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Minimal clinical data sets for spine-related musculoskeletal disorders in primary care and outpatient settings: a scoping review protocol

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ABSTRACT

Introduction Lack of standardised clinical data collection may lead to reduced quality in musculoskeletal (MSK)-related clinical care and research. Little is known about the availability and characteristics of minimal clinical data sets for spine-related MSK disorders in primary care and outpatient settings and their utility for improving healthcare quality. Our objective is to undertake a scoping review aiming to identify and map current literature on minimal clinical data sets for measuring and monitoring health status in patients with spine-related MSK disorders in primary and outpatient healthcare settings.

Methods and analysis The 2020 Joanna Briggs Institute methodology for scoping reviews will guide review conduct. The review will consider studies that describe and report on minimal clinical data sets for spine-related MSK disorders designed for primary care and outpatient clinical practice settings. Quantitative and qualitative study designs will be eligible, including consensus-based studies, interventional, observational, feasibility and linguistic validation studies. Studies published in English, German, French, Italian and Spanish will be included, with no limit on date of publication. MEDLINE, CINAHL, Cochrane Library, Index to Chiropractic Literature, MANTIS, ProQuest Dissertations & Theses Global and medRxiv preprint repository will be searched from database inception to 25 July 2021. Two reviewers will independently screen identified titles, abstracts and relevant full-text records, and then extract data using review-specific data extraction forms. Findings will be synthesised and presented as a descriptive summary using PRISMA ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews).

Ethics and dissemination Ethics review and approval is not required for this scoping review. Our target audience for this review will be clinicians, researchers, patients and other relevant stakeholders involved in the measurement and health status monitoring of patients with spine-related MSK disorders. Results will be shared through peer-reviewed publication and presentations at relevant conferences.

Protocol registration number https://osf.io/fkw5b.

Strengths and limitations of this study

⇒ Scoping reviews identify and map currently existing evidence to explore a research topic from a broad perspective and to identify research gaps.
⇒ This type of review was chosen as it allows us to describe and identify key concepts and definitions of minimal clinical data sets for measuring and monitoring health status in patients with spine-related musculoskeletal disorders in primary and outpatient healthcare settings.
⇒ Scoping reviews do not evaluate the quality of evidence but provide mainly descriptive information on a broad research topic.

INTRODUCTION

Musculoskeletal (MSK) disorders are the highest contributor to disability worldwide, with approximately 1.2 billion people affected.[1] In particular, back and neck pain affect over 790 million people globally, and were estimated to account for 88 million years lived with disability in 2019.[1] While more research involving patients with back and neck pain is being conducted, the lack of data standardisation and consensus on the relevance and importance of collected data elements and reported outcomes in clinical trials has led to avoidable waste in the production and reporting of MSK-related research.[2 3] Initiatives to develop and implement core outcome sets for clinical research studies have facilitated the synthesis and understanding of clinical research findings.[4] More recently, there is increasing interest in integrating research into real-world clinical practice settings to create efficient learning healthcare systems,[5 6] in which data from patients and populations are linked to researchers and practitioners to increase continuous knowledge development and guidance on the effectiveness of interventions. However, real-world clinical data

are often not collected or reported in a standardised way, which may limit healthcare quality.[7] Core outcome sets have been primarily designed for research purposes and may not be adapted, acceptable or meaningfully useful within real-world clinical practice settings.[8] For example, due to their length, they can be too time-consuming for patients and clinicians to complete, causing response burden and poor data quality.[9]

To enhance the quality of healthcare data routinely collected in primary care and outpatient settings and to facilitate reliable and valid measuring and monitoring of health status, minimal clinical data sets are needed.[10] A minimal clinical data set is defined as a standardised set of data elements covering key information for an assessed health condition and are developed for use in real-world clinical practice.[11] Valid and reliable patient-reported outcome measures (PROMs) and health-related quality of life scales can be part of a minimal clinical data set, and are useful tools to collect patient-centred data in a standardised and comprehensive way.[12] On the other hand, core outcome sets are mainly designed for clinical research and clinical trial settings. Little is known about the availability and characteristics of minimal clinical data sets for spine-related MSK disorders and their utility for improving healthcare quality in routine clinical settings.

