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Corresponding author:

Changhao Liang

changhaoliang@bucm.edu.cn

Author Affiliation:

Beijing University of Chinese Medicine.

Liang, CH; Yin, GX; Wu, WL.

ADMINISTRATIVE INFORMATION**Support** - Xinjiang Key R&D Project.**Review Stage at time of this submission** - Data analysis.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202650009**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 3 May 2026 and was last updated on 3 May 2026.**INTRODUCTION**

Review question / Objective This study employs a scope review methodology to systematically search for and synthesize methodological research on the integration of values and preferences in guideline development, identifying key challenges and unexplored areas in current research. This aims to provide a theoretical foundation and methodological reference for subsequent in-depth methodological studies, optimization of guideline development processes, and advancement of patient-centered recommendations.

Background Within the framework of evidence-based medicine, the development of clinical practice guidelines requires not only the integration of optimal research evidence but also a clear consideration of the value judgments and preference orientations of relevant interest groups—particularly patients—regarding different health outcomes during implementation. The World Health Organization (WHO) Guidelines Development Manual, Guidelines 2.0, and the

GRADE Evidence-to-Decision Framework all incorporate values and preferences (V&P) as critical dimensions in recommendation formulation, recognizing their joint influence with evidence certainty, cost-benefit analysis, and resource allocation on determining recommendation direction and strength. In this sense, values and preferences are no longer ancillary considerations in guideline development but have become essential methodological components for achieving patient-centered recommendations and enhancing guideline acceptability and implementability.

Nevertheless, there has long been considerable divergence in the academic community regarding the conceptual boundaries of V&P, data collection methods, and its integration pathways. Zhang et al. noted that differing interpretations persist regarding the definition and integration of patient V&P during guideline development, particularly between "patients' relative judgment of outcome importance" and "patients' preferences for specific intervention attributes" with inconsistent conceptual usage. The Grade workshop further proposed focusing V&P on patients' assessments

of the relative importance of primary health outcomes and provided methodological guidance on evaluating the bias risk and relevance of such evidence. Meanwhile, Kelson et al. emphasized the need to distinguish between two complementary approaches in guideline development: "direct patient and public participation in the process" and "utilizing research evidence to obtain V&P information". These developments indicate that V&P methodology research has evolved from principle advocacy toward framework development, though conceptual consistency and standardized implementation still require further refinement.

From a methodological perspective, the identification, measurement, and integration of values and preferences (V&P) exhibit significant methodological heterogeneity. Existing research has developed various methodologies, including qualitative interviews, focus groups, cross-sectional questionnaires, the Standard Gamble (SG) method, the Time Trade-Off (TTO) method, Discrete Choice Experiments (DCE), and Best-Worst Scaling (BWS). Soekhai et al. summarized 32 distinct preference measurement methods in a systematic literature review, indicating that the methodological toolkit in this field is relatively comprehensive; however, different methods differ markedly in research objectives, applicable scenarios, data characteristics, and result interpretation. Additionally, a systematic review and meta-analysis by Witteman et al. on value judgment clarification methods demonstrated that explicit value judgment clarification methods help reduce inconsistent value judgments, thereby mitigating decision conflicts, suggesting that V&P are not abstract concepts but can be identified, expressed, and transformed through standardized methods, thereby substantially influencing the development of clinical decision support tools and recommendations. Nevertheless, these methodological advancements remain scattered across various research domains such as clinical decision-making, health technology assessment, regulatory science, and guideline development, lacking a systematic synthesis focused on "how to integrate values and preferences in guideline development".

Rationale Although previous studies have fully recognized the importance of patient and public participation in guideline development, several prominent issues remain in the application of V&P methodology at the guideline formulation level. A systematic review by Bryant et al. on the scope of patient and public engagement in clinical practice guideline development indicates that it remains challenging to establish a standardized

engagement model, with inconsistent terminologies for "patients," "the public," and their engagement methods across studies. Similarly, Zhang et al. noted that evidence supporting localized or context-specific V&P approaches in real-world guideline development remains limited, and further empirical summarization and methodological guidance are needed to systematically retrieve, evaluate, synthesize, and transparently present relevant evidence within the EtD framework. Consequently, current research in this field should not merely address "whether V&P should be included," but rather focus on "what specific V&P measures should be incorporated, how they should be implemented, what methodologies should be employed, and how to assess their methodological quality and evidentiary credibility." This underscores the necessity of conducting systematic reviews to synthesize relevant studies, identifying the distribution patterns, core findings, primary challenges, and evidence gaps in existing methodological research.

