



# Update to the Centers for Disease Control and Prevention and the Healthcare Infection Control Practices Advisory Committee Recommendation Categorization Scheme for Infection Control and Prevention Guideline Recommendations

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## Background

The Healthcare Infection Control Practices Advisory Committee (HICPAC) is a federal advisory committee chartered in 1991 to provide advice and guidance to the Centers for Disease Control and Prevention (CDC) and the Secretary of the Department of Health and Human Services (HHS) regarding issues related to the detection and prevention of healthcare-associated infections, including antimicrobial resistance, in United States healthcare settings. Committee activities include providing advice and guidance on the development and evaluation of healthcare infection prevention and control guidelines and recommendations. In April 2017, HICPAC formed the Workgroup on Updating the CDC and HICPAC Recommendation Categories. The Workgroup was charged with updating the scheme used to categorize recommendations in order to reflect evolving methodology, provide options for incorporating expert opinion into guideline development, and to increase transparency regarding the rationale for decisions regarding the strength of recommendations.

CDC has led the development of recommendations aimed at the prevention of healthcare-associated infections since the 1970s. These recommendations continue to evolve over time as evidence bases are built, and they serve as a foundation for healthcare safety across settings; as a basis for quality improvement efforts; and as part of the process that identifies important research gaps. CDC's infection prevention and control recommendation categorization scheme has its roots in the guidelines of the 1980s, when categories were developed based primarily on the strength of supporting evidence.

HICPAC's original recommendation categorization scheme reflected the increasing rigor associated with the guideline production process:

- IA: A strong recommendation supported by high to moderate-quality evidence suggesting net clinical benefits or harms
- IB: A strong recommendation supported by low-quality evidence suggesting net clinical benefits or harms; or an accepted practice supported by low to very-low quality evidence
- IC: A strong recommendation required by state or federal regulation.
- II: A weak recommendation supported by any quality evidence suggesting a trade-off between clinical benefits and harms
- No recommendation/unresolved issue: An issue for which there is low to very low quality evidence with uncertain trade-offs between the benefits and harms or no published evidence on outcomes deemed critical to weighing the risks and benefits of a given intervention.

## Update to the CDC and the HICPAC Recommendation Categorization Scheme for Infection Control and Prevention Guideline Recommendations

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This scheme, while rigorous, is complex and has limitations when applied to the field of infection prevention and control. In particular, the paucity of Level I evidence (e.g., well-designed randomized controlled trials) for many topics that are important for prevention of healthcare-associated infections frequently led to “weak” or “unresolved issue” recommendations, even for practices where existing evidence and expert opinion suggested that potential benefits outweighed risks. In addition, the factors contributing to decisions around the choice of recommendation category were not consistently described. Given these limitations, CDC requested that HICPAC develop an updated recommendation categorization scheme.

The HICPAC Workgroup on Updating the CDC and HICPAC Recommendation Categories was charged with updating the categorization scheme to reflect evolving methodological needs and to transparently indicate:

- The strength of the recommendation;
- The quality and consistency of evidence in support of the recommendation, including expert opinion;
- The balance of benefits and harms, including costs and resource utilization; and
- The criteria for distinguishing requisite versus supplemental practices.

In conceiving and shaping the updated recommendation categorization scheme, the Workgroup focused on a series of questions:

- How can HICPAC simplify its categories?
- How can HICPAC improve transparency around the rationale for choosing specific recommendation categories?
- How should HICPAC address practices for which evidence is scant or absent?
- How should HICPAC address bundled practices?
- How should HICPAC partner with professional societies and other guideline-promulgating organizations?

## Methods

The Workgroup reviewed and assessed existing recommendation categorization schemes<sup>1-4</sup> and infection control guidelines<sup>5-12</sup> created by a range of guideline-promulgating groups, including government agencies and professional organizations, and assessed limitations and challenges related to the current CDC categorization scheme. The Workgroup then drafted an updated categorization scheme, which was presented to HICPAC at public meetings in July 2017 and November 2017. Based on committee input received at those public meetings, the Workgroup refined the draft categorization scheme and the draft new scheme was approved by unanimous HICPAC vote at the February 2018 meeting. CDC posted notice in the *Federal Register* for a period of public comment from September 17, 2018, to October 17, 2018. After this period, in which no public comments were submitted, HICPAC reviewed the draft scheme at the public November 2018 meeting, incorporated Workgroup edits, and voted unanimously to approve the new recommendation categorization scheme.

