



American Society of Hematology

Helping hematologists conquer blood diseases worldwide

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2026

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Deputy Assistant Secretary for Planning and Evaluation

Performing the Delegable Duties of the Assistant Secretary for Planning and Evaluation

Office of the Secretary, Department of Health and Human Services

200 Independence Avenue, SW

Washington, DC 20201

Re: Request for Information: Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making (Docket No. [HHS-OS-2026-0332](#))

Dear Ms. Goss,

On behalf of the American Society of Hematology (ASH), thank you for the opportunity to provide comments in response to the Request for Information (RFI) on Categories Used in Federal Vaccine Recommendations and the Role of Shared Clinical Decision-Making (Docket No. HHS-OS-2026-0332).

ASH represents more than 18,000 clinicians and scientists who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell disease (SCD), thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are innovators in the field of medicine and continue to develop lifesaving treatments in areas such as stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. Our mission is to foster high-quality care, transformative research, and innovative education to improve the lives of patients with blood and bone marrow disorders.

Vaccines are critical for individuals with hematologic conditions, such as leukemia, lymphoma, sickle cell disease (SCD), and bone marrow failure syndromes, many of whom are immunocompromised due to their disease, treatment, or both. Therapies such as chemotherapy, bone marrow transplantation, cellular therapies, and gene therapies can cause profound immune suppression, placing patients at heightened risk of severe, potentially life-threatening outcomes from vaccine-preventable infections. What may ordinarily be a minor viral or bacterial infection for individuals with normal immune systems can become life-threatening for those who are immunocompromised. For many patients with these conditions, the clinical question is not whether vaccination is recommended, but when and how it should be administered to maximize safety and immune response. Treatment and immune status may require individualized timing, revaccination, or modification of vaccine administration. The categories of vaccine recommendations should not conflate clinical considerations with uncertainty about the underlying recommendation to vaccinate.

ASH urges the Department of Health and Human Services (HHS) to: (1) maintain the existing routine, risk-based, and shared clinical decision-making (SCDM) recommendation categories rather than creating additional categories; (2) reserve SCDM for circumstances in which the

benefit-risk assessment truly varies by individual, rather than circumstances in which only timing or administration must be individualized; and (3) ensure that no change in recommendation category or terminology reduces vaccine coverage, access, or protections for patients, particularly those who are immunocompromised or otherwise at increased risk of vaccine-preventable disease. We discuss these recommendations in more detail below.

Maintain the Current Categories and Improve Their Clarity

ASH believes the current categories of routine, risk-based, and SCDM are sufficient when they are clearly defined and consistently applied. There are clear data for the current evidence-based vaccination recommendations from the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics (AAP). HHS has not demonstrated that additional categories are necessary or that they would improve clinical decision-making. The Society recommends maintaining a clear distinction between routine or risk-based recommendations and SCDM. A risk-based recommendation should communicate that a vaccination is recommended because an underlying condition increases risk. The conversation between the physician and patient, which includes informed consent, is fundamental to clinical care and should apply regardless of whether a vaccine recommendation is routine or risk-based. The recommendation category communicates the strength and applicability of the recommendation; it does not determine whether patients and clinicians discuss the risks, benefits, and individual circumstances surrounding vaccination.

ASH recommends that HHS improve the clarity of existing recommendations. For patients with blood cancers and serious hematologic conditions, current categories can be confusing. Patients may not recognize that leukemia, lymphoma, multiple myeloma, SCD, asplenia, transplant status, chemotherapy, cellular therapy, or other immunosuppressive treatments place them in a high-risk category. Patients may also interpret SCDM as meaning that vaccination is optional or supported by weaker evidence. ASH recommends that these categories be accompanied by plain-language explanations and condition-specific examples, such as: "This vaccine is recommended for people with weakened immune systems, including many people with blood cancers, SCD, asplenia, stem cell transplant, CAR-T therapy, or chemotherapy."

ASH does not recommend adoption of additional categories unless there is compelling evidence that they would improve clarity without creating confusion, access barriers, or payer uncertainty. Vaccine recommendations should remain simple, clear, and evidence-based. Rather than creating additional categories, HHS should improve the clarity of existing risk-based recommendations by explicitly identifying the populations to whom they apply.

Distinguish Individualized Vaccine Administration from Shared Clinical Decision-Making

ASH cautions against using SCDM as a substitute for clear routine or risk-based recommendations. If individual-based decision-making means tailoring vaccine administration to a patient's medical circumstances, that is already an integral part of appropriate clinical care. However, it could undermine vaccine uptake and patient safety if the designation suggests that an otherwise evidence-based recommendation is optional or uncertain. ASH suggests federal guidance use language such as: "This vaccine is recommended; for patients who are immunocompromised or receiving immunosuppressive therapy, clinicians may need to adjust timing to optimize safety and immune response." Flexibility may be appropriate for medically complex patients but should not be confused with optional vaccination.

This distinction is particularly important for patients with hematologic conditions who require individualized timing and care. For example, patients undergoing chemotherapy, hematopoietic stem cell transplantation, CAR-T therapy, or B-cell depleting therapy may need tailored guidance regarding when to vaccinate, revaccinate, or avoid live vaccines. However, this reflects individualized timing, not uncertainty about whether vaccination is recommended.

