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Development of a core measurement set for research in degenerative cervical myelopathy: a study protocol (AO Spine RECODE-DCM CMS)

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ABSTRACT

Introduction: Progress in degenerative cervical myelopathy (DCM) is hindered by inconsistent measurement and reporting. This can, for example, impede the aggregation of data and comparison of outcomes between studies. This limitation can be reversed by developing a core measurement set (CMS) for use in DCM research. Previously, the AO Spine Research Objectives and Common Data Elements for DCM (AO Spine RECODE-DCM) defined 'what' should be measured in DCM: specifically, the core data elements and core outcome set of the disease. The next step of this initiative is to determine 'how' to measure these features. The current protocol outlines the steps necessary for the development of a CMS for DCM research and audit.

Methods and analysis: The CMS will be developed in accordance with the guidance developed by the Core Outcome Measures in Effectiveness Trials (COMET) and the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN). The process will involve five phases: (1) agreement on the measurement constructs and approaches to their evaluation; (2) the formation of a long list of potential measurement instruments, by identifying existing instruments and assessing their psychometric properties; (3) the aggregation of evidence concerning 'when' measurements should be taken; (4) consensus about which instruments to include in the CMS and (5) implementation.

Ethics and dissemination: Ethical approval was obtained from the University of Cambridge. Dissemination strategies to promote awareness and adoption of the CMS include peer-reviewed scientific publications; conference presentations; podcasts; the identification of AO Spine RECODE-DCM ambassadors; and engagement with relevant journals, funders, and the DCM community.

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ARTICLE SUMMARY

Strengths and limitations of this study

- The CMS will be established using a robust, global, and multi-stakeholder consensus process, with broad representation of healthcare professionals and individuals living with the disease.
- The CMS will focus on measurement instruments currently in use.
- The CMS will be selected using nominal group techniques that have been effectively used during previous consensus processes.

Keywords: degenerative cervical myelopathy; cervical spondylotic myelopathy; spinal cord compression; outcome measures; core measurement set

INTRODUCTION

Background

Degenerative cervical myelopathy (DCM) is a common and often disabling disease (1). Estimated to affect as many as one in fifty adults (1), it develops due to degenerative and/or congenital changes in the cervical spine leading to mechanical stress and a progressive spinal cord injury (2-4). This disease can lead to a wide variety of symptoms, affecting the whole body (5). These symptoms commonly include gait dysfunction, imbalance and falls, loss of strength and manual dexterity, and pain. Despite current best practice (6), a minority of patients will make a full recovery and DCM is often associated with lifelong disability, impaired quality of life, and significant costs to both the individual and to society (7, 8).

Whilst progress has been and is being made (6, 9), there remain significant knowledge gaps. For people affected by DCM, solutions to these challenges cannot come soon enough (10). AO Spine Research Objectives and Common Data Elements for Degenerative Cervical Myelopathy (AO Spine RECODE-DCM; www.aospine.org/recode) is an international, multi-stakeholder initiative originally formed to create a 'research toolkit' that could help accelerate knowledge discovery and improve outcomes in DCM (11, 12). This project aimed to unify terminology, and develop minimum standards for measurement and data reporting (12-14), in order to enable data aggregation and implementation of management recommendations (15-17). The value of addressing these inefficiencies is likely magnified for DCM, as the research community is relatively small, fragmented, and has not received commensurate attention or funding (18, 19).

So far, AO Spine RECODE-DCM has established the top research priorities and agreed on a single definition and index term. It has also agreed on 'what' should be measured in DCM research: that is, a minimum data set, which is comprised of core data elements (CDE) and a core outcome set (COS). The COS is composed of 6 domains: neuromuscular function, life impact, pain, radiology, economic impact, and adverse events. Each domain contains a list of more specific outcomes that should be measured. Whilst adherence to this minimum dataset should ensure a more comprehensive assessment of DCM, to ensure data is reported in a consistent manner, best suited for between study comparison and evidence synthesis, this

standardisation should also extend to 'how' the dataset should be measured and reported. This additional phase is referred to as the development of a core measurement set (CMS) (20-22).

A CMS is a set of agreed upon tools that are used to measure the CDE and COS (23). A CMS is needed to improve the consistency of data measurement and reporting across DCM and will ultimately accelerate changes that will improve outcomes for this population (12). This protocol defines how AO Spine RECODE-DCM will establish a CMS for DCM.

Table 1. RECODE-DCM Definitions and Terminology

Acronym	Definition
CDE	Core data elements
ClinROM	Clinician Reported Outcome Measure
CMS	Core measurement set
COMET	Core outcome measures in effectiveness trials
COS	Core outcome set
COSMIN	Consensus-based standards for the selection of health measurement instruments
DCM	Degenerative cervical myelopathy
IMMPACT	Initiative on methods, measurement, and pain assessment in clinical trials
PROM	Patient Reported Outcome Measure
SC	Steering committee
Minimum Data Set Terminology	
The Minimum Data Set refers to the COS and CDE together. At a collective level we refer to each individual feature as elements. When referring to an element of the COS, we use the term outcome. When referring to an element of the CDE, we use Data Element.	
The COS is composed of 6 domains, each of which contains a number of specific outcomes:	
Neuromuscular Function	*Radiology*
Life Impact	*Economic Impact*
Pain	*Adverse Events*

[a]This field is rich with acronyms and terms, often bearing close resemblance in sentiment but with different precise meaning. This table lists the acronyms and terms used in this protocol.

METHODS AND ANALYSIS

Overview and scope

The CMS will continue to be managed within the framework of AO Spine RECODE-DCM (11). Ethical approval for this project was obtained from the University of Cambridge (Ethical approval number: HBREC2019.14). A multi-disciplinary, global steering committee (SC) was formed for the oversight of the project (www.aospine.org/recode). In addition to interim correspondence, the committee meets at least twice a year. For a meeting to be considered quorate, it must include at least two people with lived experience and four healthcare professionals. When a steering group member is unable to attend, decisions made at quorate meetings are respected. Day-to-day administration is provided by a multi-stakeholder management group.

As outlined earlier, the standardisation of data measurement and reporting is an immediate priority for DCM. However, the research priority-setting process further recognised a need to develop new measurement instruments for DCM (24). Acknowledging that such development demands a significant period of time and financial support, it was decided that the initial CMS should focus on selecting the most relevant—but existing—instruments, as opposed to developing new tools or selecting those early in development. The added benefit would be to enable comparisons with historic data while simplifying the implementation of DCM's first minimum dataset. This rationale is expanded in the discussion.

The development of the CMS is based on relevant guidance, including that developed by the Core Outcome Measures in Effectiveness Trials (COMET) and the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) (23, 25-32). Notably, no more than one measurement tool will be selected per core outcome (23). The developmental process will be conducted in five phases (**Figure 1**):

(1) Phase 1: To agree on the measurement construct and preferred measurement approach.
(2) Phase 2: To identify measurement tools and evaluate their evidence base.
(3) Phase 3: To aggregate the evidence on timing of assessment.

(4) Phase 4: To select the most appropriate instruments through multi-stakeholder consensus and provide reporting guidance.
(5) Phase 5: To implement the CMS

Figure 1. Overview of the CMS process.

The CMS will cover each element contained within the CDE but each domain of the COS (the minimum dataset). For Phases 1 and 2, preparatory scoping work will focus on the specific outcomes but during Phase 4 (Consensus), this detail will be used to inform a representative measurement instrument or instruments for the domain as a whole. Elements in the CDE which are descriptive (e.g., individual's age or sex) and do not require measurement *per se*, will only feature in Phases 3 and 4. These elements will be identified and agreed during Phase 1.

