

**Integrating Health System Data With Systematic
Reviews: A Framework for When and How
Unpublished Health System Data Can Be Used With
Systematic Reviews To Support Health System
Decision Making**



Integrating Health System Data With Systematic Reviews: A Framework for When and How Unpublished Health System Data Can Be Used With Systematic Reviews To Support Health System Decision Making

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Key Messages

Purpose of Report

Given that health-system decision making would benefit from both traditional systematic reviews and health-system-specific data, this report investigates when and how to use primary data from health systems in real time with systematic reviews and articulates a framework for using health system data with systematic reviews to support health system decision making.

Key Messages

Based on our review of examples and methodologic guidance, as well as our experience conducting systematic reviews for various stakeholders, we recommend five basic principles regarding when and how to use unpublished health system data alongside of systematically reviewed data.

- Explicitly state the rationale for using unpublished data (i.e., to improve the strength and applicability of evidence, and/or to inform its implementation).
- Describe the details of the data source being used and why it was chosen (e.g. how relevant are the data).
- Characterize the limitations and biases of any included data through formal critical appraisal and if possible, working with a health system's QI and information systems staff and health system researchers to understand data and information-quality limitations.
- Specify how the findings from unpublished data support, refute, and/or otherwise add to findings from published data. If the unpublished evidence conflicts with the review's conclusions, discuss possible reasons for the discrepancy.
- Consider working in close partnership with health systems, which ideally includes a range of individuals such as clinical leaders and decision makers as well as QI staff and health system researchers.

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None of the investigators has any affiliations or financial involvement that conflicts with the material presented in this report.

The information in this report is intended to help EPCs and AHRQ understand health systems' needs for and use of evidence to inform their decision making. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of healthcare in the United States.

The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new healthcare technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To improve the scientific rigor of these evidence reports, AHRQ supports empiric research by the EPCs to help understand or improve complex methodologic issues in systematic reviews. These methods research projects are intended to contribute to the research base in, and be used to improve, the science of systematic reviews. They are not intended to be guidance to the EPC program, although they may be considered by EPCs along with other scientific research when determining EPC program methods guidance.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the healthcare system as a whole by providing important information to help improve healthcare quality. The reports undergo peer review prior to their release as a final report.

If you have comments on this Methods Research Project they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

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Integrating Health System Data With Systematic Reviews: A Framework for When and How Unpublished Health System Data Can Be Used With Systematic Reviews To Support Health System Decision Making

Abstract

Systematic reviews are an important and necessary source of information to improve healthcare delivery; however, reviews of the existing research are often insufficient to address the decision-making needs of health systems. Incorporating data from health systems into traditional systematic reviews may be one way to improve their utility. In this paper, we map out ways in which health system data can be used with systematic reviews, articulate the scenarios for when health system data may be most helpful to use alongside systematic reviews (i.e., to improve the strength of evidence, to improve the applicability of evidence, and to improve the implementation of evidence), and discuss the importance of framing the limitations and considerations when using unpublished health system data in reviews (i.e., critical appraisal to understand the study design biases as well as limitations in information and data quality). To develop this framework, we used examples identified through literature searches and affiliations with four health systems that have the ability to use both internal and external evidence to support their clinical operations. Finally, we also offer recommendations to systematic reviewers who choose to integrate health system data and possible next steps in developing processes and capacity to routinely conduct this type of work.

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Introduction

Systematic reviews are intended to inform decisions made by a wide variety of stakeholders, including health systems. The reviews use rigorous, systematic methods to identify and select studies, which most commonly are published but can be and are unpublished evidence as well. Systematic reviews, while an important source of information, are often insufficient to address the decision-making needs of health systems.^{1,2} The EPC program is working to make its evidence syntheses more useful for health systems. Therefore, it is critical to better understand what other sources of data and information outside of traditional systematic reviews health systems need and use to move the evidence into implementation. Incorporating data from health systems is one strategy for making reviews more useful to health systems; however, these data are often unpublished or proprietary and thus not accessible to traditional systematic review methods. Thus, understanding when and how health system data can improve upon traditional review methods is important to evolving the EPC program methods.

