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REVIEW

Assessing concordance of financial conflicts of interest disclosures with payments' databases: a systematic survey of the health literature

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Abstract

Objectives: The objective of the study is to review the literature for studies that assessed the concordance of financial conflicts of interest disclosures with payments' databases and evaluate their methods.

Study Design and Setting: We conducted a systematic survey of the health literature to identify eligible studies. We searched both Medline and EMBASE up to February 2017. We conducted study selection, data abstraction, and methodological quality assessment in duplicate and independently using standardized forms. We subcategorized 'nonconcordant disclosures' as either 'partially nonconcordant' or 'completely nonconcordant'. The main outcome was the percentage of authors with 'nonconcordant' disclosures. We summarized results by three levels of analysis: authors, companies, and studies.

Results: We identified 27 eligible journal articles. The top two types of documents assessed were published articles (n = 13) and published guidelines (n = 9). The most commonly used payment database was the Open Payments Database (n = 16). The median percentage of authors with 'nonconcordant' disclosures was 81%; the median percentage was 43% for 'completely nonconcordant' disclosures. The percentage of 'nonconcordant' conflict of interest (COI) reporting by companies varied between 23% and 85%. The methods of concordance assessment, as well as the labeling and definitions of assessed outcomes varied widely across the included studies. We judged three of the included studies as high-quality studies.

Conclusion: Underreporting of health science researchers' financial COIs is pervasive. Studies assessing COI underreporting suffer from a number of limitations that could have overestimated their findings.

Keywords: Financial conflict of interest; Conflict of interest verification; Concordance; Systematic review; Financial disclosures; Disclosure accuracy; Open Payments Data

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What is new?

Key findings

- The median across included studies of the percentage of authors with 'inaccurate' disclosures was 81.2% (43.4% for 'completely inaccurate' disclosures).
- All but three studies used appropriate payments' databases. Most studies had clear inclusion/exclusion criteria for individuals.
- Three of the studies had good methodological quality, whereas the remaining studies failed to meet a variable number of criteria.

What this adds to what was known?

- Health researchers underreport their financial COIs frequently. Similarly, companies inaccurately report financial relationships of health researchers.
- Methods of verification and definitions of accuracy of disclosures varied widely among published studies.

What is the implication and what should change now?

- There is an increasing trend of studies verifying the disclosures of conflict of interests against payments' databases and estimating its accuracy. Future studies verifying conflicts of interest disclosures in health research should avoid the limitations of previously published studies we uncovered in this review.

1. Introduction

On September 8, 2018, the New York Times (NYT) published the alarming results of their investigation into the undisclosed financial ties of a renowned US oncologist [1]. According to the report, the physician failed to declare in major research journals millions of dollars' worth of payments received from pharmaceutical and health care companies. He was also known to have advocated for several clinical trials by Roche which other experts felt were unsuccessful. The NYT estimates that, over the last 4 years, Roche paid him more than $3 million. This timely news report illustrates how disclosure requirements of journals can be vague if the conflict of interest (COI) disclosure relevance is open to interpretation.

According to the National Academy of Science, a COI is "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest [2]." COIs may reduce the credibility of the individuals or institutions who present new data that may ultimately be used to develop clinical practice guidelines [3]. A recent systematic review found that studies with industry involvement had higher risk of reporting favorable results and conclusions and less on the harms [4].

Disclosures of COIs are essential for ensuring the credibility of research findings. However, there is evidence that such disclosures are not always accurate [5]. Although previous attempts at COI verification included comparison of disclosures to the author's previous disclosures and assessment of concordance with payments' databases, there are no commonly accepted or validated methods of verification [6]. Presently, the International Committee of Medical Journal Editors has no recommendations on how disclosures should be verified [7,8]. In a recent study, 17% of journals reported having procedures in place to verify COI disclosures, although details regarding the methods of verification were only available from half of these journals [9]. Despite having verification methods in place, the verification process often occurs only if concern is expressed, either by reviewers before publication or by readers after publication [9].

