Pre-read Materials

REsearch objectives and COmmon Data Elements for Degenerative Cervical Myelopathy (RE-CODE DCM)

AOSpine RE-CODE DCM Kick-off meeting

16 April 2019

RE-CODE DCM

James Lind Alliance
Priority Setting Partnerships

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James Lind Alliance
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Setting up a Priority Setting Partnership
Some questions answered

This is a summary of the steps involved in establishing a James Lind Alliance (JLA) Priority Setting Partnership (PSP). If you are interested in setting up a PSP, it is essential that you read the JLA Guidebook at www.jla.nihr.ac.uk.to familiarise yourself with the detailed JLA process.

What is the JLA?

The JLA is a non-profit making initiative, established in 2004. It brings patients, carers and clinicians together in PSPs. These PSPs identify and prioritise evidence uncertainties, or unanswered questions, that they agree are the most important. The aim of this is to help ensure that those who fund health research are aware of what really matters to the people who need to use the research in their everyday lives. The coordination of the JLA is funded by the National Institute for Health Research (NIHR) and the JLA team is based at the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) at the University of Southampton.

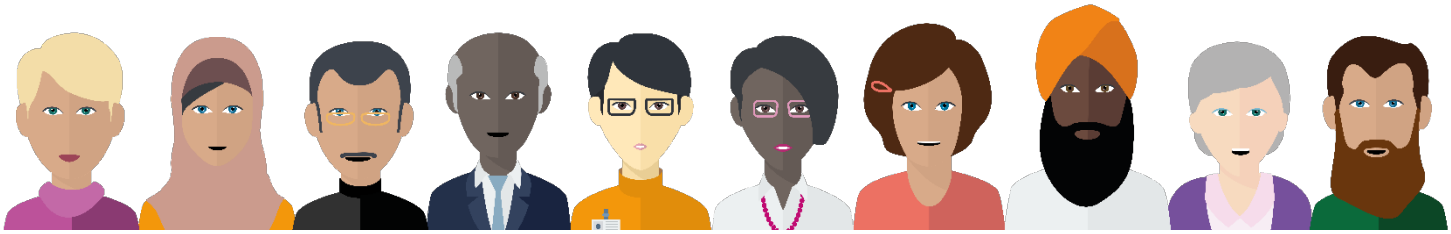
Groups wishing to initiate a PSP will submit a Readiness Questionnaire to the JLA. The JLA coordinating team reviews the questionnaire to ensure that appropriate preparations and resources are in place to complete the PSP successfully. A JLA Adviser is then allocated to chair and advise the PSP. The PSP contracts directly with the JLA Adviser and pays for the JLA Adviser's time.

You can ask for a copy of the readiness questionnaire by emailing jla@soton.ac.uk

What are the principles of JLA priority setting?

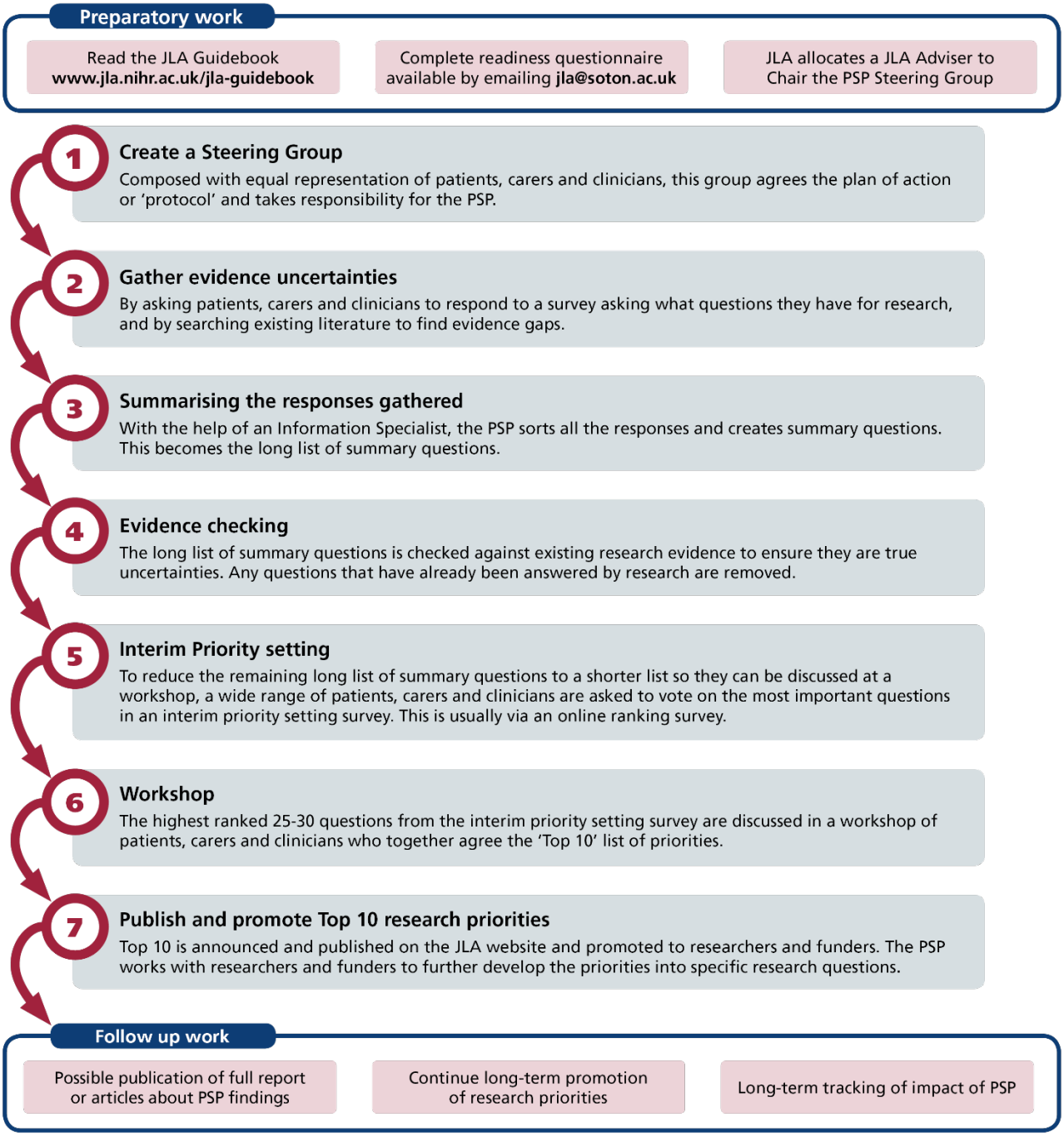
PSPs enable clinicians, patients and carers to work together to identify and prioritise important evidence uncertainties that could be answered by research. To ensure consistency and maximum learning, the JLA asks PSPs to demonstrate the following features:

- transparency of process
- balanced inclusion of patient, carer and clinician interests and perspectives
- exclusion of non-clinician researchers for voting purposes (they may be involved and helpful in all other aspects of the process)
- exclusion of groups/organisations that have significant competing or commercial interests, for example pharmaceutical companies
- audit trail of original submitted uncertainties, to final prioritised list
- priority setting only commencing after the uncertainties have been formally verified as unanswered.



What is the PSP process?

Below is a diagram representing the stages of a PSP. A detailed explanation is in the JLA Guidebook.



What is in the online JLA Guidebook?

It is essential to read the Guidebook early in the planning stages of the PSP. The Guidebook is a practical guide to all of the steps involved in running a PSP. It includes helpful templates and ideas, including:

- Templates for use when setting up a Steering Group
- Examples of methods and questionnaires used by previous PSPs for gathering uncertainties
- Methods and questionnaires that PSPs have used for interim priority setting
- Templates for reporting methods and results on the JLA website
- Examples of how PSPs have promoted their final list of research priorities.

Shaping the scope of the PSP

The Steering Group needs to define the PSP's scope. Scope may be defined by the patient population of interest (e.g. adults and or/children) or the breadth of the condition or health area and its unique issues. It is important to consider the scope of the PSP in terms of the resources available. A PSP with a broad remit, such as Sight Loss and Vision or Palliative and end of life care, may be likely to gather more uncertainties, which will increase the time and resources required to process the responses, compared with a PSP with a more focussed remit. The scope of the PSP might also have implications for type and amount of evidence to be checked.

The JLA website gives details of the current and completed PSPs, showing their scope and health areas. In the Guidebook, you will find examples of the numbers of people who responded to the initial survey and the number of uncertainties submitted to different PSPs.

What are evidence uncertainties?

Evidence uncertainties are questions about healthcare that cannot be answered by existing research. These might be questions about particular treatment options, methods of care, or diagnostic tests. The JLA definition of an evidence uncertainty is that:

- No up-to-date, reliable systematic reviews of research evidence addressing the uncertainty exist.
- Up-to-date systematic reviews of research evidence show that uncertainty exists.

Many PSPs now extend their scope beyond identifying and prioritising simply 'treatment uncertainties' and include other healthcare interventions like prevention, diagnosis, rehabilitation, care, and service organisation and delivery. The JLA recognises that a systematic review may not always be the best source of evidence for every topic area or type of uncertainty. Many of these other areas will require different evidence checking, extending beyond searching for systematic reviews.

How are evidence uncertainties gathered?

Uncertainties usually come from four main sources – patients/service users, carers, clinicians and existing guidelines and systematic reviews. Typically, patients, carers and clinicians are asked to submit their unanswered questions via an online survey, with paper questionnaires provided where requested. Other methods should be considered if a survey is not appropriate for all audiences. One of the key roles of the Steering Group is to identify how to communicate the survey to as wide a range of patients, relatives, carers and health and care professionals as possible. Social media, press releases, contacts of the Steering Group, the PSP website, and contacts with professional and patient organisations are all good ways of communicating the survey.

How are survey responses turned into uncertainties?

The questionnaire used to gather unanswered questions is open-ended, to encourage responses from a wide range of people. Responses are therefore qualitative and can be complex and personal. The Information Specialist (who processes the information on behalf of the PSP) will pick out the unanswered questions from the survey responses and review whether they are within the scope of the PSP, referring to the Steering Group for agreement. The Steering Group should consider how to deal with questions received that are outside the scope of the PSP (and those which are already answered) as these may still be important. The Information Specialist, working closely with the Steering Group, will form summary questions from all the responses, ensuring the summary questions remain true to the original responses received.

The summary questions must be checked against existing research evidence to ensure they are unanswered before prioritisation can begin. This is one of the most labour-intensive stages of the JLA process and the Steering Group needs to identify how it will be resourced and actioned. How the evidence will be checked will be agreed by the Steering Group and set out in the Evidence Checking Form, which will be published by the Steering Group to ensure transparency of process.

Any questions that are shown to be answered during the evidence checking process can be deemed as not requiring further research and can be removed from the process. Questions that cannot be answered by existing evidence can go forward into the prioritisation process. At the end of this process, the PSP will have a long list of summary questions that are ready to go into the next phase of the PSP.

How are the uncertainties shortlisted for discussion at the prioritisation workshop?

In order to reduce the long list of summary questions into a shorter list to be discussed at a final prioritisation workshop, the questions go into an interim priority setting exercise. This usually takes the form of an online survey of patients, carers and clinicians who are asked to rank, from their point of view, the most important questions. The highest-ranking 20-30 questions from this exercise are then taken to the prioritisation workshop for discussion. Examples of how PSPs have done interim priority setting are available in the JLA Guidebook.

What happens at the prioritisation workshop?

At the final prioritisation workshop, a group of patients, carers and clinicians come together and share their knowledge and experience to discuss the 20-30 highest-ranked questions and agree together the Top 10 list of priorities for research. The day follows a standard JLA format consisting of a mix of plenary and small group discussion sessions. The PSP's JLA Adviser chairs the workshop, and two further JLA Advisers facilitate the small group discussions. By the end of the day, the final Top 10 priorities for research are agreed.

