

# Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries

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## Executive Summary

On December 5, 2025, President Trump issued a Presidential Memorandum<sup>1</sup> directing the Secretary of the U.S. Department of Health and Human Services (HHS) and the Acting Director of the Centers for Disease Control and Prevention (CDC) to review best practices from peer, developed nations regarding childhood vaccination recommendations and the scientific evidence underlying those practices. The President instructed them to update the U.S. core childhood vaccine schedule if they determine that superior practices exist abroad.

This assessment is a scientific, evidence-based, data-driven response to the President’s directive. It argues that a change in the U.S. childhood vaccine schedule is necessary. It compares the U.S. with peer nations, examines vaccine uptake and trust, addresses clinical and epidemiological considerations and knowledge gaps, analyzes vaccine mandates, and outlines recommendations and next steps for immediate and long-term action.

The U.S. is a global outlier among peer nations in the number of target diseases included in its childhood vaccination schedule and in the total number of recommended vaccine doses.<sup>2</sup>

The Acting CDC Director should immediately consider updating the Childhood Immunization Schedule to keep vaccines for 10 diseases—measles, mumps, rubella, polio, pertussis, tetanus, diphtheria, Haemophilus influenzae type B (Hib), pneumococcal disease, and human papillomavirus (HPV)—for which peer, developed nations share international consensus, as well as varicella (chickenpox) (the “consensus vaccines”) in the category of vaccines recommended for all children. These consensus vaccines will represent the core childhood vaccine schedule. This report does not substantively address the consensus vaccines. All other vaccines currently on the U.S. schedule (the “non-consensus vaccines”) should be recommended for high-risk groups and populations and/or through shared clinical decision-making, by taking individual patient characteristics into account (Figure 1). No vaccine should be moved to the “not recommended” category.

Therefore, the Acting CDC Director should update the childhood immunization schedule to reflect these three distinct components:

#### IMMUNIZATIONS RECOMMENDED FOR ALL CHILDREN

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	7 mos	8 mos	12 mos	15 mos	18 mos	19 mos	20-23 mos	2-3 yrs	4-6 yrs	7 yrs	8 yrs
Diphtheria, tetanus, acellular pertussis (DTaP < 7 yrs)			1st dose	2nd dose	3rd dose				4th dose					5th dose		
Tetanus, diphtheria, acellular pertussis (Tdap ≥ 7 yrs)																
Haemophilus influenzae type b (Hib)			1st dose	2nd dose	3rd dose			3rd / 4th dose								
Pneumococcal conjugate (PCV15, PCV20)			1st dose	2nd dose	3rd dose			4th dose								
Inactivated poliovirus (IPV < 18 yrs)			1st dose	2nd dose	3rd dose									4th dose		
Measles, mumps, rubella (MMR)								1st dose						2nd dose		
Varicella (VAR)								1st dose						2nd dose		
Human papillomavirus (HPV)																

Vaccine and other immunizing agents	9 yrs	10 yrs	11 yrs	12 yrs	13 yrs	14 yrs	15 yrs	16 yrs	17 yrs
Diphtheria, tetanus, acellular pertussis (DTaP < 7 yrs)									
Tetanus, diphtheria, acellular pertussis (Tdap ≥ 7 yrs)			1st dose						
Haemophilus influenzae type b (Hib)									
Pneumococcal conjugate (PCV15, PCV20)									
Inactivated poliovirus (IPV < 18 yrs)									
Measles, mumps, rubella (MMR)									
Varicella (VAR)									
Human papillomavirus (HPV)			1 dose						



Some children should get a dose at this age depending on the vaccine brand.

#### IMMUNIZATIONS RECOMMENDED FOR CERTAIN HIGH-RISK GROUPS OR POPULATIONS

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	7 mos	8 mos	12 mos	15 mos	18 mos	19 mos	20-23 mos	2-3 yrs	4-6 yrs	7 yrs	8 yrs
Respiratory syncytial virus (RSV-mAb) <sup>1</sup>	1 dose															
Respiratory syncytial virus (RSV-mAb) <sup>2</sup>	1 dose						2nd dose									
Hepatitis B (HepB) <sup>3</sup>	1st dose	2nd dose					3rd dose									
Dengue <sup>4</sup>																
Meningococcal ACWY <sup>5</sup>			2, 3 or 4 dose series													
Meningococcal B <sup>6</sup>																
Hepatitis A (HepA) <sup>7</sup>																

Vaccine and other immunizing agents	9 yrs	10 yrs	11 yrs	12 yrs	13 yrs	14 yrs	15 yrs	16 yrs	17 yrs
Respiratory syncytial virus (RSV-mAb) <sup>1</sup>									
Respiratory syncytial virus (RSV-mAb) <sup>2</sup>									
Hepatitis B (HepB) <sup>3</sup>									
Dengue <sup>4</sup>	3 dose series								
Meningococcal ACWY <sup>5</sup>									
Meningococcal B <sup>6</sup>			1 dose						
Hepatitis A (HepA) <sup>7</sup>									

<sup>1</sup> All children whose mother did not have the vaccine should get one dose.

<sup>2</sup> High-risk children, such as those with chronic lung disease, should receive a second dose at ages 8 to 19 months.

<sup>3</sup> Vaccination recommended for infants born to women who tested positive for the hepatitis B virus or whose status is unknown.

<sup>4</sup> Recommended ONLY if living in areas with endemic dengue AND with a laboratory confirmation of previous dengue infection.

<sup>5</sup> For high-risk groups (e.g., those with anatomic or functional asplenia or HIV infection), those traveling to countries with hyperendemic or epidemic meningococcal disease, and first-year college students living in residential housing, vaccination is recommended.

<sup>6</sup> Recommended for high-risk groups, e.g., with anatomic or functional asplenia, and during outbreaks.

<sup>7</sup> Vaccination recommended for international travel to areas with high or intermediate hepatitis A endemicity.

# IMMUNIZATIONS BASED ON SHARED CLINICAL DECISION-MAKING

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	7 mos	8 mos	12 mos	15 mos	18 mos	19 mos	20–23 mos	2–3 yrs	4–6 yrs	7 yrs	8 yrs	
Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)			1st dose	2nd dose	3rd dose												
COVID-19 (IvCOV-mRNA, IvCOV-aP5)					2 doses first year, then 1 dose annually								1 dose annually				
Influenza (IIV3, ccIIV3)	OR				2 doses first year, then 1 dose annually								OR				
Influenza (IAIV3)												2 doses first year, then 1 dose annually					
Hepatitis A (HepA)								2-dose series									
Hepatitis B (HepB) *			1st dose	2nd dose	3rd dose												
Meningococcal ACWY																	
Meningococcal B																	

Vaccine and other immunizing agents	9 yrs	10 yrs	11 yrs	12 yrs	13 yrs	14 yrs	15 yrs	16 yrs	17 yrs
Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)									
COVID-19 (IvCOV-mRNA, IvCOV-aP5)									
Influenza (IIV3, ccIIV3)	OR	1 dose annually							
Influenza (IAIV3)		1 dose annually							
Hepatitis A (HepA)									
Hepatitis B (HepB) *									
Meningococcal ACWY			1st dose					2nd dose	
Meningococcal B								2 or 3 doses	



Some children should get a dose at this age depending on the vaccine brand.

\* For parents deciding whether to vaccinate for HepB in infants born to women who tested negative for the hepatitis B virus, it is suggested that the initial dose is administered no earlier than 2 months of age.

*Figure 1: Proposed immunization schedule from birth up to age 18, with recommendations for all children (yellow), recommendations for high-risk groups or populations (purple), and immunizations with shared clinical decision-making (blue), all available and covered by insurance for all children and adolescents without cost sharing.*

Importantly, all immunizations recommended by the CDC at the end of 2025—and covered by insurance at that time—should remain covered by insurance without cost sharing, as they should all remain on the schedule. This would include all diseases covered by the 2025 childhood and adolescent immunization schedule. By comparison, in many European countries, vaccines not recommended for routine use are typically not covered. By distinguishing non-consensus vaccines as options based on individual risk factors, we can better define those risk factors and identify the children who are most likely to have a net-benefit from these vaccines.

