HICPAC Recommendation Categorization Update Workgroup: Public Comment Summary and Finalization

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HICPAC Presentation, November 2018

Disclaimer: The findings and conclusions herein are **draft** and have not been formally disseminated by the Centers for Disease Control and Prevention and should not be construed to represent any agency determination or policy.

Background

- How can HICPAC:
  - Simplify its recommendation categories?
  - Improve transparency around the rationale for choosing specific recommendation categories?
  - Address practices for which evidence is scant or absent?
  - Address bundled practices?
- HICPAC Recommendation Categorization Workgroup activities:
  - Monthly Workgroup calls
  - Discussion at HICPAC meetings: 07/2017, 11/2017, 02/2018
  - Test draft scheme with CAUTI Guideline
  - NICU Guideline Workgroup experience

Table 1: Overall Strength of Recommendations

Strength	Definition	Implied Obligation	Language
Recommendation	A Recommendation means that we 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 the Recommendation is required by federal law.	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.	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) • Declarative verbs, e.g., use, perform, maintain, replace • Should, should not • Recommend/ is recommended, recommend against/ is not recommended • Is indicated/ is not indicated
Conditional Recommendation	A Conditional Recommendation means that we have determined that the benefits of the recommended approach are **likely** 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: • there is high-quality evidence, but the benefit/harm balance is not clearly tipped in one direction • the evidence is weak enough to cast doubt on whether the recommendation will consistently lead to benefit • 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., evidence obtained during outbreaks used to support probable benefit during endemic periods) • the impact of the specific intervention is difficult to disentangle from the impact of other simultaneously implemented interventions (e.g., studies evaluating "bundled" practices) • there appears to be benefit based on available evidence, but the benefit/harm balance may change with further research • benefit is most likely if the intervention is used as a supplemental measure in addition to basic practices	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.	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) • Consider • Could • May/ may consider
No Recommendation	No Recommendation is made when there is both a lack of pertinent evidence and an unclear balance between benefits and harms.		"No recommendation can be made regarding"

Table 1: Recommendation

Strength	Definition	Implied Obligation	Language
Recommendation	A **Recommendation** means that we 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 the Recommendation is required by federal law.	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.	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) • Declarative verbs, e.g., use, perform, maintain, replace • Should, should not • Recommend/ is recommended, recommend against/ is not recommended • Is indicated/ is not indicated

Table 1: Conditional Recommendation

Strength	Definition	Implied Obligation	Language
Conditional Recommendation	A Conditional Recommendation means that we have determined that the benefits of the recommended approach are **likely** 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: • there is high-quality evidence, but the benefit/harm balance is not clearly tipped in one direction • the evidence is weak enough to cast doubt on whether the recommendation will consistently lead to benefit • 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., evidence obtained during outbreaks used to support probable benefit during endemic periods) • the impact of the specific intervention is difficult to disentangle from the impact of other simultaneously implemented interventions (e.g., studies evaluating "bundled" practices) • there appears to be benefit based on available evidence, but the benefit/harm balance may change with further research • benefit is most likely if the intervention is used as a supplemental measure in addition to basic practices	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.	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) • Consider • Could • May/ may consider

Table 1: No Recommendation

Strength	Definition	Implied Obligation	Language
No Recommendation	**No Recommendation** is made when there is both a lack of pertinent evidence and an unclear balance between benefits and harms.		"No recommendation can be made regarding"

Table 2: Justification for Choice of Recommendation

Components	What to include	Comments
Aggregate evidence quality	See below (Table 3)	
Benefit	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
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.
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 .
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 where the recommendation should not be applied	

Table 2, Part 1

Components	What to include	Comments
Supporting evidence	See below	Number and type of available evidence used, eg, "…10 observational studies"
Confidence in Evidence	Level of confidence is low/moderate/high (Table 3)	eg, "The level of confidence in this evidence is low as observational studies are at increased risk of bias"
Benefit	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
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.
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.

Table 2, Part 2

Components	What to include	Comments
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 where the recommendation should not be applied	

Table 3: Level of Confidence in the Evidence

Level of Confidence in the Evidence for Each Recommendation	
High	Highly confident that the true effect lies close to that of the estimated size and direction of the effect. For example, confidence 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.
Moderate	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 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.
Low	The true effect may be substantially different from the estimated size and direction of the effect. For example, confidence 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

Public Comment Period

- Announced in the *Federal Register* on September 17, 2018 (Docket # CDC-2018-0090)
- Was available for public review and comment on www.regulations.gov until October 17, 2018
- No comments from the public were received

Discussion

- Questions