

## Review



# RATIONALE AND METHODOLOGICAL STEPS FOR A SCOPING REVIEW ON THE AVAILABLE CORE OUTCOME SETS IN HEART FAILURE: A DISCURSIVE ANALYSIS OF LITERATURE AND STUDY PROTOCOL

Giulia Paglione<sup>1,2,\*</sup>, Rosario Caruso<sup>3</sup>

<sup>1</sup> Department of Biomedicine and Prevention, University of Rome Tor Vergata, Roma, Italy.

<sup>2</sup> Clinical Research Service, IRCCS Policlinico San Donato, San Donato Milanese, Italy.

<sup>3</sup> Department of Biomedical Sciences for Health, University of Milan, Milan, Italy.

Author for correspondence: Giulia Paglione ✉ [Giulia.Paglione@grupposandonato.it](mailto:Giulia.Paglione@grupposandonato.it)

DOI: <https://doi.org/10.65241/wh.8.1.7>

For citation: Paglione G, Caruso R. Rationale and Methodological Steps for a Scoping Review on the Available Core Outcome Sets in Heart Failure: A Discursive Analysis of Literature and Study Protocol. *World of Health*. 2025;1(8):53-61. <https://doi.org/10.65241/wh.8.1.7>

Received: 4 June 2025 | Revised: 3 July 2025 | Accepted: 7 July 2025

## ABSTRACT

**Background:** Heart failure (HF) is a complex clinical syndrome marked by high heterogeneity in presentation, progression, and response to treatment. This variability, coupled with inconsistent outcome selection across clinical studies, complicates data synthesis and the development of generalizable evidence. Core Outcome Sets (COS) have been proposed to enhance outcome standardization, but their use in HF research and practice remains fragmented and underexamined. This paper presents two complementary components: (1) a discursive analysis of two exemplary COS, one developed for clinical trials (EuroHeart COS) and one for symptom monitoring in routine care (Lawson et al. COS), and (2) a methodological protocol for a future scoping review.

**Methods:** The scoping review protocol follows Joanna Briggs Institute (JBI) and PRISMA-ScR guidelines and is designed to map existing COS in HF, identify development processes, outcome domains, and gaps. The discursive analysis explores stakeholder involvement, methodological rigor, patient-centeredness, and contextual adaptation.

**Results:** The discursive analysis revealed epistemological contrasts between COS designed for research standardization versus those tailored to patient monitoring and decision support. EuroHeart

emphasizes registry-based, clinically anchored endpoints, while Lawson et al. foregrounds patient-reported symptoms and usability in telemonitoring contexts. The forthcoming scoping review is anticipated to identify significant variability in the scope of COS, stakeholder engagement, and relevance across populations, with likely gaps in COS tailored to specific phenotypes, underrepresented groups, and real-world clinical practice.

**Conclusions:** The development and implementation of COS in HF require a context-sensitive, inclusive, and methodologically transparent approach. This manuscript serves as both a critical reflection on COS logic and a practical guide to synthesizing available sets. Bridging theoretical discourse with systematic review methodology contributes to a more coordinated and patient-centered agenda for outcome standardization in research and care for patients with HF.

**Keywords:** Core Outcome Sets, Heart Failure, Outcome Standardization, Scoping Review Protocol, Patient-Centered Outcomes

## INTRODUCTION

Heart failure (HF) is a complex clinical syndrome characterized by the heart's inability to pump blood

adequately to meet the metabolic demands of the body (1). It encompasses a broad spectrum of symptoms, including dyspnea, fatigue, ankle swelling, and signs such as elevated jugular venous pressure and peripheral edema, often resulting in reduced quality of life and frequent hospitalization (2). HF affects approximately 1–2% of the adult population in developed countries, increasing to over 10% among those aged 70 years and older (3). For instance, in the United States alone, the prevalence of HF is projected to reach 8.5 million individuals by 2030, with estimated direct medical costs of \$53 billion and total cardiovascular-related costs of \$160 billion annually (4).

HF is classified based on left ventricular ejection fraction (LVEF), etiology, and clinical trajectory (5). The European Society of Cardiology (ESC) recognizes three primary phenotypes: heart failure with reduced ejection fraction (HFrEF; LVEF <40%), heart failure with mildly reduced ejection fraction (HFmrEF; LVEF 41–49%), and heart failure with preserved ejection fraction (HFpEF; LVEF ≥50%) (2). These phenotypes differ in underlying pathophysiology, therapeutic response, and prognosis. HF is also categorized by its clinical course, i.e., acute versus chronic, and by etiology, including ischemic, hypertensive, valvular, or idiopathic origins (5). Such classifications are essential for diagnosis and management but also introduce complexity into the design of research studies, as patients enrolled under the umbrella of “heart failure” may present with markedly different characteristics, comorbidities, and treatment responses.