What happens after the workshop?

Using a range of communication tools, the Steering Group should take responsibility for finding ways to disseminate the Top 10 and identifying potential opportunities for funded research, targeting in particular research funders, charities and the research community. The JLA will support this process by passing the list of priorities for consideration to the NIHR research programmes.

Top 10s vary in the way they are worded and presented. They contain questions and topics that matter to patients, carers and clinicians, written in terms that a wide audience can understand. However, they are not usually precisely worded research questions that research

funders can immediately work with. The Steering Group may need to work with funders to discuss the full background to the questions.

Steering Groups are also encouraged to monitor what happens to the research priorities in the long term and, where possible, to keep interested parties updated with details of research that results from the work of the PSP. The JLA website includes examples of research funded as a result of PSPs.

Roles and responsibilities within a PSP

What does the PSP lead do?

The PSP lead is usually the individual or representative of the group who made the initial approach to the JLA to carry out the PSP. This person will work closely with the JLA Adviser and the coordinator or administrator and take overall responsibility for successful completion of the PSP. The PSP lead needs to demonstrate commitment to the process, drive the PSP forward to completion and be able to generate wider stakeholder engagement and enthusiasm across the sector that the PSP will cover.

What does the JLA Adviser do?

The JLA Adviser supports and guides the PSP as a neutral facilitator, ensuring that the process is fair and transparent, with equal input from the perspectives of patients, carers and clinicians. For some PSPs, the first time they need the help of an Adviser will be when they are setting up the first Steering Group meeting. Some PSPs may choose to run an initial awareness meeting to raise the profile of the exercise amongst key stakeholders, and will involve the JLA Adviser at this stage. The JLA Adviser throughout the 12-18 month life of the PSP chairs the PSP Steering Group. JLA Advisers are independent consultants and are paid directly by the PSP.

What does the PSP Steering Group do?

PSPs need a committed and proactive Steering Group. The Steering Group oversees the PSP, organises its activities, and is ultimately accountable for key decisions made about the PSP.

The group must include representatives of patients, carers and clinicians, and these are often members of a charity or professional organisation within the area of the PSP. Members will bring with them knowledge of the condition or health setting, an understanding of the patient population and access to networks of patients, carers and clinicians. Members will need to be fully engaged in the process and have the time to carry out the work involved.

Amongst the tasks that the Steering Group is responsible for are publicising the PSP, overseeing the checking and collating of uncertainties, and taking the final priorities to research funders. There are no rules about how many people should be on a PSP Steering Group, but typically, it is around 12. Too large and it becomes difficult to arrange meetings and make decisions, too small and not all of the required people may be represented.

What does an Information Specialist do?

A PSP needs to be able to manage data. This includes reviewing and sorting survey responses, reviewing existing research evidence, and formulating and presenting summary research questions. In some cases, one Information Specialist has the skills to perform all of the tasks; in other cases, more than one person is needed. The tasks will involve:

- Reviewing and sorting the responses from the initial PSP survey to gather uncertainties

- Categorising the survey responses, then creating clear, formatted summary questions which capture the meaning of the original submissions, and presenting these to the Steering Group for review and agreement
- Checking existing systematic reviews and guidelines or other evidence, to an agreed search strategy, to identify which questions have already been answered and to find any other research recommendations
- Checking for relevant ongoing studies
- Preparing a long list of summary questions for interim prioritisation, ensuring that they are understandable for the patients, carers and clinicians who will be involved in this step and in the final workshop
- Managing a record of all PSP survey data, traceable back to the original survey submissions
- Supplying the PSP's working spreadsheet of summary questions or uncertainties and the prioritised list from the final workshop to the JLA, for publication on the JLA website

The precise amount of time will depend on the number of survey responses and the scope of the PSP but the estimated number of days work for these activities is approximately 25-30 days.

What does the PSP Coordinator do?

Tasks for a PSP Coordinator may include organising teleconferences, Steering Group meetings and the final workshop, which will include recruitment of the individuals attending, writing and following up on action notes and managing communications with stakeholders and the wider community. Depending on skills, this person could also get involved with communication activity such as preparing a website, communicating via Twitter, and producing and publicising the survey and downloading the survey results ready for the Information Specialist.

The amount of time this takes should not be underestimated and could be 1 - 2 days a week across the life of the project, with some periods being busier than others. Some larger PSPs have employed a project coordinator for this role, other smaller groups have been supported by someone already available in their own organisation.

What are the costs involved in running a PSP?

PSPs need to find their own resources for undertaking a PSP. The costs involved in running a PSP can vary considerably. Many of the costs depend on the in-house knowledge and resources of the PSP, the help that can be provided in kind by Steering Group members and other supporters and the scope of the PSP. As a guide, the JLA has a spreadsheet of indicative costs, based on examples from previous PSPs. Funds may come from one main organisation or charity or a number of partners in the PSP may make smaller contributions. If supporters of your PSP can provide, for example, administration support, meeting rooms and catering, or the time of an Information Specialist, at no cost, then overall PSP costs will be kept to a minimum.

If you have any questions, please email us at jla@soton.ac.uk

2. AOSpine RE-CODE DCM Priority Setting Partnership - Term of Reference

Priority Setting Partnerships

AOSpine RE-CODE DCM Priority Setting Partnership

Steering Group – Terms of Reference

09 April 2019

This document sets out the Terms of Reference for the Steering Group of the James Lind Alliance AOSpine RE-CODE Degenerative Cervical Myelopathy (DCM) Priority Setting Partnership. The Steering Group coordinates the Priority Setting Partnership (PSP) and organises its activities.

The Steering Group must include representatives of patients, carers and clinicians. These may be members of a charity or professional organisation within the area of the PSP. Members will bring with them knowledge of the condition, an understanding of the patient, carer and clinician populations and access to networks of patients, carers and clinicians. Members will need to be fully engaged in the process and have the time to carry out the work involved.

The background and wider aims and responsibilities of the AOSpine RE-CODE DCM PSP are set out in its Protocol.

Introduction to the James Lind Alliance and priority setting

The James Lind Alliance (JLA) is a non-profit making initiative which was established in 2004 with the aim of enabling groups of patients, carers and clinicians to work together to agree priorities for health research. The JLA facilitates PSPs in particular health areas.

Each PSP consists of patients, carers and their representatives, and clinicians, and is led by a Steering Group. Collaboration between patients, carers and clinicians to set the research agenda is extremely rare, but vital in drawing issues to the attention of research funders that might not otherwise be suggested or prioritised.

The role of the PSP is to identify questions that have not been answered by research to date, and then to prioritise these. The first stage is to ask patients, carers and clinicians, often via an online survey, for unanswered questions about Detecting DCM, Managing DCM; Living with DCM and other questions about DCM that do not fit into the provided categories. These questions are then assessed to check they are in scope for the PSP, and are checked and verified as true uncertainties. An interim prioritisation exercise then takes place, before a priority-setting workshop is convened where participants debate and finally arrive at a Top 10 list of research priorities.

The eventual aim is to turn these priorities into research questions, and for members of the Steering Group to work with researchers and research funders to obtain funding for that research.

The AOSpine RE-CODE DCM Priority Setting Partnership

Membership of the Steering Group

The Steering Group membership must be a balance of patients, carers and professionals.

It is agreed that for the AOSpine RE-CODE DCM PSP, two patient/carer representatives and four healthcare professionals will need to be present in order for Steering Group meetings to go ahead and for decisions to be made.

Role of Steering Group members

Steering Group members are asked to contribute, as a minimum, their expertise and their time, and to be prepared to approach their established contacts and networks.

All Steering Group members are asked to commit to working according to the JLA principles:

- Inclusivity: working with other members respectfully and constructively and ensuring the full range of patient, carer and clinical stakeholder are involved in the PSP process
- Equality: patients, carers and clinicians, and the knowledge and experience they bring, are of equal value to the PSP
- Fairness and transparency: declaring any personals interests, and ensuring decisions and activities are documented openly
- Evidence based: ensuring the work of the PSP recognises the existing knowledge based for Degenerative Cervical Myelopathy and contributes to this through the PSP's evidence checking and open publication of information from the PSP.

Specifically, Members of the AOSpine RE-CODE DCM Steering Group will:

- Take part in monthly Steering Group teleconference calls
- Publicise the initiative to potential partners to encourage them to join the PSP. This includes advising on membership of the PSP (to ensure a wide and representative group of patients, carers and clinicians) and emailing contacts to invite them to participate
- Agree on the content of the survey to be completed by patients, carers, the public and healthcare staff
- Identify and work with a wide range of partner organisations to circulate the survey widely to patients, carers, the public and healthcare staff
- Publicise and participate in an initial kick-off meeting taking place on 16 April 2019
- If unable to attend, submit comments ahead of the meeting. Where a Steering Group member is unable to attend a meeting, decisions made at the meeting will be respected
- Respond promptly with feedback on project materials by responding to emails
- Support the collection of evidence uncertainties from patients, carers, clinicians and existing literature, if needed
- Have oversight of the interim priority setting stage
- Agree the final shortlist of questions to be taken to the final priority setting workshop
- Participate in the final priority-setting workshop, which is a one-day workshop in November 2019 to bring together patients, carers and clinicians to debate, rank and agree on the final Top 10 research questions. Please note that not all members of the Steering Group will attend the final priority-setting workshop, allowing space for new participants
- Help publicise the final top 10 uncertainties to the research community

Specific Roles

Chair: The PSP will be chaired by Toto Gronlund, a JLA Adviser. The JLA Adviser also Chairs and runs the final priority-setting workshop. The JLA Adviser's role is to support and guide the PSP, as a neutral facilitator, ensuring that the process is followed in a fair, transparent way, with equal input from patients, carers and clinicians and their representatives.

Lead: Mark Kotter and Benjamin Davis are the leads for the PSP. The Leads work closely with the JLA Adviser and the PSP coordinator to champion the PSP and ensure it is successfully promoted, completed and disseminated to funders.

Coordinator: Olesja Hazenbiller is responsible for the coordination and administration of the PSP. This includes arranging all meetings and workshops, and ensuring that:

- requests for agenda items are discussed with the group
- papers are available at least a week before meetings
- meeting notes are reviewed by the Chair, circulated within two weeks, and reviewed and agreed at the next meeting.

Information Specialist: Lindsay Tetreault is the Information Specialist for the PSP. The role of the Information Specialist is to advise the Steering Group on data management and analysis strategies and agree these with the group. They also review and analyse the data collected, review existing evidence, and help develop the long list of questions, under the guidance and assurance of the Steering Group. The outputs delivered by the Information Specialist will be approved by the Steering Group.

Declaring interests

Steering Group members are asked to declare any interests relevant to the AOSpine RE-CODE DCM PSP. The JLA provides an example form, and the interests of each member will be shared among the group. This is to encourage a culture of openness and transparency. Relevant interests may be professional, personal or related to an interest in or involvement in clinical research.

Researchers may sit on the Steering Group if the group feels this is appropriate and useful – the JLA Adviser will ensure that they do not have an undue influence on the outcome. Researchers who are currently clinically active may participate in the priority setting if they declare their interests.

Timescales

The AOSpine RE-CODE DCM PSP first Steering Group meeting will be on 16 April 2019. We propose that the final priority-setting workshop takes place on 20 November 2019 in New York, USA.

3. PROTOCOL

RE-CODE DCM: **RE**search objectives and **C**ommon **D**ata **E**lements for **D**egenerative **C**ervical **M**yelopathy

A consensus process to improve research efficiency in DCM, through establishment of a standardised dataset for clinical research and the definition of the research priorities.

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Key words:

Cervical, Myelopathy, OPLL, Spondylosis, Disc Herniation, Cervical Stenosis, protocol, outcome, dataset, Core outcomes in effectiveness trials (COMET), James Lind Alliance (JLA), research priorities, Delphi, consensus, audit, surveillance, common data elements (CDE)

Running title:

Standardisation for degenerative cervical myelopathy research: a consensus process

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The views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health.

