



**Systematic review on the primary and secondary reporting
of the prevalence of ghostwriting in the medical literature**

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TITLE

Systematic review on the primary and secondary reporting of the prevalence of ghostwriting in the medical literature

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KEYWORDS

Authorship, ghostwriting, systematic review

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ABSTRACT

Background: Ghostwriting of industry-sponsored articles is unethical and is perceived to be common practice in the medical literature.

Objective: The conduct a systematic review on how evidence for the prevalence of ghostwriting is reported in the medical literature.

Data sources: MEDLINE via PubMed 1966+, EMBASE 1966+, The Cochrane Library 1988+, Medical Writing 1998+, The AMWA Journal 1986+, Council of Science Editors Annual Meetings 2007+, and the Peer Review Congress 1994+ were searched electronically (23 May 2013) using the search terms ghostwrit*, ghostauthor*, ghost AND writ*, ghost AND author*.

Eligibility criteria: All publication types were considered; only publications reporting a numerical estimate of possible ghostwriting prevalence were included.

Data extraction: Two independent reviewers screened the publications; discrepancies were resolved by consensus. Data to be collected included a numerical estimate of the prevalence of possible ghostwriting (primary outcome measure), definitions of ghostwriting reported, source of the reported prevalence, publication type and year, study design, and sample population.

Results: Of the 848 publications retrieved and screened for eligibility, 48 reported numerical estimates for the prevalence of possible ghostwriting and were analyzed further. Sixteen primary publications reported findings from cross-sectional surveys or descriptive analyses of published articles and 32 secondary publications cited published or unpublished evidence. Estimates on the prevalence of possible ghostwriting in primary and secondary publications varied markedly. Estimates were influenced by the definition of ghostwriting used, the type of population or sample assessed, and whether evidence from primary publications was cited correctly or appropriately.

Conclusions: Estimates of ghostwriting reported in the medical literature can be outdated, misleading, or mistaken. Researchers should not inflate estimates using nonstandard definitions

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of ghostwriting nor conflate ghostwriting with other unethical authorship practices. Editors and peer reviewers should not accept articles that incorrectly cite or interpret primary publications that report the prevalence of ghostwriting.

For peer review only

MAIN STRENGTHS AND LIMITATIONS

Strengths

- First systematic review on the reporting of the prevalence of ghostwriting in the medical literature
- Abroad search strategy was employed with few restrictions to minimize any potential for publication or language bias; there were no restrictions on language.
- All study designs and publication types were considered

Limitations

- Study heterogeneity in the outcomes reported and populations investigated precluded synthesis of the data
- Retrospective and self-reported nature of the data collection resulted increased the risk of selection bias in the studies
- Most included studies were not broadly representative of the peer-reviewed medical literature

INTRODUCTION

Ghostwriting of peer-reviewed journal publications in the medical literature is believed to be common practice.[1-3] This belief is supported, to a large extent, by highly publicized cases, primarily from the 1990s and early 2000s, of pharmaceutical companies and authors who had used ghostwriters to prepare manuscripts for publication in medical journals.[4-6] Such cases are highly unethical because the role of the commercial sponsor and any other potential conflicts of interest were hidden.

Ghostwriting occurs when writing contributions to a manuscript that do not meet authorship criteria are not disclosed in the acknowledgments. This practice is distinct from ghost authoring, where contributions to a manuscript that do merit authorship are not disclosed in the author byline.[7] However, part of the challenge in understanding the prevalence of ghostwriting is the current confusion surrounding the two unethical practices. For example, the widely used Council of Science Editors definition of ghost authors (ie, individuals who participate in research, data analysis, and/or writing of a manuscript but are not named or disclosed in the author byline or acknowledgments) does not distinguish between ghost authors and ghostwriters.[8] Estimating the prevalence of ghostwriting has also been hindered by the failure of authors to distinguish ghostwriting, which is unethical, from professional medical writing support, which is ethical.[9, 10] Ghostwriters keep their involvement in a manuscript hidden, whereas professional medical writers disclose their involvement and follow ethical publication practices.[7, 9-11] The prevalence of disclosed professional medical writing assistance in medical journals has been estimated to be between 6.0% and 11.0%[10, 12] and the legitimate value that this medical writing assistance can bring to improving the quality, timeliness, and integrity of reporting in medical journals has been demonstrated.[7, 13, 14] However, the exact prevalence of

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3 ghostwriting and other forms of undisclosed contributions to papers published in medical
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5 journals is unknown.
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10 The primary objective of this study was to conduct the first systematic review on how the
11 prevalence of ghostwriting is reported in the medical literature. The secondary objectives were
12 to assess the variability of the reported estimates of the prevalence of ghostwriting and
13 investigate the source for these estimates.
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22 **MATERIALS AND METHODS**

23 **Literature search strategy**

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27 A search strategy was developed to retrieve publications from the medical literature that
28 reported quantitative estimates of the prevalence of ghostwriting. The following databases were
29 searched on 23 May 2013: MEDLINE via PubMed (1966+); EMBASE (1966+); The Cochrane
30 Library, including the Cochrane Database of Systematic Reviews and Cochrane Central
31 Register of Controlled Trials (1988+); The AMWA Journal (1986+, journal of the American
32 Medical Writers Association); Medical Writing (1998+, journal of the European Medical Writers
33 Association, formerly known as The Write Stuff); Council of Science Editors annual meetings
34 (2007+); and the International Congress on Peer Review and Biomedical Publication meetings
35 (1994+). General text was searched using the following search terms: ghostwrit*, ghostauthor*,
36 ghost AND writ*, ghost AND author*. Truncation symbols and Boolean operators (AND, OR)
37 were used wherever possible.
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55 Two reviewers (SS, SMG) independently screened the title and abstracts of all retrieved
56 publications using prespecified eligibility criteria; the full text of potentially eligible publications
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3 was screened to confirm eligibility for inclusion. Any discrepancies between the reviewers were
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5 resolved by consensus. The reference lists of relevant reviews and other publications were
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7 screened by hand to identify any additional publications for inclusion.
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10 11 **Eligibility criteria**

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13 Publications were included if they reported a numerical estimate of the prevalence of possible
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15 ghostwriting. Publications were excluded if they were duplicate publications from different
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17 databases or abstracts of subsequently published full-text articles, did not report any outcomes
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19 related to ghostwriting, or reported qualitative estimate(s) of the prevalence of possible
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21 ghostwriting. No restrictions on language were included in the eligibility criteria.
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25 26 27 **Data extraction and analysis**

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29 Data to be collected were prespecified and included publication type and year, study design and
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31 sample population, definitions of ghostwriting reported, reported prevalence of possible
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33 ghostwriting, and the source of the reported prevalence of ghostwriting.
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38 The primary outcome measure for the systematic review was a numerical estimate of the
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40 prevalence of possible ghostwriting. The reported definitions of possible ghostwriting were
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42 categorized according to the following standard definitions, irrespective of the term used to
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44 describe the practice in the publication. Undisclosed writing contributions to a manuscript were
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46 defined as (i) ghostwriting if they were described as not meriting authorship and were not listed
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48 in the acknowledgments[9, 15] and (ii) ghost authoring if they did merit authorship and were not
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50 listed in the author byline.[7] Consistent with recommendations from international medical
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52 journal editors,[13, 16] Good Publication Practice guidelines,[11] and professional medical
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54 writing associations,[17, 18] disclosed writing contributions to a manuscript that did not merit
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56 authorship and were disclosed in the acknowledgments were not categorized as ghostwriting.
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RESULTS

Publication selection

A total of 848 articles were retrieved from the literature search, 800 were excluded, and 48 met the eligibility criteria and were included in the systematic review (Figure 1). The main reasons for exclusion were publications not relevant to ghostwriting (n = 539), duplicate publications from different databases (n = 129), and publications not reporting a numerical estimate of the prevalence of possible ghostwriting (n = 124). The titles or abstracts of the 8 publications that were excluded because the full text or abstract could not be retrieved were reviewed; none were considered to report a numerical estimate of the prevalence of possible ghostwriting. Overall, eligible publications included 16 primary publications that reported original research on the prevalence of possible ghostwriting and 32 secondary publications that cited published or unpublished evidence of possible ghostwriting.

Primary publications

Publication characteristics

Of the 16 primary publications (Table 1), there were 13 full-text publications[4, 6, 19-29] and three conference abstracts[30-32] that reported a numerical estimate of possible ghostwriting. Twelve publications[19-27, 30-32] reported findings from cross-sectional surveys and four publications[4, 6, 28, 29] reported findings from descriptive analyses of published articles. While there is no consensus on the best practice for reporting survey research,[33] most cross-sectional surveys were reasonably well reported. The surveys used were not validated but most included pretested questions, required an anonymous response, were conducted in targeted populations (ie, all individuals invited to participate were involved in the preparation of peer-reviewed manuscripts), and reported a sample size and response rate. Of the cross-sectional surveys conducted in targeted populations (eg, corresponding or first authors), six had response

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3 rates greater than 50%, two had response rates less than 50%, and one did not report a
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5 response rate (Table 1).
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10 Of the cross-sectional surveys conducted in nontargeted populations (eg, individuals invited to
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12 participate who may or may not have been involved in providing medical writing assistance for
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14 peer-reviewed publications), three had low (12% to 28%) response rates and one did not report
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16 a response rate (Table 1).
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22 **Table 1.** Characteristics of Primary Publications Reporting Original Evidence of Ghostwriting
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Publication	Population	Survey description	Data collected	N	RR
<i>Cross-sectional surveys – authors or corresponding authors</i>					
Flanagin 1998[26]	6 general medicine journals ^a	Self-administered, postal, anonymous, pretested, targeted	1996	809	69%
Mowatt 2002[22]	Published Cochrane reviews	Self-administered, online, anonymous, pretested, targeted	1999	362	63%
Hao 2009[31] (Abstract)	Chin Med J	Self-administered, email, not anonymous, targeted	2008 ^c	220	86%
Dotson 2011[27]	3 pharmacy journals	Self-administered, online, anonymous, pretested, targeted	2009	112	25%
Mirzazadeh 2011[23]	3 Iranian journals	Self-administered, email, not anonymous, targeted	2009- 2010	NR	NR
Wislar 2011[19]	6 general medicine journals ^b	Self-administered, online, anonymous, pretested, targeted	2008	622	70%
Ghajarzadeh 2012[25]	Arch Iran Med (based on student theses)	Self-administered, email, anonymous, targeted	2005- 2007	30	49%

Publication	Population	Survey description	Data collected	N	RR
Vinther 2012[20]	Ugeskr Laeger & Dan Med J	Self-administered, online, anonymous, pretested, targeted	2010	272	62%
<i>Cross-sectional surveys – healthcare professionals</i>					
Price 2000[21]	Health academic staff	Self-administered, postal, anonymous, pretested, targeted	NR	166	59%
Rees 2013[30] (Abstract)	Registered users of EPG Online	Self-administered, online, anonymous, nontargeted	NR	295	NR
<i>Cross-sectional surveys – members of medical writing associations</i>					
Jacobs 2009[24]	EMWA / AMWA members	Self-administered, online, anonymous, pretested, nontargeted	2005 2008	843 773	28% 14%
Hamilton 2012[32] (Abstract)	EMWA / AMWA members	Self-administered, online, anonymous, pretested, nontargeted	2011	620	12% ^d
<i>Publication reviews and descriptive analysis</i>					
Healy 2003[4]	Articles on sertraline	NA	1998- 2000	96	NA
Gøtzsche 2007[29]	Articles on Danish industry-initiated trials approved 1994-1995	NA	NR	44	NA
Ross 2008[6]	Reviews on rofecoxib associated with Merck support	NA	1996- 2004	72	NA
Suda 2011[28]	Noninferiority clinical trials	NA	1989- 2009	583	NA

^a Annals of Internal Medicine, JAMA, the New England Journal of Medicine, American Journal of Cardiology, American Journal of Medicine, American Journal of Obstetrics and Gynecology.

^b Annals of Internal Medicine, JAMA, the New England Journal of Medicine, Lancet, Nature Medicine, PLoS Medicine.

^c Submission date.

^d Personal communication, C. Hamilton.

Abbreviations: AMWA, American Medical Writers Association; EMWA, European Medical Writers Association; NA, not applicable; NR, not reported; RR, response rate.

Not all cross-sectional surveys were broadly representative of the peer-reviewed medical literature. The cross-sectional surveys were conducted in single populations of academic staff or healthcare professionals[21, 30], members of medical writing associations[24, 32], or corresponding or first authors. The corresponding or first authors were surveyed from single journals (Cochrane reviews, Chinese Medical Journal, Archives of Iranian Medicine),[22, 25, 31] two Danish journals,[20] three Iranian journals,[23] and three pharmacy journals.[27] Two cross-sectional surveys of corresponding authors were conducted in six general medicine journals.[19, 26]

The descriptive analyses of published articles were conducted in single populations and included an analysis of sertraline publications from 1998 to 2000,[4] rofecoxib reviews from 1996 to 2004,[6] publications from industry-initiated trials in Denmark from 1994 to 1995,[29] and from published noninferiority trials from 1989 to 2009.[28]

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3 Reported prevalence of ghostwriting
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5 The reported prevalence of possible ghostwriting in the primary publications varied markedly
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7 and was difficult to compare because of the different populations assessed, methods used to
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9 generate the estimates, and definitions that were used (Tables 1 and 2). All cross-sectional
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11 surveys reported a definition of ghostwriting or ghost authoring, but most definitions did not
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13 differentiate contributions that merited authorship from those that did not merit authorship (Table
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21 **Table 2.** Primary Publications Reporting Estimates of the Prevalence of Possible Ghostwriting
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Publication	Reported measure	Estimate % (n)
<i>Cross-sectional surveys reporting ghostwriting</i>		
Flanagin 1998[26]	Unnamed individual who participated in the writing	1.4% (11/809) of articles
Wislar 2011[19]	Unnamed individual who participated in the writing	0.2% ^a (1/622) of articles
Jacobs 2009, Hamilton 2012[24, 32]	Undisclosed medical writing assistance not qualifying for authorship	2005: 61.8% (NR) 2009: 41.7% (NR) 2011: 33.0% (NR) of writers
<i>Cross-sectional surveys reporting combined ghost authoring and ghostwriting</i>		
Flanagin 1998[26]	Failure to name, as an author, individuals who made substantial contributions to the research or writing or an unidentified medical writer	11.5% (93/809) of articles
Price 2000[21]	Failure to name, as an author, individuals who made substantial contributions to the research or writing	24.1% (40/166) of authors
Mowatt 2002[22]	Individual merited authorship or had assisted with drafting but not listed as an author or acknowledged	8.8% (32/362) of articles

Publication	Reported measure	Estimate % (n)
Hao 2009[31]	English-language speakers assisted with writing but not identified as authors or acknowledged	10.4% (NR) of authors
Dotson 2011[27]	Failure to name, as an author, individuals who made substantial contributions to the research or writing	0.9% (1/112) of articles
Wislar 2011[19]	Failure to name, as an author, individuals who made substantial contributions to the research or writing of the article or an unnamed individual who participated in the writing	7.9% (49/622) of articles
<i>Cross-sectional surveys reporting ghost authoring</i>		
Mirzazadeh 2011[23]	Failure to name, as an author, individuals who made substantial contributions to the research	21.4% (25/NR) of authors
Ghajarzadeh 2012[25]	Failure to name, as an author, students who made substantial contributions to the research ^b	0.7% (2/296) of articles
Vinther 2012[20]	Individual merited authorship but not listed as an author	2.4% (6/245) of articles
Rees 2013[30]	Individual merited authorship but not listed as an author	70% (NR/202) of published authors
<i>Publication reviews and descriptive analysis reporting possible ghost authoring or ghostwriting</i>		
Healy 2003[4]	Published articles coordinated by a medical information company, including acknowledged medical writing support ^c	57.3% (55/96) of articles
Gøtzsche 2007[29]	Individuals who wrote the trial protocol, conducted the statistical analyses, or wrote the manuscript but were not listed as authors, not members of a study group or steering committee, or not disclosed in an acknowledgment	75.0% (33/44) of trials
Ross 2008[6]	Published reviews associated with Merck support and with a single external author ^d	69.4% (50/72) of reviews

^a Available as online supplementary data.

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3 ^b Students were classified as ghostwriters if the student was not named as an author and if the results
4 reported in the publications were based on the results of their theses.
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7 ^c Authors conclude data provide quantification of the possible extent of ghostwriting based on a single
8 drug. Of the 55 published articles that were coordinated through a medical information company, 2
9 included medical writing assistance that was acknowledged in the published article.
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12 ^d Published review articles had been identified from correspondence between Merck and a medical
13 publishing company, from Merck publication status reports, or were affiliated with an author named within
14 the correspondence or publication status reports. The authors did not report whether medical writing
15 assistance was acknowledged in the published article.
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18 Abbreviations: NR, not reported.
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27 Four cross-sectional surveys reported the prevalence of ghostwriting where the definition
28 provided could be categorized as undisclosed contributions that do not merit authorship.[19, 24,
29 26, 32] Findings from these surveys, which were repeated at different time points, suggested
30 that the prevalence of ghostwriting is low and decreasing. Flanagin[26] and Wislar[19]
31 conducted two similar cross-sectional surveys of corresponding authors of articles published in
32 six general medicine journals in 1996[26] and in 2008.[19] The surveys, which included a core
33 set of three journals (Annals of Internal Medicine, JAMA, the New England Journal of Medicine)
34 at each time point and in targeted populations, used pretested questions that required an
35 anonymous response and had response rates greater than 65%. The prevalence of ghost
36 authoring (which included ghostwriting) was estimated to be 11.5% in 1996 and 7.9% in 2008.
37 The prevalence of ghostwriting from these surveys was estimated to be 1.4% in 1996 and 0.2%
38 in 2008. Hamilton and Jacobs conducted a cross-sectional survey of members of two medical
39 writing associations in 2005, 2008, and 2011.[24, 32] The survey, which was not conducted in
40 targeted populations, used pretested questions that required an anonymous response and had
41 response rates from 12% to 28% of the total population surveyed (ie, not all participants
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3 surveyed were involved in the preparation of peer-reviewed manuscripts). Findings from these
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5 surveys suggested that the percentage of association members who contributed to peer-
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7 reviewed publications and had ghostwritten at least once during the survey year had decreased
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9 from 61.8% in 2005 to 33.0% in 2011.
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14 Six cross-sectional survey publications reported the prevalence of possible ghostwriting (ie, the
15
16 prevalence of ghostwriting and ghost authoring combined).[19, 21, 22, 26, 27, 31] The
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18 prevalence of possible ghostwriting reported in these cross-sectional surveys varied from 0.9%
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20 to 24.1% of publications or authors.
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25 Four cross-sectional survey publications reported the prevalence of ghost authoring.[20, 23, 25,
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27 30] The prevalence of ghost authoring reported in these cross-sectional surveys varied from
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29 0.7% to 70% of publications or authors.
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34 The descriptive analyses of published articles on sertraline and rofecoxib did not include a
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36 prespecified definition of ghost authoring or ghostwriting;[4, 6] in these studies, possible
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38 ghostwriting or ghost authoring was assumed in publications associated with industry-
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40 sponsored support (Table 2). The descriptive analysis of industry-initiated trials in Denmark
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42 used a nonstandard definition of ghost authors; in this study ghost authors were defined as
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44 individuals, not named as authors, who were involved in writing the protocol, conducting the
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46 statistical analyses, or writing the manuscript.[29] The prevalence of possible ghostwriting in the
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48 two descriptive analyses of single drugs that did not include a prespecified definition of
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50 ghostwriting was 57% of articles on sertraline published from 1998 to 2000[4] and 69% of
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52 reviews on rofecoxib published from 1996 to 2004.[6] The prevalence of possible ghostwriting in
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54 the descriptive analysis of Danish industry-initiated trials, which used a nonstandard definition of
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56 authorship, was 75% of Danish initiated trials approved in 1994 to 1995.[29] The descriptive
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3 analysis of noninferiority trials[28] was not considered further as the definition of ghostwriting
4 used was consistent with disclosed medical writing assistance. In this study ghostwriters were
5 defined as acknowledged individuals, other than authors, who contributed to the writing and
6 were affiliated with an industry-sponsored study.[28] The prevalence of disclosed medical
7 writing assistance in this descriptive analysis was 17.3% (101/583) of clinical trials.
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14 15 16 **Secondary publications**

17 18 **Publication characteristics**

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20 Of the 32 secondary publications, there were 13 review articles, 10 editorials, 5 commentaries,
21 3 news articles, and 1 government report, with most being published after 2008 (Table 3). Most
22 publications cited primary sources as evidence of the prevalence of possible ghostwriting (Table
23 3), with the cited prevalence of possible ghostwriting varying from 6% of publications to 100% of
24 publications involving drugs. In most secondary publications, the information on the prevalence
25 of ghostwriting was not reported consistently compared with the cited evidence (Table 3).
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33 Misleading and mistaken information was reported in many publications that (i) did not
34 distinguish between ghostwriting and ghost authoring, (ii) included acknowledged medical
35 writing assistance or a combined estimate of guest authorship and ghost authorship as
36 ghostwriting, (iii) generalized findings from publication reviews and analyses of specific datasets
37 to wider populations of publications or industry-sponsored trials, or (iv) cited personal
38 communications or informal surveys where the original source was unpublished and could not
39 be verified (Table 3).
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Table 3. Characteristics of Secondary Publications Citing Evidence of Possible Ghostwriting

Publication	Cited evidence	Consistent with cited source(s)	Comment
Elliot Hastings Cent Rep 2004[35]	Primary	No	Did not distinguish GW from GA
Moffat Perspect Biol Med 2007[36]	Primary	No	Did not distinguish GW from GA
Schiefe Pharmacotherapy 2009[47]	Primary	No	Did not distinguish GW from GA
MacLennan Climacteric 2010[48]	Primary	No	Did not distinguish GW from GA
Nahai Aesthet Surg J 2010[49]	Secondary	No	Did not distinguish GW from GA
Ngai Account Res 2005[50]	Primary	Yes	Did not distinguish GW from GA
Bosch EMBO Rep 2011[43]	Primary	Yes	Did not distinguish GW from GA
Wiwanitkit Am J Med 2012[51]	Primary	No	Did not distinguish GW from GA or GA from guest authorship
Krimsky Med Law 2007[52]	Primary	No	Did not distinguish GW from GA or GA from guest authorship
Langdon-Neuner Mens Sana Monogr 2008[53]	Primary & secondary	No	Did not distinguish GW from GA or GW from disclosed medical writing support
Tharyan Indian J Med Ethics 2011[45]	Primary	Yes	Did not distinguish GW from GA or GW from disclosed medical writing assistance
Paul Clin Microbiol Infect 2009[54]	Primary	Yes	Did not distinguish GW / GA from disclosed medical writing assistance
Bavdekar Lung India 2012[42]	Primary	No	Did not distinguish GW from GA and generalized evidence to a wider population
Górski Transplant Proc 2010[55]	Primary &	No	Did not distinguish GW from GA

Publication	Cited evidence	Consistent with cited source(s)	Comment
	secondary		and generalized evidence to a wider population
Matias-Guiu Neurologia 2011[44]	Primary & secondary	No	Did not distinguish GW from GA and generalized evidence to a wider population
McHenry Mens Sana Monogr 2010[56]	Gov. report	No	Generalized evidence to a wider population
Healy BMJ 2004[57]	Primary & secondary	No / ND	Generalized evidence to a wider population and reported personal opinion of GW prevalence
Abbasi BMJ 2004[2]	Secondary	No	Secondary publication cited named individual
Mitrany Science Editor 2005[58]	None	ND	Cited named individual
Collier Can Med Assoc J 2009[3]	None	ND	Cited named individual
Kmietowicz BMJ 2004[59]	None	ND	Cited named individual
Matthews Wall St J 2005[1]	None	ND	Cited unpublished data
Bonita Heart Fail Clin 2011[60]	Primary	Yes	Consistent with cited source
Grassley Int J Occup Environ Health 2011[61]	Primary	Yes	Consistent with cited source
Nat Clin Pract Nephrol 2007[62]	Primary	Yes	Consistent with cited source
Editors J Urol 2008[14]	Primary	Yes	Consistent with cited source
Baethge Deutsches Arzteblatt 2009[63]	Primary	Yes	Consistent with cited source
Flanagin CSE Annual Mtg 2010[64]	Primary	Yes	Consistent with cited source
Murray Open Med 2010[65]	Primary	Yes	Consistent with cited source

Publication	Cited evidence	Consistent with cited source(s)	Comment
Moore BMJ 2004[66]	Secondary	Yes	Consistent with cited source
Hargreaves BMJ 2007[67]	Primary	Yes	Consistent with cited source
Jones Nature 2009[68]	Primary	Yes	Consistent with cited source

Abbreviations: CSE, Council of Science Editors; GA, ghost authoring; Gov, government; GW, ghostwriting; ND, not determined.

