

Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making

Department of Health and Human Services | Office of the Secretary

ECRI's Comments in Response to Notice from HHS

Docket No. HHS-OS-2026-0332

ECRI is a non-profit organization advancing the safety and quality of healthcare. The following comments are being submitted by ECRI in response to the request from HHS for insights on the childhood vaccine schedule. For more information about ECRI, visit [ECRI.org](https://www.ecri.org).

Question #7: If categories remain the same, what modifications to timing and frequency of vaccine administration (for example, clearer presentation of flexible age ranges such as the 12-through-15-month window for the first dose of measles- containing vaccine) or guidance on administering vaccines individually versus at a single visit would help parents and clinicians understand that a vaccine is recommended while affording flexibility in timing of administration?

The primary goal of any vaccine timing and frequency recommendations should be to preserve protection against vaccine-preventable diseases while helping patients, parents, and clinicians understand the rationale for recommended administration windows. Decisions to modify timing guidance should be supported by transparent review of high-quality scientific evidence and consideration of both individual and population-level health outcomes.

ECRI believes that any recommendations regarding vaccine timing and frequency should remain grounded in the best available scientific evidence. Current childhood immunization schedules were developed through rigorous evaluation of vaccine safety, effectiveness, and epidemiology and are intentionally timed to provide protection during periods when infants and children are most vulnerable to vaccine-preventable diseases.

Available evidence supports this concern. National kindergarten MMR coverage declined from 95.2 percent in the 2019–2020 school year to 92.7 percent in 2023–2024, leaving an estimated 280,000 kindergartners without documented protection, and reported pertussis cases in 2024 were more than six times higher than in 2023 (*ECRI, Increasing Rates of Preventable Acute Diseases in Communities and Healthcare Settings, 2026²*; *ECRI, Top 10 Patient Safety Concerns 2026³*).

ECRI's review of vaccination timing data found that children who are late on the 2- and 4-month immunizations are significantly less likely to receive the MMR vaccine by age 2 (*ECRI, Children Late on Vaccination Schedule Less Likely to Receive MMR Vaccination, January 2026¹*).

Furthermore, published evidence has not demonstrated that spacing routinely co-administered vaccines across multiple visits improves safety outcomes. The National Academies of Medicine (formerly the Institute of Medicine) examined this question directly in its 2013 report⁵, *The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies*, and found no evidence of major safety concerns associated with the recommended schedule, while noting that testing a more spread-out schedule through a randomized controlled trial would be unethical because it would require withholding or delaying protection from some children. In fact, requiring additional visits may create barriers to completion and leave children unprotected for longer periods.

Question #14: What considerations should be relied upon in establishing vaccine recommendations and assigning categories, and under what conditions should each predominate?

ECRI believes that vaccine recommendations should be guided principally by the strength, quality, and consistency of the available scientific evidence regarding safety and effectiveness. Public confidence in vaccine recommendations depends on transparent, evidence-based decision-making that is free from political, ideological, or other non-scientific influences. ECRI has consistently supported evidence-based medicine and rigorous evaluation of healthcare interventions as the foundation of clinical decision-making.

Several considerations are important when establishing recommendations and assigning categories:

- Quality and strength of evidence. Recommendations should reflect the totality of available evidence, including randomized trials, observational studies, systematic reviews, epidemiologic data, and post-marketing surveillance when appropriate. The strength and certainty of evidence should be explicitly communicated.
- Balance of benefits and harms. Recommendations should consider both individual-level outcomes and broader public health effects. This includes evaluating disease burden, disease severity, vaccine effectiveness, safety outcomes, and the consequences of delayed or foregone vaccination.
- Scientific feasibility. For some questions, randomized controlled trials may be infeasible or unethical to conduct. In such cases, recommendations should reflect the highest-quality evidence reasonably obtainable while acknowledging remaining uncertainty. ECRI's evidence assessment methodology routinely evaluates diverse sources of evidence to support healthcare decision-making when ideal evidence is unavailable.
- Transparency and reproducibility. Decision-makers should clearly describe the evidence reviewed, the rationale for recommendations, and any uncertainties or limitations that influence the final recommendation. Transparent review processes help maintain scientific credibility and public trust.
- Patient and public health impact. Individual autonomy, informed consent, and religious or personal beliefs are important aspects of healthcare decision-making, and existing legal and policy mechanisms, such as medical, religious, and philosophical exemption processes, already provide avenues to accommodate them. These considerations are best addressed through such mechanisms rather than through the scientific categorization of a vaccine's evidence base;

conflating the two risks obscuring the strength of the underlying evidence and creating confusion about which vaccines are supported by the same rigorous safety and effectiveness data. Recommendation categories should therefore continue to help clinicians and the public understand how the evidence supports expected benefits and risks.

In ECRI's view, the quality and strength of evidence should remain the primary consideration guiding vaccine recommendations. Other factors may inform implementation and communication, but they should not supersede well-established scientific evidence regarding safety and effectiveness.

Consistent with its prior public statement⁸ on the August 2026 Executive Order⁶, ECRI notes that the process used to assign vaccines to categories should itself be transparent and grounded in a documented, evidence-based review. ECRI has expressed concern that the current categorization was adopted without such a review and without new scientific evidence supporting the changes. HHS should ensure that any additional modifications to the categories are accompanied by publicly available documentation of the evidence considered and the rationale applied.

Question #17: What communication practices should accompany vaccine recommendations so that they earn and keep public trust, and what lessons from COVID–19-era communication should inform them?

Public trust is strengthened when health recommendations are communicated transparently, consistently, and with clear reference to the supporting evidence. ECRI believes that healthcare organizations and government agencies should clearly explain both what is known and what remains uncertain, while making the underlying scientific rationale for recommendations accessible to clinicians, patients, and families.

Communications should be grounded in several principles:

- Transparency regarding evidence. Recommendations should clearly identify the evidence supporting them and explain how that evidence was evaluated. Changes to recommendations should be accompanied by a transparent description of the scientific basis for the change.
- Scientific integrity and objectivity. Healthcare organizations should communicate findings based on rigorous analysis of available evidence and avoid overstating certainty where uncertainty exists. ECRI has emphasized that institutions must remain committed to objective evaluation of the facts and scientific rigor.
- Consistency and clarity. Recommendation frameworks and terminology should be sufficiently clear that patients, families, and clinicians understand their practical implications. Communication should reduce confusion rather than introduce ambiguity regarding vaccine safety, effectiveness, or availability.
- Trustworthy information sources. Clinicians, researchers, patients, and families should have access to credible, evidence-based information presented in understandable formats. Decision-support materials, evidence summaries, and plain-language explanations can help improve understanding while supporting informed decision-making.

A widely recognized lesson from the COVID-19 pandemic response is that public trust eroded when scientific decisions were perceived as insufficiently transparent, when guidance changed without a clear

explanation of the underlying evidence, or when messaging appeared to be shaped by non-scientific considerations. Maintaining public confidence requires open communication about evidence, uncertainty, and the rationale for policy decisions.

References

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5. Institute of Medicine. The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies. Washington, DC: National Academies Press; 2013. <https://www.ncbi.nlm.nih.gov/books/NBK206948/>
6. The White House. Delivering Gold Standard Childhood Vaccine Recommendations for Americans (Executive Order). August 10, 2026. <https://www.whitehouse.gov/presidential-actions/2026/08/delivering-gold-standard-childhood-vaccine-recommendations-for-americans/>
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