In summary, SCDM should be reserved for circumstances in which the benefit-risk assessment meaningfully varies among individuals. It should not be used when vaccination remains recommended but timing, formulation, sequence, or other aspects of administration require clinical judgment. Applying SCDM more broadly could cause patients to interpret a vaccine as optional or supported by weaker evidence, lead clinicians to apply recommendations inconsistently, and create uncertainty among payers and health systems. For medically vulnerable hematology patients, these consequences could result in delayed or missed vaccination and preventable morbidity and mortality.

Preserve Vaccine Access, Coverage, and Legal Protections Under Any Category Framework

ASH recommends that if there is any change in vaccine recommendation categories that they include explicit federal protections to preserve vaccine access, insurance coverage, program eligibility, injury-compensation protections, and consistent treatment under state law. HHS should assess the full legal and operational consequences of any changes in recommendation categories prior to implementation to ensure these federal protections remain in place.

Patients, families, pediatricians, primary care clinicians, hematologists, oncologists, transplant physicians, and pharmacists should not have to take additional steps to establish the medical necessity of routine or risk-based vaccines. A change in category should not result in prior authorization barriers, cost-sharing, loss of coverage, inconsistent state interpretation, or reduced access.

ASH recommends that federal guidance make clear that vaccines in any recommended category remain covered when clinically indicated, including vaccines recommended through SCDM. Payers should not interpret SCDM as evidence that a vaccine is not medically necessary.

ASH also recommends that federal agencies clearly communicate the evidence base supporting vaccine recommendations, including randomized clinical trials where available, observational evidence, immunogenicity data, safety surveillance, epidemiologic data, and evidence regarding both individual and community benefit.

Maintain a Transparent, Evidence-Based Recommendation Process

Vaccine recommendations should be based on a rigorous and transparent evidence-based process. They should consider the totality of available evidence, including disease severity, disease epidemiology, vaccine safety, effectiveness, immunogenicity, feasibility, population-level benefit, and impact on medically vulnerable populations. ASH recommends that routine or risk-based categories predominate when there is strong evidence of benefit, substantial disease burden, clear safety data, or significant risk to vulnerable populations.

Randomized controlled trials are an important evidentiary source where available, but they should not be the sole basis for vaccine recommendations. In some circumstances, randomized trials may be infeasible, unethical, or underpowered to detect rare outcomes or population-level benefits. Federal agencies should also rely on observational effectiveness studies, safety surveillance, epidemiologic data, immunogenicity studies, modeling, implementation data, and expert consensus from clinicians with relevant disease-specific expertise.

ASH supports individual autonomy, informed consent, and patient education. These are critical to patient-clinician relationships and underpin recommendations for treatment in addition to vaccination. However, strong patient-clinician relationships require that the patient be presented with information about the evidence supporting each option, rather than receiving information that presents all choices as scientifically equal.

Maintain Evidence-Based Recommendations That Clearly Protect High-Risk Patients

Risk-based recommendations are essential but should be clearer and more actionable for individuals with SCD and other hematologic conditions that increase susceptibility to vaccine-preventable infections. Individuals with SCD, particularly those with functional or surgical asplenia, face serious and potentially life-threatening risks from vaccine-preventable infections. Vaccination for these patients is a direct patient-protection measure, not merely a population-level public health strategy. ASH recommends that federal guidance explicitly name SCD, functional asplenia, surgical asplenia, hematologic malignancy, transplant status, cellular therapy, complement inhibitor therapy, and other relevant conditions in plain language as risk-based conditions that increase susceptibility to vaccine-preventable infections. Patients should not have to infer that they qualify for risk-based vaccination. Changes in recommendation categories or schedules could create missed opportunities, delayed boosters, and inconsistent counseling, especially in populations that already experience fragmented care.

ASH also strongly recommends maintaining clear, standardized revaccination guidance for people after they undergo hematopoietic stem cell transplantation, cellular therapy, and other treatments that profoundly affect immune memory. Revaccination after transplant is a structured component of post-transplant care because previously acquired immunity may be lost. Patients may become functionally unimmunized and require systematic

revaccination to restore protection. Timing may need to be individualized based on immune recovery, graft-versus-host disease, immunosuppression, B-cell depletion, or other factors, but the need for revaccination should remain clear. For these patients, recommended vaccines should not be reclassified into a shared or individual-based decision-making category, which could imply revaccination as optional. ASH recommends that revaccination be presented as a core element of transplant and cellular therapy survivorship and infection prevention. Patients should be informed during care planning that revaccination is a key component of long-term safety.

Additionally, the Society emphasizes the importance of community immunity. Many hematology patients cannot mount full immune responses to vaccines, cannot receive certain vaccines at certain times, or remain at risk despite vaccination. High vaccination rates in the broader community reduce exposure to measles, influenza, varicella, pertussis, pneumococcal disease, meningococcal disease, and other serious infections. Lower vaccination rates place immunocompromised children and adults at direct risk.

In summary, ASH recommends that federal agencies maintain strong, evidence-based vaccine recommendations; preserve access and coverage; provide plain-language explanations; explicitly identify high-risk hematology populations; and avoid category changes that undermine vaccine confidence or create uncertainty about whether vaccination is recommended. Thank you again for the opportunity to share this critical feedback. Should you have any questions or require additional information, please contact ASH Director of Government Relations and Public Health Stephanie Kaplan (skaplan@hematology.org or 202-776-0544).

Sincerely,

A handwritten signature in black ink, appearing to read 'Robert Negrin', is positioned to the left of a vertical line.

Robert Negrin, MD
President