In a 2016 paper, my colleagues and I evaluated the association between vaccine delay, refusal, or exemption and the epidemiology of measles in the United States (*Phadke et al.; JAMA, 2016*). We found that since the elimination of measles from the United States in 2000, more than half (56.8%) of measles cases had no history of measles vaccination. Among the unvaccinated, age-eligible measles cases for whom the reason for non-vaccination was available, 70.6% had a nonmedical exemption to vaccination.

One tool epidemiologists use to chart the temporal course of outbreaks is the epidemic curve in which the daily cases of a disease are plotted against time. In the 2016 paper, we created

a cumulative epidemic curve comprising of all measles outbreaks since 2000 for which relevant data were available. According to this cumulative epidemic curve, unvaccinated individuals made up a greater proportion of measles cases in early parts of epidemics –meaning that unvaccinated people provided the tinder to start the fires of these epidemics.

In an earlier national study, the risk of measles among children with vaccine exemptions was 35 times that of the vaccinated population (*Salmon et.al; JAMA, 1999*). Equally importantly, higher rates of vaccine exemption in a community are associated with greater measles incidence in that community, among both the exempt and nonexempt population. One reason for ongoing outbreaks is the epidemiological phenomenon of clustering of susceptible individuals — which happens when a group of unvaccinated individuals in a specific area grows large enough to render protection from overall high immunization rates less effective.

Is vaccine refusal the only reason for recent outbreaks?

While vaccine refusal is an important risk factor for vaccine preventable disease outbreaks, it is not the only reason why these outbreaks occur. For example, CDC reported insurance status is an important factor in non-vaccination (*Hill et al.; MMWR; 2018*). Similarly, while vaccine refusal plays a role, waning immunity is an important cause of decline in pertussis (whooping cough) vaccine effectiveness and subsequent outbreaks (*Klein et al.; NEJM; 2012*).

Are vaccine mandates a useful policy option for controlling vaccine-preventable diseases?

State laws in the United States mandate that every child entering kindergarten either provide proof of being immunized or file for an exemption. All 50 states allow for medical exemptions from mandated vaccinations. Eighteen states allow religious and personal belief exemptions, 30 states permit religious exemptions only, and 3 states only allow medical exemptions. Mandates have played a key role in keeping disease rates low. Because vaccination and exemption laws are established at the state level, there is substantial variation in immunization requirements, types of nonmedical exemptions offered (i.e. personal belief exemption vs. only religious exemption), ease of obtaining an exemption, and enforcement of immunization legislation across the United States (*Omer et al.; NEJM; 2009*).

The amount of administrative effort needed to complete the exemption process varies by state. Vaccine laws in the U.S. work by changing the balance of convenience in favor of vaccination and away from non-vaccination. Ease of obtaining a nonmedical exemption has been shown to be associated with state vaccine exemption rates — and, more importantly, higher rates of vaccine-preventable diseases. In a 2006 study published in *The Journal of the American Medical Association*, for example, we documented that states with easy procedures for granting nonmedical exemptions had higher rates of vaccine refusal and approximately 50 percent higher rates of whooping cough (*Omer et al.; JAMA; 2006*). The association between ease of exemption

and vaccine refusal rates has been consistent in our subsequent studies as well (*Omer et al.; NEJM, 2012 & Omer et al.; Open Forum Infect Dis.; 2017*).

The policy option of eliminating all nonmedical exemptions is being discussed in a few states. However, the evidence on the impact of this option is nuanced and evolving. Until recently, West Virginia and Mississippi were the only two states that did not allow any nonmedical exemptions. These states have traditionally had some of the highest immunization rates in the country. California recently eliminated nonmedical exemptions. The initial results from this policy change (through California law SB277) are nuanced. In addition to the implementation of this law, there was a state-level administrative initiative to correctly apply “conditional entrance” requirements – a category meant for children who had started but not completed their vaccine schedule or had temporary medical exemptions. Prior to the enforcement initiative, this category was inconsistently applied and, sometimes, misused. While there has been an increase in the percentage of California kindergarteners entering school fully vaccinated, publicly available data suggest that this increase may be mostly due to the pre-SB277 education- and enforcement-based effort to correctly apply the conditional entrance requirements. Importantly, there is evidence of an emerging *replacement effect* as a result of increase in children being not up-to-date for vaccines due to other categories e.g. through increase in medical exemptions.

Irrespective of emerging evidence from California, states have other policy options short of eliminating all nonmedical exemptions. For example, states can tweak their rules to make sure parents are as informed as possible by adding a legally mandated physician counseling requirement for those seeking exemptions. This approach has been effective in reducing nonmedical exemptions (*Omer et al.; Pediatrics; 2018*). Moreover, states can reconfigure their immunization requirements to tilt the balance of convenience in favor of vaccination (*Omer et al.; NEJM; 2019*).

