Comments of the Global Healthy Living Foundation

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

The Global Healthy Living Foundation (GHLF) appreciates the opportunity to comment to the Department of Health and Human Services (HHS) on the categories used in Federal vaccine recommendations and the role of shared clinical decision-making (SCDM).

GHLF is a 501(c)(3) non-profit representing people and their families impacted by major chronic diseases, including patients living with autoimmune and inflammatory conditions. GHLF has conducted extensive patient-centered research concerning adult vaccination, including access to immunization in low-income communities, the role of pharmacists, vaccine reimbursement, State pharmacist vaccination authority, barriers experienced by patients with chronic diseases, and the impact of SCDM and risk-based recommendations on vaccine uptake.

Our research has consistently focused on a straightforward question: **How do vaccine policies affect patient access and vaccine uptake in real-world healthcare settings?**

The same question should guide HHS's evaluation of SCDM.

Most importantly, shared clinical decision-making is already part of the normal vaccination process. A patient does not enter a physician's office or pharmacy and automatically receive a vaccine. Either the patient requests the vaccine or a physician, pharmacist, or other healthcare professional recommends or offers it. The healthcare professional and patient interact, relevant questions are addressed, and the patient ultimately decides whether to receive the vaccine.

Hence, shared clinical decision-making already occurs whether a vaccine carries a routine, risk-based, or SCDM recommendation.

HHS recognizes this point in the RFI. The Department states that personal autonomy, informed consent, and patient decision-making apply across all vaccine recommendations. The fundamental difference is that routine and risk-based recommendations default to vaccination when the patient meets the criteria, while under SCDM there is "no default."[1]

Therefore, creating an SCDM category does not create patient participation or patient choice. Those already exist. The more important question is whether removing a clear Federal recommendation and replacing it with an individualized recommendation

introduces additional complexity that may confuse patients and healthcare professionals and ultimately reduce vaccine access and uptake.

Question 1: Are the current recommendation categories adequate, clear, and well understood?

GHLF believes that SCDM can create unnecessary confusion for patients and healthcare professionals.

The concept of SCDM is well intended. It encourages healthcare professionals and patients to discuss the risks and benefits of vaccination and arrive at an appropriate decision. However, such interactions already occur as part of routine vaccination practice.

The practical effect of the SCDM designation is different. It changes the Federal recommendation from vaccination as the default for an eligible patient to one that requires additional individual assessment.

Evidence suggests this distinction is difficult to implement. A national physician survey found that 90% to 95% of physicians reported that SCDM requires more time than routine recommendations, 64% to 76% agreed that SCDM creates confusion, and only approximately 42% understood that vaccines recommended through SCDM were covered by most health insurance.[2]

Unfortunately, confusion at the healthcare professional level will ultimately be experienced by patients.

For patients with chronic diseases, particularly autoimmune and inflammatory conditions, this can be even more complicated because the recommendation may depend on underlying disease, immune status, or treatment with biologic, immunosuppressive, or other therapies. For these individuals, clear Federal recommendations are therefore especially important so that patients and healthcare professionals can readily understand when vaccination is recommended and appropriate. Without that clarity, patients may interpret an individualized recommendation as uncertainty about whether vaccination is advisable, potentially delaying vaccination or missing an opportunity to be immunized.

Question 3: Does the SCDM category unintentionally imply that consent or meaningful clinical discussion applies only to SCDM recommendations?

Yes.

A routine vaccine recommendation does not eliminate patient choice. Nor does it eliminate a physician's or pharmacist's responsibility to answer questions, review relevant clinical considerations, and determine whether the vaccine is appropriate for the patient.

Patients receiving routinely recommended influenza, shingles, pneumococcal, COVID-19, or other adult vaccines still participate in the decision to be vaccinated.

Hence, HHS should distinguish between the **strength and clarity of the Federal vaccine recommendation** and the **clinical discussion between the healthcare professional and patient**.

Shared clinical decision making is part of the latter and should occur regardless of the Federal recommendation category.

Questions 8 and 9: What should shared clinical decision making mean, and should the terminology change?

GHLF believes shared clinical decision-making should describe the interaction between a healthcare professional and patient rather than serve as a separate Federal vaccine recommendation category.

If the scientific evidence shows that a vaccine's expected benefit differs significantly based on an individual's clinical circumstances, HHS could describe the recommendation as requiring an **individualized clinical assessment**.

This terminology would more accurately describe what differs about the recommendation.

The difference is not whether the patient participates in the decision. The patient already participates.

The difference is whether the Federal Government recommends vaccination for an identified population as the default or whether additional individualized clinical assessment is necessary.

Shared clinical decision-making describes how healthcare is practiced. It should not be used to determine whether the Federal Government clearly recommends a vaccine.

Questions 10 and 11: What are the benefits and risks of an SCDM category?

GHLF supports patient autonomy, informed consent, and the ability of healthcare professionals to exercise clinical judgment.

However, these principles exist regardless of the vaccine recommendation category. Therefore, the most crucial question HHS should evaluate is whether the SCDM category improves or reduces vaccine uptake and patient access, based on empirical evidence.

The available evidence raises concerns.

Following the 2019 SCDM recommendation for PCV13 among adults aged 65 years and older, investigators evaluating more than 12 million Medicare beneficiaries found that PCV13 declined from more than 70% of pneumococcal vaccinations before SCDM to less than 60% after implementation. Reductions were also observed among vulnerable subgroups and immunocompromised patients.[3]

These findings do not demonstrate that SCDM alone was responsible for every reduction in PCV13 uptake. However, they demonstrate that changes in Federal recommendation policy can have measurable real-world consequences and should be evaluated accordingly.

