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SERIES

Reporting transparency and completeness in trials: Paper 3 – trials conducted using administrative databases do not adequately report elements related to use of databases

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Abstract

Objective: We evaluated reporting completeness and transparency in randomized controlled trials (RCTs) conducted using administrative data based on 2021 CONSORT Extension for Trials Conducted Using Cohorts and Routinely Collected Data (CONSORT-ROUTINE) criteria.

Study Design and Setting: MEDLINE and the Cochrane Methodology Register were searched (2011 and 2018). Eligible RCTs used administrative databases for identifying eligible participants or collecting outcomes. We evaluated reporting based on CONSORT-ROUTINE, which modified eight items from CONSORT 2010 and added five new items.

Results: Of 33 included trials (76% used administrative databases for outcomes, 3% for identifying participants, 21% both), most were conducted in the United States (55%), Canada (18%), or the United Kingdom (12%). Of eight items modified in the extension; six were adequately reported in a majority (>50%) of trials. For the CONSORT-ROUTINE modification portion of those items, three items were reported adequately in >50% of trials, two in <50%, two only applied to some trials, and one only had wording modifications and was not evaluated. For five new items, four that address use of routine data in trials were reported inadequately in most trials.

All authors declare no competing interests.

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Conclusion: How administrative data are used in trials is often sub-optimally reported. CONSORT-ROUTINE uptake may improve reporting. © 2021 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/)

Key Words: Administrative data; CONSORT; CONSORT-ROUTINE; Randomized controlled trials; Reporting guideline; Routinely collected data

What is new?

Key Findings

- Among items modified from the 2010 CONSORT statement, items on describing the use of an administrative database in the abstract (91%), including the administrative dataset in the statement of trial design (82%), and describing the source of outcome data (88%) were adequately reported in most trials; modifications related to how the use of administrative data may have influenced generalizability (21%) and funding of the database (6%) were not reported adequately in most trials.
- New CONSORT-ROUTINE items on eligibility criteria for inclusion in the administrative database (6% adequate, 21% partially adequate), description of record linkages (3%, 33%), listing of codes and adjudication of outcomes (0%, 15%), and providing a full description of the administrative database (9%, 82%) were not reported adequately in most trials.

What this study adds to what was known?

- No previous studies have examined completeness and transparency of reporting of recent randomized controlled trials conducted using administrative databases published prior to the development of the CONSORT-ROUTINE statement.

What is the implication and what should change now?

- The way in which administrative data are used in trials is often not reported adequately and may reduce utility of published trial reports.
- Authors should refer to the 2021 CONSORT Extension for Trials Conducted Using Cohorts and Routinely Collected Data (CONSORT-ROUTINE) for guidance on reporting of trials conducted using cohorts, registries, electronic health records, and administrative databases.

1. Introduction

There is growing interest in the use of administrative databases to evaluate health care interventions [1]. Health system administrative databases include information collected for administrative or billing purposes (e.g., Medicare data in the United States) that is routinely collected during clinic, hospital, laboratory, or pharmacy visits. These data can provide a readily available source of "real-world" data on a large population over expansive geographic regions [2]. Administrative databases are increasingly accessible to researchers and are being more frequently utilized in randomized controlled trials (RCTs) as an inexpensive and reliable resource of data at multiple stages of trials, from identifying and recruiting eligible participants to determining study outcomes [3,4].

There are several possible advantages of using administrative data to conduct RCTs, such as more efficient identification and recruitment of participants, improved data collection and outcome ascertainment, and improved feasibility due to reductions in cost, time, and resources [5]. However, several factors must be considered in these types of RCTs. For instance, the accuracy of administrative data and potential for bias should be taken into account if complete data are not available for all potential trial participants. Many large administrative databases have been developed by governments and private insurers, primarily for financial and administrative purposes, rather than clinical research, and therefore vary in completeness and accuracy [3,6,7]. Characteristics of participants in an administrative database used to select trial participants and how well they match the true target population for the trial should be taken into consideration because the representativeness of trial participants is dependent on that of the administrative database. In addition, there may be unique challenges in linking administrative data to other sources of data, stemming, for example, from linkage errors when records cannot be linked or are linked incorrectly [8].

