International Platform of Registered Systematic Review and Meta-analysis Protocols

INPLASY

INPLASY202650064
doi: 10.37766/inplasy2026.5.0064
Received: 10 May 2026
Published: 10 May 2026

Corresponding author:
Ahmad Alkhatib

alkhatib.ahmad@mayo.edu

Author Affiliation:
Mayo Clinic.

The Phenomenon of Informed Consent in Clinical Care Among Patients with Limited English Proficiency: Structural, Communication, and System-Level Factors — A Scoping Review

Al-Khatib, AZ; Barwise, AK; Sen, H; Tang, M; Fathi, E; Brankovic, K; McGinnis, M; Gerberi, D.

ADMINISTRATIVE INFORMATION

Support - Mayo Clinic.

Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202650064

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 May 2026 and was last updated on 10 May 2026.

INTRODUCTION

Review question / Objective This scoping review aims to examine how informed consent is conceptualized, operationalized, and influenced by communication-related, structural, and system-level factors in clinical care involving patients with limited English proficiency (LEP) in English-speaking healthcare settings.
Specifically, the review will:
Map how informed consent is defined and operationalized in studies involving patients with LEP.
Identify communication-related, interpreter-mediated, structural, and workflow factors influencing informed consent processes.
Examine reported implications for patient comprehension, voluntariness, participation in decision-making, and consent documentation.
Identify interventions, strategies, and recommendations intended to improve informed consent processes in language-discordant clinical settings.
The review question is:
How do communication-related, interpreter-mediated, structural, and system-level factors influence informed consent processes in clinical care involving patients with limited English proficiency?

Rationale Patients with limited English proficiency (LEP) experience well-documented communication barriers in healthcare settings. These barriers have been associated with reduced patient understanding, decreased participation in shared decision-making, lower satisfaction with care, and increased risk of adverse clinical outcomes. Such challenges are particularly consequential during informed consent discussions, which depend on effective communication to support adequate disclosure, patient comprehension, voluntariness, and meaningful authorization of care.
Informed consent is widely regarded as both an ethical and clinical process rather than solely a legal or documentation requirement. However, in language-discordant healthcare encounters, achieving meaningful informed consent may be

difficult. Although professional medical interpreters are intended to reduce language barriers, evidence suggests that interpreter availability, interpreter modality (in-person, video, or telephone), clinician communication practices, workflow pressures, institutional documentation requirements, and broader structural constraints may continue to influence the quality and depth of consent discussions. Communication challenges may also be shaped by cultural expectations, interactional dynamics, and variability in clinicians' approaches to interpreter-mediated communication.

Existing literature examining informed consent among patients with LEP is substantial but fragmented across multiple disciplines, including interpreter-mediated healthcare communication, clinical ethics, surgery, perioperative care, health services research, emergency medicine, and health equity scholarship. Studies vary considerably in how informed consent is conceptualized and operationalized. Some studies focus primarily on documentation completeness, while others examine comprehension, communication quality, interpreter use, shared decision-making, or ethical concerns related to patient autonomy. Additionally, studies use inconsistent terminology to describe patients with LEP and language-discordant encounters, which may complicate synthesis of the literature.

Despite increasing attention to language access and healthcare equity, no scoping review has comprehensively mapped the literature examining how communication-related, structural, and system-level factors influence informed consent processes among patients with LEP in clinical healthcare settings. A scoping review is therefore appropriate to clarify how informed consent is defined and studied in this context, identify reported barriers and facilitators, examine implications for patient understanding and participation in decision-making, and identify interventions or strategies intended to improve consent processes in language-discordant clinical care.

This review will focus on clinical healthcare settings within English-speaking healthcare systems to improve contextual comparability of interpreter infrastructure, consent standards, and healthcare delivery processes. Findings from this review may help inform future research, communication practices, interpreter service development, and institutional approaches to improving informed consent for patients with LEP.

Condition being studied This scoping review examines informed consent processes in clinical healthcare involving patients with limited English proficiency (LEP). The review focuses on how communication-related, interpreter-mediated, structural, and system-level factors influence informed consent discussions, including disclosure, comprehension, voluntariness, participation in decision-making, and consent documentation. Relevant factors may include language discordance, interpreter modality and availability, clinician communication practices, workflow constraints, and institutional documentation systems across clinical healthcare settings in English-speaking countries.