Abstract

Study Design:
Mixed-method consensus process
Objectives:
Degenerative cervical myelopathy (DCM) is a common and disabling condition that arises when mechanical stress damages the spinal cord as a result of degenerative changes in the surrounding spinal structures[1]. RECODE-DCM [Research Objectives and Common Data Elements for Degenerative Cervical Myelopathy] aims to improve efficient use of health care resources within the field of DCM by using a multi-stakeholder partnership to define the DCM research priorities, to develop a minimum dataset for DCM clinical studies and confirm a definition of DCM.
Methods:
This requires a multi-stakeholder partnership and multiple parallel consensus development processes. It will be conducted via 4 phases, adhering to the guidance set out by the COMET and JLA initiatives. Phase 1 will consist of preliminary work to inform an online Delphi processes (Phase 2) and a consensus meeting (Phase 3). Following the findings of the consensus meeting, a synthesis of relevant measurement instruments will be compiled and assessed as per the COSMIN criteria, to allow recommendations to be made on how to measure agreed data points. Phase 4 will monitor and promote the use of eventual recommendations.
Conclusions:
RECODE-DCM sets out to establish for the first time an index term, minimum dataset and research priorities together. Our aim is to reduce waste of healthcare resources in the future by using patient priorities to inform the scope of future DCM research activities. The consistent use of a standard dataset in DCM clinical studies, audit and clinical surveillance will facilitate pooled analysis of future data and, ultimately, a deeper understanding of DCM.

Introduction

Degenerative cervical myelopathy (DCM) is a common and disabling disorder. It arises when degenerative changes in the surrounding spinal structures exert mechanical stress on the spinal cord and trigger a progressive injury [1]. Such degenerative changes include disc herniation, osteophyte formation, ligament hypertrophy or ossification [2]. Patients may initially experience minimal symptoms [3,4], but subsequently often develop pain, sensory deficits especially affecting their hands and feet, spasticity, imbalance, bladder symptoms, and experience frequent falls [1]. Left untreated DCM can lead to spastic tetraparesis [5]. A recent study investigating quality of life in DCM patients, indicated they suffer amongst the worst SF36 health scores of all chronic diseases [6].

Due to widespread under-diagnosis the true incidence and prevalence of DCM is unknown. Current epidemiological studies quote the lifetime prevalence of DCM in the region of 0.5/1000 [7]. However indirect experience suggests this is an under-estimation [1]. For example, in a recent study of 181 healthy volunteers aged between 40 and 80, radiological features of DCM were seen in 59%, and diagnosis of DCM had been made in only 1% of cases [3]. Observational studies have demonstrated that up to 22% of people with asymptomatic spinal cord compression will go onto develop DCM. [8,9] As a degenerative pathology, the incidence is expected to rise with aging populations.

Surgery aimed at decompressing the spinal cord is the mainstay of treatment [10]. This is able to induce limited improvements across a number of outcome domains [11]. However, owing to the limited intrinsic regenerative capacity of the spinal cord [12], few patients make a complete recovery [13]. As a consequence, most patients suffer life-

long disability.

Over the past 20 years, clinical research on DCM has significantly increased *(Mowforth et al, Under review).* This has clarified some basic tenets with regards to the understanding and treatment of DCM, but many questions remain unanswered, including fundamental aspects of DCM pathology, the contribution of genetic predispositions, as well as mechanisms by which DCM could be prevented and recovery improved [14,15].

Lack of patient involvement in the design of research risks it not addressing patient needs

In recent years, the importance of involving patients in the design of research has become apparent. The term “research wastage” was coined for research which does not result in healthcare benefits for patients. In their seminal series, Chalmers et al (2014) estimated that of the $240 billion invested in North American healthcare research during 2010, 85% was misspent [16]. They identified a number of key contributory factors including (1) missing or ineffective research synthesis (e.g. systematic review), leading to research duplication, and (2) misalignment of researcher and end-user objectives. These are equally applicable with DCM.

Inconsistent reporting of research findings compromises research synthesis

Efficient research synthesis requires three things: matched variables, reported in the same manner and easily identifiable studies. Recent systematic reviews indicated that clinical trials in DCM do not use the same outcome measures or reporting style [17]. Whilst some discrepancies can be overcome by acquiring the original data, this is time-consuming, rarely straightforward and often not possible [18]. Moreover, the interpretation of any pooled outcomes must also consider the comparability of the

studied population and the trial methodology. In DCM this is particularly pertinent due to the recognition that baseline characteristics are important predictors of response to treatment [19,20]. This reporting is also inconsistent [21]. Consequently, studies are often excluded [11].

DCM lacks an index term that enables efficient literature searches

'*DCM'* (Degenerative Cervical Myelopathy) has recently been introduced as an umbrella term for a number of degenerative conditions of the spine that result in cervical myelopathy [22]. Whilst there has been good uptake within the medical literature since its introduction, cervical myelopathy in its various etiologies lacks a recognized ICD [International Classification of Disease] diagnostic code, Medical Subject Heading [MeSH] for MEDLINE or equivalent grouping index term. Moreover, key search terms are not unique: myelopathy can be caused by a range of other conditions, degenerative pathology of the spine can occur in the absence of DCM, and the surgical treatments can be applied to other spinal conditions. This complicates literature searches and research synthesis [23].

Limited involvement of patients in DCM research design may lead to misalignment of research

A recent survey, conducted through Myelopathy.org, an international charity for those working with or directly affected by DCM, explored the recovery priorities of individuals suffering from DCM. The responses to the questionnaire indicated that next to walking and hand function, which are often used as a study outcomes [17,24], the number one priority was the resolution of pain *(Davies et al, underreview)*. In contrast to patient responses, pain is however infrequently assessed in DCM trials and reported by less than 25% of studies [17,21].

In order to enable more efficient research synthesis and to align research with patient needs, global initiatives have been formed that aim to develop standards for researchers. These processes use a multi-stakeholder consensus process to solicit knowledge, experience and judgement from stakeholders with a broad range of direct interest on a particular issue and derive shared and relevant agreement. Stakeholders are defined as *"individuals, organizations or communities that have a direct interest in the process and outcomes of a project, research or policy endeavor".* [25].

Definition of core outcome variables aid research quality and synthesis

Organizations such as the Core Outcome Measures in Effectiveness Trials (COMET) Initiative promotes the definition of Core Outcome Set (COS), and additional data points (Core Data Elements, CDE). Often standards also define how data points should be measured, referred to as a Core Measurement Set (CMS) [26-28]. Apart from promoting comparability amongst studies, such core outcome sets also reduce reporting bias, a well-recognized issue in clinical research, which leads to under-representation of negative research findings [29].

Definition of priorities help to align research with patient needs

The James Lind Alliance (JLA) is an organization supporting the definition of research priorities [30] by mediating "Priority Setting Partnerships" (PSP), which aim to involve multiple stakeholders, including those affected by the condition, their carers and health professionals.

The significance of these standards is referenced by funding and regulatory bodies, such as the National Institute of Health Research (NIHR) UK, the Food and Drug

Administration (FDA)USA and the European Medicines Agency (EMA), who now seek assurances that proposed studies comply with such policy [29].

RECODE-DCM [Research Objectives and Common Data Elements for Degenerative Cervical Myelopathy]

RECODE-DCM aims to reduce research wastage within the field of DCM by using a multi-stakeholder partnership to define the DCM research priorities, to develop a minimum dataset for DCM clinical studies and confirm a definition of DCM suitable for establishment of a Medical Subject Headings (MeSH) index term.

The natural evolution of DCM is unpredictable and current treatments do not alter the underlying degenerative processes. Spinal cord compression may reoccur in individuals who have undergone surgery [1]; consequently, recent international guidelines[10] advocate lifelong surveillance for all patients with DCM. However, the assessments suitable and necessary for follow-up have not been defined. Similarly, benchmarks for audit, to ensure effective practice, have not been established. It is anticipated that the principal findings of RECODE-DCM can be used to make such recommendations. As a secondary objective, RECODE-DCM therefore aims to support clinical practice, by defining clinically relevant subsets of CMEs for clinical audit and clinical surveillance.

Methods

RECODE-DCM seeks to bring together stakeholders with lived or professional experience from all phases of DCM clinical care, including diagnosis and work-up, surgical treatment, non-operative treatment, rehabilitation and long-term follow up in order to establish a COS, CDE, CMS and PSP for use in DCM clinical research and routine practice. The key objectives are as follows.

1) To achieve consensus between key stakeholder groups on the choice and definition of the umbrella term specific to this condition (index term)
2) To establish the top 10 research uncertainties (PSP)
3) To determine which outcomes are applicable and relevant for use in clinical efficacy studies of patients with a diagnosis (COS)
4) To determine which additional data elements are required for the robust interpretation of outcomes (CDE)
5) To determine how to measure agreed data points (CMS)

On this basis, the project also aims to make a pragmatic recommendation of which data points and measurement tools should be used in routine care to enable clinical audit and DCM clinical surveillance. The challenge will be ensuring a valid and comprehensive set, easily deliverable in routine care.

The overall delivery of the project will be overseen by a steering group, who will meet at least twice a year in addition to interim correspondence. Each meeting will include at least *2* people with lived experience and 4 professionals present to be considered quorate. Where a steering group member is unable to attend a meeting, decisions made at a quorate meeting will be respected. The day to day administration of RECODE-DCM will be overseen by a sub-committee, referred to as the management group. These groups will ensure representation from those with lived and professional experience of DCM, and in addition the steering group will have representation from the identified key professional subgroups. This process is registered with the COMET and JLA initiatives [31].

The recommendations of supporting organisations, such as NINDS, OMERACT, COMET and JLA, alongside the reported experience of completed processes have been incorporated into the following protocol.

RECODE-DCM can therefore be considered as a number of different, but interlinked work streams ( ). The index term will be established using a Delphi process. The PSP will use the Delphi process to inform a final and separate, face-to-face consensus meeting. The COS will be established on the basis of systematic reviews and qualitative interview work to inform an online Delphi process and final face-to-face consensus meeting. Similarly, the CDE will be established using systematic reviews to inform an online Delphi process and a final face-to-face consensus meeting. The CMS will be established using systematic reviews and the final COS, at a face-to-face consensus meeting. Based on the findings of these phases, the steering group will produce a pragmatic, distilled version or versions of the COS/CDE for use in clinical audit and clinical surveillance.

We will streamline the process into four phases (Figure 1): phase 1 will consist of preliminary work, including a systematic review and qualitative interviews for the COS and CDE. In phase 2 the Delphi process will take place. Phase 3 will incorporate the consensus meetings, and a final phase 4 will monitor and promote the dissemination and use of the eventual recommendations.

RECODE-DCM Work Streams

Each work stream will be discussed in turn. The components are outlined in Table 2. Concepts specific to multiple processes, such as the recruitment to and administration of the Delphi process or consensus meetings, are outlined subsequently.

(1) Definition of an Index Term

The index term will be established using the online Delphi. A definition of DCM, developed by the steering group, will be presented to stakeholders. Stakeholders will have the option to approve or disagree with the definition. Those who disagree, will be required to provide their reasoning, including definition amendments or alternative terms. If agreement is not reached, further rounds will follow.

(2) Definition of research priorities: The Priority Setting Partnership (PSP)

The PSP sets out to establish the research uncertainties for DCM. There is no limitation on the type of DCM patient or phase of care. It will be established using an online Delphi process and a final face-to-face consensus meeting. This will be overseen by a JLA advisor.

Delphi

Round 1: Stakeholders will be asked to list their research priorities and include a justification for their reasoning. To help prompt respondent reflection, priorities will be sought in relation to the following themes: diagnosis, treatment, long-term care and other. There will be no limit on the number of uncertainties that can be submitted.