Case study of misleading and mistaken evidence

An analysis of secondary publications citing the possible prevalence of ghostwriting in sertraline publications provides an illuminating case study on how misleading or mistaken evidence can enter and remain in the medical literature. In 2003, Healy and Cattell showed that 57% (55/96) of articles on sertraline published from 1998 to 2000 were coordinated through a medical information company and only two acknowledged medical writing assistance.[4] The authors concluded that these data provided information on the “possible extent of ghostwriting based on a single drug”. In 2004 (October 14), Healy also provided evidence on the influence of the pharmaceutical industry on key groups at a United Kingdom House of Commons Health Select Committee investigation.[34] In answer to Question 197, Healy stated the following:

“My estimate is that, even in journals like the BMJ, the Lancet, the New England Journal of Medicine and JAMA, the leading journals in the field, if these articles have to do with therapeutics, with drugs, it may be worse perhaps for psychiatry than elsewhere, but I doubt it, 50% of these articles are ghostwritten. It may be higher.”

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3 Healy and Cattell's original evidence has been cited incorrectly and interchangeably with Healy's
4 statement to the House of Commons Health Select Committee investigation (Figure 2). Although
5 findings from the primary publication have been cited and interpreted correctly in two secondary
6 publications,[35, 36] many secondary publications incorrectly cited Healy's original evidence and
7 statement to the House of Commons Health Select Committee investigation (Figure 2).
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14 15 16 17 18 **DISCUSSION** 19

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22 This systematic review on the reported prevalence of ghostwriting in the medical literature
23 showed that the estimates of the prevalence of ghostwriting in primary publications varied
24 markedly and were influenced by the definitions used, the types of study designs, and the
25 populations assessed. In addition, secondary publications often cited outdated, misleading, or
26 mistaken evidence of the reported prevalence of ghostwriting, with many publications not
27 distinguishing ghostwriting from ghost authoring.
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37 Although evidence from descriptive analyses can highlight the extent of ghostwriting in single
38 populations, evidence from well-conducted cross-sectional surveys have the potential to provide
39 estimates of the prevalence of ghostwriting that may be generalized to the majority of peer-
40 reviewed publications. Despite this, many of the cross-sectional surveys retrieved in this
41 systematic review were conducted in limited populations that were not broadly representative of
42 the peer-reviewed medical literature. In addition, many of the cross-sectional surveys did not
43 differentiate between contributions that merited authorship from those that did not merit
44 authorship and provided at best, an estimate of possible ghostwriting. The reported prevalence
45 of ghostwriting, where ghostwriting was defined as undisclosed contributions that did not merit
46 authorship, was retrieved from the two cross-sectional surveys of corresponding authors from
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3 several general medicine journals and by cross-sectional surveys (repeated on three separate
4 occasions from 2005 to 2011) of members of two major medical writing associations. Together
5 the findings from these surveys suggested that the prevalence of ghostwriting has decreased in
6 recent years. However, while the findings from these surveys may be considered more broadly
7 representative of the peer-reviewed medical literature than surveys focused on single journals,
8 single countries, or single subject areas, interpretation of these findings should take into account
9 that respondents were required to retrospectively self-report potentially unethical or
10 unprofessional behaviour.
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22 Unethical authorship practices are a major concern and are an increasingly recognized problem
23 in the medical literature.[37] As the findings from this systematic review suggest, some of these
24 perceived problems may arise from the considerable, but unnecessary, confusion and
25 disagreement surrounding the definitions of ghostwriting. As recognized by the World
26 Association of Medical Editors, professional medical writers can have a legitimate role in
27 assisting authors to communicate their research findings in the peer-reviewed literature.[13]
28
29 Professional medical writers can and do improve the timeliness and quality of reporting and can
30 assist investigators and industry sponsors to meet their ethical commitments to the disclosure
31 and publishing of clinical trial results.[7, 38-40] As such, the misleading and mistaken reporting
32 of the prevalence of ghostwriting that was evident in the secondary publications retrieved in this
33 systematic review is disappointing. Specifically, the confusion surrounding definitions of ghost
34 authorship and ghostwriting and the unbalanced focus on industry as the source of unethical
35 authorship practices in the secondary publications takes attention away from the need to focus
36 on all types of unethical contributions in peer-reviewed publications, irrespective of the source of
37 the unethical practice.
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3 The strengths of this systematic review are that a broad search strategy was employed with few
4 restrictions to minimize any potential for publication or language bias. All study designs and
5 publication types were considered and there were no restrictions on language. Although the full
6 text or abstracts of 8 publications could not be retrieved, omission of these publications was
7 unlikely to have biased the findings. Review of the abstracts or titles of these publications
8 suggested that none reported numerical estimates of the prevalence of ghostwriting. The major
9 finding of this review was the limitations of the reported evidence of ghostwriting in the medical
10 literature. These limitations included the heterogeneity among the studies in the outcomes
11 reported and populations investigated, the observational study designs, and the retrospective
12 nature of data collection. Given the nature of unethical authorship practices, it may not be
13 feasible to conduct a prospective study on ghostwriting. However, based on the findings from
14 this review, recommendations can be made to help researchers, authors, editors, and peer-
15 reviewers apply the same rigorous standards that are applied to the conduct and assessment of
16 all clinical research and actively improve the quality of reporting of the evidence of unethical
17 authorship practices.
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38 Researchers should use a standard definition of ghostwriting so that the confusion around
39 ghostwriters and ghost authors is not perpetuated. Ghostwriting is paid or unpaid writing
40 assistance by individuals who generally do not merit authorship and whose contributions are not
41 disclosed in the acknowledgments.[7] In contrast, ghost authoring is contributions to the
42 research, data analysis, and/or writing of a manuscript by individuals who do merit authorship
43 and whose contributions are not disclosed in the author byline.[7] For example, the descriptive
44 analysis of Danish industry-initiated trials used a nonstandard definition of authorship, which is
45 likely to have contributed to the very high prevalence of possible ghostwriting reported in this
46 study (75%). In this study, Gøtzsche et al.[29] suggested that individuals who write the trial
47 protocol, conduct the statistical analyses, or who contribute to the writing of a publication should
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3 be included as authors. Indeed, the prevalence of ghost authorship in this study was 91% when
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5 the analyses included these individuals, irrespective of whether they had been appropriately
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7 acknowledged elsewhere. Given that the Gøtzsche et al.[29] study has been downloaded more
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9 than 3,000 times since publication[41] and cited repeatedly as evidence not only of ghost
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11 authorship but also of ghostwriting,[42-45] it would have been illuminating if the authors had
12
13 included an estimate of the prevalence of ghostwriting using standard definitions for
14
15 comparison. In addition to using standard definitions of ghostwriting, researchers and authors
16
17 should ensure that cited evidence of ghostwriting is reported accurately without unwarranted
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19 generalizations. Publications based on personal commentary should be avoided and studies
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21 that use nonstandard definitions, specific populations, or that were conducted before a change
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23 in practice (eg, before the adoption of the Good Publication Practice guidelines for
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25 communicating company sponsored research in 2003 [GPP][46] and in 2009 [GPP2][11])
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27 should be described in context.
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34 Editors and peer reviewers have a duty to prevent outdated, misleading, or mistaken evidence
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36 on the prevalence of ghostwriting from being published and perpetuated. Close attention should
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38 be paid to the internal and external validity of the study, the definitions used, how the data are
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40 reported, and whether the data are interpreted within the context of current practices. When
41
42 assessing a submitted manuscript on ghostwriting, editors should consider using peer reviewers
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44 with expertise in the appropriate study designs (eg, survey research) and ethical publication
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46 practices. Collectively, these actions could help prevent further questionable evidence on the
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48 prevalence of ghostwriting from being published.
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54 In conclusion, the findings from this systematic review showed that reports of the prevalence of
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56 ghostwriting in the medical literature are limited by the varied definitions used to describe
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58 unethical authorship practices, the types of study designs employed, and the populations
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3 assessed. To improve reporting, researchers should not inflate estimates using nonstandard
4 definitions of ghostwriting nor conflate ghostwriting with other unethical authorship practices.
5
6 While open and transparent debate should be encouraged, editors and peer reviewers should
7
8 not accept articles that incorrectly cite or interpret primary publications that report the
9
10 prevalence of ghostwriting.
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13 14 15 16 17 18 **ACKNOWLEDGMENTS** 19

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21 collection and screening of publications, and the analysis and interpretation of the findings. SS
22 drafted and critically revised draft versions of the manuscript, gave final approval for
23 submission, and agrees to be accountable for all aspects of the work.
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40 review during the drafting of the manuscript.
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COMPETING INTERESTS

The author is a professional medical writer who is actively involved in national and international not-for-profit organizations that encourage ethical medical writing practices. The author has no relationships with any pharmaceutical company that might have an interest in the submitted work and has no other relationships that could be construed as a competing interest.

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FIGURE LEGENDS

Figure 1. Selection of publications reporting a numerical estimate of the prevalence of ghostwriting. Electronic databases were searched on 23 May 2013.

^a Journal of the European Medical Writers Association, formerly known as The Write Stuff.

^b Journal of the American Medical Writers Association.

^c Council of Science Editors Annual Meetings.

^d International Congress on Peer Review and Biomedical Publication.

Figure 2. Case study of original versus cited evidence of ghostwriting prevalence.

Contrast between original evidence on the prevalence of possible ghostwriting in sertraline publications from 1998 to 2000 and the subsequent citations of this evidence. Source of the original published evidence: Healy and Cattell[4] showed that 55 of 96 (57%) articles published on sertraline from 1998 to 2000 were coordinated through a medical communications company and concluded that these data provided information on the “possible extent of ghostwriting based on a single drug”. Inaccurate reporting from the cited source is marked with a cross.

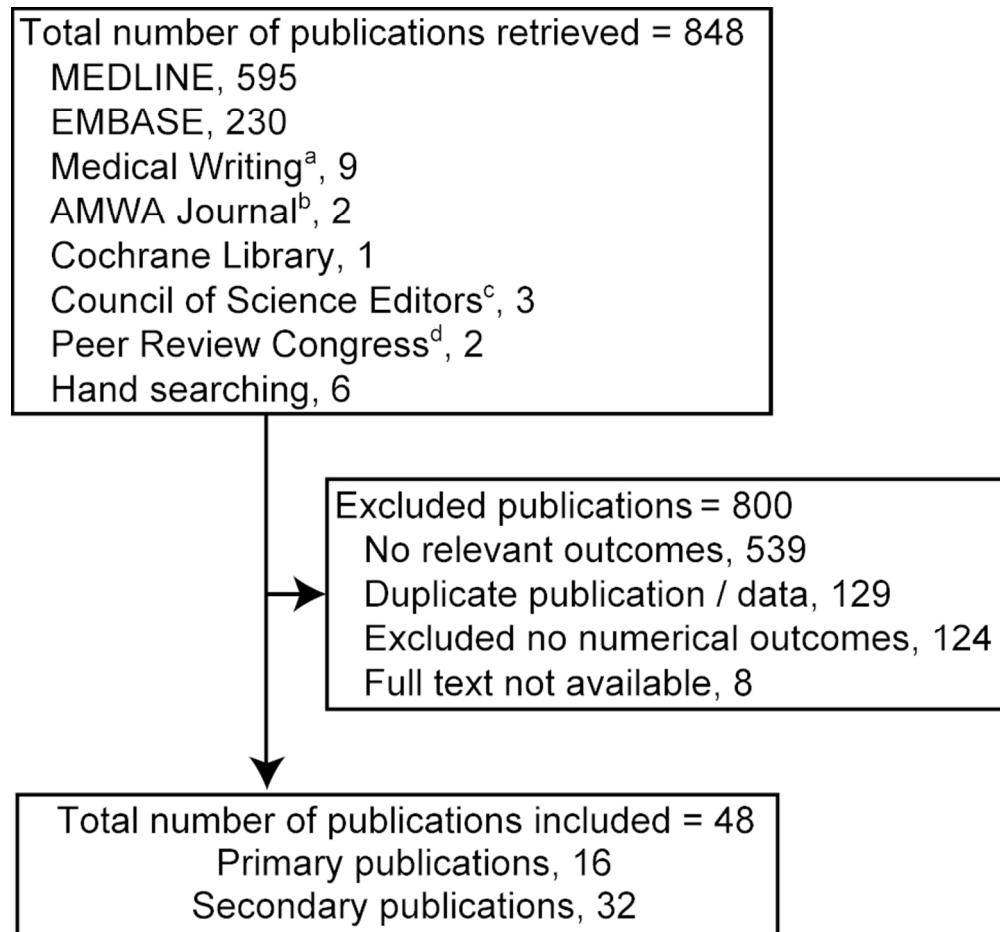


Figure 1. Selection of publications reporting a numerical estimate of the prevalence of ghostwriting.

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a Journal of the European Medical Writers Association, formerly known as The Write Stuff.

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d International Congress on Peer Review and Biomedical Publication.

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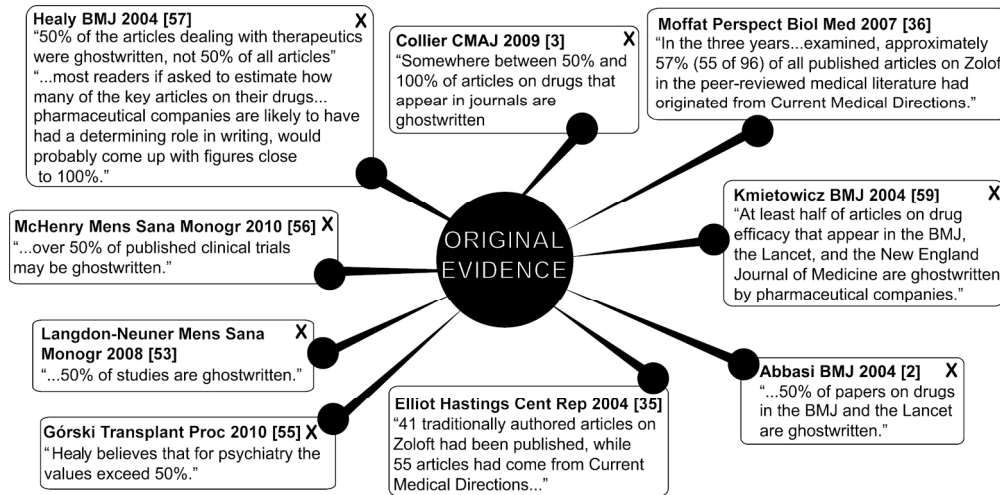


Figure 2. Case study of original versus cited evidence of ghostwriting prevalence. Contrast between original evidence on the prevalence of possible ghostwriting in sertraline publications from 1998 to 2000 and the subsequent citations of this evidence. Source of the original published evidence: Healy and Cattell[4] showed that 55 of 96 (57%) articles published on sertraline from 1998 to 2000 were coordinated through a medical communications company and concluded that these data provided information on the “possible extent of ghostwriting based on a single drug”. Inaccurate reporting from the cited source is marked with a cross.

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2/3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Not applicable
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	6
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6/7
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	Not applicable
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Not applicable
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2 for each meta-analysis).	Not applicable



PRISMA 2009 Checklist

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Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	Not applicable
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	Not applicable
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8, Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	8-11, 15, Tables 1-3
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Not applicable
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Tables 1-3
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Not applicable
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Not applicable
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	Not applicable
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	20-24
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	20-22
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	22-24
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	Not applicable

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BMJ Open

Systematic review on the primary and secondary reporting of the prevalence of ghostwriting in the medical literature

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TITLE

Systematic review on the primary and secondary reporting of the prevalence of ghostwriting
in the medical literature

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KEYWORDS

Authorship, ghostwriting, systematic review

WORD COUNT

3,588

ABSTRACT

Background: Ghostwriting of industry-sponsored articles is unethical and is perceived to be common practice.

Objective: To systematically review how evidence for the prevalence of ghostwriting is reported in the medical literature.

Data sources: MEDLINE via PubMed 1966+, EMBASE 1966+, The Cochrane Library 1988+, Medical Writing 1998+, The AMWA Journal 1986+, Council of Science Editors Annual Meetings 2007+, and the Peer Review Congress 1994+ were searched electronically (23 May 2013) using the search terms ghostwrit*, ghostauthor*, ghost AND writ*, ghost AND author*.

Eligibility criteria: All publication types were considered; only publications reporting a numerical estimate of possible ghostwriting prevalence were included.

Data extraction: Two independent reviewers screened the publications; discrepancies were resolved by consensus. Data to be collected included a numerical estimate of the prevalence of possible ghostwriting (primary outcome measure), definitions of ghostwriting reported, source of the reported prevalence, publication type and year, study design, and sample population.

Results Of the 848 publications retrieved and screened for eligibility, 48 reported numerical estimates for the prevalence of possible ghostwriting. Sixteen primary publications reported findings from cross-sectional surveys or descriptive analyses of published articles; 32 secondary publications cited published or unpublished evidence. Estimates on the prevalence of possible ghostwriting in primary and secondary publications varied markedly. Primary estimates were not suitable for meta-analysis because of the various definitions of ghostwriting used, study designs, and types of populations or samples. Secondary estimates were not always reported or cited correctly or appropriately.

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3 **Conclusions** Evidence for the prevalence of ghostwriting in the medical literature is limited
4 and can be outdated, misleading, or mistaken. Researchers should not inflate estimates
5 using nonstandard definitions of ghostwriting nor conflate ghostwriting with other unethical
6 authorship practices. Editors and peer reviewers should not accept articles that incorrectly
7 cite or interpret primary publications that report the prevalence of ghostwriting.
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Strengths

- First systematic review on the reporting of the prevalence of ghostwriting in the medical literature
- A broad search strategy was employed with few restrictions to minimize any potential for publication or language bias; there were no restrictions on language.
- All study designs and publication types were considered

Limitations

- Study heterogeneity in the outcomes reported and populations investigated precluded synthesis of the data
- Retrospective and self-reported nature of the data collection increased the risk of selection bias in the studies
- Most included studies were not broadly representative of the peer-reviewed medical literature

INTRODUCTION

Ghostwriting of peer-reviewed journal publications in the medical literature is believed to be common practice.[1-3] This belief is supported, to a large extent, by highly publicized cases, primarily from the 1990s and early 2000s, of pharmaceutical companies and authors who had used ghostwriters to prepare manuscripts for publication in medical journals.[4-6] Such cases are highly unethical because the role of the commercial sponsor and any other potential conflicts of interest were hidden.

Ghostwriting occurs when writing contributions to a manuscript that do not meet authorship criteria are not disclosed in the acknowledgments. This practice is distinct from ghost authoring, where contributions to a manuscript that do merit authorship are not disclosed in the author byline.[7] However, part of the challenge in understanding the prevalence of ghostwriting is the current confusion surrounding the two unethical practices. For example, the widely used Council of Science Editors definition of ghost authors (ie, individuals who participate in research, data analysis, and/or writing of a manuscript but are not named or disclosed in the author byline or acknowledgments) does not distinguish between ghost authors and ghostwriters.[8] Estimating the prevalence of ghostwriting has also been hindered by the failure of authors to distinguish ghostwriting, which is unethical, from professional medical writing support, which is ethical.[9, 10] Ghostwriters keep their involvement in a manuscript hidden, whereas professional medical writers disclose their involvement and follow ethical publication practices.[7, 9-11] Consistent with the authorship criteria recommended by the International Committee of Medical Journal Editors (ICMJE), professional medical writers who provide writing assistance and do not meet all of the ICMJE authorship criteria, should be acknowledged rather than listed as authors.[12] The prevalence of disclosed professional medical writing assistance in medical journals has been estimated to be between 6.0% and 11.0%[10, 13] and the legitimate value that this medical

1
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3 writing assistance can bring to improving the quality, timeliness, and integrity of reporting in
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5 medical journals has been demonstrated.[7, 14, 15] However, the exact prevalence of
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7 ghostwriting and other forms of undisclosed contributions to papers published in medical
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9 journals is unknown.

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13 The primary objective of this study was to conduct the first systematic review on how the
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15 prevalence of ghostwriting is reported in the medical literature. The secondary objectives
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17 were to assess the variability of the reported estimates of the prevalence of ghostwriting and
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19 investigate the source for these estimates.
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MATERIALS AND METHODS

Literature search strategy

A search strategy was developed to retrieve publications from the medical literature that reported quantitative estimates of the prevalence of ghostwriting. The following databases were searched on 23 May 2013: MEDLINE via PubMed (1966+); EMBASE (1966+); The Cochrane Library, including the Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Trials (1988+); The AMWA Journal (1986+, journal of the American Medical Writers Association); Medical Writing (1998+, journal of the European Medical Writers Association, formerly known as The Write Stuff); Council of Science Editors annual meetings (2007+); and the International Congress on Peer Review and Biomedical Publication meetings (1994+). General text was searched using the following search terms: ghostwrit*, ghostauthor*, ghost AND writ*, ghost AND author*. Truncation symbols and Boolean operators (AND, OR) were used wherever possible.

Two reviewers (SS, SMG) independently screened the title and abstracts of all retrieved publications using prespecified eligibility criteria; the full text of potentially eligible publications was screened to confirm eligibility for inclusion. Any discrepancies between the reviewers were resolved by consensus. The reference lists of relevant reviews and other publications were screened by hand to identify any additional publications for inclusion.

Eligibility criteria

The eligibility criteria were prespecified. Publications were included if they reported a numerical estimate of the prevalence of possible ghostwriting. Publications were excluded if they were duplicate publications from different databases or abstracts of subsequently published full-text articles, did not report any outcomes related to ghostwriting, or reported

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3 qualitative estimate(s) of the prevalence of possible ghostwriting. No restrictions on
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5 language were included in the eligibility criteria.
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8 9 **Data extraction and analysis**

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11 The primary and secondary outcomes and data to be collected were prespecified. Data to
12
13 be collected included publication type and year, study design and sample population,
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15 definitions of ghostwriting reported, reported prevalence of possible ghostwriting, and the
16
17 source of the reported prevalence of ghostwriting. The prevalence of possible ghostwriting
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19 was reported as published. No unpublished data from the retrieved literature were reported
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21 and values for prevalence were not extrapolated from published data.
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25 The primary outcome measure for the systematic review was a numerical estimate of the
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27 prevalence of possible ghostwriting. The reported definitions of possible ghostwriting were
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29 categorized according to the following standard definitions, irrespective of the term used to
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31 describe the practice in the publication. Undisclosed writing contributions to a manuscript
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33 were defined as (i) ghostwriting if they were described as not meriting authorship and were
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35 not listed in the acknowledgments[9, 16] and (ii) ghost authoring if they did merit authorship
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37 and were not listed in the author byline.[7] Consistent with recommendations from
38
39 international medical journal editors,[12, 14] Good Publication Practice guidelines,[11] and
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41 professional medical writing associations,[17, 18] disclosed writing contributions to a
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43 manuscript that did not merit authorship and were disclosed in the acknowledgments were
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45 not categorized as ghostwriting.
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49 The key factors considered when assessing study quality were study design, the population
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51 assessed, and how ghostwriting was defined. While there is no consensus on the best
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53 practice for reporting survey research,[19] the quality of the cross-sectional surveys was
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determined by an assessment of the following factors: validation or pretesting of the survey questions, anonymity of the response, sample size, and response rate.

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RESULTS

Publication selection

A total of 848 articles were retrieved from the literature search, 800 were excluded, and 48 met the eligibility criteria and were included in the systematic review (Figure 1). The main reasons for exclusion were publications not relevant to ghostwriting (n = 539), duplicate publications from different databases (n = 129), and publications not reporting a numerical estimate of the prevalence of possible ghostwriting (n = 124). The titles or abstracts of the 8 publications that were excluded because the full text or abstract could not be retrieved were reviewed; none were considered to report a numerical estimate of the prevalence of possible ghostwriting. Overall, eligible publications included 16 primary publications that reported original research on the prevalence of possible ghostwriting and 32 secondary publications that cited published or unpublished evidence of possible ghostwriting.