From the health system perspective, even well-conducted systematic reviews may be insufficient for informing decisions to improve the delivery of care (i.e., what to do and how to do it). Often, findings of systematic reviews are unactionable due to low certainty in the evidence from published research, leaving decision makers without a clear path forward on what to do. Even when an evidence base provides high certainty regarding the effectiveness of an intervention, reviews generally lack contextual details that inform successful implementation. What health systems often need, therefore, is insight into how their own data can be integrated with review findings to achieve change in practice. Improving clinical operations (and thus patient outcomes) often entails questions other than the effectiveness and harms/safety of a given clinical service, but rather, for example, understanding gaps in uptake or use of a clinical service and questions and considerations of how best to implement a given clinical service (e.g., detail of service/intervention, cost and cost-effectiveness, ethical/legal considerations, organizational aspects).³ In addition, answers to questions about clinical operations (e.g., effectiveness, harms, implementation considerations), may be highly dependent on local practice variation. The applicability of systematically reviewed data to any health system wanting to implement the review's findings, such as how similar or different the populations studied are to the health system's population or the fidelity of the health system's intervention to the interventions studied, is critical to decision making. We know from our experience with reviewing published evidence that conclusions from studies conducted in clinical settings often differ from ones conducted in research settings. For example, trials evaluating carotid endarterectomy demonstrate lower complication rates compared with observed harms in clinical practice, possibly due to the highly selected nature of patients, skill of the surgeons, or other factors related to the surgical setting in trials compared with other settings.⁴ Understanding the true magnitude of harms in clinical practice from carotid endarterectomy is critical, given that the evidence suggests harms versus benefits for carotid endarterectomy are closely balanced in people with moderate carotid artery stenosis.

Information specific to local health systems that is derived from electronic health records (EHRs), other clinical databases (e.g., clinical registries), or claims and administrative data often is unpublished but is frequently used in healthcare decision making. These types of data can be derived from, for example, a single health system (e.g. Kaiser Permanente, Mayo Clinic), a collaborative of similar types of healthcare delivery systems (e.g., High Value Healthcare Collaborative, Health System Research Network, Oregon Community Health Information Network), or an entire region (e.g., country, state, province). Primary health system data, often

unpublished, may be used alongside traditional systematic reviews to answer questions addressed but unanswered by reviews, or provide context to allow for decision makers to interpret and apply review findings within their own health settings. Given that health-system decision making would benefit from both traditional systematic reviews and health-system-specific data, this paper investigates when and how to use primary data from health systems in real time with systematic reviews. We have identified numerous examples of this, but no guidance exists on when this is important or how to incorporate the data. Thus, this paper, aimed primarily at systematic reviews and AHRQ's EPC program, articulates a framework for when and how unpublished health system data can be used with systematic reviews to support health system decision making.

Methods

We sought to identify relevant examples and/or guidance on how to integrate unpublished data into systematic reviews, and how health systems have used locally applicable data with systematic reviews to inform their decision making. We examined existing literature and obtained case examples from EPCs and others with related experiences. The EPC Program Scientific Resource Center (SRC)'s information specialist conducted a search of Ovid Medline (1946-February 2019) to identify relevant guidance and examples of evidence synthesis integrating unpublished primary data into systematic reviews (see Appendix). The information specialist also searched systematic review (Cochrane Collaboration) and health technology assessment organizations (EUnetHTA, HTAi, and INAHTA) to find additional relevant examples and methods guidance (see Appendix). We also asked EPC investigators and persons within our own health systems for additional relevant examples or guidance. Each of the health systems has experience conducting or using systematic reviews and has developed (or is developing) processes to integrate local data or other unpublished data alongside systematic reviews into health system evidence-based decision making. These include:

- Kaiser Permanente, which has a centralized national guideline program that has processes in place to leverage both external and internal data to develop internal guidelines, as well as regional (e.g., Kaiser Permanente Northwest [KPNW], Washington [KPWA]) learning health systems with processes and dedicated staff to conduct rapid reviews and interrogate their health system data to inform healthcare delivery decisions.
- Mayo Clinic, which has conducted a number of traditional systematic reviews incorporating its own unpublished health system data to inform clinical decision making.
- Penn Medicine's Center for Evidence-based Practice (CEP), which supports decision making to inform practice guidelines, departmental policies, clinical processes, purchasing decisions, and decision support tools for the University of Pennsylvania's Health System.
- The Veterans Administration (VA) Evidence Synthesis Program (ESP), which provides decision makers within the VA with timely, high-quality evidence syntheses (and more recently incorporation of various forms of primary research methodology such as secondary analysis of administrative or EHR data, or qualitative methods, into the evidence syntheses) on key areas tied to clinical policy, future research prioritization, or dissemination activities identified by stakeholders within the VA.

Database searches yielded 686 abstracts and 38 full text articles for review. Full-text articles were evaluated to determine whether they provided examples of unpublished data used before, during, or after a systematic review (respectively for scoping, evidence accumulation, or interpretation/implementation) or methods guidance on incorporating unpublished data or health system data into systematic reviews. Sixteen articles provided examples of incorporating unpublished health system relevant data into systematic reviews, and five articles provided some guidance or context on methods considerations related to incorporating unpublished and/or health system data into systematic reviews. In addition to these 21 articles, we identified eight additional published examples and multiple other unpublished examples from EPC or health system stakeholders. All articles that provided examples of incorporating health system-relevant data into systematic reviews were evaluated to determine the rationale for using nonsystematically obtained data, details regarding the data used, and the impact of the unpublished data on overall review findings.