As assessment of concordance of financial COI disclosures with payments' databases is one of the main methods currently used to verify COI disclosure, the objective of this study was to review the literature for studies that assessed the concordance and evaluate their methods.

2. Materials and methods

2.1. Study design and definitions

We conducted a systematic survey to identify studies that assessed the concordance of financial COI disclosures with payments' databases.

2.2. We used the following definitions

- *COI:* "a financial or intellectual relationship that may impact an individual's ability to approach a scientific question with an open mind." [10,11] We did not consider the reporting of the funding of the work under consideration as a COI.
- *A COI disclosure:* the reporting by an individual of the presence of a specific COI, or the lack thereof [11].
- *A COI declaration statement:* a statement that may include one or more COI disclosures.
- *Reporting of financial relationships:* the listing by a body (e.g., a device company or governmental database) of one or more financial relationships between the industry and an individual.
- *Reference time point:* the time point that the investigators considered as starting point going backward to compare published COI with the payment database.

Table 1. Contingency table displaying data of self-disclosure of COI (in rows) and industry reporting of financial relationship (in columns) to guide the calculation of accuracy measures

	Industry reporting (payment database)		
Self-disclosure	**Reported**	**Not reported**	
Disclosed	a (completely concordant disclosure statement)	b (nonconcordant reporting)	a + b
Not disclosed	c1 (partially nonconcordant disclosure statement)	d (not reported, not disclosed)	
	c2 (completely nonconcordant disclosure statement)		
	a + c		Total

c1 + c2 = nonconcordant disclosure.

Table 1 shows the calculation of accuracy measures based on data of self-disclosure of COI (in rows) and industry reporting of financial relationship (in columns). For example, completely concordant reporting (cell 'a') refers to a financial relationship that is both disclosed by an individual and reported in an industry database. Nonconcordant disclosure can be characterized as partially nonconcordant (cell 'c1'; some of the COI declared) or completely nonconcordant (cell 'c2'; none of the COI declared). Nonconcordant reporting (cell 'b') refers to payments disclosed by individuals but not found in payment databases. Cell 'd' refers to the case where the individual disclosed no COI and the industry database reports no financial relationships for that individual. A number of conditions should be considered before the calculations of accuracy, such as unit of analyses (COI declaration statement or authors) and definition of accuracy (complete accurate or partially inaccurate).

We presented the main accuracy measures that have been reported in the literature. Table 2 shows the definitions of categories of accuracy of disclosure (i.e., completely concordant vs. partially nonconcordant vs. completely nonconcordant) in accordance with the level of analysis (i.e., single disclosure vs. statement vs. document).

2.3. Eligibility criteria

We included studies meeting the following criteria:

- Study design: observational studies excluding case studies and case series.
- Variable of interest: COI disclosure statement as defined above.
- Type of documents: published articles, published guidelines, and meeting disclosure.
- Outcome assessed:
  - Authors' nondisclosures as assessed by payments' databases.
  - Company nonreporting as assessed by authors' disclosures.
- Field of study: health field, including the clinical, health systems and policy, public health, and biomedical science areas.
- Year of publication of the study: any year.
- Language: any language.

We excluded studies that addressed the following:

- Methods or conceptual approaches to verifying COI.
- Reliability of authors' disclosures (i.e., comparison of more than one disclosure by the same author).
- What organizations are doing in terms of COI verification.

2.4. Search strategy

We searched both Medline and EMBASE (inception date up to February 2017). Since then, we monitored the literature for relevant new studies using a preset search strategy in Google Scholar. We designed the search strategy with the help of an experienced librarian using both key word and MESH terms (see Appendix 1a and 1b for the full search strategies). The search strategies combined the concepts of COI disclosure and concordance. We did not limit the search to any language and we did not use any study design filters. In addition, we searched the reference list of included studies and conducted forward searching for studies cited by the included studies.

