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The state of reporting of primary biomedical research: A scoping review protocol

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The state of reporting of primary biomedical research: A scoping review protocol

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Strengths and limitations of this study

1. In this systematic scoping review, we will assess the completeness of reporting in the literature and adherence to reporting guidelines, consistency between protocols or registrations and full reports, and agreement between abstracts and full-text articles.
2. Results from our study will significantly advance our understanding of the extent of incomplete and biased reporting, factors related to improved completeness and consistency of reporting, and potential recommendations for various stakeholders in the biomedical community.
3. Potential limitation may include small number of eligible studies in the literature for this scoping review.

Abstract

Introduction: Incomplete or biased reporting remains a major concern in the biomedical literature. Incomplete or biased reporting may yield the published findings unreliable, irreproducible or sometimes misleading. In this study, we aim to conduct a scoping review of systematic reviews and systematic surveys that have evaluated incomplete and biased reporting in primary biomedical studies, with focuses on 1) the state-of-the-art extent of adherence to the emerging reporting guidelines in primary biomedical research, 2) the inconsistency between protocols or registrations and full reports, and 3) the disagreement between abstracts and full-text articles.

Methods and analyses: We will use a systematic and comprehensive approach to retrieve all available and eligible systematic reviews and systematic surveys in the literature. Electronic databases including Web of Science, EMBASE, MEDLINE, and Cumulative Index to Nursing and Allied Health Literature (CINAHL) will be searched for relevant studies. Our outcomes include levels of adherence to reporting guidelines, levels of consistency between protocols or registrations and full reports, and the agreement between abstracts and full reports, all of which are expressed as percentages, quality scores or categorized rating (such as high, medium, low). No pooled analyses will be performed quantitatively given the heterogeneity of the included systematic reviews and surveys. Likewise, factors associated with improved completeness and consistency of reporting will be summarized qualitatively. Quality of the included systematic reviews will be evaluated by the AMSTAR (a measurement tool to assess systematic reviews) criteria.

Ethics and dissemination: All findings will be published in peer-reviewed journals electronically and in print. Results from our study may significantly advance our understanding of the extent of incomplete and biased reporting, factors related to improved completeness and consistency of reporting, and potential recommendations for various stakeholders in the biomedical community.

Keywords: incomplete reporting; biased reporting; reporting guideline; consistency; scoping review

Introduction

The current reporting in primary biomedical research remains an issue of concern in the literature (1). For instance, it is widely recognized that incomplete reporting is pervasive in biomedical research, leading to potential waste of resources, skeptical interpretation of findings and even scientific misconduct (1). One study showed that over 50% of research findings were not sufficiently or completely reported to make them usable or replicable, which represented a substantial waste of resources and efforts (2). Likewise, it is difficult to make an informed judgement about the risk of bias and credibility of findings in a study due to its incomplete reporting and lack of linkage to protocol or registration (3). Moreover, incomplete reporting can result in unnecessary exposure or harm to patients and lead to imprecise or biased treatment effect estimates to inform decision-making (1, 4). To improve transparent and complete reporting in biomedical research, reporting guidelines have been developed and widely adopted by more and more journals. The EQUATOR (Enhancing Quality and Transparency in Health Research) network provides support for the dissemination of such guidelines including the CONSORT (Consolidated Standards of Reporting Trials) for clinical trials, STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) for observational studies, PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) for systematic reviews, STARD (Standards for Reporting Diagnostic accuracy studies) for diagnostic or prognostic studies, and ARRIVE (Animal Research: Reporting In Vivo Experiments) for animal studies, among others (5). Evidence has shown that application of guidelines is associated with improved standards of reporting, and looking for missing items from guidelines of submissions in the peer review process can enhance the quality of peer reviews and the finalized publications (6-9). Despite the usefulness of reporting guidelines, adherence to such guidelines in the biomedical research remains substantially low (3, 10).

Beyond poor adherence to reporting guidelines, inconsistent or biased reporting between protocols or registrations and full-published articles has also raised significant concerns. For instance, one study comparing protocols and full reports in clinical trials found that approximately two-thirds of full reports had at least planned primary outcome modified, introduced, or omitted (11). Similarly, another study focusing on trials funded by CIHR (Canadian Institutes of Health Research) reported that 40% of the trials had a difference in primary outcomes between protocols and full reports (12). Furthermore, abstracts as the generally most read and accessed section of a publication, were found to be distorted or over-optimistic presentations of results than were shown in full reports (13). Discrepancy between abstracts and full reports deserves more intensive attention and stringent examination in biomedical

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4 research, because 1) abstracts are usually prepared with the least care; 2) readers draw conclusions about
5 a study mainly depending on abstracts; and 3) audience may make their decisions only based on abstracts
6 especially when full reports are not accessible (3, 13, 14).
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11 Though increasing evidence on incomplete and biased reporting is available, it remains unclear 1) the
12 state-of-the-art extent of adherence to the emerging reporting guidelines in primary biomedical research, 2)
13 the inconsistency between protocols or registrations and full reports, or 3) the disagreement between
14 abstracts and full-text articles. Therefore we aim to conduct a scoping review of systematic reviews and
15 systematic surveys that have evaluated incomplete and biased reporting in primary biomedical studies.
16 The objective of this study is to explore the current state of incomplete and biased reporting in primary
17 biomedical research and to identify factors associated with improved completeness and consistency of
18 reporting.
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25 26 **Methods**

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28 In this scoping review, we will use a systematic and comprehensive approach to retrieve all available and
29 eligible systematic reviews and systematic surveys in the literature (15). Our findings will be reported
30 based on the PRISMA guideline (16). Results will be presented in three parts including 1) current
31 adherence to reporting guidelines; 2) inconsistency between protocols or registrations and full reports;
32 and 3) discrepancy between abstracts and full reports. The outline of this scoping review is shown in
33 **Figure 1**. For the first part, we will build upon previous work on adherence to reporting guidelines which
34 was limited to six guidelines for human studies and up to 2012 (10). Our previous work will be expanded,
35 updated and included in this scoping review.
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43 *Study eligibility*

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45 Systematic reviews evaluating incomplete or biased reporting with primary focuses on adherence to
46 guidelines, comparison between protocols or registrations and full reports, or consistency between
47 abstracts and full reports will be eligible. For the purposes of this review, a systematic review will be
48 defined as study with predetermined objectives, eligibility criteria, at least one electronic database
49 searched, data extraction, and at least one study included. Systematic surveys that use a random selection
50 of studies will also be eligible.
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57 For the adherence to reporting guidelines, we will locate the guidelines included in the EQUATOR
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4 network as well as others widely adopted in the literature, which includes CONSORT, PRISMA,
5 STROBE, STARD, ARRIVE, QUOROM (Quality of Reporting of Meta-analysis), TREND (Transparent
6 Reporting of Evaluations with Nonrandomized Designs), MOOSE (Meta-analysis Of Observational
7 Studies in Epidemiology), CARE (Case Report), SRQR (Standards for Reporting Qualitative Research),
8 COREQ (Consolidated criteria for Reporting Qualitative research), TRIPOD (Transparent Reporting of a
9 multivariable prediction model for Individual Prognosis or Diagnosis), SQUIRE (Standards for Quality
10 Improvement Reporting Excellence), CHEERES (Consolidated Health Economic Evaluation Reporting
11 Standards), SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials), and
12 REMARK (Reporting Recommendations for Tumor Marker Prognostic Studies). Systematic reviews that
13 do not evaluate adherence to one of the aforementioned guidelines will not be included in our study. We
14 will also exclude systematic reviews if their primary focuses are not incomplete reporting, or they only
15 publish editorials, abstracts, letters or commentaries without full reports, or they are duplicates of
16 included systematic reviews.
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28 For the inconsistency between protocols or registrations and full reports and between abstracts and full
29 reports, systematic reviews or surveys from all fields of medicine will be eligible if they clearly described
30 their objectives, identified the sources of data used and the aspects of reporting they were comparing.
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35 Furthermore, to expand the extent of this scoping review, we will also include systematic reviews or
36 surveys that specifically investigated the incomplete or biased reporting for study subgroups (**Figure 1**).
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39 *Search strategy*