Primary publications

Publication characteristics

Of the 16 primary publications (Table 1), there were 13 full-text publications[4, 6, 20-30] and three conference abstracts[31-33] that reported a numerical estimate of possible ghostwriting. Twelve publications[20-28, 31-33] reported findings from cross-sectional surveys and four publications[4, 6, 29, 30] reported findings from descriptive analyses of published articles. Most cross-sectional surveys were reasonably well reported. The surveys used were not validated but most included pretested questions, required an anonymous response, were conducted in targeted populations (ie, all individuals invited to participate were involved in the preparation of peer-reviewed manuscripts), and reported a sample size and response rate. Of the cross-sectional surveys conducted in targeted populations (eg, corresponding or first authors), six had response rates greater than 50%, two had response rates less than 50%, and one did not report a response rate (Table 1). Of the cross-sectional

Table 1. Characteristics of Primary Publications Reporting Original Evidence of Ghostwriting

Publication	Population	Survey description	Data collected	N	RR
<i>Cross-sectional surveys – authors or corresponding authors</i>					
Flanagin 1998[27]	6 general medicine journals ^a	Self-administered, postal, anonymous, pretested, targeted	1996	809	69%
Mowatt 2002[23]	Published Cochrane reviews	Self-administered, online, anonymous, pretested, targeted	1999	362	63%
Hao 2009[32] (Abstract)	Chin Med J	Self-administered, email, not anonymous, targeted	2008 ^c	220	86%
Dotson 2011[28]	3 pharmacy journals	Self-administered, online, anonymous, pretested, targeted	2009	112	25%
Mirzazadeh 2011[24]	3 Iranian journals	Self-administered, email, not anonymous, targeted	2009- 2010	NR	NR
Wislar 2011[20]	6 general medicine journals ^b	Self-administered, online, anonymous, pretested, targeted	2008	622	70%
Ghajarzadeh 2012[26]	Arch Iran Med (based on student theses)	Self-administered, email, anonymous, targeted	2005- 2007	30	49%
Vinther 2012[21]	Ugeskr Laeger & Dan Med J	Self-administered, online, anonymous, pretested, targeted	2010	272	62%
<i>Cross-sectional surveys – healthcare professionals</i>					
Price 2000[22]	Health academic staff	Self-administered, postal, anonymous, pretested, targeted	NR	166	59%
Rees 2013[31] (Abstract)	Registered users of EPG Online	Self-administered, online, anonymous, nontargeted	NR	295	NR
<i>Cross-sectional surveys – members of medical writing associations</i>					
Jacobs 2009[25]	EMWA / AMWA members	Self-administered, online, anonymous, pretested, nontargeted	2005 2008	843 773	28% 14%
Hamilton	EMWA / AMWA	Self-administered, online,	2011	620	12% ^d

2012[33] members anonymous, pretested,
(Abstract) nontargeted

Publication reviews and descriptive analysis

Healy 2003[4]	Articles on sertraline	NA	1998- 2000	96	NA
Gøtzsche 2007[30]	Articles on Danish industry-initiated trials approved 1994-1995	NA	NR	44	NA
Ross 2008[6]	Reviews on rofecoxib associated with Merck support	NA	1996- 2004	72	NA
Suda 2011[29]	Noninferiority clinical trials	NA	1989- 2009	583	NA

^a Annals of Internal Medicine, JAMA, the New England Journal of Medicine, American Journal of Cardiology, American Journal of Medicine, American Journal of Obstetrics and Gynecology.

^b Annals of Internal Medicine, JAMA, the New England Journal of Medicine, Lancet, Nature Medicine, PLoS Medicine.

^c Submission date.

^d Personal communication, C. Hamilton.

Abbreviations: AMWA, American Medical Writers Association; EMWA, European Medical Writers Association; NA, not applicable; NR, not reported; RR, response rate.

surveys conducted in nontargeted populations (eg, individuals invited to participate who may or may not have been involved in providing medical writing assistance for peer-reviewed publications), three had low (12% to 28%) response rates and one did not report a response rate (Table 1).

Not all cross-sectional surveys were broadly representative of the peer-reviewed medical literature. The cross-sectional surveys were conducted in single populations of academic staff or healthcare professionals[22, 31], members of medical writing associations[25, 33], or

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3 corresponding or first authors. The corresponding or first authors were surveyed from single
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5 journals (Cochrane reviews, Chinese Medical Journal, Archives of Iranian Medicine),[23, 26,
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7 32] two Danish journals,[21] three Iranian journals,[24] and three pharmacy journals.[28] Two
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9 cross-sectional surveys of corresponding authors were conducted in six general medicine
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11 journals.[20, 27]
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15 The descriptive analyses of published articles were conducted in single populations and
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17 included an analysis of sertraline publications from 1998 to 2000,[4] rofecoxib reviews from
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19 1996 to 2004,[6] publications from industry-initiated trials in Denmark from 1994 to 1995,[30]
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21 and from published noninferiority trials from 1989 to 2009.[29]
22

23 24 25 Reported prevalence of ghostwriting

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27 The reported prevalence of possible ghostwriting in the primary publications varied markedly
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29 and were not suitable for meta-analysis because of the different populations assessed, the
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31 different methods used to generate the estimates, and the various definitions that were used
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33 (Tables 1 and 2). All cross-sectional surveys reported a definition of ghostwriting or ghost
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35 authoring, but most definitions did not differentiate contributions that merited authorship from
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37 those that did not merit authorship (Table 2).
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41 Four cross-sectional surveys reported the prevalence of ghostwriting where the definition
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43 provided could be categorized as undisclosed contributions that do not merit authorship.[20,
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45 25, 27, 33] Findings from these surveys, which were repeated at different time points,
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47 suggested that the prevalence of ghostwriting is low and decreasing. Flanagin[27] and
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49 Wislar[20] conducted two similar cross-sectional surveys of corresponding authors of articles
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51 published in six general medicine journals in 1996[27] and in 2008.[20] The surveys, which
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53 included a core set of three journals (Annals of Internal Medicine, JAMA, the New England
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55 Journal of Medicine) at each time point and in targeted populations, used pretested
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Table 2. Primary Publications Reporting Estimates of the Prevalence of Possible Ghostwriting

Publication	Measure of Possible Ghostwriting Reported by Authors	Estimate % (n)
<i>Cross-sectional surveys reporting ghostwriting</i>		
Flanagin 1998[27]	Unnamed individual who participated in the writing	1.4% (11/809) of articles
Wislar 2011[20]	Unnamed individual who participated in the writing	0.2% ^a (1/622) of articles
Jacobs 2009, Hamilton 2012[25, 33]	Undisclosed medical writing assistance not qualifying for authorship	2005: 61.8% (NR) 2009: 41.7% (NR) 2011: 33.0% (NR) of articles ^b
<i>Cross-sectional surveys reporting combined ghost authoring and ghostwriting</i>		
Flanagin 1998[27]	Failure to name, as an author, individuals who made substantial contributions to the research or writing or an unidentified medical writer	11.5% (93/809) of articles
Price 2000[22]	Failure to name, as an author, individuals who made substantial contributions to the research or writing	24.1% (40/166) of authors
Mowatt 2002[23]	Individual merited authorship or had assisted with drafting but not listed as an author or acknowledged	8.8% (32/362) of articles
Hao 2009[32]	English-language speakers assisted with writing but not identified as authors or acknowledged	10.4% (NR) of authors
Dotson 2011[28]	Failure to name, as an author, individuals who made substantial contributions to the research or writing	0.9% (1/112) of articles
Wislar 2011[20]	Failure to name, as an author, individuals who made substantial contributions to the research or writing of the article or an unnamed individual who participated in the writing	7.9% (49/622) of articles
<i>Cross-sectional surveys reporting ghost authoring</i>		
Mirzazadeh 2011[24]	Failure to name, as an author, individuals who made substantial contributions to the research	21.4% (25/NR) of authors
Ghajarzadeh	Failure to name, as an author, students who made substantial	0.7% (2/296) of

2012[26]	contributions to the research ^c	articles
Vinther 2012[21]	Individual merited authorship but not listed as an author	2.4% (6/245) of articles
Rees 2013[31]	Individual merited authorship but not listed as an author	70% (NR/202) of published authors

Publication reviews and descriptive analysis reporting possible ghost authoring or ghostwriting

Healy 2003[4]	Published articles coordinated by a medical information company, including acknowledged medical writing support ^d	57.3% (55/96) of articles
Gøtzsche 2007[30]	Individuals who wrote the trial protocol, conducted the statistical analyses, or wrote the manuscript but were not listed as authors, not members of a study group or steering committee, or not disclosed in an acknowledgment	75.0% (33/44) of trials
Ross 2008[6]	Published reviews associated with Merck support and with a single external author ^e	69.4% (50/72) of reviews

^a Available as online supplementary data.

^b Values represent the mean weighted percentage of publications that were ghostwritten by respondents. Findings were weighted in proportion to the number of manuscripts the respondent wrote per year.

^c Students were classified as ghostwriters if the student was not named as an author and if the results reported in the publications were based on the results of their theses.

^d Authors conclude data provide quantification of the possible extent of ghostwriting based on a single drug. Of the 55 published articles that were coordinated through a medical information company, 2 included medical writing assistance that was acknowledged in the published article.

^e Published review articles had been identified from correspondence between Merck and a medical publishing company, from Merck publication status reports, or were affiliated with an author named within the correspondence or publication status reports. The authors did not report whether medical writing assistance was acknowledged in the published article.

Abbreviations: NR, not reported.

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3 questions that required an anonymous response and had response rates greater than 65%.
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5 The prevalence of ghost authoring (which included ghostwriting) was estimated to be 11.5%
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7 in 1996 and 7.9% in 2008. The prevalence of ghostwriting from these surveys was estimated
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9 to be 1.4% in 1996 and 0.2% in 2008. Hamilton and Jacobs conducted a cross-sectional
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11 survey of members of two medical writing associations in 2005, 2008, and 2011.[25, 33] The
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13 survey, which was not conducted in targeted populations, used pretested questions that
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15 required an anonymous response and had response rates from 12% to 28% of the total
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17 population surveyed (ie, not all participants surveyed were involved in the preparation of
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19 peer-reviewed manuscripts). Findings from these surveys showed that the mean weighted
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21 percentage of publications that were ghostwritten by respondents had decreased from
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23 61.8% in 2005 to 33.0% in 2011. Findings were weighted in proportion to the number of
24
25 manuscripts the respondent wrote per year.
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29 Six cross-sectional survey publications reported the prevalence of possible ghostwriting (ie,
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31 the prevalence of ghostwriting and ghost authoring combined).[20, 22, 23, 27, 28, 32] The
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33 prevalence of possible ghostwriting reported in these cross-sectional surveys varied from
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35 0.9% to 24.1% of publications or authors.
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39 Four cross-sectional survey publications reported the prevalence of ghost authoring.[21, 24,
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41 26, 31] The prevalence of ghost authoring reported in these cross-sectional surveys varied
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43 from 0.7% to 70% of publications or authors.
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47 The descriptive analyses of published articles on sertraline and rofecoxib did not include a
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49 prespecified definition of ghost authoring or ghostwriting;[4, 6] in these studies, possible
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51 ghostwriting or ghost authoring was assumed in publications associated with industry-
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53 sponsored support (Table 2). The descriptive analysis of industry-initiated trials in Denmark
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55 used a nonstandard definition of ghost authors; in this study ghost authors were defined as
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57 individuals, not named as authors, who were involved in writing the protocol, conducting the
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3 statistical analyses, or writing the manuscript.[30] The prevalence of possible ghostwriting in
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5 the two descriptive analyses of single drugs that did not include a prespecified definition of
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7 ghostwriting was 57% of articles on sertraline published from 1998 to 2000[4] and 69% of
8
9 reviews on rofecoxib published from 1996 to 2004.[6] The prevalence of possible
10
11 ghostwriting in the descriptive analysis of Danish industry-initiated trials, which used a
12
13 nonstandard definition of authorship, was 75% of Danish initiated trials approved in 1994 to
14
15 1995.[30] The descriptive analysis of noninferiority trials[29] was not considered further as
16
17 the definition of ghostwriting used was consistent with disclosed medical writing assistance.
18
19 In this study ghostwriters were defined as acknowledged individuals, other than authors, who
20
21 contributed to the writing and were affiliated with an industry-sponsored study.[29] The
22
23 prevalence of disclosed medical writing assistance in this descriptive analysis was 17.3%
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25 (101/583) of clinical trials.
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30 **Secondary publications**

31 Publication characteristics

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33 Of the 32 secondary publications, there were 13 review articles, 10 editorials, 5
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35 commentaries, 3 news articles, and 1 government report, with most being published after
36
37 2008 (Table 3). Most publications cited primary sources as evidence of the prevalence of
38
39 possible ghostwriting (Table 3), with the cited prevalence of possible ghostwriting varying
40
41 from 6% of publications to 100% of publications involving drugs. In most secondary
42
43 publications, the information on the prevalence of ghostwriting was not reported consistently
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45 compared with the cited evidence (Table 3). Misleading and mistaken information was
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47 reported in many publications that (i) did not distinguish between ghostwriting and ghost
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49 authoring, (ii) included acknowledged medical writing assistance or a combined estimate of
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51 guest authorship and ghost authorship as ghostwriting, (iii) generalized findings from
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53 publication reviews and analyses of specific datasets to wider populations of publications or
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Table 3. Characteristics of Secondary Publications Citing Evidence of Possible Ghostwriting

Publication	Cited evidence	Consistent with cited source(s)	Comment
Elliot Hastings Cent Rep 2004[35]	Primary	No	Did not distinguish GW from GA
Moffat Perspect Biol Med 2007[36]	Primary	No	Did not distinguish GW from GA
Schiefe Pharmacotherapy 2009[47]	Primary	No	Did not distinguish GW from GA
MacLennan Climacteric 2010[48]	Primary	No	Did not distinguish GW from GA
Nahai Aesthet Surg J 2010[49]	Secondary	No	Did not distinguish GW from GA
Ngai Account Res 2005[50]	Primary	Yes	Did not distinguish GW from GA
Bosch EMBO Rep 2011[43]	Primary	Yes	Did not distinguish GW from GA
Wiwanitkit Am J Med 2012[51]	Primary	No	Did not distinguish GW from GA or GA from guest authorship
Krimsky Med Law 2007[52]	Primary	No	Did not distinguish GW from GA or GA from guest authorship
Langdon-Neuner Mens Sana Monogr 2008[53]	Primary & secondary	No	Did not distinguish GW from GA or GW from disclosed medical writing support
Tharyan Indian J Med Ethics 2011[45]	Primary	Yes	Did not distinguish GW from GA or GW from disclosed medical writing assistance
Paul Clin Microbiol Infect 2009[54]	Primary	Yes	Did not distinguish GW / GA from disclosed medical writing assistance
Bavdekar Lung India 2012[42]	Primary	No	Did not distinguish GW from GA and generalized evidence to a wider population
Górski Transplant Proc 2010[55]	Primary & secondary	No	Did not distinguish GW from GA and generalized evidence to a wider population

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3	Matias-Guiu Neurologia 2011[44]	Primary &	No	Did not distinguish GW from GA
4		secondary		and generalized evidence to a
5				wider population
6				
7				
8	McHenry Mens Sana Monogr 2010[56]	Gov. report	No	Generalized evidence to a wider
9				population
10				
11	Healy BMJ 2004[57]	Primary &	No / ND	Generalized evidence to a wider
12		secondary		population and reported
13				personal opinion of GW
14				prevalence
15				
16	Abbasi BMJ 2004[2]	Secondary	No	Secondary publication cited
17				named individual
18				
19	Mitrany Science Editor 2005[58]	None	ND	Cited named individual
20				
21	Collier Can Med Assoc J 2009[3]	None	ND	Cited named individual
22				
23	Kmietowicz BMJ 2004[59]	None	ND	Cited named individual
24				
25	Matthews Wall St J 2005[1]	None	ND	Cited unpublished data
26				
27	Bonita Heart Fail Clin 2011[60]	Primary	Yes	Consistent with cited source
28				
29	Grassley Int J Occup Environ Health	Primary	Yes	Consistent with cited source
30	2011[61]			
31				
32	Nat Clin Pract Nephrol 2007[62]	Primary	Yes	Consistent with cited source
33				
34	Editors J Urol 2008[15]	Primary	Yes	Consistent with cited source
35				
36	Baethge Deutsches Arzteblatt 2009[63]	Primary	Yes	Consistent with cited source
37				
38	Flanagin CSE Annual Mtg 2010[64]	Primary	Yes	Consistent with cited source
39				
40	Murray Open Med 2010[65]	Primary	Yes	Consistent with cited source
41				
42	Moore BMJ 2004[66]	Secondary	Yes	Consistent with cited source
43				
44	Hargreaves BMJ 2007[67]	Primary	Yes	Consistent with cited source
45				
46	Jones Nature 2009[68]	Primary	Yes	Consistent with cited source
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48				
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Abbreviations: CSE, Council of Science Editors; GA, ghost authoring; Gov, government; GW, ghostwriting; ND, not determined.

industry-sponsored trials, or (iv) cited personal communications or informal surveys where the original source was unpublished and could not be verified (Table 3).

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5 Case study of misleading and mistaken evidence
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7 An analysis of secondary publications citing the possible prevalence of ghostwriting in
8 sertraline publications provides an illuminating case study on how misleading or mistaken
9 evidence can enter and remain in the medical literature. In 2003, Healy and Cattell showed
10 that 57% (55/96) of articles on sertraline published from 1998 to 2000 were coordinated
11 through a medical information company and only two acknowledged medical writing
12 assistance.[4] The authors concluded that these data provided information on the “possible
13 extent of ghostwriting based on a single drug”. In 2004 (October 14), Healy also provided
14 evidence on the influence of the pharmaceutical industry on key groups at a United Kingdom
15 House of Commons Health Select Committee investigation.[34] In answer to Question 197,
16 Healy stated the following:
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29 *“My estimate is that, even in journals like the BMJ, the Lancet, the New England Journal of*
30 *Medicine and JAMA, the leading journals in the field, if these articles have to do with*
31 *therapeutics, with drugs, it may be worse perhaps for psychiatry than elsewhere, but I doubt*
32 *it, 50% of these articles are ghostwritten. It may be higher.”*
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39 Healy and Cattell’s original evidence has been cited incorrectly and interchangeably with
40 Healy’s statement to the House of Commons Health Select Committee investigation (Figure
41 2). Although findings from the primary publication have been cited and interpreted correctly
42 in two secondary publications,[35, 36] many secondary publications incorrectly cited Healy’s
43 original evidence and statement to the House of Commons Health Select Committee
44 investigation (Figure 2).
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DISCUSSION

This systematic review on the reported prevalence of ghostwriting in the medical literature showed that the estimates of the prevalence of ghostwriting in primary publications varied markedly and were influenced by the definitions used, the types of study designs, and the type of population or sample assessed. In addition, secondary publications often cited outdated, misleading, or mistaken evidence of the reported prevalence of ghostwriting, with many publications not distinguishing ghostwriting from ghost authoring.

Although evidence from descriptive analyses can highlight the extent of ghostwriting in single populations, evidence from well-conducted cross-sectional surveys have the potential to provide estimates of the prevalence of ghostwriting that may be generalized to the majority of peer-reviewed publications. Despite this, many of the cross-sectional surveys retrieved in this systematic review were conducted in limited populations that were not broadly representative of the peer-reviewed medical literature. In addition, many of the cross-sectional surveys did not differentiate between contributions that merited authorship from those that did not merit authorship and provided at best, an estimate of possible ghostwriting. The reported prevalence of ghostwriting, where ghostwriting was defined as undisclosed contributions that did not merit authorship, was retrieved from the two cross-sectional surveys of corresponding authors from several general medicine journals and by cross-sectional surveys (repeated on three separate occasions from 2005 to 2011) of members of two major medical writing associations. Together the findings from these surveys suggested that the prevalence of ghostwriting has decreased in recent years. However, while the findings from these surveys may be considered more broadly representative of the peer-reviewed medical literature than surveys focused on single journals, single countries, or single subject areas, interpretation of these findings should take

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3 into account that respondents were required to retrospectively self-report potentially
4 unethical or unprofessional behaviour.
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9 Unethical authorship practices are a major concern and are an increasingly recognized
10 problem in the medical literature.[37] As the findings from this systematic review suggest,
11 some of these perceived problems may arise from the considerable, but unnecessary,
12 confusion and disagreement surrounding the definitions of ghostwriting. As recognized by
13 the World Association of Medical Editors, professional medical writers can have a legitimate
14 role in assisting authors to communicate their research findings in the peer-reviewed
15 literature.[14] Professional medical writers can and do improve the timeliness and quality of
16 reporting and can assist investigators and industry sponsors to meet their ethical
17 commitments to the disclosure and publishing of clinical trial results.[7, 38-40] As such, the
18 misleading and mistaken reporting of the prevalence of ghostwriting that was evident in the
19 secondary publications retrieved in this systematic review is disappointing. Specifically, the
20 confusion surrounding definitions of ghost authorship and ghostwriting and the unbalanced
21 focus on industry as the source of unethical authorship practices in the secondary
22 publications takes attention away from the need to focus on all types of unethical
23 contributions in peer-reviewed publications, irrespective of the source of the unethical
24 practice.
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43 The strengths of this systematic review are that a broad search strategy was employed with
44 few restrictions to minimize any potential for publication or language bias. All study designs
45 and publication types were considered and there were no restrictions on language. Although
46 the full text or abstracts of 8 publications could not be retrieved, omission of these
47 publications was unlikely to have biased the findings. Review of the abstracts or titles of
48 these publications suggested that none reported numerical estimates of the prevalence of
49 ghostwriting. The major finding of this review was the limitations of the reported evidence of
50 ghostwriting in the medical literature. These limitations included the heterogeneity among the
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3 studies in the outcomes reported and populations investigated, the observational study
4 designs, and the retrospective nature of data collection. Given the nature of unethical
5 authorship practices, it may not be feasible to conduct a prospective study on ghostwriting.
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7 However, based on the findings from this review, recommendations can be made to help
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9 researchers, authors, editors, and peer-reviewers apply the same rigorous standards that
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11 are applied to the conduct and assessment of all clinical research and actively improve the
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13 quality of reporting of the evidence of unethical authorship practices.
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19 Researchers should use a standard definition of ghostwriting so that the confusion around
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21 ghostwriters and ghost authors is not perpetuated. Ghostwriting is paid or unpaid writing
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23 assistance by individuals who generally do not merit authorship and whose contributions are
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25 not disclosed in the acknowledgments.[7] In contrast, ghost authoring is contributions to the
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27 research, data analysis, and/or writing of a manuscript by individuals who do merit
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29 authorship and whose contributions are not disclosed in the author byline.[7] For example,
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31 the descriptive analysis of Danish industry-initiated trials used a nonstandard definition of
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33 authorship, which is likely to have contributed to the very high prevalence of possible
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35 ghostwriting reported in this study (75%). In this study, Gøtzsche et al.[30] suggested that
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37 individuals who write the trial protocol, conduct the statistical analyses, or who contribute to
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39 the writing of a publication should be included as authors. Indeed, the prevalence of ghost
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41 authorship in this study was 91% when the analyses included these individuals, irrespective
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43 of whether they had been appropriately acknowledged elsewhere. Given that the Gøtzsche
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45 et al.[30] study has been downloaded more than 3,000 times since publication[41] and cited
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47 repeatedly as evidence not only of ghost authorship but also of ghostwriting,[42-45] it would
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49 have been illuminating if the authors had included an estimate of the prevalence of
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51 ghostwriting using standard definitions for comparison. In addition to using standard
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53 definitions of ghostwriting, researchers and authors should ensure that cited evidence of
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55 ghostwriting is reported accurately without unwarranted generalizations. Publications based
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57 on personal commentary should be avoided and studies that use nonstandard definitions,
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3 specific populations, or that were conducted before a change in practice (eg, before the
4 adoption of the Good Publication Practice guidelines for communicating company sponsored
5 research in 2003 [GPP][46] and in 2009 [GPP2][11]) should be described in context.
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11 Editors and peer reviewers have a duty to prevent outdated, misleading, or mistaken
12 evidence on the prevalence of ghostwriting from being published and perpetuated. Close
13 attention should be paid to the internal and external validity of the study, the definitions used,
14 how the data are reported, and whether the data are interpreted within the context of current
15 practices. When assessing a submitted manuscript on ghostwriting, editors should consider
16 using peer reviewers with expertise in the appropriate study designs (eg, survey research)
17 and ethical publication practices. Collectively, these actions could help prevent further
18 questionable evidence on the prevalence of ghostwriting from being published.
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29 In conclusion, the findings from this systematic review showed that reports of the prevalence
30 of ghostwriting in the medical literature are limited by the varied definitions used to describe
31 unethical authorship practices, the types of study designs employed, and the populations
32 assessed. To improve reporting, researchers should not inflate estimates using nonstandard
33 definitions of ghostwriting nor conflate ghostwriting with other unethical authorship practices.
34 While open and transparent debate should be encouraged, editors and peer reviewers
35 should not accept articles that incorrectly cite or interpret primary publications that report the
36 prevalence of ghostwriting.
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COMPETING INTERESTS

The author is a professional medical writer who is actively involved in national and international not-for-profit organizations that encourage ethical medical writing practices. The author has no relationships with any pharmaceutical company that might have an interest in the submitted work and has no other relationships that could be construed as a competing interest.

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DATA SHARING STATEMENT

All data associated with the study are fully available to the author.

For peer review only

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FIGURE LEGENDS

Figure 1. Selection of publications reporting a numerical estimate of the prevalence of ghostwriting. Electronic databases were searched on 23 May 2013.

^a Journal of the European Medical Writers Association, formerly known as The Write Stuff.

^b Journal of the American Medical Writers Association.

^c Council of Science Editors Annual Meetings.

^d International Congress on Peer Review and Biomedical Publication.

Figure 2. Case study of original versus cited evidence of ghostwriting prevalence.