## Summary

The updated HICPAC Recommendation Categorization Scheme includes three tables describing:

1. The recommendation categories,

2. The justification for the choice of recommendation strength, and
3. The level of confidence in the evidence.

*Table 1: Overall Strength of Recommendations* defines and describes three recommendation categories: Recommendation, Conditional Recommendation, and No Recommendation. The shift from five categories in the original scheme to three in the updated scheme simplifies and clarifies its structure. The recommendation definitions clarify how the combination of the quality of evidence and the balance of benefits and harms are used to determine each category. The table outlines the implied obligation for each category and provides examples of wording for each of the recommendation categories, noting the importance of specificity regarding the population, environment, and setting to which a recommendation applies.

*Table 2: Transparency: Justification for Choice of Recommendation Strength to be Included in Text* is a new element of HICPAC's recommendation categorization scheme that articulates the elements weighed for each recommendation. The "Justification Table" includes nine components and also describes considerations that were important in formulating the recommendation. These justifications accompany recommendations when they are published, transparently explaining the deliberations and conclusions undergirding them.

*Table 3: Level of Confidence in the Evidence* is based on Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) and the Canadian Task Force on Preventive Health Care. This table defines the three levels of confidence in the evidence, ranging from high to low. Each definition is a measure of how likely the results depicted in the aggregate evidence are likely to reflect the true effect. These definitions are reported in the justification tables used to inform the decision regarding which category to use for each recommendation.

## Conclusion

In updating the Recommendation Categorization scheme, HICPAC sought to streamline, simplify, and clarify its recommendation categories. In addition, the updated scheme adds transparency to the guideline-writing process by not only basing the strength of recommendations on the quality of available evidence, but also providing a standard format for summarizing a number of factors, including the quality of evidence, that impact the choice of the strength of recommendation category. HICPAC also recognized the need to incorporate lesser evidence or even expert opinion when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.

With these updates and improvements, the HICPAC Recommendation Categorization Scheme Update will support the development of actionable recommendations for the field.

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## HICPAC Recommendation Categorization Scheme (2019)

**TABLE 1: Strength of Recommendations**

Strength	Definition	Implied Obligation	Language
<b>Recommendation</b>	<p>A Recommendation means that CDC and HICPAC are confident that the benefits of the recommended approach clearly exceed the harms (or, in the case of a negative recommendation, that the harms clearly exceed the benefits). In general, Recommendations should be supported by high- to moderate-quality evidence. In some circumstances, however, Recommendations may be made based on lesser evidence or even expert opinion when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms or when then Recommendation is required by federal law.</p>	<p>A Recommendation implies that healthcare personnel/healthcare facilities “should” implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.</p>	<p>The wording of the Recommendation should specify the setting and population to which the Recommendation applies (e.g., adult patients in intensive care unit settings).</p> <ul style="list-style-type: none"> <li>• Action verbs, e.g., use, perform, maintain, replace</li> <li>• Should, should not</li> <li>• Recommend/ is recommended, recommend against/ is not recommended</li> <li>• Is indicated/ is not indicated</li> </ul>
<b>Conditional Recommendation</b>	<p>A Conditional Recommendation means that CDC and HICPAC have determined that the benefits of the recommended approach are <i>likely</i> to exceed the harms (or, in the case of a negative recommendation, that the harms are likely to exceed the benefits). Conditional Recommendations may be supported by either low-, moderate- or high-quality evidence when:</p> <ul style="list-style-type: none"> <li>• there is high-quality evidence, but the benefit/harm balance is not clearly tipped in one direction</li> <li>• the evidence is weak enough to cast doubt on whether the recommendation will consistently lead to benefit</li> <li>• the likelihood of benefit for a specific patient population or clinical situation is extrapolated from relatively high-quality evidence demonstrating impact on other patient populations or in other clinical situations (e.g.,</li> </ul>	<p>A Conditional Recommendation implies that healthcare facilities/ personnel “could,” or could “consider” implementing the recommended approach. The degree of appropriateness may vary depending on the benefit vs. harm balance for the specific setting.</p>	<p>The wording of the Conditional Recommendation should specify the setting and population to which the Conditional Recommendation applies when relevant, including select settings (e.g., during outbreaks); select environments (e.g., ICUs); select populations (e.g., neonates, transplant patients).</p> <ul style="list-style-type: none"> <li>• Consider</li> <li>• Could</li> <li>• May/ may consider</li> </ul>