Between 2020 and 2024, trust in health care declined steeply from 71.5% to 40.1%, coinciding with school closures, other lockdowns, mandatory face masks, COVID-19 vaccination mandates with their de facto denial of infection acquired immunity, and other public health recommendations that lacked scientific rationale and went against basic principles of public health.<sup>3</sup> The distrust of public health agencies during the pandemic has spilled over to other recommendations made by these agencies, including those with respect to vaccines. Over the same period, there was a decline in childhood vaccination rates across the country, with, for example, a reduction in measles, mumps, and rubella (MMR) vaccination from 95.2% to 92.7%.<sup>4,5</sup> This has increased the potential risk for measles cases.<sup>6</sup>

Instead of implementing vaccination mandates, most peer nations maintain high childhood vaccination rates through public trust and education (Table 1). This is in contrast to the U.S.,

where individual states can set mandatory vaccination requirements for children as a requirement to attend school.<sup>7</sup> Among the fundamental principles of public health are respect for personal autonomy and self-determination, and informed consent is a cornerstone of medical care.<sup>8,9,10</sup> While vaccine mandates may increase short-term vaccination rates,<sup>11</sup> coercive measures can also have negative consequences on trust that may decrease long-term vaccination rates for consensus vaccines.<sup>12,13,14</sup> Increased emphasis on personalized medicine would improve informed consent and the doctor patient relationship, leading to a better educated and empowered public. The increased emphasis on shared clinical decision-making would help restore trust in public health recommendations made by CDC.

Vaccines are intended to benefit children by preventing them from being infected by certain infectious diseases. But, like all medicines, vaccines come with risk that must be balanced against their benefits.<sup>15</sup> Before and after licensure, manufacturers have inadequate incentives to study vaccine adverse effects. Regulatory bodies, including the FDA and the CDC have sometimes been slow to identify adverse effects in post-market studies.<sup>16</sup> Vaccine safety and risks are therefore often poorly characterized, quantified, or understood. Scientifically valid rates of adverse events are rarely available to determine the relationship, if any, between our country's immunization schedule and the increasing prevalence of chronic diseases in American children.<sup>17</sup> Medical interventions given to healthy children to prevent diseases, rather than treat or cure them, should have the highest standard of safety pre-and-post marketing.<sup>18</sup>

To address the safety concerns regarding the child and adolescent immunization schedule, HHS should fund gold standard scientific research, including large placebo-controlled randomized trials as needed, both on individual vaccines, combination of vaccines, and vaccination schedules. Putting aside the ethics of administering a medical product that was not properly trialed to affirm its safety, this can be ethically accomplished by, among other methods, randomizing the timing of vaccination.<sup>19</sup> HHS should also fund and conduct observational studies concerning long-term chronic adverse effects of both individual vaccines and the immunization schedule. This will better inform patients/parents and physicians moving forward, increase trust in public health, and improve the state of vaccine science globally.

This assessment only considers immunizations that CDC recommended for all children at the end of 2024. It does not consider the timing or order of vaccines, nor the number of doses, with the exception of the HPV vaccine.

Bringing the U.S. pediatric immunization schedule in line with the consensus of peer nations while keeping non-consensus vaccines available for high-risk groups and populations and/or through shared clinical decision-making is a balanced approach to reform and restore trust in public health. Coupled with an evaluation of potential vaccine harms, this reform seeks to restore

public confidence, provide much-needed clarity for parents of young children, and preserve the benefits of immunization programs.

## **1. Vaccine Uptake and Trust**

In 1980, American children following the CDC immunization schedule received 23 vaccine doses in 7 shots against 7 different diseases (1 MMR, 5 DTP, 1 Td) plus 4 OPV drops. In 2024, the recommended number of routine vaccines had risen to at least 84 vaccine doses in at least 57 shots for 17 diseases, plus the RSV monoclonal antibody immunization for a total of 18 diseases.<sup>20,21,22,23,24,25,26,27</sup> This is more than other developed nations (Table 2).<sup>28</sup>

### **1.1 Vaccine Uptake**

In the decade before the COVID-19 pandemic, the U.S. had high and stable childhood vaccination rates.<sup>29</sup> This changed with the pandemic lockdowns, which generated a drop in childhood vaccine uptake across all age groups (Figure 2). While the vaccination rates have rebounded, the created gaps have never been compensated for through catch-up vaccinations.<sup>30</sup>

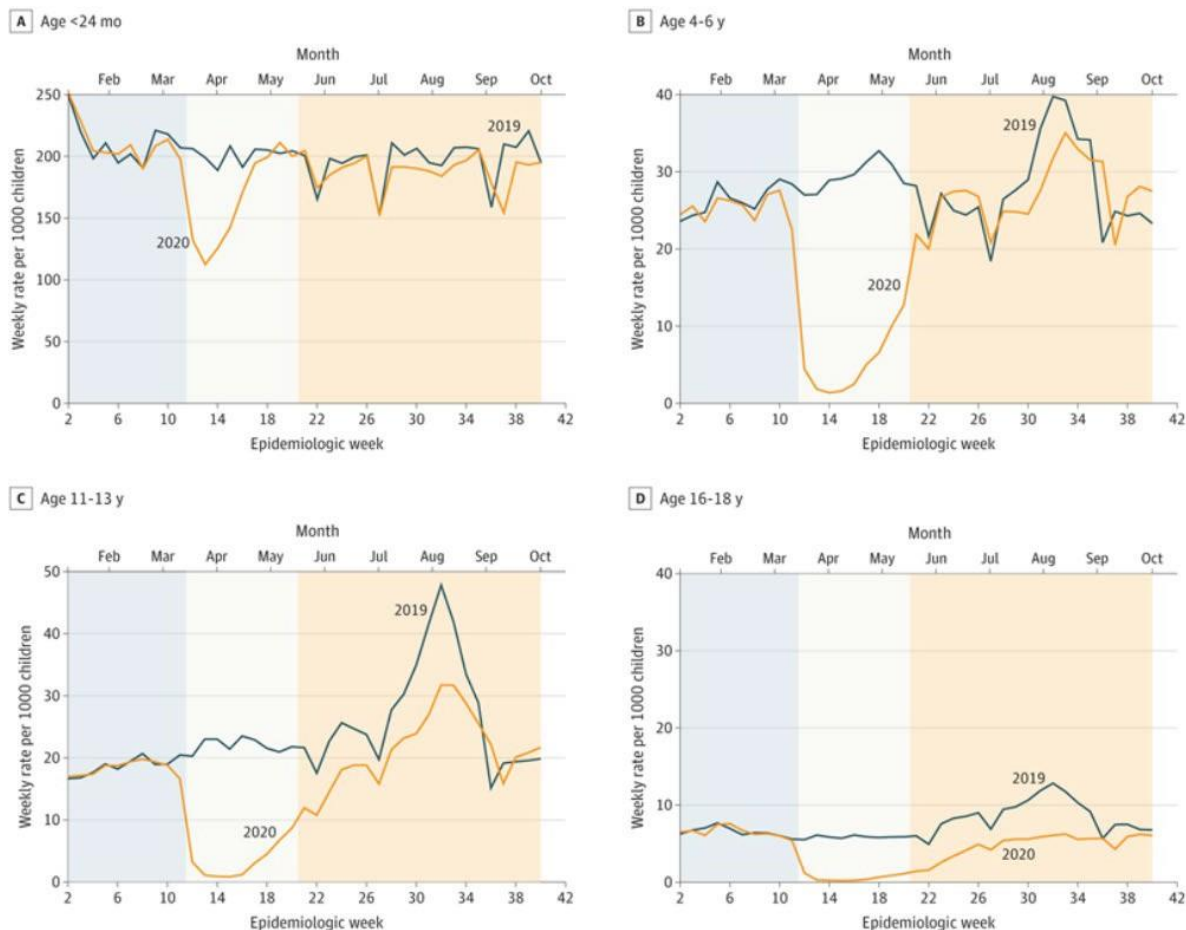
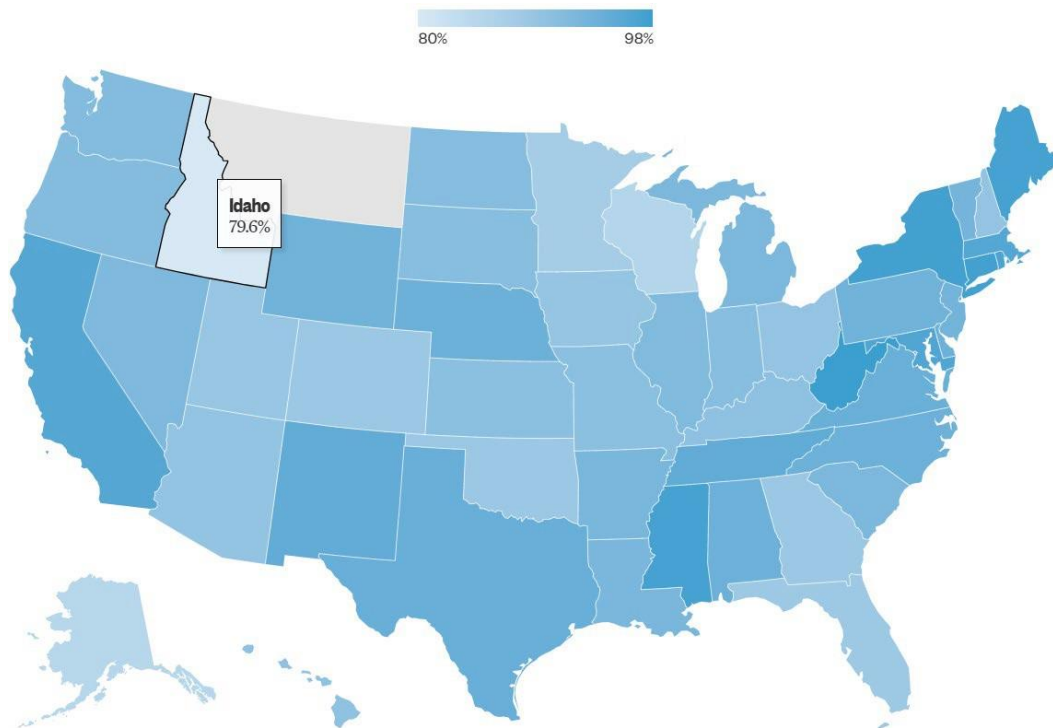


