Improving the Reporting of Studies Using Routinely Collected Health Data in Physical Therapy

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Routinely collected observational health data encompass all forms of information collected during clinical care or through administrative means, and may be compiled in database repositories, proprietary data sets, data registries, or within hospital networks. Although these data have no prospective research intent, they have markedly impacted the landscape of research[11] by providing opportunities to define real-world health behavioral patterns at a fraction of the cost of traditional clinical trials. Despite this, it is only recently that physical therapist researchers have embraced the benefits of studying routine health data from physical therapy clinics,[1] military databases,[5] government-sponsored medical databases,[10] and payment records.[4]

The use of routinely collected observational health data for research poses considerable challenges, all of which are germane to physical therapists. The inadequate and missing observational data commonly encountered by researchers in any genre are only 2 of many provenance-related issues associated with data quality. Within the field of physical therapy, the most common form of database-oriented research has focused on data that represent patterns of care, requiring the use of procedural codes, variables associated with timing of care, and diagnostic codes that represent morbidity status.[7] Further, research on the cost-effectiveness of care often requires the merger of multiple databases and the assumption of good-faith programming by the research team.

Reporting guidelines have been developed to improve the reporting of research, with the explicit aims that readers of research should understand what was planned, what was done, and what was found. Poor reporting is a major source of research waste and has been identified by the REduce research Waste And Reward Diligence (REWARD) initiative[6] as a major area for improvement. Reporting guidelines have been shown to improve the quality of research reporting and hence help to reduce research waste, as they increase the usefulness of the research findings and prevent any unnecessary research duplication.[2] The Strengthening of Reporting of Observational Studies in Epidemiology (STROBE)[12] reporting guidelines were created to improve the transparency of reporting of observational studies, such as cohort, case-control, and cross-sectional studies, and recommend minimum reporting standards for observational studies. However, the unique elements of routinely collected health data, such as

the use of codes and algorithms to identify populations, exposures, and outcomes, and the use of linked data sets highlight the need to develop a new reporting tool as an extension to STROBE. This need has been addressed by the REporting of studies Conducted using Observational Routinely collected Data (RECORD) initiative.

The RECORD statement[2] was created using an approach proposed by the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) network,[9] including a modified electronic Delphi approach comprising 2 surveys of stakeholders, followed by face-to-face discussion by the RECORD Working Committee, and subsequent feedback from stakeholders using an online message board.[12] The RECORD stakeholder group had representation from 20 countries and included researchers who actively use routine data, journal editors, pharmaceutical industry professionals, and individuals involved in developing health care policy informed by routine data.

We are delighted that the *Journal of Orthopaedic & Sports Physical Therapy* has decided to endorse the RECORD guidelines for relevant manuscripts. The RECORD Steering Committee is looking forward to working with the *Journal* to maximize the implementation of, and benefit from, the RECORD guidelines in terms of completeness and transparency of reporting to ultimately help patients undergoing physical therapy (see **ONLINE APPENDIX**, available at *www.jospt.org*). We welcome comments and recommendations on the RECORD guidelines through our website (www.record-statement.org). We hope to use the comments and discussion on the message board (www.record-statement.org/forum) to update the RECORD guidelines to reflect the rapid evolution of routinely collected health data sources. Our aim is to use the RECORD guidelines to transform the reporting of research using routine data and provide transparency in this rapidly growing field of observational research.

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APPENDIX

THE RECORD STATEMENT: CHECKLIST OF ITEMS, EXTENDED FROM THE STROBE STATEMENT, THAT SHOULD BE REPORTED IN OBSERVATIONAL STUDIES USING ROUTINELY COLLECTED HEALTH DATA

	Item	STROBE Item	Location in Manuscript Where Items Are Reported	RECORD Item	Location in Manuscript Where Items Are Reported
Title and abstract					
	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found		RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included RECORD 1.2: If applicable, the geographic region and time frame within which the study took place should be reported in the title or abstract RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract	
Introduction					
Background rationale	2	Explain the scientific background and rationale for the investigation being reported			
Objectives	3	State specific objectives, including any prespecified hypotheses			
Methods					
Study design	4	Present key elements of study design early in the paper			
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection			

