PROTOCOL

Patients' experiences of mechanical ventilation in intensive care units in low- and lower-middle-income countries: protocol of a systematic review

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Abstract

Background Mechanical ventilation (MV) in intensive care units (ICUs) is a stressful experience for patients. However, these experiences have not been systematically explored in low- and lower-middle-income countries (LLMICs). This systematic review (SR) aims to explore the patients' experiences of MV in ICUs in LLMICs and the factors influencing their experiences.

Methods The PICO framework will be used to operationalize the review question into key concepts: population (mechanically ventilated adult patients in ICUs), phenomenon of interest (experiences) and context (LLMICs). PubMed, Embase, PsycINFO, CINAHL, Cochrane Library, Scopus and Web of Science will be systematically searched since database inception. Citation, reference list and PubMed-related article searching of included studies will be done to ensure literature saturation. Empirical peer-reviewed literature exploring adult patients' (aged ≥ 18 years) experiences of MV in ICUs in LLMIC will be included. All study designs (quantitative, qualitative and mixed methods) will be included. Two independent reviewers will perform screening, data extraction and critical appraisal. The mixed-methods appraisal tool (MMAT) and Popay's narrative synthesis will be used for critical appraisal and data synthesis, respectively.

Discussion This SR aims to bridge a gap in knowledge as previous evidence synthesis has described this phenomenon in developed countries. The review design, with the inclusion of quantitative, qualitative and mixed-methods studies, intends to provide a rich and in-depth exploration of the issue. The findings will be presented as themes, subthemes and their explanatory narratives. The gaps in available literature will be identified, and implications of SR findings on policy, practice and future research will be presented. The strength of this SR lies in its systematic, comprehensive, transparent, robust and explicit methodology of identifying, collating, assessing and synthesizing available evidence. By prior registration and reporting of this SR protocol, we aim to ensure transparency and accountability and minimize bias.

Systematic review registration PROSPERO CRD42024507187

Keywords Critical illness, Experiences, Intensive care unit, Low- and middle-income countries, Mechanical ventilation, Systematic review

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Background

Intensive care units (ICUs) provide intensive and specialized care, monitoring and support to patients with acute life-threatening organ dysfunctions [1]. Mechanical ventilation (MV) is a crucial life-sustaining intervention in ICUs, aiding gas exchange in individuals experiencing airway compromise, hypoventilation, hypoxemic respiratory failure and heightened ventilatory demands [2]. Millions of patients worldwide undergo MV in ICUs each year [1]. While medical advancements have significantly improved patient outcomes, with the majority surviving hospital discharge, MV is a stressful journey for patients and their families [1, 3, 4].

Patients undergoing MV in the ICUs encounter a myriad of challenges, including invasive instrumentation, disrupted sleep and psychological disturbances [5]. Communication is impeded by the endotracheal or tracheostomy tube, intensifying their isolation and frustration [6]. Patient's self-report of experience is an independent measure of healthcare quality and is increasingly a focus of healthcare organizations [7, 8]. However, available systematic reviews (SRs) on the topic have included studies predominantly from high-income countries (HICs) [3]. Low- and lower-middle-income countries (LLMICs) have a disproportionately higher burden of critical illnesses, have distinct socio-cultural backgrounds and lack well-established care, sedation, weaning and withdrawal/withholding life-sustaining treatment protocols in ICUs [9–12]. LLMICs also lag behind HICs with respect to ICU capacity, resources, trained manpower and critical care services provided [1, 10, 13, 14]. These differences may potentially impact patients' outcomes, experiences and satisfaction [15, 16]. This limits the transferability of findings of available SRs (skewed towards HICs) to LLMICs. To address this gap, this SR aims to systematically identify, collate, appraise and synthesize the available literature on the patients' experiences of MV in ICUs in LLMICs.