The CONsolidated Standards of Reporting Trials (CONSORT) 2010 reporting guideline, which includes a 25-item checklist and flow diagram, was developed to improve the quality of reporting of parallel group RCTs [9]. Several extensions of the CONSORT Statement have been developed to encourage better reporting of alternative trial designs, including multiarm parallel group randomized trials [10], cluster trials [11], pilot and feasibility trials [12], and pragmatic trials [13], for example. CONSORT-ROUTINE, which was published in 2021, was developed as an extension for trials conducted using cohorts and routinely collected data, including registries, electronic health records, and administrative data, and provides a minimal set of items that should be included in reports of these types

of trials [14]. CONSORT-ROUTINE was needed because, although RCTs conducted using cohorts and routinely collected data share elements with two-arm parallel groups RCTs covered in the CONSORT 2010 statement, there are aspects that differ and require additional or modified reporting elements.

The present review examines RCTs identified as part of a broader scoping review [15] that was conducted to support the development of CONSORT-ROUTINE [14]. We aimed to (1) describe characteristics of RCTs conducted using administrative data and published after the CONSORT 2010 statement; and (2) assess and describe the quality of reporting of trials using administrative data by coding the completeness and transparency of all newly added and modified items from CONSORT-ROUTINE. For modified items, we also evaluated the transparency and completeness of reporting of the CONSORT 2010 items to determine if any suboptimal reporting was specific to the extension or if reporting was deficient even based on the CONSORT 2010 checklist item available at the time of publication. Since CONSORT-ROUTINE was published in 2021, the present study serves as a benchmark for pre-CONSORT-ROUTINE reporting of trials conducted using administrative databases.

2. Methods

The study protocol is accessible via the Open Science Framework: https://osf.io/dp23x/.

2.1. Inclusion and exclusion criteria for RCTs using administrative databases

The main scoping review included reports of trials that had used cohorts or routinely collected data to both identify or screen for participants and ascertain trial outcomes, as well as protocols, commentaries, and reviews of methodological aspects of conducting trials using cohorts or routinely collected data [15]. For the present review, eligible RCTs had to have used an administrative database to: (1) identify potentially eligible participants for the trial; (2) ascertain trial outcomes; or (3) both. Administrative databases were defined as databases not originally intended for research that are used for routine governance and program administration. Some examples include public or private insurance databases, birth or death registries, or employment and social care databases.

Methodological reviews, commentaries, and trial protocols were excluded. Publications that reported cost-effectiveness studies or RCTs assessing non-health outcomes were also excluded. Although the main scoping review searched for publications from 2007 to 2018, we restricted the present review to trials published from 2011 to 2018 to include only those published following the publication of the CONSORT 2010 statement.

2.2. Search strategy and study selection

Ovid MEDLINE Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE Daily and Ovid MEDLINE and EBM Reviews – Cochrane Methodology Registry (Final issue, third Quarter 2012) were searched from January 2007 to March 2018 (Cochrane Methodology Register up to last update in July 2012). Search strategies were developed by an experienced research librarian familiar with knowledge synthesis related to research methods and reporting with input from the project team and were peer reviewed using the Peer Review of the Electronic Search Strategy (PRESS) [16]. Appendix 1 provides search terms used to identify RCTs conducted using administrative data. References were imported into Refworks, and duplicates were removed. References were then imported into the systematic review software DistillerSR (Evidence Partners, Ottawa, Canada) [17]. The coding manual for inclusion and exclusion is shown in Appendix 2.

Titles and abstracts were screened independently by two reviewers. A liberal accelerated method, where titles and abstracts are screened by one reviewer and excluded publications are screened by a second reviewer, was used to identify publications for inclusion for full text review [18]. This was done in random order so that reviewers were blind to whether the other reviewer had already made a decision on any given title and abstract. Any trial that appeared potentially eligible was selected for full-text review, even if administrative database use was not described explicitly in the abstract. Full texts were screened independently by two reviewers, and any disagreements were resolved by discussion and consensus with involvement of a third reviewer, if necessary.