Figure 2: Childhood vaccine uptake by age during the 2020 lockdowns compared to 2019, in health plans providing data to CDC's Vaccine Safety Datalink.<sup>31</sup>

A fundamental principle of public health is trust.<sup>32</sup> For the public to trust public health agencies, those agencies must trust the public, which includes providing accurate information and being honest when the scientific knowledge is incomplete. This particularly fell apart during the COVID-19 pandemic. With COVID-19 vaccine mandates and false CDC claims that vaccine-acquired immunity was superior to infection-acquired immunity<sup>33,34,35,36</sup> and that the COVID-19 vaccine would prevent infection and transmission,<sup>37,38,39</sup> the public lost trust in the COVID-19 vaccine. For example, while CDC still recommended the COVID-19 booster for all children in 2023, the uptake was less than 10%.<sup>40</sup>

The loss of trust during the pandemic not only affected the COVID-19 vaccine uptake. It also contributed to less adherence to the full CDC childhood immunization schedule, with lower rates of consensus vaccines such as measles, rubella, pertussis, and polio.<sup>41</sup> From the 2019-2020 to 2023-2024 school years, childhood vaccination rates against measles, mumps, and rubella (MMR) declined from 95.2% to 92.7%.<sup>42</sup>

Even when the national vaccination rate is very high, lower regional rates can lead to cases of these diseases. Some states have vaccination rates below the estimated community immunity threshold for both measles and rubella.<sup>43</sup> In the 2024-2025 school year, 16 states had MMR vaccination rates below 90% (Figure 3). Rubella has a community immunity threshold of 83-85%,<sup>44</sup> leaving some states, such as Idaho and Wisconsin, at risk of rubella cases.



*Figure 3: Vaccination rates by state for the second dose of the measles, mumps and rubella vaccination among kindergarteners during the 2023-2024 school year.<sup>45</sup>*

## 1.2 Measles Outbreaks

When vaccine uptake for certain diseases decreases below a certain percentage of the community, it may lead to disease transmission or cases of those diseases.<sup>46</sup> For measles, minimum vaccination coverage threshold is estimated to be above 90%, below which the risk of cases increases.<sup>47,48</sup> Up until December 31, there had been 49 measles outbreaks reported in 2025 across the U.S., noting that an “outbreak” is defined as three or more related cases, and 88% of confirmed cases (1,820 of 2,065) were outbreak-associated<sup>49</sup> (Figure 4).

The U.S., Canada, and much of Europe have recently seen increasing measles cases and Canada recently lost its measles elimination status.<sup>50</sup>

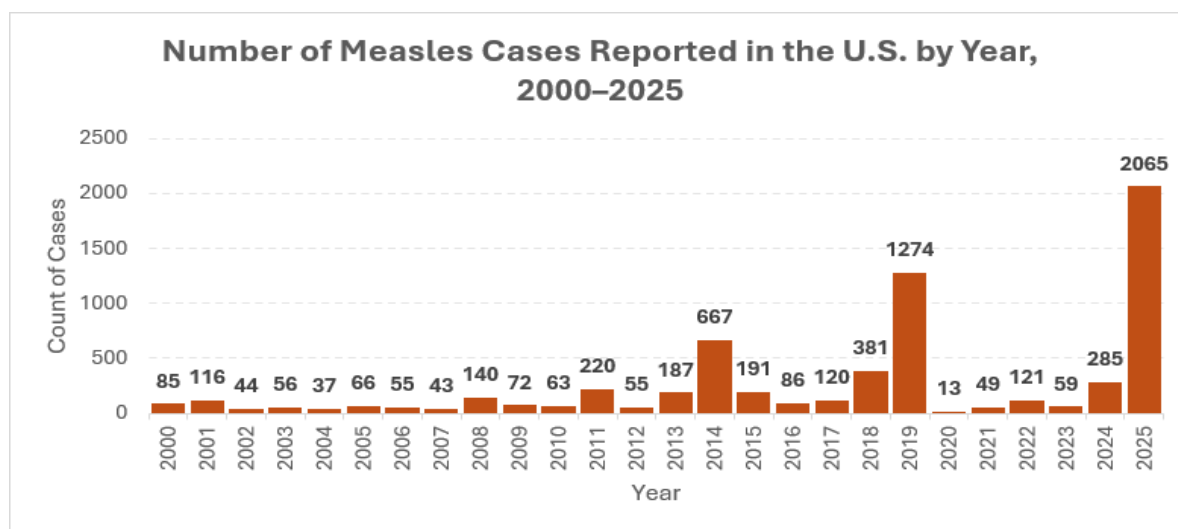


Figure 4: The number of measles cases reported in the U.S. by year, from 2000 to 2025.<sup>51</sup>