Data Processing: The results will then be processed. Firstly, research uncertainties will be grouped thematically, to identify and remove duplicates. The unique uncertainties will then be processed using the JLA Data Management Template, to identify if they are true uncertainties (i.e. not already answered through systematic review and termed ‘unrecognised knowns’) and refine the information provided into

an indicative (summary) question. This information will then be reviewed by the PSP steering group, where out of scope suggestions will be removed from the process and indicative questions refined as applicable. Where possible, out of scope uncertainties will be addressed separately, for example, through dissemination to relevant organizations, or separate research studies. It is intended a maximum of 60 uncertainties will be presented in the second round of the Delphi. If more than 60 have been generated, this will be refined by the steering group, prioritizing those specific uncertainties, or uncertainties within themes, raised in round 1, overall and by stakeholder group.

Round 2: Following the collation and refinement, the research uncertainties, now in the form of indicative questions, will be re-presented to stakeholders, who will be asked to select their top 10. Research uncertainties will be randomized to prevent ordering bias.

Data Processing: The 20-30 research uncertainties most frequently included in a top 10 will be taken forward to the consensus meeting. Subgroup analysis, per stakeholder group, and using GRADE ratings, will be undertaken to identify any popular uncertainties not yet included, for example, those prevalent amongst individuals with lived experience, but not professionals. The steering group will review this data and the final list of uncertainties for inclusion in the final consensus meeting.

PSP Consensus Meeting: 'Priority Setting Workshop'

A face to face consensus meeting will be held and facilitated by JLA advisors, in order to select the final top 10 research priorities. The complete audit trail from

original data, to final indicative uncertainties will be kept and made publicly available on the JLA website.

(3) Definition of a Core Outcomes Set (COS)

The COS is primarily intended for use in clinical efficacy studies of health interventions for use in DCM care. It will be established using systematic reviews and qualitative interview work to inform an online Delphi process and a final face-to-face consensus meeting.

Systematic Review

A systematic review of outcome reporting in DCM has already been conducted [17]; in short a broad search of MEDLINE and EMBASE, using the search strategy 'Cervical' AND 'Myelopathy' was undertaken for prospective clinical trials of more than 50 patients, and retrospective clinical trials of more than 200 patients, between the years of 1995 and 2015, assessing DCM exclusively. The reported outcomes were collated and presented with reference to their frequency and chosen measurement instrument. The author group categorized the reported outcomes by discussion and mutual agreement, into the following domains: function, pain, complications, quality of life, imaging and other.

Qualitative Interviews

Individuals with DCM and their caregivers will be invited to attend a patient and public involvement day, hosted at the University of Cambridge. Sufferers and their caregivers will participate in separate small group workshops, facilitated by an independent researcher experienced in qualitative research, to ascertain the outcomes of relevance to them. The groups will then be merged, and the findings from these separate workshops shared. The concept of outcome domains will then

be outlined, and the combined group tasked with developing a category system for their defined outcomes. All interviews will be audio-recorded and transcribed for analysis.

Delphi

Domains identified by the systematic review and from the sufferer and supporter workshop will be reviewed by two researchers and someone with lived experience, to define the key grouping themes. Outcomes identified from the systematic review, and through content analysis of audio transcripts will then be mapped to a domain, having removed duplicate or overlapping terms. Where there is uncertainty over relevance or duplication, terms will be discussed amongst the project management group, including a least one representative with lived experience and a healthcare professional. Outcomes will then be put forward into a two round online Delphi. These will be described using both lay and medical terminology, after having been piloted amongst a small working group involving both those with lived and professional experience.

Round 1: Participants within the COS Delphi will initially be introduced to the process using plain English summaries, available from COMET. Stakeholders will be presented with the list of outcomes, grouped within each predefined outcome domain and randomized to prevent ordering bias. GRADE rating will be completed. Stakeholders will be offered the opportunity to explain their reasoning and suggest other outcomes. New outcomes will be reviewed by the project management group, and if not already represented and within scope, will be coded. Out of scope suggestions will be removed from the process but retained separately and addressed as appropriate, for example, via future studies, quality control projects or dissemination to relevant organizations.

Round 2: Stakeholders will then complete the survey again, for variables without consensus or newly suggested outcomes, including feedback from round 1. Specifically, they will be able to review their scores: overall scores and score per category of stakeholder for outcomes presented in the first round. Any explanatory statements given in round 1 will be summarised and reported. Outcomes will then be rated using the GRADE system.

COS Delphi: Definition of Consensus

Outcomes meeting the Delphi consensus criteria (Table 3) will be included in the COS. Outcomes meeting the definition for exclusion will be removed, and the remaining outcomes will be taken forward to the consensus meeting. Variables can be included directly from the results of round 1, but only excluded after round 2 of the Delphi process.

COS Consensus Meeting

Outcomes not yet included or excluded will be reviewed at a face-to-face consensus meeting. Each outcome will be reviewed in turn, with the feedback results from round 2 of the Delphi presented to participants for reference. Following discussion, participants will vote for inclusion, using the same GRADE profiling and consensus criteria (Table 3). If consensus for inclusion or exclusion is not established, further discussion will follow, and a second round of voting will occur. For the second round, a threshold for inclusion of ≥60% score 7-9 and ≤20% score 1-3 will be set. If consensus is not reached after two rounds, the outcome will not be included in the COS.

The overall objective is to develop a COS with 10 or fewer outcomes, with at least one outcome amongst the core areas of adverse events, life impact and pathophysiological manifestations. These core areas were chosen as relevant to DCM from the care areas defined by OMERACT. [32] If the *a priori* definition leads to the inclusion of too many outcomes, a nominal group technique will also be used to refine the list of outcomes, to establish an overall top five, and a top two to three for professionals and those with lived experience.

(4) Definition of Common Data Elements (CDE)

The CDE is primarily intended for use in clinical efficacy studies of health interventions for use in DCM care. It will be established using systematic reviews to inform an online Delphi process and final face-to-face consensus meeting. The systematic review work has been completed.

Systematic Review

A systematic review of baseline reporting in DCM clinical trials has been completed, using the aforementioned systematic search strategy [21]. The baseline reporting of outcome measures will be excluded, as these will be captured by the COS; CONSORT statements require outcome measures to be reported before and after intervention [33]. The remainder will be used to inform the Delphi process and referred to as data elements. These will be arranged into convenient subgroups, as defined by the project management group.

Delphi

Round 1: Participants within the CDE Delphi will initially be introduced to the process using plain English summaries. Stakeholders will be presented with the list of data

elements, grouped as outlined above, randomized to prevent ordering bias. Stakeholders will be asked to consider whether or not a data element is essential for the evaluation of a DCM patient in order to make a decision as to the appropriate treatment. GRADE rating will be completed. Stakeholders will be offered the opportunity to explain their reasoning and suggest other data elements not listed.

New data elements will be reviewed by at least two members of the research team, and coded if not already represented and within scope.

Identified data elements will be cross-referenced with the existing literature for their significance in outcome interpretation, using references such as the recently updated systematic reviews by Tetreault et al (2018) on prognostic factors in DCM care [20] or disease progression [34]. Based on the literature, and following discussion amongst the management group, each data element will be assigned a certainty rating, as established by GRADE. [35]

Round 2:

Stakeholders will then complete the survey again, for identified data elements, including feedback from round 1. Specifically, they will be able to review their scores, overall scores and score per category of stakeholder for each data element in the first round. They will also be presented with a certainty rating, if such literature has been identified and a rating assigned. Any explanatory statements given in round 1 will be summarised and reported. Elements will then be rated using the GRADE system.

CDE Delphi: Definition of Consensus. Data elements with moderate or high certainty of influencing outcome interpretation will be included in the CDE. Data elements

meeting the definition for exclusion will be removed, and the remaining elements will be taken forward to the consensus meeting. Consensus will be assessed at the end of round 2 only.

CDE Consensus Meeting

Data elements not yet included or excluded will be reviewed at a face-to-face consensus meeting. Each element will be reviewed in turn, with the feedback results from round 2 of the Delphi presented to participants for reference. Following discussion, participants will vote for inclusion, using the same GRADE profiling and consensus criteria. If consensus for inclusion or exclusion is not established, the data element will not be included in the CDE, i.e. only one round of voting will take place for data elements.

(5) Definition of a Core Measurement Set (CMS) and Subsets for Clinical Practice

Systematic Review

A synthesis of relevant measurement instruments will be compiled. This will build on previous work [17,36] and will include an assessment of their measurement properties, as per the COSMIN (**CO**nsensus-based **S**tandards for the selection of health **M**easurement **IN**struments) criteria, for use in DCM. The COSMIN search filter [37], including our own filter for DCM research [23] will be used to facilitate this process.

CMS Consensus Meeting

This information will be presented to the steering group in a subsequent and separate meeting, although additional meetings may be required. The objective of this meeting will be to select the most appropriate instrument(s) for data points included in the CDE and COS. A secondary objective of this project is to develop a refined list of data

points from the CDE and COS suitable for clinical audit and surveillance. Clearly this in itself could be a separate multi-stage consensus process, however pragmatically this is not possible. Therefore, it will be left to the steering group to establish this shortlist. Their decision will be informed by the final CDE and COS, including the quantitative data from the Delphi process and Consensus Meeting.

The Delphi Process

To improve efficiency, and reduce attrition amongst stakeholders, participants will be recruited to a single Delphi process. However, in order to reduce the burden on respondents, and avoid confusion, participants will ideally be randomized to one of three parallel processes: CDE, COS and PSP. All strata will include assessment of the index term.

Stakeholders

Currently, there is no standard method for Delphi recruitment nor a required stakeholder number. A fair representation of all parties involved, world-wide, is thought to be key to deriving an applicable and transferable consensus. This includes involvement of participants from low and middle income countries. The significance of patient involvement has already been outlined, and on that basis, we will aim for a 1:1 ratio of participants with lived experience to professionals.

Our recent diagnostic pathway analysis for the East of England, UK identified the key professional groups involved in providing DCM care [38]: the majority (98%) of patients underwent initial consultation with a general practitioner, before referral to secondary care. Secondary care assessment was mainly via neurology (45%) or a physiotherapy

triage service (45%), although other specialties including rheumatology, geriatric medicine and acute medicine were involved. Most (98%) of patients received a treatment plan from a spinal surgeon. Spinal surgeons play a key role in the field of DCM, as the mainstay of treatment guidelines recommend all patients have a spinal surgery opinion [10], moreover currently they dominate the clinical research field [39]. On this basis, within the professional group we will aim for a 1:1 ratio between spinal surgeons and other professionals (e.g. other clinicians, allied health professionals and researchers).

Sampling

A dedicated study web page will be created, as both an information resource related to the study and the single registration point for participation. This information will outline the role of a stakeholder, including the expected commitment and significance of participation in all Delphi Rounds. Registration will require respondents to provide selected demographics, including age, gender, geographic location and stakeholder group. Respondents will also complete a conflict of interest disclosure. [40] The action of registration may favor continued participation [41], but will also allow live assessment of recruitment strategies and adaptation of strategies if insufficient representation amongst subgroups is found.

Principally, patients will be identified through Myelopathy.org, a DCM Charity and online support community, supported with Google Adwords advertising. We have previously utilized such strategies for the recruitment of DCM sufferers to online surveys. This approach also enables Google Analytics to be used to ascertain efficacy [42].

For each professional subgroup national or international representative bodies will be approached to advertise participation. As a project conducted in English, strategies will focus on English speaking countries, specifically America, Canada, Australia, New Zealand, Ireland, United Kingdom. However, some organizations have a broader reach, for example, the AO Foundation or Cervical Spine Research Society, and recruitment will extend beyond these counties. In addition, key academic influencers will be identified through citation analysis of DCM studies published over the last 5 years, with approaches made to authors having published more than 3 DCM articles in this period. All registered participants will be encouraged to promote the project amongst their colleagues or patients.