Contrast between original evidence on the prevalence of possible ghostwriting in sertraline publications from 1998 to 2000 and the subsequent citations of this evidence. Source of the original published evidence: Healy and Cattell[4] showed that 55 of 96 (57%) articles published on sertraline from 1998 to 2000 were coordinated through a medical communications company and concluded that these data provided information on the “possible extent of ghostwriting based on a single drug”. Inaccurate reporting from the cited source is marked with a cross.

TITLE

Systematic review on the primary and secondary reporting of the prevalence of ghostwriting
in the medical literature

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KEYWORDS

Authorship, ghostwriting, systematic review

WORD COUNT

3,588441

ABSTRACT

Background: Ghostwriting of industry-sponsored articles is unethical and is perceived to be common practice ~~in the medical literature.~~

Objective: ~~To~~ ~~he~~ ~~conduct~~ ~~a~~ systematic~~ally~~ review ~~on~~ how evidence for the prevalence of ghostwriting is reported in the medical literature.

Data sources: MEDLINE via PubMed 1966+, EMBASE 1966+, The Cochrane Library 1988+, Medical Writing 1998+, The AMWA Journal 1986+, Council of Science Editors Annual Meetings 2007+, and the Peer Review Congress 1994+ were searched electronically (23 May 2013) using the search terms ghostwrit*, ghostauthor*, ghost AND writ*, ghost AND author*.

Eligibility criteria: All publication types were considered; only publications reporting a numerical estimate of possible ghostwriting prevalence were included.

Data extraction: Two independent reviewers screened the publications; discrepancies were resolved by consensus. Data to be collected included a numerical estimate of the prevalence of possible ghostwriting (primary outcome measure), definitions of ghostwriting reported, source of the reported prevalence, publication type and year, study design, and sample population.

Results Of the 848 publications retrieved and screened for eligibility, 48 reported numerical estimates for the prevalence of possible ghostwriting ~~and were analyzed further.~~ Sixteen primary publications reported findings from cross-sectional surveys or descriptive analyses of published articles; ~~and~~ 32 secondary publications cited published or unpublished evidence. Estimates on the prevalence of possible ghostwriting in primary and secondary publications varied markedly. Primary estimates were not suitable for meta-analysis because of the various. ~~Estimates were influenced by the~~ definitions of ghostwriting used, ~~the study designs, and types~~ of populations or samples ~~assessed.~~ Secondary estimates were not

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3 always reported or, ~~and whether evidence from primary publications was~~ cited correctly or
4 appropriately.
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7 **Conclusions** Evidence for the prevalence of ghostwriting ~~Estimates of ghostwriting~~
8 ~~report ed~~ in the medical literature is limited and can be outdated, misleading, or mistaken.
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11 Researchers should not inflate estimates using nonstandard definitions of ghostwriting nor
12 conflate ghostwriting with other unethical authorship practices. Editors and peer reviewers
13 should not accept articles that incorrectly cite or interpret primary publications that report the
14 prevalence of ghostwriting.
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Strengths

- First systematic review on the reporting of the prevalence of ghostwriting in the medical literature
- A broad search strategy was employed with few restrictions to minimize any potential for publication or language bias; there were no restrictions on language.
- All study designs and publication types were considered

Limitations

- Study heterogeneity in the outcomes reported and populations investigated precluded synthesis of the data
- Retrospective and self-reported nature of the data collection increased the risk of selection bias in the studies
- Most included studies were not broadly representative of the peer-reviewed medical literature

INTRODUCTION

Ghostwriting of peer-reviewed journal publications in the medical literature is believed to be common practice.[1-3] This belief is supported, to a large extent, by highly publicized cases, primarily from the 1990s and early 2000s, of pharmaceutical companies and authors who had used ghostwriters to prepare manuscripts for publication in medical journals.[4-6] Such cases are highly unethical because the role of the commercial sponsor and any other potential conflicts of interest were hidden.

Ghostwriting occurs when writing contributions to a manuscript that do not meet authorship criteria are not disclosed in the acknowledgments. This practice is distinct from ghost authoring, where contributions to a manuscript that do merit authorship are not disclosed in the author byline.[7] However, part of the challenge in understanding the prevalence of ghostwriting is the current confusion surrounding the two unethical practices. For example, the widely used Council of Science Editors definition of ghost authors (ie, individuals who participate in research, data analysis, and/or writing of a manuscript but are not named or disclosed in the author byline or acknowledgments) does not distinguish between ghost authors and ghostwriters.[8] Estimating the prevalence of ghostwriting has also been hindered by the failure of authors to distinguish ghostwriting, which is unethical, from professional medical writing support, which is ethical.[9, 10] Ghostwriters keep their involvement in a manuscript hidden, whereas professional medical writers disclose their involvement and follow ethical publication practices.[7, 9-11] Consistent with the authorship criteria recommended by the International Committee of Medical Journal Editors (ICMJE), professional medical writers who provide writing assistance and do not meet all of the ICMJE authorship criteria, should be acknowledged rather than listed as authors.[12] The prevalence of disclosed professional medical writing assistance in medical journals has been estimated to be between 6.0% and 11.0%[10, 13] and the legitimate value that this medical

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3 writing assistance can bring to improving the quality, timeliness, and integrity of reporting in
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5 medical journals has been demonstrated.[7, 14, 15] However, the exact prevalence of
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7 ghostwriting and other forms of undisclosed contributions to papers published in medical
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9 journals is unknown.

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13 The primary objective of this study was to conduct the first systematic review on how the
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15 prevalence of ghostwriting is reported in the medical literature. The secondary objectives
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17 were to assess the variability of the reported estimates of the prevalence of ghostwriting and
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19 investigate the source for these estimates.
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MATERIALS AND METHODS

Literature search strategy

A search strategy was developed to retrieve publications from the medical literature that reported quantitative estimates of the prevalence of ghostwriting. The following databases were searched on 23 May 2013: MEDLINE via PubMed (1966+); EMBASE (1966+); The Cochrane Library, including the Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Trials (1988+); The AMWA Journal (1986+, journal of the American Medical Writers Association); Medical Writing (1998+, journal of the European Medical Writers Association, formerly known as The Write Stuff); Council of Science Editors annual meetings (2007+); and the International Congress on Peer Review and Biomedical Publication meetings (1994+). General text was searched using the following search terms: ghostwrit*, ghostauthor*, ghost AND writ*, ghost AND author*. Truncation symbols and Boolean operators (AND, OR) were used wherever possible.

Two reviewers (SS, SMG) independently screened the title and abstracts of all retrieved publications using prespecified eligibility criteria; the full text of potentially eligible publications was screened to confirm eligibility for inclusion. Any discrepancies between the reviewers were resolved by consensus. The reference lists of relevant reviews and other publications were screened by hand to identify any additional publications for inclusion.

Eligibility criteria

The eligibility criteria were prespecified. Publications were included if they reported a numerical estimate of the prevalence of possible ghostwriting. Publications were excluded if they were duplicate publications from different databases or abstracts of subsequently published full-text articles, did not report any outcomes related to ghostwriting, or reported

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3 qualitative estimate(s) of the prevalence of possible ghostwriting. No restrictions on
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5 language were included in the eligibility criteria.
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8 9 **Data extraction and analysis**

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11 The primary and secondary outcomes and data to be collected were prespecified. Data to
12 be collected and included publication type and year, study design and sample population,
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14 definitions of ghostwriting reported, reported prevalence of possible ghostwriting, and the
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16 source of the reported prevalence of ghostwriting. The prevalence of possible ghostwriting
17 was reported as published. No unpublished data from the retrieved literature were reported
18 and values for prevalence were not extrapolated from published data.
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25 The primary outcome measure for the systematic review was a numerical estimate of the
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27 prevalence of possible ghostwriting. The reported definitions of possible ghostwriting were
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29 categorized according to the following standard definitions, irrespective of the term used to
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31 describe the practice in the publication. Undisclosed writing contributions to a manuscript
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33 were defined as (i) ghostwriting if they were described as not meriting authorship and were
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35 not listed in the acknowledgments[9, 16] and (ii) ghost authoring if they did merit authorship
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37 and were not listed in the author byline.[7] Consistent with recommendations from
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39 international medical journal editors,[12, 14] Good Publication Practice guidelines,[11] and
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41 professional medical writing associations,[17, 18] disclosed writing contributions to a
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43 manuscript that did not merit authorship and were disclosed in the acknowledgments were
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45 not categorized as ghostwriting.
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50 The key factors considered when assessing study quality were study design, the population
51 assessed, and how ghostwriting was defined. While there is no consensus on the best
52 practice for reporting survey research,[19] the quality of the cross-sectional surveys was
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3 determined by an assessment of the following factors: validation or pretesting of the survey
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5 questions, anonymity of the response, sample size, and response rate.
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For peer review only

RESULTS

Publication selection

A total of 848 articles were retrieved from the literature search, 800 were excluded, and 48 met the eligibility criteria and were included in the systematic review (Figure 1). The main reasons for exclusion were publications not relevant to ghostwriting (n = 539), duplicate publications from different databases (n = 129), and publications not reporting a numerical estimate of the prevalence of possible ghostwriting (n = 124). The titles or abstracts of the 8 publications that were excluded because the full text or abstract could not be retrieved were reviewed; none were considered to report a numerical estimate of the prevalence of possible ghostwriting. Overall, eligible publications included 16 primary publications that reported original research on the prevalence of possible ghostwriting and 32 secondary publications that cited published or unpublished evidence of possible ghostwriting.

Primary publications

Publication characteristics

Of the 16 primary publications (Table 1), there were 13 full-text publications[4, 6, 20-30] and three conference abstracts[31-33] that reported a numerical estimate of possible ghostwriting. Twelve publications[20-28, 31-33] reported findings from cross-sectional surveys and four publications[4, 6, 29, 30] reported findings from descriptive analyses of published articles. **While there is no consensus on the best practice for reporting survey research,[33]M** most cross-sectional surveys were reasonably well reported. The surveys used were not validated but most included pretested questions, required an anonymous response, were conducted in targeted populations (ie, all individuals invited to participate were involved in the preparation of peer-reviewed manuscripts), and reported a sample size and response rate. Of the cross-sectional surveys conducted in targeted populations (eg,

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3 corresponding or first authors), six had response rates greater than 50%, two had response
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5 rates less than 50%, and one did not report a response rate (Table 1). Of the cross-sectional
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For peer review only

Table 1. Characteristics of Primary Publications Reporting Original Evidence of Ghostwriting

Publication	Population	Survey description	Data collected	N	RR
<i>Cross-sectional surveys – authors or corresponding authors</i>					
Flanagin 1998[27]	6 general medicine journals ^a	Self-administered, postal, anonymous, pretested, targeted	1996	809	69%
Mowatt 2002[23]	Published Cochrane reviews	Self-administered, online, anonymous, pretested, targeted	1999	362	63%
Hao 2009[32] (Abstract)	Chin Med J	Self-administered, email, not anonymous, targeted	2008 ^c	220	86%
Dotson 2011[28]	3 pharmacy journals	Self-administered, online, anonymous, pretested, targeted	2009	112	25%
Mirzazadeh 2011[24]	3 Iranian journals	Self-administered, email, not anonymous, targeted	2009-2010	NR	NR
Wislar 2011[20]	6 general medicine journals ^b	Self-administered, online, anonymous, pretested, targeted	2008	622	70%
Ghajarzadeh 2012[26]	Arch Iran Med (based on student theses)	Self-administered, email, anonymous, targeted	2005-2007	30	49%
Vinther 2012[21]	Ugeskr Laeger & Dan Med J	Self-administered, online, anonymous, pretested, targeted	2010	272	62%
<i>Cross-sectional surveys – healthcare professionals</i>					
Price 2000[22]	Health academic staff	Self-administered, postal, anonymous, pretested, targeted	NR	166	59%
Rees 2013[31] (Abstract)	Registered users of EPG Online	Self-administered, online, anonymous, nontargeted	NR	295	NR
<i>Cross-sectional surveys – members of medical writing associations</i>					
Jacobs 2009[25]	EMWA / AMWA members	Self-administered, online, anonymous, pretested, nontargeted	2005, 2008	843, 773	28%, 14%
Hamilton	EMWA / AMWA	Self-administered, online,	2011	620	12% ^d

2012[33] members anonymous, pretested,
(Abstract) nontargeted

Publication reviews and descriptive analysis

Healy 2003[4]	Articles on sertraline	NA	1998- 2000	96	NA
Götzsche 2007[30]	Articles on Danish industry-initiated trials approved 1994-1995	NA	NR	44	NA
Ross 2008[6]	Reviews on rofecoxib associated with Merck support	NA	1996- 2004	72	NA
Suda 2011[29]	Noninferiority clinical trials	NA	1989- 2009	583	NA

^a Annals of Internal Medicine, JAMA, the New England Journal of Medicine, American Journal of Cardiology, American Journal of Medicine, American Journal of Obstetrics and Gynecology.

^b Annals of Internal Medicine, JAMA, the New England Journal of Medicine, Lancet, Nature Medicine, PLoS Medicine.

^c Submission date.

^d Personal communication, C. Hamilton.

Abbreviations: AMWA, American Medical Writers Association; EMWA, European Medical Writers Association; NA, not applicable; NR, not reported; RR, response rate.

surveys conducted in nontargeted populations (eg, individuals invited to participate who may or may not have been involved in providing medical writing assistance for peer-reviewed publications), three had low (12% to 28%) response rates and one did not report a response rate (Table 1).

Not all cross-sectional surveys were broadly representative of the peer-reviewed medical literature. The cross-sectional surveys were conducted in single populations of academic staff or healthcare professionals[22, 31], members of medical writing associations[25, 33], or

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3 corresponding or first authors. The corresponding or first authors were surveyed from single
4 journals (Cochrane reviews, Chinese Medical Journal, Archives of Iranian Medicine),[23, 26,
5 32] two Danish journals,[21] three Iranian journals,[24] and three pharmacy journals.[28] Two
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7 cross-sectional surveys of corresponding authors were conducted in six general medicine
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9 journals.[20, 27]
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15 The descriptive analyses of published articles were conducted in single populations and
16 included an analysis of sertraline publications from 1998 to 2000,[4] rofecoxib reviews from
17 1996 to 2004,[6] publications from industry-initiated trials in Denmark from 1994 to 1995,[30]
18 and from published noninferiority trials from 1989 to 2009.[29]
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23 24 25 Reported prevalence of ghostwriting

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27 The reported prevalence of possible ghostwriting in the primary publications varied markedly
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29 and were not suitable for meta-analysis and was difficult to compare because of the different
30 populations assessed, the different methods used to generate the estimates, and the various
31 definitions that were used (Tables 1 and 2). All cross-sectional surveys reported a definition
32 of ghostwriting or ghost authoring, but most definitions did not differentiate contributions that
33 merited authorship from those that did not merit authorship (Table 2).
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41 Four cross-sectional surveys reported the prevalence of ghostwriting where the definition
42 provided could be categorized as undisclosed contributions that do not merit authorship.[20,
43 25, 27, 33] Findings from these surveys, which were repeated at different time points,
44 suggested that the prevalence of ghostwriting is low and decreasing. Flanagin[27] and
45 Wislar[20] conducted two similar cross-sectional surveys of corresponding authors of articles
46 published in six general medicine journals in 1996[27] and in 2008.[20] The surveys, which
47 included a core set of three journals (Annals of Internal Medicine, JAMA, the New England
48 Journal of Medicine) at each time point and in targeted populations, used pretested
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Table 2. Primary Publications Reporting Estimates of the Prevalence of Possible Ghostwriting

Publication	<u>Measure of Possible Ghostwriting Reported</u> <u>Authors</u>	<u>Estimate % (n)</u>
<i>Cross-sectional surveys reporting ghostwriting</i>		
Flanagin 1998[27]	Unnamed individual who participated in the writing	1.4% (11/809) of articles
Wislar 2011[20]	Unnamed individual who participated in the writing	0.2% ^a (1/622) of articles
Jacobs 2009, Hamilton 2012[25, 33]	Undisclosed medical writing assistance not qualifying for authorship	2005: 61.8% (NR) 2009: 41.7% (NR) 2011: 33.0% (NR) of <u>writers</u> <u>articles</u> ^b
<i>Cross-sectional surveys reporting combined ghost authoring and ghostwriting</i>		
Flanagin 1998[27]	Failure to name, as an author, individuals who made substantial contributions to the research or writing or an unidentified medical writer	11.5% (93/809) of articles
Price 2000[22]	Failure to name, as an author, individuals who made substantial contributions to the research or writing	24.1% (40/166) of authors
Mowatt 2002[23]	Individual merited authorship or had assisted with drafting but not listed as an author or acknowledged	8.8% (32/362) of articles
Hao 2009[32]	English-language speakers assisted with writing but not identified as authors or acknowledged	10.4% (NR) of authors
Dotson 2011[28]	Failure to name, as an author, individuals who made substantial contributions to the research or writing	0.9% (1/112) of articles
Wislar 2011[20]	Failure to name, as an author, individuals who made substantial contributions to the research or writing of the article or an unnamed individual who participated in the writing	7.9% (49/622) of articles
<i>Cross-sectional surveys reporting ghost authoring</i>		
Mirzazadeh 2011[24]	Failure to name, as an author, individuals who made substantial contributions to the research	21.4% (25/NR) of authors

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3	Ghajarzadeh	Failure to name, as an author, students who made substantial	0.7% (2/296) of
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5	2012[26]	contributions to the research ^c	articles
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7	Vinther 2012[21]	Individual merited authorship but not listed as an author	2.4% (6/245) of
8			articles
9			
10	Rees 2013[31]	Individual merited authorship but not listed as an author	70% (NR/202) of
11			published authors
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Publication reviews and descriptive analysis reporting possible ghost authoring or ghostwriting

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16	Healy 2003[4]	Published articles coordinated by a medical information	57.3% (55/96) of
17		company, including acknowledged medical writing support ^{d,e}	articles
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19	Gøtzsche	Individuals who wrote the trial protocol, conducted the	75.0% (33/44) of
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21	2007[30]	statistical analyses, or wrote the manuscript but were not listed	trials
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23		as authors, not members of a study group or steering	
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25		committee, or not disclosed in an acknowledgment	
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27	Ross 2008[6]	Published reviews associated with Merck support and with a	69.4% (50/72) of
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29		single external author ^{e,d}	reviews
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^a Available as online supplementary data.

^b Values represent the mean weighted percentage of publications that were ghostwritten by respondents. Findings were weighted in proportion to the number of manuscripts the respondent wrote per year.

^{b,c} Students were classified as ghostwriters if the student was not named as an author and if the results reported in the publications were based on the results of their theses.

^{e,d} Authors conclude data provide quantification of the possible extent of ghostwriting based on a single drug. Of the 55 published articles that were coordinated through a medical information company, 2 included medical writing assistance that was acknowledged in the published article.

^{e,e} Published review articles had been identified from correspondence between Merck and a medical publishing company, from Merck publication status reports, or were affiliated with an author named within the correspondence or publication status reports. The authors did not report whether medical writing assistance was acknowledged in the published article.

Abbreviations: NR, not reported.

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3 questions that required an anonymous response and had response rates greater than 65%.
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5 The prevalence of ghost authoring (which included ghostwriting) was estimated to be 11.5%
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7 in 1996 and 7.9% in 2008. The prevalence of ghostwriting from these surveys was estimated
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9 to be 1.4% in 1996 and 0.2% in 2008. Hamilton and Jacobs conducted a cross-sectional
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11 survey of members of two medical writing associations in 2005, 2008, and 2011.[25, 33] The
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13 survey, which was not conducted in targeted populations, used pretested questions that
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15 required an anonymous response and had response rates from 12% to 28% of the total
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17 population surveyed (ie, not all participants surveyed were involved in the preparation of
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19 peer-reviewed manuscripts). Findings from these surveys showed that the mean weighted
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21 percentage of publications that were association members who contributed to peer reviewed
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23 publications and had ghostwritten by respondents at least once during the survey year had
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25 decreased from 61.8% in 2005 to 33.0% in 2011. Findings were weighted in proportion to
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27 the number of manuscripts the respondent wrote per year.
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31 Six cross-sectional survey publications reported the prevalence of possible ghostwriting (ie,
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33 the prevalence of ghostwriting and ghost authoring combined).[20, 22, 23, 27, 28, 32] The
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35 prevalence of possible ghostwriting reported in these cross-sectional surveys varied from
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37 0.9% to 24.1% of publications or authors.
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41 Four cross-sectional survey publications reported the prevalence of ghost authoring.[21, 24,
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43 26, 31] The prevalence of ghost authoring reported in these cross-sectional surveys varied
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45 from 0.7% to 70% of publications or authors.
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49 The descriptive analyses of published articles on sertraline and rofecoxib did not include a
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51 prespecified definition of ghost authoring or ghostwriting;[4, 6] in these studies, possible
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53 ghostwriting or ghost authoring was assumed in publications associated with industry-
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55 sponsored support (Table 2). The descriptive analysis of industry-initiated trials in Denmark
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57 used a nonstandard definition of ghost authors; in this study ghost authors were defined as
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3 individuals, not named as authors, who were involved in writing the protocol, conducting the
4 statistical analyses, or writing the manuscript.[30] The prevalence of possible ghostwriting in
5 the two descriptive analyses of single drugs that did not include a prespecified definition of
6 ghostwriting was 57% of articles on sertraline published from 1998 to 2000[4] and 69% of
7 reviews on rofecoxib published from 1996 to 2004.[6] The prevalence of possible
8 ghostwriting in the descriptive analysis of Danish industry-initiated trials, which used a
9 nonstandard definition of authorship, was 75% of Danish initiated trials approved in 1994 to
10 1995.[30] The descriptive analysis of noninferiority trials[29] was not considered further as
11 the definition of ghostwriting used was consistent with disclosed medical writing assistance.
12 In this study ghostwriters were defined as acknowledged individuals, other than authors, who
13 contributed to the writing and were affiliated with an industry-sponsored study.[29] The
14 prevalence of disclosed medical writing assistance in this descriptive analysis was 17.3%
15 (101/583) of clinical trials.
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32 **Secondary publications**

33 Publication characteristics

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35 Of the 32 secondary publications, there were 13 review articles, 10 editorials, 5
36 commentaries, 3 news articles, and 1 government report, with most being published after
37 2008 (Table 3). Most publications cited primary sources as evidence of the prevalence of
38 possible ghostwriting (Table 3), with the cited prevalence of possible ghostwriting varying
39 from 6% of publications to 100% of publications involving drugs. In most secondary
40 publications, the information on the prevalence of ghostwriting was not reported consistently
41 compared with the cited evidence (Table 3). Misleading and mistaken information was
42 reported in many publications that (i) did not distinguish between ghostwriting and ghost
43 authoring, (ii) included acknowledged medical writing assistance or a combined estimate of
44 guest authorship and ghost authorship as ghostwriting, (iii) generalized findings from
45 publication reviews and analyses of specific datasets to wider populations of publications or
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Table 3. Characteristics of Secondary Publications Citing Evidence of Possible Ghostwriting

Publication	Cited evidence	Consistent with cited source(s)	Comment
Elliot Hastings Cent Rep 2004[35]	Primary	No	Did not distinguish GW from GA
Moffat Perspect Biol Med 2007[36]	Primary	No	Did not distinguish GW from GA
Schiefe Pharmacotherapy 2009[47]	Primary	No	Did not distinguish GW from GA
MacLennan Climacteric 2010[48]	Primary	No	Did not distinguish GW from GA
Nahai Aesthet Surg J 2010[49]	Secondary	No	Did not distinguish GW from GA
Ngai Account Res 2005[50]	Primary	Yes	Did not distinguish GW from GA
Bosch EMBO Rep 2011[43]	Primary	Yes	Did not distinguish GW from GA
Wiwanitkit Am J Med 2012[51]	Primary	No	Did not distinguish GW from GA or GA from guest authorship
Krimsky Med Law 2007[52]	Primary	No	Did not distinguish GW from GA or GA from guest authorship
Langdon-Neuner Mens Sana Monogr 2008[53]	Primary & secondary	No	Did not distinguish GW from GA or GW from disclosed medical writing support
Tharyan Indian J Med Ethics 2011[45]	Primary	Yes	Did not distinguish GW from GA or GW from disclosed medical writing assistance
Paul Clin Microbiol Infect 2009[54]	Primary	Yes	Did not distinguish GW / GA from disclosed medical writing assistance
Bavdekar Lung India 2012[42]	Primary	No	Did not distinguish GW from GA and generalized evidence to a wider population
Górski Transplant Proc 2010[55]	Primary & secondary	No	Did not distinguish GW from GA and generalized evidence to a wider population

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3	Matias-Guiu Neurologia 2011[44]	Primary &	No	Did not distinguish GW from GA
4		secondary		and generalized evidence to a
5				wider population
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8	McHenry Mens Sana Monogr 2010[56]	Gov. report	No	Generalized evidence to a wider
9				population
10				
11	Healy BMJ 2004[57]	Primary &	No / ND	Generalized evidence to a wider
12		secondary		population and reported
13				personal opinion of GW
14				prevalence
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16	Abbasi BMJ 2004[2]	Secondary	No	Secondary publication cited
17				named individual
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19	Mitrany Science Editor 2005[58]	None	ND	Cited named individual
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21	Collier Can Med Assoc J 2009[3]	None	ND	Cited named individual
22				
23	Kmietowicz BMJ 2004[59]	None	ND	Cited named individual
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25	Matthews Wall St J 2005[1]	None	ND	Cited unpublished data
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27	Bonita Heart Fail Clin 2011[60]	Primary	Yes	Consistent with cited source
28				
29	Grassley Int J Occup Environ Health	Primary	Yes	Consistent with cited source
30	2011[61]			
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32	Nat Clin Pract Nephrol 2007[62]	Primary	Yes	Consistent with cited source
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34	Editors J Urol 2008[15]	Primary	Yes	Consistent with cited source
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36	Baethge Deutsches Arzteblatt 2009[63]	Primary	Yes	Consistent with cited source
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38	Flanagin CSE Annual Mtg 2010[64]	Primary	Yes	Consistent with cited source
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40	Murray Open Med 2010[65]	Primary	Yes	Consistent with cited source
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42	Moore BMJ 2004[66]	Secondary	Yes	Consistent with cited source
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44	Hargreaves BMJ 2007[67]	Primary	Yes	Consistent with cited source
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46	Jones Nature 2009[68]	Primary	Yes	Consistent with cited source
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Abbreviations: CSE, Council of Science Editors; GA, ghost authoring; Gov, government; GW, ghostwriting; ND, not determined.

industry-sponsored trials, or (iv) cited personal communications or informal surveys where the original source was unpublished and could not be verified (Table 3).