Given the clinical heterogeneity of HF and its increasing burden on healthcare systems, high-quality evidence is essential to inform decision-making (6). However, inconsistency in outcome selection, measurement, and reporting across HF studies remains a persistent barrier to data synthesis, comparative effectiveness research, and evidence translation into practice (7). The use of varied and often non-comparable endpoints complicates the aggregation of findings and undermines the value of meta-analyses, limiting their relevance for clinical guidelines (8–10).

To address this challenge, Core Outcome Sets (COS) have emerged as a methodological solution (11,12). A COS is a standardized set of outcomes that should be measured and reported in all trials for a specific clinical condition (13–15). The development and implementation of COS aim to ensure that outcomes of greatest relevance to patients, clinicians, researchers, and policymakers are consistently considered across studies (7,11). COS also support the reduction of research waste, enhance the comparability of trial results, and facilitate patient-centered care by aligning outcomes with stakeholder priorities (11,12,14,15).

In response to growing concerns about heterogeneity in outcome reporting across clinical trials, the Core Outcome Measures in Effectiveness Trials (COMET) Initiative was launched to promote the development, dissemination, and adoption of core outcome sets across health research (16,17). COMET provides methodological guidance and a comprehensive repository of COS, aiming to enhance research quality, comparability, and impact by encouraging consensus on what outcomes should be measured and reported in all trials for a given condition. The initiative emphasizes transparency, stakeholder engagement, including patients, clinicians, researchers, and regulators, and adherence to standardized development processes. While COMET has contributed significantly to awareness and methodological advancement in the field, its database and supporting literature highlight a need to systematically assess how COS are being developed and implemented in specific clinical areas, such as heart failure (5,11,12).

This contrast between COS designed for trials and those developed for clinical care is crucial because it underscores different epistemological priorities: research COS emphasizes standardized, comparable clinical endpoints to support regulatory and scientific rigor. At the same time, care-focused COS prioritize patient-reported outcomes to enable personalized monitoring and support shared decision-making in routine care. Recognizing these differences is crucial for aligning COS development with both scientific and patient-centered objectives.

Despite increasing interest in COS, it remains unclear which core outcome sets are currently available for HF and how they have been developed or implemented (6,7). Existing COS may differ in scope, methodological rigor, stakeholder engagement, and alignment with evolving definitions and classifications of HF. Thus far, no comprehensive synthesis has mapped these COS or critically examined their characteristics, methodological underpinnings, or relevance for future HF research and clinical applications.

This knowledge gap limits efforts to standardize outcome reporting in HF studies and hinders the advancement of a unified research agenda. Before conducting a scoping review of COS in HF, it is essential to develop and publish a detailed protocol to ensure methodological transparency, avoid duplication, and enable critical appraisal by the scientific community. The present manuscript therefore has two main objectives: first, to critically examine two existing COS to illustrate methodological and epistemological divergence; and second, to present a transparent protocol for a comprehensive scoping review aimed at mapping, analyzing, and synthesizing all available COS in heart failure.

## METHODS

### DESIGN

This study is designed to present a discursive analysis of the role and development of COS in HF, with particular attention to their methodological diversity, conceptual scope, and relevance to evolving clinical definitions. In parallel, it outlines the protocol for a scoping review aimed at identifying, mapping, and summarizing all available COS in HF. The dual focus serves to (1) critically reflect on how COS contribute to outcome standardization and research coherence in HF, and (2) provide a transparent, reproducible methodology for synthesizing existing COS using recognized scoping review frameworks. This integrative design addresses the need for both theoretical grounding and practical guidance in navigating the expanding field of outcome standardization in HF research.

### PROTOCOL FOR THE SCOPING REVIEW

The following section outlines a protocol for a scoping review that has yet to be conducted. The scoping review will be conducted following the Joanna Briggs Institute (JBI) Manual for Evidence Synthesis (19) and will be reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) (20). This dual adherence ensures methodological rigor, transparency, and replicability throughout the review process.

The overarching research question is: “What Core Outcome Sets (COS) have been developed and implemented in the heart failure population?”