We present the protocol for a scoping review that aims to identify and map currently existing evidence on minimal clinical data sets for measuring and monitoring health status in patients with spine-related MSK disorders in primary and outpatient healthcare settings. Preliminary searches for existing reviews (scoping and systematic) on the topic were conducted on 25 July 2021 using the following search engines: Cochrane Database of Systematic Reviews, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and MEDLINE. Registered protocols were also searched on PROSPERO and the Open Science Framework (OSF). No existing reviews were identified.

METHODS AND ANALYSIS

This scoping review protocol was developed in accordance with the 2020 Joanna Briggs Institute methodology for scoping reviews,[13] and registered on the Centre for Open Science Framework[14]. The final report will align with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) statement.[15] Scoping reviews explore a research topic from a broad perspective. They aim to map the state of evidence in a structured yet reflexive manner to identify research gaps or summarise findings from a body of knowledge that is heterogeneous in methods or discipline.[15] This type of review was chosen as it allows us to describe and identify key concepts and definitions of minimal clinical data sets for spine-related MSK disorders, which will help to clarify approaches for implementation in clinical practice and future research.

Research questions

This scoping review is based on the following research questions:

1. What are the general characteristics of minimal clinical data sets for spine-related MSK disorders in primary care and outpatient settings?
2. How are the minimal clinical data sets defined?
3. How were the minimal clinical data sets developed and was there any stakeholder involvement (ie, patients, healthcare providers, policymakers) in the development process?
4. What information is available on the psychometric properties, implementation, acceptability and usability of the minimal clinical data sets?
5. If the minimal clinical data set was primarily designed for clinical research, what information is available on use in routine primary and outpatient healthcare settings?

Search strategy

Our search strategy, developed through collaboration between the research team and an experienced information librarian, was based on a four-step approach.[13] First, an initial limited search of MEDLINE and CINAHL was undertaken, with analysis of the text words contained in the title and abstract of retrieved records and of the index terms used to describe the articles. Second, all identified keywords and index terms were used to develop an initial search strategy. Third, the developed search strategy was peer-reviewed by another librarian independent of this project using PRESS (Peer Review of Electronic Search Strategies) guideline.[16] Fourth, additional relevant reports or publications will be identified by reviewing the reference lists of all records deemed to be eligible for our scoping review.

The finalised search strategy will be applied to MEDLINE, CINAHL, Cochrane Library, Index to Chiropractic Literature, MANTIS, ProQuest Dissertations & Theses Global and medRxiv preprint repository. In addition, any potentially relevant clinical trials will be searched on ClinicalTrials.gov. A supplemental Google search for '.org' and '.gov' domains and spine organisations (North American Spine Association, EUROSPINE and the Canadian Spine Society) will also be conducted to search for relevant governmental guidelines and reports. We will attempt to contact corresponding authors of primary sources for further information, if needed, with up to three contacts being made if there is no response. The search strategies for each database are detailed in the online supplemental appendices A–G.

Study selection

The search results will be uploaded to Covidence systematic review software[17] and duplicates removed. Two independent reviewers (JM and LH) will screen titles and abstracts for relevance and eligibility for the review. The same two reviewers (JM and LH) will carry out full-text analysis of potentially eligible reports based on the scoping

review eligibility criteria detailed below in the eligibility criteria section. Reasons for exclusion after full-text analysis will be documented. Any discrepancies between the two reviewers that arise at each stage of the study selection process will be resolved through consensus and arbitration by a third reviewer (CAH), if needed.

Prior to the study selection process, a training and calibration exercise will be conducted. A random sample of 25 citation records will be screened. The process and any discrepancies will be discussed by the review team and modifications to the eligibility criteria will be made if necessary. The full study selection process will begin once ≥75% agreement on record selection is achieved. The same training and calibration exercise will be performed for full-text screening with a random sample of 10 articles.