By focusing on countries classified as LLMICs by the World Bank country and lending group classification (Additional file I) [17], we seek to identify challenges faced by and factors influencing patients' experience in these settings. This might inform future interventions and policies tailored to the specific needs of patients in LLMICs. A preliminary search on PubMed, MEDLINE, International Prospective Register of Systematic Reviews and Meta-analysis (PROSPERO), Cochrane Database of Systematic Review and JBI Evidence Synthesis did not identify any existing or ongoing similar SR, thereby establishing the novelty of the review.
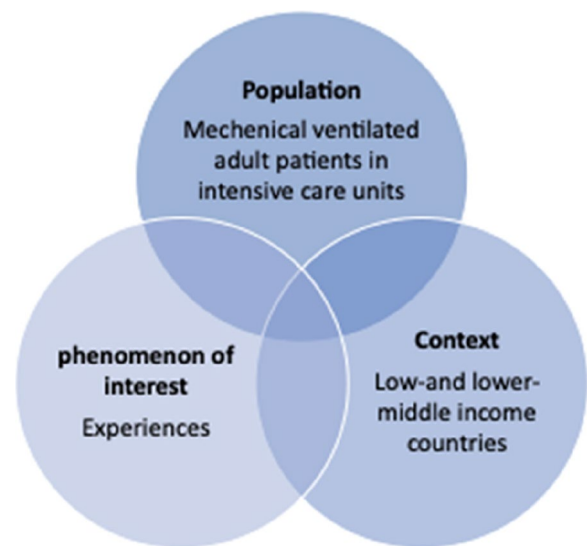
Fig. 1 Key concepts guiding the eligibility criteria and search strategy

Methods

The SR protocol followed the Preferred Reporting Items for Systematic Reviews and Meta-analysis Protocol (PRISMA-P) guidelines (Additional file II). The protocol has registered in the PROSPERO (*CRD42024507187*).

Review question

This systematic review aims to explore the review question: "What are the patients' experiences of being mechanically ventilated in ICUs in LLMICs?".

FINER criteria (feasible, interesting, novel, ethical and relevant), as recommended by the Cochrane Handbook for Systematic Reviews (CHSR), were referred to while formulating the review question [18]. A preliminary scoping search from 15 to 25 October 2023 helped refine the review question. The scoping search helped establish the feasibility in terms of availability of evidence by identifying six relevant studies addressing the review question and novelty by lack of similar existing or ongoing SRs. A research priority-setting meeting among the concerned stakeholders (administrators, intensivists, ICU survivors and their families) established that the review topic is interesting, ethical and relevant [18].

Eligibility criteria

Experiential reviews (focussing on experiences and perspectives) such as ours usually lack a comparator and outcome, making the traditional PICO framework not the best fit for such reviews [19]. PICO framework, as recommended by the Joanna Briggs Institute (JBI), translated our review question into key concepts (Fig. 1) [20].

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Table 1 Eligibility criteria

Inclusion criteria	Exclusion criteria
Studies exploring experiences of adult (≥ 18 years) patients undergoing MV in ICUs	Mechanical ventilation in settings other than ICUs
Set in LLMICs	Paediatric (< 18 years), non-patient population or mix of population
Empirical peer-reviewed literature (quantitative, qualitative and mixed methods)	Studies set in UMICs, HICs or mix of countries without data provided separately for LLMICs
Published in English language	Nonempirical (editorials, letter to editors and other opinion papers, case reports and series)
	Systematic and other reviews, grey literature, thesis and dissertations
	Published in language other than English

Study selection will be based on pre-defined inclusion and exclusion criteria (Table 1).

Population

The population of interest is adult (≥ 18 years) patients undergoing MV (both invasive and non-invasive) in ICUs. ICU settings will include medical ICU, surgical ICU, mixed medical-surgical ICU, neuro ICU, critical care, respiratory care, cardiac coronary and high dependency units. We will exclude studies of MV in home settings and hospital wards or settings other than ICUs. Studies with a mix of settings without data provided separately for patients undergoing MV in ICUs will be excluded.

Phenomenon of interest

Studies exploring patients' experiences of MV in ICUs. No restriction on the duration of MV or time limit on the collection of patients' experiences after MV will be imposed. Studies exploring experiences of paediatric (< 18 years), non-patient population (caregivers, family members, healthcare professionals) or a mix of populations will be excluded.

Context

Studies set in low- and lower-middle-income countries as classified by the World Bank Country and Lending Groups (2024) [17]. We will exclude studies exploring experiences of patients from LLMIC residing and admitted in ICUs in upper-middle-income countries (UMICs) or HICs (e.g. Indians residing and mechanically ventilated in ICUs in the UK). Studies with a mix of population from LLMIC, UMIC and/or HIC without data provided for patients from LLMIC will be excluded. Additional file III outlines the operation definitions for key concepts adopted in this review.