To comprehensively map the landscape of COS in heart failure, the following sub-questions will guide data extraction and synthesis:

1. Which COS have already been developed for heart failure?
2. What are the reported benefits and limitations of implementing COS in patients with heart failure?
3. In which countries or geographical contexts have COS for heart failure been developed and implemented?
4. What barriers and facilitators have been identified for COS implementation in rural versus urban settings?
5. How do socioeconomic and cultural factors influence the selection and use of COS in heart failure research?
6. Are there differences in COS based on patient characteristics (e.g., age, sex, comorbidity, disease severity, NYHA class)?
7. Do COS vary across different heart failure phenotypes (e.g., HFrEF, HFpEF, HFmrEF)?

Eligibility for this scoping review will be established using the Population–Concept–Context (PCC) framework, as recommended by the Joanna Briggs Institute (19). The population of interest includes individuals diagnosed with any form or phenotype of HF, regardless of age, sex, or disease severity. The central concept under investigation is the development, description, validation, or implementation of COS specifically tailored to HF. The context encompasses all healthcare settings and geographical locations, with no restrictions based on cultural, subcultural, racial, or gender characteristics.

The review will include empirical studies employing any research design, including quantitative, qualitative, or mixed-method approaches. Eligible studies must focus explicitly on individuals with heart failure, encompassing all phenotypes, such as heart failure with reduced ejection fraction (HFrEF), preserved ejection fraction (HFpEF), and mildly reduced ejection fraction (HFmrEF), and all levels of severity, including NYHA classes I through IV (6). Included studies must report on the development, implementation, or evaluation of COS designed for use in the heart failure population. No restrictions will be applied based on the healthcare setting or country of origin, and studies published in any language will be considered eligible. Articles in languages other than English will be screened and, if necessary, translated using professional translation services, multilingual team members, or web-based translation tools (when an HTML version is available), to ensure accurate data extraction and synthesis. Studies will be excluded if they focus on cardiovascular conditions other than HF and do not clearly apply COS to an HF context. The review will also exclude editorials, opinion pieces, conference abstracts, and theoretical works that do not report original empirical research.

This scoping review will include all peer-reviewed studies that meet the above eligibility criteria. If the database search yields a limited number of relevant records, grey literature, including policy documents, technical reports, and entries from established COS repositories, will be examined to identify additional sources that may contribute meaningfully to the research objectives.

To ensure comprehensive coverage of the literature, a structured search strategy will be implemented across five primary electronic databases: PubMed/MEDLINE, Embase, Scopus, Web of Science, and CINAHL. To complement these sources and capture relevant unpublished or non-indexed studies, additional searches will be conducted in grey literature repositories such as Google Scholar and the COMET Initiative database.

The initial search strategy was developed for PubMed using a combination of Medical Subject Headings (MeSH) and free-text keywords. This strategy was then translated for use in the other databases. Complete search strategies for

Table 1: Search Strategy

Database	Query	Records
<b>Pubmed</b>	("heart failure"[MeSH Terms] OR "heart failure"[All Fields] OR "cardiac failure"[All Fields] OR "congestive heart failure"[All Fields] OR "HFrEF"[All Fields] OR "HFmrEF"[All Fields] OR "HFpEF"[All Fields] OR "right heart failure"[All Fields] OR "left heart failure"[All Fields]) AND ("Core Outcome Set"[All Fields] OR "Core Outcomes"[All Fields] OR "Standardized Outcomes"[All Fields] OR "consensus based"[All Fields] OR "Minimum Outcome Set"[All Fields])	<b>N = 72</b> (02–28–2025)
<b>Embase</b>	('heart failure'/exp OR 'heart failure' OR 'cardiac failure' OR 'congestive heart failure' OR 'HFrEF' OR 'HFmrEF' OR 'HFpEF' OR 'right heart failure' OR 'left heart failure') AND ('core outcome set'/exp OR 'core outcome set' OR 'core outcomes' OR 'standardized outcomes' OR 'consensus based' OR 'minimum outcome set')	<b>N = 273</b> (02–28–2025)
<b>Web of Science</b>	TS=("heart failure" OR "cardiac failure" OR "congestive heart failure" OR "HFrEF" OR "HFmrEF" OR "HFpEF" OR "right heart failure" OR "left heart failure") AND TS=("core outcome set" OR "core outcomes" OR "standardized outcomes" OR "consensus based" OR "minimum outcome set")	<b>N = 126</b> (02–28–2025)
<b>Scopus</b>	( TITLE-ABS-KEY ("heart failure") OR TITLE-ABS-KEY ("cardiac failure") OR TITLE-ABS-KEY ("congestive heart failure") OR TITLE-ABS-KEY ("HFrEF") OR TITLE-ABS-KEY ("HFmrEF") OR TITLE-ABS-KEY ("HFpEF") OR TITLE-ABS-KEY ("right heart failure") OR TITLE-ABS-KEY ("left heart failure") ) AND ( TITLE-ABS-KEY ("core outcome set") OR TITLE-ABS-KEY ("core outcomes") OR TITLE-ABS-KEY ("standardized outcomes") OR TITLE-ABS-KEY ("consensus based") OR TITLE-ABS-KEY ("minimum outcome set"))	<b>N = 133</b> (02–28–2025)
<b>Cinhal</b>	(MH "Heart Failure" OR "heart failure" OR "cardiac failure" OR "congestive heart failure" OR "HFrEF" OR "HFmrEF" OR "HFpEF" OR "right heart failure" OR "left heart failure") AND (MH "Core Outcome Set" OR "core outcomes" OR "standardized outcomes" OR "consensus based" OR "minimum outcome set")	<b>N = 25</b> (02–28–2025)

