Considerations in Medicine

How have systems approaches been used to understand how antimicrobials are used and governed in healthcare organisations? A scoping review protocol

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ABSTRACT

Sepsis is a life-threatening condition requiring timely antimicrobial treatment. However, inappropriate antimicrobial use exacerbates antimicrobial resistance (AMR), creating a tension between treating sepsis promptly and minimising antimicrobial overuse. Despite numerous policies and significant research related to sepsis and AMR, there remains a persistent gap between recommendations and real-world practice due to system factors that impact normal work in all healthcare contexts. The aim of this scoping review is to understand how systems approaches have been used to study the use and governance of antimicrobials in clinical work.Methodsd analysisThe scoping review protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews guidelines. Empirical research, reviews, protocols, theses/dissertations and quality improvement projects across all healthcare settings will be included if a primary focus includes studying antimicrobial use from a systems perspective. Searches will be conducted in EMBASE, MEDLINE and CINAHL with grey literature searching and backward citation tracking. Data on the geography and contexts studied, use of system theory, study design, approaches to data collection and analysis, limitations and implications will be extracted. Quantitative data will be categorised and qualitative data will be analysed thematically. Ethical approval is not required for the use of secondary, published data. Findings will be disseminated through academic publications and national and international presentations. Insights will be used to inform improvement work and empirical research to better support the sepsis-antimicrobial stewardship tension across multiple organisational levels.

INTRODUCTION

Rationale

Sepsis is a leading cause of preventable harm in healthcare and is defined as the body's life-threatening response to an infection.[1] Clinically, sepsis may be difficult to detect for a myriad of reasons, including barriers to adoption of sepsis biomarkers,[2] ambiguous symptom presentation[3] and the small window of opportunity to treat.[4] Antimicrobials, mainly antibiotics for bacterial infections, are the first line of treatment to prevent and treat infections that contribute to sepsis. Inappropriate use of antimicrobials is increasingly contributing to antimicrobial resistance (AMR), in which pathogens become less responsive to antimicrobial therapies as a result of overuse.[5]

Leading research and policy authorities around the world have highlighted the need for immediate action to minimise the threat of AMR.[6] Similar global calls to action have been issued for sepsis.[7] However, previous literature has highlighted the persistent difficulty in overcoming the tension between reducing antimicrobial exposure while preventing harm due to infection and sepsis. For example, Rhee and colleagues found that many patients treated with antibiotics for suspected sepsis ultimately had viral or noninfectious illnesses and patients without bacterial sepsis did not require the broad spectrum antibiotics they were given.[8 9] In this study, unnecessary empiric therapy contributed to higher mortality rates, underscoring the need for improved use of broad spectrum antimicrobials. In addition to the clinical evidence, clinicians themselves have highlighted the need for more judicious use of antimicrobials. A national survey of physicians and pharmacists found that decreasing inappropriate use of broad-spectrum antimicrobials was perceived to be the number one opportunity to reduce resistance.[10]

Clinicians often face complex trade-offs amid uncertainties related to sepsis and AMR. For example, administering potentially inappropriate antimicrobials can minimise delays in beginning treatment for sepsis but may complicate future infection management. Conversely, delaying antimicrobial therapy while awaiting diagnostic results may preserve future treatment options at the expense of early infection management. Given evidence that delays to treatment are associated with increased mortality in sepsis,[4 11 12] researchers have suggested that to reconcile the inherent tension between sepsis management and

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AMR, the focus should shift to stopping antimicrobial therapy once it is started.[13] Indeed, there are extensive resources to guide both the starting of appropriate antimicrobials and the revision of the antimicrobial treatment plan in the context of sepsis.[14–18] However, evidence shows that antibiotic use continues to increase in UK hospitals, with an estimated 4% increase in consumption per year[19] and an estimated 5% increase in antibiotic prescribing from 2019 to 2023.[20] Increasing rates of antimicrobial use, despite numerous best practice resources, suggest a complex interplay between guidance and practice that should be further explored.

This gap, often referred to as the 'work-as-imagined, work-as-done' gap, is well known in the safety literature and is influenced by a wide range of system factors.[21] However, very little is known about how systems approaches have been used to understand this 'work-as-imagined, work-as-done' gap as it relates to antimicrobial use. Systems approaches have been used widely in safety improvement work in other high-risk sociotechnical systems, such as aviation, and have more recently emerged in healthcare. System factors that influence work may include efficiency pressures, misalignments between demand and capacity, ambiguities in care delivery processes or technologies that do not align with what is needed.[22–25]

While systems approaches have been used to study a variety of frontline contexts,[26] system factors impact work at every level of an organisation, including those responsible for organisational oversight, such as clinical governance groups. For example, inadequate access to data about antimicrobial use may impact how safety governance staff conduct their learning reviews. Organisational oversight and day-to-day clinical practice intersect on a regular basis. Therefore, uncovering system facilitators and barriers at both the frontline and governance levels will help inform how multilevel work impacts antimicrobial use holistically within healthcare organisations.[27] In order to design aligned work processes within organisational systems that support, rather than hinder, the sepsis-AMR tension, there is a need to first thoroughly understand the problem through a systems lens.

