Evidence-based Practice Center Rapid Review Protocol

Project Title: *Making Healthcare Safer IV: Supply Chain Disruption Monitoring Programs*

Review Questions

Review Question

How effective are patient safety practices (PSPs) for identifying and monitoring critical supplies and drugs for supply chain disruptions, and what are their unintended effects?

Contextual Questions

1. How could supply chain disruption monitoring programs prevent or mitigate harms?
2. What are common barriers and facilitators to implementation of supply chain disruption monitoring programs?
3. What resources (e.g., cost, staff, time) are required for implementation of supply chain disruption monitoring programs?
4. What toolkits are available to support implementation of supply chain disruption monitoring programs?

Context and Domain Being Studied

The Agency for Healthcare Research and Quality (AHRQ) Making Healthcare Safer (MHS) reports consolidate information for healthcare providers, health system administrators, researchers, and government agencies about PSPs that can improve patient safety across the healthcare system—from hospitals to primary care practices,

long-term care facilities, and other healthcare settings. In Spring of 2023, AHRQ launched its fourth iteration of the MHS Report (MHS IV).

Supply chain disruptions were identified as high priority for inclusion in the MHS IV reports using a modified Delphi technique by a Technical Expert Panel (TEP) that met in December 2022. The TEP included 15 experts in patient safety with representatives of governmental agencies, healthcare stakeholders, clinical specialists, experts in patient safety issues, and a patient/consumer perspective. See the MHS IV Prioritization Report for additional details.[1]

This rapid review focuses on monitoring programs for supply chain disruptions in healthcare settings and includes monitoring programs for various medical supplies including medications, medical devices, and other equipment (e.g., personal protective equipment [PPE] for patients and clinical providers, bandages and gauze, and sterile surgical and aftercare instruments) needed to deliver high-quality and safe healthcare. The medical supply chain encompasses multiple factors, entities, and processes that affect manufacturing, logistics, and distribution, and the availability of products required to deliver efficient, and safe care to patients.[2, 3] Implementing supply chain monitoring programs is one way healthcare organizations are attempting to predict and manage supply chain disruptions.

Overview of the Topic

The medical supply chain is a complex network of interconnected parts related to procuring raw materials, processing and manufacturing essential medical supplies, transporting and storing them, and ultimately delivering them to patients.[2, 4] Due to the interconnectivity, any disruptions – even seemingly small ones – in any part of the process can cause large-scale problems.[2, 4, 5] These involve reduced availability of medications, medical devices, and supplies to patients and providers, potentially lowering quality care and increasing harms.[4] Disruptions can occur due to myriad reasons ranging from the scarcity of raw materials,[4] unforeseen events at production and manufacturing facilities,[2, 6] intentional attacks (including cyberattacks),[4] to natural disasters and pandemics.[2]

Mitigating harms due to supply chain disruptions is complex due to the interconnected network of several entities. National efforts include the Coronavirus Aid, Relief, and Economic Security (CARES) Act, established in 2020, which required manufacturers of certain drugs and medical devices to notify the U.S. Food and Drug Administration about permanent discontinuances or manufacturing interruptions that are likely to lead to meaningful disruptions. Further, the Department of Health and Human Services created a new Supply Chain Resilience and Shortage Coordinator role, along with a number of policies to prevent drug shortages and mitigate supply chain risks.[6] Individual healthcare facilities and health systems are also implementing supply chain monitoring programs to anticipate and prepare for vital supply shortages, with some implementing Radio Frequency Identification (RFID) systems to electronically assist inventory management.[7] It is unclear how widespread such monitoring programs are.

Though it is difficult to estimate the full extent of medical supply chain disruptions in the United States, approximately 80 percent of hospitals reported supply chain shortages in 2021,[8] and supply chain shortages were second among the top 10 risks for healthcare organizations in 2022.[9] Supply chain disruptions can impact numerous aspects of care delivery, though their prevalence may depend on both severity and disruption type.