each database are provided in Table 1. Search terms will include a combination of keywords and subject headings related to heart failure (e.g., "Heart Failure," "Cardiac Failure," "HFrEF," "HFpEF," "NYHA") and core outcome sets (e.g., "Core Outcome Set," "Core Outcomes," "Outcome Standardization," "COS development").

All identified records will be imported into reference management software (e.g., EndNote or Zotero), and duplicates will be removed. Following deduplication, titles, and abstracts will be independently screened by two reviewers to assess their relevance against the predefined eligibility criteria. Studies that clearly do not meet the inclusion criteria will be excluded at this stage. The full texts of potentially relevant articles will then be retrieved and reviewed in detail by the same reviewers to confirm final eligibility.

Discrepancies at any stage of the selection process will be resolved through discussion and, if necessary, consultation with a third reviewer. Reasons for exclusion at the full-text review stage will be documented and reported in the final review. The selection process will be transparently presented using the PRISMA-ScR flow diagram, detailing the number of records identified, screened, assessed for eligibility, and included in the final synthesis.

Data extraction will be performed using a standardized charting form developed by the research team in accordance with the JBI guidelines for scoping reviews. This form will be pilot-tested on a sample of included studies to ensure its clarity, completeness, and relevance to the research objectives. Following pilot testing, any necessary modifications to the form will be made before full implementation.

Two reviewers will independently extract data from all eligible sources. Any discrepancies between the reviewers will be resolved through discussion, and when consensus cannot be reached, a third reviewer will be consulted. Extracted data will be managed using Microsoft Excel or a comparable data management platform. The extracted information will include bibliographic details such as author names, year of publication, and country of origin. Study characteristics will be documented, including the study design, research objectives, methodological approach, setting, and relevant details about the heart failure population under investigation, such as age, sex, heart failure phenotype, NYHA classification, and the presence of comorbidities.

Information specific to each COS will be collected, including the name of the COS (if specified), the



development process undertaken, the types of stakeholders involved (e.g., patients, clinicians, researchers), the consensus-building methodology used (such as the Delphi technique or nominal group process), and the total number and nature of outcomes included in the set. In addition, the context in which each COS was applied will be recorded, including clinical or research settings, geographical regions, and any cultural or socioeconomic considerations that may have influenced implementation. Reported benefits and limitations associated with the use of COS, as identified by the study authors, will also be documented, with particular attention to challenges encountered during development or implementation. Lastly, information on funding sources and any declared conflicts of interest will be extracted to assess transparency and potential bias.

The extracted data will be organized to support both narrative synthesis and tabular presentation. This approach will allow for the identification of common themes, methodological trends, and existing gaps in the development and application of COS in heart failure research. If feasible, topic modeling, as described by Caruso et al. (21), will be used to extract trends and topics in the narrative synthesis.

### DISCURSIVE ANALYSIS

Alongside the methodological protocol for the forthcoming scoping review, this paper includes a discursive analysis of selected examples from the literature to explore how COS in HF are conceptualized and operationalized in different contexts. This dual approach clarifies the epistemological and methodological underpinnings of COS development and highlights the complementary roles of research and practice perspectives.