### 1.3 Vaccine Mandates and Trust

With a few exceptions, peer nations do not have childhood vaccination mandates. They have shown that transparent and trustworthy public health authorities can achieve very high voluntary vaccination rates while preserving informed consent (Table 1). The U.S. is among a minority of peer nations with childhood vaccine mandates (enacted by individual U.S. states) for school entry (Table 2). Education is critical to the development of children, and among other things is highly correlated with health and income. Many children lost over a year of schooling during the COVID-19 pandemic, with negative impacts on their academic performance.<sup>52</sup>



	dose:	Measles		Rubella	DTP		Polio		Hib	PCV	HPV		Average
		1st	2nd	1st	1st	3rd	1st	3rd	3rd	3rd	girls 1st	boys 1st	
<b>Many Vaccine Mandates</b>		<b>93%</b>	<b>91%</b>	<b>93%</b>	<b>96%</b>	<b>94%</b>	<b>96%</b>	<b>94%</b>	<b>94%</b>	<b>91%</b>	<b>65%</b>	<b>59%</b>	<b>88%</b>
Australia (13 vaccines)		91%	92%	91%	93%	93%	93%	94%	93%	95%	73%	70%	89%
France (11)		95%	93%	95%	99%	96%	99%	96%	96%	96%	48%	37%	86%
Italy (10)		95%	84%	95%	94%	94%	94%	94%	95%	90%	66%	59%	87%
United States (# varies by state)		92%	95%	92%	98%	94%	97%	93%	92%	84%	74%	70%	89%
<b>No Vaccine Mandates</b>		<b>93%</b>	<b>89%</b>	<b>93%</b>	<b>96%</b>	<b>94%</b>	<b>96%</b>	<b>94%</b>	<b>94%</b>	<b>89%</b>	<b>74%</b>	<b>71%</b>	<b>89%</b>
Austria		90%	84%	90%	95%	85%	95%	85%	85%	..	53%	42%	80%
Denmark		94%	93%	94%	97%	96%	97%	96%	96%	96%	89%	87%	94%
Finland		94%	92%	94%	97%	91%	97%	91%	91%	87%	71%	63%	88%
Greece		91%	71%	91%	98%	95%	98%	95%	99%	90%	..	..	92%
Ireland		90%	90%	90%	93%	92%	93%	92%	92%	84%	73%	69%	87%
Japan		95%	96%	95%	99%	99%	98%	98%	96%	91%	39%	..	91%
Netherlands		89%	81%	89%	91%	91%	91%	91%	89%	88%	63%	59%	84%
New Zealand		89%	87%	89%	94%	89%	99%	97%	89%	60%	53%	52%	82%
Norway		96%	94%	96%	99%	97%	99%	97%	97%	95%	93%	92%	96%
Portugal		99%	96%	99%	99%	99%	99%	99%	99%	98%	91%	88%	97%
Spain		97%	92%	97%	98%	94%	98%	94%	94%	92%	90%	83%	94%
Sweden		93%	92%	93%	97%	96%	97%	95%	95%	94%	91%	87%	94%
Switzerland		96%	93%	96%	97%	96%	97%	96%	95%	91%	78%	64%	91%
United Kingdom		89%	85%	89%	92%	92%	92%	92%	92%	89%	75%	70%	87%
<b>Partial Vaccine Mandates</b>													
Belgium (only polio)		96%	82%	96%	98%	97%	99%	98%	97%	94%	80%	73%	92%
Canada (2/10 provinces)		92%	79%	92%	92%	92%	92%	92%	90%	85%	86%	81%	88%
Germany (only measles)		96%	92%	96%	97%	89%	97%	88%	88%	75%	68%	46%	85%

Table 1: WHO/UNICEF estimates of national immunization coverage (WUENIC) for some core vaccines in 2024. No estimates available for the other core vaccines, nor for PCV/Austria, HPV/Greece or HPV/boys/Japan. For HPV the percentages are for the vaccination program coverage, that is, the percent of the target population that received the vaccine that year. Note that, if vaccination rates are declining, the uptake of a second or third dose can sometimes be higher than the first dose.<sup>53,54</sup>

It is generally considered contrary to basic medical ethics to coerce or require a medical intervention, and informed consent is a cornerstone of medical care in the U.S. and abroad.<sup>55</sup> In its Code of Medical Ethics, the American Medical Association states that “*Informed consent in medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making.*”<sup>56</sup> In its Public Health Code of Ethics, the American Public Health Association asserts that “*the effective and ethical practice of public health depends upon social and cultural conditions of respect for personal autonomy, self-determination, privacy, and the absence of domination in its many interpersonal and institutional forms.*”<sup>57</sup>

Some peer countries have recognized that each additional vaccine may erode trust in the entire childhood immunization schedule, resulting in lower uptake of consensus childhood vaccines. Danish health authorities have specifically expressed concerns about adding vaccines to the routine childhood immunization schedule when the opportunity for benefit in non-high-risk populations is low and/or when the disease does not pose a mortality or long-term disability risk.<sup>58</sup> For example, when deciding not to recommend the hepatitis B (HepB) vaccine for all children, the Danish public health authority stated that *“if one includes a vaccine which some consider less important, it could negatively affect the view of vaccines in general. The result of this could be that the current [vaccination] program would have lower uptake,”* and that *“A prerequisite for a successful vaccination program with high uptake has been, in other words, that [the vaccine] is seen as an attractive offer.”*<sup>59</sup>

Another key aspect of medicine is mutual trust between patients and physicians.<sup>60</sup> In the U.S., health insurers incentivize physicians with financial bonuses tied to vaccination rates of their patient population,<sup>61</sup> which can encourage coercive vaccination experiences. This can create both distrust in the vaccination schedule and a medical culture which may be reluctant to question vaccine safety. Some children from families who do not consent to certain vaccines have difficulty obtaining medical care because many pediatricians dismiss children from their practice if the parents refuse to have their children vaccinated.<sup>62</sup>

The concomitant administration of multiple separate (not combined into one multivalent product) childhood vaccines on the same day, has raised concerns among some parents about following the recommended vaccines schedules,<sup>63</sup> as there is limited post-market epidemiological research on interaction effects between vaccines in the same schedule.<sup>64</sup> Denmark has managed to minimize the concomitant administration of multiple vaccines by giving a pentavalent (with 5 diseases-targeted-in-one vaccine) three times in the first year of life; separating administration of the MMR and DTaP vaccines into different visits; and vaccinating children for fewer diseases.<sup>65</sup> Without resorting to vaccine mandates, Denmark has achieved consistently high rates of uptake for the consensus recommended vaccines and a lack of serious disease outbreaks.<sup>66,67</sup>

A new U.S. childhood schedule that removes the routine recommendation for non-consensus vaccines could lessen coercion and increase public trust.

**A successful childhood vaccination program requires mutual trust between patients/parents and physicians/public health authorities. This is built on four pillars:**

1. Scientific honesty about vaccines, including what is known and not known.
2. Informed consent; not coercion.
3. A vaccine approval process using evidence-based science and thorough post-licensure evaluation of vaccine safety and risks.
4. Recommendations that take account of the experience of peer nations.

## **2. Knowledge Gaps**

A 2013 report from the Institute of Medicine (IOM) stated that “*vaccines—like all drugs or medical interventions—are neither 100 percent risk-free nor 100 percent effective.*”<sup>68</sup> It is hence essential to have a robust science-based system to detect potential risks, using both pre-licensure placebo-controlled randomized trials and post-licensure observational pharmacovigilance studies. If there is a problem that is not detected in pre-licensure trials, it needs to be detected as soon as possible.<sup>69,70</sup> A robust clinical trial and safety surveillance system is critical to ensure trust in the recommended childhood vaccine schedule.

### **2.1 State of the Evidence for Childhood Vaccinations**

Given the growing distrust that the American people have in the current childhood vaccine schedule, there is a need for more and better science, including gold standard placebo-controlled randomized trials.<sup>71</sup> This could help address knowledge gaps about potential side effects and risk/benefit profiles. Until more studies are completed, the childhood vaccination recommendations must be based on the best available evidence, however limited, and the best practices of peer, developed nations.

To establish a solid scientific basis for the childhood vaccine schedule and to inform global best practices for childhood vaccinations, HHS agencies should fund gold standard science to assess overall health outcomes related to both consensus and non-consensus vaccines, the interaction effects between different vaccines, as well as other aspects of the vaccine schedule. Placebo-controlled randomized trials can be done in an ethical manner by, for example, randomizing the age of vaccination, with the control group getting a placebo at the earlier age but the vaccine at a later time<sup>72</sup> or by studying vaccines for which there is no international consensus about the recommendation.

Those who are convinced that vaccines are safe will welcome randomized, placebo-controlled trials, as they will show that the vaccines are safe if they are safe. Those who are concerned about potential side effects of vaccines will also welcome these trials, as they will detect

problems if problems exist. Prior to completion of these studies, HHS should continue to make determinations about childhood vaccination recommendations based on the best available evidence and the best practices of peer, developed nations.