Recruitment strategies will principally employ email or social media. Piloted, promotional material will be used to support these recruitment strategies. There are no recommendations for set sample sizes to include in a Delphi study. Instead a pragmatic approach will be taken, prioritizing balance across stakeholder groups.

Administration

Recruited stakeholders will be divided into their matching groups, namely those with lived experience, spinal surgeons and other professionals. The sample size and representation will be reviewed by the steering group. Ideally, stratified randomization will then be undertaken, to ensure three equal groups meeting the predefined criteria [43]. Respondents will remain in the same strata, with no crossover. However if it is felt that there is insufficient representation to allow three parallel Delphi processes, the number of strata may be reduced.

Strategies identified from the literature to reduce attrition between rounds, will be used, including pre-registration, use of plain and clear language, regular updates, transparency regarding time commitments, and personalized reminders [44,45]. Additionally, respondents completing all Delphi rounds will receive a personalized certificate of participation and listing as a collaborator to the RECODE-DCM study [46].

Each list of items within the various Delphi surveys will be accompanied by plain language descriptions, grouped into categories and organised randomly at a category level and item level. All items and descriptions will be reviewed by the steering group and may be piloted or externally reviewed to encourage development of survey language that all stakeholder groups will equally comprehend.

Assessment of each item will largely be using the GRADE process [47]; a 9-point Likert scale where a score of 1 is least important and 9 most important. On occasion stakeholders will be able to make suggestions or justify their answers as free text. The *a priori* consensus definition is defined in Table 3.

The ambition is to complete the Delphi survey as outlined, although if insufficient agreement has been made to facilitate a consensus meeting this may be extended (Figure 2).

Sensitivity Analysis

The respondent rankings and choices will be analysed by sub-group to explore whether subgroups favoured certain selections. Whilst the information will not be used within the eDelphi, at the discretion of the steering group, these findings will be presented at the consensus meeting, to support decision making.

The Consensus Meetings

An international and multi-disciplinary spine conference will provide the platform for a face to face consensus meeting. In addition to healthcare professionals and researchers involved in DCM, patient and carer stakeholders will be invited. The aim is to have a sample which is representative of the larger consensus group, both in stakeholder makeup but also prioritizing individuals who have provided responses approximating the average opinion from the Delphi process. Invitations to the meeting will be orchestrated to ensure fair representation of expertise and demographic but will be weighted to the location of the conference for convenience. Meetings will be facilitated by those with trained experience, specifically for the PSP consensus meeting which will be performed by JLA advisors.

Ethics and Dissemination

Ethical approval for the qualitative interviews, Delphi process and consensus meetings will be sought.

Myelopathy.org, an international charity and online platform for those with the condition, carers and professionals interested in DCM, and AOSpine will host the eventual consensus guidelines. They will act as a portal for supporting information and assistance (if required). The COMET and JLA databases will also be updated, and traditional journal publication sought. A strategic dissemination plan will be developed in concert with a healthcare public relations expert (ES). Following a quality improvement strategy, methods of advertisement and distribution will be evaluated periodically and adapted over a five-year period to track and accelerate uptake of the guidance. Further professional bodies and funding partners will also be involved.

Discussion

The Delphi approach is a proven way of reaching multi-stakeholder consensus

Consensus standards have been reached by a variety of methods, ranging from stand-alone meetings to more complex, multifaceted approaches [48]. Whilst there are some technical differences, both the aforementioned organizations advise a sequential Delphi process to inform a final face-to-face consensus meeting. The Delphi method is well established with regards to the development of consensus guidelines as it facilitates the refinement of multiple opinions into an accepted and applicable recommendation [32,41]. Whilst a PSP has not previously been interwoven with a COS or CDE, their overlapping methodology and the challenges of bringing multi-stakeholder groups together offers an opportunity to meet both important objectives, more efficiently. This will also provide an opportunity to define an index term.

Ensuring adequate representation and participation of stakeholders

Adequate and balanced representation must be present at each stage; within the steering group, the online surveys and the final consensus meeting. Exactly what constitutes a balanced makeup is yet not defined [49]. This applies both to groups, but also the number of representatives per group and the overall weighting or proportions of each group. In the recent COS-STAD guidelines key stakeholder groups were identified as those who would use the CDE, healthcare professionals with experience of the condition and patients and their representatives [49]. The guidelines were not able to define this further, but it is recognized that the makeup will differ depending on the objectives, for example a PSP for breast reconstruction had a large patient weighting which would seem logical as it is a largely 'body image' based outcome [45].

Online surveys are efficient tools to reach stakeholders but suffer from attrition

The majority of information is collated and refined using online surveys. The advantage of this is efficient access to large number of individuals from across the globe. We have recently shown this in DCM [42]. However, particularly if sequential surveys are conducted, there is risk of attrition amongst participants which can lead to an overestimation of stakeholder agreement [41]. There is little published research on strategies to reduce attrition within Delphi surveys but lessons from related processes may be applicable: a Cochrane Review of patient recruitment to one-off electronic questionnaires identified a number of factors which improved response rates, including

the benefit of short surveys [50]. How transferable these findings are to a serial process is unclear. Retention amongst randomized controlled trial patients may be more pertinent, but findings of a Cochrane Review again are not specific to an electronic process [51]. Alternative strategies specific to consensus processes have sought to introduce efficiencies to reduce attrition. For example in CDEs systematic reviews are often used to inform the core domains, and the Delphi process is employed to identify the measurement instruments [52,53]. With regards to PSPs, the JLA recommends the use of the steering group to refine the number of research uncertainties before each stage.

Commonly, a degree of pragmatism is accepted to ensure the project is deliverable [45], but the limitations of adaptations must be noted. The steering group offers important oversight of the process, and therefore must equally offer balanced representation to prevent bias.

Conclusion

We propose an ambitious and comprehensive protocol, designed to deliver recommendations that will shape the direction and improve the efficiency of future DCM research. For the first time, RECODE-DCM will integrate consensus processes to establish an index term, COS, CDE and PSP. Our aim is to improve the use of future resources to deliver efficient research by using patient priorities to inform the scope of future DCM research activities. The consistent use of a CDE in DCM clinical studies, audit and clinical surveillance will facilitate pooled analysis of future data and, ultimately, a deeper understanding of DCM.

Figures and Tables

Figure 1: Structure of RECODE-DCM.

RECODE DCM will be undertaken in 4 phases. Existing systematic reviews (Phase 1) will inform a Delphi consensus process (Phase 2), which in turn will inform a final consensus meeting (Phase 3). It is anticipated the index term can be confirmed using the Delphi process alone. Phase 4 is the dissemination of findings.

Table 1: RECODE-DCM Definitions.

This consensus field is rich with acronyms, often bearing close resemblance in sentiment but different precise meaning. This table lists the acronyms used in this protocol, including a summary (with link out resources where appropriate) of their meaning.

Acronym	Definition	
DCM	Degenerative Cervical Myelopathy	-
MeSH	Medical Subject Heading	MEDLINE is a database of life science publications. MeSH are hierarchically-organized terminology for indexing and cataloguing its contents, to facilitate search.
JLA	James Lind Alliance	http://www.jla.nihr.ac.uk/ A non-profit initiative to support and oversee the establishment of healthcare research priorities
PSP	Priority Setting Partnership	This process is carried out using a collaborative approach of relevant stakeholders referred to as a PSP
OMERACT	Outcome Measures in Rheumatology	www.omeract.org An initative supporting the development of consensus in outcome measurement for arthritis
COMET	Core Outcome Measures in Effectiveness Trials	http://www.comet-initiative.org/ A UK based organisation supporting the development of COS

NINDS	National Institute for Neurological Disorders and Stroke	www.commondataelements.ninds.nih.gov NINDS is the neurological arm of the National Institute for Health, United States. They pioneered and continue to support CDEs for neurological disorders.
COS	Core Outcome Sets	A set of agreed outcome variables and their measures to be reported in clinical trials
CDE	Common Data Elements	A set of agreed variables to be measured and reported in clinical trials
CMS	Core Measurement Set	A set of agreed tools used to measure outcomes or other data elements
COSMIN	COnsensus-based Standards for the selection of health Measurement INstruments	http://www.cosmin.nl/ The COSMIN initiative aims to improve the selection of health measurement instruments, by ensuring instruments have undergone appropriate evaluation
GRADE	Grading of Recommendations Assessment, Development and Evaluation	http://www.gradeworkinggroup.org/ A working group working group who developed a

		transparent approach to grading quality (or certainty) of evidence and strength of recommendations.
eDELPHI	Electronic DELPHI	An electronic system used to deliver the Delphi process over the internet

Table 2: Route to Consensus

Consensus Processes	Consensus Stages / Tools
Index Term	- Delphi
Core Outcome Set (COS)	- Systematic Review + Qualitative Interviews - Delphi - Consensus Meeting
Common Data Elements (CDE)	- Systematic Review

	- Delphi - Consensus Meeting
Priority Setting Partnership (PSP)	- Delphi - Consensus Meeting
Core Measurement Set (CMS)	- Systematic Review (COSMIN) - Consensus Meeting
Clinical Subsets, for Audit and Surveillance	- Consensus Meeting

Table 3: *A Priori* consensus definitions

"Consensus In" will be described as: 1) ≥70% score 7-9 and ≤15% score 1-3, with ≥50% score 7-9 per stakeholder group, 2) Or ≥90% score 7–9 for one stakeholder group (those with lived experience or health care professionals). "Consensus out" will be defined as ≤15% score 7-9 and ≥70% score 1-3, with ≤50% score 7-9 per stakeholder group.

Definition

‘Consensus In’, one of:				
	1)	≥70% score 7-9 and ≤15% score 1-3	**AND**	≥50% score 7-9 per stakeholder group
	2)	≥90% score 7-9 within a single stakeholder group		
‘Consensus Out’				
		≥70% score 1-3 and ≤15% score 7-9	**AND**	≥50% score 1-3 per stakeholder group
‘No Consensus’		Neither of the above criteria are met		