Patients may experience a number of harms related to supply chain disruptions. These can include drug/device shortages, delays in care which can result in sourcing inferior or illegitimate products,[10] increased risk of adverse events, and increased costs. Increased morbidity and mortality is also associated with supply chain disruptions.[11] Perhaps the most large-scale recent disruption to the global medical supply chain was the coronavirus disease 2019 (COVID-19) pandemic, which led to supply shortages that affected healthcare workers' ability to deliver care safely, drug and supply shortages for patients, delays in the delivery of care such as surgeries, shortages in diagnostic equipment and tests, and increased costs due to inflation and increased demand.[5, 11-13]

This topic was not addressed in previous MHS reports.

In the prioritization process, the MHS IV TEP noted a moderate amount of studies may be available to assess this PSP and there were no recent high-quality systematic reviews.

Purpose of the Review

The purpose of this rapid review is to evaluate and synthesize the evidence on benefits and harms of supply chain disruption monitoring programs in healthcare settings. We will also identify and describe how supply chain disruption monitoring programs (a) may prevent or mitigate harms to patients; (b) their common barriers and facilitators to implementation; (c) what resources may be required for implementation; and (d) what toolkits are available to assist with implementation. This rapid review is intended to inform policymakers, healthcare organization administrators, and quality and safety leaders when considering implementing supply chain disruption monitoring programs.

Methodologic Approach

For this rapid review, strategic adjustments will be made to streamline traditional systematic review processes and deliver an evidence product in the allotted time. We will follow adjustments and streamlining processes proposed by the AHRQ Evidence-based Practice Center (EPC) Program. Adjustments include being as specific as possible about the questions, limiting the number of databases searched, modifying search strategies to focus on finding the most valuable studies (i.e., being flexible on sensitivity to increase the specificity of the search), and restricting the search to English-language studies conducted in the United States published in 2010 and after in order to complete this rapid review in a timely manner and simultaneously capture all relevant published studies, and having each study assessed by a single reviewer. A second team member will review a randomly selected 10 percent of excluded citations at the title and abstract screening stage, as described below in the section on Data Extraction.

For contextual questions 1 (rationale), 2 (barriers and facilitators), and 3 (resources), we will draw on information reported in the studies included for the Review Question. For contextual questions 2 and 3, we will also include case reports from healthcare organizations that describe barriers and facilitators and/or resources required for implementing supply chain monitoring programs if included studies for the Review Question do not address these aspects.

For contextual question 4, we will identify publicly available patient safety toolkits developed by AHRQ or other organizations that could help to support implementation of the PSPs. To accomplish that task, we will review AHRQ's Patient Safety Network (PSNet) (https:/psnet.ahrq.gov) and AHRQ's listing of patient safety related toolkits (https://www.ahrq.gov/tools/index.html?search_api_views_fulltext=&field_toolkit_topics=14170&sort_by=title&sort_order=ASC) and we will include any toolkits mentioned in the studies we find for the Review Question. We will identify toolkits without assessing or endorsing them.

Eligibility Criteria

We will search for recent (i.e., published in 2010 or later), original, comparative studies conducted in the United States according to the inclusion and exclusion criteria presented in Table 1. We will not include systematic reviews as primary data sources, but will use reference lists of all relevant systematic reviews to identify any additional studies that meet our inclusion criteria.

Table 1. Inclusion and Exclusion Criteria for the Review Question

Study Parameter	Inclusion criteria	Exclusion criteria
Population	Any patient population	No patient population exclusions
Intervention	A structured process or policy for monitoring supply chain disruptions before they occur. We will consider not only the supply chain itself, but also any logistics and distribution processes leading up to patient care.	Processes that solely measure inventory without the intent of detecting potential supply chain disruptions in advance; other interventions
Comparator	No process or policy for monitoring supply chain disruptions	No comparator
Outcome	• Patient safety measures/patient harms (e.g., mortality, SSIs, lack of necessary care) • Rehospitalizations; ED visits • Surrogate outcomes (e.g., supply availability, access to supplies, prescription fill-rates)	• Clinical effectiveness of devices • Cost/cost-effectiveness • Clinician burden • Hypothetical supply
Timing	Any followup	No timing exclusions
Setting	Healthcare facilities, including healthcare systems, hospitals, primary care and other ambulatory care settings (e.g., specialty practices, urgent care facilities), pharmacies, hospice care, long-term care facilities, prisons (for healthcare-related needs)	Nonhealthcare settings (e.g., schools)

Study Parameter	Inclusion criteria	Exclusion criteria
Study Design	RCTs and nonrandomized comparative studies	Reviews, statistical models, commentaries, uncontrolled studies, case reports

Abbreviations: ED = emergency department; RCT = randomized controlled trial; SSI = surgical site infection.