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	Item	STROBE Item	Location in Manuscript Where Items Are Reported	RECORD Item	Location in Manuscript Where Items Are Reported
Participants	6	(a) Cohort study: give the eligibility criteria and the sources and methods of selection of participants. Describe methods of follow-up. Case-control study: give the eligibility criteria and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls. Cross-sectional study: give the eligibility criteria and the sources and methods of selection of participants (b) Cohort study: for matched studies, give matching criteria and the number of exposed and unexposed. Case-control study: for matched studies, give matching criteria and the number of controls per case		RECORD 6.1: The methods of study population selection (eg, codes or algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided RECORD 6.2: Any validation studies of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, detailed methods and results should be provided RECORD 6.3: If the study involved linkage of databases, consider use of a flow diagram or other graphical display to demonstrate the data linkage process, including the number of individuals with linked data at each stage	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable		RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, an explanation should be provided	
Data sources/ measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement) Describe comparability of assessment methods if there is more than 1 group			
Bias	9	Describe any efforts to address potential sources of bias			
Study size	10	Explain how the study size was arrived at			
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why			

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Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) Cohort study: if applicable, explain how loss to follow-up was addressed. Case-control study: if applicable, explain how matching of cases and controls was addressed. Cross-sectional study: if applicable, describe analytical methods, taking account of sampling strategy (e) Describe any sensitivity analyses			
Data access and cleaning methods		...		RECORD 12.1: Authors should describe the extent to which the investigators had access to the database population used to create the study population RECORD 12.2: Authors should provide information on the data-cleaning methods used in the study	
Linkage		...		RECORD 12.3: State whether the study included person-level, institutional-level, or other data linkage across 2 or more databases. The methods of linkage and methods of linkage quality evaluation should be provided	
Results					
Participants	13	(a) Report the numbers of individuals at each stage of the study (eg, numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed) (b) Give reasons for nonparticipation at each stage (c) Consider use of a flow diagram		RECORD 13.1: Describe in detail the selection of the persons included in the study (ie, study population selection), including filtering based on data quality, data availability, and linkage. The selection of included persons can be described in the text and/or by means of the study flow diagram	

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Descriptive data	14	(a) Give characteristics of study participants (eg, demographic, clinical, social) and information on exposures and potential confounders (b) Indicate the number of participants with missing data for each variable of interest (c) Cohort study: summarize follow-up time (eg, average and total amount)			
Outcome data	15	Cohort study: report numbers of outcome events or summary measures over time. Case-control study: report numbers in each exposure category, or summary measures of exposure. Cross-sectional study: report numbers of outcome events or summary measures			
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period			
Other analyses	17	Report other analyses done—for example, analyses of subgroups and interactions and sensitivity analyses			

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Discussion					
Key results	18	Summarize key results with reference to study objectives			
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias		RECORD 19.1: Discuss the implications of using data that were not created or collected to answer the specific research question(s). Include discussion of misclassification bias, unmeasured confounding, missing data, and changing eligibility over time, as they pertain to the study being reported	
Interpretation	20	Give a cautious overall interpretation of results, considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence			
Generalizability	21	Discuss the generalizability (external validity) of the study results			
Other Information					
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based			
Accessibility of protocol, raw data, and programming code		...		RECORD 22.1: Authors should provide information on how to access any supplemental information, such as the study protocol, raw data, or programming code	

Abbreviations: RECORD, REporting of studies Conducted using Observational Routinely-collected health Data; STROBE, Strengthening the Reporting of Observational Studies in Epidemiology. Adapted from Benchimol EI, Smeeth L, Guttmann A, et al. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) statement. PLoS Med. 2015;12:e1001885. http://dx.doi.org/10.1371/journal.pmed.1001885 Checklist is protected under a Creative Commons Attribution (CC-BY) license.

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1. J. Haxby Abbott. 2016. Reporting Guidelines and Checklists Improve the Reliability and Rigor of Research Reports. *Journal of Orthopaedic & Sports Physical Therapy* **46**:3, 130-130. [Abstract] [Full Text] [PDF] [PDF Plus]