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41 We will search the electronic databases including Web of Science, EMBASE, MEDLINE, and
42 Cumulative Index to Nursing and Allied Health Literature (CINAHL), for relevant studies. The search
43 will be limited between January 1996 and September 30th 2016 given that the CONSORT (Consolidated
44 Standards of Reporting Trials) statement was the first reporting guideline in biomedical research and
45 developed in 1996 (17). The search strategy will be designed with the assistance of an experienced
46 librarian. Key descriptors that include terms for systematic reviews or systematic surveys, reporting, and
47 guidelines or adherence or inconsistency or registrations or protocols or abstracts will be used for the
48 search, for instance, (Systematic reviews OR surveys OR reviews) AND (quality of reporting OR
49 completeness of reporting OR selective reporting OR consistency of reporting OR biased reporting OR
50 subgroup) AND ((QUOROM OR TREND OR MOOSE OR CONSORT OR STROBE OR PRISMA OR
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CARE OR SRQR OR COREQ OR STARD OR TRIPOD OR SQUIRE OR CHEERES OR ARRIVE OR SPIRIT OR REMARK) OR (Adherence OR Consistency OR Protocol OR Registration OR Abstract)). Titles and abstracts retrieved will be first screened for eligibility before full texts are thoroughly examined. Reasons will be documented for excluded studies when assessing full texts. All the reference lists from the included systematic reviews or surveys will be also reviewed to retrieve additional relevant studies. We will limit the search to English language because of the lack of resources for translation of other languages. All the search processes will be performed by two reviewers (YJ and IN) independently. Disagreement will be addressed by consensus after discussion, and a third reviewer (GL) will be consulted if no consensus is reached. The Kappa statistic will be used to quantify the level of agreement between the two reviewers (YJ and IN) (18).

Outcomes

In this scoping review, our outcomes include levels of adherence to reporting guidelines, levels of consistency between protocols or registrations and full reports, and the agreement between abstracts and full reports, all of which are expressed as percentages, quality scores or categorized rating (such as high, medium, low). Specifically, incomplete reporting will be assessed by the levels of adherence to reporting guidelines and their checklists when available. Levels of consistency will be evaluated by the agreement on research questions, study designs, study samples, interventions or exposures, time duration, comparators, statistical plan, result presentations and interpretations, and conclusions between protocols or registrations and full reports and between abstracts and full reports.

Data collection

Two reviewers (YJ and IN) will independently collect data from the included systematic reviews or surveys using data extraction forms. The data extraction forms will be piloted and modified before its final version to be used. Specifically, we will extract the data as shown below:

- 1) basic characteristics: authors, publication year, journal in which the study is published, field of study, study region, number of primary studies included, number of study samples (including animals and participants), and reporting guideline (or its extension or modification) assessed in the systematic review or survey;
- 2) for the adherence to guidelines, we will gather the reported adherence to the items specified in the corresponding guideline; for the consistency between protocols or registrations and full reports, and the agreement between abstracts and full reports, data extracted include (dis)concordance for research

question, study samples, intervention (or exposure), comparator, outcome, time duration, study design, statistical plan, result presentations and interpretations, conclusion, and other information specifically evaluated in the systematic review or survey;

3) outcome measures presented as levels of adherence to reporting guidelines or levels of consistency will be collected for all the relevant items if provided;

4) factors that are found to be related to improved completeness and consistency of reporting in the individual systematic reviews or survey; and

5) authors' overall conclusion in the systematic review or survey.

Any disagreement will be resolved by the two reviewers' discussion and consensus. In addition, we will contact the authors of included systematic reviews to collect essential and relevant data if necessary.

Data analysis

The levels of adherence to guidelines and the levels of consistency will be described in a narrative manner.

The general characteristics of included studies, levels of adherence to reporting guidelines or levels of consistency between protocols or registrations and full reports and between abstracts and full reports, factors related to improved completeness and consistency of reporting, and conclusions in the included studies, will be summarized and discussed in our study. No pooled analyses will be performed quantitatively given the heterogeneity of the included systematic reviews and surveys. Likewise, factors associated with improved completeness and consistency of reporting will be summarized qualitatively.

Quality assessment of included systematic reviews

We will evaluate the quality of all the included systematic reviews, using the AMSTAR (a measurement tool to assess systematic reviews) criteria (19). The R(evised)-AMSTAR will not be used in our study, given its limited application and unknown measurement properties (20). However, some items of AMSTAR may not be applicable to all the included systematic reviews. For instance, the item 9 'were the methods used to combine the findings of studies appropriate' (because not all the systematic reviews used a pooled estimate) is not relevant to some included studies, thereby being omitted from the quality evaluation. Likewise, we will not assess quality of the included systematic surveys, due to lack of relevant assessment tools or guidelines.

Discussion

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4 Incomplete or biased reporting remains a major concern in the biomedical literature including preclinical
5 studies, diagnostic research, qualitative studies, economic studies, clinical trials, and observational studies,
6 among others (1, 3). When the reporting is incomplete or biased, the apparent methodological quality of
7 published findings may not reveal the actual quality of the study as evaluated from the protocol or
8 registration or abstracts, yielding the published findings unreliable, irreproducible or sometimes
9 misleading (2, 3, 11, 21). In this systematic scoping review, we will assess the completeness of reporting
10 in the literature and adherence to reporting guidelines, consistency between protocols or registrations and
11 full reports, and agreement between abstracts and full-text articles. We will present our results as three
12 parts, where the first part of adherence to reporting guidelines is an updated and expanded research based
13 on our previous work (10). In contrast, for the other parts of inconsistency between protocols or
14 registrations and full reports and discrepancy between abstracts and full reports, no study summarizing all
15 the best current evidence in multi-disciplines is available. Therefore results from our study may
16 significantly advance our understanding of the extent of incomplete and biased reporting, factors related
17 to improved completeness and consistency of reporting, and potential recommendations for various
18 stakeholders in the biomedical community. All findings will be published in peer-reviewed journals
19 electronically and in print.
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35 **Contributors**

