A Process for Assessing Products for Infection Prevention in Healthcare Settings: a framework from HICPAC

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Background

The Healthcare Infection Control Practices Advisory Committee (HICPAC) is a federal advisory committee that focuses on the practice of infection control and strategies for surveillance, prevention, and control of healthcare-associated infections (HAIs), antimicrobial resistance, and related events in United States healthcare settings. At the July 2017 HICPAC Meeting, the Centers for Disease Control and Prevention (CDC) asked HICPAC to develop a process for HICPAC and CDC to use when formulating product-specific recommendations. HICPAC formed a workgroup to achieve this goal. The workgroup provided updates and obtained HICPAC input at the July and November 2017 HICPAC meetings and the May and November 2018 HICPAC meetings. HICPAC voted to finalize the tool and workflow at the November 2018 meeting.

Introduction

Innovations in healthcare infection prevention are essential to improve patient safety and increase our ability to provide optimal care. During the last decade, numerous novel products have entered the healthcare market. CDC and HICPAC recognize the importance of being able to meaningfully and consistently assess these innovations, for which supporting evidence is often limited or of heterogeneous quality. To address these issues, CDC asked HICPAC to develop a transparent and rigorous process for the Committee to use when formulating product-specific recommendations, and to provide the rationale for the criteria proposed.

Methods

The process used by the workgroup to develop the workflow is described here: A Process for Assessing Products for Infection Prevention in Health Care Settings: A Framework From the Healthcare Infection Control Practices Advisory Committee of the Centers for Disease Control and Prevention [PDF – 6 pages] (http://annals.org/aim/article/doi/10.7326/M19-2172)

Summary

The workgroup developed a tool consisting of discrete elements for the review of product-specific evidence. This tool is intended to be used to assess the evidence for a novel product, compare and contrast two similar products, and serve as a workflow when guidelines are considering recommendations for a product.

HICPAC Infection Prevention Product Review Worksheet

A

Is the product or device FDA approved/cleared or EPA registered?

- ☐ Yes (Proceed to Node B)
- ☐ No: FDA/EPA label is not required and marketing materials do not make medical or mitigation claims (Proceed to Node B)
- ☐ No: marketing materials make medical or mitigation claims: (**STOP - HICPAC will not review products or devices that are not approved and make these claims)**

B

What is the FDA or EPA approval type? (Note: search the FDA or EPA databases for similar products)

→ Describe: _____

C

For the purposes of this analysis, is the product or device being considered for used in accordance with FDA- or EPA-approved labels? (Note: review FDA- or EPA-approved labels)

- ☐ Yes
- ☐ No → Describe (e.g., population, indicated use, setting, etc.): _____
  - → If off-label use is considered, is the product/device not approved due to possible safety concerns?
    - ☐ No safety concerns on label (Proceed to Node D)
    - ☐ Possible safety concerns (**STOP - HICPAC will not draft recommendations for products that are not approved due to possible safety concerns**)

D, E, F, G

	Key Question	What to Include	Dates/Timeframes for Data Source	Comments
D	What are the clinically relevant human outcomes? Proxy outcomes?	List all outcomes reported in publications including metrics of how they are reported (e.g., catheter days, percent, etc.)		
E	What are the indications for use? Label claim?	Indications for use and label claims as described by the manufacturer when submitting products for review to FDA, and detailed on the FDA-approved label.		
F	Is the product marketed for infection prevention?	Summary of manufacturer's marketing material.		
G	What evidence of efficacy is available? • Pre-specified clinically relevant outcomes? • Supporting indications for use? • Supporting label claims? • Marketing data?	Summarize the available evidence. Note: • Follow guideline approach to evidence appraisal • Source of evidence (e.g., was the evidence published in peer-reviewed journals or was it provided to FDA as premarket data?) • Type and quality of the evidence • Funding source of the evidence • Provide references for the evidence • Does the evidence support the marketing?		

	Key Question	Examples of What to Include	Dates/Timeframes for Data Source	Comments
H	What evidence of safety or assessment of potential harms is available? • Pre-market evidence? • Post-market evidence?	Review FDA submissions. Also review harm assessments in published data, if available (e.g., observational studies and RCTs). Consider reviewing harms in additional locations (see node O).		
I	What is the assessment of the balance of harms vs. benefits?	Review the evidence available to summarize the risks and benefits related to the product. Summarize risk/benefit from patient, provider, and system-level perspectives.		
J	Is it equivalent or superior to established alternatives (standard of care)?	Describe the context of the study performance. What were the standards of care when the product was reviewed? Does the study evaluate compliance with these standards of care?		
K	Is there a demonstrated impact when the product is used alone or as part of a bundle?	Is this device or product evaluated in addition to bundle elements or in place of one of the bundle elements? Is the impact measurable or reported outside of this bundle?		
L	Are the findings generalizable to a product class at the time the evidence is reviewed?	e.g., active ingredients, mechanism of action, product design, instructions for use, etc.		
M	Does evidence support generalizability across settings, environments, populations?	Is the harm and benefit assessment the same across patients, outbreak and non-outbreak settings, etc.? Is it the same across neonatal and adult populations?		
N	What are the resource implications?	Include human, materials, education and training, and financial costs (including purchase, repair, maintenance).		
O	Does this assessment support proceeding with the development of a recommendation? This sentence will include a summary of nodes B-N with or without a statement regarding support for the development a recommendation. If the recommendation supports use of a product, consider performing further review for harms or new information in other databases, for example: *clinicaltrials.gov, MAUDE database, ECRI site.*			

Legend: FDA=Food and Drug Administration; EPA=Environmental Protection Agency; HICPAC=Healthcare infection Control Practice Advisory Committee; RCTs=randomized controlled trials; MAUDE=Manufacturer And User facility Device Experience; ECRI=Emergency Care Research Institute

Available from: http://www.cdc.gov/hicpac/workgroup/product-assessment.html

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Declarations of Interest

None of the Workgroup members reported financial or intellectual interests related to the topics in this document.