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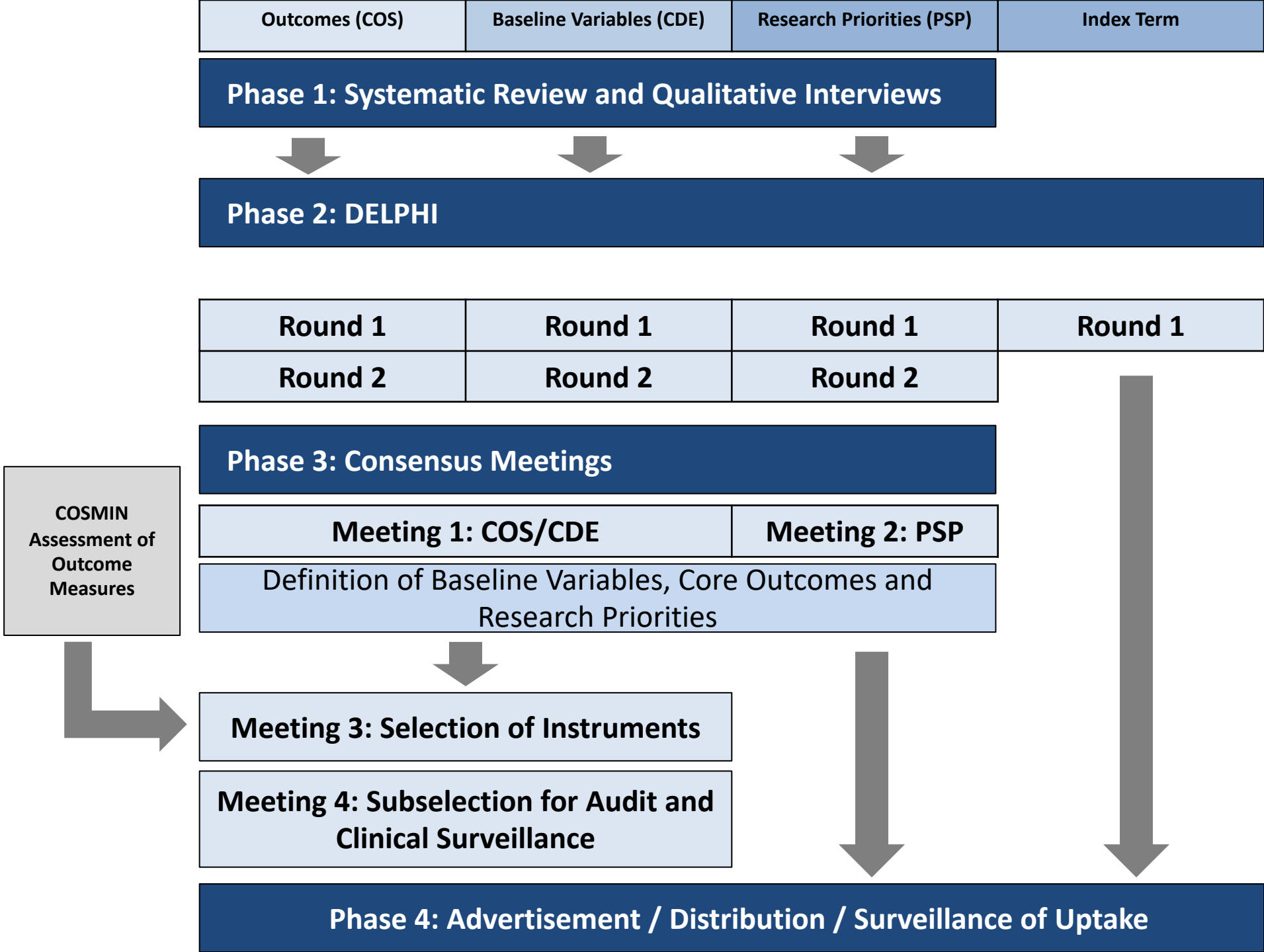
Outcomes (COS)
Baseline Variables (CDE)
Research Priorities (PSP)
Index Term
Phase 1: Systematic Review and Qualitative Interviews
Phase 2: DELPHI
Round 1
Round 1
Round 1
Round 1
Round 2
Round 2
Round 2
Phase 3: Consensus Meetings
COSMIN Assessment of Outcome Measures
Meeting 1: COS/CDE
Meeting 2: PSP
Definition of Baseline Variables, Core Outcomes and Research Priorities
Meeting 3: Selection of Instruments
Meeting 4: Subselection for Audit and Clinical Surveillance
Phase 4: Advertisement / Distribution / Surveillance of Uptake

4. Project Milestones and Key Checkpoints

AOSpine RE-CODE DCM Priority Setting Partnership - Establish the top 10 research priorities in DCM field through a multi SK partnership				
Milestones	**Deadlines**	**Status**	**Steering Committee Checkpoints**	**Comments**
Confirm the steering group	March 2019	completed		Composed with equal representation of patients, carers and clinicans.
Steering Committee Kick-off meeting	April 2019	ready	**x**	Rationale for a Priority Setting Partnership; Scope and Protocol approval; Round 1: Survey to collect uncertainties approval; Dissemination Strategy.
Website launch	April 2019	ready/ approval required	Danyal/Ben	Steering Committee approval required.
Start disseminating Round 1: Survey to gather evidence uncertainties	April 2019	ready/ approval required	Olesja/Ben/JLA advisor	By asking patients, carers, clinicians to respond to our survey asking what questions they have for research, and by searching existing literature to find evidence gaps.
Promote the survey (4 weeks)	May/June 2019	planning	**x**	Social Media, Website, Contact Database, JLA, Steering committee members input.
Summarise responses	June/July 2019		Ben/Infomation Specialist	With the help of an information specialist, all responses are sorted and summary questions created. This becomes the long list of summary questions.
Group results thematically	July 2019		**x**	The summary questions are grouped into categories - diagnosis, treatment, long-term care, and other - and reviewed by the Steering Committee members.
Evidence checking	Aug 2019		Ben/Infomation Specialist	The long list of summary questions is checked against existing research evidence to ensure they are true uncertainties. Any questions that are already answered through research will be removed.
Review Questions	Aug 2019		**x**	Questions will be reviewed and out of scope uncertainties removed. Outcome: Only 60 questions should proceed to the next round. If more are identified, the SCM will refine and prioritize them.
Start disseminating Round 2: Survey to rank uncertainties	Sept 2019			Same dissemination strategy as before. Participants will rank them from 1 to 10 (1 most important, 10 least important).
Promote the survey (4 weeks)	Sept/Oct 2019		Olesja/JLA advisor/ Ben/SCM	Social Media, Website, Contact Database, JLA, Steering committee members input.
Data Processing	Oct 2019		Ben/Danyal/ Information Specialist	Summarize The 25 uncertainties most frequently included in a top 10 will be taken forward to the consensus meeting. Also, subgroup analysis will be conducted to understand the top priorities for per stakeholder group.
Review of uncertaintites by SCM	Oct/Nov			After the sub group analysis, the SCM will review the list of uncertainties not included in the final 25 but very popular for potential inclusion in the final consensus meeting. The discussion will be via email.
Consensus workshop	20 Nov 2019		**xxx**	The highest ranked 25-30 questions from the interim priority setting survey are discussed in a workshop of patients, carers and clinicians who together agree on the top 10 research priorities. 20 November 2019 in New York, USA.
Project closing	Dec 2019		Olesja/JLA advisor/ Ben/SCM	Submit engagement summary to JLA, Publish the findings in a manuscript and on JLA website.
Outcome tracking	Jan/Feb 2020		Ben/Olesja/SCM	Develop a long term tracking plan for the AOSpine RE-CODE DCM PSP.
Promotion	Ongoing after the completion of project		**x**	The top 10 uncertaintites are published and announced on the JLA website and promoted to researchers and funders. The PSP works with researchers and funders to further develop the prioritites into specific research questions.

x	**Steering Committee conference call**
xxx	**In-person meeting. Not all Steering Committee Members required to attend**
	Milestone completed
	Milestone on track
	Milestone delayed

James Lind Alliance
Priority Setting Partnerships

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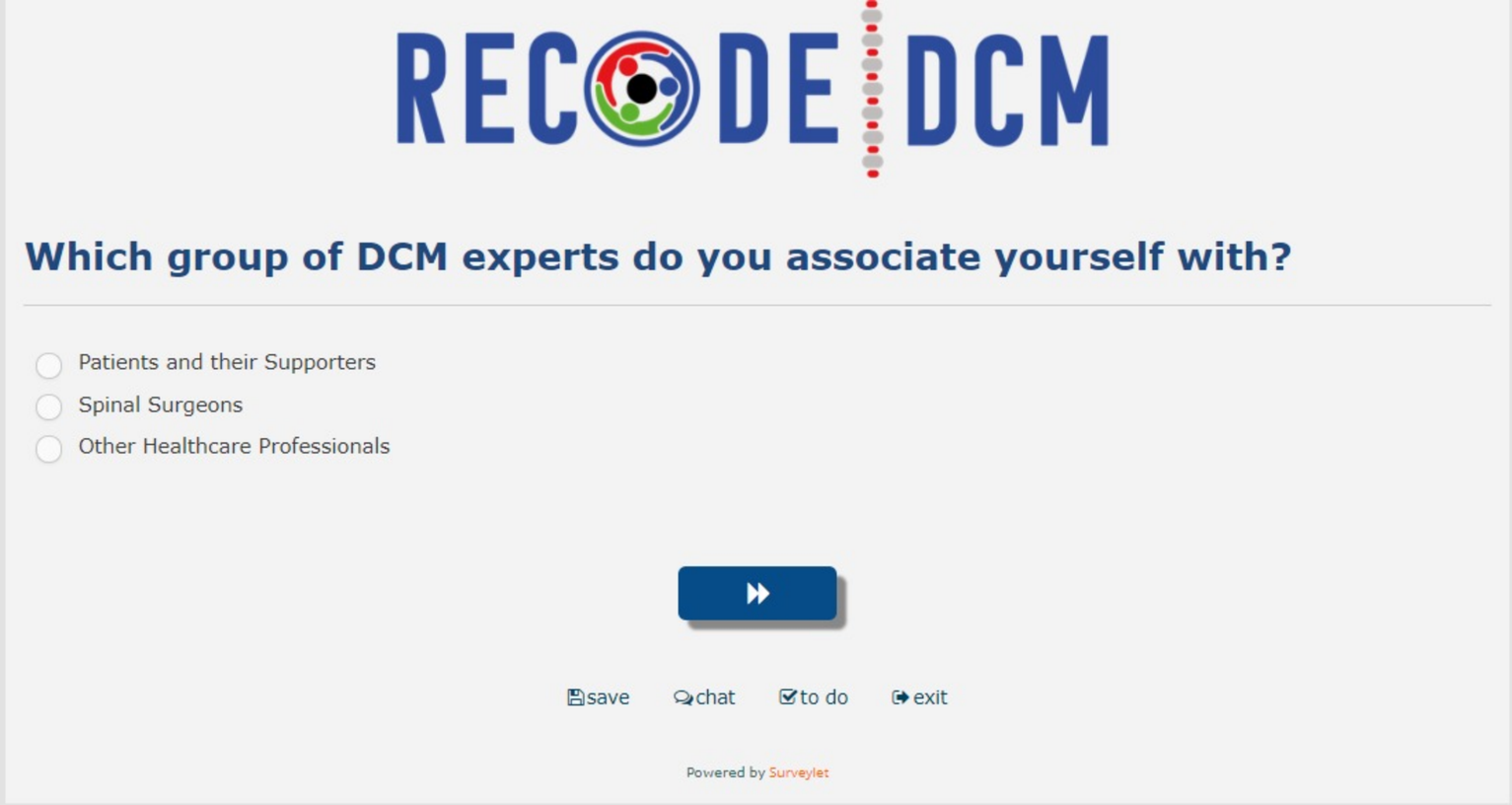
5. PSP Round 1: Survey Draft

James Lind Alliance
Priority Setting Partnerships

UNIVERSITY OF CAMBRIDGE



Please note the survey has branching logics built in. Depending on the selected role different questions may appear.

AOSpine RECODE-DCM Study

Participant Registration Form

Principal Investigators: Mark Kotter, Benjamin M Davies.

You are registering to participate in RECODE-Myelopathy, a consensus project to define the key research questions and measurements that researchers should follow in Degenerative Cervical Myelopathy [DCM].

This video will be replaced with a RE-CODE project animation informing about PSP and COS (Core Outcome Set)

What is DCM?

DCM is an umbrella term that describes a number of conditions in which the cervical spinal cord is injured due to degeneration of surrounding structures. Wear and tear of the bones, joints, ligaments and discs of the cervical spine can lead deformities of the structure of the spine, compressing the spinal cord that is contained within it. Another common name for DCM you may have heard is Cervical Spondylotic Myelopathy (CSM).

What is a Consensus Project?

A consensus project gathers and shares opinions from all experts involved. You are participating as an expert in DCM, either because you suffer from the condition or help someone who does. Other types of experts include surgeons and other medical professionals. Initially, opinions will be gathered and shared using a series of online surveys. Further information can be found in the following document, or by contacting admin@recode-dcm.com.

Which of these bests describes your experience of DCM?

- ( ) Patient
- ( ) Supporter

Age

Sex

- ( ) Female
- ( ) Male
- ( ) Other:
- ( ) Prefer not to say

Country of Residence

County/State/Province

You have been randomized to answer questions on research priorities. Therefore, there is an option to complete this survey anonymously.
Please be aware, in order to be acknowledged on published material and invited to the consensus meeting, a name and email contact are required.