METHODS

Search strategy A comprehensive search strategy will be developed in collaboration with a medical librarian. Electronic databases will include MEDLINE (via PubMed or Ovid), Embase, and additional databases identified as relevant to the topic. Search strategies will combine controlled vocabulary terms and keywords related to informed consent, limited English proficiency (LEP), language barriers, interpreter services, interpreter-mediated communication, and language discordance.

Example search concepts will include:
> * "Informed consent"
> * "Surgical consent"
> * "Clinical consent"
> * "Limited English proficiency"
> * "LEP"
> * "Language barriers"
> * "Interpreter services"
> * "Medical interpreters"
> * "Interpreter-mediated communication"
> * "Language discordance"

Searches will be limited to English-language publications. Conference abstracts and conference proceedings will be excluded. Reference list screening and citation searching of relevant included studies and reviews may also be conducted to identify additional eligible studies.

Participant or population Patients with limited English proficiency (LEP) receiving clinical healthcare in English-speaking countries, including the United States, Canada, United Kingdom, Ireland, Australia, and New Zealand. Studies involving clinicians, professional medical interpreters, and other stakeholders participating in informed consent discussions involving patients with LEP will also be included. Both adult and pediatric clinical care settings may be considered.

Intervention As this is a scoping review, no single intervention is required for study inclusion. The review will examine communication-related, interpreter-mediated, structural, and system-level factors influencing informed consent processes in clinical care involving patients with limited English proficiency (LEP). Relevant factors may include interpreter modality (in-person, telephone, or video), interpreter availability, clinician communication practices, language discordance, workflow constraints, electronic consent systems, and institutional policies or strategies intended to improve informed consent processes.

Comparator Comparator groups are not required for inclusion. Studies with or without comparison groups will be eligible. Where applicable, studies may compare patients with limited English proficiency (LEP) to English-proficient patients, compare different interpreter modalities, or compare different informed consent practices or institutional approaches.

Study designs to be included This scoping review will include empirical studies using qualitative, quantitative, or mixed-methods designs. Eligible study designs may include observational studies, cohort studies, cross-sectional studies, surveys, qualitative interview or focus group studies, quality improvement studies, prospective or retrospective clinical studies, and interventional studies related to informed consent processes in clinical care involving patients with limited English proficiency (LEP). Relevant systematic or narrative reviews may be screened for citation searching but will not be included in the final.

Eligibility criteria Inclusion criteria:
* Empirical studies examining informed consent processes in clinical healthcare involving patients with limited English proficiency (LEP).
* Studies addressing communication-related, interpreter-mediated, structural, workflow, or system-level factors influencing informed consent.
* Studies conducted in clinical healthcare settings, including inpatient, outpatient, perioperative, emergency, procedural, or specialty care settings.
* Studies conducted in English-speaking healthcare systems, including the United States, Canada, United Kingdom, Ireland, Australia, and New Zealand.
* Qualitative, quantitative, mixed-methods, observational, interventional, survey, and quality improvement studies.
* English-language publications
Exclusion criteria:

* Studies focused exclusively on research consent or consent for participation in clinical trials.
* Studies addressing consent solely from a legal or theoretical perspective without clinical grounding.
* Studies not involving patients with LEP or language-discordant clinical encounters.
* Studies focused exclusively on sign-language interpretation.
* Non-clinical educational or community-only settings without healthcare delivery.
* Conference abstracts, conference proceedings, editorials, commentaries, and letters without primary empirical data.
* Studies conducted exclusively in non-English-speaking healthcare systems or refugee camp settings.

Information sources Electronic database searches will be conducted in MEDLINE (via PubMed or Ovid), Embase, and additional databases selected in consultation with a medical librarian based on relevance to the topic. Citation searching of included studies and relevant reviews will also be conducted to identify additional eligible studies. Reference list screening and forward citation tracking may be used as supplementary search methods. Screening and study management will be conducted using Covidence and EndNote.

Main outcome(s) Primary outcome domains include:
1. How informed consent is conceptualized and operationalized in studies involving patients with limited English proficiency (LEP), including disclosure, comprehension, voluntariness, decision-making, and authorization.
2. Communication-related barriers and facilitators influencing informed consent processes, including language discordance, interpreter use, interpreter modality, clinician communication practices, and shared decision-making approaches.
3. Structural and system-level influences affecting informed consent, including interpreter availability, workflow constraints, institutional policies, and documentation systems.
4. Reported implications for patient comprehension, participation in decision-making, voluntariness, consent quality, and documentation practices.
5. Interventions, strategies, or recommendations intended to improve informed consent processes in language-discordant clinical settings.