Study designs

We will include empirical peer-reviewed literature exploring adult patients' experience of undergoing MV in ICUs published since database inception to present. No restriction on study design will be imposed, and SR will include quantitative, qualitative and mixed-methods studies. We will exclude opinion and other nonempirical papers, conference abstracts and grey literature. Evidence synthesis will be excluded. However, reference lists of relevant SRs will be screened to identify any additional articles missed during database searching.

Information sources

We will search the following electronic databases: MEDLINE (Ovid), Embase (Ovid) and PsycINFO (Ovid), Cumulative Index to Nursing and Allied Health Literature (CINAHL, EBSCOhost platform), Scopus (http://www.scopus.com), Web of Science (Clarivate) and Cochrane Library (https://www.cochranelibrary.com).

To ensure literature saturation, we will manually scan reference lists of included studies and relevant evidence syntheses to identify additional studies [21]. Articles citing the included studies will be searched using Google Scholar to identify additional studies. Reference list screening and citation tracking will continue until data saturation, defined as no new relevant study being identified, an indicator for stopping further literature search [22]. In addition, PubMed's related article search on all the included studies will be performed to reduce the likelihood of missing relevant studies.

Search strategy

Efforts will be made to ensure that the literature search is transparent, comprehensive, robust and reproducible, with the aim to identify all the relevant reports [18, 20]. An initial scoping search of PubMed will be performed to identify free text words used to describe the key concepts. The search strategy will be developed iteratively with input from all the reviewers, going through and adapting from relevant SRs and going through the title, abstracts, thesaurus terms used to index and keywords used by the authors of the relevant articles. With the aim to comprehensively search the literature and identify the maximum

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relevant literature, text words will be combined with the MeSH terms in a "belt and braces" approach, and the latter will be exploded to increase the sensitivity of the search [22]. The database-specific thesaurus and free text words for a similar concept will be combined using the Boolean operator "OR" to formulate search strings for each individual concept. The search strings for individual concepts will be nested and combined with those for different concepts using the Boolean operator AND. A version control and an audit trail of all the iterations and changes made in the search strategy will be maintained.

The search strategy will be first devised for PubMed and CINAHL and sent to an experienced systematic reviewer and a subject expert for peer review. The final search strategy will be adapted for other electronic databases. No study design, date or language restrictions will be imposed on the search. However, only articles published in the English language will be included. Another experienced researcher will rerun the search strategies to rule out any syntax or other errors. An explicit, detailed and transparent reporting of search strategies (including database name, search platform, date run and corresponding number of hits) will be done. A draft PubMed search strategy is presented in Additional file IV.

Data management and selection process

All records identified will be transported to EndNote reference manager software (V.20, Clarivate Analytics, Philadelphia, PA, USA), and duplicate entries will be removed. Deduplicated references will be exported to Rayyan (https://www.rayyan.ai/) in which two researchers will independently screen the title and abstracts to identify records that meet the inclusion criteria [23]. Full-text articles of potentially eligible records and those where eligibility could not be determined from the title and abstract will be retrieved and screened for inclusion by two independent reviewers. The final consensus will be made by referring to the a priori-specified eligibility criteria and whether the article answers the review question or not. Disagreements will be resolved through discussion between the two reviewers and arbitrated by a third reviewer where necessary. The search and selection process results, including the number of records excluded at each step and reasons for exclusion, will be reported in a PRISMA flow diagram (Additional file V).

The inter-rater reliability (IRR) among the reviewers will be calculated using percent agreement and Cohen's kappa [24, 25]. Percentage agreement does not consider chance agreement among coders and hence has been discouraged as the sole indicator of IRR [26]. In that respect, Cohen's k, by estimating and removing chance agreement, represents a chance-corrected measure of IRR [27].

Data collection

Data extraction form and data items

An Excel *data extraction form* customized to meet the review aim, objectives, purpose and typology of studies identified during the scoping search will be developed, discussed and revised in consultation with all the researchers to avoid missing relevant data. Extracted data will include information on bibliographic details; study aims/objectives, participant characteristics, context and setting; study methods; data collection (including the timing of data collection) and analysis; and ethical issues, study findings and direct quotations from study participants to contextualize the authors' interpretation of findings and to support our synthesized themes and subthemes (where appropriate).

Piloting

The data extraction form will be *piloted* in five studies to ensure that the data extraction form captures all the relevant information consistent with the research question and purpose [18]. The piloting will be done independently by two researchers, after which necessary changes will be made in agreement. Repiloting of data extraction form will be done to ensure that it is comprehensive and specific to our review purpose [28].