## **2.2 Vaccine Safety Surveillance Systems**

Safety surveillance systems need to be very robust, minimize bias, and large enough to adequately detect risks which could tip the benefit-risk ratio in a direction that is unfavorable to the vaccine. Number needed to vaccinate (NNV) and number needed to harm (NNH) calculations should be performed for low- and high-risk children for each vaccination on an ongoing basis as harms are identified and as new information is obtained about efficacy against severe disease. These should inform CDC recommendations on an ongoing basis.

The U.S. has a limited post-licensure infrastructure focused on monitoring potential adverse reactions that occur within a few days or weeks after vaccination. This includes the Vaccine Adverse Event Reporting System (VAERS),<sup>73</sup> CDC's Vaccine Safety Datalink (VSD)<sup>74</sup> and FDA's Biologics Effectiveness and Safety (BEST) System.<sup>75</sup> Within a year of vaccine approval, these systems have confirmed serious harm, including intussusception after rotavirus vaccines,<sup>76,77</sup> febrile seizures after the MMRV vaccine,<sup>78</sup> and anaphylaxis<sup>79</sup> and myocarditis<sup>80</sup> after the mRNA COVID-19 vaccines.

However, these systems have serious shortcomings in that they have been underutilized, including for evaluating long-term effects of vaccines and the effect of various combined aspects of the vaccine schedule. Vaccines may cause adverse reactions that occur or are diagnosed months or years after vaccination. For example, a 2023 study from CDC's VSD found that children receiving more aluminum adjuvants had higher rates of persistent asthma, with an estimated hazard ratio of 1.19 per mg of aluminum (95% CI: 1.14-1.25).<sup>81</sup> When comparing mean aluminum exposure to no exposure, this corresponds to a hazard ratio of 2.0 (95% CI: 1.7-2.5), a doubling of the risk. However, this is an exception, and adequate studies of the association between vaccines and long-term health outcomes, including asthma, allergies, autoimmune diseases, neurological disorders, ear infections, or other infectious diseases, have not been performed.<sup>82</sup>

## **2.3 The Vaccine Schedule**

As the childhood vaccination schedule has expanded over the past four decades, the effects of the overall schedule have never been fully evaluated and published by a major institution. The Institute of Medicine (IOM) has called for such studies to be completed.<sup>83,84</sup> A 2013 IOM report recommended that HHS *"incorporate study of the safety of the overall childhood immunization schedule into its processes for setting priorities for research, recognizing stakeholder concerns,*

*and establishing the 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.”*<sup>85</sup> While some important studies have been conducted, on for example the above-mentioned relationship between vaccine adjuvants and asthma,<sup>86</sup> progress has been slow. There are many knowledge gaps, and only a few of the many studies that the IOM sought and deemed feasible have been conducted.

## **2.4 Filling the Knowledge Gap**

In addition to randomized placebo-controlled vaccine trials, HHS should increase and strengthen the use of large population-based observational studies and data to evaluate the safety of vaccines. Any changes in the vaccination schedule should be accompanied by scientific research to evaluate the short- and long-term impact of the updated immunization schedule on the targeted infectious diseases, other infectious diseases, acute adverse reactions and chronic conditions such as asthma, allergies, auto-immune diseases, developmental disorders (including ADHD, developmental delay, learning disabilities, intellectual disabilities, speech disorders, and tics), neurological disorders, seizures, diabetes, fertility issues, and eczema. Some important priorities include observational cohort studies comparing health outcomes between vaccinated and unvaccinated children, and if issues are identified, drilling down to evaluate the ideal number of doses, the timing and order of childhood vaccines; interaction effects of administering multiple vaccines on the same day; multivalent versus monovalent vaccines for the same diseases; vaccine adjuvants; and different immunization schedules.

In order to assess the long-term impacts of vaccines on chronic conditions, both retrospective and prospective cohort study designs should be utilized, with sufficient sample size and follow-up.

Sophisticated statistical methods for large population-based samples can be effectively used to minimize bias in observational studies. Examples include different forms of propensity score matching<sup>87,88</sup> and inverse probability weighting,<sup>89</sup> which can improve the covariate balance between exposed and unexposed groups. Self-control methods are another way to reduce bias in observational vaccine studies, by removing any between person confounding.<sup>90</sup>

With a large sample size, it may also be possible to identify specific population groups that are at increased risk for adverse events, as long as such analyses are carefully and systematically done.

**A successful childhood immunization program must be built on solid scientific evidence.**

**This means:**

1. Approvals of new vaccines designed for mass uptake should be based on double-blind placebo-controlled randomized trials. This has seldom been the case.
2. For new vaccines, there must be a post-market system in place to quickly detect unexpected adverse reactions.
3. In addition to acute adverse reactions, we must evaluate long-term effects on the immune system, such as asthma, auto-immune diseases, neurological disorders, and non-targeted infections. We have parts of the infrastructure in place to this, but it has been underutilized.
4. In addition to individual vaccines, we must thoroughly evaluate the safety of the immunization schedule, including cumulative effects, vaccine types and ingredients, the timing and order of vaccines, and interaction effects. The IOM has long called for such studies, but progress has been slow.

### **3. International Comparison of Childhood Immunization Schedules**

Table 2 compares the U.S. childhood vaccination schedule<sup>91</sup> to those of 20 peer nations: Australia,<sup>92</sup> Austria,<sup>93</sup> Belgium,<sup>94</sup> Canada,<sup>95</sup> Denmark,<sup>96</sup> Finland,<sup>97</sup> France,<sup>98</sup> Germany,<sup>99</sup> Greece,<sup>100</sup> Ireland,<sup>101</sup> Italy,<sup>102</sup> Japan,<sup>103</sup> Netherlands,<sup>104</sup> New Zealand,<sup>105</sup> Norway,<sup>106</sup> Portugal,<sup>107</sup> Spain,<sup>108</sup> Sweden,<sup>109</sup> Switzerland,<sup>110</sup> and the United Kingdom.<sup>111</sup>

Universal Vaccine Recommendations Funded by the Government	Age at 1st Vaccine (months)	Rotavirus	Diphtheria	Tetanus	Pertussis	Polio	Hib	Tuberculosis	Japanese Encephalitis	Hepatitis A	Hepatitis B	Pneumococcal	Measles	Mumps	Rubella	Varicella	HPV	Meningococcal	Influenza	Covid-19	# Vaccine Doses	# Diseases	# Mandated
Australia	0	2	6	6	6	4	4	..	..	..	4	3	2	2	2	1	1	2	5-6	..	50-51	15	13
Austria	2	2-3	5	5	5	5	3	..	..	..	4	3	2	2	2	..	2	1	17-18	..	58-60	14	0
Belgium	2	..	6	6	6	5	4	..	..	..	4	3	2	2	2	..	2	1	..	..	43	12	1
Canada	2	2-3	6	6	6	5	4	..	..	..	2-3	3-4	2	2	2	2	1	2	18-19	..	64-68	15	0
Denmark	3	..	4	4	4	4	3	..	..	..	..	3	2	2	2	..	2	..	..	..	30	10	0
Finland	2	3	5	5	5	4	3	..	..	..	..	3	2	2	2	2	2	..	6-7	..	44-45	13	0
France	2	2-3	5	5	5	5	3	..	..	..	3	3	2	2	2	..	2	6	..	..	45-46	13	11
Germany	1.5	2-3	5	5	5	4	3	..	..	..	3	3	2	2	2	2	2	4	..	..	44-45	14	1
Greece	2	2-3	6	6	6	4-5	4	..	..	2	3	3	2	2	2	2	2	5	5-6	..	56-58	16	0
Ireland	2	2	6	6	6	5	4	..	..	..	4	3	2	2	2	1	1	5	16	..	65	15	0
Italy	3	2	5	5	5	5	3	..	..	..	3	3	2	2	2	2	2	6	..	..	47	14	10
Japan	2	2-3	5	5	4	4	4	1	4	..	3	4	2	..	2	2	2-3	..	..	..	44-46	14	0
Netherlands	1.5	2	6	6	5	5	4	..	..	..	4	3	2	2	2	..	2	2	..	..	45	13	0
New Zealand	1.5	2	5	5	5	4	4	..	..	..	3	3	2	2	2	1	2	3	..	..	43	14	0
Norway	1.5	2	5	5	5	5	3	..	..	..	3	3	2	2	2	..	2	..	..	..	39	12	0
Portugal	0	..	6	6	5	5	4	..	..	..	3	3	2	2	2	..	2	4	..	..	44	12	0
Spain	2	2-3	5	5	4	4	3	..	..	..	3	3	2	2	2	2	1	6	4-5	..	48-50	15	0
Sweden	1.5	2-3	5	5	5	4	3	..	..	..	3	3	2	2	2	..	2	..	..	..	38-39	12	0
Switzerland	2	2	5	5	5	4	3	..	..	..	3	3	2	2	2	2	2	6	..	..	46	14	0
United Kingdom	2	2	6	6	5	6	4	..	..	..	4	2	2	2	2	2	1	4	14	..	62	15	0
# Recommended		17	20	20	20	20	20	1	1	1	18	20	20	19	20	12	20	15	8	0			
# Mandated		1	3	3	3	4	3	0	0	0	3	2	4	3	3	2	0	2	0	0			
USA 2024	0	2-3	6	6	6	4	3-4	..	..	2	3	4	2	2	2	2	2	2	18-19	18-19	84-88	17	12
USA Suggested	2	A	6	6	6	4	3-4	..	..	A	A	4	2	2	2	2	1	A	A	A	38-39	11	0