Additional outcome(s) Additional outcome domains may include ethical implications of language-discordant informed consent, clinician and interpreter perspectives, institutional or operational barriers, disparities in consent processes, communication training initiatives, interpreter service delivery practices, and identified gaps requiring future research. Findings may also be categorized by clinical setting, interpreter modality, and study design where relevant.

Data management Search results will be exported into EndNote for reference management and deduplication prior to upload into Covidence for screening and study selection. Covidence will be used to manage title and abstract screening, full-text review, documentation of exclusion reasons, and study flow tracking. Data extraction will be conducted using a standardized extraction form maintained in Microsoft Excel. All screening and data extraction decisions will be independently verified by at least two reviewers, with discrepancies resolved through discussion and adjudication by an additional reviewer when necessary.

Quality assessment / Risk of bias analysis Consistent with Joanna Briggs Institute (JBI) guidance for scoping reviews, a formal risk-of-bias or methodological quality assessment will not be conducted. The purpose of this review is to map and characterize the existing literature rather than to estimate pooled effects or determine intervention effectiveness. Methodological characteristics of included studies, such as study design, setting, and sample characteristics, will be described narratively to provide context for interpretation of findings.

Strategy of data synthesis A structured narrative synthesis will be conducted following Joanna Briggs Institute (JBI) recommendations for scoping reviews. Extracted data will be synthesized through descriptive mapping, thematic categorization, and conceptual analysis. Findings will be organized according to key domains, including conceptualizations of informed consent, communication-related factors, interpreter-mediated factors, structural and workflow influences, documentation practices, and reported clinical or ethical implications. Results will be presented using summary tables, evidence mapping tables, and narrative thematic summaries. Quantitative meta-analysis is not planned due to the anticipated heterogeneity of study designs, methodologies, and outcome measures.

Subgroup analysis No formal subgroup meta-analysis is planned. However, findings may be descriptively categorized according to clinical setting, interpreter modality (in-person, telephone, or video), healthcare context, study design, and type of informed consent process where relevant.

Sensitivity analysis Sensitivity analysis is not applicable because this scoping review does not involve quantitative effect estimation or meta-analysis. The review is intended to descriptively map and characterize the existing literature.

Language restriction English. Studies published in English will be included.

Country(ies) involved United States. Authors are affiliated with Mayo Clinic, Georgetown University, University of Pittsburgh, and the University of Utah.

Other relevant information This review will be conducted in accordance with the Joanna Briggs Institute (JBI) Manual for Evidence Synthesis for scoping reviews, and reporting of findings will follow the PRISMA-ScR guideline. The review focuses on informed consent as a communication-dependent clinical process rather than solely a legal or documentation requirement. The protocol is being registered prior to formal study selection to improve methodological transparency and reproducibility.

Keywords Informed consent; limited English proficiency; LEP; medical interpreters; interpreter services; language barriers; language discordance; healthcare communication; scoping review; interpreter-mediated.

Dissemination plans Findings from this scoping review will be submitted for publication in a peer-reviewed journal and may also be presented at relevant academic or healthcare conferences. Results may additionally inform future research, healthcare communication practices, interpreter service development, and institutional policies related to informed consent for patients with limited English proficiency (LEP).

Contributions of each author

Author 1 - Ahmad Alkhatib - Conceptualization; methodology; project administration; protocol development; screening oversight; data extraction; data synthesis; writing – original draft; writing – review & editing.
Email: alkhatib.ahmad@mayo.edu
Author 2 - Amelia Barwise - Supervision; methodological oversight; validation; clinical ethics expertise; writing – review & editing.The author provided mentorship, authorship, and overall supervision.
Email: barwise.amelia@mayo.edu
Author 3 - Hasan Sen - Investigation; screening; data extraction; literature review support; writing – review & editing.
Email: hasan.sen@utah.edu

Author 4 - Matthew Tang - Investigation; screening; data extraction; methodological input; writing – review & editing.
Email: mat380@pitt.edu
Author 5 - Ella Fathi - Investigation; screening; data extraction; literature review support; writing – review & editing.
Email: eaf130@georgetown.edu
Author 6 - Katarina Brankovic - Investigation; screening; data extraction; literature review support; writing – review & editing.
Email: brankovic.katarina@mayo.edu
Author 7 - Michele McGinnis.
Email: mcginnis.michele@mayo.edu
Author 8 - Danaielle Gerberi - Literature search strategy development; database selection; controlled vocabulary mapping; search methodology; writing – review & editing.
Email: gerberi.danielle@mayo.edu