36 GL, LM, ZS and LT were responsible for the study conception and design. GL, YJ and LT were
37 responsible for drafting the manuscript. LM, ZS, YJ, IN, MAHL and JDA made several revisions and
38 provided professional support. All authors read and approved the final version of the manuscript.
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46 **Competing interests** None declared.
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4 **Figure legend:**
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7 Figure 1. Flow diagram showing the outline of this scoping review
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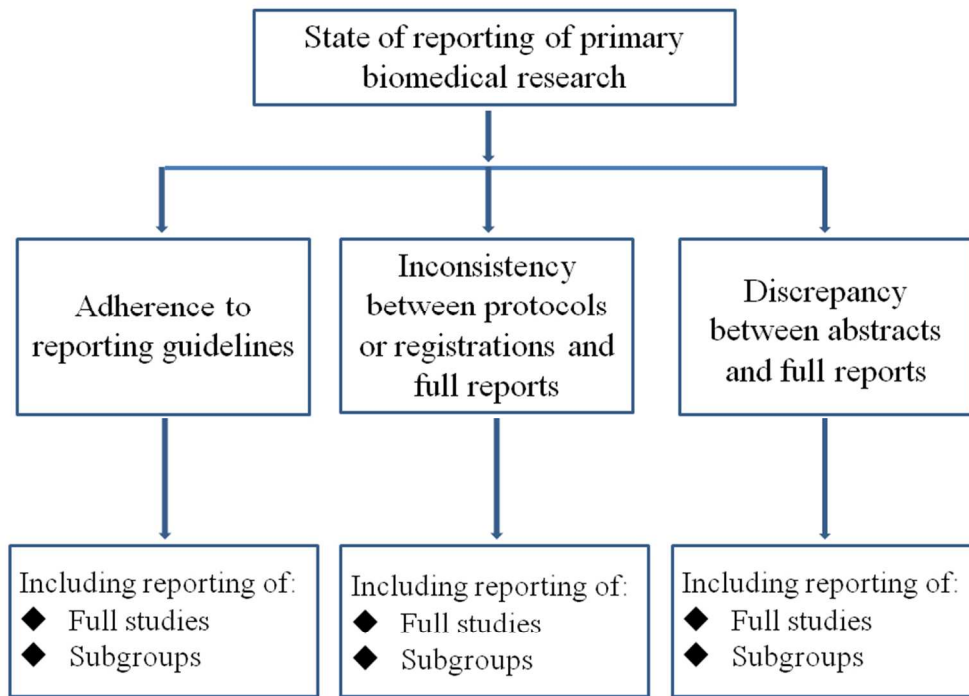


Figure 1. Flow diagram showing the outline of this scoping review

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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Page number
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	N/A
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	N/A
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1-2
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	10
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support:			
Sources	5a	Indicate sources of financial or other support for the review	10
Sponsor	5b	Provide name for the review funder and/or sponsor	N/A
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	N/A
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	5-6
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	6
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	6-7
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	7-8
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	7-8

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	8-9
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	7-8
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	8-9
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	8-9
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	8
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	9
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	N/A
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)	N/A
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	9
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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For peer review only

Strengths and limitations of this study

1. [In this scoping review](#), we will assess the completeness of reporting in the literature and adherence to reporting guidelines, consistency between protocols or registrations and full reports, and agreement between abstracts and full-text articles.
2. Results from our study will significantly advance our understanding of the extent of incomplete and inconsistent reporting, factors related to improved completeness and consistency of reporting, and potential recommendations for various stakeholders in the biomedical community.
3. Potential limitation may include small number of eligible studies in the literature for this scoping review.

Abstract

Introduction: Incomplete or inconsistent reporting remains a major concern in the biomedical literature. Incomplete or inconsistent reporting may yield the published findings unreliable, irreproducible or sometimes misleading. In this study based on evidence from systematic reviews and surveys that have evaluated the reporting issues in primary biomedical studies, we aim to conduct a scoping review of with focuses on 1) the state-of-the-art extent of adherence to the emerging reporting guidelines in primary biomedical research, 2) the inconsistency between protocols or registrations and full reports, and 3) the disagreement between abstracts and full-text articles.

Methods and analyses: We will use a comprehensive approach to retrieve all available and eligible systematic reviews and surveys in the literature. Electronic databases including Web of Science, EMBASE, MEDLINE, and Cumulative Index to Nursing and Allied Health Literature (CINAHL) will be searched for relevant studies. Our outcomes include levels of adherence to reporting guidelines, levels of consistency between protocols or registrations and full reports, and the agreement between abstracts and full reports, all of which are expressed as percentages, quality scores or categorized rating (such as high, medium, low). No pooled analyses will be performed quantitatively given the heterogeneity of the included systematic reviews and surveys. Likewise, factors associated with improved completeness and consistency of reporting will be summarized qualitatively. Quality of the included systematic reviews will be evaluated by the AMSTAR (a measurement tool to assess systematic reviews) criteria.

Ethics and dissemination: All findings will be published in peer-reviewed journals electronically and in print. Results from our study may significantly advance our understanding of the extent of incomplete and inconsistent reporting, factors related to improved completeness and consistency of reporting, and potential recommendations for various stakeholders in the biomedical community.

Keywords: incomplete reporting; inconsistent reporting; reporting guideline; bias; scoping review

Introduction

Primary research is generally defined as the empirical research studies with collection of original primary data (1). The current reporting in primary biomedical research remains an issue of concern in the literature (2). For instance, it is widely recognized that incomplete reporting is pervasive in biomedical research, leading to potential waste of resources, skeptical interpretation of findings and even scientific misconduct (2). One study showed that over 50% of research findings were not sufficiently or completely reported to make them usable or replicable, which represented a substantial waste of resources and efforts (3). Likewise, it is difficult to make an informed judgement about the risk of bias and credibility of findings in a study due to its incomplete reporting and lack of linkage to protocol or registration (4). Moreover, incomplete reporting can result in unnecessary exposure or harm to patients and lead to imprecise or biased treatment effect estimates to inform decision-making (2, 5). To improve transparent and complete reporting in biomedical research, reporting guidelines have been developed and widely adopted by more and more journals. The EQUATOR (Enhancing Quality and Transparency in Health Research) network provides support for the dissemination of such guidelines including the CONSORT (Consolidated Standards of Reporting Trials) for clinical trials, STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) for observational studies, PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) for systematic reviews, STARD (Standards for Reporting Diagnostic accuracy studies) for diagnostic or prognostic studies, and ARRIVE (Animal Research: Reporting In Vivo Experiments) for animal studies, among others (6). Evidence has shown that application of guidelines is associated with improved standards of reporting, and looking for missing items from guidelines of submissions in the peer review process can enhance the quality of peer reviews and the finalized publications (7-10). Despite the usefulness of reporting guidelines, adherence to such guidelines in the biomedical research remains unsatisfactorily low (4, 11, 12).

Beyond poor adherence to reporting guidelines, inconsistent or biased reporting between protocols or registrations and full-published articles has also raised significant concerns (13-16). For instance, one study comparing protocols and full reports in clinical trials found that approximately two-thirds of full reports had at least planned primary outcome modified, introduced, or omitted (17). Similarly, another study focusing on trials funded by CIHR (Canadian Institutes of Health Research) reported that 40% of the trials had a difference in primary outcomes between protocols and full reports (18). Furthermore, abstracts as the generally most read and accessed section of a publication, were found to be distorted or overly-optimistic presentations of results than were shown in full reports (19). Discrepancy between

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4 abstracts and full reports deserves more intensive attention and stringent examination in biomedical
5 research, because 1) abstracts are usually prepared with the least care; 2) readers draw conclusions about
6 a study mainly depending on abstracts; and 3) audience may make their decisions only based on abstracts
7 especially when full reports are not accessible (4, 19, 20).
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12 Though increasing evidence on incomplete and inconsistent reporting is available, it remains unclear 1)
13 the state-of-the-art extent of adherence to the emerging reporting guidelines in primary biomedical
14 research, 2) the inconsistency between protocols or registrations and full reports, or 3) the disagreement
15 between abstracts and full-text articles. Therefore we aim to conduct a scoping review to explore the
16 current state of incomplete and inconsistent reporting in primary biomedical research and to investigate
17 factors associated with improved completeness and consistency of reporting, based on evidence from
18 systematic reviews and surveys. While the existing systematic reviews and surveys generally evaluate a
19 specific research area, or a group of journals or diseases with quantitative syntheses conducted, our
20 scoping review will differ from them in mapping literature and addressing the state of reporting in the
21 overall primary biomedical community, comprehensively summarizing the heterogeneous evidence with a
22 qualitative description reported, and assessing evidence gaps and providing recommendations for future
23 research (21, 22).
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33 34 35 **Methods**

