■ EDITORIAL

SEARCHeD: Supporting Evaluation, Analysis and Reporting of routinely Collected Healthcare Data

REPORTING STANDARDS FOR ORTHOPAEDIC STUDIES USING ROUTINELY COLLECTED OR REGISTRY DATA

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As we begin a new decade of research in trauma and orthopaedics, we should aim to make the most of the best available data. The last decade saw a huge increase in the volume of routinely recorded healthcare data. These datasets, particularly clinical registries and large administrative databases, can be valuable sources of information but need to be understood, analysed, interpreted, and reported carefully. We have previously highlighted the importance of understanding why a dataset was established, as well as the quality of the data in order to guide the interpretation of research findings.[1,2] In this editorial, we aim to revisit both the importance of such data sources and the critical methodological principles that should be followed when drawing inferences from large datasets.

We recognise that big data offers the potential to answer many questions, particularly in relation to rare events and rare diseases, that cannot be answered using traditional methods.[3,4] It also offers an opportunity to track practice over time and examine healthcare delivery throughout big healthcare systems.[5-12] There is also huge potential in linking big data sets to address questions that cannot be looked at in any other ways.[5,13]

We have previously highlighted the dangers of misclassification bias, lumping, reliance on proxy outcomes, and overlooking both measured and unmeasured confounders.[1] We have also both celebrated and warned against the power of such large numbers; while alluring, they must be interpreted using sound clinical understanding. There is a risk that size of a datasets may expand at the expense of data quality,[14,15] which needs to be carefully understood before inferences are drawn.

We should embrace the opportunities provided by large datasets, both to guide practice and generate hypotheses. However, although inferences drawn from registry data and administrative databases will increasingly contribute to debates, they cannot replace other study designs, particularly prospective cohort studies and randomised controlled trials. The appended framework for the reporting of registry and big data studies lays out the minimum information that should be presented, both to help readers interpret study findings appropriately and to improve the reproducibility of these important studies. Transparent reporting is at least as important in this arena as it is in others, and will be mandated.

Over the past few years, we have raised our expectations around study reporting and supported the use of well-established guidelines, such as the Consolidated Standards of Reporting Trials (CONSORT), the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) and Strengthening and Reporting of Observational Studies in Epidemiology (STROBE) statements. We have previously suggested using the Reporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement for 'big data' studies. The information and guidelines recommended by Perry et al in 2014 were excellent and set a new standard that should be followed when reporting big data studies.[1] We suggested at the time that these should be used as an adjunct to the STROBE statement.

We now propose an expanded version that seeks to guide authors and to reassure readers. This document will further support methodological transparency and allow us to fully exploit the huge opportunities made available by large datasets. We also encourage authors to publish protocols for big data studies in our sister journal *Bone & Joint Open*, to reassure readers that any findings were not simply the result of statistical oddities from data mining, but were considered analyses based on a priori hypotheses. We do not believe that there is a conflict between our expanded recommendations and the RECORD statement, but welcome the views of our authors, readers, reviewers and other colleagues who work with big data or rely on such studies to inform their clinical practice.

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Section/Topic	Item No.	Checklist item
Title and abstract		
	1a	Identification as a healthcare registry study in the title or abstract
	1b	Structured summary of study design, methods, results, and conclusions
	1c	Data source including name of databases and geographic location
	1d	Data processing undertaken including linkage and cleaning
Introduction		
Background and objectives	2a	Scientific background and rationale for study
	2b	Specific objectives (if exploratory) and/or hypotheses
Methods		
Study design	3a	Description of study design including data sources used, geographic location and data linkage
	3b	Description of the routine healthcare data utilised, data set completeness and internal QA of the registry
	3c	Reference to study registration document or protocol if available. Approval number and date must be included
Participants	4a	A clear statement of the inclusion criteria for participants included in the study
	4b	Population level selection criteria including filtering based on data quality, availability and linkage
	4c	Data source and/or queries used including codes, time frames for recruitment, exposure and outcomes
	4d	Settings and locations where the data were collected
Variables	5	Extent of missing co-variable data, handling of incomplete data, and flow diagram for dataset
	6a	Completely defined co-variables, demographic variables, justification for selection including potential confounders and missing potentially relevant data
	6b	If using matched or comparison cohort series (e.g. propensity matching) selection and matching criteria
Outcomes	7	How outcomes were determined. Justification of outcome measures, including choice of follow-up duration
Statistical methods	8a	Precisely define access to source datasets – is this an extract?
	8b	Methods for data processing and handling of missing data. Flow chart for data cleaning
	8c	Methods for data linkage if appropriate, e.g. single identifier or other method of linkage Describe any QA steps for linkage
Results		
Participant flow	9	Patients available described by text and flow diagram (required)
Matching	10a	Patient numbers in each cohort based on matching criteria, or other criteria (if undertaken)
	10b	A table showing baseline demographic and clinical characteristics for each group, and QA for matching (if undertaken)
Numbers analysed	11	For each group, number of participants (denominator) included in each analysis and what proportion of the potential registry population was included
Outcomes and estimation	12a	Effect estimates (e.g. odds ratios) along with precision estimates (e.g. 95% CI) for each analysis
	12b	Make clear which confounders were adjusted for and which were not. Provide data to support the choice of statistical model, e.g. explicitly test the proportional hazards assumption before reporting data from Cox regression models
Sensitivity analysis	13	Where sensitivity analyses have been undertaken, they should be reported completely
Discussion		
Generalisability	14	Generalisability (external validity, applicability) of the findings to individual and population settings
Limitations	15a	Discussion of implications of using routinely collected data not collected for this research question should be thoroughly discussed and explored. Finding should be set against pre-existing research and justification of the use of registry data as opposed to other methods.
	15b	Study limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Biases	16	Specific considerations should be given to misclassification bias, unmeasured confounders, and changing eligibility criteria over time
Other information		
Registration	17	Registration number and name of study registry or source dataset
Protocol	18	Where the full protocol can be accessed, if available. Who and when approval was given for the analysis along with application reference number
Funding	19	Sources of funding and other support

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