Literature Searches

Our search strategy will focus on databases expected to have the highest yield of relevant studies, including PubMed, Embase, and the Cochrane Library, supplemented by a narrowly focused search for unpublished reports that are publicly available from governmental agencies or professional societies having a strong interest in supply chain disruptions.

Data Extraction

The primary reviewer will screen titles and abstracts for potential inclusion. The team may opt to use AI as a semi-automated screening tool to conduct the review efficiently at the title and abstract screening stage. In that case, the title and abstract of each citation will be reviewed by the primary reviewer, and then the AI tool will serve as a second reviewer of each citation. In this case, a second reviewer will dual review the top 10 percent of citations identified by the AI feature. The full text of each remaining potentially eligible article will be reviewed by the primary reviewer to confirm eligibility and extract data. A second team member will check a randomly selected 10 percent sample of the articles to verify that important studies were not excluded and confirm the accuracy of extracted data.

Information will be organized according to the review and contextual questions, and will include author, year, study design, frequency and severity of the harms, measures of harm, characteristics of the PSP, rationale for the PSP, outcomes, unintended consequences, implementation barriers and facilitators, required resources, and description of toolkits. To streamline data extraction, we will sort eligible studies by specific PSP (if the report covers more than one specific type of monitoring program), and focus on extracting information about characteristics, outcomes, and barriers/facilitators most pertinent to a specific PSP.

Risk of Bias Assessment

For studies that address the Review Question about the effectiveness of PSPs, the primary reviewer will use the Cochrane Collaboration's tool for assessing the risk of bias of randomized controlled trials (RCTs) or the ROBINS-I tool for assessing the Risk Of Bias In Non-randomized Studies – of Interventions.[14, 15] When assessing RCTs, we will use the 7 items in the Cochrane Collaboration's tool that cover the domains of selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias.[16] When assessing non-randomized studies, we will use specific items in the ROBINS-I tool that assess bias due to confounding, bias in selection of participants into the study, bias in classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes, and bias in selection of the reported results.[15] The risk of bias assessments will focus on the main outcome of interest in each study.

The Task Leader will review the risk of bias assessments and any disagreements will be resolved through discussion with the team.

Data Synthesis

Selected data will be compiled into evidence tables and synthesized narratively. We will not conduct a meta-analysis. For the Review Question about the effectiveness of this PSP, we will record information about the context of each study and whether the effectiveness of the PSP differs across patient subgroups. If we include more than one study of effectiveness assessing included outcomes for a specific type of monitoring program, we will grade the strength of evidence using the methods outlined in the AHRQ Effective Health Care Program (EHC) Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[17] Evidence grading would not add value for PSPs that do not have more than one available study.

Analysis of Subgroups or Subsets

We will report if the effectiveness of the PSP differs across patient subgroups, but will not conduct subgroup analyses.

Registration

We will submit the protocol to AHRQ and to the PROSPERO international prospective register of systematic reviews.

EPC Team Disclosures

EPC core team members must disclose any financial conflicts of interest greater than $1,000 and any other relevant business or professional conflicts of interest. Related financial conflicts of interest that cumulatively total greater than $1,000 will usually disqualify EPC core team investigators from participation in the review.

External Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodological expertise. The EPC considers all peer review comments on the draft report in preparation of the final report. Peer reviewers do not participate in writing or editing of the final report or other products. The final report does not necessarily represent the views of individual reviewers.

We will ask at least one clinical content expert and one methodological expert to review the draft report. Potential peer reviewers must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Invited peer reviewers may not have any financial conflict of interest greater than $5,000.

Role of the Funder

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