36 In this scoping review, we will use a systematic and comprehensive approach to retrieve all available and
37 eligible systematic reviews and surveys in the literature (23). Our study will be conducted and reported
38 based on the PRISMA guideline (24). However, no risk-of-bias assessment in individual studies or
39 quantitative synthesis will be performed because they are not relevant to this scoping review.
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45 Our results will be presented in three parts including 1) current adherence to reporting guidelines; 2)
46 inconsistency between protocols or registrations and full reports; and 3) discrepancy between abstracts
47 and full reports. The outline of this scoping review is shown in **Figure 1**. We also provide a summary
48 table for these three parts (**Table 1**). For the first part, we will build upon previous work on adherence to
49 reporting guidelines which was limited to six guidelines for human studies and up to 2012 (11). Our
50 previous work will be expanded, updated and included in this scoping review.
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55 56 57 *Study eligibility*

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4 Systematic reviews evaluating incomplete or inconsistent reporting with primary focuses on adherence to
5 guidelines, comparison between protocols or registrations and full reports, or consistency between
6 abstracts and full reports will be eligible. For the purposes of this review, an eligible systematic review
7 will be defined as study with predetermined objectives, eligibility criteria, at least one electronic database
8 searched, data extraction, and at least one study included. [All the surveys focusing on specific research
9 questions in primary biomedical research will be eligible for inclusion in this scoping review.](#)
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16 For the adherence to reporting guidelines, we will locate the guidelines included in the EQUATOR
17 network as well as others widely adopted in the literature, which includes CONSORT, PRISMA,
18 STROBE, STARD, ARRIVE, QUOROM (Quality of Reporting of Meta-analysis), TREND (Transparent
19 Reporting of Evaluations with Nonrandomized Designs), MOOSE (Meta-analysis Of Observational
20 Studies in Epidemiology), CARE (Case Report), SRQR (Standards for Reporting Qualitative Research),
21 COREQ (Consolidated criteria for Reporting Qualitative research), TRIPOD (Transparent Reporting of a
22 multivariable prediction model for Individual Prognosis or Diagnosis), SQUIRE (Standards for Quality
23 Improvement Reporting Excellence), CHEERES (Consolidated Health Economic Evaluation Reporting
24 Standards), SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials), and
25 REMARK (Reporting Recommendations for Tumor Marker Prognostic Studies). Systematic reviews that
26 do not evaluate adherence to one of the aforementioned guidelines will not be included in our study. We
27 will also exclude systematic reviews or surveys if their objectives are not incomplete reporting, or they do
28 focus on primary biomedical research studies, or they only publish editorials, abstracts, letters or
29 commentaries without full reports, or they are duplicates of included systematic reviews or surveys.
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41 For the inconsistency between protocols or registrations and full reports and between abstracts and full
42 reports, systematic reviews or surveys from all fields of biomedical research will be eligible if they
43 clearly described their objectives, identified the sources of data used and the aspects of reporting they
44 were comparing.
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50 Furthermore, to expand the extent of this scoping review, we will also include systematic reviews or
51 surveys that specifically investigated the incomplete or inconsistent reporting for study subgroups (**Figure
52 1**).
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57 *Search strategy*
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We will search the electronic databases including Web of Science, EMBASE, MEDLINE, and Cumulative Index to Nursing and Allied Health Literature (CINAHL), for relevant studies. The search will be limited between January 1996 and September 30th 2016 given that the CONSORT (Consolidated Standards of Reporting Trials) statement was the first reporting guideline in biomedical research and developed in 1996 (25). The search strategy will be designed with the assistance of an experienced librarian. Key descriptors that include terms for systematic reviews or surveys, reporting, and guidelines or adherence or inconsistency or registrations or protocols or abstracts will be used for the search, for instance, (Systematic reviews OR surveys OR reviews) AND (quality of reporting OR completeness of reporting OR selective reporting OR consistency of reporting OR biased reporting OR subgroup) AND ((QUOROM OR TREND OR MOOSE OR CONSORT OR STROBE OR PRISMA OR CARE OR SRQR OR COREQ OR STARD OR TRIPOD OR SQUIRE OR CHEERES OR ARRIVE OR SPIRIT OR REMARK) OR (Adherence OR Consistency OR Protocol OR Registration OR Abstract)). **Supplemental Table 1** shows the detailed search terms used in this scoping review. Titles and abstracts retrieved will be first screened for eligibility before full texts are thoroughly examined. Reasons will be documented for excluded studies when assessing full texts. All the reference lists from the included systematic reviews or surveys will be also reviewed to retrieve additional relevant studies. We will limit the search to English language because of the lack of resources for translation of other languages. All the search processes will be performed by two reviewers (YJ and IN) independently. Disagreement will be addressed by consensus after discussion, and a third reviewer (GL) will be consulted if no consensus is reached. **The Kappa statistic will be used to quantify the level of agreement previous to their consensus between the two reviewers (YJ and IN) (26).**

Outcomes

In this scoping review, our outcomes include levels of adherence to reporting guidelines, levels of consistency between protocols or registrations and full reports, and the agreement between abstracts and full reports, all of which are expressed as percentages, quality scores or categorized rating (such as high, medium, low). Specifically, incomplete reporting will be assessed by the levels of adherence to reporting guidelines and their checklists when available. Levels of consistency will be evaluated by the agreement on the study-validity-related factors including research questions, study designs, study samples, interventions or exposures, time duration, comparators, statistical plan, result presentations and interpretations, and conclusions or recommendations between protocols or registrations and full reports and between abstracts and full reports.

Data collection

Two reviewers (YJ and IN) will independently collect data from the included systematic reviews or surveys using data extraction forms. The data extraction forms will be piloted and modified before its final version to be used. Specifically, we will extract the data as shown below:

- 1) basic characteristics: authors, publication year, journal in which the study is published, field of study, study region, number of primary studies included, number of study samples (including animals and participants), and reporting guideline (or its extension or modification) assessed in the systematic review or survey;
- 2) for the adherence to guidelines, we will gather the reported adherence to the items specified in the corresponding guideline; for the consistency between protocols or registrations and full reports, and the agreement between abstracts and full reports, data extracted include (dis)concordance for research question, study samples, intervention (or exposure), comparator, outcome, time duration, study design, statistical plan, result presentations and interpretations, conclusion, and other information specifically evaluated in the systematic review or survey;
- 3) outcome measures presented as levels of adherence to reporting guidelines or levels of consistency will be collected for all the relevant items if provided;
- 4) factors that are found to be related to improved completeness and consistency of reporting in the individual systematic reviews or survey; and
- 5) authors' overall conclusion in the systematic review or survey.

Any disagreement will be resolved by the two reviewers' discussion and consensus. In addition, we will contact the authors of included systematic reviews to collect essential and relevant data if necessary.

Data analysis

The levels of adherence to guidelines and the levels of consistency will be described in a narrative manner. The general characteristics of included studies, levels of adherence to reporting guidelines or levels of consistency between protocols or registrations and full reports and between abstracts and full reports, factors related to improved completeness and consistency of reporting, and conclusions in the included studies, will be summarized and discussed in our study. No pooled analyses will be performed quantitatively given the heterogeneity of the included systematic reviews and surveys. Likewise, factors associated with improved completeness and consistency of reporting will be summarized qualitatively.