The results of the search will be reported in full in the final scoping review and presented in a PRISMA flow diagram.[18]

Eligibility criteria

Types of evidence sources

We will consider eligible for inclusion peer-reviewed literature, including journal articles, reports, research letters, conference papers (if sufficient information to address a research question is reported), protocols, preprints and other publications reporting original results. Grey literature or information published outside the typical academic environment, such as relevant doctoral theses and governmental publications will also be included in our search. Specifically, we will include consensus-based study designs (eg, Delphi study), all types of reviews, controlled, observational, feasibility and linguistic validation study designs. Case reports, editorials, commentaries and letters to the editor will be excluded. Also, case series will be excluded because the study design itself and the number of needed participants are not well defined in the literature.[19] Studies published in English, German, French, Italian and Spanish will be included as at least one author is fluent in these languages.

Concept

The overarching concept of interest for this scoping review are minimal clinical data sets that are intended to be used in real-world primary care and outpatient clinical practice settings for spine-related MSK disorders. Real-world data are data related to patient health status or delivered healthcare routinely collected from a variety of sources, for example, electronic health records, patient-generated clinical data or health insurance claims.[20] We broadly conceptualise a minimal clinical data set for spine-related MSK disorders as a specified set of elements covering key data and patient-centred outcomes for MSK spine-related disorders that should be minimally reported and measured.[11] A minimal clinical data set should be practical and time efficient to use during routine clinical care in an outpatient or primary care setting. Contents of the minimal clinical data sets could be, but are not limited to, general demographic information, questionnaires and measurement tools (eg, assessing pain characteristics, physical function, patient expectations of treatment outcome, psychological and social aspects), physical examination, laboratory or imaging findings. Information about development, implementation and psychometric testing of the minimal clinical data sets will also be of interest for mapping in this scoping review.

Context

The relevant context for the purpose of our review is routine primary care and all outpatient settings, including specialty outpatient care settings related to physical medicine, rehabilitation, orthopaedics, neurology, chiropractic care, physiotherapy and pain management. Studies only about inpatient care settings will be excluded, because they usually involve a more severe patient population requiring more intense care and provision, which is not the focus of this review. Although our focus will be on minimal clinical data sets in the above context, we will also include minimal data sets designed for clinical research contexts (RQ5), if they are described as also applicable or usable in routine, real-world primary and outpatient healthcare settings.

Participants

We will consider studies describing or investigating minimal clinical data sets for patients with spine-related MSK disorders, including patients of all ages, sex and genders. Specifically, studies for all MSK disorders will be included if the minimal clinical data set was designed for disorders including neck, thoracic or low back pain. A list of relevant MSK spine-related disorders to be considered was prespecified using the International Classification of Diseases 11th Revision and is detailed in the conditions area of the MEDLINE search strategy in online supplemental appendix A.[21] Studies investigating minimal clinical data sets only for patients with spine-related pathologies of non-MSK origin (eg, infection, malignancy, spinal cord injury, osteoporotic spinal fractures) will be excluded.[22]

Data charting

Standardised data extraction forms will be created through an iterative review process with the research team. Forms will be designed to capture all relevant study data and contextual information addressing the prespecified research questions. General publication details will be extracted for each source separately (table 1). Then, all sources investigating the same minimal clinical data set will be compiled in another form to summarise the characteristics per data set (table 2). Prior to starting data extraction at the review stage, the form will be pilot-tested by two reviewers (JM and LH) on a random sample of at least three sources. Additional data to be included will be identified through the iterative process of pilot-testing and the form refined accordingly. In cases of disagreement, consensus will be reached through discussion or

Table 1 Publication and general details of included studies

Data items	Associated questions
Authors and affiliations	Who conducted the research?
Year	When was the study published?
Type	In what type of literature was the study published?
Country/region	In which geographical region(s) did the study take place?
Study design	What was the study design?
Study aims	What were the study aims?
Study population	What population was studied? Were there any specific inclusion/exclusion criteria such as disease severity, duration or age?
Study size	How many people participated in the study?

resolved by a third reviewer (CAH), if needed. Formal data charting will start after consensus is reached by the entire team. For the full data extraction process, data from the selected studies will be extracted by two independent reviewers (JM and LH) and any discrepancies will be resolved through consensus and arbitration by a third reviewer (CAH), if needed.