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5 Case study of misleading and mistaken evidence
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7 An analysis of secondary publications citing the possible prevalence of ghostwriting in
8 sertraline publications provides an illuminating case study on how misleading or mistaken
9 evidence can enter and remain in the medical literature. In 2003, Healy and Cattell showed
10 that 57% (55/96) of articles on sertraline published from 1998 to 2000 were coordinated
11 through a medical information company and only two acknowledged medical writing
12 assistance.[4] The authors concluded that these data provided information on the “possible
13 extent of ghostwriting based on a single drug”. In 2004 (October 14), Healy also provided
14 evidence on the influence of the pharmaceutical industry on key groups at a United Kingdom
15 House of Commons Health Select Committee investigation.[34] In answer to Question 197,
16 Healy stated the following:
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29 *“My estimate is that, even in journals like the BMJ, the Lancet, the New England Journal of*
30 *Medicine and JAMA, the leading journals in the field, if these articles have to do with*
31 *therapeutics, with drugs, it may be worse perhaps for psychiatry than elsewhere, but I doubt*
32 *it, 50% of these articles are ghostwritten. It may be higher.”*
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39 Healy and Cattell’s original evidence has been cited incorrectly and interchangeably with
40 Healy’s statement to the House of Commons Health Select Committee investigation (Figure
41 2). Although findings from the primary publication have been cited and interpreted correctly
42 in two secondary publications,[35, 36] many secondary publications incorrectly cited Healy’s
43 original evidence and statement to the House of Commons Health Select Committee
44 investigation (Figure 2).
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DISCUSSION

This systematic review on the reported prevalence of ghostwriting in the medical literature showed that the estimates of the prevalence of ghostwriting in primary publications varied markedly and were influenced by the definitions used, the types of study designs, and the type of population or samples assessed. In addition, secondary publications often cited outdated, misleading, or mistaken evidence of the reported prevalence of ghostwriting, with many publications not distinguishing ghostwriting from ghost authoring.

Although evidence from descriptive analyses can highlight the extent of ghostwriting in single populations, evidence from well-conducted cross-sectional surveys have the potential to provide estimates of the prevalence of ghostwriting that may be generalized to the majority of peer-reviewed publications. Despite this, many of the cross-sectional surveys retrieved in this systematic review were conducted in limited populations that were not broadly representative of the peer-reviewed medical literature. In addition, many of the cross-sectional surveys did not differentiate between contributions that merited authorship from those that did not merit authorship and provided at best, an estimate of possible ghostwriting. The reported prevalence of ghostwriting, where ghostwriting was defined as undisclosed contributions that did not merit authorship, was retrieved from the two cross-sectional surveys of corresponding authors from several general medicine journals and by cross-sectional surveys (repeated on three separate occasions from 2005 to 2011) of members of two major medical writing associations. Together the findings from these surveys suggested that the prevalence of ghostwriting has decreased in recent years. However, while the findings from these surveys may be considered more broadly representative of the peer-reviewed medical literature than surveys focused on single journals, single countries, or single subject areas, interpretation of these findings should take

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3 into account that respondents were required to retrospectively self-report potentially
4 unethical or unprofessional behaviour.
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9 Unethical authorship practices are a major concern and are an increasingly recognized
10 problem in the medical literature.[37] As the findings from this systematic review suggest,
11 some of these perceived problems may arise from the considerable, but unnecessary,
12 confusion and disagreement surrounding the definitions of ghostwriting. As recognized by
13 the World Association of Medical Editors, professional medical writers can have a legitimate
14 role in assisting authors to communicate their research findings in the peer-reviewed
15 literature.[14] Professional medical writers can and do improve the timeliness and quality of
16 reporting and can assist investigators and industry sponsors to meet their ethical
17 commitments to the disclosure and publishing of clinical trial results.[7, 38-40] As such, the
18 misleading and mistaken reporting of the prevalence of ghostwriting that was evident in the
19 secondary publications retrieved in this systematic review is disappointing. Specifically, the
20 confusion surrounding definitions of ghost authorship and ghostwriting and the unbalanced
21 focus on industry as the source of unethical authorship practices in the secondary
22 publications takes attention away from the need to focus on all types of unethical
23 contributions in peer-reviewed publications, irrespective of the source of the unethical
24 practice.
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43 The strengths of this systematic review are that a broad search strategy was employed with
44 few restrictions to minimize any potential for publication or language bias. All study designs
45 and publication types were considered and there were no restrictions on language. Although
46 the full text or abstracts of 8 publications could not be retrieved, omission of these
47 publications was unlikely to have biased the findings. Review of the abstracts or titles of
48 these publications suggested that none reported numerical estimates of the prevalence of
49 ghostwriting. The major finding of this review was the limitations of the reported evidence of
50 ghostwriting in the medical literature. These limitations included the heterogeneity among the
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3 studies in the outcomes reported and populations investigated, the observational study
4 designs, and the retrospective nature of data collection. Given the nature of unethical
5 authorship practices, it may not be feasible to conduct a prospective study on ghostwriting.
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7 However, based on the findings from this review, recommendations can be made to help
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9 researchers, authors, editors, and peer-reviewers apply the same rigorous standards that
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11 are applied to the conduct and assessment of all clinical research and actively improve the
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13 quality of reporting of the evidence of unethical authorship practices.
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19 Researchers should use a standard definition of ghostwriting so that the confusion around
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21 ghostwriters and ghost authors is not perpetuated. Ghostwriting is paid or unpaid writing
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23 assistance by individuals who generally do not merit authorship and whose contributions are
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25 not disclosed in the acknowledgments.[7] In contrast, ghost authoring is contributions to the
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27 research, data analysis, and/or writing of a manuscript by individuals who do merit
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29 authorship and whose contributions are not disclosed in the author byline.[7] For example,
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31 the descriptive analysis of Danish industry-initiated trials used a nonstandard definition of
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33 authorship, which is likely to have contributed to the very high prevalence of possible
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35 ghostwriting reported in this study (75%). In this study, Gøtzsche et al.[30] suggested that
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37 individuals who write the trial protocol, conduct the statistical analyses, or who contribute to
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39 the writing of a publication should be included as authors. Indeed, the prevalence of ghost
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41 authorship in this study was 91% when the analyses included these individuals, irrespective
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43 of whether they had been appropriately acknowledged elsewhere. Given that the Gøtzsche
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45 et al.[30] study has been downloaded more than 3,000 times since publication[41] and cited
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47 repeatedly as evidence not only of ghost authorship but also of ghostwriting,[42-45] it would
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49 have been illuminating if the authors had included an estimate of the prevalence of
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51 ghostwriting using standard definitions for comparison. In addition to using standard
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53 definitions of ghostwriting, researchers and authors should ensure that cited evidence of
54
55 ghostwriting is reported accurately without unwarranted generalizations. Publications based
56
57 on personal commentary should be avoided and studies that use nonstandard definitions,
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3 specific populations, or that were conducted before a change in practice (eg, before the
4 adoption of the Good Publication Practice guidelines for communicating company sponsored
5 research in 2003 [GPP][46] and in 2009 [GPP2][11]) should be described in context.
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11 Editors and peer reviewers have a duty to prevent outdated, misleading, or mistaken
12 evidence on the prevalence of ghostwriting from being published and perpetuated. Close
13 attention should be paid to the internal and external validity of the study, the definitions used,
14 how the data are reported, and whether the data are interpreted within the context of current
15 practices. When assessing a submitted manuscript on ghostwriting, editors should consider
16 using peer reviewers with expertise in the appropriate study designs (eg, survey research)
17 and ethical publication practices. Collectively, these actions could help prevent further
18 questionable evidence on the prevalence of ghostwriting from being published.
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29 In conclusion, the findings from this systematic review showed that reports of the prevalence
30 of ghostwriting in the medical literature are limited by the varied definitions used to describe
31 unethical authorship practices, the types of study designs employed, and the populations
32 assessed. To improve reporting, researchers should not inflate estimates using nonstandard
33 definitions of ghostwriting nor conflate ghostwriting with other unethical authorship practices.
34 While open and transparent debate should be encouraged, editors and peer reviewers
35 should not accept articles that incorrectly cite or interpret primary publications that report the
36 prevalence of ghostwriting.
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COMPETING INTERESTS

The author is a professional medical writer who is actively involved in national and international not-for-profit organizations that encourage ethical medical writing practices. The author has no relationships with any pharmaceutical company that might have an interest in the submitted work and has no other relationships that could be construed as a competing interest.

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FIGURE LEGENDS

Figure 1. Selection of publications reporting a numerical estimate of the prevalence of ghostwriting. Electronic databases were searched on 23 May 2013.

^a Journal of the European Medical Writers Association, formerly known as The Write Stuff.

^b Journal of the American Medical Writers Association.

^c Council of Science Editors Annual Meetings.

^d International Congress on Peer Review and Biomedical Publication.

Figure 2. Case study of original versus cited evidence of ghostwriting prevalence.

Contrast between original evidence on the prevalence of possible ghostwriting in sertraline publications from 1998 to 2000 and the subsequent citations of this evidence. Source of the original published evidence: Healy and Cattell[4] showed that 55 of 96 (57%) articles published on sertraline from 1998 to 2000 were coordinated through a medical communications company and concluded that these data provided information on the “possible extent of ghostwriting based on a single drug”. Inaccurate reporting from the cited source is marked with a cross.

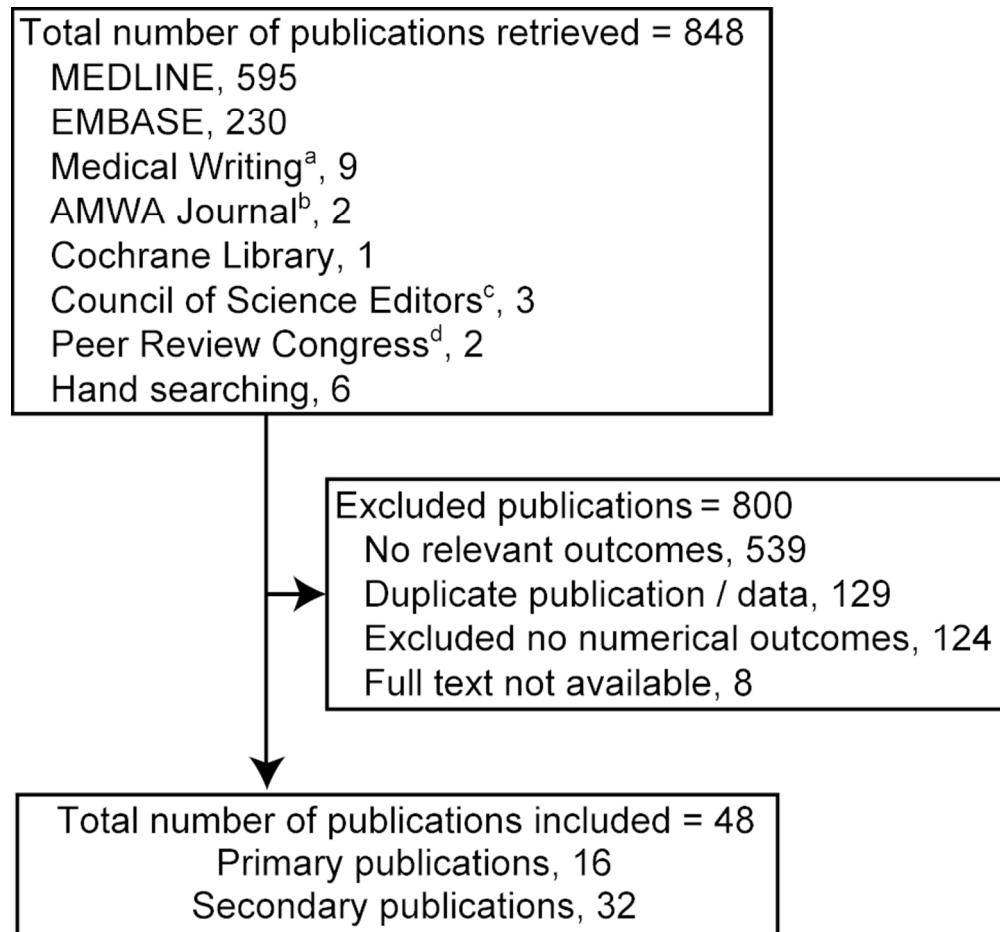


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c Council of Science Editors Annual Meetings.

d International Congress on Peer Review and Biomedical Publication.

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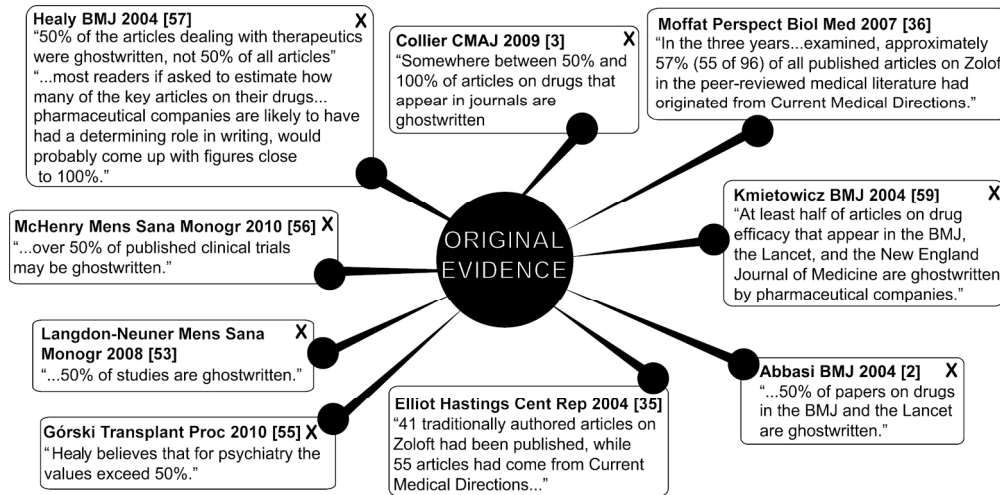


Figure 2. Case study of original versus cited evidence of ghostwriting prevalence. Contrast between original evidence on the prevalence of possible ghostwriting in sertraline publications from 1998 to 2000 and the subsequent citations of this evidence. Source of the original published evidence: Healy and Cattell[4] showed that 55 of 96 (57%) articles published on sertraline from 1998 to 2000 were coordinated through a medical communications company and concluded that these data provided information on the “possible extent of ghostwriting based on a single drug”. Inaccurate reporting from the cited source is marked with a cross.

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Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	p. 1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	pp. 2/3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	p. 5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	p. 6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	A review protocol was prepared that prespecified the primary and secondary objectives of the literature review, eligibility criteria, data to be collected, and primary and secondary outcome measures. The review protocol was not registered in a public registry but is available upon request.
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	p. 7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	p. 6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	p. 6
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	pp. 6/7
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	p. 7



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Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	p. 7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	Risk of bias was not conducted formally because data were not synthesised and because of the various study types retrieved. Given the various study designs and methods used across the retrieved studies, the quality of the study methods were assessed on a study-by-study basis. The key factors considered were the study design, definition of ghostwriting used, and study population. The factors considered when determining the quality of the cross-sectional surveys are described in the Methods section (p. 7).
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Not applicable because study data were not synthesised
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	Not applicable because study data were not synthesised.

Page 1 of 2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	Risk of bias across studies was not conducted formally because data were not synthesised and because of the considerable variation in study designs, populations, and definitions of ghostwriting used in the retrieved publications.
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	No additional analyses were conducted
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8, Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	8-11, 15, Tables 1-3
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Risk of bias was not conducted formally because data were not synthesised. All studies retrieved were limited by the observational nature of the data collection. The quality of individual components of each study are listed in Table 1



PRISMA 2009 Checklist

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			and are summarised in the results section (Publication Characteristics) (pp. 8/9).
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Tables 1-3
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Not applicable because study data were not synthesised
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Not applicable because study data were not synthesised and because of the considerable variation in study designs, populations, and definitions of ghostwriting used in the retrieved publications.
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	No additional analyses were conducted
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	20-24
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	20-22
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	22-24
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	No funding was received to conduct this study

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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Systematic review on the primary and secondary reporting of the prevalence of ghostwriting in the medical literature

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TITLE

Systematic review on the primary and secondary reporting of the prevalence of ghostwriting
in the medical literature

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KEYWORDS

Authorship, ghostwriting, systematic review

WORD COUNT

3,967

ABSTRACT

Background: Ghostwriting of industry-sponsored articles is unethical and is perceived to be common practice.

Objective: To systematically review how evidence for the prevalence of ghostwriting is reported in the medical literature.

Data sources: MEDLINE via PubMed 1966+, EMBASE 1966+, The Cochrane Library 1988+, Medical Writing 1998+, The AMWA Journal 1986+, Council of Science Editors Annual Meetings 2007+, and the Peer Review Congress 1994+ were searched electronically (23 May 2013) using the search terms ghostwrit*, ghostauthor*, ghost AND writ*, ghost AND author*.

Eligibility criteria: All publication types were considered; only publications reporting a numerical estimate of possible ghostwriting prevalence were included.

Data extraction: Two independent reviewers screened the publications; discrepancies were resolved by consensus. Data to be collected included a numerical estimate of the prevalence of possible ghostwriting (primary outcome measure), definitions of ghostwriting reported, source of the reported prevalence, publication type and year, study design, and sample population.

Results: Of the 848 publications retrieved and screened for eligibility, 48 reported numerical estimates for the prevalence of possible ghostwriting. Sixteen primary publications reported findings from cross-sectional surveys or descriptive analyses of published articles; 32 secondary publications cited published or unpublished evidence. Estimates on the prevalence of possible ghostwriting in primary and secondary publications varied markedly. Primary estimates were not suitable for meta-analysis because of the various definitions of ghostwriting used, study designs, and types of populations or samples. Secondary estimates were not always reported or cited correctly or appropriately.

Conclusions: Evidence for the prevalence of ghostwriting in the medical literature is limited and can be outdated, misleading, or mistaken. Researchers should not inflate estimates

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using nonstandard definitions of ghostwriting nor conflate ghostwriting with other unethical authorship practices. Editors and peer reviewers should not accept articles that incorrectly cite or interpret primary publications that report the prevalence of ghostwriting.

For peer review only

Strengths

- First systematic review on the reporting of the prevalence of ghostwriting in the medical literature
- A broad search strategy was employed with few restrictions to minimize any potential for publication or language bias; there were no restrictions on language.
- All study designs and publication types were considered

Limitations

- Study heterogeneity in the outcomes reported and populations investigated precluded synthesis of the data
- Retrospective and self-reported nature of the data collection increased the risk of selection bias in the studies
- Most included studies were not broadly representative of the peer-reviewed medical literature

INTRODUCTION

Ghostwriting occurs when paid or unpaid writing contributions to a manuscript that do not meet authorship criteria are not disclosed in the acknowledgments.[1] This practice is considered to be distinct from ghost authoring, where contributions to a manuscript that do merit authorship are not disclosed in the author byline.[1] However, part of the challenge in understanding the prevalence of ghostwriting is the current confusion surrounding these unethical practices. For example, the widely used Council of Science Editors definition of ghost authors (ie, individuals who participate in research, data analysis, and/or writing of a manuscript but are not named or disclosed in the author byline or acknowledgments) does not distinguish between ghost authors and ghostwriters.[2]

Ghostwriting of peer-reviewed journal publications in the medical literature is believed to be common practice.[3-5] This belief is supported, to a large extent, by highly publicized cases, primarily from the 1990s and early 2000s, of pharmaceutical companies and authors who had used ghostwriters to prepare manuscripts for publication in medical journals.[6-8] Such cases are highly unethical because the role of the commercial sponsor and any other potential conflicts of interest were hidden. Estimating the prevalence of ghostwriting in the medical literature has been hindered not only by the different definitions of ghostwriting and ghost authoring, but also by the failure of authors to distinguish ghostwriting, which is unethical, from professional medical writing support, which is ethical.[9, 10] Ghostwriters keep their involvement in a manuscript hidden, whereas professional medical writers disclose their involvement and follow ethical publication practices.[1, 9-11] Consistent with the authorship criteria recommended by the International Committee of Medical Journal Editors (ICMJE), professional medical writers who provide writing assistance and do not meet all of the ICMJE authorship criteria, should be acknowledged rather than listed as authors.[12] The prevalence of disclosed professional medical writing assistance in medical journals has been estimated to be between 6.0% and 11.0%[10, 13] and the legitimate value

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3 that this medical writing assistance can bring to improving the quality, timeliness, and
4 integrity of reporting in medical journals has been demonstrated.[1, 14, 15] However, the
5 exact prevalence of ghostwriting and other forms of undisclosed contributions to papers
6 published in medical journals is unknown.
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13 The primary objective of this study was to conduct the first systematic review on how the
14 prevalence of ghostwriting is reported in the medical literature. The secondary objectives
15 were to assess the variability of the reported estimates of the prevalence of ghostwriting and
16 investigate the source for these estimates.
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MATERIALS AND METHODS

Literature search strategy

A search strategy was developed to retrieve publications from the medical literature that reported quantitative estimates of the prevalence of ghostwriting. The following databases were searched on 23 May 2013: MEDLINE via PubMed (1966+); EMBASE (1966+); The Cochrane Library, including the Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Trials (1988+); The AMWA Journal (1986+, journal of the American Medical Writers Association); Medical Writing (1998+, journal of the European Medical Writers Association, formerly known as The Write Stuff); Council of Science Editors annual meetings (2007+); and the International Congress on Peer Review and Biomedical Publication meetings (1994+). General text was searched using the following search terms: ghostwrit*, ghostauthor*, ghost AND writ*, ghost AND author*. Truncation symbols and Boolean operators (AND, OR) were used wherever possible.

Two reviewers (SS, SMG) independently screened the title and abstracts of all retrieved publications using prespecified eligibility criteria; the full text of potentially eligible publications was screened to confirm eligibility for inclusion. Any discrepancies between the reviewers were resolved by consensus. The reference lists of relevant reviews and other publications were screened by hand to identify any additional publications for inclusion.

Eligibility criteria

The eligibility criteria were prespecified. Publications were included if they reported a numerical estimate of the prevalence of possible ghostwriting. Publications were excluded if they were duplicate publications from different databases or abstracts of subsequently published full-text articles, did not report any outcomes related to ghostwriting, or reported qualitative estimate(s) of the prevalence of possible ghostwriting. No restrictions on language were included in the eligibility criteria. If needed, the abstracts of publications

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3 written in non-English language were to be translated to assist in screening for eligibility. If
4 publications were eligible for inclusion, the full text of the publications were to be translated
5 to English.
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10 11 **Data extraction and analysis**

12 The primary and secondary outcomes and data to be collected were prespecified. Data to
13 be collected included publication type and year, study design and sample population,
14 definitions of ghostwriting reported, reported prevalence of possible ghostwriting, and the
15 source of the reported prevalence of ghostwriting. The prevalence of possible ghostwriting
16 was reported as published. No unpublished data from the retrieved literature were reported
17 and values for prevalence were not extrapolated from published data.
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27 The primary outcome measure for the systematic review was a numerical estimate of the
28 prevalence of possible ghostwriting. The reported definitions of possible ghostwriting were
29 categorized according to the following standard definitions, irrespective of the term used to
30 describe the practice in the publication. Undisclosed writing contributions to a manuscript
31 were defined as (i) ghostwriting if they were described as not meriting authorship and were
32 not listed in the acknowledgments[9, 16] and (ii) ghost authoring if they did merit authorship
33 and were not listed in the author byline.[1] Consistent with recommendations from
34 international medical journal editors,[12, 14] Good Publication Practice guidelines,[11] and
35 professional medical writing associations,[17, 18] disclosed writing contributions to a
36 manuscript that did not merit authorship and were disclosed in the acknowledgments were
37 not categorized as ghostwriting.
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50 The key factors considered when assessing study quality were study design, the population
51 assessed, and how ghostwriting was defined. While there is no consensus on the best
52 practice for reporting survey research,[19] the quality of the cross-sectional surveys was
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determined by an assessment of the following factors: validation or pretesting of the survey questions, anonymity of the response, sample size, and response rate.