2.3. Data extraction

Data were extracted from all identified studies into a predefined form. Items extracted from each RCT publication included: research question of the trial, level of randomisation (cluster, individual), setting, disease of interest, use of administrative database (participant identification, trial data collection), intervention (surgical, screening, drug, other), comparator (placebo, active comparison, usual care), primary outcome, whether primary outcome was assessed using the administrative database, country where the RCT was conducted, and the number of clusters or participants randomized. These items were presented for all trials and separately by cluster RCTs and individually randomized RCTs. We also classified studies into reports of primary or secondary trial outcomes to evaluate any differences in the quality of reporting between primary and secondary reports. *Primary publications* were defined as reports on the trial's primary outcome(s) and also, possibly, other trial outcomes. *Secondary publications* were defined as reports on only secondary outcomes or other

post-hoc outcomes; reports that described reporting secondary outcomes or that referred to a previous publication of trial outcomes were coded as secondary reports.

Data were extracted by one investigator and validated by a second investigator.

2.4. Evaluation of completeness and transparency of reporting

We evaluated the completeness and transparency of all items in CONSORT-ROUTINE that were either new items (N = 5) or were items from the CONSORT 2010 statement [14] that were modified (N = 8). For modified items, we evaluated reporting both based on the original CONSORT 2010 items and based on the modified portion of the items. We did this in order to determine if any suboptimal reporting was related to inadequate reporting based on the original CONSORT 2010 checklist item, which was available at the time of publication of the included trials, or to the item modification. We did not evaluate reporting of items that were unmodified from the CONSORT 2010 statement.

For each included trial, reporting of each item was categorized as 'adequately reported', 'partially reported', 'inadequately or not reported', or 'not applicable'. A coding manual was devised to ensure consistent assessment of reporting (see Appendix 3). This manual was also used in separate studies that assessed the completeness and transparency of reporting in registries and electronic health records [19,20]. The data extraction rules and coding manual were pilot tested in five RCTs by four investigators to clarify wording and calibrate agreement between reviewers. The assessment of completeness and transparency of reporting was then conducted by one reviewer and validated by a second reviewer. Any disagreements were resolved by discussion and consensus with a third reviewer consulted as necessary. Results were synthesized by totalling the number and percentage of studies adequately, partially, and inadequately or not applicable for each item.

3. Results

We retrieved 660 unique citations from the electronic database search, of which 509 were excluded after title and abstract review and 118 after full-text review, leaving 33 publications for data extraction and quality assessment. See Figure 1. References for all includes studies are in Appendix 4.

3.1. Characteristics of included RCTs

Of the 33 included studies, 25 (76%) were primary publications, and eight (24%) were secondary publications; 20 (61%) were individually randomized, and 13 (39%) were cluster RCTs. There were 25 (76%) that used administrative databases to assess outcomes only, seven (21%) that used them for both participant identification and outcome assessment, and one (3%) that used them for identification of participants only.

Most trials were performed in the United States (N = 18, 55%), followed by Canada (N = 6, 18%) and the United Kingdom (N = 4, 12%). The interventions most frequently tested were educational (N = 10, 30%), multicomponent (N = 7, 21%), and drugs (N = 4, 12%). Comparators included usual care (N = 25, 76%) and alternative therapies (N = 8, 24%). Commonly reported primary outcomes were mortality (N = 5, 15%), hospitalization (N = 5, 15%), and surrogate outcomes (N = 4, 12%). Of the 33 included studies, 22 (67%) used the administrative database for ascertaining the primary trial outcome and 10 (30%) for ascertaining secondary outcomes; for one trial (3%) it was unclear whether primary or secondary outcomes were ascertained (see Table 1 and Appendix 5 for table by cluster versus individually randomized trials).

3.2. Baseline assessment of completeness and transparency of reporting

Results for all included trials are available at https://osf.io/hs9tz/.

3.2.1. CONSORT 2010 items with modifications in CONSORT-ROUTINE

Eight CONSORT 2010 items were modified in CONSORT-ROUTINE. As shown in Table 2, the original version of six of these items ("Structured summary" (88%), "Eligibility criteria" (85%), "Outcome definition" (94%), "Participant flow" (67%), "Interpretation" (97%) and "Funding" (58%)) were adequately reported in a majority of trials (Table 2). Item "Trial design" was adequately reported in 39%, and Item "Allocation concealment mechanism" was adequately reported in 27%. Compliance to the CONSORT 2010 criteria was generally similar in primary and secondary publications (see Appendix 6).