We relied on an informal consensus process, based on all of the examples and our collective experience conducting systematic reviews, to develop the framework and recommendations in this paper. A core group (JL, MHM, BL, JT, RC) reviewed and discussed included examples and guidance over a series of monthly conference calls and through electronic communication.

Results

We organize our findings in three sections: (1) the different ways health system data are used with systematic reviews, (2) scenarios when health system data may be most helpful to use alongside systematic reviews, and (3) the limitations of and considerations to take into account when using unpublished health system data.

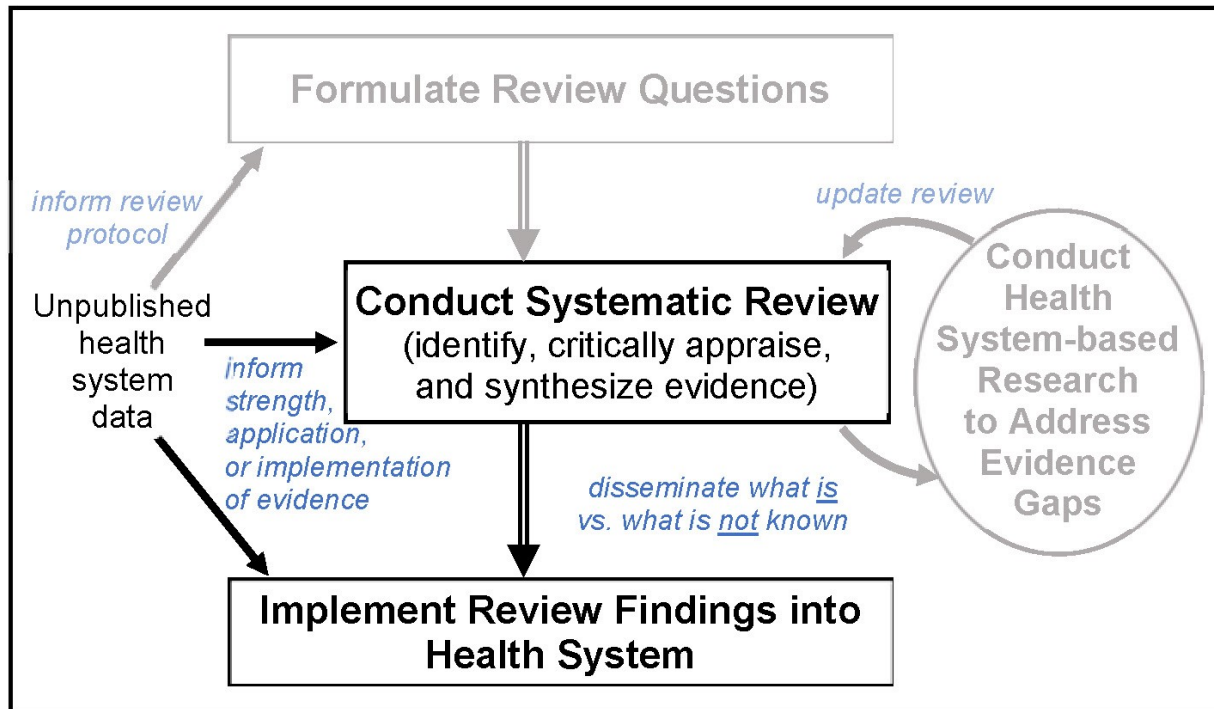
Ways in Which Health System Data are Used With Systematic Reviews to Support Healthcare Decision Making

Primary data from health systems can be used in several ways with systematic reviews to inform decision making (Figure 1). Health system data can inform the review protocol, inform the strength or application of the evidence contained in a review, and/or inform implementation of the evidence. Health systems may also conduct their own *de novo* research to address evidence gaps identified in reviews, which subsequently can be used to update reviews. In this section, we elaborate on how health system data can be used before, during and after the systematic reviews to support decision making.