Quality assessment of included systematic reviews

We will evaluate the quality of all the included systematic reviews, using the AMSTAR (a measurement tool to assess systematic reviews) criteria (27). The R(evised)-AMSTAR will not be used in our study, given its limited application and unknown measurement properties (28). However, some items of AMSTAR may not be applicable to all the included systematic reviews. For instance, the item 9 ‘were the methods used to combine the findings of studies appropriate’ (because not all the systematic reviews used a pooled estimate) is not relevant to some included studies, thereby being omitted from the quality evaluation. Likewise, we will not assess quality of the included surveys, due to lack of relevant assessment tools or guidelines.

Discussion

Incomplete or inconsistent reporting remains a major concern in the biomedical literature including preclinical studies, diagnostic research, qualitative studies, economic studies, clinical trials, and observational studies, among others (2, 4). When the reporting is incomplete or inconsistent, the apparent methodological quality of published findings may not reveal the actual quality of the study as evaluated from the protocol or registration or abstracts, yielding the published findings unreliable, irreproducible or sometimes misleading (3, 4, 17, 29). [In this scoping review](#), we will assess the completeness of reporting in the literature and adherence to reporting guidelines, consistency between protocols or registrations and full reports, and agreement between abstracts and full-text articles. We will present our results as three parts, where the first part of adherence to reporting guidelines is an updated and expanded research based on our previous work (11). In contrast, for the other parts of inconsistency between protocols or registrations and full reports and discrepancy between abstracts and full reports, no study summarizing all the best current evidence in multi-disciplines is available. [Unlike the individual systematic review and survey that reports confirmatory point estimates in a specific area or disease, or in a group of journals \(13, 16, 17, 30\)](#), our scoping review will show the general mapping for the state of reporting in the overall primary biomedical research. [With the evidence gaps explored in this scoping review](#), findings may significantly advance our understanding of the extent of incomplete and inconsistent reporting, factors related to improved completeness and consistency of reporting, and potential recommendations for [various stakeholders in the biomedical community](#). All findings will be published in peer-reviewed journals electronically and in print.

Contributors

GL, LM, ZS and LT were responsible for the study conception and design. GL, YJ and LT were responsible for drafting the manuscript. LM, ZS, YJ, IN, MAHL and JDA made several revisions and provided professional support. All authors read and approved the final version of the manuscript.

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Competing interests None declared.

Ethics approval Not required.

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4 **Table and Figure legend:**
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7 Table 1. Summary of key factors for the three parts (guideline adherence, inconsistency between
8 protocols/registrations and full reports, inconsistency between abstracts and full reports) included in this
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14 Figure 1. Flow diagram showing the outline of this scoping review
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19 Supplemental Table 1. Ovid search terms modified for MEDLINE, EMBASE, CINAHL and Web of
20 Science (from January 1996 and September 30th 2016)
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Table 1. Summary of key factors for the three parts (guideline adherence, inconsistency between protocols/registrations and full reports, inconsistency between abstracts and full reports) included in the scoping review

Key factor	Guideline adherence	Inconsistency between protocols or registrations and full reports	Inconsistency between abstracts and full reports
Primary objective	Current state of reporting in primary biomedical research		
Secondary objective	Factor associated with improved completeness or consistency of reporting		
Outcome	Level of guideline adherence	Level of consistent reporting	
Comparison	Reporting guidelines	Full reports	
Main data collected	Adherence to the items listed in guidelines	Inconsistent reporting on study-validity-related factors*	
Data analysis	Qualitative description summarized		

* Study-validity-related factors Including research questions, study designs, study samples, interventions or exposures, time duration, comparators, statistical plan, result presentations and interpretations, and conclusions or recommendations.

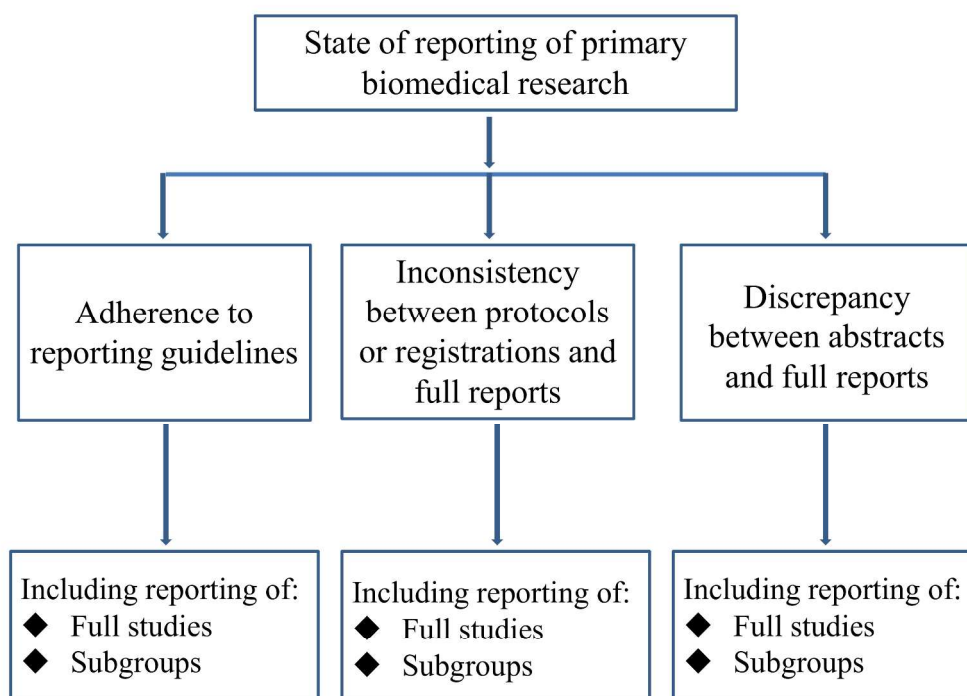


Figure 1. flow diagram

254x190mm (300 x 300 DPI)

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Supplemental Table 1. Ovid search terms modified for MEDLINE, EMBASE, CINAHL and Web of Science (from January 1996 and September 30th 2016)

Search steps	Search terms
1	systematic review.mp.
2	survey.mp.
3	("review\$" or "survey\$").tw.
4	1 or 2 or 3
5	quality of reporting. mp.
6	(completeness or consistency or discrepance or agreement or accuracy or discordance or deficiency or spin or omission).mp.
7	selective reporting. mp.
8	misreporing.mp.
9	poor reporting.mp.
10	biased reporting. mp.
11	inadequate reporting.mp.
12	reporting.tw.
13	("subgroup\$").tw.
14	5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
15	Transparent Reporting of Evaluations with Nonrandomized Designs.mp.
16	Meta-analysis Of Observational Studies in Epidemiology.mp.
17	Consolidated Standards of Reporting Trials.mp.
18	Strengthening the Reporting of Observational Studies in Epidemiology.mp.
19	Preferred Reporting Items for Systematic reviews and Meta-Analyses.mp.
20	Case Report.mp.
21	Standards for Reporting Qualitative Research.mp.
22	Consolidated criteria for Reporting Qualitative research.mp.
23	Standards for QQuality Improvement Reporting Excellence.mp.
24	Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis.mp.
25	Consolidated Health Economic Evaluation Reporting Standards.mp.
26	Standard Protocol Items: Recommendations for Interventional Trials.mp.
27	Reporting Recommendations for Tumor Marker Prognostic Studies.mp.
28	Animal Research: Reporting In Vivo Experiments.mp.
29	Standards for Reporting Diagnostic accuracy studies.mp.
30	Quality of Reporting of Meta-analysis.mp.
31	15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
32	("adherence\$").mp.
33	("consistenc\$").mp.
34	protocol.mp.
35	("registr\$").mp.
36	abstract.tw.
37	31 or 32 or 33 or 34 or 35 or 36
38	4 and 14 and 37
39	limit 38 to yr="1996 - 2016"

BMJ Open

The state of reporting of primary biomedical research: A scoping review protocol

Journal:	<i>BMJ Open</i>
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Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	Epidemiology
Keywords:	incomplete reporting, biased reporting, reporting guideline, consistency, scoping review

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The state of reporting of primary biomedical research: A scoping review protocol

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For peer review only

Strengths and limitations of this study

1. In this scoping review, we will assess the consistency and completeness of reporting in the biomedical literature with regards to adherence to reporting guidelines, consistency between protocols or registrations and full reports, and agreement between abstracts and full-text articles.
2. Results from our study will advance our understanding of the extent of incomplete and inconsistent reporting, factors related to improved completeness and consistency of reporting, and potential recommendations for various stakeholders in the biomedical community.
3. A potential limitation may be the small number of eligible studies for this scoping review.