In the modified portions of the modified items, three items were adequately reported in a majority of trial publications; ("Modified – Administrative database use and name in the abstract" (91%), "Modified – Description of trial design" (82%) and "Modified – Outcomes" (88%)). One item "Modified – Funding" was adequately reported for only 6% but partially reported for 61%. Another, "Modified – Interpretation of results", was reported adequately in only 21%. The remaining two items were not applicable for assessment in a majority of trials because the trials used administrative data for assessing outcomes only, but not for identifying eligible participants or as a mechanism for allocating participants to trial arms: ("Modified – Eligibility criteria for participants" (82%) and "Modified – Participant flow" (84%)). Item "Modified – Allocation concealment" was not coded separately as the modification was a clarification of the original item. Results were

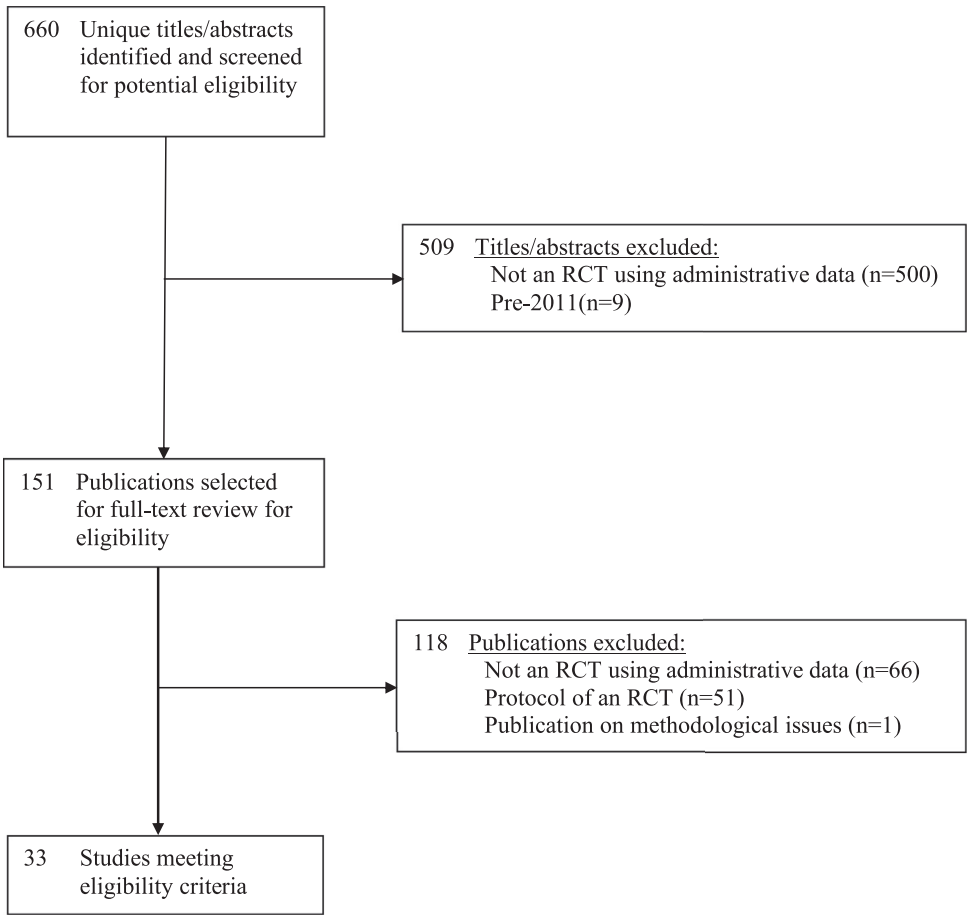

Figure 1. Flow diagram of publication selection process – randomized controlled trials conducted using administrative data

similar when stratified by primary and secondary publication type (Appendix 6).