Patient and public involvement

This project forms part of a larger, international multi-stakeholder co-production initiative called AO Spine RECODE-DCM, which aims to develop a framework to accelerate knowledge discovery that can improve outcomes in DCM. Patients and the public were therefore involved in its overall design, conduct, management, and dissemination, and are recognised amongst the authors of this article. For further information, please refer to aospine.org/recode.

Phase 1. Forming measurement constructs and establishing the preferred measurement approach.

During the formation of the CDE and COS, each element was summarised with a lay description. Whilst this provided an explanation as to how the term was originally proposed, for example based on content from interviews (5, 10), these descriptions were not intended as construct definitions. Further, as some outcomes were merged and/or renamed during the process, they lacked a unifying explanatory statement.

Consequently, the first step of this CMS is to agree on the specific construct to be measured (23, 25-32). These will be expressed by forming a definition for each element. Draft definitions will be generated from original source documents including published literature or interviews with patients and professionals. This will be

undertaken by the management group. These provisional definitions will then be reviewed by the SC and iterated as indicated. Each definition must reach >70% approval at a quorate meeting to be considered final.

For elements requiring measurement, the SC will also define through agreement, whether it should be ideally measured by people with DCM (i.e., a patient reported outcome measure, or PROM), a healthcare professional (i.e., a clinician reported outcome measure, or ClinROM), or both. This decision will not be considered binding for the final CMS owing to the uncertainty at this stage around the availability and quality of candidate measures. The decision instead will be used during Phase 4, to help inform the selection of instruments for the CMS.

Phase 2. Identifying potential instruments and evaluating their measurement properties.

Phase 2 will be conducted in three stages: (2.1) a systematic review to assess the quality of existing measurement instruments used in DCM; (2.2) a gap analysis of elements, to identify those for which a measurement instrument of sufficient quality within DCM does not exist; and (2.3) targeted scoping reviews of these gap elements, to identify potentially relevant instruments used outside of DCM.

Phases 2.1 and 2.2 have been completed. Phase 2.1 will be published separately; thus, only a summary is provided here. Phase 2.2 and its results are included here.

2.1 Systematic review of existing measurement instruments

A systematic review was used to evaluate the quality of a predefined list of existing measurement instruments, identified from three previous scoping reviews (13, 33, 34). The term ‘measurement instrument’ was used to refer to how the element was being measured (i.e., the instrument used to assess the outcome) and could refer to a single question, a questionnaire, or other instruments (35, 36), including PROMs and ClinROMs.

The search was performed in EMBASE and MEDLINE from inception until 4 August 2020 to identify original research assessing the measurement properties of instruments used in clinical research of DCM. The search string was built using the

relevant DCM search filter (37, 38) and the COSMIN filter for studies evaluating measurement properties (39). Abstracts were screened by four reviewers against a set of pre-defined criteria (**Supplementary Table 1**). Only primary clinical research studies evaluating one or more measurement properties were included.

All data were collected, processed, and analysed in accordance with the COSMIN manual for systematic reviews of PROMs. This involved collecting results across 10 measurement properties: content validity, structural validity, internal consistency, cross-cultural validity/measurement invariance, reliability, measurement error, criterion validity, hypotheses testing for construct validity, responsiveness, and clinically important differences. Results were rated as 'sufficient', 'indeterminate', or 'insufficient' and overall methodological quality scores were scored as 'very good', 'adequate', 'doubtful', 'inadequate', or 'not applicable', as described in the manual. Results were then qualitatively summarised and an overall rating of the quality of the studies was made using a modified Grading of Recommendations Assessment, Development, and Evaluation (mGRADE) approach, as described in the manual. Recommendations were formulated based on all evidence, a list of interpretable instruments was collated, and findings were subsequently reported as a narrative synthesis (40).

2.2 Gap analysis

Whilst the review identified clinically interpretable instruments that were common to DCM research and could be used to measure outcomes in the COS, there were: (a) several elements for which no existing instrument was appropriate and (b) several instruments for which the evidence base was deemed inadequate (23).

To identify candidate instruments for these gaps, we looked for appropriate instruments outside of the field of DCM. Before conducting scoping reviews for each gap *de novo*, a pragmatic MEDLINE search was performed to assert if such reviews already existed. Outcomes within the domain of pain were excluded as it was felt the resources and recommendations aggregated by the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) were sufficient (41). Search strings were formed, comprising the core outcome, synonyms of 'psychometric' and 'Neuroscience' (37, 39), and were limited to the last five years to

ensure relevance. The search was restricted to Neuroscience as it was anticipated this would most likely identify instruments with appropriate content validity. Abstracts were screened by one reviewer against the same criteria from the review (**Supplementary Table 1**). Results from this gap analysis are aggregated in **Table 2.** Notably, no systematic reviews were identified, but a published protocol with respect to fatigue was (42), obtained via personal communication.

Table 2. Gap analysis. Elements with at least one interpretable instrument (see Phase 2.1) are shaded green and will be published separately. Targeted searches of MEDLINE were performed for the remaining elements (i.e., 'gaps', unshaded, see Phase 2.2). For gaps within the domain of pain (shaded blue), the resources aggregated by IMMPACT were deemed sufficient (43). The number of articles (*N*) screened is indicated for each gap. Notably, only one suitable resource was identified for 'fatigue'.

Domain	Outcome	Interpretable measurement instrument(s) identified
Adverse Events	Death	
	Surgical adverse events	0 (*N* = 55)
Economic Impact	Cost of care	
	Employment status	0 (*N* = 5)
Life Impact	Dependence	
	Falls	0 (*N* = 173)
	Fatigue	1 (*N* = 207)
	Mental health	
	Mobility	
Neuromuscular Function	Arm Strength	
	Balance	
	Bladder function	
	Faecal incontinence	0 (*N* = 308)
	Finger/hand dexterity	
	Finger strength	
	Grip strength	
	Leg Strength	
	Muscle tone and Spasticity	0 (*N* = 39)

	Neck mobility	
	Sensation	
Pain	Location	
	Intensity	
	Pain control	
	Perception	
Radiology	Adjacent segment degeneration	0 (*N* = 69)
	Cervical spine alignment	0 (*N* = 24)
	Cord compression	0 (*N* = 69)
	Cord signal change	0 (*N* = 24)

2.3 Targeted scoping reviews

For those remaining outcomes without potential instruments, focused scoping reviews will be conducted using MEDLINE and EMBASE. These reviews will be conducted in two stages and will aim: (a) to identify instruments used in a related target population; and (b) to evaluate the methodological quality of those identified instruments.

Searches will be conducted in disease populations likely to measure the same construct. For example, 'faecal incontinence', could be a symptom of many diseases. However, since this symptom is also measured in other spinal disorders with neurological injury (e.g., traumatic spinal cord injury and cauda-equina syndrome), these disorders would be considered appropriate populations. These will be defined with input from stakeholders *a priori*.

As a scoping exercise, this initial search will focus on reviews to develop lists of measurement instruments. These identified instruments will then be specifically combined with the COSMIN filter (39) and the chosen target population, to aggregate studies evaluating their measurement properties. In addition, these instruments will be searched in the COSMIN database,

Phase 3. Evidence on timing of assessment.

The timing of the assessment is an additional source of variation with respect to aggregating outcomes. For studies considering non-operative management due to the current uncertainty around the natural history of DCM (recognised as a critical research priority) (44) this will not be possible. However, for DCM managed operatively, the recovery profile is more stereotyped and felt amenable to standardisation measurement time points.