Inform Review Protocol

Health systems may interrogate their data to identify important areas of clinical need (e.g., identify practice gaps or variation in patient outcomes that may inform review questions). Within our health systems, this is commonly done as part of QI activities and not performed by systematic reviewers themselves. For example, at Penn Medicine, quality leaders examining hospital readmission trends discovered that patients with sickle cell disease represented a disproportionate share of patients who presented at an emergency department shortly after a prior hospitalization. CEP was then asked to conduct a series of systematic reviews to identify risk factors for poor outcomes and effective approaches for improving care for this population. The reviews examined a range of strategies including patient-controlled analgesia, psychosocial interventions, dedicated sickle cell units, and provider education. Similarly, infection control specialists at Penn examining *Clostridium difficile* infection rates found that the strategies being used to deploy diagnostic testing were often insufficient to distinguish between colonization and active infection in patients with cancer. They therefore requested that CEP conduct a review of published studies that evaluated diagnostic testing in oncology patients. The resulting review informed development of a new testing algorithm. Thus, using health system data can generate and define scope of important clinical or practice question(s) that then serve as the impetus for systematic reviews.

Figure 1. How health system data can be used in developing, conducting, and implementing systematic reviews*



*In this paper we focus primarily on the use of health system data during the conduct of review and the implementation of review findings.

Inform Strength, Application, or Implementation of Evidence

During the conduct of the review itself, health system data can be formally incorporated into review findings, i.e., to answer systematically reviewed questions. This does not appear to be common practice, perhaps because it requires access to this type of data in real time (e.g., partnering with a healthcare system or collaborative with registry of data to which health systems submit data). However, we identified several examples when unpublished data were used to address limitations in the systematically identified data. In most instances, these examples were explicit about their rationale for incorporating unpublished data, primarily because the published data was sparse or lacked granularity (i.e., to increase certainty of findings by addressing strength of evidence), and/or to determine whether the published data were applicable to health system populations (i.e., to increase the certainty of findings by addressing the applicability of evidence).⁵⁻¹⁸ For example, we identified several times that the Mayo Clinic combined local health system data with systematically reviewed published data to support various clinical groups' patient care management decisions, that illustrate different reasons for combining unpublished local data and published data:

- Published data on outcomes post total pancreatectomy was sparse, and adding unpublished data more than doubled the sample size;⁶ in another instance the local health system data on endovascular treatment carotid artery bifurcation aneurysms was sparse, and adding published data helped with precision.⁷
- Published data lacked granular clinical details and therefore pathological details in children with familial adenomatous polyposis syndrome were added from unpublished local health system data.¹⁴

- Published data lacked important outcomes, and local health system data provided longer-term outcomes on total pancreatectomy.⁶
- In two instances, the procedural expertise for endovascular procedures at the Mayo Clinic was thought to be more advanced than published community practice or smaller centers' experience, so local data were used to determine applicability of published data to the health system.^{7, 8}

In some instances, there may be multiple reasons for wanting to combine selected health system data and systematically reviewed data. We identified an example from the VA ESP in which secondary data analyses of VA data¹⁷ were carried out in parallel with a systematic review¹⁸ to improve the certainty and applicability of review findings. Because of underpowered trials and methodologically limited observational studies, there remained some uncertainty as to the best anticoagulation with bioprosthetic aortic valve replacement (bAVR); thus, stakeholders advocated for gaining an understanding of current VA practice patterns (e.g., clinical outcomes after bAVR using different anticoagulation regimens) to improve the certainty and applicability of the systematic review findings. In addition, the secondary data analysis identified practice-level variation by facility to help tailor dissemination of evidence by practice location. In other examples, unpublished data were used to provide contextual information (other than effectiveness or harms/safety information); for example, to detail uptake of services, patient characteristics, epidemiology, natural history, or cost or data for cost-effectiveness analyses.¹⁹⁻²³

In some instances, the rationale for using unpublished data was not evident and/or appeared opportunistic (i.e., researchers had access to their own unpublished data and included it because it was available), and was not applied to healthcare decision making. Overall the examples we identified applied clinical practice data or specific registry data from a single health system (e.g., Mayo Clinic) or regional or nationally representative data (e.g., clinical registries, hospital database). In the vast majority of cases, findings from the unpublished data were concordant with overall findings from published evidence.

After completion of the review, the unpublished health system data can be used as a “data appendage” to help filter, interpret, and/or apply the review findings to an individual health system’s practice. This may not involve the systematic reviewers themselves and can be performed by the health system using the systematic review. For example, at Penn Medicine, questions were raised by clinicians and administrative leadership regarding the effectiveness, safety, and cost of osteobiologic bone grafts for patients undergoing back surgery. CEP was asked to conduct a systematic review of patient outcomes in the relevant published clinical studies. After reviewing CEP’s findings, a leadership committee evaluated unpublished health system data that included utilization rates for osteobiologics by type of surgery for patients at Penn Medicine and a cohort of regional and national peer institutions. These additional data provided important context for Penn’s decision makers by showing that Penn facilities were not comparatively high utilizers of osteobiologics during back surgery, and demonstrating that the specific surgical procedures involved were appropriately indicated. Local data may also inform efforts to implement QI initiatives built on the findings of a systematic review. When a quality review team recently launched a project to address the high frequency of patients failing to show for a scheduled colonoscopy or arriving at their appointments unprepared for the procedure, CEP was asked to conduct a systematic review of strategies to reduce no-shows and improve patient education. After completing the report, which examined several types of interventions, the quality team reviewed detailed clinic-level data—including patient characteristics and reasons reported for missed appointments—to select optimal improvement strategies from those that