For this purpose, two COS documents were purposively selected to represent distinct domains of COS application: one developed for clinical research and trials (22) and one developed for routine clinical practice (23). A qualitative interpretive approach was employed (24). Each document was read in full by two researchers, who independently annotated key excerpts using abductive reasoning to identify dominant themes and implicit discursive patterns. The analysis focused on how each COS was framed (e.g., in terms of clinical utility, regulatory relevance, or patient-centeredness), the types of stakeholders involved, the consensus processes used, and the nature of the outcomes prioritized (e.g., biomedical, patient-reported, system-level metrics). Emphasis was also placed on identifying the contextual assumptions (such as health system structure, data infrastructure, or sociopolitical imperatives) that shaped each COS's development and intended application.

Disagreements in thematic interpretation were discussed until a consensus was reached. This focused discursive analysis does not aim to generalize across all COS in heart failure but rather to critically interrogate how varying logics of outcome standardization manifest across different purposes and implementation contexts. The insights generated serve to support the rationale for a broader, systematic scoping review by illustrating the need for a more transparent, inclusive, and context-aware understanding of COS in heart failure.

## RESULTS

### ANTICIPATED RESULTS OF THE SCOPING REVIEW

The results presented here refer to anticipated outcomes based on the planned scoping review and should be interpreted as preliminary expectations rather than findings from completed empirical work. The anticipated results of the scoping review include a comprehensive mapping of all COS developed and implemented for populations with HF across clinical research and practice settings. It is expected that the review will identify substantial variability in the scope, methodological rigor, stakeholder involvement, and outcome domains prioritized across COS initiatives. The findings are likely to highlight a predominance of biomedical endpoints in COS designed for regulatory or trial contexts, alongside emerging trends toward incorporating patient-reported outcomes in COS developed for clinical monitoring and symptom management. Geographic and contextual differences in COS development processes may also emerge, reflecting local research priorities, healthcare infrastructures, and levels of stakeholder engagement. Ultimately, the review will provide a synthesized overview of the available COS, clarify areas of overlap and divergence, and identify gaps where further COS development or harmonization is needed, particularly in underserved populations, diverse clinical contexts, or patient subgroups often underrepresented in HF research.

### Discursive analysis of two Core Outcome Sets examples: Research and Practice

The first example derives from the European Unified Registries for Heart Care Evaluation and Randomized Trials (EuroHeart), which aims to harmonize clinical trial outcomes across Europe (22). The second, developed by Lawson et al. (2022), focuses on patient-centered symptom monitoring to prevent hospital admissions, representing a practice-oriented COS (23). Table 2 describes the main differences between the 2 COS.

The EuroHeart COS exemplifies a top-down, registry-integrated effort intended to ensure standardized outcome reporting in observational and interventional cardiovascular studies (22). It leverages expert consensus to identify mandatory and optional data variables that facilitate cross-study comparability, meta-analytic aggregation, and regulatory alignment. Developed by the European Society of Cardiology and affiliated stakeholders, its methodology prioritizes epidemiological robustness and interoperability with existing data infrastructures. It includes endpoints such as all-cause and cardiovascular mortality, hospitalizations, and quality of life, integrating clinical and imaging parameters. The process was methodologically rigorous, incorporating Delphi rounds and international stakeholder review. Its intended users are primarily researchers, regulators, and data managers operating within academic and clinical trial ecosystems.

Conversely, the COS for clinical practice developed by Lawson et al. employs a more bottom-up approach centered on lived experience and symptom relevance to daily self-monitoring (23). The process involved a rigorous mixed-methods design, including a systematic review, a three-round modified Delphi process, and a nominal group technique (NGT) meeting. It incorporated 24 patients with HF, 4 carers, and 38 clinicians (nurses and physicians). This COS culminated in a set of eight key symptoms, including dyspnea, edema, bloating, palpitations, weight gain, chest pain, anxiety, and overall health status, operationalized through single-item patient-reported outcome measures (PROMs). Unlike EuroHeart, this COS specifically targets pre-emptive symptom detection and individual decision-making, making it more suitable for integration into remote monitoring and patient-managed care pathways.

A key point of divergence lies in stakeholder orientation. EuroHeart reflects a clinician- and policy-driven agenda with less direct patient involvement. By contrast, Lawson et al. foreground patient and caregiver perspectives, aligning closely with value-based care models and WHO's person-centered health framework. Moreover, while the EuroHeart COS is designed to support longitudinal research and clinical registries (22), Lawson et al. COS is more dynamic and responsive to acute change, tailored to the temporality of symptom worsening and hospitalization risk (23).