2.5. Study selection

Reviewers working on study selection completed calibration exercises. Then, they worked in pairs to screen in duplicate and independently the titles and abstracts of citations identified by the search. We obtained the full texts of any citation judged as potentially eligible by at least one of the two reviewers. Reviewers subsequently screened in duplicate and independently the full texts. They checked agreement and resolved any disagreements by discussion. A third reviewer was involved as needed.

2.6. Data abstraction

Three pairs of two reviewers abstracted data in a duplicate and independent manner. They compared results, resolved disagreements, and when needed involved a third reviewer to resolve disagreements. All reviewers participated in calibration exercises.

We extracted information on the general characteristics of each included study:

Table 2. Measures of concordance of disclosure by the level of analysis

Level of analysis	Assessment of the concordance of disclosure		
		Nonconcordant disclosure (c1 + c2)	
	Completely concordant disclosure statement (a)	Partially nonconcordant disclosure statement (c1)	Completely nonconcordant disclosure statement (c2)
Single COI disclosure	Every single detail (e.g., type, source, relation of the source to the trial subject, the timing, and monetary value) of the disclosure is concordant if available	At least one but not all the details of the disclosure is nonconcordant	All the details of the disclosure are nonconcordant
Statement (may include one or more disclosures per person or a statement of absence of COI)[a]	All the disclosures in the statement are concordant	At least one but not all disclosures in the statement is nonconcordant	All the disclosures in the statement are nonconcordant
Document (may include one or more statements)	All the statements in the document are concordant	At least one but not all the statements in the document is nonconcordant	All the statements in the document are nonconcordant

[a] one could consider two statements from the same authors either separately or together.

- Inclusion and exclusion criteria of documents and individuals.
- Number of included documents and/or individuals.
- Types of documents.
- Health specialty of documents.
- Declared COI and source of disclosure.
- Concordance assessment process.
  - Determining the financial relationships captured by the payments' databases;
  - Determining which of the captured financial relationships are required by the COI policy;
- Outcomes assessed.
- Notes.

In addition, we extracted information on the details of the analytical approach of each included study:

- Outcomes definitions.
- Analysis level (payment, individual, or document).
- Inclusion of documents with no COI statements.
- How accuracy measures were calculated by study authors (please refer to Table 1).
- Measurements and results.
- Inclusion in the summary of findings table.

2.7. Methodological quality assessment

We assessed the methodological quality of included studies using the seven criteria that we selected based on a thorough assessment of the limitations of the included studies (see box on bottom of right of the page).

Two reviewers applied the tool to each included study in duplicate and independently. They resolved any disagreement by discussion. They rated each criterion as 'yes' or 'no' and extracted text from the included study that supports the judgment, whenever available.

2.8. Data analysis

We assessed the studies' general characteristics and their findings in terms of accuracy. The findings were organized in tabular format. The percentage of concordant or

1 The investigators report on the COI details provided by the payments' databases.
- Timeframe
- Characteristics of COI (types and categories of COI, timeframe for financial relationship, product in relation to the payments, etc.)

2 The investigators report on the inclusion/exclusion criteria of individuals included in the payments' databases

3 The investigators consider the relatedness of the declared COI to the research question/topic.

4 The investigators take into account the organization/entity's COI disclosure policy
- Definition of COI
- Types and categories of COI
- Timeframe for disclosure
- Time of submission
- Related individuals for whom COI should be declared
- Product in relation to which COI should be declared

5 The investigators report clear definitions for concordant/nonconcordant COI, disclosed/undisclosed COI, or discrepancy

6 The investigators report an adequate data matching methodology (e.g., overlapping authors' names, different COI categories between disclosure, and payments' databases)