To help inform this recommendation, an evaluation of the AO Spine Cervical Spondylotic Myelopathy (CSM) North America and International datasets will be conducted (45, 46). These are two high-quality observational studies of patients undergoing surgery for DCM, followed up at three, six, twelve, and twenty-four months after surgery. These incorporate the most frequently used follow-up timepoints from DCM research (13). Recovery trajectories will be modelled over time, including the proportion of patients achieving maximal recovery at each follow up point and the

percentage change from last follow up. The significant of contextual factors that may influence this (e.g., age or comorbidities) will also be explored. These findings will be shared during Phase 4.

Phase 4. Consensus recommendations.

4.1 Formation of an expert consensus panel

A multi-disciplinary panel of experts will be formed to finalise the CMS through consensus. These experts will be identified using purposive sampling to include people with lived experience; professionals from key clinical disciplines commonly involved in DCM care (i.e., spinal surgery, neurology, rehabilitation medicine, physiotherapy, and primary care) (12, 47); professionals with clinical trials experience, particularly with respect to measuring each of the six domains (i.e., adverse events, economic impact, life impact, neuromuscular function, pain, and radiology); and professionals with experience in trial statistics. At least half of all participants will be external to the SC; at least one in five participants will have lived experience; and no more than half of all participants will be spinal surgeons. It is also intended to have a 1:1 ratio of women to men. All panellists must declare any conflicts of interest, and be approved by the SC.

4.2 Pre-meeting short-listing

Panellists will be provided with a summary containing the identified measurement instruments considered of sufficient quality for each element, including their evidence base, and the original steering committee decision concerning the preferred reporting method (i.e., PROM or ClinROM). Each panellist will be asked to submit three preferred measurement instruments in advance of the meeting, with a justification for each, and to optionally suggest unrepresented instruments (no more than 1).

4.3 Face-to-face consensus meeting

A consensus meeting of the panel will then be convened. The aims will be: (a) to select the preferred measurement instruments, (b) to define how they should be reported, and (c) to outline when they should be reported in surgically treated DCM cohorts. The management group will prepare documentation for each domain, comprising those instruments shortlisted by the panel during Phase 4.2 together with their evidence. Each domain will be discussed in turn with a majority decision considered consensus

agreement. Where applicable, this will also continue for each element of the CDE. The consensus meeting will be overseen by an independent facilitator and follow a nominal group technique. Moderated discussion and re-voting will be undertaken as necessary until consensus is achieved for all components of the COS and CDE. Consensus will be defined as >70% agreement.

Phase 5. Implementation

The dissemination of the CMS will be incorporated into the active knowledge translation proposal for the entire AO Spine RECODE-DCM initiative. This includes scientific publication; conference presentations; podcasts; identifying AO Spine RECODE-DCM ambassadors; and engaging with relevant journals and funders. This process will be subject to periodic review to ensure strategies are effective and adaptive.

This will include a survey of the RECODE-DCM community, designed to share the CMS and ascertain barriers to implementation. This information will be used to inform overall strategy.

The AO Spinal Cord Injury Knowledge Forum, an international and multidisciplinary group of professionals working in this field, will review the relevance of the CMS at 4 years from release, to consider whether an update is required.

DISCUSSION

This protocol outlines the process for developing a CMS for DCM, based on the CDE and COS already defined by AO Spine RECODE-DCM. Whilst some pragmatic steps have been taken, this process remains faithful to consensus methodology and CMS precedent (23, 25-32, 35) and, ultimately, remains robust.

The CMS will focus on measurement instruments currently in usage.

From the outset, it was decided that the CMS would principally focus on existing instruments currently in use. Although the development of better assessment instruments is a top 10 research priority (24), the strategy to use existing instruments was preferred for several reasons. First, the aim of this project was to develop a CMS that could be immediately implemented in clinical practice and research studies. The

development of new tools remains a work in progress, including microstructural MRI, gait laboratory analysis, and clinical assessments (24, 48, 49). Whilst it seems inevitable that these measurement instruments will change DCM assessment, there remain important methodological uncertainties, practical challenges, and technological requirements that pose potential barriers to adoption.

Widespread adoption is necessary for a minimum data set to improve research efficiency. Unless individual DCM researchers have unified data collection, the comparison of findings across studies will remain limited (50). Changing practice, however, is challenging, particularly when a concept is unfamiliar or questioned (51-53). It is therefore important to recognise that CMSs can be updated (54) and that individual studies can incorporate additional instruments at their discretion. Furthermore, the inclusion of emerging technology should only be included in future CMS iterations when their selection is undisputable.

For DCM, an equally important but more achievable priority is to ensure that the intended breadth of outcomes is being measured. As highlighted in Phase 2.2, previous studies may have underrepresented the disease. (13, 18). This holds significant implications for interpreting the literature. A recent example is the results of the CSM-Protect study, a randomised controlled trial comparing riluzole as an adjuvant to surgery to surgery alone (55). While there were no differences between treatment groups with respect to the primary endpoint (i.e., neuromuscular function), there were indications of meaningful benefit amongst secondary outcomes (e.g., complications such as C5 Nerve Palsy, and pain).

As a nascent research field with a paucity of high-quality prospective studies (9, 56), ensuring that current research is comparable to these benchmarks will be important for their generalisation and implementation in the short-term (17). This will require existing measurement instruments to be represented.

The CMS will be selected using nominal group techniques.

Several methods exist to achieve meaningful consensus (57, 58). Ultimately, these methods aim to ensure that all relevant perspectives are captured and appropriately represented in the decisions taken (59). Consensus processes are increasingly

approached by combining literature evidence, serial surveys, and a final consensus meeting—a modified Delphi (57, 60, 61). This approach was effectively used during our previous three consensus processes (i.e., for the index term, CDE, and COS).

The diverse perspectives from different stakeholder groups was imperative in determining 'what' to measure, identifying previously unprioritised outcomes (62) and developing a global multi-stakeholder community focused on DCM (63). Arguably, 'how' to measure these outcomes will require further focused perspectives on clinical assessment and trials. When conducting our international Delphi processes, engaging under-represented stakeholders was challenging (12, 64, 65). At the outset, we aimed to capture perspectives of people with lived experiences, surgeons, and other healthcare professionals in a 2:1:1 ratio (12). However, this could not be achieved, and engaging spinal surgeons—who most frequently treat, research, and specialise in DCM—was much easier (65). Given that the CDE and COS have been defined, and that the decision on how to measure them is likely to benefit from specific expertise, a purposively selected group using a nominal group technique was favoured for the CMS. It is also hypothesised that the step of sharing the results of the CMS with the wider DCM research community will facilitate dissemination and improve face validity.

CONCLUSIONS

This protocol describes the formation of the first CMS for DCM, which will focus on instruments in current use. This aims to facilitate the standardised and comprehensive measurement of DCM and will create a venue for the development and introduction of novel measures. We anticipate that this process will greatly facilitate knowledge generation and knowledge translation in DCM by enabling clinicians and researchers to 'speak a common language' with regard to outcomes instruments.

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CONTRIBUTORS

BMD was responsible for conceiving the article. AM contributed to the study design. BMD and AYT wrote the protocol and manuscript and contributed equally to this paper. BK, MGF, MRNK, and IS facilitated international collaboration. BMD, AYT, ODM, KSL, DK, JCF, MGF, JH, CMZ, RRP, JM, ES, AC, VRM, BA, TFB, LT, RC, JDG, SKR, IS, SW, AGKM, MRNK provided critical appraisal of the manuscript. All authors critically revised and approved the manuscript.