3.2.2. New items in CONSORT-ROUTINE

Of the five new items evaluated, four items were inadequately reported in >50% of trials; "Eligibility (for cohort or routinely collected database)" (73%), "Description of record linkage" (64%) and "List of codes, monitoring and adjudication for outcomes" (82%). Item "Description of the cohort or routinely collected database" was adequately reported in only 9% but partially reported in 82%. Only one item "Informed consent" (79%) was adequately reported in most of the trials.

4. Discussion

We evaluated the degree to which 33 RCTs conducted using administrative data reported results consistent with existing CONSORT reporting criteria and with new criteria in CONSORT-ROUTINE [14]. Among eight modified items, seven included additional content in the modification. Based on the CONSORT 2010 versions of the eight items, six items related to elements of trial design, interpretation, and funding were adequately reported in at least 50% of included trials, but two items related to randomisation and allocation methodology were not typically reported adequately. Considering only the modified parts of the seven items with additional content, three items related to describing that routinely collected data were used in the abstract, including the administrative dataset in the statement of the trial design, and describing the source of outcome data were adequately reported in a majority of the trials. Modifications related to interpreting how the use of routinely collected data may have influenced the trial or its generalizability and reporting funding of the routinely collected database were not reported adequately in most trials. Two items with modifications were not evaluated in most trials because they were only applicable to trials that used administrative databases for purposes other than assessing outcomes (e.g., eligibility, recruitment, allocation). Among the five new items, four related to aspects of using the routinely collected data were not reported adequately in most trials, whereas one item that requires reporting of aspects of consent was adequately reported in more than 50% of trials.

Among key reporting gaps, most studies did not adequately describe the administrative database used in the RCT, which is important for assessing the validity of the

Table 1. Characteristics of trials conducted using administrative databases

	Total (%) (n = 33)
Primary publication (versus secondary)	25 (76%)
Use of administrative data in trial	
Identification of patients	1 (3%)
Outcome ascertainment	25 (76%)
Both identification and outcomes	7 (21%)
Administrative data used for primary outcome (versus no or unclear)	22 (67%)
Setting	
Inpatient	11 (33%)
Primary care	10 (30%)
Other[I]	12 (36%)
Country	
USA	18 (55%)
Canada	6 (18%)
UK	4 (12%)
Other[II]	2 (6%)
Disease type	
General health	12 (36%)
Cardiovascular disease	9 (27%)
Other[III]	12 (36%)
Intervention	
Educational	10 (30%)
Multicomponent	7 (21%)
Drug	4 (12%)
Other[IV]	12 (36%)
Active comparator (versus usual care)	8 (24%)
Primary outcome	
Mortality	5 (15%)
Hospitalization	5 (15%)
Surrogate	4 (12%)
Other[V]	19 (58%)
Sample size	
Clusters (Median and IQR) in 13 cluster randomised trials	101 [73–221]
Participants (Median and IQR) in 13 cluster randomised trials	119,910 [86,998–526,850]
Participants (Median and IQR) in 20 individually randomised trials	32,804 [32,804–33,081]

[I] Community medicine, outpatient, residential setting, multiple settings.
[II] Europe, Australia, India, New Zealand.
[III] Mental health, respiratory disease, diabetes, cancer, potentially inapproproate medicines, drug side effects, infection, disability, homelessness.
[IV] Guideline/reminder-based, elephone/web-based care, Family Finding program, referral, housing, health care provider support, surgical.
[V] Self-reported, insurance claims, uptake of treatment, disease occurence, no primary outcome, adherence, risk of injury, multiple/composite outcomes, injury rate.

data used and may have implications for trial generalizability. Information related to database eligibility criteria was also inadequately reported, which could negatively affect the ability of readers to judge the representativeness of the database to the population targeted for the RCT intervention. Details on linkage methodology between databases, which can add biases due to incomplete or incorrect matching of participants, was also poorly reported

Table 2. Completeness and transparency of reporting for CONSORT 2010 items that were modified, modified items, and new items in CONSORT-ROUTINE[I]