Data extraction by two independent researchers

To ensure rigour and minimize bias, two reviewers will do data extraction independently in parallel [18, 29]. Prior to data extraction, the two researchers will discuss in detail the instructions for data extraction and coding [18, 28]. Any discrepancies will be reconciled through discussions. An audit trail of disagreements and resolutions made will be maintained.

Outcomes and prioritization

The primary outcome of interest will be patients' experiences defined as patients' self-report of their views, attitudes, perspectives, opinions, perceptions, difficulties, acceptance and satisfaction while undergoing a health procedure (MV) shaped by healthcare people, processes, physical settings and their expectations of healthcare [29]. Patients' experiences will also include their self-report of emotions and physical (e.g. pain, thirst) and psychological (stress, distress, anxiety) factors while undergoing MV in ICUs. Apart from the outcome data, non-outcome data will be extracted to contextualize the findings of primary studies and assess their trustworthiness, applicability and transferability to other settings [28].

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Table 2 Overall quality score of each included study

Score	Description
5	100% quality criteria met
4	80% quality criteria met
3	60% quality criteria met
2	40% quality criteria met
1	20% quality criteria met

Critical appraisal

Critical appraisal refers to appraising quality of studies for methodological rigor, trustworthiness, sources of bias and validity and reliability of their findings [30, 31]. Critical appraisal tools provide a stepwise and structured approach to systematically appraise the eligible studies and uncover their methodological limitations [32]. The choice of critical appraisal tool is influenced by the ease of use, brevity, the context in which it developed, availability (free or fee based) and research question, which in turn determine the typology of included studies, available expertise and resources [33]. Without clear-cut consensus, Noyes et al. recommend using a validated tool to assess the methodological strengths and limitations of the included studies [34].

Mixed-Methods Appraisal Tool (MMAT) will be used to assess the methodological rigour and risk of bias in included studies [35]. MMAT was found as the best fit as it has been specifically designed and used extensively to appraise different typology of studies (qualitative, quantitative and mixed methods) as identified during our scoping search, structured format, easy accessibility, ease of use, brevity and detailed guidance available for its use (Additional file VI) [36, 37]. MMAT was developed through a rigorous development process comprising of literature review, e-Delphi and researchers inputs and has been shown to be comprehensive, valid, reliable and feasible [35, 36].

The initial two screening questions of MMAT will ensure that the study being appraised is an empirical study and, hence, eligible for inclusion in this SR [35]. Each study will be appraised by using one of the five study-design-specific categories (qualitative, quantitative randomized controlled trial, quantitative non-randomized, quantitative descriptive and mixed methods) of questions provided in the MMAT. For each question in the study-design appropriate category, each study will be rated as *yes* (*quality criteria met), *no* (study does not satisfy the criterion) or can't ***tell*** (lack of sufficient information to answer). Although initially recommended against [35], Hong et al. later reported a method to calculate the overall quality score of a study (Table 2) [38]. As per the recommendations, the overall quality score

for mixed-methods studies will be the lowest score of the study components (quantitative, qualitative and mixed methods) [38].

Two reviewers will do a critical appraisal independently, and discrepancies will be settled with consensus [35]. Critical appraisal involves judgment making necessitating two independent appraisers having experience in the domain assessed [35]. The MMAT will first be piloted independently by both reviewers on five studies of different study designs to ensure consistent application [18]. An audit trail of all the disputes and resolutions made will be maintained. To be more informative, both overall quality scores along with a detailed description will be provided [38].

No studies will be excluded based on critical appraisal. Exclusion of studies based upon quality appraisal may adversely impact the evidence synthesis by excluding methodologically less robust but important descriptive findings and excluding fewer studies available on the phenomenon of interest, which has been advised against [18, 33, 34, 39, 40]. However, depending on the quality appraisal results, we might do a sensitivity analysis to assess the impact of study quality on the SR findings [37].