ETHICS APPROVAL

Ethical approval for this project was obtained from the University of Cambridge (Ethical approval number: HBREC2019.14)

DATA AVAILABILITY STATEMENT

All data produced in the present work are contained in the manuscript.

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COMPETING INTERESTS

None declared.

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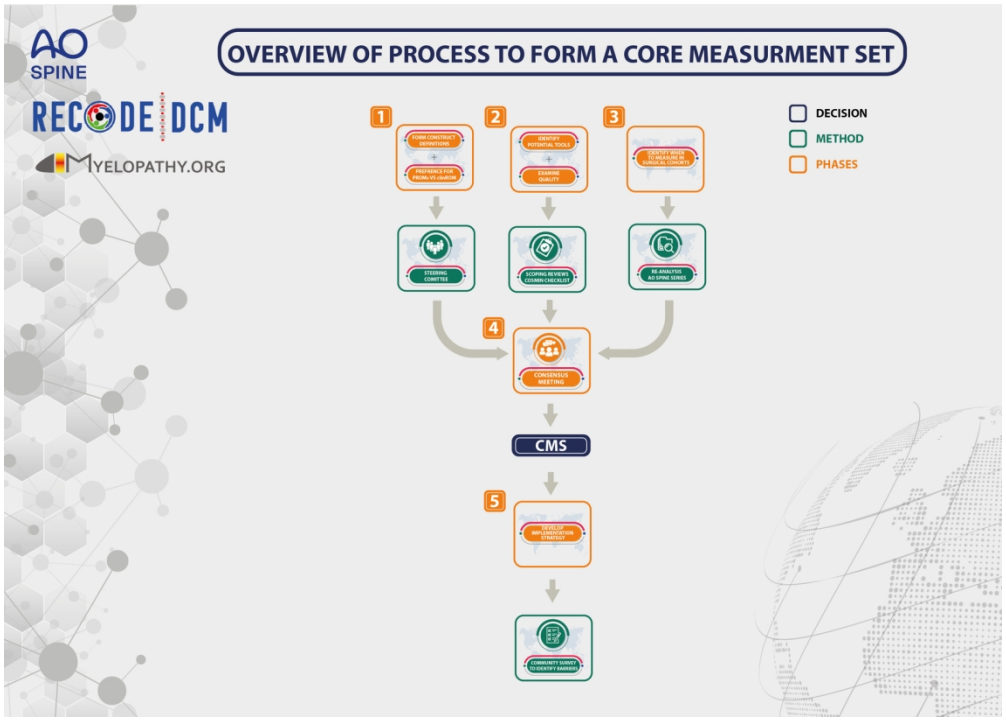

Figure 1. Overview of the CMS process.

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SUPPLEMENTARY INFORMATION

Supplementary Table 1. Inclusion and exclusion criteria for the systematic review.

Inclusion	Exclusion
Publication type	
• Article written in English • Primary clinical research articles	• Article not written in English • Conference abstracts or posters • Editorials, commentaries, opinion papers or letters • Book chapters or theses
Study type	
• Study includes primary clinical data	• Study uses only secondary data • Case reports • Narrative reviews • Systematic reviews • Meta-analyses
Populations	
• Human studies	• Non-human studies
Indications	
• Exclusively DCM (CSM, ossification of the posterior longitudinal ligament, cervical stenosis, spondylosis, spinal cord compression, cervical myelopathy)	• Populations with DCM and at least one other condition (e.g., radiculopathy)
Comparator	
• At least one assessment tool from (13, 33, 34)	
Outcomes	
• At least one psychometric property • At least one MCID or SCB	

BMJ Open

Development of a core measurement set for research in degenerative cervical myelopathy: a study protocol (AO Spine RECODE-DCM CMS)

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Development of a core measurement set for research in degenerative cervical myelopathy: a study protocol (AO Spine RECODE-DCM CMS)

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ABSTRACT

Introduction: Progress in degenerative cervical myelopathy (DCM) is hindered by inconsistent measurement and reporting. This impedes data aggregation and outcome comparison across studies. This limitation can be reversed by developing a core measurement set (CMS) for DCM research. Previously, the AO Spine Research Objectives and Common Data Elements for DCM (AO Spine RECODE-DCM) defined 'what' should be measured in DCM: the next step of this initiative is to determine 'how' to measure these features. This protocol outlines the steps necessary for the development of a CMS for DCM research and audit.

Methods and analysis: The CMS will be developed in accordance with the guidance developed by the Core Outcome Measures in Effectiveness Trials (COMET) and the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN). The process involves five phases. In Phase 1, the steering committee agreed on the constructs to be measured by sourcing consensus definitions from patients, professionals, and the literature. In Phases 2 and 3, systematic reviews were conducted to identify tools for each construct and aggregate their evidence. Constructs with and without tools were identified, and scoping reviews were conducted for constructs without tools. Evidence on measurement properties, as well as on timing of assessments, are currently being aggregated. These will be presented in Phase 4: a consensus meeting where a multi-disciplinary panel of experts will select the instruments that will form the CMS. Following selection, guidance on the implementation of the CMS will be developed and disseminated (Phase 5). A preliminary CMS review scheduled at four years from release.

Ethics and dissemination: Ethical approval was obtained from the University of Cambridge (HBREC2019.14). Dissemination strategies will include peer-reviewed scientific publications; conference presentations; podcasts; the identification of AO Spine RECODE-DCM ambassadors; and engagement with relevant journals, funders, and the DCM community.

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ARTICLE SUMMARY

Strengths and limitations of this study

- The CMS will be established using a robust, global, and multi-stakeholder consensus process, with broad representation of healthcare professionals and individuals living with the disease.
- The core measurement set (CMS) will focus on measurement instruments currently in use.
- Where there are gaps in DCM outcome measurement, systematic and targeted scoping reviews will be performed to identify instruments used in related populations, which are likely to measure equivalent outcome constructs.
- The CMS will be selected using modified nominal group techniques that have been effectively used during previous consensus processes.

Keywords: degenerative cervical myelopathy; cervical spondylotic myelopathy; spinal cord compression; outcome measures; core measurement set

INTRODUCTION

Background

Degenerative cervical myelopathy (DCM) is a common and often disabling disease (1). Estimated to affect as many as one in fifty adults (1), it develops due to degenerative and/or congenital changes in the cervical spine leading to mechanical stress and a progressive spinal cord injury (2-4). This disease can lead to a wide variety of symptoms, affecting the whole body (5). These symptoms commonly include gait dysfunction, imbalance and falls, loss of strength and manual dexterity, and pain. Despite current best practice (6), a minority of patients will make a full recovery and DCM is often associated with lifelong disability, impaired quality of life, and significant costs to both the individual and to society (7, 8).

Whilst progress has been and is being made (6, 9), there remain significant knowledge gaps. For people affected by DCM, solutions to these challenges cannot come soon enough (10). AO Spine Research Objectives and Common Data Elements for Degenerative Cervical Myelopathy (AO Spine RECODE-DCM; www.aospine.org/recode) is an international, multi-stakeholder initiative originally formed to create a 'research toolkit' that could help accelerate knowledge discovery and improve outcomes in DCM (11, 12). This project aimed to unify terminology, and develop minimum standards for measurement and data reporting (12-14), in order to enable data aggregation and implementation of management recommendations (15-17). The value of addressing these inefficiencies is likely magnified for DCM, as the research community is relatively small, fragmented, and has not received commensurate attention or funding (18, 19). This is magnified by the use of 14 different names around the world, with common alternatives including cervical spondylotic myelopathy, cervical myelopathy, and cervical stenosis (20).