*Table 2: The number of vaccines recommended for all children in peer nations, not including monoclonal antibodies. The number of vaccine doses is more than the number of injections or diseases covered. For example, the MMR shot contains three vaccine doses, one each for measles, mumps and rubella. Red indicates that the vaccine is mandated for e.g. school,<sup>112</sup> and dark green that it is recommended for all children and covered by insurance. For the U.S., “A” means that it should be available through health insurance for all children. In Canada, provincial recommendations may differ for some vaccines, and there are school vaccine mandates in Ontario and New Brunswick. In the U.S., the mandated vaccines vary by state; shown is New York State. The rotavirus vaccine can come in either 2 or 3 doses. For the influenza and COVID-19 vaccines, 2 doses are sometimes given the first time and 1 dose each subsequent year. If it is recommended annually from age 6 months, some children get it 17 times and others 18 times before their 18<sup>th</sup> birthday. For U.S. infants also receiving the RSV monoclonal antibody injection, the total number of diseases for which protection was provided in 2024 was 18.*

In 2024, the U.S. recommended more childhood vaccines than any peer nation, and more than twice as many doses as some European nations. At the lower end is Denmark, which immunizes children against 10 diseases with a total of 30 doses. By using multivalent vaccines, Denmark’s schedule only requires 11 vaccine injections/shots/needles: 3 x (diphtheria + tetanus + pertussis + Hib + polio), 1 x (diphtheria + tetanus + pertussis + polio), 3 x pneumococcal, 2 x (measles + mumps + rubella) and 2 x HPV.<sup>113</sup>

By contrast, in 2024 the U.S. recommended routine vaccination against 17 diseases with 84 to 88 vaccine doses, depending on vaccine product and date of birth. Depending on the number of multivalent vaccines used, this required between 57 and 71 vaccine injections, of which the 2 or 3 for rotavirus are oral. For infants also receiving the RSV monoclonal antibody injection, the total number of injections could be 72 to provide protection against 18 diseases.<sup>114</sup>

Many considerations are relevant as countries develop their vaccination recommendations. However, if disease prevalences are comparable and children without underlying risk factors face similar risks from the target disease, variations in practice in terms of doses, number of diseases, and timing of vaccinations often reflects valid uncertainties as to what is the best practice. Such uncertainties and disagreements within the medical community are known as “*clinical equipoise*.”<sup>115</sup>

Each disease addressed by the U.S. child immunization schedule poses a health risk, but the level of risk varies widely by disease and sometimes by individual underlying risk factors. Yet the mere existence of a vaccine does not automatically make it appropriate for every child, nor does it necessarily justify routine vaccination.

While a set of consensus vaccines are consistently recommended in all peer countries, several vaccines currently included in the childhood immunization schedule in the U.S. (hepatitis A, varicella, influenza, rotavirus and meningococcal vaccines) are limited in their recommendation or excluded in some other developed countries (Table 2). Another stark difference is that most countries maintain high vaccination rates through trust in public health authorities rather than vaccine mandates (red in Table 2).

There is global variation in the universal use and timing of numerous childhood vaccines. Although these differences sometimes reflect the unique epidemiology of diseases in each region, they more often arise from uncertain science and knowledge gaps, which lead to inadequately informed assessments of risks and benefits that are subject to differing interpretations. Disagreement among states and professional societies<sup>116</sup> in the U.S. further underscores the need and opportunity for a more adaptable childhood immunization schedule.

Countries differ in terms of both disease exposure and health care system. The U.S. provides health care access for children through a combination of private insurance, state Medicaid programs, the Children’s Health Insurance Program (CHIP), and the Vaccines for Children (VFC) program.

Broad insurance coverage of both consensus and non-consensus immunizations should remain in effect following the updates to the immunization schedule. Identifying the consensus vaccines on the schedule would help Americans make informed decision while making all vaccines available



for parents also opting for their child to receive non-consensus immunizations. Through proper vaccine research, it is important to improve our understanding of populations who are most likely to benefit from individual vaccines as well as situations where vaccination may not be needed.

**A successful childhood vaccination program can learn from successful peer nations. In particular:**

1. The U.S. has been an international outlier in the number of vaccines given, and uptake of consensus vaccinations has decreased.
2. One way to restore trust in the U.S. childhood immunization schedule is to better align the country with consensus vaccine components of the schedules of peer nations, while not restricting anyone's access to other immunizations.

## **4. Recommended Childhood Immunization Schedule**

To increase trust, public health agencies should be honest regarding knowledge gaps about vaccines. Without placebo-controlled randomized trials with sufficient sample size and follow-up time for thorough safety evaluation, and post-marketing cohort studies comparing exposed and unexposed populations with long follow-up, we do not have the basic data needed to assess potential vaccine harms. Childhood vaccination recommendations must therefore be based on the best available evidence and the best practices of peer, developed nations. If there is a clear benefit of the vaccine, as for measles vaccines, the risks will need to be more substantial to outweigh the benefit. On the other hand, if the benefits are limited, as for the hepatitis A vaccine, even a small risk will tip the balance, where harms outweigh the benefits. For such vaccines, it is prudent to adopt a more conservative approach. Many peer countries have chosen to limit their core vaccines to diseases where the potential for benefit is understood to be the largest. There can be honest disagreements about where to draw the line, and different countries have made different decisions.

As with all medical procedures, vaccine decisions should never involve coercion but instead should always be the result of informed consent and with the final decision resting with the patient/parents. Coercion renders informed consent invalid and undermines this basic right.

### **4.1 Immunization Categories**

**Immunizations Recommended for All Children:** These are vaccines, such as the measles vaccine, for which there is consensus among peer nations that all children should receive them. These vaccines should be covered by all forms of health insurance without cost sharing.

**Immunizations Recommended for Certain High-Risk Groups or Populations:** Like all medical products, vaccines have different risk-benefit profiles for different people. This can either be because of underlying comorbidities, unusual exposure to the disease, or the risk of disease transmission to others. For example, the hepatitis A vaccine when children travel internationally to an endemic area or the birth dose of the hepatitis B vaccine for infants born to mothers that are hepatitis B positive. This document has not assessed and does not propose any changes in vaccine recommendations for high-risk populations. These vaccines should be covered by all forms of health insurance without cost sharing.