were included in the systematic review, and to identify which outpatient sites were best suited for specific interventions. The systematic review and the health system's patient-level data informed the design and development of new educational materials and outreach strategies. Pilot testing of these approaches is currently underway in Penn Medicine clinics. In another example, Kaiser Permanente used their own internal data to help operationalize the implementation of guidelines on screening for abnormal glucose which was derived from an EPC review to support the USPSTF.²⁴ Based on an analysis of KPNW data showing a differential rate of progression of prediabetes to type 2 diabetes (using HbA1c) across different groups (e.g., baseline HbA1c, BMI, weight gain, use of glucocorticoids), Kaiser Permanente's national guidelines recommends tailored screening/monitoring intervals based on one of three risk groups as opposed to universally applied screening/monitoring intervals.

Update the Review

Health systems could conduct *de novo* research to address evidence gaps identified in systematic reviews. For example, the VA ESP works closely with both operational and research stakeholders and in some cases is explicitly tasked with producing evidence products identifying key evidence gaps in order to highlight opportunities to advance research on highly prioritized areas in the VA health system. For example, depression management and suicide prevention have been top priorities for the VA in recent years. In response to a request to examine pharmacogenomic strategies to inform antidepressant selection, the VA ESP conducted a rapid evidence synthesis that identified specific gaps in evidence.²⁵ This report informed a request for proposals for studies of pharmacogenomic testing in veterans, and there is currently a funded multisite study underway. In another example, in response to a request from the VA's Office of Health Equity to help identify research priority areas, the VA ESP developed an evidence map to graphically illustrate major evidence gaps in VA health disparities research.²⁶ Outside of self-contained programs such as those of the VA, it is unclear how often health system researchers link evidence syntheses to evidence development. We found one example of a PCORI-funded study, Blood Pressure Checks and Diagnosing Hypertension (BP-CHECK), conducted in KPWA to address the future research needs articulated in an EPC report for the USPSTF, Screening for High Blood Pressure in Adults, on the accuracy of confirmatory ambulatory blood pressure monitoring in screening for hypertension.²⁷ A rapid review from the EPC program, Addressing Social Isolation to Improve the Health of Older Adult, found sparse and inconsistent evidence to support interventions to reduce social isolation in older adults, and included a call to research, explicitly asking health systems to rigorously evaluate their efforts to increase the evidence base and share results with other healthcare systems.²⁸ Although whether this call will yield success remains to be seen.

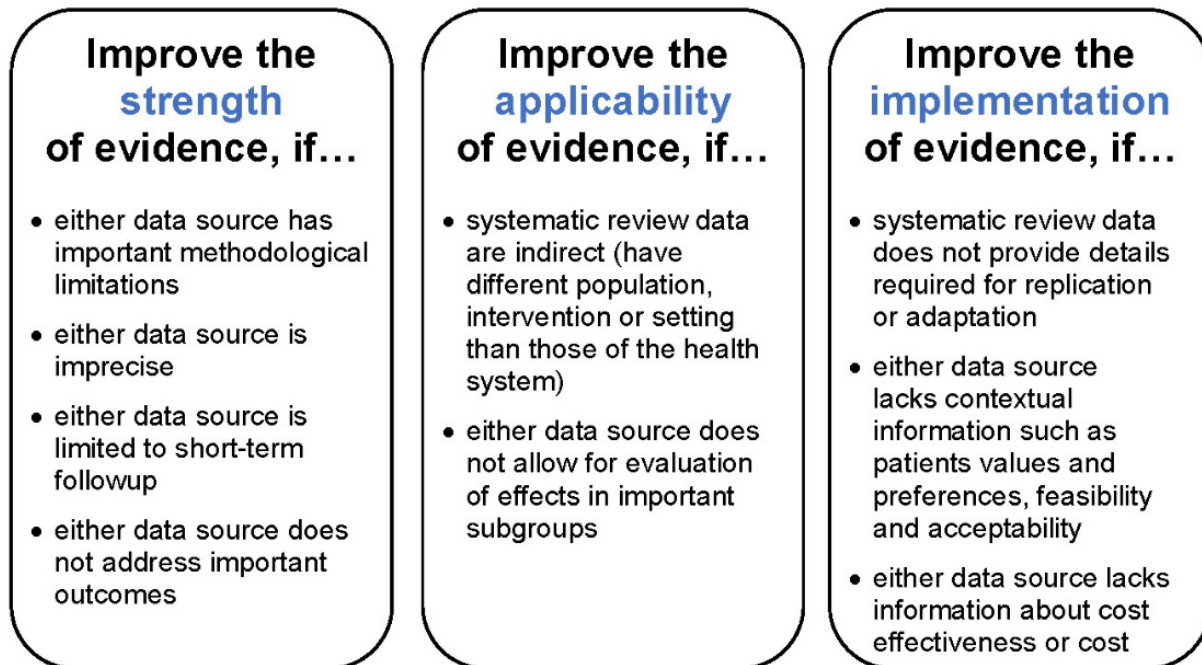
Scenarios When Health System Data May Be Incorporated Into or Used in Addition to Systematic Reviews To Support Healthcare Decision Making