- ( ) I would prefer to continue anonymously
- ( ) I am happy to provide my personal contact information (this will be stored securely and not used for additional purposes)

Name Prefix

- ( ) Mr.
- ( ) Mrs.
- ( ) Ms.
- ( ) Dr
- ( ) Prof

First Name

Last Name

Preferred email address

I would like to to be acknowledged as a contributor to RECODE on any published material:

- ( ) Yes
- ( ) No
- ( ) Other:

After completing ALL rounds of the online survey, I would be interested in being contacted about attending our international face-to-face consensus meetings:

- ( ) Yes
- ( ) No
- ( ) Other:

I would like to be contacted about other DCM research:

- ( ) Yes
- ( ) No
- ( ) Other:

I confirm that I have read the relevant Conflict of Interest Information Sheet and hereby declare any conflicts of interest I may hold (e.g. competing professional or financial interests, or any other factor that may influence your responses):

- ( ) I have no relevant conflicts of interest
- ( ) Other:

I confirm that I have read the relevant Participant Information Sheet including details of the management of my personal data and risks/benefits. I have had the opportunity to consider the information and ask any questions I may have. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. I hereby consent to be a RECODE-DCM study participant:

- ( ) Yes, I consent to being a RECODE-DCM study participant
- ( ) No, I do not consent to be a RECODE-DCM study participant

For more information, please see our study website:
https://recode-dcm.com

If you have any questions or concerns, please contact us via email:
admin@recode-dcm.com

If you are upset or concerned following completion of the questionnaire, support can be sought by contacting our charity partner:
www.Myelopathy.org

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Principal Investigators: Mark Kotter, Benjamin M Davies.

You are registering to participate in RECODE-Myelopathy, a consensus project to define the key research questions and measurements that researchers should follow in Degenerative Cervical Myelopathy [DCM].

Video will be replaced with an animation

Degenerative cervical myelopathy (DCM) is an umbrella term for cervical spinal cord compression and dysfunction from spinal stenosis due to degeneration of the cervical spine (bone, joints, discs or ligaments). This includes **Cervical Spondylotic Myelopathy** and **Ossification of the Posterior Longitudinal Ligament**.

You are participating as an expert in DCM because you surgically treat those affected. This consensus process will start with an online survey, to inform an eventual face-to-face consensus meeting. To reduce your time commitments, you will be randomly allocated to a subsection of this project. Regardless, those contributing to this process, who wish to, will be acknowledged on **all** published output. Further information can be found in the published protocol or participation information sheet.

Training Specialty

- Orthopaedics
- Neurosurgery

Job title

(including grade and specialty)

Hospital and/or University Affiliation

Sex

- Female
- Male
- Other:
- Prefer not to say

Age

Country of Residence

County/State/Province

On average, how many patients with DCM do you encounter every month as part of your clinical practice?

- 0-10
- 10-50
- 50-100
- 100+

For how many years have your managed people with DCM?:

Do you plan on attending the Cervical Spine Research Society Annual Meeting in New York, 21st – 23rd November 2019?

- Yes
- No
- Unsure

You have been randomized to answer questions on research priorities. Therefore, there is an option to complete this survey anonymously. Please be aware, in order to be acknowledged on published material and invited to the consensus meeting, a name and email contact are required.

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- Mrs.
- Ms.
- Dr
- Prof

First Name

Last Name

Preferred email address

I would like to to be acknowledged as a contributor to RECODE on any published material:

- Yes
- No
- Other:

After completing ALL rounds of the online survey, I would be interested in being contacted about attending our international face-to-face consensus meetings:

- Yes
- No
- Other:

I would like to be contacted about other DCM research:

- Yes
- No
- Other:

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AOSpine RECODE-DCM Study

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You are participating as an expert in DCM because you surgically treat those affected. This consensus process will start with an online survey, to inform an eventual face-to-face consensus meeting. To reduce your time commitments, you will be randomly allocated to a subsection of this project. Regardless, those contributing to this process, who wish to, will be acknowledged on **all** published output. Further information can be found in the published protocol or participation information sheet.

Which of these bests describes your experience of DCM?

- Family Doctor or General Practitioner
- Neurologist
- Researcher
- Specialist Nurse
- Physiotherapist
- Other(Clinician, Allied Health Professional, etc.)

Job title

(including grade and specialty)

Hospital and/or University Affiliation

Sex

- Female
- Male
- Other:
- Prefer not to say

Age

Country of Residence

County/State/Province

On average, how many patients with DCM do you encounter every month as part of your clinical practice?

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- 10-50
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- 100+

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Do you plan on attending the Cervical Spine Research Society Annual Meeting in New York, 21st – 23rd November 2019?

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- No
- Other:

After completing ALL rounds of the online survey, I would be interested in being contacted about attending our international face-to-face consensus meetings:

- Yes
- No
- Other:

I would like to be contacted about other DCM research:

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Patient Demographics

In order to ensure that we have heard opinions that represent the whole of DCM, it is important to gain some insight into how you are affected by the disease.

In which year were you diagnosed with DCM?

Have you had surgery for DCM?

- Yes
- No
- No but scheduled

Have you had physiotherapy for DCM?

- Yes
- No
- No but scheduled

Have you undergone any additional treatment for DCM?

My Answer

How much does your DCM affect the function of your arms and hands?

(Please choose the statement that best fits.)

I am...

- 0 - Unable to move my hands
- 1 - Unable to eat with a spoon but am able to move my hands0 - Unable to move my hands
- 2 - Unable to button my shirt but able to eat with a spoon1 - Unable to eat with a spoon but am able to move my hands
- 3 - Able to button my shirt with great difficulty2 - Unable to button my shirt but able to eat with a spoon
- 4 - Able to button my shirt with slight difficulty3 - Able to button my shirt with great difficulty
- 5 - Not having any trouble using my hands.4 - Able to button my shirt with slight difficulty

How much does your DCM affect your legs?

(Please choose the statement that best fits.)

I am...

- 0 - Completely unable to move legs at all and have no feeling in legs
- 1 - Having feeling in legs but not able to move them at all
- 2 - Able to move my legs but am unable to walk
- 3 - Able to walk on flat floor with a walking aid (cane or crutch)
- 4 - Able to walk up-&/or downstairs w/aid of a handrail
- 5 - Able to walk up-&/or downstairs without handrail but I notice moderate-to-significant lack of stability/feeling of imbalance when I walk
- 6 - Able to walk unaided (no crutches, canes, walker) with smooth reciprocation (ie, legs move smoothly) but I still notice mild lack of stability/feeling of imbalance when walking
- 7 - Able to walk without any problems of imbalance or instability

How much does your DCM affect the feeling in hands?

(Please choose the statement that best fits.)

I am...

- 0 - Complete loss of feeling in hands
- 1 - Severe loss of feeling, or have pain in my hands
- 2 - Mild loss of feeling in hands
- 3 - No loss of feeling in hands

How much does your DCM affect your ability to go to the toilet to urinate?

(Please choose the statement that best fits.)

I am...

- 0 - Am completely unable to control urination
- 1 - Have marked difficulty controlling urination
- 2 - Have mild to moderate difficulty controlling urination
- 3 - No difficulty controlling urination

On average, how much pain do you experience with DCM?

Where 0 is no pain, and 10 is the worse pain imaginable.

Have you ever participated in a DCM research study before?

- Yes
- No

Your Employment Status

- Employed
- Unemployed
- Retired

If you have any questions or concerns, please contact us via email:

admin@recode-dcm.com

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Supporter Demographics

In order to ensure that we have heard opinions that represent the whole of DCM, it is important to gain some insight into how you are affected by the disease but also how the individual that you support is

Your Employment Status

- Employed
- Unemployed
- Retired

In which year were they diagnosed with DCM?

Have they had surgery for DCM?

- Yes
- No
- No but scheduled

Have they had physiotherapy for DCM?

- Yes
- No
- No but scheduled

Have they undergone any additional treatment for DCM?

- No
- Yes. Please specify:

How much does DCM affect the function of their arms and hands?

Please choose the statement that best fits.

They are...

- 0 - Unable to move their hands
- 1 - Unable to eat with a spoon but they are able to move their hands
- 2 - Unable to button their shirt but able to eat with a spoon
- 3 - Able to button their shirt with great difficulty
- 4 - Able to button their shirt with slight difficulty
- 5 - Not having any trouble using their hands

How much does your DCM affect their legs?

Please choose the statement that best fits.

They are...

- 0 - Completely unable to move their legs at all and have no feeling in their legs
- 1 - Having feeling in their legs but not able to move them at all
- 2 - Able to move their legs but are unable to walk
- 3 - Able to walk on flat floor with a walking aid (cane or crutch)
- 4 - Able to walk up-&/or downstairs w/aid of a handrail
- 5 - Able to walk up-&/or downstairs without handrail but there is moderate-to-significant lack of stability/feeling of imbalance when they walk
- 6 - Able to walk unaided (no crutches, canes, walker) with smooth reciprocation (ie, legs move smoothly) but there still is mild lack of stability/feeling of imbalance when walking
- 7 - Able to walk without any problems of imbalance or instability

How much does DCM affect the feeling in their hands?

Please choose the statement that best fits.

They have...

- 0 - Complete loss of feeling in hands
- 1 - Severe loss of feeling, or having pain in their hands
- 2 - Mild loss of feeling in hands
- 3 - No loss of feeling in hands

How much does DCM affect their ability to go to the toilet to urinate?

Please choose the statement that best fits.

They...

- 0 - Are completely unable to control urination
- 1 - Have marked difficulty controlling urination
- 2 - Have mild to moderate difficulty controlling urination
- 3 - Have no difficulty controlling urination

On average, how much pain do they experience with DCM?

Where 0 is no pain, and 10 is the worse pain imaginable.

Are they currently employed?

- Employed
- Unemployed
- Retired

Have you ever participated in a DCM research study before?

- Yes
- No

If you have any questions or concerns, please contact us via email:

admin@recode-dcm.com

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RECODE-DCM Study

Priority Setting Partnership - Round 1 Survey

Principal Investigators: Benjamin M Davies, Mark Kotter.

You have been randomised to participate in the Priority Setting Partnership - a process to define the top 10 research uncertainties in DCM

What is a Priority Setting Partnership (PSP)?

A PSP is a collaboration between patients, careers, health care professionals and researchers that aims to understand what areas for future research are most important to people with Degenerative Cervical Myelopathy. We would like to welcome you to our PSP workflow. Our process is focussed on ensuring transparency and balanced inclusion of all groups to reach consensus on the areas of DCM for which research **has not yet answered** and **needs to be answered**.

Our overall aim is to produce a list of the **Top 10 Most Important Unanswered Areas in DCM Research**. Our hope is that future DCM research and funding is guided by our collective list and that these uncertainties are promptly and thoroughly explored. This means future DCM research is as meaningful as possible to the people who need it most.

What Happens During Participation?

The PSP consists of 2 stages, an online survey and a face-to-face consensus meeting. Below you will find the Round 1 of the survey, with each survey taking between 10-20 minutes. In each survey, a group of experts (you) are asked a series of questions asking them what they believe the most important research uncertainties are. Round 1 is a series of open questions. It is broken up into sections to help stimulate your ideas. After Round 1 closes, we will combine these opinions into a series of research questions and review the literature to see whether they have been answered. Unanswered questions will then be sent back to you in Round 2, where you will be asked to choose what you think are the top 10 most important. The results of round 2 will then be discussed at a face-to-face meeting, and a final shortlist produced.

It is very important that you complete all rounds of the survey, as without full completion, we are unable to add your valuable opinion to our study. It may also mean some key groups are underrepresented and influence the final findings. However, please be aware that you are free to withdraw from the study at any point.

Below you will find the categories within which you can submit what you think are the most important questions to answer in DCM research. These categories have been chosen simply to help stimulate your thoughts, and it does not matter in which box you write your ideas.

There are no restrictions on the amount of questions you can submit or the format they are written in.

Diagnosis: "Detecting DCM"-What question(s) about the diagnosis of Degenerative Cervical Myelopathy would you like to see answered by research?