Each item of the included minimal clinical data set will be classified in health and health-related domains using the WHO's International Classification of Functioning, Disability and Health (ICF).[23] This framework is widely accepted internationally to describe functioning and disability from a biopsychosocial perspective and has been observed to cover most concepts of disability in low back pain.[24] The ICF model includes the following four main constructs: body functions, body structure, activity and participation and environment factors. A hierarchy of up to four levels is organised within each construct, with gradually more detailed information. An example from the Body Structure construct is as follows:

- First level: s7 Structure related to movement.
- Second level: s760 Structure of trunk.
- Third level: s7600 Structure of vertebral column.
- Fourth level: s76000 Cervical vertebral column.

Each item of the minimal clinical data set will be linked to the corresponding ICF category or domain using the ICF linking rules developed and refined by Cieza and colleagues.[25] Personal factors like age, gender or education are not covered in the ICF classification. Those items will be linked to 'pf'. For example, gender will be linked as 'pf-Gender'. Items that cannot be classified in the ICF will be assigned as 'nc' (not covered) or 'nd' (not definable).

Following the recommendations of Cieza and colleagues,[25] the domain linking process will be recorded in a research diary. Each reviewer's interpretation of the item in the minimal clinical data set and its classification in the ICF health domains will be documented. This process will document decision-making procedures when multiple domains are discussed and will enhance both transparency and consistency. The following prespecified project specific rules, adapted from Nicol *et al*,[24] will be used for the linking process:

1. Instructions found in the preamble of a minimal clinical data set will not be linked to the ICF. This information, however, could be useful to identify the location of pain if it is not specified in the items or response options.
2. When an item refers to a composite score of a questionnaire, clinical test or instrument (eg, another PROM integrated into a minimal clinical data set), the item will be deconstructed into subgroups of questions and each subgroup will be reviewed and linked to the ICF individually. Each linked subgroup domain will be presented together as part of this specific item.
3. If an item makes general reference to 'work', it will be assumed that it refers to either paid work, or unpaid work and housework. It will be linked to both *Work and employment (d840-d859)* and *Domestic life (d6)*. If the item refers, more specifically, to paid work or sick leave, it will be linked to *Remunerative employment (d850)*.
4. If a main concept refers to multiple similar constructs, it will be linked to more than one ICF domain. The rationale and interpretation will be documented by each reviewer.

If other specific project rules that were not anticipated arise during the linking process, they will be documented and described in the final publication.

Every item will be linked independently by two reviewers (JM and LH) to the most precise level possible and discrepancies resolved through consensus. If consensus cannot be reached, remaining discrepancies will be resolved through consensus and arbitration by a third reviewer (CAH).

Data presentation

We will follow the Arksey and O'Malley framework for collation and synthesis of data.[26 27] We will map the existing literature on minimal clinical data sets for spine-related MSK disorders addressing our prespecified research questions. The general and specific descriptions of each minimal clinical data set will be combined and then compiled, generating a table summarising the relevant data charted from the literature. We will use broad categories to summarise the data. Analysing the existing evidence will identify research gaps and inform areas of future research. Findings will be presented with tables, figures and graphs where appropriate.

Patient and public involvement

Patients and the public will not be involved in the design, conduct or reporting plans of this scoping review due to lack of resources to facilitate their participation.