Data synthesis

The findings of this review will be synthesized using Popay's narrative synthesis [41]. Narrative synthesis is a well-recognized and recommended form of data synthesis, portraying findings as a trustworthy story. Popay's narrative synthesis was chosen as it (1) allows the synthesis of quantitative results with qualitative findings from diverse study designs, thereby allowing comprehensive understanding and answering of the review question; (2) aims to adopt the same rigorous, systematic, transparent and non-bias approach to narrative synthesis as employed at other steps of a SR; (3) can be used for data synthesis for reviews addressing review questions as varied as effectiveness, implementation, needs and preferences; (4) has been successfully used as the synthesis method in a number of MMSRs (as reflected by 4833 citations on Google Scholar on 08 February 2024); and (5) synthesized findings can be and have been used to inform policy and practice: one of the penultimate goal of conducting a SR [41]. Rather than prescriptive guidance, Popay's framework comprises of a number of steps (rather than stages) with an array of tools and techniques which can be utilized at each step [41]. Popay's approach to narrative synthesis is iterative without the need to carry out steps in the same sequence as described [41]. This allows the flexibility needed to address the review type and study characteristics without compromising transparency and rigor [41].

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Developing preliminary synthesis

First of all, a brief textual description of each study detailing its aims, design, setting, participants, findings and limitations will be developed to familiarize with and contextualize the study findings. These study characteristics will be tabulated to identify patterns across the studies. This will form the basis for grouping studies on the basis of study designs and context, for example.

Considering the review question can be answered by both qualitative (phenomenological studies exploring patients' experiences) and quantitative (cross-sectional surveys) study designs, a convergent integrated with a data-based convergent approach to data synthesis will be used [18, 42]. Data transformation in the form of qualitization of the quantitative results will be done [42]. Data transformation allows data transformation into mutually compatible and synthesizable formats, with qualitization (extracting survey questions as themes or textual narratives) being less prone than and recommended over quantization (converting qualitative findings into words or frequencies) [42]. The extracted findings will then be analysed thematically. Line-by-line coding of the extracted findings will be done. The process will be iterative without any a priori codes or categories.

Exploring relationship within and across studies

Tabulation and grouping during the preliminary synthesis will help to explore relationships and patterns across studies. Heterogeneity in terms of population, duration of MV, timing of data collection after MV, context and methodology will be explored during this step. Idea webbing or concept mapping will be used to group conceptually similar codes into categories and explore relationships between the categories.

Data translation: thematic synthesis

Translation refers to identifying similar concepts expressed differently in different studies [37]. Though devised initially for qualitative studies, thematic analysis allows the translation of data from diverse study designs [41]. Meaningful subthemes and themes will be generated to understand patients' experiences of MV in ICUs and the factors moderating these experiences. The aim of synthesized findings will be to allow an interpretative understanding of the current state of knowledge on the concept rather than just mere aggregation of the data [41, 43]. An iterative process will be followed wherein the themes and subthemes will be reviewed and refined in consultation with reviewers with previous experience in doing narrative synthesis. The SR findings will be presented as themes, subthemes and their explanatory narratives.

Theoretical framework to interpret the review findings

Popay suggested using theory to inform the review question and interpret the review findings [41]. Although an element of Popay's framework, it is not mandatory to use theory [41]. PICO framework informed our review question, negating the need for theory at this stage. By linking, organizing and summarizing information, theories help make sense of the synthesized findings and provide a framework to facilitate understanding a complex phenomenon [44]. Depending upon the review findings, the theory may be used to facilitate the interpretation of review findings. This will allow an inductive approach to data analysis without any a priori categories.

Assessing the robustness of the synthesis

The findings of a SR are as trustworthy as the quality of the included studies [41]. The synthesis findings will be critically reflected upon its limitations, implications and studies (their methodological quality, sources of bias and concordance with the review's aims) informing the review. Sensitivity analysis will be done to assess the impact of including studies of differing quality and studies employing different study designs (quantitative, qualitative and mixed method) on the synthesis findings [40]. To assess the impact of applying critical appraisal on the synthesis findings, we will calculate a quality score for each included study by dividing the number of quality criteria met (yes) by the total quality criteria possible [45]. A sensitivity analysis will be performed wherein it will be assessed whether the exclusion of weak quality studies (i.e. studies with a quality score of ≤ 0.5) impacts the depth, richness or complexity of the synthesis findings [40, 45].