**Immunizations Based on Shared Clinical Decision-Making:** Shared clinical decision-making recommendations are individually based and informed by a discussion between the health care provider and the patient or parent/guardian.<sup>117</sup> It is not always possible for public health to clearly define who will benefit from a vaccine, who has relevant risk factors, or who are at risk of exposure. Parents and physicians, who know the child, may be better placed to make that judgement. With shared clinical decision-making, the characteristics of the individual are considered, including their likelihood of being exposed to the diseases, their risks of morbidity and mortality if contracting the diseases, their likelihood of benefitting from the vaccine, their likelihood of vaccine adverse reactions, and their risk of transmitting the disease to others. Sometimes, it is also important to consider personal and family preferences, beliefs, and knowledge, including when a patient presents specific information regarding the pre-and-post licensure safety data of a vaccine or presents specific familial experience with a vaccine.

While these immunizations are not routinely recommended for all children, they should be available for anyone who wants them and they should be covered by Medicaid, CHIP, the Vaccine for Children (VFC) Program, and private health insurance, without cost sharing. This is in contrast to some peer nations, where such vaccines must be purchased out-of-pocket.<sup>118</sup>

**Not Recommended Immunizations:** No currently recommended vaccines should be moved into this category. Some vaccines are not recommended for anyone, either because a lack of efficacy, known side effects, or low disease prevalence in the U.S. For example, while the BCG tuberculosis vaccine is used in many countries, it is not recommended for children in the U.S.<sup>119</sup> If approved by FDA, these vaccines may be available for purchase, but they are not covered by Medicaid, the Children's Health Insurance Program (CHIP), or the Vaccine for Children (VFC) Program.

## **4.2 Immunizations Recommended for All Children**

**Measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Hib and pneumococcal disease vaccines (MMR, DTaP, IPV, Hib, and PCV):** These are consensus vaccines that are part of the recommended childhood immunization schedules for all 20 peer nations, with the

exception of mumps in Japan (Table 2). As consensus vaccines, they should remain on the immunization schedule in the U.S. as vaccines recommended for all children. While the safety/risk profiles are not fully understood, and in need of further study, there is consensus among peer nations that they provide material benefits against the target disease. Focusing on these vaccines is more likely to reverse the declining uptake<sup>120</sup> of these vaccines.

**HPV:** There is also international consensus on the HPV vaccine, and it should continue to be recommended for all children/adolescents, but with one dose instead of two. Vaccination with one dose is as or nearly as effective as two doses.<sup>121,122,123,124</sup> Australia, Canada, Ireland, Spain, and the United Kingdom have already updated their recommendations to one dose (Table 2).<sup>125,126,127</sup>

**Varicella:** The varicella zoster virus causes chickenpox (typically in children), and, for those infected, can reemerge as shingles (typically in adults). The uncertainty of its long-term consequences on adults is one reason why some countries have been cautious about adding the varicella vaccine to the childhood schedule,<sup>128</sup> but similar caution may be warranted regarding a removal once there has been widespread use of this vaccine.<sup>129</sup> The rate of two dose vaccination for varicella among American children is estimated at 92%.<sup>130</sup> Partial population varicella vaccination (60-80% for two doses) could increase the average age at which the population naturally gets chickenpox when this disease could cause more complications, and hence there is a consensus among peer nations that once vaccination for chicken pox has become widespread, stopping use of this vaccine could cause certain complications.<sup>131,132</sup> For these reasons, the varicella vaccine should remain recommended for all children.

### **4.3 Immunizations Recommended for Certain High-Risk Groups or Populations**

**Respiratory syncytial virus (RSV) monoclonal antibodies, and Hepatitis A, Hepatitis B, Meningococcal B, Meningococcal ACWY, and Dengue vaccines:** This document does not contain an assessment of which high-risk groups and populations should receive which immunizations, and hence, it does not propose any changes to such recommendations.

### **4.4 Immunizations Based on Shared Clinical Decision-Making**

**Hepatitis A:** There are two FDA approved hepatitis A vaccines: Havrix since 1995 and Vaqta since 1996. At that time, the primary candidates for vaccination were *“travelers to regions of endemic disease, children living in high prevalence areas, homosexual males, users of illicit intravenous drugs, persons working directly with nonhuman primates or hepatitis A virus, patients older than 30 years of age with chronic liver disease, and persons who have received a liver transplant or are awaiting one.”*<sup>133</sup> For children, the vaccine was originally only

recommended in high endemic communities. Those had disappeared in the U.S. by 2006, at which time a 2-dose regimen at age 12 to 23 months was added to the universally recommended childhood immunization schedule. In 2006, the annual incidence rate of hepatitis A was very low at around 1 per 100,000 and it remains similarly low. The annual mortality rate is 1 per 10 million, with the highest rate among older men.<sup>134,135,136</sup>

There has been one randomized trial (n=40,119) for Havrix in young children, which used the Engerix-B vaccine for hepatitis B as the control group.<sup>137</sup> For Vaqta, the phase 3 randomized trial for children (n=1037) gave an aluminum and mercury containing diluent to the control group.<sup>138</sup> Hence, without a proper placebo-controlled randomized trial, reliable safety data is limited.

Among peer nations, Greece is the only one with a routine childhood vaccine recommendation (Table 2). Given the low U.S. incidence and mortality, and the lack of randomized placebo-controlled safety data, the benefit-risk ratio is at best very low for most children. There is a clear benefit, but still undefined risk, for children travelling to high endemic countries in the developing world.<sup>139</sup>

The Hep A vaccine should not be recommended for all children, but it should be available for all children whose parents want it through shared clinical decision making, and it should be covered by insurance without cost sharing.

**Hepatitis B:** Together with hepatitis B immune globulin, infants should be administered the hepatitis B vaccine at birth if the mother is HBsAg-positive or status is unknown. If the mother tests negative, only two of the 20 peer nations recommend universal vaccination at birth: Australia and Portugal, while two countries do not recommend it at all (Table 2). At their December 2025 meeting, the Advisory Committee on Immunization Practices followed the majority of peer nations and voted to no longer recommend the birth dose if the mother tested negative. Instead, it recommended shared clinical decision-making, taking the risk profile of each unique child into account.<sup>140</sup>

**Rotavirus:** Rotavirus is a common infection, and prior to the rotavirus vaccine, nearly every child would be infected, both in the U.S. and abroad.<sup>141</sup> In the developing world, many children die from dehydration after catching the virus, and there is greater opportunity for benefit from vaccination.<sup>142</sup>

In the U.S., it can cause hospitalization for gastroenteritis, but the virus poses almost no risk of either mortality or chronic morbidity. Data from CDC indicate that among all U.S. children <15 years of age, there were an average of 3.3 deaths per year with the rotavirus diagnostic code listed on the death certificate between 1999 and 2005.<sup>143</sup> This was after the RotaShield vaccine

was withdrawn from the market in 1999 and before the RotaTeq vaccine was approved in 2006. Another vaccine, Rotarix, was approved in 2008. After these vaccines were recommended for all children, there were 1.6 deaths per year from 2009 to 2020.<sup>144</sup> There may be many reasons for this very small decrease in mortality that are unrelated to the vaccine, including improved medical care, changes in diagnostic practices or random fluctuations.

RotaShield was removed from the market due to an excess risk of intussusception.<sup>145</sup> The newer current vaccines have a lower intussusception risk, at around 1 or 2 per 100,000 vaccinated children.<sup>146</sup>

Reasonable people can reach different conclusions about recommending the rotavirus vaccine for all children. Among peer nations, Belgium, Denmark and Portugal do not recommend it. Denmark has cited the very low risk of mortality and chronic morbidity to nearly all children in their rationale for not adding the vaccine to their childhood immunization schedule,<sup>147</sup>

The rotavirus vaccine should not be a consensus vaccine recommended for all children, but it should be available for all children whose parents want it through shared clinical decision making, and it should be covered by insurance without cost sharing.

**Meningococcal Disease:** Among peer nations, 15 recommend meningococcal vaccination for all children while five limit it to high-risk groups (Table 2). The incidence of meningococcal disease has declined during the past decades, both in countries with and without the routine vaccine recommendations for children, and the magnitude of the decline appears to be independent of vaccination policy (Table 3). The current incidence in the U.S. is 0.12/100,000 or about one case per million per year.