Vaccine mandates are implemented at the state level. Can the federal government do anything about vaccine acceptance and controlling outbreaks?

I believe the federal government has a substantial role to play in increasing vaccine acceptance. While vaccine mandates are a state-level issue, there are many policy options within the purview of the federal government. I will highlight a few of them:

1. Consider making vaccine counseling reimbursable

Several factors associated with vaccine acceptance vary by location and demographics. But there is one constant: healthcare providers, particularly physicians, are the most trusted source of vaccine information – even among those who refuse vaccines (e.g. *Freed et al.; Pediatrics; 2011*). A strong physician recommendation for vaccines is an extremely useful tool for immunization acceptance. However, having an effective conversation with vaccine hesitant parents requires time and effort.

Unfortunately, the time spent on vaccine hesitant patients is not billable – further disincentivizing physicians from having this difficult but useful conversation.

2. Invest in vaccine acceptance/communication research.

While vaccine communication and acceptance interventions are an active area of research, a lot more needs to be done. In recent years, several promising leads have emerged –many from federally funded research. For example, research on “presumptive communication” leverages power of verbal defaults-based “nudges” for framing vaccine conversations (*Opel & Omer; JAMA Pediatr.; 2015*). Similarly, motivational interviewing – a well-established counseling technique that has been evaluated to increase vaccine acceptance – works through people’s internal motivation for desirable health behavior (*Dempsey et al.; JAMA Pediatr.; 2018*). In my research group, multi-tiered practice-provider-patient based interventions (the so called P3 model) have shown promise. However, current vaccine acceptance research is sporadic and a focused, high priority research program is needed. Fortunately, there are examples of similar high priority behavioral and communication research that can be emulated. These examples and potential templates include National Cancer Institute’s Behavioral Research Program – a comprehensive program of research to increase the breadth, depth, and quality of behavioral research in cancer prevention and control. Given its role as the nation’s premier biomedical and behavioral health research agency, it would be natural for NIH to have a leading role in guiding these investments.

3. Implement the National Vaccine Advisory Committee’s recommendations

While there is need for new research, there are existing approaches that can increase confidence in and acceptance of vaccines. Fortunately, an evidence-based blueprint exists in the form of recommendations published in 2015 by the National Vaccine Advisory Committee, an independent committee charged with the advising the Department of Health and Human Services (*NVAC; Public Health Rep.; 2015*). These recommendations focus on evidence-based strategies for increasing confidence in vaccines. Unfortunately, these recommendations have not been fully implemented.

4. Support CDC’s mission of controlling measles outbreaks

As I mentioned earlier, CDC – in collaboration with state and local health departments – plays an important role in controlling outbreaks of vaccine preventable diseases such as measles. Responding to these outbreaks is costly and time and labor-intensive. Ensuring that CDC continues to have adequate resources will help with maintaining adequate outbreak response capabilities in the face of increasing outbreaks.

5. Continue to prioritize vaccine safety research

Over the years, the U.S. has developed a robust vaccine safety research infrastructure. CDC’s Vaccine Safety Datalink system utilizes data from 9 HMOs from across the country to conduct active epidemiologic surveillance for vaccine safety. The Vaccine Adverse Events Reporting System maintained by the CDC and the FDA captures spontaneous reports of potential vaccine side effects. The FDA’s Sentinel is the largest system available in the U.S. for vaccines adverse event surveillance. Similarly, the FDA’s pre-licensure and post licensure safety review of vaccines is useful in ensuring vaccine safety. Continued support for these vaccine safety initiatives is not just useful for ensuring confidence in vaccines but, more importantly, it’s the right thing to do. However, it is important that assessment of vaccine safety continues to be science-based.

6. Maintain bipartisan and vociferous support for vaccines

This committee has previously expressed strong support for vaccines –through statements supporting vaccines. Such statements matter. They indicate broad social support for vaccines and signal to the so-called fence sitters that vaccination is the social norm. As someone who has spent his professional life ensuring children and adults are protected from infectious diseases, I personally thank you for these statements.

We have a history of bipartisan action for vaccines

In the aftermath of the last measles resurgence in the United States in 1989-1991, there was a remarkably bipartisan effort to address the main cause of that resurgence: vaccine access. President Bill Clinton and congressional Republicans and Democrats came together to establish the Vaccines for Children program to remove affordability as a barrier to vaccination. This program was effective in addressing inequities in immunization coverage. Preventing the next potential resurgence of measles will require a similar broad-based response.

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