7 The investigators reported using duplicate approach (e.g., for assessing relatedness, for data abstraction)

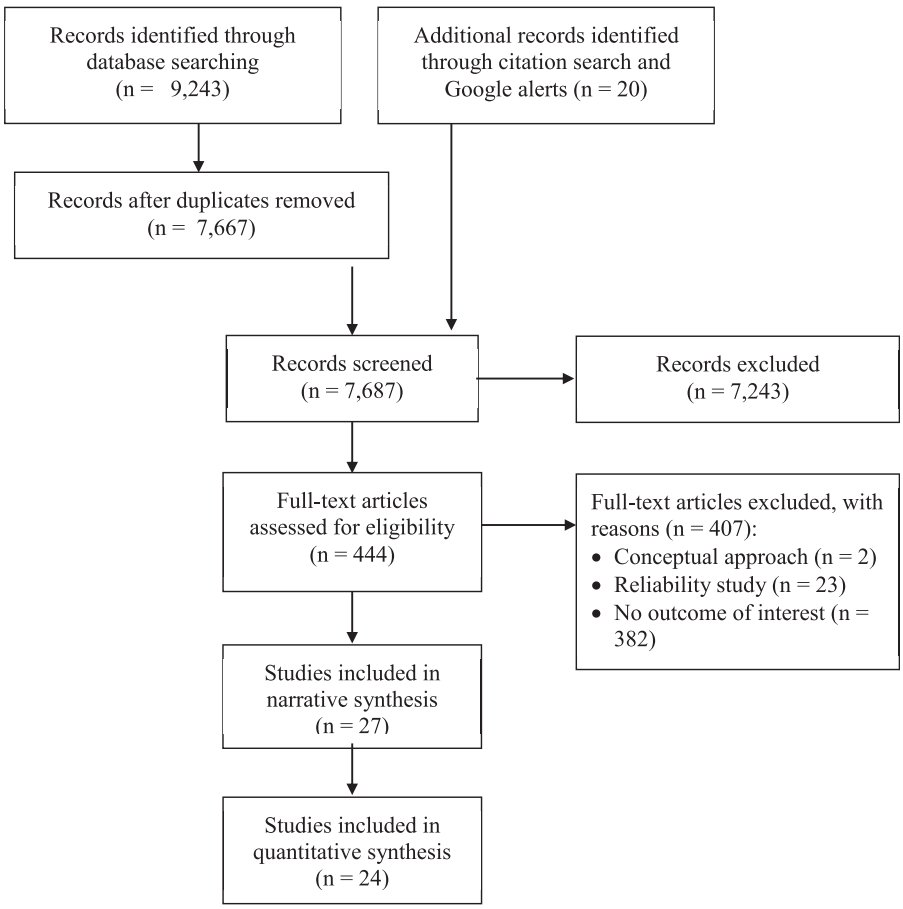

Fig. 1. PRISMA diagram.

nonconcordant disclosures for each study was calculated based on each publication's definitions. We reported the median of these percentages across studies because of the relatively small number of studies and the presence of outliers.

3. Results

The PRISMA flow diagram shows the summary of the selection process. In total, we identified 27 eligible journal articles (Figure 1) [5,7,12–36].

3.1. General characteristics of included studies

Appendix 2 and Table 3 show, respectively, the detailed and the summary information of the general characteristics of the included studies. The included studies used a variety of terms to describe their objectives. For example, they assessed for "discrepancy", "accuracy", "differences", "completeness", "inconsistency", "underreporting", or "undisclosed COIs" (Appendix 3). Similarly, the outcomes assessed by the included studies varied widely in terms of their labeling and their definitions, as shown in Appendix 3.

The two most common types of documents assessed were published articles (n = 13) and published guidelines (n = 9). The included studies examined a median of 95 documents and a median of 340 participants. The included studies assessed only disclosures for financial COIs. The most common source of disclosure was the disclosure section of documents. The most commonly used database was the Open Payments Database (OPD) (n = 16).

Reference time points used included publication dates (n = 12), acceptance dates (n = 3), date of literature search (n = 2), submission dates (n = 1), or those which were not reported in the studies' methods (n = 8) (Table 3). Units of analysis used were authors (n = 19), documents as a whole (n = 3), or individual payments (n = 1). Four studies excluded documents with no COI declaration statements, whereas 16 did not state whether or not such documents were excluded.