From a methodological standpoint, both studies demonstrate high rigor; however, they differ in the operationalization of their outcomes. EuroHeart employs complex composite endpoints and time-to-event measures, whereas the practice-oriented COS utilizes simplified PROMs that facilitate ease of use, scalability, and digital implementation. These distinctions underscore the inherent tension between research precision and clinical pragmatism.

This analysis highlights the complementarity, not interchangeability, of COS for research and practice. The EuroHeart COS reinforces cross-border research consistency and epidemiological quality (22), whereas the Lawson et al. COS addresses unmet needs in patient monitoring and admission prevention (23). Their juxtaposition exemplifies the multifaceted role COS can play in enhancing both the scientific robustness and practical utility of HF outcome assessment.

*Table 2. Comparison of Two Core Outcome Sets in Heart Failure*

Dimension	EuroHeart COS (Research)	Lawson et al. COS (Practice)
Purpose	Standardize outcomes for clinical trials and registries	Improve symptom monitoring and prevent hospitalizations
Development Approach	Top-down, expert-driven consensus via ESC task force	Bottom-up, participatory mixed-methods (Delphi + NGT)
Stakeholder Involvement	Primarily clinicians, researchers, and data managers	Patients, carers, nurses, and clinicians
Outcome Type	Clinical endpoints (mortality, hospitalizations, QoL)	Patient-reported symptoms (dyspnea, edema, anxiety, etc.)
Data Collection Method	Structured registry data and clinical databases	PROMs via single-item patient self-report
Context of Use	Multicenter research and academic trials	Routine clinical care and telemonitoring pathways
Operational Complexity	High – requires structured data systems and definitions	Low – simple symptom questions suitable for daily use
Patient-Centeredness	Low – limited direct patient involvement	High – designed from patient experience
Scalability	Moderate – dependent on existing registry infrastructure	High – adaptable for remote or digital health tools
Regulatory Alignment	High – designed for alignment with EU regulatory standards	Low – not designed for regulatory trials

## DISCUSSION

This paper integrates two complementary components to address the evolving landscape of COS in HF. First, it presents a detailed protocol for a forthcoming scoping review aimed at systematically identifying, mapping, and evaluating all available COS developed for the HF population (25). This protocol is grounded in the JBI methodology and the PRISMA-ScR framework, ensuring methodological transparency and replicability. Second, the study offers a discursive analysis of two purposefully selected COS, one developed for clinical research and the other for routine practice, to illustrate how outcome prioritization in HF varies based on epistemological and contextual drivers.

The discursive analysis highlighted two distinct logics of outcome prioritization (26): one rooted in the rigor of registry-based, epidemiological frameworks (EuroHeart) and the other in patient-centered, symptom-driven monitoring (Lawson et al.) (22,23). These approaches diverge epistemologically, reflecting different priorities: population-level outcome standardization for cross-national comparability versus individualized, real-time health management. EuroHeart prioritizes structured clinical endpoints that align with regulatory and research needs, while Lawson et al. foregrounds the subjective experience of patients, tailoring metrics to support personalized care and pre-emptive intervention. This contrast illustrates how methodological choices in COS development are embedded within broader healthcare goals and contexts.

The future scoping review will map the full spectrum of COS in HF, and it is expected to reveal critical polarities and divergences in current outcome standardization practices (27). Geographic disparities may emerge, reflecting the uneven distribution of COS development across high- and low-resource settings. Stakeholder exclusions, particularly limited patient or caregiver involvement, may highlight ongoing challenges in inclusivity and representativeness. Substantial variability is anticipated in COS development methodologies, including differences in consensus-building techniques (e.g., Delphi panels, nominal group processes), stakeholder compositions, and the extent of transparent reporting. These methodological inconsistencies may affect the credibility, uptake, and cross-context applicability of COS. The scoping review is also likely to identify notable gaps in COS tailored to specific HF phenotypes, such as HFpEF or HFmrEF, as well as underrepresented populations, including older adults, individuals with multiple comorbidities, and socioeconomically disadvantaged groups. Addressing these gaps will be essential to ensure that future COS are equitable, comprehensive, and clinically meaningful.