Examples from other PSPs:
"Are lifestyle factors such as diet, alcohol intake, weight change and smoking involved in causing psoriasis?"
"What are the early signs and symptoms of cellulitis that can help to ensure speedy treatment?"

My Answer

Treatment: "Managing DCM"- What question(s) about the treatment of Degenerative Cervical Myelopathy would you like to see answered by research?

Examples from other PSPs:
"What factors predict how well psoriasis will respond to treatment?"
"What non-surgical treatments can reduce the need for hip/knee replacement?"

My Answer

Long-term Care and Follow Up: "Living with DCM" - What question(s) about the long-term care of Degenerative Cervical Myelopathy would you like to see answered by research? This includes various aspects of living with Degenerative Cervical Myelopathy, for example, monitoring requirements and lifestyle changes.

Examples from other PSPs:
"Which wheelchair cushions are most effective in the prevention of pressure ulcers in wheelchair users?"
"What is the best method of monitoring a person with Parkinson's response to treatments?"

My Answer

Other – What other question(s) about Degenerative Cervical Myelopathy that do not fit into the above categories would you like to see answered by research?

Examples from other PSPs:
"Do variations in GP awareness of prostate cancer affect outcomes?"

My Answer

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RECODE-DCM Study

Priority Setting Partnership - Round 1 Survey

Principal Investigators: Benjamin M Davies, Mark Kotter.

The survey will be administered with and without word clouds. The purpose of the word clouds is to stimulate ideas.

You have been randomised to participate in the Priority Setting Partnership - a process to define the top 10 research uncertainties in DCM

What is a Priority Setting Partnership (PSP)?

A PSP is a collaboration between patients, careers, health care professionals and researchers that aims to understand what areas for future research are most important to people with Degenerative Cervical Myelopathy. We would like to welcome you to our PSP workflow. Our process is focussed on ensuring transparency and balanced inclusion of all groups to reach consensus on the areas of DCM for which research **has not yet answered** and **needs to be answered**.

Our overall aim is to produce a list of the **Top 10 Most Important Unanswered Areas in DCM Research**. Our hope is that future DCM research and funding is guided by our collective list and that these uncertainties are promptly and thoroughly explored. This means future DCM research is as meaningful as possible to the people who need it most.

What Happens During Participation?

The PSP consists of 2 stages, an online survey and a face-to-face consensus meeting. Below you will find Round 1 of the online survey, with each survey taking between 10-20 minutes. In this survey, a group of experts (you) are asked a series of questions asking them what they believe the most important research uncertainties are. Round 1 is a series of open questions. It is broken up into sections to help stimulate your ideas. After Round 1 closes, we will combine these opinions into a series of research questions and review the literature to see whether they have been answered. Unanswered questions will then be sent back to you in Round 2, where you will be asked to choose what you think are the top 10 most important. The results of round 2 will then be discussed at a face-to-face meeting, and a final shortlist produced.

It is very important that you complete all rounds of the survey, as without full completion, we are unable to add your valuable opinion to our study. It may also mean some key groups are underrepresented and influence the final findings. However, please be aware that you are free to withdraw from the study at any point.

Below you will find the categories within which you can submit what you think are the most important questions to answer in DCM research. These categories have been chosen simply to help stimulate your thoughts, and it does not matter in which box you write your ideas.

There are no restrictions on the amount of questions you can submit or the format they are written in.

Diagnosis: "Detecting DCM"-What question(s) about the diagnosis of Degenerative Cervical Myelopathy would you like to see answered by research?

The following list of words has been associated with the diagnostic phase of DCM, by patients and professionals. The word cloud has been developed to help stimulate your ideas.

Examples from other PSPs

"Are lifestyle factors such as diet, alcohol intake, weight change and smoking involved in causing psoriasis?"
"What are the early signs and symptoms of cellulitis that can help to ensure speedy treatment?"

My Answer

Treatment: "Managing DCM"- What question(s) about the treatment of Degenerative Cervical Myelopathy would you like to see answered by research?

The following list of words has been associated with the diagnostic phase of DCM, by patients and professionals. The word cloud has been developed to help stimulate your ideas.

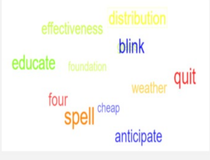
Examples from other PSPs

"What factors predict how well psoriasis will respond to treatment?"
"What non-surgical treatments can reduce the need for hip/knee replacement?"

My Answer

Long-term Care and Follow Up: "Living with DCM" - What question(s) about the long-term care of Degenerative Cervical Myelopathy would you like to see answered by research? This includes various aspects of living with Degenerative Cervical Myelopathy, for example, monitoring requirements and lifestyle changes.

The following list of words has been associated with the diagnostic phase of DCM, by patients and professionals. The word cloud has been developed to help stimulate your ideas.



Examples from other PSPs

"Which wheelchair cushions are most effective in the prevention of pressure ulcers in wheelchair users?"
"What is the best method of monitoring a person with Parkinson's response to treatments?"

My Answer

Other – What other question(s) about Degenerative Cervical Myelopathy that do not fit into the above categories would you like to see answered by research?

The following list of words has been associated with the diagnostic phase of DCM, by patients and professionals. The word cloud has been developed to help stimulate your ideas.

Examples from other PSPs

"Do variations in GP awareness of prostate cancer affect outcomes?"

My Answer

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RECODE-DCM Study

Core Outcomes Set - Round 1 Survey

Principal Investigators: Benjamin M Davies, Mark RN Kotter.

You have been assigned to participate in the Core Outcome Set and Core Data Elements stream, a process to define the outcomes and key influencers that should be measured in DCM research

What is a Core Outcomes Set (COS)?

A COS is a collaboration between patients, careers, health care professionals and researchers that aims to determine what outcomes should be assessed as a minimum in DCM research. We would like to welcome you to our COS workflow.

What is the problem we are addressing?

At the moment, different studies often measure different outcomes. For instance, imagine two studies on how to treat DCM.
- Study A - researchers measure grip strength as an outcome
- Study B - researchers measure symptoms of pain as an outcome

When the two studies are finished, we cannot compare or combine their results because they have used different outcomes. We would not be comparing like with like. This creates inefficiency in research.

If all studies in a particular health condition used the same outcomes, they could all be compared and combined. This would reduce waste by making the best use of all the research. When a set of main outcomes has been agreed for a health condition, it's called a 'core outcome set'.

What Happens During Participation?

A COS starts by defining what should be measured. This is not the same as how something should be measured, which is a later stage, once what should be measured is finalised. The COS consists of an online Delphi survey and a face-to-face consensus meeting.

Below you will find the opening round of the Delphi survey, with each survey taking between 10-20 minutes. A Delphi is a technique where a group of experts (you) are asked a series of questions asking them what they believe the most important outcomes are. The list of outcomes so far is based upon what is currently measured in DCM research and a series of interviews conducted with DCM patients. You will be asked to rate the importance of measuring these outcomes on a scale of 0 (not important at all) to 10 (extremely important). You will also have the opportunity to add in outcomes you think are missing. These outcomes have been grouped into categories.

After Round 1 closes, these findings will then be processed, before we invite you to participate a second time. In Round 2 you will be presented with the results of Round 1 (the overall results, the results per group of experts, and your previous rating). This will give you the opportunity to change your rating if you so wish, but also to rate newly suggested outcomes. The findings of round 2 will be processed, and for any outcomes for which the group remain undecided, will be discussed at a face-to-face meeting.

It is very important that you complete all rounds of the survey, as without full completion, we are unable to add your valuable opinion to our study. It may also mean some key groups are underrepresented and influence the final findings. However, please be aware that you are free to withdraw from the study at any point.

DOMAIN

SUBDOMAIN

Please rate the following outcomes based on how important you think they are to measure.	**1-3 = Not important. 4-6 = Important but not critical. 7-9 = Critical.**									
	1	2	3	4	5	6	7	8	9	I don't know
Additional blood loss after treatment										
Total blood loss after child birth, up to cessation of bleeding	○	○	○	○	○	○	○	○	○	○
Time to cessation to bleeding	○	○	○	○	○	○	○	○	○	○
Changes in hemoglobin before and after bleeding	○	○	○	○	○	○	○	○	○	○
Postpartum Hb	○	○	○	○	○	○	○	○	○	○

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RECODE-DCM Study

Core Outcomes Set - Round 1 Survey

Principal Investigators: Benjamin M Davies, Mark RN Kotter.

You have been assigned to participate in the Core Outcome Set and Core Data Elements stream, a process to define the outcomes and key influencers that should be measured in DCM research

What is a Core Outcomes Set (COS)?

A COS is a collaboration between patients, careers, health care professionals and researchers that aims to determine what outcomes should be assessed as a minimum in DCM research. This is addressing the common problem currently, whereby different researchers measure different outcomes, preventing pooled analysis.

What are Core Data Elements (CDE)?

CDE are the additional measurements which are made at baseline and are important for interpreting an outcome. This could be because they may influence outcomes or because they will help understand whether this finding is relevant for your patient. Common examples are age or gender.

It is important to remember that most outcomes are measured before and after an intervention. Therefore they will already be captured. The CDE refers to the additional data points which must be measured, to ensure the research is useful.

What Happens During Participation?

This process starts by defining **what** should be measured. This is not the same as how something should be measured, which is a later stage, once what should be measured is finalised. This process starts with an online Delphi survey and a face-to-face consensus meeting.

Below you will find the opening round of the Delphi survey, which will take about 10-20 minutes to complete. The list of outcomes and data elements so far is based upon what is currently measured in DCM research. You will be asked to rate the importance of measuring these outcomes on a scale of 0 (not important at all) to 10 (extremely important). You will also have the opportunity to add in outcomes or data elements you think are missing. The outcomes and data elements have been grouped for convenience.

After Round 1 closes, these findings will then be processed, before we invite you to participate a second time. In Round 2 you will be presented with the results of Round 1 (the overall results, the results per group of experts, and your previous rating). This will give you the opportunity to change your rating if you so wish, but also to rate newly suggested outcomes. For the CDE we will also provide a summary of the evidence base for the significance of any data point, if available. The findings of round 2 will be processed, and for any outcomes for which the group remain undecided, will be discussed at a face-to-face meeting.

It is very important that you complete all rounds of the survey, as without full completion, we are unable to add your valuable opinion to our study. It may also mean some key groups are underrepresented and influence the final findings. However, please be aware that you are free to withdraw from the study at any point.

Domain

Subdomain

This is the matrix label	1-3 = Not important. 4-6 = Important but not critical. 7-9 = Critical.									
	1	2	3	4	5	6	7	8	9	I don't know
This is the row label										
Additional blood loss after treatment	○	○	○	○	○	○	○	○	○	○
Total blood loss after child birth, up to cessation of bleeding	○	○	○	○	○	○	○	○	○	○
Time to cessation to bleeding	○	○	○	○	○	○	○	○	○	○
Changes in hemoglobin before and after bleeding	○	○	○	○	○	○	○	○	○	○
Postpartum Hb	○	○	○	○	○	○	○	○	○	○

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Thank you for taking the time to share your opinions today

For more information, please see our study website: https://recode-dcm.com

If you have any questions or concerns, please contact us via email: admin@recode-dcm.com

If you are upset or concerned following completion of the questionnaire, support can be sought by contacting our charity partner: www.Myelopathy.org

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6. AOSpine RE-CODE DCM Website

The AOSpine RE-CODE DCM Management Group has developed a study website:

https://recode-dcm.com/

The 4 key purposes of this website are:

1) provide information about the study,
2) encourage participation,
3) introduce members of the team,
4) promote the study objectives and achievements.

The website may show your photograph retrieved from other publicly available websites or provided directly by you. Please let us know if you do not consent for the picture to be displayed on the AOSpine RE-CODE DCM website.

We also looking forward to receiving any other feedback you may have about the study website.

For more information about the website or to submit/retrieve your photographs, please contact Danyal Khan (danyalkhan@rcsi.ie).