3.2. Methodological quality assessment of included studies

Appendix 4 shows the methodological quality assessment for each included study. All except three studies included used appropriate payments' databases. These three

Table 3. General characteristics of included studies (N = 27); summary information

	Median (interquartile range) for continuous variables, *n* (%) for categorical variables
Number of included documents (n = 21)	95 (14–172)
Number of included individuals (n = 24)	340 (129–698)
Type of the document	
Published articles	13 (48.2)
Published guidelines	9 (33.3)
Meeting disclosure	5 (18.5)
Speciality	
Surgery	16 (59.3)
Medicine	7 (25.9)
Multiple disciplines	3 (11.1)
Not specified	1 (3.7)
Source of disclosure	
Disclosure section of the document	23 (85.2)
Not specified	4 (14.8)
Payments' database [a]	
Open Payments Database	16 (59.3)
Company databases	5 (18.5)
ProPublica Dollars for Docs website	4 (14.8)
Patent databases	3 (11.1)
Danish Health and Medicines Authority	2 (7.4)
Time point of disclosure	
Publication date	12 (44.4)
Acceptance date	3 (11.1)
Literature search	2 (7.4)
Submission date	1 (3.7)
Other	1 (3.7)
Not reported	8 (29.6)
Unit of analysis	
Individuals (e.g., authors)	20 (74.1)
Documents	3 (11.1)
Both individuals and documents	3 (11.1)
Payments	1 (3.7)
Inclusion of documents with no COI	
Not reported	16 (59.3)
Not applicable	5 (18.5)
Excluded	4 (14.8)
Included	2 (7.4)

[a] more than one source used for assessing concordance.

studies used self-declared COI disclosure which is suboptimal to assess concordance [5,22,23]. Most studies had clear inclusion/exclusion criteria for individuals. We judged three studies as having good methodological quality (i.e., met all criteria) [7,16,27]. The remaining studies failed to meet a variable number of criteria (see Appendix 4).

Appendix 3 shows the detailed results of the included studies, whereas Tables 4–6 show the corresponding summary results for the analyses at the author, company, and study levels, respectively. Three of the 27 studies are not included in any of these tables as two did not report on any of the outcomes of interests [5,17], whereas one did not use adequate analytical methods [15].

3.3. Author level analysis

For the author level analysis (Table 4), we summarized results in accordance with whether the disclosure was 'nonconcordant' or 'completely nonconcordant'. The percentage of authors with 'nonconcordant' disclosures had a median of 81.2% (range 41.8% to 98.6%). The percentage of authors with 'completely nonconcordant' disclosures had a median of 43.4% (range 15% to 89.5%).

3.4. Company level analysis

Of the seven studies that performed company-level analysis (Table 5), three assessed "company nonreporting as verified by authors' disclosures, two examined "funding declared and not found in the OPD", and the remaining two studies assessed "company error" (Appendix 3). The percentage of companies that did not report payments to authors varied between 23.1% and 85.4%. The study by Lopez et al. had the highest methodological quality; this study also found the lowest rates of the company nonreporting (24.4%) [27].

3.5. Study level analysis

Of the five studies that analyzed data at the study level (Table 6), Patel et al. had the best methodological quality [32]. Each study found some degree of discrepancy between disclosures and actual payments received or industry relationships. The highest rate of nonconcordant disclosures was 92.6% [20], whereas the lowest was 6 percent [28]. Olavarria et al. and Patel et al. found low percentages of nonconcordant company reporting, which were 12.1% and 7.9%, respectively [31,32].