When developing COS, it is relevant to consider that COS have to be both scientifically rigorous and practically applicable (28). Scientific robustness ensures that

COS facilitate research comparability and regulatory approval, while clinical usability supports integration into everyday care. To achieve this balance, regulatory bodies and funding agencies should consider mechanisms, such as trial incentives or mandatory reporting frameworks, that promote the adoption of COS. Additionally, more meaningful involvement of patients and caregivers is essential, particularly in the design of COS for digital or remote health contexts. Participatory models that incorporate real-world experiences and symptom narratives can enhance the relevance and uptake of COS in settings where self-management and telemonitoring are critical (29).

This paper presents several limitations. The discursive analysis focused on only two purposefully selected COS examples, one for research and one for practice, which may limit the generalizability of the findings. These examples were chosen to illustrate conceptual contrasts but do not capture the full diversity of COS initiatives in heart failure. Additionally, the scoping review component is protocol-based, and empirical findings are not yet available. There is also a potential for selection bias in the choice of illustrative COS and interpretive bias in the discursive analysis, as thematic interpretations depend on researchers' perspectives. Furthermore, by relying on available literature and stakeholder reports, there is a risk of publication bias and incomplete representation of unpublished or ongoing COS initiatives. Despite these limitations, the integration of discursive methodology with a structured evidence synthesis approach represents a novel and valuable contribution.

## CONCLUSION

This work advances the proposition that the future of outcome standardization in HF requires a context-sensitive, inclusive, and epistemologically informed approach to COS development and implementation. The juxtaposition of COS designed for research versus those intended for clinical practice highlights fundamental divergences not only in outcome prioritization but also in underlying values and goals. By bridging theoretical analysis with a structured scoping protocol, this paper lays the foundation for more transparent and harmonized COS adoption. Future findings from the planned scoping review can inform clinical practice by guiding the integration of patient-centered outcomes into care pathways, support policymakers in developing guidelines that mandate or incentivize COS use, and encourage researchers to design studies that are both methodologically rigorous and aligned with patient and stakeholder priorities. Ultimately, this approach aims to improve evidence comparability, enhance patient engagement, and strengthen decision-making across the continuum of heart failure care.