	Item[II]	CONSORT 2010 Item that was modified	CONSORT-ROUTINE item text	N = 33			
				Adequately reported N (%)	Partially reported N (%)	Inadequately or not reported N (%)	Not applicable N (%)
Title and abstract							
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts).		29 (88%)	4 (12%)	0 (0%)	-
			Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts). **Specify that a cohort or routinely collected data were used to conduct the trial and, if applicable, provide the name of the cohort or routinely collected database(s) (Modified)**	30 (91%)	3 (9%)	0 (0%)	-
Methods							
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio		11 (33%)	9 (27%)	13 (39%)	-
			Description of trial design (such as parallel, factorial) including allocation ratio, **that a cohort or routinely collected database(s) was used to conduct the trial (such as electronic health record, registry) and how the data were used within the trial (such as identification of eligible trial participants, trial outcomes) (Modified)**	27 (82%)	6 (18%)	0 (0%)	-
Cohort or routinely collected database	ROUTINE-1		Name, if applicable, and description of the cohort or routinely collected database(s) used to conduct the trial, including information on the setting (such as primary care), locations, and dates, (such as periods of recruitment, follow-up, and data collection) (New)	3 (9%)	27 (82%)	3 (9%)	-
	ROUTINE-2		Eligibility criteria for participants in the cohort or routinely collected database(s) (New)	2 (6%)	7 (21%)	24 (73%)	-
	ROUTINE-3		State whether the study included person-level, institutional-level, or other data linkage across two or more databases and, if so, linkage techniques and methods used to evaluate completeness and accuracy of linkage (New)	1 (3%)	11 (33%)	21 (64%)	-

(*continued on next page*)

Table 2 (*continued*)

	Item[ll]	CONSORT 2010 Item that was modified	CONSORT-ROUTINE item text	N = 33			
				Adequately reported N (%)	Partially reported N (%)	Inadequately or not reported N (%)	Not applicable N (%)
Trials participants	4a	Eligibility criteria for participants		28 (85%)	4 (12%)	1 (3%)	-
			Eligibility criteria for trial participants, **including information on how to access the list of codes and algorithms used to identify eligible participants, information on accuracy and completeness of data used to ascertain eligibility, and methods used to validate accuracy and completeness (e.g., monitoring, adjudication), if applicable (Modified)**	0 (0%)	5 (15%)	1 (3%)	27 (82%)
	ROUTINE-4		Describe whether and how consent was obtained (New)	26 (79%)	1 (3%)	6 (18%)	-
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed		31 (94%)	2 (6%)	0 (0%)	-
			Completely defined prespecified primary and secondary outcome measures, including how and when they were ascertained and **the cohort or routinely collected database(s) used to ascertain each outcome (Modified)**	29 (88%)	4 (12%)	0 (0%)	0 (0%)
	ROUTINE-5		Information on how to access the list of codes and algorithms used to define or derive the outcomes from the cohort or routinely collected database(s) used to conduct the trial, information on accuracy and completeness of outcome variables, and methods used to validate accuracy and completeness (e.g., monitoring, adjudication), if applicable (New)	0 (0%)	5 (15%)	27 (82%)	1 (3%)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Mechanism used to implement the random allocation sequence **(such as embedding an automated randomizer within the cohort or routinely collected database(s)),** describing any steps taken to conceal the sequence until interventions were assigned (Modified)	9 (27%)	3 (9%)	21 (64%)	-

(*continued on next page*)

Table 2 (*continued*)

	Item[II]	CONSORT 2010 Item that was modified	CONSORT-ROUTINE item text	N = 33			
				Adequately reported N (%)	Partially reported N (%)	Inadequately or not reported N (%)	Not applicable N (%)
Results							
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome		22 (67%)	9 (27%)	2 (6%)	-
			For each group, the number of participants **in the cohort or routinely collected database(s) used to conduct the trial and the numbers screened for eligibility,** randomly assigned, **offered and accepted interventions (e.g., cohort multiple RCTs),** received intended treatment, and analysed for the primary outcome (Modified)	1 (3%)	5 (15%)	1 (3%)	26 (84%)
Discussion							
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		32 (97%)	1 (3%)	0 (0%)	-
			Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence, **including the implications of using data that were not collected to answer the trial research questions (Modified)**	7 (21%)	1 (3%)	25 (76%)	-
Other information							
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders		19 (58%)	13 (39%)	1 (3%)	-
			Sources of funding and other support **for** both the trial and **the cohort or routinely collected database(s), role of funders (Modified)**	2 (6%)	20 (61%)	11 (33%)	-