Strength	Definition	Implied Obligation	Language
	<p>evidence obtained during outbreaks used to support probable benefit during endemic periods)</p> <ul style="list-style-type: none"> <li>the impact of the specific intervention is difficult to disentangle from the impact of other simultaneously implemented interventions (e.g., studies evaluating “bundled” practices)</li> <li>there appears to be benefit based on available evidence, but the benefit/harm balance may change with further research</li> <li>benefit is most likely if the intervention is used as a supplemental measure in addition to basic practices</li> </ul>		
<b>No Recommendation</b>	No Recommendation is made when there is both a lack of pertinent evidence and an unclear balance between benefits and harms.	n/a	“No recommendation can be made regarding”

**TABLE 2: Justification for Choice of Recommendation Strength**

Components	What to include	Comments
Supporting Evidence	List the number and type(s) of available evidence used.	e.g., “ ... 10 observational studies”
Level of Confidence in the Evidence	Level of confidence is low/moderate/high (See Table 3).	e.g., “The level of confidence in this evidence is low, as observational studies are at increased risk of bias”
Benefits	List the favorable changes in outcomes that would likely occur if the Recommendation were followed.	Be explicit, clear about pros/cons
Risks and Harms	List the adverse events or other unfavorable outcomes that may occur if the Recommendation were followed.	Be explicit, clear about pros/cons
Resource Use	Describe (if applicable) direct costs, opportunity costs, material or human resources requirements, facility needs, etc, that may be associated with following the Recommendation.	HICPAC does not perform its own cost analyses and is not obliged to address cost if analyses are not available and no useful statements can be made. State clearly if information on resource use is lacking.

Components	What to include	Comments
Benefit-Harm Assessment	Classify as “preponderance of benefit over harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual patient perspective, the societal perspective, or both.	Recommendations are possible when clear benefit is not offset by important harms or costs (or vice versa); conversely, when the benefit is small or offset by important adverse factors, the balance between benefit and harm prevents a Recommendation.
Value Judgments	Summarize value judgments used by the group in creating the Recommendation; if none were involved, state “none.”	Translating evidence into action often involves value judgments, which include guiding principles, ethical considerations, or other beliefs and priorities. Stating them clearly helps users understand their influence on interpreting objective evidence.
Intentional Vagueness	State reasons for any intentional vagueness in the Recommendation; if none was intended, state “none.”	Recommendations should be clear and specific, but if the group chooses to be vague, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include insufficient evidence; inability to achieve consensus among panel regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/religious issues.
Exceptions	List situations or circumstances in which the Recommendation should not be applied.	n/a

**TABLE 3: Aggregate Level of Confidence in Effect Estimate\***

Level of Confidence	Description
<b>High</b>	Highly confident that the true effect lies close to that of the estimated size and direction of the effect. For example, confidence in the evidence is rated as “High” when there are multiple studies with no major limitations, there are consistent findings, and the summary estimate has a narrow confidence interval.
<b>Moderate</b>	The true effect is likely to be close to the estimated size and direction of the effect, but there is a possibility that it is substantially different. For example, confidence in the evidence is rated as “Moderate” when there are only a few studies and some have limitations but not major flaws, there is some variation between study results, or the confidence interval of the summary estimate is wide.
<b>Low</b>	The true effect may be substantially different from the estimated size and direction of the effect. For example, confidence in the evidence is rated as “Low” when supporting studies have major flaws, there is important variation between study results, the confidence interval of the summary estimate is very wide, or there are no rigorous studies.

\*Based on Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) and the Canadian Task Force on Preventive Health Care



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