For peer review only

RESULTS

Publication selection

A total of 848 articles were retrieved from the literature search, 800 were excluded, and 48 met the eligibility criteria and were included in the systematic review (Figure 1). The main reasons for exclusion were publications not relevant to ghostwriting (n = 539), duplicate publications from different databases (n = 129), and publications not reporting a numerical estimate of the prevalence of possible ghostwriting (n = 124). The titles or abstracts of the 8 publications that were excluded because the full text or abstract could not be retrieved were reviewed; none were considered to report a numerical estimate of the prevalence of possible ghostwriting. Overall, eligible publications included 16 primary publications that reported original research on the prevalence of possible ghostwriting and 32 secondary publications that cited published or unpublished evidence of possible ghostwriting.

Primary publications

Publication characteristics

Of the 16 primary publications (Table 1), there were 13 full-text publications[6, 8, 20-30] and three conference abstracts[31-33] that reported a numerical estimate of possible ghostwriting. Twelve publications[20-28, 31-33] reported findings from cross-sectional surveys and four publications[6, 8, 29, 30] reported findings from descriptive analyses of published articles. Most cross-sectional surveys were reasonably well reported. The surveys used were not validated but most included pretested questions, required an anonymous response, were conducted in targeted populations (ie, all individuals invited to participate were involved in the preparation of peer-reviewed manuscripts), and reported a sample size and response rate. Of the cross-sectional surveys conducted in targeted populations (eg, corresponding or first authors), six had response rates greater than 50%, two had response rates less than 50%, and one did not report a response rate (Table 1). Of the cross-sectional surveys conducted in nontargeted populations (eg, individuals invited to participate who may

or may not have been involved in providing medical writing assistance for peer-reviewed publications), three had low (12% to 28%) response rates and one did not report a response rate (Table 1).

Table 1. Characteristics of Primary Publications Reporting Original Evidence of Ghostwriting

Publication	Population	Survey description	Data collected	N	RR
<i>Cross-sectional surveys – authors or corresponding authors</i>					
Flanagin 1998[27]	6 general medicine journals ^a	Self-administered, postal, anonymous, pretested, targeted	1996	809	69%
Mowatt 2002[23]	Published Cochrane reviews	Self-administered, online, anonymous, pretested, targeted	1999	362	63%
Hao 2009[32] (Abstract)	Chin Med J	Self-administered, email, not anonymous, targeted	2008 ^c	220	86%
Dotson 2011[28]	3 pharmacy journals	Self-administered, online, anonymous, pretested, targeted	2009	112	25%
Mirzazadeh 2011[24]	3 Iranian journals	Self-administered, email, not anonymous, targeted	2009-2010	NR	NR
Wislar 2011[20]	6 general medicine journals ^b	Self-administered, online, anonymous, pretested, targeted	2008	622	70%
Ghajarzadeh 2012[26]	Arch Iran Med (based on student theses)	Self-administered, email, anonymous, targeted	2005-2007	30	49%
Vinther 2012[21]	Ugeskr Laeger & Dan Med J	Self-administered, online, anonymous, pretested, targeted	2010	272	62%
<i>Cross-sectional surveys – healthcare professionals</i>					
Price 2000[22]	Health academic staff	Self-administered, postal, anonymous, pretested, targeted	NR	166	59%
Rees 2013[31] (Abstract)	Registered users of EPG Online	Self-administered, online, anonymous, nontargeted	NR	295	NR

Cross-sectional surveys – members of medical writing associations

Jacobs	EMWA / AMWA	Self-administered, online,	2005	843	28%
2009[25]	members	anonymous, pretested, nontargeted	2008	773	14%
Hamilton	EMWA / AMWA	Self-administered, online,	2011	620	12% ^d
2012[33]	members	anonymous, pretested, (Abstract) nontargeted			

Publication reviews and descriptive analysis

Healy 2003[6]	Articles on sertraline	NA	1998- 2000	96	NA
Gøtzsche	Articles on Danish	NA	NR	44	NA
2007[30]	industry-initiated trials approved 1994-1995				
Ross 2008[8]	Reviews on rofecoxib	NA	1996- 2004	72	NA
	associated with Merck support				
Suda 2011[29]	Noninferiority clinical trials	NA	1989- 2009	583	NA

^a Annals of Internal Medicine, JAMA, the New England Journal of Medicine, American Journal of Cardiology, American Journal of Medicine, American Journal of Obstetrics and Gynecology.

^b Annals of Internal Medicine, JAMA, the New England Journal of Medicine, Lancet, Nature Medicine, PLoS Medicine.

^c Submission date.

^d Personal communication, C. Hamilton.

Abbreviations: AMWA, American Medical Writers Association; EMWA, European Medical Writers Association; NA, not applicable; NR, not reported; RR, response rate.

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3 Not all cross-sectional surveys were broadly representative of the peer-reviewed medical
4 literature. The cross-sectional surveys were conducted in single populations of academic
5 staff or healthcare professionals[22, 31], members of medical writing associations[25, 33], or
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7 corresponding or first authors. The corresponding or first authors were surveyed from single
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9 journals (Cochrane reviews, Chinese Medical Journal, Archives of Iranian Medicine),[23, 26,
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11 32] two Danish journals,[21] three Iranian journals,[24] and three pharmacy journals.[28] Two
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13 cross-sectional surveys of corresponding authors were conducted in six general medicine
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15 journals.[20, 27]
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21 The descriptive analyses of published articles were conducted in single populations and
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23 included an analysis of sertraline publications from 1998 to 2000,[6] rofecoxib reviews from
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25 1996 to 2004,[8] publications from industry-initiated trials in Denmark from 1994 to 1995,[30]
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27 and from published noninferiority trials from 1989 to 2009.[29]
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31 Reported prevalence of ghostwriting

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33 The reported prevalence of possible ghostwriting in the primary publications varied markedly
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35 and were not suitable for meta-analysis because of the different populations assessed, the
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37 different methods used to generate the estimates, and the various definitions that were used
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39 (Tables 1 and 2). All cross-sectional surveys reported a definition of ghostwriting or ghost
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41 authoring, but most definitions did not differentiate contributions that merited authorship from
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43 those that did not merit authorship (Table 2).
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Table 2. Primary Publications Reporting Estimates of the Prevalence of Possible Ghostwriting

Publication	Measure of Possible Ghostwriting Reported by Authors	Estimate % (n)
<i>Cross-sectional surveys reporting ghostwriting</i>		
Flanagin 1998[27]	Unnamed individual who participated in the writing	1.4% (11/809) of articles
Wislar 2011[20]	Unnamed individual who participated in the writing	0.2% ^a (1/622) of articles
Jacobs 2009, Hamilton 2012[25, 33]	Undisclosed medical writing assistance not qualifying for authorship	2005: 61.8% (NR) 2009: 41.7% (NR) 2011: 33.0% (NR) of articles ^b
<i>Cross-sectional surveys reporting combined ghost authoring and ghostwriting</i>		
Flanagin 1998[27]	Failure to name, as an author, individuals who made substantial contributions to the research or writing or an unidentified medical writer	11.5% (93/809) of articles
Price 2000[22]	Failure to name, as an author, individuals who made substantial contributions to the research or writing	24.1% (40/166) of authors
Mowatt 2002[23]	Individual merited authorship or had assisted with drafting but not listed as an author or acknowledged	8.8% (32/362) of articles
Hao 2009[32]	English-language speakers assisted with writing but not identified as authors or acknowledged	10.4% (NR) of authors
Dotson 2011[28]	Failure to name, as an author, individuals who made substantial contributions to the research or writing	0.9% (1/112) of articles
Wislar 2011[20]	Failure to name, as an author, individuals who made substantial contributions to the research or writing of the article or an unnamed individual who participated in the writing	7.9% (49/622) of articles
<i>Cross-sectional surveys reporting ghost authoring</i>		
Mirzazadeh 2011[24]	Failure to name, as an author, individuals who made substantial contributions to the research	21.4% (25/NR) of authors
Ghajarzadeh	Failure to name, as an author, students who made substantial	0.7% (2/296) of

2012[26]	contributions to the research ^c	articles
Vinther 2012[21]	Individual merited authorship but not listed as an author	2.4% (6/245) of articles
Rees 2013[31]	Individual merited authorship but not listed as an author	70% (NR/202) of published authors

Publication reviews and descriptive analysis reporting possible ghost authoring or ghostwriting

Healy 2003[6]	Published articles coordinated by a medical information company, including acknowledged medical writing support ^d	57.3% (55/96) of articles
Gøtzsche 2007[30]	Individuals who wrote the trial protocol, conducted the statistical analyses, or wrote the manuscript but were not listed as authors, not members of a study group or steering committee, or not disclosed in an acknowledgment	75.0% (33/44) of trials
Ross 2008[8]	Published reviews associated with Merck support and with a single external author ^e	69.4% (50/72) of reviews

^a Available as online supplementary data.

^b Values represent the mean weighted percentage of publications that were ghostwritten by respondents. Findings were weighted in proportion to the number of manuscripts the respondent wrote per year.

^c Students were classified as ghostwriters if the student was not named as an author and if the results reported in the publications were based on the results of their theses.

^d Authors conclude data provide quantification of the possible extent of ghostwriting based on a single drug. Of the 55 published articles that were coordinated through a medical information company, 2 included medical writing assistance that was acknowledged in the published article.

^e Published review articles had been identified from correspondence between Merck and a medical publishing company, from Merck publication status reports, or were affiliated with an author named within the correspondence or publication status reports. The authors did not report whether medical writing assistance was acknowledged in the published article.

Abbreviations: NR, not reported.

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3 Four cross-sectional surveys reported the prevalence of ghostwriting where the definition
4 provided could be categorized as undisclosed contributions that do not merit authorship.[20,
5 25, 27, 33] Findings from these surveys, which were repeated at different time points,
6 suggested that the prevalence of ghostwriting is low and decreasing. Flanagin[27] and
7 Wislar[20] conducted two similar cross-sectional surveys of corresponding authors of articles
8 published in six general medicine journals in 1996[27] and in 2008.[20] The surveys, which
9 included a core set of three journals (Annals of Internal Medicine, JAMA, the New England
10 Journal of Medicine) at each time point and in targeted populations, used pretested
11 questions that required an anonymous response and had response rates greater than 65%.
12 The prevalence of ghost authoring (which included ghostwriting) was estimated to be 11.5%
13 in 1996 and 7.9% in 2008. The prevalence of ghostwriting from these surveys was estimated
14 to be 1.4% in 1996 and 0.2% in 2008. Hamilton and Jacobs conducted a cross-sectional
15 survey of members of two medical writing associations in 2005, 2008, and 2011.[25, 33] The
16 survey, which was not conducted in targeted populations, used pretested questions that
17 required an anonymous response and had response rates from 12% to 28% of the total
18 population surveyed (ie, not all participants surveyed were involved in the preparation of
19 peer-reviewed manuscripts). Findings from these surveys showed that the mean weighted
20 percentage of publications that were ghostwritten by respondents had decreased from
21 61.8% in 2005 to 33.0% in 2011. Findings were weighted in proportion to the number of
22 manuscripts the respondent wrote per year.
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45 Six cross-sectional survey publications reported the prevalence of possible ghostwriting (ie,
46 the prevalence of ghostwriting and ghost authoring combined).[20, 22, 23, 27, 28, 32] The
47 prevalence of possible ghostwriting reported in these cross-sectional surveys varied from
48 0.9% to 24.1% of publications or authors.
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3 Four cross-sectional survey publications reported the prevalence of ghost authoring.[21, 24,
4 26, 31] The prevalence of ghost authoring reported in these cross-sectional surveys varied
5 from 0.7% to 70% of publications or authors.
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11 The descriptive analyses of published articles on sertraline and rofecoxib did not include a
12 prespecified definition of ghost authoring or ghostwriting;[6, 8] in these studies, possible
13 ghostwriting or ghost authoring was assumed in publications associated with industry-
14 sponsored support (Table 2). The descriptive analysis of industry-initiated trials in Denmark
15 used a nonstandard definition of ghost authors; in this study ghost authors were defined as
16 individuals, not named as authors, who were involved in writing the protocol, conducting the
17 statistical analyses, or writing the manuscript.[30] The prevalence of possible ghostwriting in
18 the two descriptive analyses of single drugs that did not include a prespecified definition of
19 ghostwriting was 57% of articles on sertraline published from 1998 to 2000[6] and 69% of
20 reviews on rofecoxib published from 1996 to 2004.[8] The prevalence of possible
21 ghostwriting in the descriptive analysis of Danish industry-initiated trials, which used a
22 nonstandard definition of authorship, was 75% of Danish initiated trials approved in 1994 to
23 1995.[30] The descriptive analysis of noninferiority trials[29] was not considered further as
24 the definition of ghostwriting used was consistent with disclosed medical writing assistance.
25 In this study ghostwriters were defined as acknowledged individuals, other than authors, who
26 contributed to the writing and were affiliated with an industry-sponsored study.[29] The
27 prevalence of disclosed medical writing assistance in this descriptive analysis was 17.3%
28 (101/583) of clinical trials.
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50 **Secondary publications**

51 Publication characteristics

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53 Of the 32 secondary publications, there were 13 review articles, 10 editorials, 5
54 commentaries, 3 news articles, and 1 government report, with most being published after
55 2008 (Table 3). Most publications cited primary sources as evidence of the prevalence of
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possible ghostwriting (Table 3), with the cited prevalence of possible ghostwriting varying from 6% of publications to 100% of publications involving drugs. In most secondary publications, the information on the prevalence of ghostwriting was not reported consistently compared with the cited evidence (Table 3). Misleading and mistaken information was reported in many publications that (i) did not distinguish between ghostwriting and ghost authoring, (ii) included acknowledged medical writing assistance or a combined estimate of guest authorship and ghost authorship as ghostwriting, (iii) generalized findings from publication reviews and analyses of specific datasets to wider populations of publications or industry-sponsored trials, or (iv) cited personal communications or informal surveys where the original source was unpublished and could not be verified (Table 3).

Table 3. Characteristics of Secondary Publications Citing Evidence of Possible Ghostwriting

Publication	Cited evidence	Consistent with cited source(s)	Comment
Elliot Hastings Cent Rep 2004[34]	Primary	No	Did not distinguish GW from GA
Moffat Perspect Biol Med 2007[35]	Primary	No	Did not distinguish GW from GA
Schiefe Pharmacotherapy 2009[36]	Primary	No	Did not distinguish GW from GA
MacLennan Climacteric 2010[37]	Primary	No	Did not distinguish GW from GA
Nahai Aesthet Surg J 2010[38]	Secondary	No	Did not distinguish GW from GA
Ngai Account Res 2005[39]	Primary	Yes	Did not distinguish GW from GA
Bosch EMBO Rep 2011[40]	Primary	Yes	Did not distinguish GW from GA
Wiwanitkit Am J Med 2012[41]	Primary	No	Did not distinguish GW from GA or GA from guest authorship
Krimsky Med Law 2007[42]	Primary	No	Did not distinguish GW from GA or GA from guest authorship
Langdon-Neuner Mens Sana Monogr 2008[43]	Primary & secondary	No	Did not distinguish GW from GA or GW from disclosed medical writing support

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3	Tharyan Indian J Med Ethics 2011[44]	Primary	Yes	Did not distinguish GW from GA
4				or GW from disclosed medical
5				writing assistance
6				
7				
8	Paul Clin Microbiol Infect 2009[45]	Primary	Yes	Did not distinguish GW / GA
9				from disclosed medical writing
10				assistance
11				
12				
13	Bavdekar Lung India 2012[46]	Primary	No	Did not distinguish GW from GA
14				and generalized evidence to a
15				wider population
16				
17				
18	Górski Transplant Proc 2010[47]	Primary &	No	Did not distinguish GW from GA
19		secondary		and generalized evidence to a
20				wider population
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22				
23	Matias-Guiu Neurologia 2011[48]	Primary &	No	Did not distinguish GW from GA
24		secondary		and generalized evidence to a
25				wider population
26				
27				
28	McHenry Mens Sana Monogr 2010[49]	Gov. report	No	Generalized evidence to a wider
29				population
30				
31				
32				
33	Healy BMJ 2004[50]	Primary &	No / ND	Generalized evidence to a wider
34		secondary		population and reported
35				personal opinion of GW
36				prevalence
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41	Abbasi BMJ 2004[4]	Secondary	No	Secondary publication cited
42				named individual
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44				
45	Mitrany Science Editor 2005[51]	None	ND	Cited named individual
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47	Collier Can Med Assoc J 2009[5]	None	ND	Cited named individual
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49	Kmietowicz BMJ 2004[52]	None	ND	Cited named individual
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51	Matthews Wall St J 2005[3]	None	ND	Cited unpublished data
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53	Bonita Heart Fail Clin 2011[53]	Primary	Yes	Consistent with cited source
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55	Grassley Int J Occup Environ Health	Primary	Yes	Consistent with cited source
56	2011[54]			
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3	Nat Clin Pract Nephrol 2007[55]	Primary	Yes	Consistent with cited source
4	Editors J Urol 2008[15]	Primary	Yes	Consistent with cited source
5				
6	Baethge Deutsches Arzteblatt 2009[56]	Primary	Yes	Consistent with cited source
7				
8	Flanagin CSE Annual Mtg 2010[57]	Primary	Yes	Consistent with cited source
9				
10	Murray Open Med 2010[58]	Primary	Yes	Consistent with cited source
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12	Moore BMJ 2004[59]	Secondary	Yes	Consistent with cited source
13				
14	Hargreaves BMJ 2007[60]	Primary	Yes	Consistent with cited source
15				
16	Jones Nature 2009[61]	Primary	Yes	Consistent with cited source

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18 Abbreviations: CSE, Council of Science Editors; GA, ghost authoring; Gov, government; GW,
19 ghostwriting; ND, not determined.
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22 Case study of misleading and mistaken evidence

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24 An analysis of secondary publications citing the possible prevalence of ghostwriting in
25 sertraline publications provides an illuminating case study on how misleading or mistaken
26 evidence can enter and remain in the medical literature. In 2003, Healy and Cattell showed
27 that 57% (55/96) of articles on sertraline published from 1998 to 2000 were coordinated
28 through a medical information company and only two acknowledged medical writing
29 assistance.[6] The authors concluded that these data provided information on the “possible
30 extent of ghostwriting based on a single drug”. In 2004 (October 14), Healy also provided
31 evidence on the influence of the pharmaceutical industry on key groups at a United Kingdom
32 House of Commons Health Select Committee investigation.[62] In answer to Question 197,
33 Healy stated the following:
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48 *“My estimate is that, even in journals like the BMJ, the Lancet, the New England Journal of*
49 *Medicine and JAMA, the leading journals in the field, if these articles have to do with*
50 *therapeutics, with drugs, it may be worse perhaps for psychiatry than elsewhere, but I doubt*
51 *it, 50% of these articles are ghostwritten. It may be higher.”*
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3 Healy and Cattell's original evidence has been cited incorrectly and interchangeably with
4 Healy's statement to the House of Commons Health Select Committee investigation (Figure
5 2). Although findings from the primary publication have been cited and interpreted correctly in
6
7 two secondary publications,[34, 35] many secondary publications incorrectly cited Healy's
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9 original evidence and statement to the House of Commons Health Select Committee
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11 investigation (Figure 2).
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DISCUSSION

This systematic review on the reported prevalence of ghostwriting in the medical literature showed that the estimates of the prevalence of ghostwriting in primary publications varied markedly and were influenced by the definitions used, the types of study designs, and the type of population or sample assessed. In addition, secondary publications often cited outdated, misleading, or mistaken evidence of the reported prevalence of ghostwriting, with many publications not distinguishing ghostwriting from ghost authoring.

Although evidence from descriptive analyses can highlight the extent of ghostwriting in single populations, evidence from well-conducted cross-sectional surveys have the potential to provide estimates of the prevalence of ghostwriting that may be generalized to the majority of peer-reviewed publications. Despite this, many of the cross-sectional surveys retrieved in this systematic review were conducted in limited populations that were not broadly representative of the peer-reviewed medical literature. In addition, many of the cross-sectional surveys did not differentiate between contributions that merited authorship from those that did not merit authorship and provided at best, an estimate of possible ghostwriting. The reported prevalence of ghostwriting, where ghostwriting was defined as undisclosed contributions that did not merit authorship, was retrieved from the two cross-sectional surveys of corresponding authors from several general medicine journals and by cross-sectional surveys (repeated on three separate occasions from 2005 to 2011) of members of two major medical writing associations. Together the findings from these surveys suggested that the prevalence of ghostwriting has decreased in recent years. However, while the findings from these surveys may be considered more broadly representative of the peer-reviewed medical literature than surveys focused on single journals, single countries, or single subject areas, interpretation of these findings should take into account that respondents were required to retrospectively self-report potentially unethical or unprofessional behaviour.