Abstract

Introduction: Incomplete or inconsistent reporting remains a major concern in the biomedical literature. Incomplete or inconsistent reporting may yield the published findings unreliable, irreproducible or sometimes misleading. In this study based on evidence from systematic reviews and surveys that have evaluated the reporting issues in primary biomedical studies, we aim to conduct a scoping review with focuses on 1) the state-of-the-art extent of adherence to the emerging reporting guidelines in primary biomedical research, 2) the inconsistency between protocols or registrations and full reports, and 3) the disagreement between abstracts and full-text articles.

Methods and analyses: We will use a comprehensive search strategy to retrieve all available and eligible systematic reviews and surveys in the literature. We will search the following electronic databases: Web of Science, EMBASE, MEDLINE, and Cumulative Index to Nursing and Allied Health Literature (CINAHL). Our outcomes are levels of adherence to reporting guidelines, levels of consistency between protocols or registrations and full reports, and the agreement between abstracts and full reports, all of which will be expressed as percentages, quality scores or categorized rating (such as high, medium, low). No pooled analyses will be performed quantitatively given the heterogeneity of the included systematic reviews and surveys. Likewise, factors associated with improved completeness and consistency of reporting will be summarized qualitatively. The quality of the included systematic reviews will be evaluated using AMSTAR (a measurement tool to assess systematic reviews).

Ethics and dissemination: All findings will be published in peer-reviewed journals and relevant conferences. These results may advance our understanding of the extent of incomplete and inconsistent reporting, factors related to improved completeness and consistency of reporting, and potential recommendations for various stakeholders in the biomedical community.

Keywords: incomplete reporting; inconsistent reporting; reporting guideline; bias; scoping review

Introduction

Primary research is generally defined as the empirical research studies with collection of original primary data (1). The current reporting in primary biomedical research remains an issue of concern in the literature (2). For instance, it is widely recognized that incomplete reporting is pervasive in biomedical research, leading to potential waste of resources, skeptical interpretation of findings and even scientific misconduct (2). One study showed that over 50% of research findings were not sufficiently or completely reported to make them usable or replicable, which represented a substantial waste of resources and efforts (3). Likewise, it is difficult to make an informed judgement about the risk of bias and credibility of findings in a study due to its incomplete reporting and lack of linkage to protocol or registration (4). Moreover, incomplete reporting can result in unnecessary exposure or harm to patients and lead to imprecise or biased treatment effect estimates to inform decision-making (2, 5). To improve transparent and complete reporting in biomedical research, reporting guidelines have been developed and widely adopted by more and more journals. The EQUATOR (Enhancing Quality and Transparency in Health Research) network provides support for the dissemination of such guidelines including the CONSORT (Consolidated Standards of Reporting Trials) for clinical trials, STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) for observational studies, PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) for systematic reviews, STARD (Standards for Reporting Diagnostic accuracy studies) for diagnostic or prognostic studies, and ARRIVE (Animal Research: Reporting In Vivo Experiments) for animal studies, among others (6). Evidence has shown that application of guidelines is associated with improved standards of reporting, and looking for missing items from guidelines of submissions in the peer review process can enhance the quality of peer reviews and the finalized publications (7-10). Despite the usefulness of reporting guidelines, adherence to such guidelines in the biomedical research remains unsatisfactorily low (4, 11, 12).

Beyond poor adherence to reporting guidelines, inconsistent or biased reporting between protocols or registrations and full-published articles has also raised significant concerns (13-16). For instance, one study comparing protocols and full reports in clinical trials found that approximately two-thirds of full reports had at least planned primary outcome modified, introduced, or omitted (17). Similarly, another study focusing on trials funded by CIHR (Canadian Institutes of Health Research) reported that 40% of the trials had a difference in primary outcomes between protocols and full reports (18). Furthermore, abstracts as the generally most read and accessed section of a publication, were found to be distorted or overly-optimistic presentations of results than were shown in full reports (19). Discrepancy between

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4 abstracts and full reports deserves more intensive attention and stringent examination in biomedical
5 research, because 1) abstracts are usually prepared with the least care; 2) readers draw conclusions about
6 a study mainly depending on abstracts; and 3) audiences may make their decisions only based on abstracts
7 especially when full reports are not accessible (4, 19, 20).
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12 Even though there is increasing evidence on incomplete and inconsistent reporting in different fields of
13 biomedicine and for different guidelines, there is no overarching summary of the evidence with regards to
14 1) the state-of-the-art extent of adherence to the emerging reporting guidelines in primary biomedical
15 research, 2) the inconsistency between protocols or registrations and full reports, or 3) the disagreement
16 between abstracts and full-text articles. Therefore we aim to conduct a scoping review to explore the
17 current state of incomplete and inconsistent reporting in primary biomedical research and to investigate
18 factors associated with improved completeness and consistency of reporting, based on evidence from
19 systematic reviews and surveys. While the existing systematic reviews and surveys generally evaluate a
20 specific research area, or a group of journals or diseases with quantitative syntheses conducted, our
21 scoping review will differ from them in mapping literature and addressing the state of reporting in the
22 overall primary biomedical community, comprehensively summarizing the heterogeneous evidence with a
23 qualitative description reported, and assessing evidence gaps and providing recommendations for future
24 research (21, 22).
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36 **Methods**

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38 In this scoping review, we will use a systematic and comprehensive approach to retrieve all available and
39 eligible systematic reviews and surveys in the literature (23). Our study will be conducted and reported
40 based on the PRISMA guideline (24). However, no risk-of-bias assessment in individual studies or
41 quantitative synthesis will be performed because they are not relevant to this scoping review.
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47 Our results will be presented in three parts including 1) current adherence to reporting guidelines; 2)
48 inconsistency between protocols or registrations and full reports; and 3) discrepancy between abstracts
49 and full reports. The outline of this scoping review is shown in **Figure 1**. For the first part, we will build
50 upon previous work on adherence to reporting guidelines which was limited to six guidelines for human
51 studies and up to 2012 (11). Our previous work will be expanded, updated and included in this scoping
52 review.
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Study eligibility

Systematic reviews that include primary studies and evaluate incomplete or inconsistent reporting with a focus on adherence to guidelines, comparison between protocols or registrations and full reports, or consistency between abstracts and full reports, will be eligible. For the purposes of this review, an eligible systematic review will be defined as study with predetermined objectives, eligibility criteria, at least one electronic database searched, data extraction, and at least one study included. All the surveys that include primary studies and focus on specific research questions in primary biomedical research will be eligible for inclusion in this scoping review.