So far, AO Spine RECODE-DCM has established the top research priorities and agreed on a single definition and index term (21-34). It has also agreed on 'what' should be measured in DCM research: that is, a minimum data set, which is comprised of core data elements (CDE) and a core outcome set (COS). The COS is composed of 6 domains: neuromuscular function, life impact, pain, radiology, economic impact, and adverse events. Each domain contains a list of more specific outcomes that should be measured. Whilst adherence to this minimum dataset should ensure a more

comprehensive assessment of DCM, to ensure data is reported in a consistent manner, best suited for between study comparison and evidence synthesis, this standardisation should also extend to 'how' the dataset should be measured and reported. This additional phase is referred to as the development of a core measurement set (CMS) (35-37).

A CMS is a set of agreed upon tools that are used to measure the CDE and COS (38). A CMS is needed to improve the consistency of data measurement and reporting across DCM and will ultimately accelerate changes that will improve outcomes for this population (12). This protocol defines how AO Spine RECODE-DCM will establish a CMS for DCM.

Table 1. RECODE-DCM Definitions and Terminology

Acronym	Definition
CDE	Core data elements
ClinROM	Clinician Reported Outcome Measure
CMS	Core measurement set
COMET	Core outcome measures in effectiveness trials
COS	Core outcome set
COSMIN	Consensus-based standards for the selection of health measurement instruments
DCM	Degenerative cervical myelopathy
IMMPACT	Initiative on methods, measurement, and pain assessment in clinical trials
PROM	Patient Reported Outcome Measure
SC	Steering committee
Minimum Data Set Terminology	
The Minimum Data Set refers to the COS and CDE together.	
At a collective level we refer to each individual feature as elements. When referring to an element of the COS, we use the term outcome. When referring to an element of the CDE, we use Data Element.	
The COS is composed of 6 domains, each of which contains a number of specific outcomes:	
Neuromuscular Function	*Radiology*
Life Impact	*Economic Impact*
Pain	*Adverse Events*

[a]This field is rich with acronyms and terms, often bearing close resemblance in sentiment but with different precise meaning. This table lists the acronyms and terms used in this protocol.

METHODS AND ANALYSIS

Overview and scope

The CMS will continue to be managed within the framework of AO Spine RECODE-DCM (11). Ethical approval for this project was obtained from the University of Cambridge (Ethical approval number: HBREC2019.14). A multi-disciplinary, global steering committee (SC) was formed for the oversight of the project (www.aospine.org/recode). In addition to interim correspondence, the committee meets at least twice a year. For a meeting to be considered quorate, it must include at least two people with lived experience and four healthcare professionals. When a steering group member is unable to attend, decisions made at quorate meetings are respected. Day-to-day administration is provided by a multi-stakeholder management group.

As outlined earlier, the standardisation of data measurement and reporting is an immediate priority for DCM. However, the research priority-setting process further recognised a need to develop new measurement instruments for DCM (39). Acknowledging that such development demands a significant period of time and financial support, it was decided that the initial CMS should focus on selecting the most relevant—but existing—instruments, as opposed to developing new tools or selecting those early in development. The added benefit would be to enable comparisons with historic data while simplifying the implementation of DCM's first minimum dataset. This rationale is expanded in the discussion.

The development of the CMS is based on relevant guidance, including that developed by the Core Outcome Measures in Effectiveness Trials (COMET) and the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) (38, 40-47). Notably, no more than one measurement tool will be selected per core outcome (38). The developmental process will be conducted in five phases (**Figure 1**):

(1) Phase 1: To agree on the measurement construct and preferred measurement approach.
(2) Phase 2: To identify measurement tools and evaluate their evidence base.

(3) Phase 3: To aggregate the evidence on timing of assessment.
(4) Phase 4: To select the most appropriate instruments through multi-stakeholder consensus and provide reporting guidance.
(5) Phase 5: To implement the CMS

Figure 1. Overview of the CMS process.

The CMS will cover each element contained within the CDE but each domain of the COS (the minimum dataset). For Phases 1 and 2, preparatory scoping work will focus on the specific outcomes but during Phase 4 (Consensus), this detail will be used to inform a representative measurement instrument or instruments for the domain as a whole. Elements in the CDE which are descriptive (e.g., individual's age or sex) and do not require measurement *per se*, will only feature in Phases 3 and 4. These elements will be identified and agreed during Phase 1.

Information on the status of each phase is shown in **Table 2**. Where a phase has not yet been completed, information on the planned timeline for completion is described as of the time of writing.

Table 2. Status of the CMS process.

Phase	Status	Description
1	Complete	
2	In progress	Systematic review of the quality of existing measurement instruments published (48) Gap analysis completed (**Table 3**) Targeted scoping reviews in progress (ETC April 2022)
3	In progress	ETC May 2022
4	Scheduled	Consensus meeting is scheduled for 1st June 2022
5	In planning	Strategy to be refined with finalised CMS

ETC, Estimated time of completion

Patient and public involvement

This project forms part of a larger, international multi-stakeholder co-production initiative called AO Spine RECODE-DCM, which aims to develop a framework to

accelerate knowledge discovery that can improve outcomes in DCM. Patients and the public were therefore involved in its overall design, conduct, management, and dissemination, and are recognised amongst the authors of this article. For further information, please refer to aospine.org/recode.

Phase 1. Forming measurement constructs and establishing the preferred measurement approach.

During the formation of the CDE and COS, each element was summarised with a lay description. Whilst this provided an explanation as to how the term was originally proposed, for example based on content from interviews (5, 10), these descriptions were not intended as construct definitions. Further, as some outcomes were merged and/or renamed during the process, they lacked a unifying explanatory statement.

Consequently, the first step of this CMS is to agree on the specific construct to be measured (38, 40-47). These will be expressed by forming a definition for each element. Draft definitions will be generated from original source documents including published literature or interviews with patients and professionals. This will be undertaken by the management group. These provisional definitions will then be reviewed by the SC and iterated as indicated. Each definition must reach >70% approval at a quorate meeting to be considered final.

For elements requiring measurement, the SC will also define through agreement, whether it should be ideally measured by people with DCM (i.e., a patient reported outcome measure, or PROM), a healthcare professional (i.e., a clinician reported outcome measure, or ClinROM), or both. These decisions will not necessarily be considered binding for the final CMS owing to the uncertainty at this stage around the availability and quality of candidate measures. The decision instead will be used during Phase 4, to help inform the selection of instruments for the CMS.

Phase 2. Identifying potential instruments and evaluating their measurement properties.

Phase 2 will be conducted in three stages: (2.1) a systematic review to assess the quality of existing measurement instruments used in DCM; (2.2) a gap analysis of elements, to identify those for which a measurement instrument of sufficient quality

within DCM does not exist; and (2.3) targeted scoping reviews of these gap elements, to identify potentially relevant instruments used outside of DCM.

Phases 2.1 and 2.2 have been completed. Phase 2.1 has been published separately (48); thus, only a summary is provided here. Phase 2.2 and its results are included here.

2.1 Systematic review of existing measurement instruments

A systematic review was used to evaluate the quality of a predefined list of existing measurement instruments, identified from three previous scoping reviews (13, 48-50). The term 'measurement instrument' was used to refer to how the element was being measured (i.e., the instrument used to assess the outcome) and could refer to a single question, a questionnaire, or other instruments (51, 52), including PROMs and ClinROMs.