Overarching question

How have systems approaches been used to understand antimicrobial use and governance in healthcare organisations?

Objectives

- Examine settings and populations studied in previous work,
- Understand the key system theories that have underpinned previous work,
- Map the existing literature to understand how systems approaches have been applied and what data collection and analysis approaches have been used, and
- Identify gaps and limitations in the current body of work.

METHODS

Reporting guidelines

The aim of this work is to understand the breadth and depth of previous work, rather than critically appraise evidence for a more narrowly-defined question. Therefore, a scoping review, rather than a systematic review, was deemed more suitable. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist, along with knowledge synthesis guidance from the Joanna Briggs Institute, was used to inform development of this protocol.[28 29] The planned start date for the review is February 2025 and the planned end date is November 2025.

Eligibility criteria

The eligibility criteria were developed and iterated based on previous literature, the aims of this paper and discussion among the multidisciplinary research team. Articles from all healthcare settings will be included to understand how the use of systems approaches has varied across contexts. Articles from the USA, UK, European Union, Australia, New Zealand, Canada and Norway will be included. These countries were specifically selected due to their similar structural, legal and cultural characteristics in healthcare systems. While they each have unique features, they share common challenges related to AMR and have aligned their policy responses through international collaborations such as the Transatlantic Task Force on Antimicrobial Resistance.[30]

An informal, preliminary search revealed that there are likely to be very few articles that meet inclusion criteria with a specific focus on how the sepsis and AMR tension has been studied using systems approaches. The approaches used to study the system factors that influence antimicrobial use for sepsis and infection more broadly are likely to be similar. Therefore, the decision was made to expand the inclusion criteria to include any antimicrobial use for the treatment of infection.

More information about the article type inclusion criteria is in table 1 and in the 'Information sources' section below. The inclusion criteria were developed in discussion with the multidisciplinary research team and will be refined based on continuous review of the results.

Information sources

Only peer-reviewed, empirical original research articles, reviews, protocol papers, theses/dissertations and published quality improvement (QI projects will be eligible for inclusion. Reviews will be included to ensure all relevant studies are captured through reference checking. Published QI projects will be included to better understand the practical, context-specific challenges related to antimicrobial use and governance in healthcare organisations.

Search strategy

EMBASE, MEDLINE and CINAHL were selected as the databases for this review based on librarian recommendations. EMBASE is a major database bringing together research from disciplines such as, but not limited to medicine, pharmaceuticals, toxicology, health policy, health management, public health and biomedical engineering. EMBASE includes journals from Europe that are not typically found in other databases. MEDLINE was included to capture work from similar disciplines published in the USA and globally. Because antimicrobial administration and governance is the responsibility of a multidisciplinary healthcare team, it will be important to capture resources from non-medical fields. Therefore, CINAHL was included to capture health literature for nursing and allied health professionals. The search strategy for each database is provided in online supplemental material 1.

Backward citation tracking and searching of websites of relevant organisations and journals will be used as grey literature search strategies. Additional grey literature sources and search strategies will be developed based on librarian recommendations and discussions among the author group.[31–33]

Initial screening

Search results will be imported into Covidence for deduplication and initial screening. Three reviewers will screen the titles and abstracts. 10% of articles will be screened by a combination of two of the three blinded reviewers. The results of this initial screening will be discussed between all three reviewers to reconcile results and clarify the inclusion criteria. Inclusion and exclusion criteria will be further specified as needed and remaining titles and abstracts will be screened independently by a combination of two of the three blinded reviewers. Once initial screening has been completed, any disagreements will be discussed and reconciled by the three reviewers before moving into full-text screening and data extraction.

There is a risk of duplicative counting when data is extracted from multiple sources (eg, both original articles and reviews in which they are included). This risk will be mitigated by distinguishing 'number of studies included' and 'number of reports of studies included' in the PRISMA chart and linking multiple reports from the same study per recent methodological guidance.[31–33]

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Table 1 Scoping review inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Population	All patient populations	
Setting	Any healthcare delivery organisation including, but not limited to, hospitals, urgent care, primary care, mental health and pharmacies	National public health organisations or non-healthcare settings (eg, animal health)
Concept	Systems approaches (including concepts such as, but not limited to, sociotechnical systems, systems engineering, resilience engineering, resilient healthcare, work-as-imagined vs work-as-done, human factors, ergonomics, variability, human-centred design, system design, complex adaptive systems, variability, resonance or safety II)	Behaviour change; clinical education
Aim of the articles	Articles will be included if a primary aim of the study is to understand the system factors influencing either the ► Use of antimicrobials in frontline work ('use' will be defined as prescription, dispensing, administration, monitoring, adjustment and discontinuation) or ► Organisational governance of antimicrobial use ('governance' will be characterised by organisational policies, stewardship programmes, decision frameworks or institutional oversight) Authors must have either explicitly stated that a systems approach was used or explained how the problem was studied robustly within the context of normal work.	Articles will be excluded if ► System factors are incidental findings ► The study focuses only on infection control or sepsis without a primary focus on antimicrobials (eg, *C. diff* prevention through hand hygiene) ► The study focuses on highly protocolised procedures (eg, antimicrobial administration within 60 min of an order, routine prophylaxis)
Article type	Peer-reviewed, empirical, original research articles; reviews; protocol papers; theses; dissertations; published quality improvement projects	Other grey literature such as viewpoints; governmental reports; letters to the editor; conference transcripts; conference posters or presentations; theoretical papers; books
Country	USA, UK, European Union, Australia, New Zealand, Canada and Norway	
Date range	All dates	