Recognizing that there are limitations to using only health system data to inform decision making and to traditional systematic review methods that primarily rely on synthesizing published research, we articulate a set of scenarios based on previously discussed examples in which using unpublished data from health systems either during the conduct of the review or as a data appendage after the review can be helpful, regardless if the review is specifically being commissioned by or conducted for a specific stakeholder health system or not (Figure 2). Examples of using health system data with systematic reviews fell into one of three general

scenarios: (1) health system data was used to increase the confidence or certainty in understanding the strength of evidence, (2) health system data was used to understand the applicability of the evidence, and/or (3) health system data was used to inform how best to implement the evidence.

Figure 2. Scenarios when health system data may be incorporated into or used in addition to systematic reviews

If systematic review or health system data are limited, using both types of evidence together may:



Strength of Evidence

First, it may be important to seek unpublished health system data while the review is being conducted to expand the evidence base and improve the strength of evidence, i.e., instances in which data is sparse or limited. This this may occur because data have important methodological limitations (e.g., publication bias or selective outcome reporting bias), are scant or imprecise (e.g., new intervention or technology), are limited to short-term follow-up (e.g., missing longer term data on safety), or do not address important outcomes of interest for decision makers (e.g., resource use, cost, system outcomes).

Applicability of Evidence

It may also be important to seek unpublished health system data during the conduct of the review or as a data appendage after completing the review to address uncertainty regarding applicability. This may occur when there are signals that the populations (and therefore outcomes) in published data are likely to be different from those within a given health system, i.e., concerns about applicability of studied populations to real-world populations (e.g., highly selected populations or older cohorts in published studies), and/or the data do not allow for evaluation of effects in important subgroups (e.g., large heterogeneity of treatment benefit or harms and limited data by important subgroups of interest). Unpublished data in these scenarios

may help health systems determine if and in whom to apply review findings (e.g., by knowing the absolute risk reduction or risk increase in their populations).

Implementation of Evidence

Finally, it may be important to seek unpublished health system data as a data appendage to inform the implementation of evidence from reviews. For example, published data may not provide information or data needed for replication (fidelity) or adaptation of an intervention into a given health setting/system (e.g., how to tailor an intervention within a given health system), important contextual information on patient values and preferences, feasibility or acceptability, or information on direct cost or inputs for health system relevant cost-effectiveness analyses (e.g., prevalence, adherence, cost). Local health system data may also inform who and where to target in the implementation (e.g., which populations, which sites) depending on population characteristics and practice site performance.

Limitations and Considerations When Using Unpublished Primary Data From Health Systems in Systematic Reviews To Support Healthcare Decision Making

Even though the health system data can, in some instances, provide more applicable evidence,²⁹ caution needs to be applied in deriving conclusions from nonsystematically collected, and non-peer reviewed data. Therefore, healthcare decisions that are informed by selective unpublished data need to be considered in the context of the systematically reviewed evidence (i.e., the totality of the evidence base) as well as the potential biases and limitations of the unpublished data analyses. We found no formal guidance on the use of unpublished and/or health system data in systematic reviews. Here we discuss some important considerations on the limitations of incorporating selective unpublished data into a systematic review or as a data appendage after completion of the review.