4. Discussion

4.1. Summary

We identified 27 eligible studies that assessed the concordance of financial COI disclosures with payments' databases in health research. The methods of concordance assessment, as well as the labeling and the definitions of the assessed outcomes varied widely across the included studies. The median across included studies of the percentage of authors with 'nonconcordant' disclosures was 81.2% (43.4% for 'completely nonconcordant' disclosures). The percentage of 'nonconcordant' company reporting varied between 23.1% and 85.4 percent. All but three studies used

Table 4. Results of the included studies. Author level analysis; authors nonconcordant disclosures [c/(a + c)]

Study	Completely nonconcordant disclosure (c2)	Completely or partially nonconcordant disclosure (c1 + c2)	Nonconcordant disclosure; (not specified whether complete, partial, or both)
Alhamoud 2016 [12]	54.7		
Andreatos 2017 [13]		89.3	
Boddapati 2018 [14]			25.3[a]
Carlisle 2018 [16]			62.5
Checketts 2017 [18]	15.0	55.0	
Cherla 2017 [19]		*95.4*	
Chimonas 2011 [21]	33.0	*85.0*[b]	
Cosgrove 2009 [22]			100.0
Cosgrove 2017 [23]			4.2
Hannon 2016 [24]		*49.2*	
Horn 2018 [25]			*7.7*
Jimbo 2018 [26]		77.3	
Lopez 2018 [27]			*19.6*[c]
Norris 2012 [30]	41.0	69.0	
Okike 2009[f] [7]			20.7[d]
Olavarria 2017 [31]	*60.4*	*86.6*	
Patel 2018 [32]	*82.5*		
Rasmussen 2015 [33]	*43.4*	*90.1*	
Tanzer 2016[e] [34]	41.0	44.0	
Thompson 2016 [35]	*89.5*	*98.6*	

Italic font: for numbers that were calculated using data provided in original studies.

[a] Discrepancy among *The American Journal of Sports Medicine* (AJSM) relevant payments; total payments discrepancy = 82.9%.

[b] The sum of ''14 authors were inconsistent, with some articles mentioning the company and others not; and nine authors (33%) never mentioned the company payments.''

[c] Undisclosed related payments; total undisclosed payments = 64.0% disclosure.

[d] Directly related payments, other authors nondisclosure results: indirectly related payments = 50.0%; unrelated payments = 50.8%; overall author nondisclosure = 28.8%.

[e] Among all the American Academy of Orthopedic Surgeons (AAOS) members, disclosure among AAOS attended the annual meeting: lenient definition = 1.0%; strict definition = 6.0%.

[f] Payments disclosure; all other studies are author disclosures.

appropriate payments' databases. Most studies had clear inclusion/exclusion criteria for individuals. Three of the studies had good methodological quality, whereas the remaining studies failed to meet a variable number of criteria.

4.2. Strengths and limitations

To our knowledge, this is the first attempt to systematically review and evaluate the evidence on COI disclosure concordance assessment. In spite of the fact that the included studies were very methodologically limited and heterogeneous, we were able to appraise them using a self-developed tool. One limitation of our study relates to the availability of the data (or lack of thereof) to perform the needed calculations. Specifically, the 'd' value in table 1a refers to 'authors with no disclosed COI and with no COI reported by the payment database'. This calculation assumes the payment database accurately captures all COI information (i.e., 100% sensitive and accurate). Unfortunately, we did not identify evidence supporting this assumption. In addition, most of the included studies had low methodological quality. Another limitation of our study was our inability to pool the data given the heterogeneity of the study designs, outcome assessed, and measurements used.

Table 5. Results of the included studies. Company nonreporting as assessed by authors' disclosures [b/(a + b)]

Study	% of company nonreporting
Alhamoud 2016 [12]	71.6
Cherla 2017 [19]	*85.4*
Cherla 2018 [20]	*69.8*
Hannon 2016 [24]	*28.9*
Lopez 2018 [27]	24.4
Olavarria 2017 [31]	*52.6*
Patel 2018 [32]	23.1

Italic font: for numbers that were calculated using data provided in original studies.