METHODS

Strategy of data synthesis This study employed a combination of systematic retrieval and manual supplementary retrieval to collect literature. The search period covered the period from database establishment to March 17, 2026. The search strategy utilized a combination of subject terms and free terms, focusing on three core concepts: "values and preferences", "guideline development or recommendation formulation" and "methods or methodology". Search terms mainly comprised: value, preference, patient preference, patient values, guideline, clinical practice guideline, guideline development, recommendation, GRADE, evidence to decision, EtD, method, methodology, framework, process, standard, et al.

Eligibility criteria This study included literature meeting the following criteria: ① The research topic was related to methodological issues concerning the identification, acquisition, measurement, integration, or application of Values and Preferences (V&P) during the development of clinical practice guidelines, with titles, abstracts, or keywords reflecting terms such as "values", "preferences", "patient values", "patient preferences" or related concepts; ② The research context involved the development, recommendation formulation, or relevant decision-making processes for clinical practice guidelines; ③ The literature type consisted of peer-reviewed, formally published methodological studies, including methodological research, systematic

reviews, scope reviews, and methodological reviews; ④ Studies involving patient and public participation in guideline development were also included if their core content pertained to the acquisition, expression, integration or application of V&P during the guideline development process; ⑤ No language restrictions were imposed; ⑥ For studies with multiple published versions, the most comprehensive or latest version was included. This study excluded literature meeting any of the following criteria: ① those available only as abstracts without full-text access; ② those unrelated to the study's focus, such as those discussing general clinical decision-making, patient satisfaction, or treatment adherence without addressing methodological issues of values and preferences in guideline development; ③ those focusing solely on general guideline development processes or evidence grading methods without incorporating values and preferences integration; ④ peer-reviewed gray literature; ⑤ duplicate publications; ⑥ literature from which methodological information relevant to the study's objectives could not be extracted.

Source of evidence screening and selection

Computer searches were conducted in the China National Knowledge Infrastructure (CNKI), Wanfang, VIP, PubMed, and Embase databases, with the search period covering the period from database establishment to March 17, 2026. Additionally, manual tracing was performed on the references of included literature to supplement potentially overlooked relevant studies.

The retrieved bibliographic records from various databases are imported into the NoteExpress 3.0 literature management software. First, the software's plagiarism detection function eliminates duplicate entries. Subsequently, the remaining records are reviewed against predefined inclusion criteria, with each entry either accepted or excluded accordingly.

The literature screening and data extraction were independently conducted by two researchers using predefined data extraction tables, followed by cross-checking after completion. Disagreements were resolved through mutual consultation, with third-party review sought when necessary. The extracted data primarily included: fundamental characteristics of the literature; definitions and conceptual distinctions of V&P; recommended V&P research methodologies and methodological details; considerations regarding preference heterogeneity; the role of V&P in outcome significance assessment and recommendation

formulation; patient and public engagement strategies; and current methodological challenges with improvement recommendations.

Data management The data materials are strictly archived and preserved by the research team, and subsequent access and use require application and approval from the responsible person.

Reporting results / Analysis of the evidence For the basic characteristics and structured items of included literature, Excel software was employed for organization and descriptive statistical analysis, presenting distribution patterns of features as frequencies and percentages. For textual and methodological descriptive data, thematic synthesis and narrative synthesis methods were applied to systematically analyze aspects such as the conceptual definition of V&P, acquisition methods, application processes, participation models, reporting characteristics, and prevailing challenges.

Presentation of the results Presentation of the results will firstly take the form of SCI journal publications.

Language restriction No.

Country(ies) involved China.

Other relevant information None.

Keywords Values and Preferences; Clinical Guideline Development ; Evidence-Based Decision Making; Evidence-Based Medicine; Scope Review.

Dissemination plans This research plan aims to achieve widespread dissemination through journal publications, conference presentations, and multimedia promotions.

Contributions of each author

Author 1 - Changhao Liang - Conceptualization, Methodology, Data Collection and Screening, Writing - original draft, Writing - review & editing.

Email: changhaoliang@bucm.edu.cn

Author 2 - Guanxiang Yin - Conceptualization, Data Screening and Extraction, Writing - original draft, Writing - review & editing.

Email: rudy_yin@163.com

Author 3 - Wenli Wu - Methodology, Data Collection and Screening, Formal analysis.

Email: wdon220280@163.com