Most importantly, any analyses of health system data, published or not, must be critically appraised to understand how potential biases might affect the validity of findings. Biases and limitations of nonrandomized studies (NRS) are well understood (e.g., confounding, selection, performance, attrition, detection, reporting) and are generally captured in commonly applied critical appraisal tools for these types of study designs; therefore in this paper we do not discuss further the critical appraisal of NRS. Even though there are numerous critical appraisal tools for NRS of healthcare interventions (e.g., ROBINS-I, Newcastle-Ottawa Scale, Downs and Black, SIGN 50 checklists), consensus is lacking about which tools are valid and should be preferentially used; additionally, none have been developed specifically with the use of health system data in mind.²⁹⁻³¹ While most critical appraisal tools for NRS evaluate some components of data quality (e.g., missing data), it may not be robust enough to understand all the important limitations of the data not designed for research purposes and thus may be more prone other limitations (e.g., measurement error, misclassification).³²

Understanding the limitations of the data source, its relevance and integrity, in addition to study design limitations (e.g., confounding, selection bias) is an important part of the critical appraisal process. Limitations and uncertainty regarding different types of health system data (e.g., clinical registries, administrative claims data, clinical data from EHR) are well understood by health system researchers, and many guidelines and assessment tools exist for quality assurance of registry type data.³³ These guidelines and tools generally address considerations about information and data quality, as well as other domains, such as governance and data

protection. Health system data are rarely designed from the outset to support evidence-based decision making at a population level; therefore it is important to understand the extent to which the data source can answer the question being asked (sometimes referred to as information quality). For example, how well does the data source capture the populations, interventions, and comparators and outcomes (PICO) of interest? Information quality is also dependent on integrity of the data (commonly referred to as data quality).³⁴ Data quality, a common concern about health system data, is complex because it touches on multiple dimensions (e.g., data accuracy, data completeness, interpretability and accessibility of data, relevance of the data, timeliness of the data, coherence of the data, and mode of the data collection and how it impacts data quality) and can fluctuate over time and across data sources (Table 1). For example, clinical EHR data not designed to support research may be incomplete (e.g., the collection of EHR data that are of interest to healthcare providers), be prone to error (e.g., mistakes when the data are entered), or have challenges related to retrieval of relevant data (e.g., the unstructured EHR data might not be searchable). However, understanding the degree to which the data were collected systematically (and monitored for accuracy and completeness) from the EHR may inform its suitability for use to answer some questions. The issues centered on data quality are not unique to health system data but may be more problematic depending on the data source being used and the questions being asked of the data. A full understanding of the limitations of data sources is constrained by lack of agreement regarding (1) the definition of data quality,^{35, 36} (2) data quality terminology,^{37, 38} (3) how data quality should be validated,^{35, 36, 39} and (4) the determination of data quality that is sufficient for secondary reuse (i.e., fitness for use).

Table 1. Dimensions of data quality for consideration¹⁹

Dimension	Definition
Accuracy	How well information in or derived from the data reflects the reality it was designed to measure
Completeness	The extent to which all necessary data that could have been recorded have actually been captured
Interpretability and Accessibility	The ease with which the existence of information can be ascertained, the suitability of the medium through which the information can be accessed, whether data are accompanied with appropriate metadata, and whether information on the quality is available
Relevance	The degree to which data meet the current and potential needs of the users
Timeliness	How current or up to date are the data at the time of use
Coherence	The internal consistency of data collection as well as its comparability both over time and with other data sources
Mode of collection	How well data collection is integrated into the working practice of data providers

Recommendations

Based on our review of examples and methodologic guidance, as well as our experience conducting systematic reviews for various stakeholders, we recommend five basic principles regarding when and how to use unpublished health system data alongside of systematically reviewed data.

- First, it is important to explicitly state the rationale for using unpublished data (i.e., do not include unpublished data just because you can). We suggest that the rationale can usually be articulated as one of three main scenarios we outline above (i.e., to improve the strength and applicability of evidence, and/or to inform its implementation); however, other reasons that do not fall within these scenarios should be articulated.
- Second, be explicit about the details of the data source being used and why it was chosen (e.g. how relevant are the data). Because there may be multiple data sources that are relevant to health system decision making and overcoming limitations of published literature (e.g., single health system versus network of health systems, clinical registry versus electronic health record), it is important to be intentional and explicit about the data source being drawn from because of using selective (not systematic) data.
- Third, characterize the limitations and biases of any included data. We recommend formal critical appraisal of the data analyses using study design-specific criteria (e.g., ROBINS-I). We recommend that reviewers work with a health system's QI and information systems staff and health system researchers, if possible, to understand data and information-quality limitations. If applicable, data and information-quality limitations should be articulated alongside study-design limitations and biases.
- Fourth, specify how the findings from unpublished data support, refute, and/or otherwise add to findings from published data. This is analogous to describing how a new study adds to an existing body of evidence, or how newly identified evidence adds to our understanding of older evidence when updating a systematic review. If the unpublished evidence conflicts with the review's conclusions, there should be a discussion of possible reasons for the discrepancy (e.g., internal validity, external validity). Based on selected examples, demonstrating concordance can increase the certainty for decision makers and result in practice change or coverage decisions.^{12, 17, 18, 22}
- Last, we believe this process should be conducted in close partnership with health systems, which ideally includes a range of individuals such as clinical leaders and decision makers as well as QI staff and health system researchers.