Discussion

This SR aims to bridge a gap in knowledge as previous evidence synthesis has described this phenomenon in developed countries. A preliminary scoping exercise identified a mixed typology of studies addressing the review question and justifying our selection of MMSR tools and techniques, in particular the PICO framework, MMAT, narrative synthesis and data-based convergent integrated approach to data synthesis [46–49]. SRs incorporating and integrating data from multiple study designs have been variably referred to as comprehensive [50], mixed-methods systematic reviews (MMSR) [20, 50], mixed-methods research synthesis [51], mixed studies reviews [52] and mixed research synthesis [53]. A MMSR combines strengths and mitigates limitations of different study designs and helps to explore, explain or

contextualize one type of data with another [20, 43, 51, 52, 54]. A comprehensive, systematic and reproducible search differentiates a systematic review from traditional narrative reviews, ensuring the identification of as many relevant studies as possible and minimizing the risk of reporting bias [55]. Our comprehensive search strategy will comprise of multitude of terminologies used in the literature to refer to the same concepts. We will search multiple subject-specific and multidisciplinary databases. Considering their different indexation and coverage, searching multiple databases tailored to the review topic is recommended [55, 56]. Cochrane recommends a minimum search of three databases: CENTRAL, MEDLINE and Embase [18]. We decided to use PubMed instead of MEDLINE because of its familiarity and extensive coverage, and it provides free access to MEDLINE in addition to journals not indexed with MEDLINE and access to citations not yet indexed with MEDLINE [55, 57]. Bibliographic databases search is known to miss relevant articles due to poor indexing, incomplete abstracts and limited coverage [56, 58]. Supplementary search strategies like reference list checking, citation tracking and PubMed-related article searching are therefore recommended to supplement the search and reduce bias [56].

Strengths
By prior registration and reporting, this SR protocol aims to ensure transparency and accountability and minimize bias by a priori specifying the review question, objectives, search process, eligibility criteria, a method for critical appraisal, data synthesis and sensitivity analysis [40, 45]. The strength of this SR will lie in its systematic, comprehensive, transparent, robust and explicit methodology of identifying, collating, assessing and synthesizing available evidence [18, 20]. The review design, with the inclusion of quantitative, qualitative and mixed-methods studies, intends to provide a rich and in-depth exploration of the issue. Key review decisions have been made in consultation with the experienced systematic reviewers, CHSR and JBI Manual of Evidence Synthesis. A two-independent reviewers with an arbitration and audit process will be adopted at the screening, critical appraisal and data extraction phases. The SR will employ the MMAT tool and Popay's narrative synthesis, which have been previously validated for appraising and synthesizing mixed typology of studies. The data synthesis will be carried out in consultation with all the reviewers to reduce the risk of subjective bias due to individual researchers' own preconceived notions and views on MV.

Limitations
Considering the cost and time constraints, the SR will include studies only published in English and exclude grey and unpublished literature. Given the importance of context (LLMIC) in this review, this might lead to missing out on relevant articles published in vernacular languages. However, the exclusion of other language studies has not been found to alter the review findings [59]. We envisage that using Google Scholar (cataloguing both academic and grey literature) for citation tracking of included articles will identify any relevant article not identified through database search [60]. MV decision-making is complex and involves multiple stakeholders. The SR will place the voices of patients at the centre of the analysis. To ensure complete understanding, the views of other stakeholders, that is, HCPs, caregivers and policymakers, will need to be studied and systematically reviewed.

Implications for policy and practice
The SR findings will have policy, practice and future research implications. By highlighting gaps in the existing literature, it will identify areas to be explored in future research. The SR findings will allow an inductive and systematic way to formulate an interview guide for researchers contemplating conducting similar research in their settings. This SR might help clinicians and administrators to identify macro-, micro- and meso-level factors impacting patients' experiences of MV in ICUs in LLMICs and tailor, formulate or revise their clinical pathways and policies accordingly.

Abbreviations

HIC	High-income country
ICU	Intensive care unit
LLMICs	Low- and lower-middle-income countries
MMSR	Mixed-methods systematic review
MV	Mechanical ventilation
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-analysis protocol
PROSPERO	International Prospective Register of Systematic Reviews and Meta-analysis
SR	Systematic review
UIC	Upper-income country

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13643-024-02630-0.

> Supplementary Material 1. Appendix: Additional file I: List of Low-and lower-middle income countries included. Additional file II: PRISMA-P 2015 Checklist. Additional file III: Key operation definitions. Additional file IV: Draft PubMed Search strategy (11 February 2024). Additional file V: PRISMA Flow diagram. Additional file VI: Mixed methods appraisal tool

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Declarations

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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