ACIP Evidence to Recommendations Framework

Question: Overarching policy question to be answered by the guideline panel (ACIP) using the Evidence to Recommendations (EtR) framework. The question should be precise and identify the specific intervention, comparison, and outcome, as well as the target population and the setting (specific subpopulations) in PICO format.
Population: Target population for vaccine (e.g., age range, sex, immune status, pregnancy)
Intervention: Vaccination (if applicable, dosage and schedule)
Comparison(s): No Vaccination/Standard of care/An existing vaccine/Other prevention option
Outcome: Outcome(s) associated with vaccination (e.g., prevention outcomes or adverse effects)

Background: The addressed PICO question should be described in detail, and important background information for understanding the question and why a recommendation or decision is needed should be briefly provided. If a recommendation is preferential or represents off-label use, this should be indicated.
Include sample language: Additional background information supporting the ACIP recommendations on the use of xxx vaccine can be found in the relevant publication of the recommendation referenced on the ACIP website.

	WORK GROUP JUDGMENTS	EVIDENCE	ADDITIONAL INFORMATION
PROBLEM	**Is the problem of public health importance?** ○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Provide available scientific evidence on burden of disease, preferably within the target population for the recommendation. If no published evidence is available, provide expert judgment on the public health priority considerations.	Identify any additional public health priority considerations, including consideration of disparities.

	WORK GROUP JUDGMENTS	EVIDENCE	ADDITIONAL INFORMATION
BENEFITS & HARMS	**How substantial are the desirable anticipated effects?** ○ Minimal ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	Describe the magnitude of the beneficial effects of vaccination on individual (vaccine effectiveness, duration of protection) and population (herd immunity) levels.	Take into consideration: Is the baseline benefit similar across subgroups (by age, sex, pregnancy or lactation status, occupation [i.e., healthcare workers], immune status, race, SES, and other groups)? Are there indirect effects that should be considered (e.g., herd immunity)?
	How substantial are the undesirable anticipated effects? ○ Minimal ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	Are there undesirable effects of the vaccine, either on the individual (e.g., adverse events following immunization) or population (e.g., age-shift of disease, serotype replacement) levels?	Take into consideration: Is the baseline risk for harm similar across subgroups (see above)? Should there be separate recommendations for subgroups based on harms?
	Do the desirable effects outweigh the undesirable effects? ○ Favors interventionl ○ Favors comparison ○ Favors both ○ Favors neither ○ Varies ○ Don't know	Describe the balance of benefits of the vaccine with possible harms (individual and population level).	

	WORK GROUP JUDGMENTS	EVIDENCE	ADDITIONAL INFORMATION
	What is the overall certainty of this evidence for the critical outcomes? *Effectiveness of the intervention* ○ No studies found ○ 4 (very low) ○ 3 (low) ○ 2 (moderate) ○ 1 (high) *Safety of the intervention* ○ No studies found ○ 4 (very low) ○ 3 (low) ○ 2 (moderate) ○ 1 (high)	Please refer to GRADE evidence profiles for detailed assessment of the certainty of the evidence. For more information, please see the ACIP Handbook for Developing Evidence-Based Recommendations.	If GRADE was not used to evaluate the certainty of evidence, please provide justification and the method and outcome of any other tools used to evaluate the body of evidence relevant to the critical outcomes.
VALUES	**Does the target population feel that the desirable effects are large relative to undesirable effects?** ○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Provide any available evidence on target population values & preferences related to vaccination and comparative health benefits and risks. Describe the source of these estimates.	Are values and preferences for relevant outcomes measured? Are the benefits, harms and costs of vaccination valued differently by different subgroups? If the target group doesn't value the intervention, or attributes little value to the harms and benefits, consider whether potential education measures are needed.

	WORK GROUP JUDGMENTS	EVIDENCE	ADDITIONAL INFORMATION
	Is there important uncertainty about or variability in how much people value the main outcomes? ○ Important uncertainty or variability ○ Probably important uncertainty or variability ○ Probabl not important uncertainty or variability ○ No important uncertainty or variability ○ No known undesireable outcomes	Please provide available data used to determine the relative importance that the target population attributes to the desirable and the undesirable outcomes related to the intervention as well as the comparison.	Describe the source of variability, if any. Are there methods for determining values satisfactory for this recommendation? If not, systematic assessment of values and preferences of target group may be considered.
ACCEPTABILITY	**Is the intervention acceptable to key stakeholders?** ○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Provide assessment of whether intervention would be acceptable to stakeholders (ethically, programmatically, financially, etc.)	
RESOURCE USE	**Is the intervention a reasonable and efficient allocation of resources?** ○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Provide summary of cost-effectiveness analyses (CEAs) of the vaccine in the target population. Include base case results and a sensitivity range. Include any other notable findings, for example, specific policy-relevant scenarios.	Overall findings: Summarize the findings from available CEAs, including major differences in baseline assumptions. Uncertainty: Does the analysis capture the full range of uncertainty? For example, are the findings from the uncertainty of evidence analysis, identified earlier in this document (the EtR Framework), appropriately represented in the methods of the CEAs? Multiple assessments: Are there multiple CEAs? If so, what are the major differences in methods and results?

	WORK GROUP JUDGMENTS	EVIDENCE	ADDITIONAL INFORMATION
EQUITY	**What would be the impact on health equity?** ○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ○ Don't know	Summarize the findings from a review of the literature addressing issues of health inequities or groups who may be disadvantaged.	Consider from the evidence or guideline panel: • Are there any groups or settings that might be disadvantaged in relation to the problem or options that are considered? • Are there plausible reasons for anticipating differences in the relative effectiveness of the option for disadvantaged groups or settings? • Are there different baseline conditions across groups or settings that affect the absolute effectiveness of the option or the importance of the problem for disadvantaged groups or settings? • Are there important considerations that should be made when implementing the intervention (option) in order to ensure that inequities are reduced, if possible, and that they are not increased?
FEASIBILITY	**Is the intervention feasible to implement?** ○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Are there any barriers to implementation?	Please refer to the Implementation Considerations checklist.

Balance of consequences	Undesirable consequences *clearly outweigh* desirable consequences in most settings	Undesirable consequences *probably outweigh* desirable consequences in most settings	The balance between desirable and undesirable consequences *is closely balanced* or *uncertain*	Desirable consequences *probably outweigh* undesirable consequences in most settings	Desirable consequences *clearly outweigh* undesirable consequences in most settings	There is insufficient evidence to determine the balance of consequences
	O	O	O	O	O	O

Is there sufficient information to move forward with a recommendation?
Yes O   No O

Policy options for ACIP consideration	ACIP does not recommend the intervention* *Intervention may be used within FDA licensed indications	ACIP recommends the intervention for individuals based on shared clinical decision-making	ACIP recommends the intervention
	O	O	O
Draft recommendation (text)	Please provide the draft recommendations proposed to ACIP.		
Additional considerations (optional)	Please outline any significant additional considerations (e.g., aspects related to implementation, monitoring and evaluation, research priorities, etc.).		

Final deliberation and decision by the ACIP

Final ACIP recommendation	ACIP does not recommend the intervention* *Intervention may be used within FDA licensed indications ○	ACIP recommends the intervention for individuals based on shared clinical decision-making ○	ACIP recommends the intervention ○
Additional ACIP considerations	Wording as accepted in the guide		