The search was performed in EMBASE and MEDLINE from inception until 4 August 2020 to identify original research assessing the measurement properties of instruments used in clinical research of DCM. The search string was built using the relevant DCM search filter (53, 54) and the COSMIN filter for studies evaluating measurement properties (55). Abstracts were screened by four reviewers against a set of pre-defined criteria (**Supplementary Table 1**). Only primary clinical research studies evaluating one or more measurement properties were included.

All data were collected, processed, and analysed in accordance with the COSMIN manual for systematic reviews of PROMs. This involved collecting results across 10 measurement properties: content validity, structural validity, internal consistency, cross-cultural validity/measurement invariance, reliability, measurement error, criterion validity, hypotheses testing for construct validity, responsiveness, and clinically important differences. Results were rated as 'sufficient', 'indeterminate', or 'insufficient' and overall methodological quality scores were scored as 'very good', 'adequate', 'doubtful', 'inadequate', or 'not applicable', as described in the manual. Results were then qualitatively summarised and an overall rating of the quality of the studies was made using a modified Grading of Recommendations Assessment, Development, and Evaluation (mGRADE) approach, as described in the manual.

Recommendations were formulated based on all evidence, a list of interpretable instruments was collated, and findings were subsequently reported as a narrative synthesis (56).

2.2 Gap analysis

Whilst the review identified clinically interpretable instruments that were common to DCM research and could be used to measure outcomes in the COS, there were: (a) several elements for which no existing instrument was appropriate and (b) several instruments for which the evidence base was deemed inadequate (38).

To identify candidate instruments for these gaps, we looked for appropriate instruments outside of the field of DCM. Before conducting scoping reviews for each gap *de novo*, a pragmatic MEDLINE search was performed to assert if such reviews already existed. Outcomes within the domain of pain were excluded as it was felt the resources and recommendations aggregated by the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) were sufficient (57). Search strings were formed, comprising the core outcome, synonyms of 'psychometric' and 'Neuroscience' (53, 55), and were limited to the last five years to ensure relevance. The search was restricted to Neuroscience as it was anticipated this would most likely identify instruments with appropriate content validity. Abstracts were screened by one reviewer against the same criteria from the review (**Supplementary Table 1**). Results from this gap analysis are aggregated in **Table 3.** Notably, no systematic reviews were identified, but a published protocol with respect to fatigue was, and the study results obtained via personal communication (58).

Table 3. Gap analysis. Elements with at least one interpretable instrument (see Phase 2.1) are shaded green and will be published separately. Targeted searches of MEDLINE were performed for the remaining elements (i.e., 'gaps', unshaded, see Phase 2.2). For gaps within the domain of pain (shaded blue), the resources aggregated by IMMPACT were deemed sufficient (59). The number of articles (*N*) screened is indicated for each gap. Notably, only one suitable resource was identified for 'fatigue' (58).

Domain	Outcome	Interpretable measurement instrument(s) identified
Adverse Events	Death	
	Surgical adverse events	0 (*N* = 55)
Economic Impact	Cost of care	
	Employment status	0 (*N* = 5)
Life Impact	Dependence	
	Falls	0 (*N* = 173)
	Fatigue	1 (*N* = 207)
	Mental health	
	Mobility	
Neuromuscular Function	Arm Strength	
	Balance	
	Bladder function	
	Faecal incontinence	0 (*N* = 308)
	Finger/hand dexterity	
	Finger strength	
	Grip strength	
	Leg Strength	
	Muscle tone and Spasticity	0 (*N* = 39)

	Neck mobility	
	Sensation	
Pain	Location	
	Intensity	
	Pain control	
	Perception	
Radiology	Adjacent segment degeneration	0 (*N* = 69)
	Cervical spine alignment	0 (*N* = 24)
	Cord compression	0 (*N* = 69)
	Cord signal change	0 (*N* = 24)

2.3 Targeted scoping reviews

For those remaining outcomes without potential instruments, focused scoping reviews will be conducted. These reviews will be conducted in two stages and will aim to: (a) identify instruments used in a related target population (to increase the likelihood of content validity); and (b) evaluate the methodological quality of those identified instruments. Recognising the intensive undertaking of reviewing the quality of instruments using the COSMIN methodology, in order to ensure this undertaking is manageable and likely to yield relevant results, it will be conducted in the following pragmatic fashion (**Figure 2**):

- **Stage 1:**
  - 1.1 Identify tools outside DCM for domains in Phase 2.2
  - 1.2 Screen tools from stage 1.1 according to intended format, i.e., ClinROM or PROM
- **Stage 2:**
  - 2.1 Evaluate content validity of PROMs from stage 1
  - 2.2 Evaluate content validity of ClinROMs from stage 1
  - 2.3 Select two PROMs and ClinROMs from stages 2.1 and 2.2
  - 2.4 Evaluate measurement properties of tools selected in stage 2.3
  - 2.5 Share list of tools with psychometric evaluations ahead of consensus meeting

Figure 2. Decision tree schematic illustrating the targeted scoping review process. (A and B) Stage 1: Selection of databases for identification of tools outside DCM (A) and screening of tools outside DCM (B). (C) Stage 2: Evaluation of measurement properties.

To identify instruments, each 'gap' outcome will be queried first on the COSMIN Database of systematic reviews of outcome measurement instruments (https://database.cosmin.nl/) (**Figure 2A**). As a scoping exercise, each search will focus on reviews in order to develop a list of measurement instruments. Preferably, systematic reviews identifying instruments and evaluating their methodological quality will be included (**Figure 2B**). Where these are not available, systematic reviews

identifying instruments without methodological evaluations will be favoured, followed by reviews referred from SC advice and, ultimately, primary literature.

Searches will be conducted in disease populations related to DCM in order to increase the likelihood of content validity. For example, 'faecal incontinence', could be a symptom of many diseases. However, since this symptom is also measured in other spinal disorders with neurological injury (e.g., traumatic spinal cord injury and cauda-equina syndrome), these disorders would be considered appropriate populations. These will be defined with input from stakeholders *a priori*.

As in Phase 1, instruments will be categorised as PROMs or ClinROMs (60). Only instruments whose category matches the intended outcome category, as defined in Phase 1, will be included. Namely, if 'faecal incontinence' was defined as a patient-reported outcome during Phase 1, then only PROMs of 'faecal incontinence' will be included, and ClinROMs will be excluded.

The above steps will be performed for each 'gap' outcome in **Table 3** in order to identify instruments used in related target populations. If no such instruments are found through the COSMIN Database, the same steps will be performed on the EULAR Outcomes Measures Library (OML, https://oml.eular.org/) (**Figure 2A**). If no such instruments are found through the EULAR OML, the same search will be performed, as a last resort, on the HealthMeasures Database (https://www.healthmeasures.net/), failing which, the search will be performed on PubMed using the COSMIN filter (55). These databases were selected based on their scope.

To evaluate the methodological quality of the identified instruments, the same COSMIN process as in Phase 2.1 (48) will be used. Recognising that evaluating an uncapped number of instruments with the COSMIN manual can quickly become unrealistic, we will limit the number of instruments for COSMIN review to two per 'gap' outcome. Should there be more than two PROMs or ClinROMs per 'gap' outcome, a content validity survey will be conducted on at least five people with lived experience or clinicians (as applicable) to rank the identified instruments (**Figure 2C**). The two

highest ranking instruments will be selected for COSMIN review and their psychometric properties will be evaluated as in Phase 2.1 (48).

Phase 3. Evidence on timing of assessment.

The timing of the assessment is an additional source of variation with respect to aggregating outcomes. For studies considering non-operative management due to the current uncertainty around the natural history of DCM (recognised as a critical research priority) (61) this will not be possible. However, for DCM managed operatively, the recovery profile is more stereotyped and felt amenable to standardisation measurement time points.