Limitations and Future Work

Given the focused nature of this paper and a limited time frame and resources, our paper does not address the methodological guidance on the critical appraisal or synthesis of evidence of NRS, conducting integrative reviews (i.e., reviews of mixed methods including qualitative data, survey data, and/or grey literature), integrating local cost data into cost-effectiveness analyses. Likewise, we do not summarize the guidance on identification of grey or unpublished literature.

This framework is intended to broadly apply to systematic reviews regardless of the topic, questions asked, or types of interventions/services included. As this framework and its recommendations are applied going forward, it may require amendments and additions as we learn from a broader set of examples inclusive of more complex interventions (e.g., systems based interventions), medical testing (e.g., diagnostic or prognostic tests), less commonly reviewed literature (e.g., implementation studies).

In our paper, we mainly focused on how health system data could inform the review findings, and less on how health system data should be used to generate and properly scope systematic review or how evidence development (*de novo* research within health systems) should be linked to evidence gaps identified in systematic reviews. We believe these are two important areas for the EPC program to further explore and develop.

We also do not address the necessary resources, skills, partnership, and processes required to have real-time access to and ability to utilize health system data to do this type of review work incorporating unpublished health system data. If integration of health system specific or health system relevant data is important to inform decision making, then the infrastructure and processes to allow for concurrent data analyses need to be in place, which entails both access to and analysis of the data. For example, in the VA ESP experience, the need for health system data to address the uncertainty in the published trials and observational studies was identified at an early phase of the review and the secondary data analyses of VA data was initiated, funded, and conducted concurrently to the systematic review. The VA ESP review team worked closely with funders, stakeholders, primary researchers and network of experts to do develop a proposal, secure supplementary funding and start/complete the work for VA data analyses in a short period of time. This was in part possible because of prior existing relationship of the VA ESP and another VA research group (Precision Monitoring to Transform Care QUERI National Program and Center for Health Information and Communication), and working with an internal funder (the VHA). This model may not be widely reproducible, but at minimum partnerships with health system (researchers) and/or health system collaboratives (as this iterative process requires a dialogue) and flexible funding mechanisms need to be in place for this type of work to happen. Other models could borrow from resources and processes in place from exemplar learning health systems (e.g., Penn Medicine's CEP) that have fully actualized processes for generating and analyzing their internal data and subsequently integrating with external data/knowledge for decision making and capacity to evaluate practice changes in real time.

Individual health systems have varying capacities to interrogate/analyze their own data such that decision makers seeking local data may not have access or the resources to do so. Development of a collaborative of health system and their researchers may be a more successful model than (small) individual health systems developing their own processes and resources. Data relevant to a health system does not have to be from the health system itself, but more applicable data than published research (e.g., geographically local, from a similar health system, temporally relevant). Investments into collaborative efforts should build on learnings from prior networks such as the AHRQ-funded Developing Evidence to Inform Decisions about Effectiveness

(DEcIDE) Research Network (2005-2014). However, collaboratives or other like models to facilitate broader use or sharing of unpublished data would require infrastructure (e.g., platforms to share data, resources) and funding for maintenance.

Conclusions

The use of health system data in concert with traditional systematic reviews may overcome decisional uncertainty for healthcare decision makers. Health system data can be used to initiate and design systematic reviews, incorporated into reviews, or used to interpret and implement review findings into practice. Incorporation of health system data should be considered when there is decisional uncertainty about using evidence from systematic reviews to improve the strength of evidence, the applicability of evidence, or to support the implementation of the evidence. Reviewers incorporating health system data should be explicit about the rationale for using these data, which data source(s) were used, their information and data quality, the limitations of the study design itself, and the concordance or discordance of health system data compared with systematically obtained data in the review.

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Appendix A. Search Strategy

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily 1946 to January 31, 2019

Date Searched: February 1, 2019

Searched by: Robin Paynter, MLIS

#	Searches	Results
1	(administrative data* or "big data" or claims data* or "clinical data" or "data sources" or EHR or "electronic health record" or "electronic health records" or "existing data" or "health data" or "healthcare data" or (hospital* adj3 data) or "insurance data*" or (local* adj3 data*) or "pharmacy data" or "system data" or "real world data" or registr* or register* or (routine* adj3 data)).ti,kf.	75282
2	("economic evaluation*" or "evidence synthesis" or "evidence syntheses" or HTA or HTAs or "health technology assessment" or "health technology assessments" or (integrative adj2 review*) or "rapid review" or "rapid reviews" or (systematic adj2 review*)).ti,kf.	111624
3	and/1-2	616
4	limit 3 to english language	603