C. diff, Clostridioides difficile.

Full text screening and data extraction process

Data from each article will be extracted by two independent reviewers in Covidence based on the extraction template below. The extraction template was co-designed in alignment with project aims and based on previous literature and research team discussion. The extraction template will be piloted by extracting data from the first 10% of articles. Reviewers extracting data will meet to discuss if and how the template should be changed and adjustments will be made accordingly. The data extracted for all articles will be discussed between reviewers and a final output for each article will be generated (see box 1).

Extraction template

Critical appraisal of individual sources of evidence

The aim of this scoping review is to map the breadth and depth of previous research, not critically appraise the quality of the current evidence. For this reason, unlike systematic reviews, critical appraisal of the sources of evidence is an optional step within scoping reviews.[28] Inclusion will be based on relevance to the research question rather than methodological rigour, which will allow for the capture of diverse studies. Therefore, studies will not be assessed for quality.

Synthesis of results

A PRISMA chart will be generated to illustrate the number and type of studies identified from databases and grey literature searches. Extracted data will be analysed using both qualitative and quantitative approaches. Quantitative synthesis will consist of categorical representation of the healthcare settings, evidence category, study designs and tools used to collect and analyse data. Qualitative analysis will consist of both descriptive and thematic analysis. Case studies will be used to illustrate examples of how systems approaches have been used to study antimicrobial use and governance. Clinical, policy, research and educational implications as stated by the authors and as interpreted by the reviewers will be described thematically. The specifics of data synthesis will be guided by the results of the search.

Patient and public involvement

Pollock and colleagues emphasise the importance of clearly identifying the 'knowledge users' of the research findings as early as possible.[34] In the context of this research, our immediate knowledge users will be those administering and governing the use of antimicrobials in healthcare organisations. Therefore, patients and service users will not be involved in the design or development of this research.

Ethics and dissemination

We aim that this scoping review will serve as the foundation for research partnerships with others interested in systemic approaches to AMR in

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Extraction template fields

Extraction template field
Healthcare setting
Medical, surgical, emergency, obstetrical, neonatal, paediatric, primary care, other (specify)
Date study was conducted
Evidence category
Original research articles, reviews, protocol papers, theses/dissertations, quality improvement projects
Target population
Aim(s)
Whether and how system theory was used
Study design and rationale
Data collection tools/approaches and rationale
Data analysis tools/approaches and rationale
Limitations as stated by the author
Clinical, policy and/or research implications as stated by the author
Clinical, policy and/or research implications as interpreted by the extractors

healthcare organisations. Dissemination will include poster presentations at local, national and international conferences and forums. The results of this work will be published in an academic manuscript and will inform future empirical work. Multidisciplinary team members, such as frontline staff and those responsible for organisational improvement, will be consulted iteratively throughout the design and development of this study and will be asked to support dissemination. Ethical approval was not required for the use of secondary, published data per the University of Oxford's ethical review department (ethics@medsci.ox.ac.uk).

CONCLUSION

The sepsis-AMR tension has been understudied despite urgent national and international calls to action. Healthcare workers will continue to have to reconcile the competing pressures of AMR and the need for early administration of antimicrobials to mitigate harm from infection. Further, management teams will continue to experience obstacles to managing this tension across their organisations. Therefore, there is a need to design aligned systems that support frontline and governance staff in managing the interplay between these two important issues. Our aim with this review is to understand how systems approaches have been used to study the use and governance of antimicrobials in healthcare organisations. In doing so, we intend to call attention to this urgent need, introduce the opportunity for collaboration with others interested in this problem and lay the groundwork for future empirical systems research that draws on current evidence.

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Contributors OL contributed to the conceptualisation, organisation, design, development and writing of the manuscript. LH and MOV contributed to conceptualisation, initial screening, full-text review and writing. LH contributed clinical subject matter expertise. NS contributed research subject matter expertise and to the writing of the manuscript. KW contributed clinical and improvement subject matter expertise and to the writing of the manuscript. AB, JO'H and HH served as senior clinical, research and improvement experts, guided conceptualisation and development, and secured resources to facilitate the success of this project. OL is the guarantor. ChatGPT was used only to generate an outline of the abstract, which was subsequently reviewed, edited and finalised by authors. There was no further use of AI.

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