To help inform this recommendation, an evaluation of the AO Spine Cervical Spondylotic Myelopathy (CSM) North America and International datasets will be conducted (62, 63). These are two high-quality observational studies of patients undergoing surgery for DCM, followed up at three, six, twelve, and twenty-four months after surgery. These incorporate the most frequently used follow-up timepoints from DCM research (13). Recovery trajectories will be modelled over time, including the proportion of patients achieving maximal recovery at each follow up point and the percentage change from last follow up. The significant of contextual factors that may influence this (e.g., age or comorbidities) will also be explored. These findings will be shared during Phase 4.

Phase 4. Consensus recommendations.

4.1 Formation of an expert consensus panel

A multi-disciplinary panel of experts will be formed to finalise the CMS through consensus. These experts will be identified using purposive sampling to include people with lived experience; professionals from key clinical disciplines commonly involved in DCM care (i.e., spinal surgery, neurology, rehabilitation medicine, physiotherapy, and primary care) (12, 64); professionals with clinical trials experience, particularly with respect to measuring each of the six domains (i.e., adverse events, economic impact, life impact, neuromuscular function, pain, and radiology); and professionals with experience in trial statistics. A target sample size of 12 individuals will be sought. At least half of all participants will be external to the SC; at least one in six participants will have lived experience; and no more than half of all participants will

be spinal surgeons. It is also intended to have a 1:1 ratio of women to men. All panellists must declare any conflicts of interest, and be approved by the SC.

4.2 Pre-meeting short-listing

Panellists will be provided with a summary containing the identified measurement instruments considered of sufficient quality for each element, including their evidence base, and the original steering committee decision concerning the preferred reporting method (i.e., PROM or ClinROM). Each panellist will be asked to submit two preferred measurement instruments in advance of the meeting. These may include the instruments identified and evaluated during Phase 2 or up to two instruments from outside this list. To justify the suggestion of instruments from outside the provided list, panellists will be asked to cite one primary article per psychometric domain (i.e., one for validity, one for reliability, and one for responsiveness). This literature will be evaluated using the same COSMIN methodology from Phases 2.1 and 2.3, to ensure that all instruments presented at the face-to-face consensus meeting are accompanied with a COSMIN rating and comparable.

4.3 Face-to-face consensus meeting

A consensus meeting of the panel will then be convened. The aims will be: (a) to select the preferred measurement instruments, (b) to define how they should be reported, and (c) to outline when they should be reported in surgically treated DCM cohorts. The management group will prepare documentation for each domain, comprising those instruments shortlisted by the panel during Phase 4.2 together with their evidence. Each domain will be discussed in turn with a majority decision considered consensus agreement. Where applicable, this will also continue for each element of the CDE. The consensus meeting will be overseen by an independent facilitator and follow a modified nominal group technique. Moderated discussion and re-voting will be undertaken as necessary until consensus is achieved for all components of the COS and CDE. Consensus will be defined as >70% agreement.

Phase 5. Implementation

The dissemination of the CMS will be incorporated into the active knowledge translation proposal for the entire AO Spine RECODE-DCM initiative. This includes scientific publication; conference presentations; podcasts; identifying AO Spine

RECODE-DCM ambassadors; and engaging with relevant journals and funders. This process will be subject to periodic review to ensure strategies are effective and adaptive.

This will include a survey of the RECODE-DCM community, designed to share the CMS and ascertain barriers to implementation. This information will be used to inform overall strategy.

The AO Spinal Cord Injury Knowledge Forum, an international and multidisciplinary group of professionals working in this field, will review the relevance of the CMS at four years from release, to consider whether an update is required.

ETHICS AND DISSEMINATION

Ethical approval was obtained from the University of Cambridge (HBREC2019.14). Participant consent will be sought for the consensus meeting. Members of the SC have already consented to participate in this study. Dissemination strategies for this project will include scientific publication, presentation, and communication, and are described in more detail in Phase 5.

DISCUSSION

This protocol outlines the process for developing a CMS for DCM, based on the CDE and COS already defined by AO Spine RECODE-DCM. Whilst some pragmatic steps have been taken, this process remains faithful to consensus methodology and CMS precedent (38, 40-47, 51) and, ultimately, remains robust.

The CMS will focus on measurement instruments currently in usage

From the outset, it was decided that the CMS would principally focus on existing instruments currently in use. Although the development of better assessment instruments is a top 10 research priority (39), the strategy to use existing instruments was preferred for several reasons. First, the aim of this project was to develop a CMS that could be immediately implemented in clinical practice and research studies. The development of new tools remains a work in progress, including microstructural MRI, gait laboratory analysis, and clinical assessments (39, 65, 66). Whilst it seems inevitable that these measurement instruments will change DCM assessment, there

remain important methodological uncertainties, practical challenges, and technological requirements that pose potential barriers to adoption.

Widespread adoption is necessary for a minimum data set to improve research efficiency. Unless individual DCM researchers have unified data collection, the comparison of findings across studies will remain limited (67). Changing practice, however, is challenging, particularly when a concept is unfamiliar or questioned (68-70). It is therefore important to recognise that CMSs can be updated (71) and that individual studies can incorporate additional instruments at their discretion. Furthermore, the inclusion of emerging technology should only be included in future CMS iterations when their selection is undisputable.

For DCM, an equally important but more achievable priority is to ensure that the intended breadth of outcomes is being measured. As highlighted in Phase 2.2, previous studies may have underrepresented the disease. (13, 18). This holds significant implications for interpreting the literature. A recent example is the results of the CSM-Protect study, a randomised controlled trial comparing riluzole as an adjuvant to surgery to surgery alone (72). While there were no differences between treatment groups with respect to the primary endpoint (i.e., neuromuscular function), there were indications of meaningful benefit amongst secondary outcomes (e.g., complications such as C5 Nerve Palsy, and pain).

As a nascent research field with a paucity of high-quality prospective studies (9, 73), ensuring that current research is comparable to these benchmarks will be important for their generalisation and implementation in the short-term (17). This will require existing measurement instruments to be represented.

The CMS will be selected using modified nominal group techniques

Several methods exist to achieve meaningful consensus (74, 75). Ultimately, these methods aim to ensure that all relevant perspectives are captured and appropriately represented in the decisions taken (76). Consensus processes are increasingly approached by combining literature evidence, serial surveys, and a final consensus meeting—a modified Delphi (74, 77, 78). This approach was effectively used during our previous three consensus processes (i.e., for the index term, CDE, and COS).

The diverse perspectives from different stakeholder groups was imperative in determining 'what' to measure, identifying previously unprioritised outcomes (79) and developing a global multi-stakeholder community focused on DCM (80). Arguably, 'how' to measure these outcomes will require further focused perspectives on clinical assessment and trials. When conducting our international Delphi processes, engaging under-represented stakeholders was challenging (12, 81, 82). At the outset, we aimed to capture perspectives of people with lived experiences, surgeons, and other healthcare professionals in a 2:1:1 ratio (12). However, this could not be achieved, and engaging spinal surgeons—who most frequently treat, research, and specialise in DCM—was much easier (82). Given that the CDE and COS have been defined, and that the decision on how to measure them is likely to benefit from specific expertise, a purposively selected group using a modified nominal group technique was favoured for the CMS. It is also hypothesised that the step of sharing the results of the CMS with the wider DCM research community will facilitate dissemination and improve face validity.