Countries Recommending Menigoccal Vaccine for All Children			
	Incidence 1998-2002	Incidence 2023-2024	Change in Incidence (%)
Australia	2.31	0.52	-78%
Austria	1.02	0.17	-83%
Belgium	3.75	0.72	-81%
Canada	0.76	0.26	-65%
France	0.84	0.86	2%
Germany	0.91	0.36	-61%
Greece	2.13	0.29	-86%
Ireland	12.41	1.01	-92%
Netherlands	3.73	0.73	-80%
Portugal	2.57	0.36	-86%
Spain	2.87	0.64	-78%
Switzerland	2.08	0.42	-80%
United Kingdom	1.36	0.71	-48%
United States	0.83	0.12	-85%
<b>Average</b>	<b>2.68</b>	<b>0.51</b>	<b>-72%</b>
Countries Not Recommending Menigoccal Vaccine for All Children			
Denmark	2.91	0.49	-83%
Finland	1.00	0.14	-86%
Norway	2.10	0.27	-87%
Sweden	0.66	0.37	-44%
<b>Average</b>	<b>1.67</b>	<b>0.32</b>	<b>-75%</b>

Table 3: Annual incidence rates per 100,000 population of meningococcal disease in the U.S. and peer countries, and percent change from 1998-2002 to 2023-2024. International population estimates were obtained from the U.S. Census Bureau, International Programs Center, International Database.<sup>148</sup> Because historical meningococcal surveillance data are not harmonized across countries, data sources varied by country and time period. To calculate the IR for the U.S., 1998-2002, 2019, and 2024 data were collected from Centers for Disease Control and Prevention.<sup>149,150</sup> In the remaining instances, 1998–2002 data were primarily obtained from the European Commission, Health and Consumers Directorate, European Community Health Indicators: Meningococcal Disease report; for Sweden, there existed a probable data error from the source for 2001's count of case reports that resulted in an exclusion of this data point, therefore, the 1998-2002 incidence was calculated as a four-year average with the remaining data points.<sup>151</sup> For Australia, 1998–2001 data were compiled from national surveillance publications by The Australian Meningococcal Surveillance Programme and another academic source, with a four-year IR average calculated due to 2002 data unavailability.<sup>152,153</sup> For Denmark, 2023-2024 data were from Statens Serum Institut.<sup>154</sup> 2020-2024 incidence data are reported cases of invasive meningococcal

disease collected annually through the WHO/UNICEF Joint Reporting Form on Immunization (JRF).<sup>155</sup> Reliable incidence rates were not found for Italy, New Zealand or Japan.

In a 2011 position paper, the World Health Organization (WHO) recommended that countries with more than 2 cases per 100,000 population/year maintain a “*large scale meningococcal vaccination program*,” while only vaccinating the high-risk population in countries with lower rates.<sup>156</sup> In the U.S., the current incidence of 0.1 per 100,000,<sup>157</sup> is much lower than the WHO suggested cut-off.

The current meningococcal vaccines recommended for all children (Menveo, Menquadfi, and Penbraya) were not evaluated in large-scale double-blind placebo-controlled randomized trials before FDA approval.<sup>158,159,160</sup>

Considering the low incidence of meningococcal disease in the U.S., the meningococcal vaccine should not be part of the consensus recommended vaccine schedule. High-risk children and adolescents, such as children with certain types of immune deficiencies, may have a greater chance of benefiting from the vaccine, and it should be available and covered by insurance for all children and adolescents through shared-clinical decision making.

**Influenza:** The primary purpose of the childhood influenza vaccine in children is to reduce hospitalizations and mortality in children, as well as transmission to the elderly, who are of higher risk for death but there are no randomized controlled trials demonstrating these benefits.<sup>161,162,163</sup> There are some randomized placebo-controlled trials for the influenza vaccine. The most comprehensive review was done in 2018 by the Cochrane Collaboration.<sup>164</sup> They found that “*in children aged between 3 and 16 years, live influenza vaccines probably reduce influenza (moderate-certainty evidence)*” infections while “*inactivated vaccines also reduce influenza (high certainty evidence)*.” Only a few of the trials evaluated school and parental work absenteeism, not finding a statistically significant reduction. There was no evidence about reduced transmission. The trials could not evaluate differences in hospitalizations or mortality, as there were none or few in either group, so they provide no evidence that the vaccines reduce hospitalization or deaths. There was not much information about children under 2 years old.

The conclusion of the Cochrane systematic review of randomized trials in children was that “*Decision-makers’ attention to the vaccination of very young children is not supported by the evidence summarised in our review. Although there is a growing body of evidence showing the impact of influenza on hospitalisations and deaths of children, at present we could find no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications, or community transmission of influenza.*”<sup>165</sup>

There have been some observational studies with mixed results. A test-negative case-control study claimed to show that childhood influenza vaccine reduces hospitalization,<sup>166</sup> but that is a notoriously biased study design,<sup>167</sup> with highly implausible results.<sup>168</sup>

While there is a scarcity of reliable safety data, the influenza vaccines are not without risk. The seasonal vaccine has been linked to Guillain Barré syndrome.<sup>169</sup> During the 2009/2010 H1N1 influenza pandemic, the Pandemrix pandemic vaccine was found to cause narcolepsy among vaccinated children and adolescents.<sup>170,171</sup> The Cochrane systematic review, noted that *“the lack of safety data for inactive vaccines in younger children is particularly surprising given that the inactive vaccine is now recommended for healthy children six months and older in the USA and Canada”* and that *“the manufacturers’ refusal to release all safety outcome data from trials carried out in young children, together with obvious reporting bias and inconsistencies in the primary studies, does not bode well for a fair assessment of the safety of live attenuated vaccines.”*<sup>172</sup>

Considering the evidence, and lack of evidence, it is understandable that public health agencies in different countries have come to different conclusions about the influenza vaccine for children. Among the 20 peer countries, only Austria and Canada recommend an annual influenza vaccine for all children >6 months and all adolescents. Another six recommend the shot for all children in selected age ranges. The remaining twelve peer nations do not recommend the influenza vaccine for all children in any age group (Table 2).

Based on both the evidence and uncertainties, the influenza vaccine should not be recommended for all children, but it should be available through insurance for all children >6 months old, through shared-clinical decision making.

**COVID-19:** In 2022, Denmark became the first peer nation to remove its universal recommendation of the COVID-19 vaccine for children, with the director of its public health authority recognizing that there was little benefit in giving this vaccine to children.<sup>173</sup> Since then, all other peer nations have followed (Table 2). At their September 2025 meeting, the Advisory Committee on Immunization Practices voted that shared clinical decision-making should be applied to the COVID-19 vaccine for U.S. children and adolescents.<sup>174</sup> This means that insurance continues to cover this vaccine for all children in the U.S., unlike many peer nations, where insurance only pays for recommended vaccines.



**To ensure a successful childhood vaccination program, the proposed updated schedule:**

1. Recommends for all children all the vaccines for which there is consensus among peer nations.
2. Allows for more flexibility and choice, with less coercion, by reassigning non-consensus vaccines to certain high-risk groups and populations and/or based on shared clinical decision-making.
3. Ensures that all the diseases covered by the prior immunization schedule would still be available to anyone who wants them through their private health insurance, Medicaid, the Children's Health Insurance Program (CHIP), and/or the Vaccine for Children (VFC) Program. Among peer nations, the U.S. would continue to offer the greatest number of childhood vaccines for free to those who want them.
4. Is accompanied by a strengthening of vaccine research by launching double-blind placebo controlled randomized trials if appropriate and more observational studies to evaluate long-terms effects of individual vaccines and the vaccine schedule.

## **5. Next Steps**

While closely monitoring vaccine safety and risks, vaccine uptake and infectious disease rates, the CDC and its Advisory Committee on Immunization Practices should continue its work revising recommendations based on the latest vaccine developments and scientific research. For example, they should fine-tune the schedule with recommendations for certain populations for those vaccines that are no longer routinely recommended for all children.

HHS should work with states and physician groups to educate parents and physicians on changes to the CDC childhood immunization schedule.

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