[I] For modified items, modifications are shown in bold. For those items, only portion modified was evaluated.
[II] Item numbers reflect numbers in original 2010 CONSORT checklist that were modified or new items. New items are designated by "CONSORT-ROUTINE".

in a majority of the trials; of 33 included studies, only one trial reported linkage adequately. Reporting of data validation and adjudication procedures, which is necessary to assess possible misclassification bias, was also not adequately reported in most trials. Another consistent gap related to implications of using administrative data, which is important for contextualizing trial results and understanding potential limitations of using administrative data in the trial. Finally, sources of funding for the administrative database used were rarely reported. Separate studies were conducted to evaluate reporting in trials conducted using electronic health records [19] and registries [20]. Similar trends were observed in those studies. In all trial types, items related to methodological considerations in using routinely collected data in trials, which were new CONSORT-ROUTINE items, were not adequately reported in most trials.

Our review has limitations that must be taken into account. First, our scoping review was able to capture only a sample of RCTs conducted using administrative databases rather than all trials that have been conducted using administrative databases. This was in part because of the lack of accepted specific Medical Subject Headings to identify RCTs conducted using administrative databases. In combination with our inclusion criteria on what constituted an RCT conducted using an administrative database, this led to a relatively small sample of only 33 RCTs. It is possible that this approach could have influenced the representativeness of the trials we included. For instance, we searched for trials based on their reporting of use of administrative data in the title or abstract; thus, it follows that this item would almost always be reported in our sample of trials ("Modified – Administrative database use and name in the abstract" and "Modified – Description of trial design"). Second, we did not extend our assessment to include study protocols for included trials. Some authors may have included additional study details within the protocol. However, the CONSORT extension checklist is a minimum set of standards that should be adequately reported in reports of trial outcomes, irrespective of having been previously published in a protocol or in a primary trial publication in the case of secondary reports.

5. Conclusion

In summary, this study was the first to assess the completeness and transparency of reporting of RCTs conducted using administrative databases against those elements now deemed to form a minimum reporting standard for such studies. Although we observed CONSORT 2010 criteria and items related to the application of the administrative database within the RCT to be largely adequately reported, we found a need for attention to more fulsome reporting of methodological conduct of these trials, mostly related to methodological aspects and implications of using administrative databases in RCTs. The new CONSORT-ROUTINE provides guidance to improve reporting of these types of trials. We recommend those who support, conduct, and report trials conducted using administrative databases to adhere to minimum reporting standards outlined in the newly developed CONSORT-ROUTINE, in order to ensure greater transparency and replicability and facilitate the use of trial results in healthcare decisions.

Availability of data and materials

Additional data beyond that reported in the main and supplementary materials can be requested from the corresponding author.

Author contributions

Mahrukh Imran: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Validation, Writing – original draft. **Kimberly McCord:** Conceptualization, Data curation, Investigation, Methodology, Validation, Writing – review & editing. **Stephen J. McCall:** Conceptualization, Data curation, Investigation, Methodology, Validation, Writing – review & editing. **Linda Kwakkenbos:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Supervision, Writing – review & editing. **Margaret Sampson:** Conceptualization, Methodology, Search, Writing – review & editing. **Ole Fröbert:** Conceptualization, Funding acquisition, Methodology, Writing – review & editing. **Chris Gale:** Conceptualization, Funding acquisition, Methodology, Writing – review & editing. **Lars G. Hemkens:** Conceptualization, Methodology, Supervision, Writing – review & editing. **Sinéad M. Langan:** Conceptualization, Methodology, Writing – review & editing. **David Moher:** Conceptualization, Methodology, Writing – review & editing. **Clare Relton:** Conceptualization, Funding acquisition, Methodology, Writing – review & editing. **Merrick Zwarenstein:** Conceptualization, Methodology, Writing – review & editing. **Edmund Juszczak:** Conceptualization, Funding acquisition, Methodology, Writing – review & editing. **Brett D. Thombs:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Methodology, Supervision, Writing – review & editing.

Declaration of Competing Interests

All authors have completed the ICJME uniform disclosure form and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jclinepi.2021.09.010.

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