Limitations

Despite its conscientious design, this CMS process has limitations. As in Yanez Touzet et al. (2022) (48), in searching for existing instruments, we have neither identified nor assessed tools under development, or those currently being translated into clinical or research settings, or those published in languages other than English. Further, to ensure that the identification and evaluation of candidate tools in use outside of DCM is manageable, pragmatic steps have been taken. Whilst this risks missing relevant tools, we suspect this is very unlikely to have limit the CMS. Firstly, the shortlisting takes a systematic and structured approach, adapted from the prioritisation of databases and standards in the COSMIN website and manual (respectively) (40-42, 83). This was supplemented by the perspectives of the SC, which includes significant DCM research experience and remains open to suggestions from those attending the consensus meeting.

Notably, in the gap analysis, only one suitable resource was identified out of 973 candidates (**Table 3**). This paucity of high-quality evidence is not surprising given our prior experience with the COSMIN guidelines (48). The COSMIN standards set a high

bar for evaluating psychometric assessments. For example, studies on content validity cannot score higher than 'inadequate' without focus group/interview recordings or verbatim transcriptions—and, in our experience, most of these studies rely on survey-based methods. These standards have been previously conceived as both strengths, and limitations, of the COSMIN methodology (84-86). That only one outcome out of 28 had one suitable resource was noteworthy at the gap analysis stage but, when interpreted within the context of the psychometric rigor (or stringency) of the guidelines, it is neither surprising nor worrying due to our intent to include the highest possible quality of instruments in this CMS (58).

Finally, in resorting to shortlisted instruments used in populations other than DCM, we have introduced the possibility for invalid instruments to be selected. To minimise this limitation, we stipulated that the constructs being measured in these populations must be, in all likelihood, equivalent, i.e., there is content validity. This was desirable due to the number of gaps in Phase 2.2 and feasible due to the COSMIN recommendations (40-42). As in shortlisting, the option for experts to suggest other instruments prior to the consensus meeting should provide an opportunity to resolve this limitation as much as possible. Alternatively, the expert discussions, voting, and re-voting involved in the modified nominal technique should address these concerns explicitly.

We anticipate that the formation of the first CMS for DCM will greatly facilitate knowledge generation and knowledge translation in DCM by enabling clinicians and researchers to 'speak a common language' with regard to outcomes instruments. We hope that this set, which will focus on instruments in current use, will facilitate the standardised and comprehensive measurement of DCM and inspire a framework for the development and adoption of improved measures.

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CONTRIBUTORS

BMD was responsible for conceiving the article. AM contributed to the study design. BMD and AYT wrote the protocol and manuscript and contributed equally to this paper. BK, MGF, MRNK, and IS facilitated international collaboration. BMD, AYT, ODM, KSL, DK, JCF, MGF, JH, CMZ, RRP, JM, ES, AC, VRM, BA, TFB, LT, RC, JDG, SKR, IS, SW, AGKM, MRNK provided critical appraisal of the manuscript. All authors critically revised and approved the manuscript.

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COMPETING INTERESTS

None declared.

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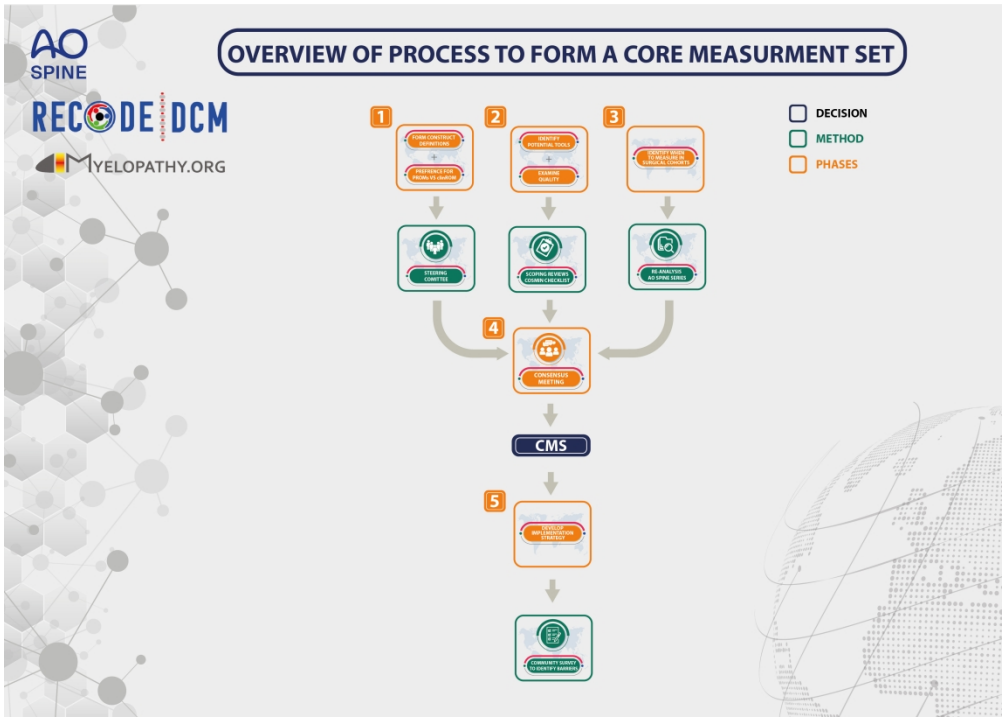

Figure 1. Overview of the CMS process.

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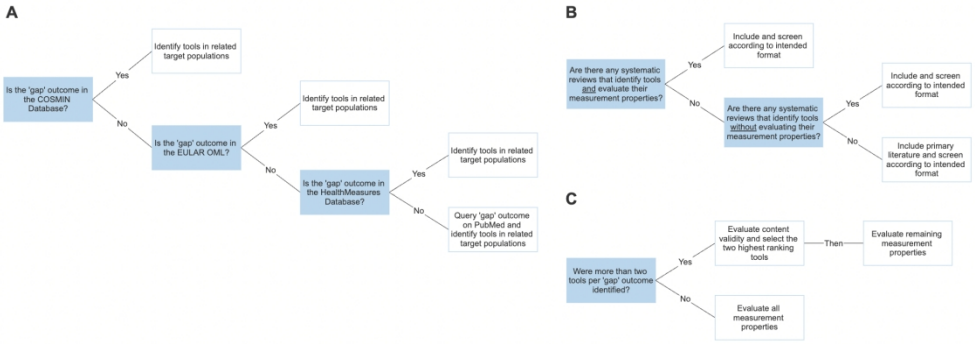

Figure 2. Decision tree schematic illustrating the targeted scoping review process. (A and B) Stage 1: Selection of databases for identification of tools outside DCM (A) and screening of tools outside DCM (B). (C) Stage 2: Evaluation of measurement properties.

SUPPLEMENTARY INFORMATION

Supplementary Table 1. Inclusion and exclusion criteria for the systematic review.

Inclusion	Exclusion
Publication type	
• Article written in English • Primary clinical research articles	• Article not written in English • Conference abstracts or posters • Editorials, commentaries, opinion papers or letters • Book chapters or theses
Study type	
• Study includes primary clinical data	• Study uses only secondary data • Case reports • Narrative reviews • Systematic reviews • Meta-analyses
Populations	
• Human studies	• Non-human studies
Indications	
• Exclusively DCM (CSM, ossification of the posterior longitudinal ligament, cervical stenosis, spondylosis, spinal cord compression, cervical myelopathy)	• Populations with DCM and at least one other condition (e.g., radiculopathy)
Comparator	
• At least one assessment tool from (1-3)	
Outcomes	
• At least one psychometric property • At least one MCID or SCB	

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