1. Adherence to reporting guidelines:

We will include systematic review and surveys of the following guidelines: CONSORT, PRISMA, STROBE, STARD, ARRIVE, QUOROM (Quality of Reporting of Meta-analysis), TREND (Transparent Reporting of Evaluations with Nonrandomized Designs), MOOSE (Meta-analysis Of Observational Studies in Epidemiology), CARE (Case Report), SRQR (Standards for Reporting Qualitative Research), COREQ (Consolidated criteria for Reporting Qualitative research), TRIPOD (Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis), SQUIRE (Standards for Quality Improvement Reporting Excellence), CHEERES (Consolidated Health Economic Evaluation Reporting Standards), SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials), and REMARK (Reporting Recommendations for Tumor Marker Prognostic Studies). Systematic reviews that do not evaluate adherence to any of the aforementioned guidelines will not be included in our study.

2. Consistency between protocols/registration and full reports:

Systematic reviews or surveys from all fields of biomedical research will be eligible if they included a study objective of comparing protocols or registrations with full reports and provided data on such comparison.

3. Agreement between abstracts and full reports

Systematic reviews or surveys from all fields of biomedical research will be eligible if they included a study objective of comparing abstracts with full reports and provided data on such comparison.

Furthermore, to expand the extent of this scoping review, we will also include systematic reviews or surveys that specifically investigated the incomplete or inconsistent reporting for study subgroups for all

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4 the three parts above (**Figure 1**).

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7 *Exclusion criteria*

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9 For all the three parts, the systematic reviews or surveys will be excluded if (1) their objectives are not
10 incomplete or inconsistent reporting, (2) they do not focus on primary biomedical research studies, (3)
11 they only publish editorials, abstracts, letters or commentaries without full-length texts, (4) they are
12 duplicates of the included systematic reviews or surveys, or (5) they do not provide data on incomplete or
13 inconsistent reporting.
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19 *Search strategy*

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21 We will search the electronic databases including Web of Science, EMBASE, MEDLINE, and
22 Cumulative Index to Nursing and Allied Health Literature (CINAHL), for relevant studies. The search
23 will be limited between January 1996 and September 30th 2016 given that the CONSORT (Consolidated
24 Standards of Reporting Trials) statement was the first reporting guideline in biomedical research and
25 developed in 1996 (25). The search strategy will be designed with the assistance of an experienced
26 librarian. Key descriptors that include terms for systematic reviews or surveys, reporting, and guidelines
27 or adherence or inconsistency or registrations or protocols or abstracts will be used for the search, for
28 instance, (Systematic reviews OR surveys OR reviews) AND (quality of reporting OR completeness of
29 reporting OR selective reporting OR consistency of reporting OR biased reporting OR subgroup) AND
30 ((QUOROM OR TREND OR MOOSE OR CONSORT OR STROBE OR PRISMA OR CARE OR SRQR
31 OR COREQ OR STARD OR TRIPOD OR SQUIRE OR CHEERES OR ARRIVE OR SPIRIT OR
32 REMARK) OR (Adherence OR Consistency OR Protocol OR Registration OR Abstract)). **Supplemental**
33 **Table 1** shows the detailed search terms used in this scoping review.
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45 *Study selection*

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47 Titles and abstracts retrieved will be first screened for eligibility before full texts are thoroughly examined.
48 Reasons will be documented for excluded studies when assessing full texts. All the reference lists from
49 the included systematic reviews or surveys will be also reviewed to retrieve additional relevant studies.
50 We will limit the search to English language because of the lack of resources for translation of other
51 languages. All the search processes will be performed by two reviewers (YJ and IN) independently.
52 Disagreement will be addressed by consensus after discussion, and a third reviewer (GL) will be
53 consulted if no consensus is reached. The Kappa statistic will be used to quantify the level of agreement
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4 previous to their consensus between the two reviewers (YJ and IN) (26).
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7 *Outcomes*

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9 In this scoping review, our primary outcomes include levels of adherence to reporting guidelines, levels of
10 consistency between protocols or registrations and full reports, and the agreement between abstracts and
11 full reports, all of which are expressed as percentages, quality scores or categorized rating (such as high,
12 medium, low).
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17 Specifically, for the first part, incomplete reporting will be assessed by the levels of adherence to
18 reporting guidelines and their checklists when available. E.g., for the CONSORT guideline, the
19 percentage of adopting the guideline and the rates/scores of adhering to the components (title and abstract,
20 introduction, methods, results, discussion and other information) among the included primary studies in
21 the systematic review or survey will be our outcomes of interest. Levels of consistency between protocols
22 or registrations and full reports and between abstracts and full reports will be evaluated by the agreement
23 on the study-validity-related factors including research questions, study designs, study samples,
24 interventions or exposures, outcome measures, time duration, comparators, statistical plan, result
25 presentations and interpretations, and conclusions or recommendations. For instance, some studies may
26 investigate the changes in the study-validity-related factors from the pre-specified protocols that are
27 identified in full reports; the percentages of such changes will be our outcomes collected.
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32 Our secondary outcomes are the factors associated with improved completeness and consistency of
33 reporting as reported from the included systematic reviews and surveys.
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36 *Data collection*

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38 Two reviewers (YJ and IN) will independently collect data from the included systematic reviews or
39 surveys using data extraction forms. The data extraction forms will be piloted and modified before its
40 final version to be used. Specifically, we will extract the data as shown below:
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45 1) basic characteristics: authors, publication year, journal in which the study is published, field of study,
46 study region, number of primary studies included, number of study samples (including animals and
47 participants), and reporting guideline (or its extension or modification) assessed in the systematic review
48 or survey;
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52 2) for the adherence to guidelines, we will gather the reported adherence to the items specified in the
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4 corresponding guideline; for the consistency between protocols or registrations and full reports, and the
5 agreement between abstracts and full reports, data extracted include (dis)concordance for research
6 question, study population or sample size, intervention (or exposure), comparator, outcome, time duration,
7 study design, statistical plan, result presentations and interpretations, conclusion, and other information
8 specifically evaluated in the systematic review or survey;

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11 3) outcome measures presented as levels of adherence to reporting guidelines or levels of consistency will
12 be collected for all the relevant items if provided;

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14 4) factors that are found to be related to improved completeness and consistency of reporting in the
15 individual systematic reviews or survey; and

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17 5) authors' overall conclusion in the systematic review or survey.
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22 Any disagreement will be resolved by the two reviewers' discussion and consensus. In addition, we will
23 contact the authors of included systematic reviews to collect essential and relevant data if necessary.
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26 27 28 *Data analysis*

29 The levels of adherence to guidelines and the levels of consistency will be described using medians and
30 interquartile ranges (IQRs) across all the included studies.
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34 The general characteristics of included studies, levels of adherence to reporting guidelines or levels of
35 consistency between protocols or registrations and full reports and between abstracts and full reports,
36 factors related to improved completeness and consistency of reporting, and conclusions in the included
37 studies, will be summarized and discussed in our review. No pooled analyses or quantitative syntheses
38 will be performed given the heterogeneity of the included systematic reviews and surveys. Likewise,
39 factors associated with improved completeness and consistency of reporting will be summarized
40 qualitatively.
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48 49 *Quality assessment of included studies*

50 We will evaluate the quality of all the included systematic reviews, using the AMSTAR (a measurement
51 tool to assess systematic reviews) criteria (27). The R(evised)-AMSTAR will not be used in our study,
52 given its limited application and unknown measurement properties (28). However, some items of
53 AMSTAR may not be applicable to all the included systematic reviews. For instance, the item 9 'were the
54 methods used to combine the findings of studies appropriate' (because not all the systematic reviews used
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4 a pooled estimate) is not relevant to some included studies, thereby being omitted from the quality
5 evaluation. Likewise, we will not assess quality of the included surveys, due to lack of relevant
6 assessment tools or guidelines.
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10 **Discussion**