## REFERENCES

1. Bauersachs J, Zieroth S, De Boer RA. The year in cardiovascular medicine 2024: the top 10 papers in heart failure. *European Heart Journal*. 2025;46(11):1014–6.
2. McDonagh TA, Metra M, Adamo M, Gardner RS, Baumbach A, Böhm M, et al. 2023 Focused Update of the 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *European Heart Journal*. 2023;44(37):3627–39.
3. Groenewegen A, Rutten FH, Mosterd A, Hoes AW. Epidemiology of heart failure. *European J of Heart Fail*. 2020;22(8):1342–56.
4. Bozkurt B, Ahmad T, Alexander KM, Baker WL, Bosak K, Breathett K, et al. Heart Failure Epidemiology and Outcomes Statistics: A Report of the Heart Failure Society of America. *Journal of Cardiac Failure*. 2023 ;29(10):1412–51.
5. Bozkurt B, Coats AJS, Tsutsui H, Abdelhamid CM, Adamopoulos S, Albert N, et al. Universal definition and classification of heart failure: a report of the Heart Failure Society of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Universal Definition of Heart Failure: Endorsed by the Canadian Heart Failure Society, Heart Failure Association of India, Cardiac Society of Australia and New Zealand, and Chinese Heart Failure Association. *European J of Heart Fail*. 2021;23(3):352–80.
6. Adebayo SO, Olunuga TO, Durodola A, Ogah OS. Heart failure: Definition, classification, and pathophysiology – A mini-review. *Nigerian Journal of Cardiology*. 2017;14(1):9–14.
7. Hicks KA, Mahaffey KW, Mehran R, Nissen SE, Wiviott SD, Dunn B, et al. 2017 Cardiovascular and Stroke Endpoint Definitions for Clinical Trials. *Circulation*. 2018;137(9):961–72.
8. Tromp J, Ouwerkerk W, Van Veldhuisen DJ, Hillege HL, Richards AM, Van Der Meer P, et al. A Systematic Review and Network Meta-Analysis of Pharmacological Treatment of Heart Failure With Reduced Ejection Fraction. *JACC: Heart Failure*. 2022;10(2):73–84.
9. Moradi M, Daneshi F, Behzadmehr R, Rafiemanesh H, Bouya S, Raeisi M. Quality of life of chronic heart failure patients: a systematic review and meta-analysis. *Heart Fail Rev*. 2020;25(6):993–1006.
10. Baéz-Gutiérrez N, Rodríguez-Ramallo H, Sánchez-Fidalgo S. Medication adherence and persistence in heart failure: A protocol for a systematic review and meta-analysis. *Farmacia Hospitalaria*. 2025;49(3):184–7.
11. Kirkham JJ, Williamson P. Core outcome sets in medical research. *BMJ Med*. 2022;1(1):e000284.
12. Clarke M, Williamson PR. Core outcome sets and systematic reviews. *Syst Rev*. 2016;5(1):11.
13. Williamson PR, Altman DG, Bagley H, Barnes KL, Blazeby JM, Brookes ST, et al. The COMET Handbook: version 1.0. *Trials*. 2017;18(S3):280.
14. Williamson PR, Altman DG, Blazeby JM, Clarke M, Devane D, Gargon E, et al. Developing core outcome sets for clinical trials: issues to consider. *Trials*. 2012 Dec;13(1):132.
15. Kirkham JJ, Gorst S, Altman DG, Blazeby JM, Clarke M, Devane D, et al. Core Outcome Set-STAndards for Reporting: The COS-STAR Statement. *PLoS Med*. 2016;13(10):e1002148.
16. Gargon E. The COMET (Core Outcome Measures in Effectiveness Trials) Initiative. *Maturitas*. 2016;91:91–2.
17. Prinsen CAC, Vohra S, Rose MR, King-Jones S, Ishaque S, Bhaloo Z, et al. Core Outcome Measures in Effectiveness Trials (COMET) initiative: protocol for an international Delphi study to achieve consensus on how to select outcome measurement instruments for outcomes included in a “core outcome set.” *Trials*. 2014;15:247.
18. Munn Z, Pollock D, Khalil H, Alexander L, McInerney P, Godfrey CM, et al. What are scoping reviews? Providing a formal definition of scoping reviews as a type of evidence synthesis. *JBIEvidence Synthesis*. 2022;20(4):950–2.
19. Peters MDJ, Marnie C, Tricco AC, Pollock D, Munn Z, Alexander L, et al. Updated methodological guidance for the conduct of scoping reviews. *JBIEvid Synth*. 2020;18(10):2119–26.
20. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Ann Intern Med*. 2018;169(7):467–73.
21. Caruso R, Terzoni S, Lusignani M, Varano E, Pittella F, Xharra V, et al. Integrating Cultural Competence in Nursing: A Scoping Review of Purnell's Model in Clinical Practice and Education With Data Mining Analytics. *J Transcult Nurs*. 2025;10436596251323273.
22. Wilkinson C, Bhatta A, Batra G, Aktaa S, Smith AB, Dwight J, et al. Definitions of clinical study outcome measures for cardiovascular diseases: the European Unified Registries for Heart Care Evaluation and Randomized Trials (EuroHeart). *Eur Heart J*. 2025;46(2):190–214.
23. Lawson CA, Lam C, Jaarsma T, Kadam U, Stromberg A, Ali M, et al. Developing a core outcome set for patient-reported symptom monitoring to reduce hospital admissions for patients with heart failure. *European Journal of Cardiovascular Nursing*. 2022 Nov;21(8):830–9.
24. Wiesner C. Doing qualitative and interpretative



- research: reflecting principles and principled challenges. *Political Research Exchange*. 2022;4(1):2127372.
25. Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC Med Res Methodol*. 2018;18(1):143.
26. Kellar J, Singh L, Bradley-Ridout G, Martimianakis MA, van der Vleuten CPM, Oude Egbrink MGA, et al. How pharmacists perceive their professional identity: a scoping review and discursive analysis. *Int J Pharm Pract*. 2021;29(4):299–307.
27. Beghini A, Sammartino AM, Papp Z, von Haehling S, Biegus J, Ponikowski P, et al. 2024 update in heart failure. *ESC Heart Fail*. 2025;12(1):8–42.
28. Gargon E. 7th Meeting of the COMET Initiative (VII), Thursday 15th and Friday 16th November 2018, De Rode Hoed, Amsterdam. *J Evid Based Med*. 2019;12 Suppl 1:5–31.
29. Shepherd M, Endacott R, Quinn H. Bridging the gap between research and clinical care: strategies to increase staff awareness and engagement in clinical research. *Journal of Research in Nursing*. 2022;27(1–2):168–81.