This concern is especially important because adult patients receive vaccines in different settings.

Research conducted by IQVIA Institute for Human Data Science and GHLF found that following the COVID-19 pandemic, almost 80% of adult vaccinations occurred at pharmacies.[4] Pharmacists are also the most accessible healthcare professionals in the U.S., and GHLF research has demonstrated that pharmacies provide substantially greater immunization access than physician offices in low-income communities.[5]

Any Federal adult vaccine recommendation must therefore be practical to implement in the community pharmacy.

Complex SCDM or risk-based recommendations can be challenging in that setting. Pharmacists may not have complete access to a patient's medical history, specialty physician records, laboratory information, or specialty medication data. These limitations are particularly relevant for patients with autoimmune and inflammatory conditions whose vaccine recommendations may depend upon their disease or treatment.

The result may be another step in the healthcare process. The pharmacist may ask the patient to contact a physician, obtain additional documentation, or return after additional clinical information is available.

Unfortunately, every additional step creates another opportunity for the patient not to receive the vaccine.

GHLF's own survey of adults with chronic diseases illustrates this concern. Although 88% of respondents believed vaccines were important and necessary to their health and 83% believed vaccines were safe and effective, almost 30% experienced difficulty obtaining a vaccine. Among patients who experienced difficulties, 42% ultimately reported being unable to obtain the vaccine they sought.[6]

These patients were not necessarily vaccine hesitant. Many were patients attempting to become immunized who encountered access barriers.

Our previous research involving pharmacist vaccination authority has demonstrated the same broader principle: policies that make pharmacy vaccination more difficult are associated with lower vaccine uptake. States requiring additional physician protocols or prescriptions had lower adult vaccination rates than States that permitted pharmacists to vaccinate independently or through statewide standing orders.[7]

Hence, HHS should be cautious about adding another layer of complexity to adult vaccination unless compelling clinical evidence shows the additional requirement improves patient outcomes.

Questions 6, 12, and 13: How should HHS preserve access and make individualized recommendations workable?

If HHS retains SCDM or adopts another individualized recommendation category, the policy should be designed around the real-world healthcare settings in which adult vaccination takes place.

Most importantly, the recommendation should be simple enough to implement at a community pharmacy.

HHS and CDC should:

- clearly communicate eligibility criteria to patients and healthcare professionals;
- specifically explain how chronic disease, immune status, and treatment with biologic or immunosuppressive therapies affect vaccine eligibility or the need for an individualized clinical assessment;
- ensure that coverage requirements are unambiguous;
- align electronic clinical decision-support systems with Federal recommendations;
- minimize documentation requirements that unnecessarily delay vaccination;
- develop straightforward decision-support tools for pharmacists and other vaccinators; and
- evaluate whether complicated clinical criteria are necessary when a simpler age- or risk-based recommendation can appropriately identify the population that benefits from vaccination.

HHS should also clarify that an individualized recommendation does not mean a vaccine is not recommended, unavailable, or not covered when the patient meets the applicable criteria.

However, education alone cannot resolve an unnecessarily complicated recommendation.

The best policy solution is to develop Federal vaccine recommendations that are evidence-based, clear to healthcare professionals and patients, and practical to implement at the point where patients receive their vaccines.

Question 18: How should HHS measure whether the recommendation framework is succeeding?

HHS should measure the impact of a vaccine recommendation through real-world evidence.

At a minimum, HHS should evaluate:

- vaccine uptake before and after a change in recommendation category;
- vaccination rates among patients with chronic diseases and immunocompromising conditions;
- vaccination rates by site of administration, particularly pharmacies;
- differences in vaccine uptake across socioeconomic and demographic populations;
- patient-reported problems obtaining vaccines;
- delays or missed vaccination opportunities associated with eligibility or documentation requirements; and
- healthcare professional understanding of the recommendation and insurance coverage.

Most importantly, when a vaccine recommendation changes, HHS should prospectively evaluate whether vaccine uptake declines among populations that can clinically benefit from immunization.

If a policy intended to improve individualized decision-making instead creates confusion and lowers appropriate vaccination rates, HHS should reassess the recommendation.

Conclusion

Vaccines remain one of the most cost-beneficial interventions in healthcare, yet adult immunization rates in the U.S. continue to fall below public health goals. Federal policy should therefore work to reduce barriers to vaccination rather than unintentionally create new ones.

Shared clinical decision-making is an important part of healthcare. However, it is not unique to an SCDM vaccine recommendation.

It already occurs every day.

Patients do not routinely receive vaccines without interacting with a physician, pharmacist, or other healthcare professional. Either the patient requests vaccination or the healthcare professional recommends or offers the vaccine. The healthcare professional addresses questions and relevant clinical considerations, and the patient ultimately decides whether to be immunized.

Therefore, the policy benefit of creating a separate SCDM category must be evaluated against its potential unintended consequences.

For adult patients, especially patients with chronic and autoimmune diseases, this is critical because pharmacies are the primary location where vaccinations are administered. A complex Federal recommendation that is difficult to implement at a pharmacy can turn a convenient immunization opportunity into another physician visit, another request for documentation, another delay, and potentially another patient who never receives the vaccine.

The most important measure of any Federal vaccine recommendation is whether it improves patient outcomes and allows eligible patients who choose to be immunized to access the vaccine.

HHS should ensure that Federal vaccine recommendations remain scientifically based, clear, and practical to implement while maintaining patient choice and healthcare professional clinical judgment.

Shared clinical decision-making should remain an integral part of patient-centered healthcare. It should not become an additional barrier to adult vaccination.

References

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