11 Incomplete or inconsistent reporting remains a major concern in the biomedical literature including
12 preclinical studies, diagnostic research, qualitative studies, economic studies, clinical trials, and
13 observational studies, among others (2, 4). When the reporting is incomplete or inconsistent, the apparent
14 methodological quality of published findings may not reveal the actual quality of the study as evaluated
15 from the protocol or registration or abstracts, yielding the published findings unreliable, irreproducible or
16 sometimes misleading (3, 4, 17, 29). In this scoping review, we will assess the completeness of reporting
17 in the literature and adherence to reporting guidelines, consistency between protocols or registrations and
18 full reports, and agreement between abstracts and full-text articles. We will present our results as three
19 parts, where the first part of adherence to reporting guidelines is an updated and expanded research based
20 on our previous work (11). In contrast, for the other parts of inconsistency between protocols or
21 registrations and full reports and discrepancy between abstracts and full reports, no study summarizing all
22 the best current evidence in multi-disciplines is available. Unlike the individual systematic review and
23 survey that reports confirmatory point estimates in a specific area or disease, or in a group of journals (13,
24 16, 17, 30), our scoping review will show the general mapping for the state of reporting in the overall
25 primary biomedical research. With the evidence gaps explored in this scoping review, findings may
26 advance our understanding of the extent of incomplete and inconsistent reporting, factors related to
27 improved completeness and consistency of reporting, and potential recommendations for various
28 stakeholders in the biomedical community. All findings will be published in peer-reviewed journals
29 electronically and in print.
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48 **Contributors**

49 GL, LM, ZS and LT were responsible for the study conception and design. GL, YJ and LT were
50 responsible for drafting the manuscript. LM, ZS, YJ, IN, MAHL and JDA made several revisions and
51 provided professional support. All authors read and approved the final version of the manuscript.
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57 **Funding** This study receives no funding.
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6 **Competing interests** None declared.
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9 **Ethics approval** Not required.
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12 **Acknowledgements** None
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For peer review only

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4 **Table and Figure legend:**
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7 Table 1. Summary of key factors for the three parts (guideline adherence, inconsistency between
8 protocols/registrations and full reports, inconsistency between abstracts and full reports) included in this
9 scoping review
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14 Figure 1. Flow diagram showing the outline of this scoping review
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19 Supplemental Table 1. Ovid search terms modified for MEDLINE, EMBASE, CINAHL and Web of
20 Science (from January 1996 and September 30th 2016)
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Table 1. Summary of key factors for the three parts (guideline adherence, inconsistency between protocols/registrations and full reports, inconsistency between abstracts and full reports) included in the scoping review

Key factor	Guideline adherence	Inconsistency between protocols or registrations and full reports	Inconsistency between abstracts and full reports
Primary objective	Current state of reporting in primary biomedical research		
Secondary objective	Factor associated with improved completeness or consistency of reporting		
Outcome	Level of guideline adherence	Level of (in)consistent reporting	
Comparator reference	Reporting guidelines	Protocols or registrations	Full reports
Main data collected	Adherence to the items listed in guidelines	Inconsistent reporting on study-validity-related factors*	
Data analysis	Qualitative description summarized		

* Study-validity-related factors Including research questions, study designs, study populations or sample sizes, interventions or exposures, time duration, comparators, statistical plan, result presentations and interpretations, and conclusions or recommendations.

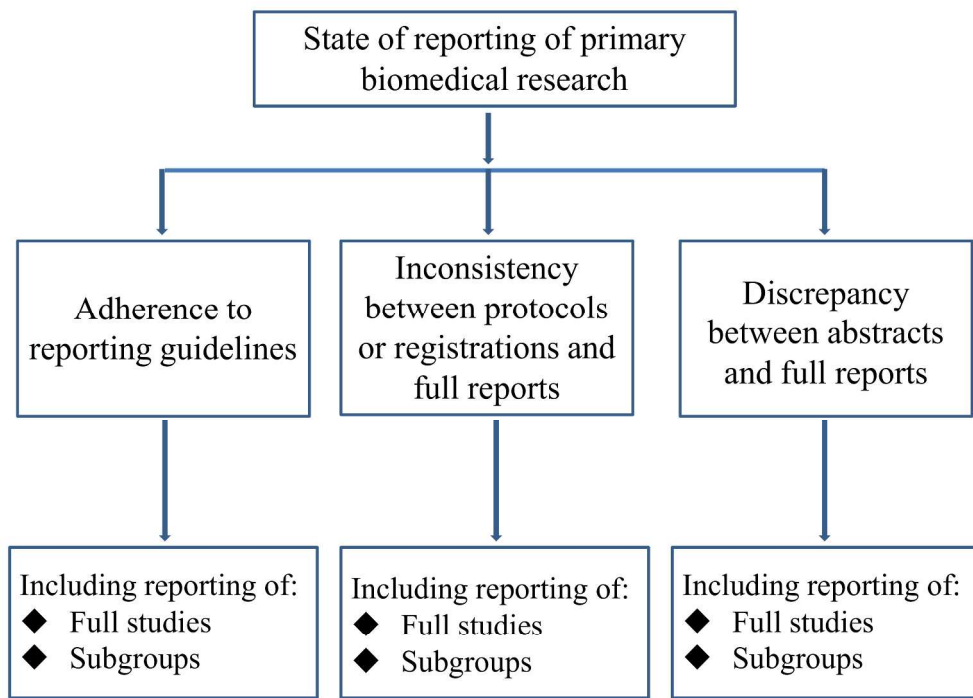


Figure 1. flow diagram

254x190mm (300 x 300 DPI)

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Supplemental Table 1. Ovid search terms modified for MEDLINE, EMBASE, CINAHL and Web of Science (from January 1996 and September 30th 2016)

Search steps	Search terms
1	systematic review.mp.
2	survey.mp.
3	("review\$" or "survey\$").tw.
4	1 or 2 or 3
5	quality of reporting. mp.
6	(completeness or consistency or discrepance or agreement or accuracy or discordance or deficiency or spin or omission).mp.
7	selective reporting. mp.
8	misreporing.mp.
9	poor reporting.mp.
10	biased reporting. mp.
11	inadequate reporting.mp.
12	reporting.tw.
13	("subgroup\$").tw.
14	5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
15	Transparent Reporting of Evaluations with Nonrandomized Designs.mp.
16	Meta-analysis Of Observational Studies in Epidemiology.mp.
17	Consolidated Standards of Reporting Trials.mp.
18	Strengthening the Reporting of Observational Studies in Epidemiology.mp.
19	Preferred Reporting Items for Systematic reviews and Meta-Analyses.mp.
20	Case Report.mp.
21	Standards for Reporting Qualitative Research.mp.
22	Consolidated criteria for Reporting Qualitative research.mp.
23	Standards for QQuality Improvement Reporting Excellence.mp.
24	Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis.mp.
25	Consolidated Health Economic Evaluation Reporting Standards.mp.
26	Standard Protocol Items: Recommendations for Interventional Trials.mp.
27	Reporting Recommendations for Tumor Marker Prognostic Studies.mp.
28	Animal Research: Reporting In Vivo Experiments.mp.
29	Standards for Reporting Diagnostic accuracy studies.mp.
30	Quality of Reporting of Meta-analysis.mp.
31	15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
32	("adherence\$").mp.
33	("consistenc\$").mp.
34	protocol.mp.
35	("registr\$").mp.
36	abstract.tw.
37	31 or 32 or 33 or 34 or 35 or 36
38	4 and 14 and 37
39	limit 38 to yr="1996 - 2016"