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5 Unethical authorship practices are a major concern and are an increasingly recognized
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7 problem in the medical literature.[63] As the findings from this systematic review suggest,
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9 some of these perceived problems may arise from the considerable, but unnecessary,
10
11 confusion and disagreement surrounding the definitions of ghostwriting. As recognized by
12
13 the World Association of Medical Editors, professional medical writers can have a legitimate
14
15 role in assisting authors to communicate their research findings in the peer-reviewed
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17 literature.[14] Professional medical writers can and do improve the timeliness and quality of
18
19 reporting and can assist investigators and industry sponsors to meet their ethical
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21 commitments to the disclosure and publishing of clinical trial results.[1, 64-66] As such, the
22
23 misleading and mistaken reporting of the prevalence of ghostwriting that was evident in the
24
25 secondary publications retrieved in this systematic review is disappointing. Specifically, the
26
27 confusion surrounding definitions of ghost authorship and ghostwriting and the unbalanced
28
29 focus on industry as the source of unethical authorship practices in the secondary
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31 publications takes attention away from the need to focus on all types of unethical
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33 contributions in peer-reviewed publications, irrespective of the source of the unethical
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35 practice.
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40 The various definitions of ghostwriting and ghost authoring found in this systematic review
41
42 highlights the considerable disagreement in the medical literature with regard to the
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44 definitions of ghostwriting and ghost authoring and whether a distinction should be made
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46 between these unethical practices. Although the Council of Science Editors uses a
47
48 straightforward and broad definition of ghost authors that does not distinguish between ghost
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50 authors and ghostwriters,[2] the distinction between ghost authorship and ghostwriting used
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52 in this manuscript is consistent with those used in the cross-sectional surveys conducted by
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54 Flanagan[67] and Wislar[68] and with the authorship criteria recommended by the ICMJE.[12]
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56 Distinguishing between these practices is important because it differentiates between
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58 undisclosed contributions that do and do not merit authorship. However, part of the reason
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3 for the disagreement about definitions of ghost authoring and ghostwriting stems from
4 differences of opinion in the medical literature over how authorship is defined, particularly
5 with regard to what constitutes “substantial” contributions to a publication and the role of
6 disclosure of contributions to a manuscript in the acknowledgments.[69] The ICMJE criteria
7 for authorship[12] are the most well recognised authorship criteria available, but leave much
8 about authorship undefined.[63, 70] Despite this, the recent emphasis on author
9 accountability in the ICMJE’s fourth criterion is an attempt to better define authors as those
10 persons who are responsible and accountable for the content of a published work. While a
11 professional medical writer can take responsibility for the writing and how research is
12 reported in a manuscript, the professional medical writer cannot take responsibility for the
13 integrity of the research or be accountable for the clinical interpretation of the findings,
14 unless he or she was involved in the generation of the research or its analysis.
15 Responsibility for the integrity of research and accountability for the clinical interpretation of
16 the findings is, and should always be, the responsibility of the authors. Until a more
17 definitive model of authorship is universally accepted, the controversy and disagreement
18 over definitions of authors, ghostwriters, and ghost authors will remain. However, no matter
19 what term is used, the practice of misleading readers about potential competing interests
20 and hiding contributions to a published work, no matter whether these contributions should
21 be most appropriately disclosed in the author byline or acknowledgements section, is
22 unethical and totally unacceptable.
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46 The strengths of this systematic review are that a broad search strategy was employed with
47 few restrictions to minimize any potential for publication or language bias. All study designs
48 and publication types were considered and there were no restrictions on language. Although
49 the full text or abstracts of 8 publications could not be retrieved, omission of these
50 publications was unlikely to have biased the findings. Review of the abstracts or titles of
51 these publications suggested that none reported numerical estimates of the prevalence of
52 ghostwriting. The major finding of this review was the limitations of the reported evidence of
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3 ghostwriting in the medical literature. These limitations included the heterogeneity among the
4 studies in the outcomes reported and populations investigated, the observational study
5 designs, and the retrospective nature of data collection. Given the nature of unethical
6 authorship practices, it may not be feasible to conduct a prospective study on ghostwriting.
7
8 However, based on the findings from this review, recommendations can be made to help
9 researchers, authors, editors, and peer-reviewers apply the same rigorous standards that
10 are applied to the conduct and assessment of all clinical research and actively improve the
11 quality of reporting of the evidence of unethical authorship practices.
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21 Researchers should use a standard definition of ghostwriting so that the confusion around
22 ghostwriters and ghost authors is not perpetuated. For example, the descriptive analysis of
23 Danish industry-initiated trials used a nonstandard definition of authorship, which is likely to
24 have contributed to the very high prevalence of possible ghostwriting reported in this study
25 (75%). In this study, Gøtzsche et al.[30] suggested that individuals who write the trial
26 protocol, conduct the statistical analyses, or who contribute to the writing of a publication
27 should be included as authors. Indeed, the prevalence of ghost authorship in this study was
28 91% when the analyses included these individuals, irrespective of whether they had been
29 appropriately acknowledged elsewhere. Given that the Gøtzsche et al.[30] study has been
30 downloaded more than 3,000 times since publication[71] and cited repeatedly as evidence
31 not only of ghost authorship but also of ghostwriting,[40, 44, 46, 48] it would have been
32 illuminating if the authors had included an estimate of the prevalence of ghostwriting using
33 standard definitions for comparison. In addition to using standard definitions of ghostwriting,
34 researchers and authors should ensure that cited evidence of ghostwriting is reported
35 accurately without unwarranted generalizations. Publications based on personal
36 commentary should be avoided and studies that use nonstandard definitions, specific
37 populations, or that were conducted before a change in practice (eg, before the adoption of
38 the Good Publication Practice guidelines for communicating company sponsored research in
39 2003 [GPP][72] and in 2009 [GPP2][11]) should be described in context.
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5 Editors and peer reviewers have a duty to prevent outdated, misleading, or mistaken
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7 evidence on the prevalence of ghostwriting from being published and perpetuated. Close
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9 attention should be paid to the internal and external validity of the study, the definitions used,
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11 how the data are reported, and whether the data are interpreted within the context of current
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13 practices. When assessing a submitted manuscript on ghostwriting, editors should consider
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15 using peer reviewers with expertise in the appropriate study designs (eg, survey research)
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17 and ethical publication practices. Collectively, these actions could help prevent further
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19 questionable evidence on the prevalence of ghostwriting from being published.
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23 In conclusion, the findings from this systematic review showed that reports of the prevalence
24
25 of ghostwriting in the medical literature are limited by the varied definitions used to describe
26
27 unethical authorship practices, the types of study designs employed, and the populations
28
29 assessed. To improve reporting, researchers should not inflate estimates using nonstandard
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31 definitions of ghostwriting nor conflate ghostwriting with other unethical authorship practices.
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33 While open and transparent debate should be encouraged, editors and peer reviewers
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35 should not accept articles that incorrectly cite or interpret primary publications that report the
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37 prevalence of ghostwriting.
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CONTRIBUTORSHIP STATEMENT

The author, SS, contributed to the conception and design of the systematic literature review, the collection and screening of publications, and the analysis and interpretation of the findings. SS drafted and critically revised draft versions of the manuscript and gave final approval for submission.

COMPETING INTERESTS

The author is a professional medical writer who is actively involved in national and international not-for-profit organizations that encourage ethical medical writing practices. The author has no relationships with any pharmaceutical company that might have an interest in the submitted work and has no other relationships that could be construed as a competing interest.

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DATA SHARING

All data associated with the study are fully available to the author.

For peer review only

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FIGURE LEGENDS

Figure 1. Selection of publications reporting a numerical estimate of the prevalence of ghostwriting. Electronic databases were searched on 23 May 2013.

^a Journal of the European Medical Writers Association, formerly known as The Write Stuff.

^b Journal of the American Medical Writers Association.

^c Council of Science Editors Annual Meetings.

^d International Congress on Peer Review and Biomedical Publication.

Figure 2. Case study of original versus cited evidence of ghostwriting prevalence.

Contrast between original evidence on the prevalence of possible ghostwriting in sertraline publications from 1998 to 2000 and the subsequent citations of this evidence. Source of the original published evidence: Healy and Cattell[6] showed that 55 of 96 (57%) articles published on sertraline from 1998 to 2000 were coordinated through a medical communications company and concluded that these data provided information on the “possible extent of ghostwriting based on a single drug”. Inaccurate reporting from the cited source is marked with a cross.

TITLE

Systematic review on the primary and secondary reporting of the prevalence of ghostwriting
in the medical literature

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KEYWORDS

Authorship, ghostwriting, systematic review

WORD COUNT

3,967

ABSTRACT

Background: Ghostwriting of industry-sponsored articles is unethical and is perceived to be common practice.

Objective: To systematically review how evidence for the prevalence of ghostwriting is reported in the medical literature.

Data sources: MEDLINE via PubMed 1966+, EMBASE 1966+, The Cochrane Library 1988+, Medical Writing 1998+, The AMWA Journal 1986+, Council of Science Editors Annual Meetings 2007+, and the Peer Review Congress 1994+ were searched electronically (23 May 2013) using the search terms ghostwrit*, ghostauthor*, ghost AND writ*, ghost AND author*.

Eligibility criteria: All publication types were considered; only publications reporting a numerical estimate of possible ghostwriting prevalence were included.

Data extraction: Two independent reviewers screened the publications; discrepancies were resolved by consensus. Data to be collected included a numerical estimate of the prevalence of possible ghostwriting (primary outcome measure), definitions of ghostwriting reported, source of the reported prevalence, publication type and year, study design, and sample population.

Results: Of the 848 publications retrieved and screened for eligibility, 48 reported numerical estimates for the prevalence of possible ghostwriting. Sixteen primary publications reported findings from cross-sectional surveys or descriptive analyses of published articles; 32 secondary publications cited published or unpublished evidence. Estimates on the prevalence of possible ghostwriting in primary and secondary publications varied markedly. Primary estimates were not suitable for meta-analysis because of the various definitions of ghostwriting used, study designs, and types of populations or samples. Secondary estimates were not always reported or cited correctly or appropriately.

Conclusions: Evidence for the prevalence of ghostwriting in the medical literature is limited and can be outdated, misleading, or mistaken. Researchers should not inflate estimates

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3 using nonstandard definitions of ghostwriting nor conflate ghostwriting with other unethical
4 authorship practices. Editors and peer reviewers should not accept articles that incorrectly
5 cite or interpret primary publications that report the prevalence of ghostwriting.
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Strengths

- First systematic review on the reporting of the prevalence of ghostwriting in the medical literature
- A broad search strategy was employed with few restrictions to minimize any potential for publication or language bias; there were no restrictions on language.
- All study designs and publication types were considered

Limitations

- Study heterogeneity in the outcomes reported and populations investigated precluded synthesis of the data
- Retrospective and self-reported nature of the data collection increased the risk of selection bias in the studies
- Most included studies were not broadly representative of the peer-reviewed medical literature

INTRODUCTION

Ghostwriting occurs when paid or unpaid writing contributions to a manuscript that do not meet authorship criteria are not disclosed in the acknowledgments.^[1] This practice is considered to be distinct from ghost authoring, where contributions to a manuscript that do merit authorship are not disclosed in the author byline.^[1] However, part of the challenge in understanding the prevalence of ghostwriting is the current confusion surrounding the two these unethical practices. For example, the widely used Council of Science Editors definition of ghost authors (ie, individuals who participate in research, data analysis, and/or writing of a manuscript but are not named or disclosed in the author byline or acknowledgments) does not distinguish between ghost authors and ghostwriters.^[2]

Ghostwriting of peer-reviewed journal publications in the medical literature is believed to be common practice.^[3-5] This belief is supported, to a large extent, by highly publicized cases, primarily from the 1990s and early 2000s, of pharmaceutical companies and authors who had used ghostwriters to prepare manuscripts for publication in medical journals.^[6-8] Such cases are highly unethical because the role of the commercial sponsor and any other potential conflicts of interest were hidden.

~~Ghostwriting occurs when writing contributions to a manuscript that do not meet authorship criteria are not disclosed in the acknowledgments. This practice is distinct from ghost authoring, where contributions to a manuscript that do merit authorship are not disclosed in the author byline.^[7] However, part of the challenge in understanding the prevalence of ghostwriting is the current confusion surrounding the two unethical practices. For example, the widely used Council of Science Editors definition of ghost authors (ie, individuals who participate in research, data analysis, and/or writing of a manuscript but are not named or disclosed in the author byline or acknowledgments) does not distinguish between ghost authors and ghostwriters.^[8] Estimating the prevalence of ghostwriting in the medical~~

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3 literature has ~~also~~ been hindered not only by the different definitions of ghostwriting and
4 ghost authoring, but also by the failure of authors to distinguish ghostwriting, which is
5 unethical, from professional medical writing support, which is ethical.[9, 10] Ghostwriters
6 keep their involvement in a manuscript hidden, whereas professional medical writers
7 disclose their involvement and follow ethical publication practices.[1, 9-11] Consistent with
8 the authorship criteria recommended by the International Committee of Medical Journal
9 Editors (ICMJE), professional medical writers who provide writing assistance and do not
10 meet all of the ICMJE authorship criteria, should be acknowledged rather than listed as
11 authors. [12] The prevalence of disclosed professional medical writing assistance in medical
12 journals has been estimated to be between 6.0% and 11.0% [10, 13] and the legitimate value
13 that this medical writing assistance can bring to improving the quality, timeliness, and
14 integrity of reporting in medical journals has been demonstrated. [1, 14, 15] However, the
15 exact prevalence of ghostwriting and other forms of undisclosed contributions to papers
16 published in medical journals is unknown.

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33 The primary objective of this study was to conduct the first systematic review on how the
34 prevalence of ghostwriting is reported in the medical literature. The secondary objectives
35 were to assess the variability of the reported estimates of the prevalence of ghostwriting and
36 investigate the source for these estimates.
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MATERIALS AND METHODS

Literature search strategy

A search strategy was developed to retrieve publications from the medical literature that reported quantitative estimates of the prevalence of ghostwriting. The following databases were searched on 23 May 2013: MEDLINE via PubMed (1966+); EMBASE (1966+); The Cochrane Library, including the Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Trials (1988+); The AMWA Journal (1986+, journal of the American Medical Writers Association); Medical Writing (1998+, journal of the European Medical Writers Association, formerly known as The Write Stuff); Council of Science Editors annual meetings (2007+); and the International Congress on Peer Review and Biomedical Publication meetings (1994+). General text was searched using the following search terms: ghostwrit*, ghostauthor*, ghost AND writ*, ghost AND author*. Truncation symbols and Boolean operators (AND, OR) were used wherever possible.

Two reviewers (SS, SMG) independently screened the title and abstracts of all retrieved publications using prespecified eligibility criteria; the full text of potentially eligible publications was screened to confirm eligibility for inclusion. Any discrepancies between the reviewers were resolved by consensus. The reference lists of relevant reviews and other publications were screened by hand to identify any additional publications for inclusion.

Eligibility criteria

The eligibility criteria were prespecified. Publications were included if they reported a numerical estimate of the prevalence of possible ghostwriting. Publications were excluded if they were duplicate publications from different databases or abstracts of subsequently published full-text articles, did not report any outcomes related to ghostwriting, or reported qualitative estimate(s) of the prevalence of possible ghostwriting. No restrictions on language were included in the eligibility criteria. If needed, the abstracts of publications

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3 written in non-English language were to be translated to assist in screening for eligibility. If
4 publications were eligible for inclusion, the full text of the publications were to be translated
5 to English.
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10 **Data extraction and analysis**

11 The primary and secondary outcomes and data to be collected were prespecified. Data to
12 be collected and included publication type and year, study design and sample population,
13 definitions of ghostwriting reported, reported prevalence of possible ghostwriting, and the
14 source of the reported prevalence of ghostwriting. The prevalence of possible ghostwriting
15 was reported as published. No unpublished data from the retrieved literature were reported
16 and values for prevalence were not extrapolated from published data.
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27 The primary outcome measure for the systematic review was a numerical estimate of the
28 prevalence of possible ghostwriting. The reported definitions of possible ghostwriting were
29 categorized according to the following standard definitions, irrespective of the term used to
30 describe the practice in the publication. Undisclosed writing contributions to a manuscript
31 were defined as (i) ghostwriting if they were described as not meriting authorship and were
32 not listed in the acknowledgments[9, 16] and (ii) ghost authoring if they did merit authorship
33 and were not listed in the author byline.[1] Consistent with recommendations from
34 international medical journal editors,[12, 14] Good Publication Practice guidelines,[11] and
35 professional medical writing associations,[17, 18] disclosed writing contributions to a
36 manuscript that did not merit authorship and were disclosed in the acknowledgments were
37 not categorized as ghostwriting.
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51 The key factors considered when assessing study quality were study design, the population
52 assessed, and how ghostwriting was defined. While there is no consensus on the best
53 practice for reporting survey research,[19] the quality of the cross-sectional surveys was
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3 determined by an assessment of the following factors: validation or pretesting of the survey
4 questions, anonymity of the response, sample size, and response rate.
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RESULTS

Publication selection

A total of 848 articles were retrieved from the literature search, 800 were excluded, and 48 met the eligibility criteria and were included in the systematic review (Figure 1). The main reasons for exclusion were publications not relevant to ghostwriting (n = 539), duplicate publications from different databases (n = 129), and publications not reporting a numerical estimate of the prevalence of possible ghostwriting (n = 124). The titles or abstracts of the 8 publications that were excluded because the full text or abstract could not be retrieved were reviewed; none were considered to report a numerical estimate of the prevalence of possible ghostwriting. Overall, eligible publications included 16 primary publications that reported original research on the prevalence of possible ghostwriting and 32 secondary publications that cited published or unpublished evidence of possible ghostwriting.

Primary publications

Publication characteristics

Of the 16 primary publications (Table 1), there were 13 full-text publications[6, 8, 20-30] and three conference abstracts[31-33] that reported a numerical estimate of possible ghostwriting. Twelve publications[20-28, 31-33] reported findings from cross-sectional surveys and four publications[6, 8, 29, 30] reported findings from descriptive analyses of published articles. ~~While there is no consensus on the best practice for reporting survey research,[33]M~~ most cross-sectional surveys were reasonably well reported. The surveys used were not validated but most included pretested questions, required an anonymous response, were conducted in targeted populations (ie, all individuals invited to participate were involved in the preparation of peer-reviewed manuscripts), and reported a sample size and response rate. Of the cross-sectional surveys conducted in targeted populations (eg, corresponding or first authors), six had response rates greater than 50%, two had response rates less than 50%, and one did not report a

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response rate (Table 1). Of the cross-sectional surveys conducted in nontargeted populations (eg, individuals invited to participate who may or may not have been involved in providing medical writing assistance for peer-reviewed publications), three had low (12% to 28%) response rates and one did not report a response rate (Table 1).

Table 1. Characteristics of Primary Publications Reporting Original Evidence of Ghostwriting

Publication	Population	Survey description	Data collected	N	RR
<i>Cross-sectional surveys – authors or corresponding authors</i>					
Flanagin 1998[27]	6 general medicine journals ^a	Self-administered, postal, anonymous, pretested, targeted	1996	809	69%
Mowatt 2002[23]	Published Cochrane reviews	Self-administered, online, anonymous, pretested, targeted	1999	362	63%
Hao 2009[32] (Abstract)	Chin Med J	Self-administered, email, not anonymous, targeted	2008 ^c	220	86%
Dotson 2011[28]	3 pharmacy journals	Self-administered, online, anonymous, pretested, targeted	2009	112	25%
Mirzazadeh 2011[24]	3 Iranian journals	Self-administered, email, not anonymous, targeted	2009-2010	NR	NR
Wislar 2011[20]	6 general medicine journals ^b	Self-administered, online, anonymous, pretested, targeted	2008	622	70%
Ghajarzadeh 2012[26]	Arch Iran Med (based on student theses)	Self-administered, email, anonymous, targeted	2005-2007	30	49%
Vinther 2012[21]	Ugeskr Laeger & Dan Med J	Self-administered, online, anonymous, pretested, targeted	2010	272	62%
<i>Cross-sectional surveys – healthcare professionals</i>					
Price 2000[22]	Health academic staff	Self-administered, postal, anonymous, pretested, targeted	NR	166	59%
Rees 2013[31]	Registered users of	Self-administered, online,	NR	295	NR

(Abstract)	EPG Online	anonymous, nontargeted			
<i>Cross-sectional surveys – members of medical writing associations</i>					
Jacobs	EMWA / AMWA	Self-administered, online,	2005	843	28%
2009[25]	members	anonymous, pretested, nontargeted	2008	773	14%
Hamilton	EMWA / AMWA	Self-administered, online,	2011	620	12% ^d
2012[33]	members	anonymous, pretested, (Abstract) nontargeted			
<i>Publication reviews and descriptive analysis</i>					
Healy 2003[6]	Articles on sertraline	NA	1998- 2000	96	NA
Gøtzsche	Articles on Danish	NA	NR	44	NA
2007[30]	industry-initiated trials approved 1994-1995				
Ross 2008[8]	Reviews on rofecoxib associated with Merck support	NA	1996- 2004	72	NA
Suda 2011[29]	Noninferiority clinical trials	NA	1989- 2009	583	NA

^a Annals of Internal Medicine, JAMA, the New England Journal of Medicine, American Journal of Cardiology, American Journal of Medicine, American Journal of Obstetrics and Gynecology.

^b Annals of Internal Medicine, JAMA, the New England Journal of Medicine, Lancet, Nature Medicine, PLoS Medicine.

^c Submission date.

^d Personal communication, C. Hamilton.

Abbreviations: AMWA, American Medical Writers Association; EMWA, European Medical Writers Association; NA, not applicable; NR, not reported; RR, response rate.

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3 Not all cross-sectional surveys were broadly representative of the peer-reviewed medical
4 literature. The cross-sectional surveys were conducted in single populations of academic
5 staff or healthcare professionals[22, 31], members of medical writing associations[25, 33], or
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7 corresponding or first authors. The corresponding or first authors were surveyed from single
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9 journals (Cochrane reviews, Chinese Medical Journal, Archives of Iranian Medicine),[23, 26,
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11 32] two Danish journals,[21] three Iranian journals,[24] and three pharmacy journals.[28] Two
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13 cross-sectional surveys of corresponding authors were conducted in six general medicine
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15 journals.[20, 27]
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21 The descriptive analyses of published articles were conducted in single populations and
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23 included an analysis of sertraline publications from 1998 to 2000,[6] rofecoxib reviews from
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25 1996 to 2004,[8] publications from industry-initiated trials in Denmark from 1994 to 1995,[30]
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27 and from published noninferiority trials from 1989 to 2009.[29]
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31 Reported prevalence of ghostwriting

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33 The reported prevalence of possible ghostwriting in the primary publications varied markedly
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35 ~~and were not suitable for meta-analysis and was difficult to compare~~ because of the different
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37 populations assessed, the different methods used to generate the estimates, and the various
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39 definitions that were used (Tables 1 and 2). All cross-sectional surveys reported a definition
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41 of ghostwriting or ghost authoring, but most definitions did not differentiate contributions that
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43 merited authorship from those that did not merit authorship (Table 2).
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Table 2. Primary Publications Reporting Estimates of the Prevalence of Possible Ghostwriting

Publication	<u>Measure of Possible Ghostwriting Reported</u> <u>measure by</u> <u>Authors</u>	Estimate % (n)
<i>Cross-sectional surveys reporting ghostwriting</i>		
Flanagin 1998[27]	Unnamed individual who participated in the writing	1.4% (11/809) of articles
Wislar 2011[20]	Unnamed individual who participated in the writing	0.2% ^a (1/622) of articles
Jacobs 2009, Hamilton 2012[25, 33]	Undisclosed medical writing assistance not qualifying for authorship	2005: 61.8% (NR) 2009: 41.7% (NR) 2011: 33.0% (NR) of <u>writers</u> <u>articles</u> ^b
<i>Cross-sectional surveys reporting combined ghost authoring and ghostwriting</i>		
Flanagin 1998[27]	Failure to name, as an author, individuals who made substantial contributions to the research or writing or an unidentified medical writer	11.5% (93/809) of articles
Price 2000[22]	Failure to name, as an author, individuals who made substantial contributions to the research or writing	24.1% (40/166) of authors
Mowatt 2002[23]	Individual merited authorship or had assisted with drafting but not listed as an author or acknowledged	8.8% (32/362) of articles
Hao 2009[32]	English-language speakers assisted with writing but not identified as authors or acknowledged	10.4% (NR) of authors
Dotson 2011[28]	Failure to name, as an author, individuals who made substantial contributions to the research or writing	0.9% (1/112) of articles
Wislar 2011[20]	Failure to name, as an author, individuals who made substantial contributions to the research or writing of the article or an unnamed individual who participated in the writing	7.9% (49/622) of articles
<i>Cross-sectional surveys reporting ghost authoring</i>		
Mirzazadeh 2011[24]	Failure to name, as an author, individuals who made substantial contributions to the research	21.4% (25/NR) of authors

Ghajarzadeh	Failure to name, as an author, students who made substantial contributions to the research ^c	0.7% (2/296) of articles
Vinther 2012[21]	Individual merited authorship but not listed as an author	2.4% (6/245) of articles
Rees 2013[31]	Individual merited authorship but not listed as an author	70% (NR/202) of published authors

Publication reviews and descriptive analysis reporting possible ghost authoring or ghostwriting

Healy 2003[6]	Published articles coordinated by a medical information company, including acknowledged medical writing support ^{de}	57.3% (55/96) of articles
Gøtzsche 2007[30]	Individuals who wrote the trial protocol, conducted the statistical analyses, or wrote the manuscript but were not listed as authors, not members of a study group or steering committee, or not disclosed in an acknowledgment	75.0% (33/44) of trials
Ross 2008[8]	Published reviews associated with Merck support and with a single external author ^{ed}	69.4% (50/72) of reviews

^a Available as online supplementary data.

^b Values represent the mean weighted percentage of publications that were ghostwritten by respondents. Findings were weighted in proportion to the number of manuscripts the respondent wrote per year.

^{b, c} Students were classified as ghostwriters if the student was not named as an author and if the results reported in the publications were based on the results of their theses.

^{e, d} Authors conclude data provide quantification of the possible extent of ghostwriting based on a single drug. Of the 55 published articles that were coordinated through a medical information company, 2 included medical writing assistance that was acknowledged in the published article.

^{d, e} Published review articles had been identified from correspondence between Merck and a medical publishing company, from Merck publication status reports, or were affiliated with an author named within the correspondence or publication status reports. The authors did not report whether medical writing assistance was acknowledged in the published article.

Abbreviations: NR, not reported.

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3 Four cross-sectional surveys reported the prevalence of ghostwriting where the definition
4 provided could be categorized as undisclosed contributions that do not merit authorship.[20,
5 25, 27, 33] Findings from these surveys, which were repeated at different time points,
6 suggested that the prevalence of ghostwriting is low and decreasing. Flanagin[27] and
7 Wislar[20] conducted two similar cross-sectional surveys of corresponding authors of articles
8 published in six general medicine journals in 1996[27] and in 2008.[20] The surveys, which
9 included a core set of three journals (Annals of Internal Medicine, JAMA, the New England
10 Journal of Medicine) at each time point and in targeted populations, used pretested
11 questions that required an anonymous response and had response rates greater than 65%.
12 The prevalence of ghost authoring (which included ghostwriting) was estimated to be 11.5%
13 in 1996 and 7.9% in 2008. The prevalence of ghostwriting from these surveys was estimated
14 to be 1.4% in 1996 and 0.2% in 2008. Hamilton and Jacobs conducted a cross-sectional
15 survey of members of two medical writing associations in 2005, 2008, and 2011.[25, 33] The
16 survey, which was not conducted in targeted populations, used pretested questions that
17 required an anonymous response and had response rates from 12% to 28% of the total
18 population surveyed (ie, not all participants surveyed were involved in the preparation of
19 peer-reviewed manuscripts). Findings from these surveys showed that the mean weighted
20 percentage of publications that were association members who contributed to peer-reviewed
21 publications and had ghostwritten by respondents at least once during the survey year had
22 decreased from 61.8% in 2005 to 33.0% in 2011. Findings were weighted in proportion to
23 the number of manuscripts the respondent wrote per year.
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Six cross-sectional survey publications reported the prevalence of possible ghostwriting (ie, the prevalence of ghostwriting and ghost authoring combined).[20, 22, 23, 27, 28, 32] The prevalence of possible ghostwriting reported in these cross-sectional surveys varied from 0.9% to 24.1% of publications or authors.

