

Spinal Research — A Field in Need of Standardization

To the Editor:

The 2014 *Lancet* series “Research: Increasing Value, Reducing Waste” proposed a number of drivers of research inefficiency, a problem estimated to prevent 85% of biomedical research from offering actual or potential clinical benefit¹. These included heterogeneous data collection and reporting, which prevents comprehensive synthesis and data comparison.

The development of standardized datasets is an effective response to this problem. The nomenclature for them is inconsistent, but these sets can be broadly separated as core outcome sets (COS) if they include only outcomes or core data elements (CDE) if they include additional data points^{2,3}. Integral to these processes is the involvement of everyone involved, including those who have the condition². Pioneered by organizations such as Outcome Measures in Rheumatology (OMERACT), and supported more recently by organizations such as Core Outcome Measures in Effectiveness Trials (COMET), such datasets are serving many medical fields, including rheumatology.

The Journal of Rheumatology serves as an exemplar for disseminating COS/CDE research, publishing many articles yearly about the methods, findings, and importance of COS/CDE sets in rheumatology. Indeed, the October 2019 issue of *The Journal* showcased 14 articles by the OMERACT group, highlighting results from the 2018 OMERACT International Consensus Conference.

Indeed, a 2018 review found 366 COS published in the (medical) literature so far, with the numbers increasing yearly⁴. The OMERACT Website currently lists 52 working groups — each covering an important area in rheumatology and COS/CDE development. These COS/CDE are effective, as shown by a review of 143 completed clinical therapeutic trials in rheumatoid arthritis (RA), 81% of which used the respective RA COS, with this proportion increasing yearly since its publication⁵.

However, the response within spinal disease is more limited. A search of the COMET registry revealed 20 entries related to the field of spinal research (18× COS, 2× COS + CDE). They were distributed among the COMET health areas of “orthopaedics & trauma,” “neurology,” and “rheumatology.” The OMERACT registry listed only 1 spinal dataset currently in process and no dedicated OMERACT working group assigned to the spinal research field.

A search of spinal journals for published COS/CDE in the last 10 years (Search strategy, Appendix 1) returned 77 articles. Of these results, 11 were related to COS/CDE (Table 1), 7 of which were completed datasets and 4 of which were in process. Of note, only 8 of these 11 datasets were registered in the COMET/OMERACT registries. Table 1 indicates study demographics and characteristics — importantly, only 2 (29% of completed datasets) have been used and referenced by subsequent literature.


Table 1. Summary of published studies of COS/CDE processes in spinal journals in the last 10 years.

PubMed ID	Year	Country of Origin	Journal	Condition	COS/CDE	COMET/OMERACT	Status	Use in Further Studies
31157148	2019	UK	<i>Global Spine Journal</i>	DCM	COS/CDE	COMET	In progress	NA
31004195	2019	Netherlands	<i>Eur Spine Journal</i>	Low back pain	COS	COMET	Complete	No
29432394	2018	UK	<i>Spine</i>	Cauda equina syndrome	COS	COMET	In progress	NA
28914116	2017	Netherlands	<i>Acta Orthopaedica</i>	Spinal deformity	COS	COMET	Complete	No
25841358	2015	Netherlands	<i>Eur Spine Journal</i>	Low back pain	COS	COMET	Complete	Yes, 10 studies
28434926	2017	USA	<i>Spine Journal</i>	Lumbar spinal stenosis	CDE	No	Complete	No
28322240	2017	USA	<i>Spinal Cord</i>	Spinal cord injury	CDE	No	Complete	No
28244501	2017	USA	<i>Spinal Cord</i>	Spinal cord injury	CDE	COMET	In progress	NA
27845358	2017	Int'l	<i>Spinal Cord</i>	Spinal cord injury	CDE	No	Complete	No
25665542	2015	Int'l	<i>Spinal Cord</i>	Spinal cord injury	CDE	COMET	Complete	Yes, 7 studies
20733589	2011	Denmark	<i>Spinal Cord</i>	Spinal cord injury	CDE	COMET	In progress	NA

COS/CDE: core outcome sets/core data elements; COMET: Core Outcome Measures in Effectiveness Trials; OMERACT: Outcome Measures in Rheumatology; DCM: degenerative cervical myelopathy; NA: not applicable; Eur: European.

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APPENDIX 1. Search strategy.

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((((((((((("Spine"[Journal]) OR ("European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society"[Journal])) OR ("The spine journal : official journal of the North American Spine Society"[Journal]) OR "Journal of neurosurgery. Spine"[Journal]) OR "Joint, bone, spine : revue du rhumatisme"[Journal]) OR "The spine journal : official journal of the North American Spine Society"[Journal]) OR "Spinal cord"[Journal]) OR "The journal of spinal cord medicine"[Journal]) OR "Journal of spinal disorders & techniques"[Journal]) OR "Journal of spinal disorders"[Journal]) OR "SCI nursing : a publication of the American Association of Spinal Cord Injury Nurses"[Journal]) OR ("Spinal cord series and cases"[Journal])) OR "Topics in spinal cord injury rehabilitation"[Journal]) OR ("Scoliosis and spinal disorders"[Journal]) OR "Asian spine journal"[Journal]) OR "Clinical spine surgery"[Journal]) OR "Global spine journal"[Journal]) OR "Spine deformity"[Journal]) OR "Journal of craniovertebral junction & spine"[Journal]) OR "International journal of spine surgery"[Journal]) OR "Journal of spine surgery (Hong Kong)"[Journal]) OR "Korean Journal of Spine"[Journal]) OR ("JSM neurosurgery and spine"[Journal]) OR "Spine (Philadelphia, Pa. : 1986)"[Journal]) OR "Journal of spine & neurosurgery"[Journal]) OR "Journal of spine"[Journal]) OR "Seminars in spine surgery"[Journal]) OR "JOR spine"[Journal]) OR ("European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society"[Journal]) OR "The journal of spinal cord medicine"[Journal]) OR "Spinal cord"[Journal]) OR "Evidence-based spine-care journal"[Journal]) OR ("Journal of neurology, neurosurgery and spine"[Journal]) OR "Journal of head, neck & spine surgery"[Journal]) OR "Neurospine"[Journal]))) AND (((((((("CORE OUTCOME"[Title/Abstract]) OR "COMMON DATA"[Title/Abstract]) OR "CORE OUTCOME SET"[Title/Abstract]) OR "CORE OUTCOMES"[Title/Abstract])))
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