Table 2 Characteristics of the minimal clinical data sets

Data items	Associated questions
Minimal clinical data set	What is the name of the minimal clinical data set?
RQ1: What are the general characteristics of the minimal clinical data sets?	
MSK disorder	For what MSK disorder(s) was the minimal clinical data set developed?
Setting	For what setting was the minimal clinical data set mainly developed? (eg, practice setting, outpatient hospital setting, research setting). If it was mainly developed for research settings, what information is provided for a use in real-world primary healthcare and outpatient clinical practice settings?
Data provider	Who provides the data? (eg, patient fills in questionnaire, healthcare provider fills in data, extraction from electronic patient record)
Health domains	Which health and health-related domains of the International Classification of Functioning, Disability and Health[23] does the minimal data set cover?
Measurement tools	What specific questionnaires or measurement tools does the minimal clinical data set contain?
Number of items	How many items does the minimal clinical data set cover?
Item scoring	How are the items scored? (ie, nominal, categorical, ordinal)
Time	How long does the minimal clinical data set take to be completed?
Language	For which languages is the minimal clinical data set available, and for which languages has the minimal clinical data set been linguistically validated?
Availability	How is the minimal clinical data set available?
RQ2: How was the minimal clinical data set defined?	
Definition	What was the definition of the minimal clinical data set?
RQ 3: How were the minimal clinical data sets developed and was there any stakeholder involvement during that process?	
Methods	How was the minimal clinical data set developed?
Stakeholder participants	Were stakeholders (eg, patients, researchers, the public) involved in the development of the minimal clinical data set? If healthcare providers were involved, what was their profession?
Stakeholder involvement	How and to what extent were the stakeholders involved in the development of the minimal clinical data set?
RQ 4: What information is available on psychometric properties, implementation, acceptability and usability for the minimal clinical data sets?	
Reliability	What information is available on the reliability of the minimal clinical data set? (eg, test–retest reliability, inter-rater reliability, measurement error)
Internal consistency	What information is available on the internal consistency of the minimal clinical data set?
Validation	What information is available on the degree to which the minimal clinical data set measures the constructs it purposes to measure? (eg, content validity, construct validity, cross-cultural validity)
Responsiveness	What information is available on the ability of the minimal clinical data set to detect change over time?
Interpretability	What information is available on the degree to which one can assign a qualitative meaning on the quantitative score of the minimal clinical data set?
Implementation	What information is available on the implementation of the minimal clinical data set?
Acceptability	What information is available on the extent to which people delivering or receiving the minimal clinical data set consider it to be appropriate?
Usability	What information is available on the usability of the minimal clinical data set?
RQ 5: If the minimal clinical was primarily designed for clinical research, what information is available for the use in routine, real-world primary and outpatient healthcare settings?	

MSK, musculoskeletal.

RELEVANCE

Our review will map the current literature, identify research gaps and inform areas of future research with respect to minimal clinical data sets for spine-related MSK disorders in primary care. This may lead to improved quality of routinely collected healthcare data in primary

care and outpatient settings and help facilitate more reliable and valid measurement and monitoring of patient health status in primary MSK healthcare in the future.

ETHICS AND DISSEMINATION

Ethics review and approval is not required for this scoping review. Our target audience for this review will be clinicians, researchers, patients and other relevant stakeholders involved in the measurement and health status monitoring of patients with spine-related MSK disorders in primary and outpatient healthcare settings. Our dissemination plan for the review includes publishing our findings in a relevant peer-reviewed journal and presenting at relevant conferences across the spectrum of spine therapy and rehabilitation contexts (eg, International Forum for Back and Neck Pain Research in Primary Care). This protocol was presented at the Chiropractic Academy of Research Leadership (CARL) virtual symposium, held during 2–4 March 2021 and at the joint meetings of the ChiroSuisse Continuing Education and the Swiss Pain Society, held in Lausanne, Switzerland, held during 9–11 September 2021.

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Contributors CAH conceived the review. All authors (CAH, LH, JM, IP, PC, ACT) made a substantive intellectual contribution to the design of the review protocol, study aims and research questions. JM led the development of the search strategy. JM, LH and CAH developed the data extraction framework. JM, LH and CAH drafted the protocol. All authors (CAH, LH, JM, IP, PC, ACT) edited the manuscript and approved the final version.

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