Table 6. Results of the included studies. Study level analysis

Study	Authors' nondisclosures as assessed by payments' databases [c/(a + c)]
Cherla 2018 [20]	*92.6*
Luce 2017 [28]	6.0[a]
Mayer 2006 [29]	33.3
Olavarria 2017 [31]	61.3
Patel 2018 [32]	75.9
	Company nonreporting as assessed by authors' disclosures [b/(a + b)]
Olavarria 2017 [31]	12.1
Patel 2018 [32]	7.9

Italic font: for numbers that were calculated using data provided in original studies.

[a] Relevant nondisclosed COI 10/166; total nondisclosed COI = 105/166 = 63.3%.

4.3. Interpretation of results

Discrepancies between researchers' disclosures of financial COIs and those reported by the payment database appear to be pervasive in health sciences. One explanation of this discrepancy is underreporting by authors. Although underreporting could be due to deceptive motives, it could be also due to unclear or ambiguous instructions by journals or meeting organizers [37]. Unfortunately, we could not find evidence about the respective prevalence of these two possibilities. Another explanation could be overestimation of underreporting by the included studies due to methodological limitations such as not considering the relatedness of COI and not considering COI disclosure policy requirements. However, there are other methodological limitations that may have led to nondirectional error such as inadequate data matching methodology (e.g., overlapping authors' names, different COI categories between disclosure and payment database) and not using a duplicate approach in assessing relatedness or data abstraction. Again here, we could not find evidence about the prevalence of these different scenarios.

4.4. Implications for verifying COIs

All peer-reviewed journals and society meetings should adopt a unified, well-delineated COI disclosure policy with clear definitions. This will minimize discrepancies in author's disclosures. We recommend that all journals and society meetings request COI disclosure on submission rather than after acceptance of research for publication or presentation. This gives editors the opportunity to assess the quality of the data interpretation and conclusions while considering industry ties or affiliations.

Assessing the accuracy of COI disclosures requires standard and precise definitions for all variables. Ideally, one should use multiple databases given the different databases cover different countries, types of researchers, types of payments, and time ranges. However, this raises challenges related to feasibility. One solution would be to agree on common fields to allow a single search for the different databases using a shared platform. A more radical solution would be to create a common repository of COI disclosures.

4.5. Implications for research

Future studies verifying COI disclosures in health research should avoid the limitations of previously published studies we uncovered in this review. Specifically, investigators should use appropriate payment databases (preferably using more than one database), have well-defined inclusion/exclusion criteria, consider topic relatedness, have clear definitions for COI, implement adequate data matching methodologies, use a duplicate approach for data abstraction, and check disclosure policy requirements (e.g., in terms of timeframe).

5. Conclusion

Underreporting of health science researchers' financial COIs is pervasive. Studies assessing COI underreporting suffer from a number of limitations that could have inflated their findings. With the growing media attention on COI among health researchers, the existing autonomy to self-regulate may be at stake [38]. Thus, it is essential for the research community to devise precise methods for both COI disclosure and verification.

CRediT authorship contribution statement

Hebah El-Rayess: Conceptualization, Methodology, Funding acquisition, Formal analysis, Data curation, Writing - original draft, Writing - review & editing. **Assem M. Khamis:** Conceptualization, Methodology, Funding acquisition, Formal analysis, Data curation, Writing - original draft, Writing - review & editing. **Sara Haddad:** Funding acquisition, Formal analysis, Data curation, Writing - original draft. **Hussein Abou Ghaddara:** Funding acquisition, Formal analysis, Data curation, Writing - original draft. **Maram Hakoum:** Funding acquisition, Formal analysis, Data curation, Writing - original draft. **Yervant Ichkhanian:** Funding acquisition, Formal analysis, Data curation, Writing - original draft. **Michael Bejjani:** Funding acquisition, Formal analysis, Data curation, Writing - original draft. **Elie A. Akl:** Conceptualization, Methodology, Funding acquisition, Formal analysis, Data curation, Writing - original draft, Writing - review & editing, Supervision.

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Supplementary data

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