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3 Four cross-sectional survey publications reported the prevalence of ghost authoring.[21, 24,
4 26, 31] The prevalence of ghost authoring reported in these cross-sectional surveys varied
5 from 0.7% to 70% of publications or authors.
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11 The descriptive analyses of published articles on sertraline and rofecoxib did not include a
12 prespecified definition of ghost authoring or ghostwriting;[6, 8] in these studies, possible
13 ghostwriting or ghost authoring was assumed in publications associated with industry-
14 sponsored support (Table 2). The descriptive analysis of industry-initiated trials in Denmark
15 used a nonstandard definition of ghost authors; in this study ghost authors were defined as
16 individuals, not named as authors, who were involved in writing the protocol, conducting the
17 statistical analyses, or writing the manuscript.[30] The prevalence of possible ghostwriting in
18 the two descriptive analyses of single drugs that did not include a prespecified definition of
19 ghostwriting was 57% of articles on sertraline published from 1998 to 2000[6] and 69% of
20 reviews on rofecoxib published from 1996 to 2004.[8] The prevalence of possible
21 ghostwriting in the descriptive analysis of Danish industry-initiated trials, which used a
22 nonstandard definition of authorship, was 75% of Danish initiated trials approved in 1994 to
23 1995.[30] The descriptive analysis of noninferiority trials[29] was not considered further as
24 the definition of ghostwriting used was consistent with disclosed medical writing assistance.
25 In this study ghostwriters were defined as acknowledged individuals, other than authors, who
26 contributed to the writing and were affiliated with an industry-sponsored study.[29] The
27 prevalence of disclosed medical writing assistance in this descriptive analysis was 17.3%
28 (101/583) of clinical trials.
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50 **Secondary publications**

51 Publication characteristics

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53 Of the 32 secondary publications, there were 13 review articles, 10 editorials, 5
54 commentaries, 3 news articles, and 1 government report, with most being published after
55 2008 (Table 3). Most publications cited primary sources as evidence of the prevalence of
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possible ghostwriting (Table 3), with the cited prevalence of possible ghostwriting varying from 6% of publications to 100% of publications involving drugs. In most secondary publications, the information on the prevalence of ghostwriting was not reported consistently compared with the cited evidence (Table 3). Misleading and mistaken information was reported in many publications that (i) did not distinguish between ghostwriting and ghost authoring, (ii) included acknowledged medical writing assistance or a combined estimate of guest authorship and ghost authorship as ghostwriting, (iii) generalized findings from publication reviews and analyses of specific datasets to wider populations of publications or industry-sponsored trials, or (iv) cited personal communications or informal surveys where the original source was unpublished and could not be verified (Table 3).

Table 3. Characteristics of Secondary Publications Citing Evidence of Possible Ghostwriting

Publication	Cited evidence	Consistent with cited source(s)	Comment
Elliot Hastings Cent Rep 2004[34]	Primary	No	Did not distinguish GW from GA
Moffat Perspect Biol Med 2007[35]	Primary	No	Did not distinguish GW from GA
Schiefe Pharmacotherapy 2009[36]	Primary	No	Did not distinguish GW from GA
MacLennan Climacteric 2010[37]	Primary	No	Did not distinguish GW from GA
Nahai Aesthet Surg J 2010[38]	Secondary	No	Did not distinguish GW from GA
Ngai Account Res 2005[39]	Primary	Yes	Did not distinguish GW from GA
Bosch EMBO Rep 2011[40]	Primary	Yes	Did not distinguish GW from GA
Wiwantkit Am J Med 2012[41]	Primary	No	Did not distinguish GW from GA or GA from guest authorship
Krimsky Med Law 2007[42]	Primary	No	Did not distinguish GW from GA or GA from guest authorship
Langdon-Neuner Mens Sana Monogr 2008[43]	Primary & secondary	No	Did not distinguish GW from GA or GW from disclosed medical writing support

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3	Tharyan Indian J Med Ethics 2011[44]	Primary	Yes	Did not distinguish GW from GA
4				or GW from disclosed medical
5				writing assistance
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8	Paul Clin Microbiol Infect 2009[45]	Primary	Yes	Did not distinguish GW / GA
9				from disclosed medical writing
10				assistance
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12				
13	Bavdekar Lung India 2012[46]	Primary	No	Did not distinguish GW from GA
14				and generalized evidence to a
15				wider population
16				
17				
18	Górski Transplant Proc 2010[47]	Primary &	No	Did not distinguish GW from GA
19		secondary		and generalized evidence to a
20				wider population
21				
22				
23	Matias-Guiu Neurologia 2011[48]	Primary &	No	Did not distinguish GW from GA
24		secondary		and generalized evidence to a
25				wider population
26				
27				
28	McHenry Mens Sana Monogr 2010[49]	Gov. report	No	Generalized evidence to a wider
29				population
30				
31				
32				
33	Healy BMJ 2004[50]	Primary &	No / ND	Generalized evidence to a wider
34		secondary		population and reported
35				personal opinion of GW
36				prevalence
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41	Abbasi BMJ 2004[4]	Secondary	No	Secondary publication cited
42				named individual
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44				
45	Mitrany Science Editor 2005[51]	None	ND	Cited named individual
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47	Collier Can Med Assoc J 2009[5]	None	ND	Cited named individual
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49	Kmietowicz BMJ 2004[52]	None	ND	Cited named individual
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51	Matthews Wall St J 2005[3]	None	ND	Cited unpublished data
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53	Bonita Heart Fail Clin 2011[53]	Primary	Yes	Consistent with cited source
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55	Grassley Int J Occup Environ Health	Primary	Yes	Consistent with cited source
56	2011[54]			
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Nat Clin Pract Nephrol 2007[55]	Primary	Yes	Consistent with cited source
Editors J Urol 2008[15]	Primary	Yes	Consistent with cited source
Baethge Deutsches Arzteblatt 2009[56]	Primary	Yes	Consistent with cited source
Flanagin CSE Annual Mtg 2010[57]	Primary	Yes	Consistent with cited source
Murray Open Med 2010[58]	Primary	Yes	Consistent with cited source
Moore BMJ 2004[59]	Secondary	Yes	Consistent with cited source
Hargreaves BMJ 2007[60]	Primary	Yes	Consistent with cited source
Jones Nature 2009[61]	Primary	Yes	Consistent with cited source

Abbreviations: CSE, Council of Science Editors; GA, ghost authoring; Gov, government; GW, ghostwriting; ND, not determined.

Case study of misleading and mistaken evidence

An analysis of secondary publications citing the possible prevalence of ghostwriting in sertraline publications provides an illuminating case study on how misleading or mistaken evidence can enter and remain in the medical literature. In 2003, Healy and Cattell showed that 57% (55/96) of articles on sertraline published from 1998 to 2000 were coordinated through a medical information company and only two acknowledged medical writing assistance.[6] The authors concluded that these data provided information on the “possible extent of ghostwriting based on a single drug”. In 2004 (October 14), Healy also provided evidence on the influence of the pharmaceutical industry on key groups at a United Kingdom House of Commons Health Select Committee investigation.[62] In answer to Question 197, Healy stated the following:

“My estimate is that, even in journals like the BMJ, the Lancet, the New England Journal of Medicine and JAMA, the leading journals in the field, if these articles have to do with therapeutics, with drugs, it may be worse perhaps for psychiatry than elsewhere, but I doubt it, 50% of these articles are ghostwritten. It may be higher.”

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3 Healy and Cattell's original evidence has been cited incorrectly and interchangeably with
4 Healy's statement to the House of Commons Health Select Committee investigation (Figure
5 2). Although findings from the primary publication have been cited and interpreted correctly in
6
7 two secondary publications,[34, 35] many secondary publications incorrectly cited Healy's
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9 original evidence and statement to the House of Commons Health Select Committee
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11 investigation (Figure 2).
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DISCUSSION

This systematic review on the reported prevalence of ghostwriting in the medical literature showed that the estimates of the prevalence of ghostwriting in primary publications varied markedly and were influenced by the definitions used, the types of study designs, and the type of population or samples assessed. In addition, secondary publications often cited outdated, misleading, or mistaken evidence of the reported prevalence of ghostwriting, with many publications not distinguishing ghostwriting from ghost authoring.

Although evidence from descriptive analyses can highlight the extent of ghostwriting in single populations, evidence from well-conducted cross-sectional surveys have the potential to provide estimates of the prevalence of ghostwriting that may be generalized to the majority of peer-reviewed publications. Despite this, many of the cross-sectional surveys retrieved in this systematic review were conducted in limited populations that were not broadly representative of the peer-reviewed medical literature. In addition, many of the cross-sectional surveys did not differentiate between contributions that merited authorship from those that did not merit authorship and provided at best, an estimate of possible ghostwriting. The reported prevalence of ghostwriting, where ghostwriting was defined as undisclosed contributions that did not merit authorship, was retrieved from the two cross-sectional surveys of corresponding authors from several general medicine journals and by cross-sectional surveys (repeated on three separate occasions from 2005 to 2011) of members of two major medical writing associations. Together the findings from these surveys suggested that the prevalence of ghostwriting has decreased in recent years. However, while the findings from these surveys may be considered more broadly representative of the peer-reviewed medical literature than surveys focused on single journals, single countries, or single subject areas, interpretation of these findings should take into account that respondents were required to retrospectively self-report potentially unethical or unprofessional behaviour.

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5 Unethical authorship practices are a major concern and are an increasingly recognized
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7 problem in the medical literature.[63] As the findings from this systematic review suggest,
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9 some of these perceived problems may arise from the considerable, but unnecessary,
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11 confusion and disagreement surrounding the definitions of ghostwriting. As recognized by
12
13 the World Association of Medical Editors, professional medical writers can have a legitimate
14
15 role in assisting authors to communicate their research findings in the peer-reviewed
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17 literature.[14] Professional medical writers can and do improve the timeliness and quality of
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19 reporting and can assist investigators and industry sponsors to meet their ethical
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21 commitments to the disclosure and publishing of clinical trial results.[1, 64-66] As such, the
22
23 misleading and mistaken reporting of the prevalence of ghostwriting that was evident in the
24
25 secondary publications retrieved in this systematic review is disappointing. Specifically, the
26
27 confusion surrounding definitions of ghost authorship and ghostwriting and the unbalanced
28
29 focus on industry as the source of unethical authorship practices in the secondary
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31 publications takes attention away from the need to focus on all types of unethical
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33 contributions in peer-reviewed publications, irrespective of the source of the unethical
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35 practice.
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The various definitions of ghostwriting and ghost authoring found in this systematic review highlights the considerable disagreement in the medical literature with regard to the definitions of ghostwriting and ghost authoring and whether a distinction should be made between these unethical practices. Although the Council of Science Editors uses a straightforward and broad definition of ghost authors that does not distinguish between ghost authors and ghostwriters.[2] the distinction between ghost authorship and ghostwriting used in this manuscript is consistent with those used in the cross-sectional surveys conducted by Flanagan[67] and Wislar[68] and with the authorship criteria recommended by the ICMJE.[12] Distinguishing between these practices is important because it differentiates between undisclosed contributions that do and do not merit authorship. However, part of the reason

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3 for the disagreement about definitions of ghost authoring and ghostwriting stems from
4 differences of opinion in the medical literature over how authorship is defined, particularly
5 with regard to what constitutes “substantial” contributions to a publication and the role of
6 disclosure of contributions to a manuscript in the acknowledgments.[69] The ICMJE criteria
7 for authorship[12] are the most well recognised authorship criteria available, but leave much
8 about authorship undefined.[63, 70] Despite this, the recent emphasis on author
9 accountability in the ICMJE’s fourth criterion is an attempt to better define authors as those
10 persons who are responsible and accountable for the content of a published work. While a
11 professional medical writer can take responsibility for the writing and how research is
12 reported in a manuscript, the professional medical writer cannot take responsibility for the
13 integrity of the research or be accountable for the clinical interpretation of the findings,
14 unless he or she was involved in the generation of the research or its analysis.
15 Responsibility for the integrity of research and accountability for the clinical interpretation of
16 the findings is, and should always be, the responsibility of the authors. Until a more
17 definitive model of authorship is universally accepted, the controversy and disagreement
18 over definitions of authors, ghostwriters, and ghost authors will remain. However, no matter
19 what term is used, the practice of misleading readers about potential competing interests
20 and hiding contributions to a published work, no matter whether these contributions should
21 be most appropriately disclosed in the author byline or acknowledgements section, is
22 unethical and totally unacceptable.
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45 The strengths of this systematic review are that a broad search strategy was employed with
46 few restrictions to minimize any potential for publication or language bias. All study designs
47 and publication types were considered and there were no restrictions on language. Although
48 the full text or abstracts of 8 publications could not be retrieved, omission of these
49 publications was unlikely to have biased the findings. Review of the abstracts or titles of
50 these publications suggested that none reported numerical estimates of the prevalence of
51 ghostwriting. The major finding of this review was the limitations of the reported evidence of
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3 ghostwriting in the medical literature. These limitations included the heterogeneity among the
4 studies in the outcomes reported and populations investigated, the observational study
5 designs, and the retrospective nature of data collection. Given the nature of unethical
6 authorship practices, it may not be feasible to conduct a prospective study on ghostwriting.
7 However, based on the findings from this review, recommendations can be made to help
8 researchers, authors, editors, and peer-reviewers apply the same rigorous standards that
9 are applied to the conduct and assessment of all clinical research and actively improve the
10 quality of reporting of the evidence of unethical authorship practices.
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21 Researchers should use a standard definition of ghostwriting so that the confusion around
22 ghostwriters and ghost authors is not perpetuated. ~~Ghostwriting is paid or unpaid writing
23 assistance by individuals who generally do not merit authorship and whose contributions are
24 not disclosed in the acknowledgments.[1] In contrast, ghost authoring is contributions to the
25 research, data analysis, and/or writing of a manuscript by individuals who do merit
26 authorship and whose contributions are not disclosed in the author byline.[1]~~ For example,
27 the descriptive analysis of Danish industry-initiated trials used a nonstandard definition of
28 authorship, which is likely to have contributed to the very high prevalence of possible
29 ghostwriting reported in this study (75%). In this study, Gøtzsche et al.[30] suggested that
30 individuals who write the trial protocol, conduct the statistical analyses, or who contribute to
31 the writing of a publication should be included as authors. Indeed, the prevalence of ghost
32 authorship in this study was 91% when the analyses included these individuals, irrespective
33 of whether they had been appropriately acknowledged elsewhere. Given that the Gøtzsche
34 et al.[30] study has been downloaded more than 3,000 times since publication[71] and cited
35 repeatedly as evidence not only of ghost authorship but also of ghostwriting,[40, 44, 46, 48]
36 it would have been illuminating if the authors had included an estimate of the prevalence of
37 ghostwriting using standard definitions for comparison. In addition to using standard
38 definitions of ghostwriting, researchers and authors should ensure that cited evidence of
39 ghostwriting is reported accurately without unwarranted generalizations. Publications based
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3 on personal commentary should be avoided and studies that use nonstandard definitions,
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5 specific populations, or that were conducted before a change in practice (eg, before the
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7 adoption of the Good Publication Practice guidelines for communicating company sponsored
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9 research in 2003 [GPP][72] and in 2009 [GPP2][11]) should be described in context.
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13 Editors and peer reviewers have a duty to prevent outdated, misleading, or mistaken
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15 evidence on the prevalence of ghostwriting from being published and perpetuated. Close
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17 attention should be paid to the internal and external validity of the study, the definitions used,
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19 how the data are reported, and whether the data are interpreted within the context of current
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21 practices. When assessing a submitted manuscript on ghostwriting, editors should consider
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23 using peer reviewers with expertise in the appropriate study designs (eg, survey research)
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25 and ethical publication practices. Collectively, these actions could help prevent further
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27 questionable evidence on the prevalence of ghostwriting from being published.
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31 In conclusion, the findings from this systematic review showed that reports of the prevalence
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33 of ghostwriting in the medical literature are limited by the varied definitions used to describe
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35 unethical authorship practices, the types of study designs employed, and the populations
36
37 assessed. To improve reporting, researchers should not inflate estimates using nonstandard
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39 definitions of ghostwriting nor conflate ghostwriting with other unethical authorship practices.
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41 While open and transparent debate should be encouraged, editors and peer reviewers
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43 should not accept articles that incorrectly cite or interpret primary publications that report the
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45 prevalence of ghostwriting.
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5
6
7 work. No other funding was received to conduct this research.
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10 DATA SHARING

11 All data associated with the study are fully available to the author.
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FIGURE LEGENDS

Figure 1. Selection of publications reporting a numerical estimate of the prevalence of ghostwriting. Electronic databases were searched on 23 May 2013.

^a Journal of the European Medical Writers Association, formerly known as The Write Stuff.

^b Journal of the American Medical Writers Association.

^c Council of Science Editors Annual Meetings.

^d International Congress on Peer Review and Biomedical Publication.

Figure 2. Case study of original versus cited evidence of ghostwriting prevalence.

Contrast between original evidence on the prevalence of possible ghostwriting in sertraline publications from 1998 to 2000 and the subsequent citations of this evidence. Source of the original published evidence: Healy and Cattell[6] showed that 55 of 96 (57%) articles published on sertraline from 1998 to 2000 were coordinated through a medical communications company and concluded that these data provided information on the “possible extent of ghostwriting based on a single drug”. Inaccurate reporting from the cited source is marked with a cross.

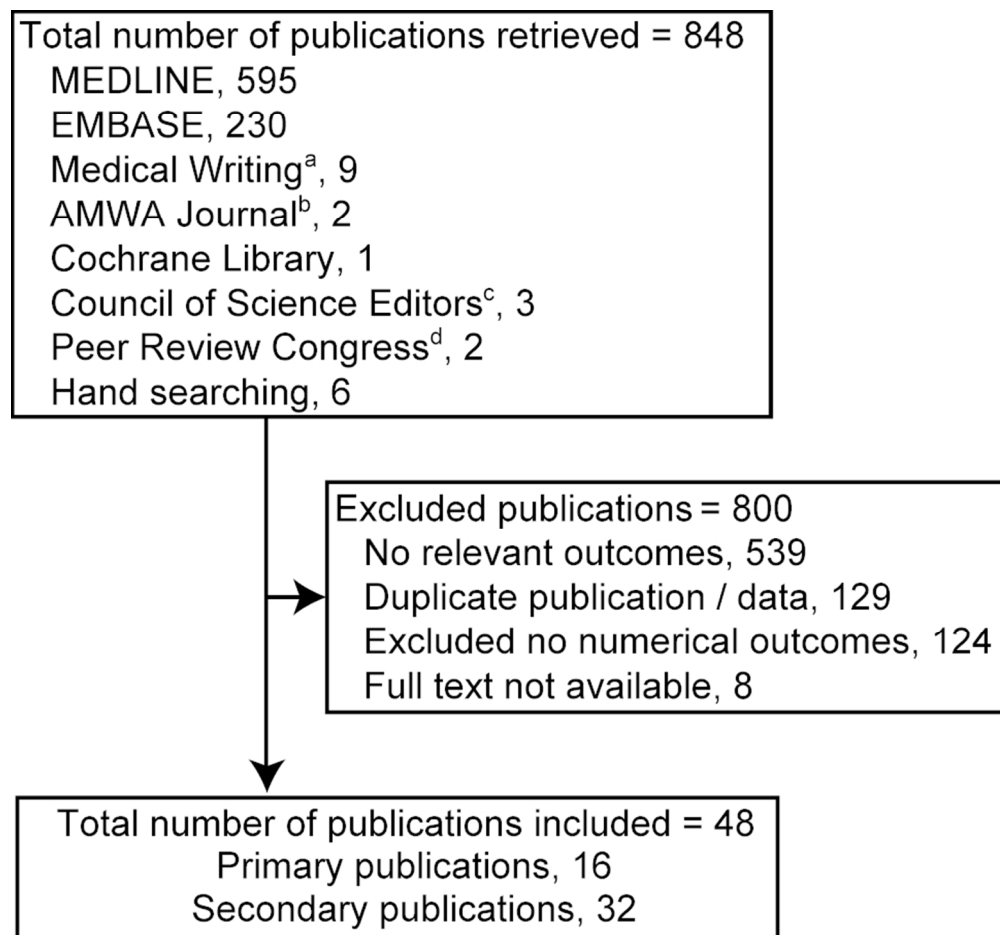


Figure 1. Selection of publications reporting a numerical estimate of the prevalence of ghostwriting.

Electronic databases were searched on 23 May 2013.

a Journal of the European Medical Writers Association, formerly known as The Write Stuff.

b Journal of the American Medical Writers Association.

c Council of Science Editors Annual Meetings.

d International Congress on Peer Review and Biomedical Publication.

82x76mm (300 x 300 DPI)

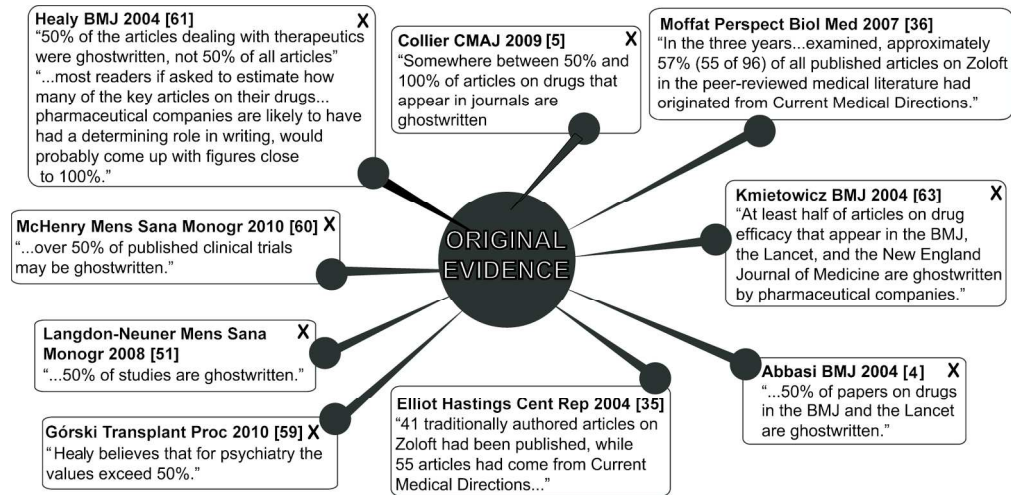


Figure 2. Case study of original versus cited evidence of ghostwriting prevalence. Contrast between original evidence on the prevalence of possible ghostwriting in sertraline publications from 1998 to 2000 and the subsequent citations of this evidence. Source of the original published evidence: Healy and Cattell[6] showed that 55 of 96 (57%) articles published on sertraline from 1998 to 2000 were coordinated through a medical communications company and concluded that these data provided information on the "possible extent of ghostwriting based on a single drug". Inaccurate reporting from the cited source is marked with a cross.

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PRISMA 2009 Checklist

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Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	p. 1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	pp. 2/3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	p. 5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	p. 6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	A review protocol was prepared that prespecified the primary and secondary objectives of the literature review, eligibility criteria, data to be collected, and primary and secondary outcome measures. The review protocol was not registered in a public registry but is available upon request.
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	p. 7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	p. 6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	p. 6
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	pp. 6/7
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	p. 7



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Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	p. 7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	Risk of bias was not conducted formally because data were not synthesised and because of the various study types retrieved. Given the various study designs and methods used across the retrieved studies, the quality of the study methods were assessed on a study-by-study basis. The key factors considered were the study design, definition of ghostwriting used, and study population. The factors considered when determining the quality of the cross-sectional surveys are described in the Methods section (p. 7).
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Not applicable because study data were not synthesised
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	Not applicable because study data were not synthesised.

Page 1 of 2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	Risk of bias across studies was not conducted formally because data were not synthesised and because of the considerable variation in study designs, populations, and definitions of ghostwriting used in the retrieved publications.
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	No additional analyses were conducted
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8, Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	8-11, 15, Tables 1-3
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Risk of bias was not conducted formally because data were not synthesised. All studies retrieved were limited by the observational nature of the data collection. The quality of individual components of each study are listed in Table 1



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			and are summarised in the results section (Publication Characteristics) (pp. 8/9).
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Tables 1-3
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Not applicable because study data were not synthesised
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Not applicable because study data were not synthesised and because of the considerable variation in study designs, populations, and definitions of ghostwriting used in the retrieved publications.
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	No additional analyses were conducted
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	20-24
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	20-22
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	22-24
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	No funding was received to conduct this study

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.